Wikipedia Handbook of Biomedical Informatics

Contents

Chapter 1

General Overview

1.1 Health information technology

Health information technology (HIT) is information technology applied to health and health care. It supports health information management across computerized systems and the secure exchange of health information between consumers, providers, payers, and quality monitors. Based on an often-cited 2008 report on a small series of studies conducted at four sites that provide ambulatory care–three U.S. medical centers and one in the Netherlands– the use of Electronic Health Records (EHRs) was viewed as the most promising tool for improving the overall quality, safety and efficiency of the health delivery system.*[1] A 2006 report by the Agency for Healthcare Research and Quality broad and consistent utilization of HIT will,*[2] :

- Improve health care quality or effectiveness:
- Increase health care productivity or efficiency;
- Prevent medical errors and increase health care accuracy and procedural correctness;
- Reduce health care costs;
- Increase administrative efficiencies and healthcare work processes;
- Decrease paperwork and unproductive or idle work time;
- Extend real-time communications of health informatics among health care professionals; and
- Expand access to affordable care.

Risk-based regulatory framework for health IT September 4, 2013 the Health IT Policy Committee (HITPC) accepted and approved recommendations from the Food and Drug Administration Safety and Innovation Act (FDASIA) working group for a risk-based regulatory framework for health information technology.*[3] The Food and Drug Administration (FDA), the Office of the National Coordinator for Health IT (ONC), and Federal Communications Commission (FCC) kicked off the FDASIA workgroup of the HITPC to provide stakeholder input into a report on a risk-based regulatory framework that promotes safety and innovation and reduces regulatory duplication, consistent with section 618 of FDASIA. This provision permitted the Secretary of Health and Human Services (HHS) to form a workgroup in order to obtain broad stakeholder input from across the health care, IT, patients and innovation spectrum. The FDA, ONC, and FCC actively participated in these discussions with stakeholders from across the health care, IT, patients and innovation spectrum.

HIMSS Good Informatics Practices-GIP is aligned with FDA risk-based regulatory framework for health information technology.*[4] GIP development began in 2004 developing risk-based IT technical guidance.*[5] Today the GIP peer-review and published modules are an excellent tool for educating Health IT professionals*[6]

Interoperable HIT will improve individual patient care, but it will also bring many public health benefits including:

- Early detection of infectious disease outbreaks around the country;
- Improved tracking of chronic disease management; and
- Evaluation of health care based on value enabled by the collection of de-identified price and quality information that can be compared.

According to the article published by the Internal Journal of Medical Informatics,Health information sharing between patients and providers helps to improve diagnosis, promotes self care, and patients also know more information about their health. The use of electronic medical records (EMRs) is still scarce now but is increasing in Canada, American and British primary care. Healthcare information in EMRs are important sources for clinical, research, and policy questions. Health information privacy (HIP) and security has been a big concern for patients and providers. Studies in Europe evaluating electronic health information poses a threat to electronic medical records and exchange of personal information.*[7]

1.1.1 Concepts and Definitions

Health information technology (HIT) is "the application of information processing involving both computer hardware and software that deals with the storage, retrieval, sharing, and use of health care information, data, and knowledge for communication and decision making".*[8] Technology is a broad concept that deals with a species' usage and knowledge of tools and crafts, and how it affects a species' ability to control and adapt to its environment. However, a strict definition is elusive; "technology" can refer to material objects of use to humanity, such as machines, hardware or utensils, but can also encompass broader themes, including systems, methods of organization, and techniques. For HIT, technology represents computers and communications attributes that can be networked to build systems for moving health information. Informatics is yet another integral aspect of HIT.

Informatics refers to the science of information, the practice of information processing, and the engineering of information systems. Informatics underlies the academic investigation and practitioner application of computing and communications technology to healthcare, health education, and biomedical research. Health informatics refers to the intersection of information science, computer science, and health care. Health informatics describes the use and sharing of information within the healthcare industry with contributions from computer science, mathematics, and psychology. It deals with the resources, devices, and methods required for optimizing the acquisition, storage, retrieval, and use of information in health and biomedicine. Health informatics tools include not only computers but also clinical guidelines, formal medical terminologies, and information and communication systems. Medical informatics, nursing informatics, public health informatics, pharmacy informatics, and translational bioinformatics are subdisciplines that inform health informatics from different disciplinary perspectives.*[9] The processes and people of concern or study are the main variables.

1.1.2 Implementation of HIT

The Institute of Medicine's (2001) call for the use of electronic prescribing systems in all healthcare organizations by 2010 heightened the urgency to accelerate United States hospitals' adoption of CPOE systems. In 2004, President Bush signed an Executive Order titled the President's Health Information Technology Plan, which established a ten-year plan to develop and implement electronic medical record systems across the US to improve the efficiency and safety of care. According to a study by RAND Health, the US healthcare system could save more than $81 billion annually, reduce adverse healthcare events and improve the quality of care if it were to widely adopt health information technology.*[10]

The American Recovery and Reinvestment Act, signed into law in 2009 under the Obama Administration, has provided approximately $19 billion in incentives for hospitals to shift from paper to electronic medical records. Meaningful Use, as a part of the 2009 Health Information Technology for Economic and Clinical Health (HITECH) was the incentive that included over $20 billion for the implementation of HIT alone, and provided further indication of the growing consensus regarding the potential salutary effect of HIT. The American Recovery and Reinvestment Act has set aside $2 billion which will go towards programs developed by the National Coordinator and Secretary to help healthcare providers implement HIT and provide technical assistance through various regional centers. The other $17 billion in incentives comes from Medicare and Medicaid funding for those who adopt HIT before 2015. Healthcare providers who implement electronic records can receive up to $44,000 over four years in Medicare funding and $63,750 over six years in Medicaid funding. The sooner that healthcare providers adopt the system, the more funding they receive. Those who do not adopt electronic health record systems before 2015 do not receive any federal funding.*[11]

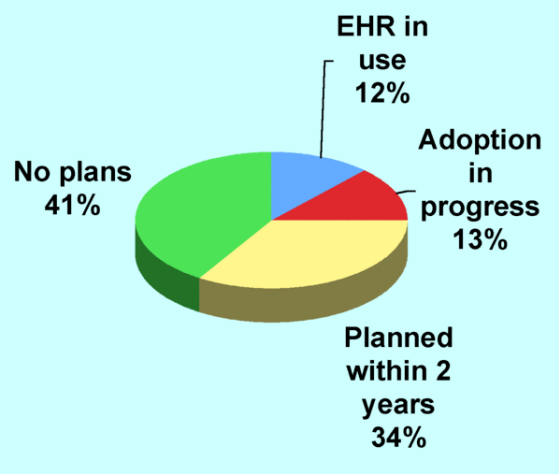
While electronic health records have potentially many advantages in terms of providing efficient and safe care, recent reports have brought to light some challenges with implementing electronic health records. The most immediate barriers for widespread adoption of this technology have been the high initial cost of implementing the new technology and the time required for doctors to train and adapt to the new system. There have also been suspected cases of fraudulent billing, where hospitals inflate their billings to Medicare. Given that healthcare providers have not reached the deadline (2015) for adopting electronic health records, it is unclear what effects this policy will have long term.*[12]

One approach to reducing the costs and promoting wider use is to develop open standards related to EHRs. In 2014 there was widespread interest in a new HL7 draft standard, Fast Healthcare Interoperability Resources (FHIR), which is designed to be open, extensible, and easier to implement, benefiting from modern web technologies.*[13]

1.1.3 Types of technology

In a 2008 study about the adoption of technology in the United States, Furukawa, and colleagues classified applications for prescribing to include electronic medical records (EMR), clinical decision support (CDS), and computerized physician order entry (CPOE).*[14] They further defined applications for dispensing to include barcoding at medication dispensing (BarD), robot for medication dispensing (ROBOT), and automated dispensing machines (ADM). And, they defined applications for administration to include electronic medication administration records (EMAR) and bar-coding at medication administration (BarA).

Electronic Health Record (EHR)



US medical groups' adoption of EHR (2005)

Although frequently cited in the literature the **Electronic health record** (EHR), previously known as the Electronic medical record (EMR), there is no consensus about the definition.*[15] However, there is consensus that EMRs can reduce several types of errors, including those related to prescription drugs, to preventive care, and to tests and procedures.*[16] Recurring alerts remind clinicians of intervals for preventive care and track referrals and test results. Clinical guidelines for disease management have a demonstrated benefit when accessible within the electronic record during the process of treating the patient.*[17] Advances in health informatics and widespread adoption of interoperable electronic health records promise access to a patient's records at any health care site. A 2005 report noted that medical practices in the United States are encountering barriers to adopting an EHR system, such as training, costs and complexity, but the adoption rate continues to rise (see chart to right).*[18] Since 2002, the National Health Service of the United Kingdom has placed emphasis on introducing computers into healthcare. As of 2005, one of the largest projects for a national EHR is by the National Health Service (NHS) in the United Kingdom. The goal of the NHS is to have 60,000,000 patients with a centralized electronic health record by 2010. The plan involves a gradual roll-out commencing May 2006, providing general practices in England access to the National Programme for IT (NPfIT), the NHS component of which is known as the "Connecting for Health Programme".*[19] However, recent surveys have shown physicians' deficiencies in understanding the patient safety features of the NPfIT-approved software.*[20]

A main problem in HIT adoption is mainly seen by physicians, an important stakeholder to the process of EHR. The Thorn et al. article, elicited that emergency physicians noticed that health information exchange disrupted workflow and was less desirable to use, even though the main goal of EHR is improving coordination of care. The problem was seen that exchanges did not address the needs of end users, e.g. simplicity, user-friendly interface, and speed of systems.*[21] The same finding was seen in an earlier article with the focus on CPOE and physician resistance to its use, Bhattacherjee et al.*[22]

Clinical point of care technology

Computerized Provider (Physician) Order Entry (CPOE) Prescribing errors are the largest identified source of preventable errors in hospitals. A 2006 report by the Institute of Medicine estimated that a hospitalized patient is exposed to a medication error each day of his or her stay.*[23] Computerized provider order entry (CPOE), formerly called **Computer physician order entry**, can reduce total medication error rates by 80%, and adverse (serious with harm to patient) errors by 55%.*[24] A 2004 survey by found that 16% of US clinics, hospitals and medical practices are expected to be utilizing CPOE within 2 years.*[25] In addition to electronic prescribing, a standardized bar code system for dispensing drugs could prevent a quarter of drug errors.*[23] Consumer information about the risks of the drugs and improved drug packaging (clear labels, avoiding similar drug names and dosage reminders) are other error-proofing measures. Despite ample evidence of the potential to reduce medication errors, competing systems of barcoding and electronic prescribing have slowed adoption of this technology by doctors and hospitals in the United States, due to concern with interoperability and compliance with future national standards.*[26] Such concerns are not inconsequential; standards for electronic prescribing for Medicare Part D conflict with regulations in many US states.*[23] And, aside from regulatory concerns, for the small-practice physician, utilizing CPOE requires a major change in practice work flow and an additional investment of time. Many physicians are not full-time hospital staff; entering orders for their hospitalized patients means taking time away from scheduled patients.*[27]

1.1.4 Technological Innovations, Opportunities, and Challenges

Handwritten reports or notes, manual order entry, nonstandard abbreviations and poor legibility lead to substantial errors and injuries, according to the Institute of Medicine (2000) report. The follow-up IOM (2004) report, *Crossing the quality chasm: A new health system for the 21st century*, advised rapid adoption of electronic patient records, electronic medication ordering, with computer- and internet-based information systems to support clinical decisions.*[28] However, many system implementations have experienced costly failures.*[29] Furthermore, there is evidence that CPOE may actually contribute to some types of adverse events and other

medical errors.*[30] For example, the period immediately following CPOE implementation resulted in significant increases in reported adverse drug events in at least one study,*[31] and evidence of other errors have been reported.*[24]*[32]*[33] Collectively, these reported adverse events describe phenomena related to the disruption of the complex adaptive system resulting from poorly implemented or inadequately planned technological innovation.

Technological Iatrogenesis

Technology may introduce new sources of error*[34]*[35] Technologically induced errors are significant and increasingly more evident in care delivery systems. Terms to describe this new area of error production include the label technological iatrogenesis*[36] for the process and e-iatrogenic*[37] for the individual error. The sources for these errors include:

- Prescriber and staff inexperience may lead to a false sense of security; that when technology suggests a course of action, errors are avoided.
- Shortcut or default selections can override non-standard medication regimens for elderly or underweight patients, resulting in toxic doses.
- CPOE and automated drug dispensing was identified as a cause of error by 84% of over 500 health care facilities participating in a surveillance system by the United States Pharmacopoeia.*[38]
- Irrelevant or frequent warnings can interrupt work flow.

Healthcare information technology can also result in iatrogenesis if design and engineering are substandard, as illustrated in a 14-part detailed analysis done at the University of Sydney.*[39]

1.1.5 Revenue Cycle HIT

The HIMSS Revenue Cycle Improvement Task Force was formed to prepare for the IT changes in the U.S. (e.g. the American Recovery and Reinvestment Act of 2009 (HITECH), Affordable Care Act, 5010 (electronic exchanges), ICD-10). An important change to the revenue cycle is the international classification of diseases (ICD) codes from 9 to 10. ICD-9 codes are set up to use three to five alphanumeric codes that represent 4,000 different types of procedures, while ICD-10 uses three to seven alphanumeric codes increasing procedural codes to 70,000. ICD-9 was outdated because there were more codes than procedures available, and to document for procedures without an ICD-9 code, a paper-work process of modifiers and supplemental documentation was used. Hence, ICD-10 was introduced to simplify the procedures with unknown codes and unify the standards closer to world standards (ICD-11). One of the main parts of Revenue Cycle HIT is charge capture, it utilizes codes to capture costs for reimbursements from different payers, such as CMS.*[40]

1.1.6 International Comparisons through HIT

International health system performance comparisons are important for understanding health system complexities and finding better opportunities, which can be done through health information technology. It gives policy makers the chance to compare and contrast the systems through established indicators from health information technology, as inaccurate comparisons can lead to adverse policies.*[41]

1.1.7 See also

- Bioinformatics
- Clinical documentation improvement
- Consumer health informatics
- Dental informatics
- eHealth
- Electronic health record (EHR)
- eMix
- European Institute for Health Records (EuroRec)
- Health informatics
- Health information management
- Hospital information system
- Imaging informatics
- List of open source healthcare software
- Medical imaging
- Medical record
- mHealth
- Patient safety
- Personal health record
- Picture archiving and communication system
- Public health informatics
- Radiology Information System

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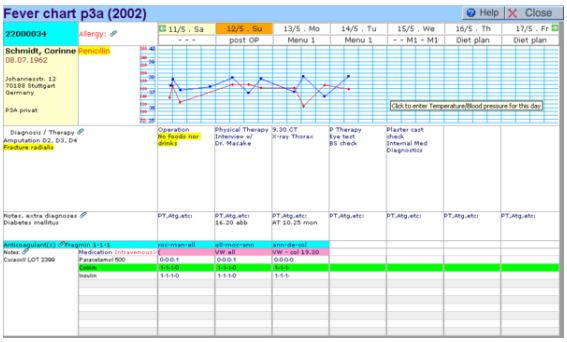
1.1.10 External links

- Health Resources and Services Administration (HRSA)
- Health Information Technology at US Department of Health & Human Services
- Healthcare Information Technology from American National Standards Institute (ANSI)
- Certification Commission for Healthcare Information Technology (CCHIT)
- Health Information Technology Videos
- Health IT Discussion Forum
- Hospital Management Information System from Center for Development of Advanced Computing (C-DAC)
- American Society of Health Informatics Managers
- Patient Safety Initiatives in India Using Health IT
- Health Information Technology Certification Programs
- Health Information Technology Careers
- Free Course on Introduction to Health IT

1.2 Clinical Informatics



Electronic patient chart from a health information system

Health informatics (also called **health care informatics**, **healthcare informatics**, **medical informatics**, **nursing informatics**, **clinical informatics**, or **biomedical informatics**) is informatics in health care. It is a multidisciplinary field that uses health information technology (HIT) to improve health care via any combination of higher quality, higher efficiency (spurring lower cost and thus greater availability), and new opportunities. The disciplines involved include information science, computer science, social science, behavioral science, management science, and others. The NLM defines health informatics as "the interdisciplinary study of the design, development, adoption and application of IT-based innovations in healthcare services delivery, management and planning." *[1] It deals with the resources, devices, and methods required to optimize the acquisition, storage, retrieval, and use of information in health and biomedicine. Health informatics tools include amongst others computers, clinical guidelines, formal medical terminologies, and information and communication systems.*[2]*[3] It is applied to the areas of nursing, clinical care, dentistry, pharmacy, public health, occupational therapy, physical therapy and (bio)medical research, and alternative medicine.*[4] All of which are designed to improve the overall of effectiveness of patient care delivery by ensuring that the data generated is of a high quality e.g. an mHealth based early warning scorecard.*[5]

- The international standards on the subject are covered by ICS 35.240.80*[6] in which ISO 27799:2008 is one of the core components.*[7]
- Molecular bioinformatics and clinical informatics have converged into the field of translational bioinformatics.

1.2.1 Sub Specialities

- Healthcare Informatics
  - Clinical Informatics
  - Pathology Informatics
  - Pharmacy Informatics*[8]*[9]*[10]*[11]*[12]*[13]
  - Public Health Informatics
  - Community Health Informatics
    - Home Health Informatics
  - Nursing Informatics
  - Medical Informatics
- Consumer Health Informatics
- Clinical Bioinformatics
- Informatics for Education & Research in Health & Medicine

1.2.2 Healthcare Informatics

Clinical Informatics

Clinical Informatics is concerned with the use of information in health care by and for clinicians.*[14]*[15]

Clinical informaticians transform health care by analyzing, designing, implementing, and evaluating information and communication systems that enhance individual and population health outcomes, improve [patient] care, and strengthen the clinician-patient relationship. Clinical informaticians use their knowledge of patient care combined with their understanding of informatics concepts, methods, and health informatics tools to:

- assess information and knowledge needs of health care professionals and patients,
- characterize, evaluate, and refine clinical processes,
- develop, implement, and refine clinical decision support systems, and
- lead or participate in the procurement, customization, development, implementation, management, evaluation, and continuous improvement of clinical information systems.

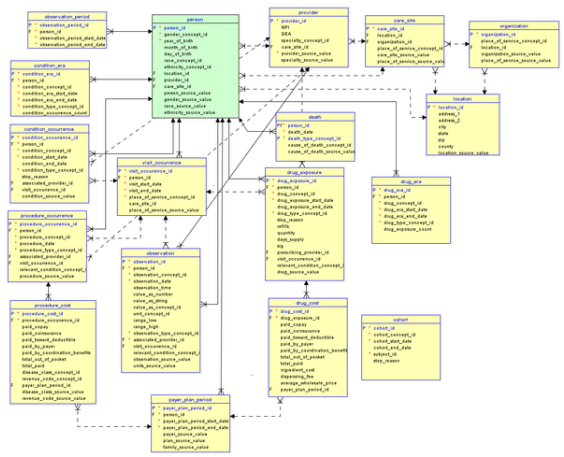
Clinicians collaborate with other health care and information technology professionals to develop health informatics tools which promote patient care that is safe, efficient, effective, timely, patient-centered, and equitable.

In October 2011 American Board of Medical Specialties (ABMS), the organization overseeing the certification of physician specialists (MD Physicians only) in the United States, announced the creation of physician (MD physicians only) certification in Clinical Informatics. The first examination for board certification in the subspecialty of Clinical Informatics was offered in October 2013 by

American Board of Preventive Medicine with 432 passing to become the 2014 inaugural class of Diplomates (ABPM) in Clinical Informatics.*[16]

Fellowship programs exist for physicians who wish to become board-certified in Clinical Informatics. Physicians must have graduated from a medical school in the United States or Canada, or a school located elsewhere that is approved by the ABPM. In addition, they must complete a primary residency program such as Internal Medicine (or any of the 24 subspecialties recognized by the ABMS) and be eligible to become licensed to practice medicine in the state where their fellowship program is located.*[17] The fellowship program is 24 months in length, with fellows dividing their time between Informatics rotations, didactics, research, and clinical work in their primary specialty.

Integrated data repository



example IDR schema

Development of the field of clinical informatics lead to creation of large data sets with electronic health record data integrated with other data (such as genomic data). Large data warehouses are often described as clinical data warehouses (also known as clinical data repositories). In research, deidentified CDWs can be used by researchers with less complex ethical oversight. CDWs with data of deceased patients were also suggested as a research resource that does not require IRB approval.*[18]*[19]

1.2.3 Human Bioinformatics

Translational bioinformatics

With the completion of the human genome and the recent advent of high throughput sequencing and genome-wide association studies of single nucleotide polymorphisms, the fields of molecular bioinformatics, biostatistics, statistical genetics and clinical informatics are converging into the emerging field of translational bioinformatics.*[20]*[21]*[22]

The relationship between bioinformatics and health informatics, while conceptually related under the umbrella of biomedical informatics,*[23] has not always been very clear. The TBI community is specifically motivated with the development of approaches to identify linkages between fundamental biological and clinical information. Along with complementary areas of emphasis, such as those focused on developing systems and approaches within clinical research contexts,*[24] insights from TBI may enable a new paradigm for the study and treatment of disease.

1.2.4 Computational Health Informatics

Computational Health Informatics

Computational health informatics is a branch of Computer Science that deals specifically with computational techniques that are relevant in healthcare. Computational health informatics is also a branch of Health Informatics, but is orthogonal to much of the work going on in health informatics because computer scientist's interest is mainly in understanding fundamental properties of computation. Health informatics, on the other hand, is primarily concerned with understanding fundamental properties of medicine that allow for the intervention of computers. The health domain provides an extremely wide variety of problems that can be tackled using computational techniques, and computer scientists are attempting to make a difference in medicine by studying the underlying principles of computer science that will allow for meaningful (to medicine) algorithms and systems to be developed. Thus, computer scientists working in computational health informatics and health scientists working in medical health informatics combine to develop the next generation of healthcare technologies.

Using computers to analyze health data has been around since the 1950s, but it wasn't until the 1990s that the first sturdy models appeared. The development of the internet has helped develop computational health informatics over the past decade. Computer models are used to examine various topics such as how exercise affects obesity, healthcare costs, and many more.*[25]

Examples of projects in computational health informatics include the COACH project.*[26]*[27]

1.2.5 Informatics for Education & Research in Health & Medicine

Clinical Research Informatics

Clinical Research Informatics (or, CRI) takes the core foundations, principles, and technologies related to Health Informatics, and applies these to clinical research contexts.*[28] As such, CRI is a sub-discipline of Health

Informatics, and interest and activities in CRI have increased greatly in recent years given the overwhelming problems associated with the explosive growth of clinical research data and information.*[29] There are a number of activities within clinical research that CRI supports, including:

- more efficient and effective data collection and acquisition
- improved recruitment into clinical trials
- optimal protocol design and efficient management
- patient recruitment and management
- adverse event reporting
- regulatory compliance
- data storage, transfer,*[30] processing and analysis
- repositories of data from completed clinical trials (for secondary analyses)

1.2.6 Medical informatics in the United States

Even though the idea of using computers in medicine emerged as technology advanced in the early 20th century, it was not until the 1950s that informatics began to have an effect in the United States.*[31]

The earliest use of electronic digital computers for medicine was for dental projects in the 1950s at the United States National Bureau of Standards by Robert Ledley.*[32] During the mid-1950s, the United States Air Force (USAF) carried out several medical projects on its computers while also encouraging civilian agencies such as the National Academy of Sciences - National Research Council (NAS-NRC) and the National Institutes of Health (NIH) to sponsor such work.*[33] In 1959, Ledley and Lee B. Lusted published "Reasoning Foundations of Medical Diagnosis," a widely read article in *Science*, which introduced computing (especially operations research) techniques to medical workers. Ledley and Lusted's article has remained influential for decades, especially within the field of medical decision making.*[34]

Guided by Ledley's late 1950s survey of computer use in biology and medicine (carried out for the NAS-NRC), and by his and Lusted's articles, the NIH undertook the first major effort to introduce computers to biology and medicine. This effort, carried out initially by the NIH's Advisory Committee on Computers in Research (ACCR), chaired by Lusted, spent over $40 million between 1960 and 1964 in order to establish dozens of large and small biomedical research centers in the US.*[33]

One early (1960, non-ACCR) use of computers was to help quantify normal human movement, as a precursor to scientifically measuring deviations from normal, and design of prostheses.*[35] The use of computers (IBM 650, 1620, and 7040) allowed analysis of a large sample size, and of more measurements and subgroups than had been previously practical with mechanical calculators, thus allowing an objective understanding of how human locomotion varies by age and body characteristics. A study co-author was Dean of the Marquette University College of Engineering; this work led to discrete Biomedical Engineering departments there and elsewhere.

The next steps, in the mid-1960s, were the development (sponsored largely by the NIH) of expert systems such as MYCIN and Internist-I. In 1965, the National Library of Medicine started to use MEDLINE and MEDLARS. Around this time, Neil Pappalardo, Curtis Marble, and Robert Greenes developed MUMPS (Massachusetts General Hospital Utility Multi-Programming System) in Octo Barnett's Laboratory of Computer Science *[36] at Massachusetts General Hospital in Boston, another center of biomedical computing that received significant support from the NIH.*[37] In the 1970s and 1980s it was the most commonly used programming language for clinical applications. The MUMPS operating system was used to support MUMPS language specifications. As of 2004, a descendent of this system is being used in the United States Veterans Affairs hospital system. The VA has the largest enterprise-wide health information system that includes an electronic medical record, known as the Veterans Health Information Systems and Technology Architecture (VistA). A graphical user interface known as the Computerized Patient Record System (CPRS) allows health care providers to review and update a patient's electronic medical record at any of the VA's over 1,000 health care facilities.

During the 1960s, Morris Collen, a physician working for Kaiser Permanente's Division of Research, developed computerized systems to automate many aspects of multiphasic health checkups. These system became the basis the larger medical databases Kaiser Permanente developed during the 1970s and 1980s.*[38] The American College of Medical Informatics (ACMI) has since 1993 annually bestowed the Morris F. Collen, MD Medal for Outstanding Contributions to the Field of Medical Informatics.*[39]

In the 1970s a growing number of commercial vendors began to market practice management and electronic medical records systems. Although many products exist, only a small number of health practitioners use fully featured electronic health care records systems.

Homer R. Warner, one of the fathers of medical informatics,*[40] founded the Department of Medical Informatics at the University of Utah in 1968. The American Medical Informatics Association (AMIA) has an award named after him on application of informatics to medicine.

Informatics Certifications

Like other IT training specialties, there are Informatics certifications available to help informatics professionals stand out and be recognized. The American Nurses Credentialing Center (ANCC) offers a board certification in Nursing Informatics. For Radiology Informatics, the CIIP (Certified Imaging Informatics Professional) certification was created by ABII (The American Board of Imaging Informatics) which was founded by SIIM (the Society for Imaging Informatics in Medicine) and ARRT (the American Registry of Radiologic Technologists) in 2005. The CIIP certification requires documented experience working in Imaging Informatics, formal testing and is a limited time credential requiring renewal every five years. The exam tests for a combination of IT technical knowledge, clinical understanding, and project management experience thought to represent the typical workload of a PACS administrator or other radiology IT clinical support role. Certifications from PARCA (PACS Administrators Registry and Certifications Association) are also recognized. The five PARCA certifications are tiered from entry level to architect level.

1.2.7 Medical informatics in the UK

The broad history of health informatics has been captured in the book *UK Health Computing : Recollections and reflections*, Hayes G, Barnett D (Eds.), BCS (May 2008) by those active in the field, predominantly members of BCS Health and its constituent groups. The book describes the path taken as 'early development of health informatics was unorganized and idiosyncratic'. In the early −1950s it was prompted by those involved in NHS finance and only in the early 1960s did solutions including those in pathology (1960), radiotherapy (1962), immunization (1963), and primary care (1968) emerge. Many of these solutions, even in the early 1970s were developed in-house by pioneers in the field to meet their own requirements. In part this was due to some areas of health services (for example the immunization and vaccination of children) still being provided by Local Authorities. Interesting, this is a situation which the coalition government propose broadly to return to in the 2010 strategy Equity and Excellence: Liberating the NHS (July 2010); stating:

"We will put patients at the heart of the NHS, through an information revolution and greater choice and control' with shared decision-making becoming the norm: 'no decision about me without me' and patients having access to the information they want, to make choices about their care. They will have increased control over their own care records."

These types of statements present a significant opportunity for health informaticians to come out of the back-office and take up a front-line role supporting clinical practice, and the business of care delivery. The UK health informatics community has long played a key role in international activity, joining TC4 of the International Federation of Information Processing (1969) which became IMIA (1979). Under the aegis of BCS Health, Cambridge was the host for the first EFMI Medical Informatics Europe (1974) conference and London was the location for IMIA's tenth global congress (MEDINFO2001).

1.2.8 Current state of health informatics and policy initiatives

Argentina

Since 1997, the Buenos Aires Biomedical Informatics Group, a nonprofit group, represents the interests of a broad range of clinical and non-clinical professionals working within the Health Informatics sphere. Its purposes are:

- Promote the implementation of the computer tool in the healthcare activity, scientific research, health administration and in all areas related to health sciences and biomedical research.
- Support, promote and disseminate content related activities with the management of health information and tools they used to do under the name of Biomedical informatics.
- Promote cooperation and exchange of actions generated in the field of biomedical informatics, both in the public and private, national and international level.
- Interact with all scientists, recognized academic stimulating the creation of new instances that have the same goal and be inspired by the same purpose.
- To promote, organize, sponsor and participate in events and activities for training in computer and information and disseminating developments in this area that might be useful for team members and health related activities.

The Argentinian health system is heterogeneous in its function, and because of that the informatics developments show a heterogeneous stage. Many private Health Care center have developed systems, such as the Hospital Aleman of Buenos Aires, or the Hospital Italiano de Buenos Aires that also has a residence program for health informatics.

Brazil

Main article: Brazilian Society of Health Informatics

The first applications of computers to medicine and healthcare in Brazil started around 1968, with the installation of the first mainframes in public university hospitals, and the use of programmable calculators in scientific research applications. Minicomputers, such as the IBM 1130 were installed in several universities, and the first applications were developed for them, such as the hospital census in the School of Medicine of Ribeirão Preto and patient master files, in the Hospital das Clínicas da Universidade de São Paulo, respectively at the cities of Ribeirão Preto and São Paulo campuses of the University of São Paulo. In the 1970s, several Digital Corporation and Hewlett Packard minicomputers were acquired for public and Armed Forces hospitals, and more intensively used for intensive-care unit, cardiology diagnostics, patient monitoring and other applications. In the early 1980s, with the arrival of cheaper microcomputers, a great upsurge of computer applications in health ensued, and in 1986 the Brazilian Society of Health Informatics was founded, the first Brazilian Congress of Health Informatics was held, and the first *Brazilian Journal of Health Informatics* was published. In Brazil, two universities are pioneers in teaching and research in Medical Informatics, both the University of Sao Paulo and the Federal University of Sao Paulo offer undergraduate programs highly qualified in the area as well as extensive graduate programs (MSc and PhD). In 2015 the Universidade Federal de Ciências da Saúde de Porto Alegre, Rio Grande do Sul, also started to offer undergraduate program.

Canada

Health Informatics projects in Canada are implemented provincially, with different provinces creating different systems. A national, federally funded, not-for-profit organization called Canada Health Infoway was created in 2001 to foster the development and adoption of electronic health records across Canada. As of December 31, 2008 there were 276 EHR projects under way in Canadian hospitals, other health-care facilities, pharmacies and laboratories, with an investment value of $1.5-billion from Canada Health Infoway.*[41]

Provincial and territorial programmes include the following:

- **eHealth Ontario** was created as an Ontario provincial government agency in September 2008. It has been plagued by delays and its CEO was fired over a multimillion-dollar contracts scandal in 2009.*[42]
- **Alberta Netcare** was created in 2003 by the Government of Alberta. Today the netCARE portal is used daily by thousands of clinicians. It provides access to demographic data, prescribed/dispensed drugs, known allergies/intolerances, immunizations, laboratory test results, diagnostic imaging reports, the diabetes registry and other medical reports. netCARE interface capabilities are being included in electronic medical record products which are being funded by the provincial government.

United States

In 2004, President George W. Bush signed Executive Order 13335, creating the Office of the National Coordinator for Health Information Technology (ONCHIT) as a division of the U.S. Department of Health and Human Services (HHS). The mission of this office is widespread adoption of interoperable electronic health records (EHRs) in the US within 10 years. See quality improvement organizations for more information on federal initiatives in this area.

In 2014 The Department of Education approved an advanced Health Informatics Undergraduate program that was submitted by The University of South Alabama. The program is designed to provide specific Health Informatics education, and is the only program in the country with a Health Informatics Lab. The program is housed in The School of Computing in Shelby Hall, a recently completed $50 million state of the art teaching facility. The University of South Alabama awarded David L. Loeser on May 10, 2014 with the first Health Informatics degree. The program currently is scheduled to have 100+ students awarded by 2016.

The Certification Commission for Healthcare Information Technology (CCHIT), a private nonprofit group, was funded in 2005 by the U.S. Department of Health and Human Services to develop a set of standards for electronic health records (EHR) and supporting networks, and certify vendors who meet them. In July 2006, CCHIT released its first list of 22 certified ambulatory EHR products, in two different announcements.*[43]

Harvard Medical School added a department of biomedical informatics in 2015.*[44]

Europe

For more details on this topic, see European Federation for Medical Informatics.

The European Union's Member States are committed to sharing their best practices and experiences to create a European eHealth Area, thereby improving access to and quality health care at the same time as stimulating growth in a promising new industrial sector. The European eHealth Action Plan plays a fundamental role in the European Union's strategy. Work on this initiative involves a collaborative approach among several parts of the Commission services.*[45]*[46] The European Institute for Health Records is involved in the promotion of high quality electronic health record systems in the European Union.*[47]

UK There are different models of health informatics delivery in each of the home countries (England, Scotland, Northern Ireland and Wales) but some bodies like UKCHIP (see below) operate for those 'in and for' all the home countries and beyond.

England NHS informatics in England was contracted out to several vendors for national health informatics solutions under the National Programme for Information Technology (NPfIT) label in the early to mid-2000's, under the auspices of NHS Connecting for Health (part of the Health and Social Care Information Centre as of 1 April 2013). NPfIT originally divided the country into five regions, with strategic 'systems integration' contracts awarded to one of several Local Service Providers (LSP). The various specific technical solutions were required to connect securely with the NHS 'Spine', a system designed to broker data between different systems and care settings.[16] NPfIT fell significantly behind schedule and its scope and design were being revised in real time, exacerbated by media and political lambasting of the Programme's spend (past and projected) against proposed budget. In 2010 a consultation was launched as part of the new Conservative/Liberal Democrat Coalition Government's White Paper 'Liberating the NHS'. This initiative provided little in the way of innovative thinking, primarily re-stating existing strategies within the proposed new context of the Coalition's vision for the NHS. The degree of computerisation in NHS secondary care was quite high before NPfIT, and the programme stagnated further development of the install base - the original NPfIT regional approach provided neither a single, nationwide solution nor local health community agility or autonomy to purchase systems, but instead tried to deal with a hinterland in the middle. Almost all general practices in England and Wales are computerised under the 'GP Systems of Choice' (GPSoC) programme, and patients have relatively extensive computerised primary care clinical records. System choice is the responsibility of individual general practices and while there is no single, standardised GP system, GPSoC sets relatively rigid minimum standards of performance and functionality for vendors to adhere to. Interoperation between primary and secondary care systems is rather primitive. It is hoped that a focus on interworking (for interfacing and integration) standards will stimulate synergy between primary and secondary care in sharing necessary information to support the care of individuals. Notable successes to date are in the electronic requesting and viewing of test results, and in some areas GPs have access to digital X-ray images from secondary care systems. Scotland has an approach to central connection under way which is more advanced than the English one in some ways. Scotland has the GPASS system whose source code is owned by the State, and controlled and developed by NHS Scotland. GPASS was accepted in 1984. It has been provided free to all GPs in Scotland but has developed poorly. Discussion of open sourcing it as a remedy is occurring.

Wales Wales has a dedicated Health Informatics function that supports NHS Wales in leading on the new integrated digital information services and promoting Health Informatics as a career.

Emerging Directions (European R&D) The European Commission's preference, as exemplified in the 5th Framework*[48] as well as currently pursued pilot projects,*[49] is for Free/Libre and Open Source Software (FLOSS) for healthcare. Another stream of research currently focuses on aspects of "big data" in health information systems. For background information on data-related aspects in health informatics see, e.g., the book "Biomedical Informatics" *[50] by Andreas Holzinger.

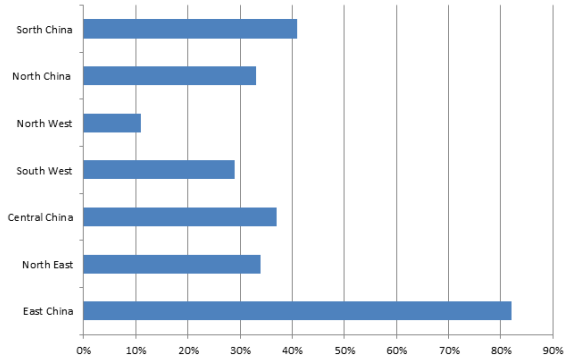
Asia and Oceania

In Asia and Australia-New Zealand, the regional group called the Asia Pacific Association for Medical Informatics (APAMI)*[51] was established in 1994 and now consists of more than 15 member regions in the Asia Pacific Region.

Australia The Australasian College of Health Informatics (ACHI) is the professional association for health informatics in the Asia-Pacific region. It represents the interests of a broad range of clinical and non-clinical professionals working within the health informatics sphere through a commitment to quality, standards and ethical practice.*[52] ACHI is an academic institutional member of the International Medical Informatics Association (IMIA)*[53] and a full member of the Australian Council of Professions.*[54] ACHI is a sponsor of the "e-Journal for Health Informatics" ,*[55] an indexed and peer-reviewed professional journal. ACHI has also supported the "Australian Health Informatics Education Council" (AHIEC) since its founding in 2009.*[56]

Although there are a number of health informatics organisations in Australia, the Health Informatics Society of Australia*[57] (HISA) is regarded as the major umbrella group and is a member of the International Medical Informatics Association (IMIA). Nursing informaticians were the driving force behind the formation of HISA, which is now a company limited by guarantee of the members. The membership comes from across the informatics spectrum that is from students to corporate affiliates. HISA has a number of branches (Queensland, New South Wales, Victoria and Western Australia) as well as special interest groups such as nursing (NIA), pathology, aged and community care, industry and medical imaging (Conrick, 2006).

China At last 20 years, China performed a successful transition from its planned economy to a socialist market economy. Along this great and earth-shaking change, China's healthcare system also experienced a significant reform to follow and adapt to this historical revolution. In 2003, the data (released from Ministry of Health of the People's Republic of China (MoH)), indicated that the national healthcare-involved expenditure was up to RMB 662.33 billion totally, which accounted for about 5.56% of nationwide gross domestic products. Before the 1980s, the entire healthcare costs were covered in central government annual budget. Since that, the construct of healthcare-expended supporters started to change gradually. Most of the expenditure was contributed by health insurance schemes and private spending, which corresponded to 40% and 45% of total expenditure, respectively. Meanwhile, the financially governmental contribution was decreased to 10% only. On the other hand, by 2004, up to 296,492 healthcare facilities were recorded in statistic summary of MoH, and an average of 2.4 clinical beds per 1000 people were mentioned as well.*[58]



Proportion of Nationwide Hospitals with HIS in China by 2004

Health Informatics in China Along with the development of information technology since the 1990s, healthcare providers realised that the information could generate significant benefits to improve their services by computerised cases and data, for instance of gaining the information for directing patient care and assessing the best patient care for specific clinical conditions. Therefore, substantial resources were collected to build China's own health informatics system. Most of these resources were arranged to construct Hospital Information System (HIS), which was aimed to minimise unnecessary waste and repetition, subsequently to promote the efficiency and quality-control of healthcare.*[59] By 2004, China had successfully spread HIS through approximately 35-40% of nationwide hospitals.*[60] However, the dispersion of hospital-owned HIS varies critically. In the east part of China, over 80% of hospitals constructed HIS, in northwest of China the equivalent was no more than 20%. Moreover, all of the Centers for Disease Control and Prevention (CDC) above rural level, approximately 80% of healthcare organisations above the rural level and 27% of hospitals over town level have the ability to perform the transmission of reports about real-time epidemic situation through public health information system and to analysis infectious diseases by dynamic statistics.*[61]

China has four tiers in its healthcare system. The first tier is street health and workplace clinics and these are cheaper than hospitals in terms of medical billing and act as prevention centers. The second tier is district and enterprise hospitals along with specialist clinics and these provide the second level of care. The third tier is provisional and municipal general hospitals and teaching hospitals which provided the third level of care. In a tier of its own is the national hospitals which are governed by the Ministry of Health. China has been greatly improving its health informatics since it finally opened its doors to the outside world and joined the World Trade Organization (WTO). In 2001, it was reported that China had 324,380 medical institutions and the majority of those were clinics. The reason for that is that clinics are prevention centers and Chinese people like using traditional Chinese medicine as opposed to Western medicine and it usually works for the minor cases. China has also been improving its higher education in regards to health informatics. At the end of 2002, there were 77 medical universities and medical colleges. There were 48 university medical colleges which offered bachelor, master, and doctorate degrees in medicine. There were 21 higher medical specialty institutions that offered diploma degrees so in total, there were 147 higher medical and educational institutions. Since joining the WTO, China has been working hard to improve its education system and bring it up to international standards.*[62] SARS played a large role in China quickly improving its healthcare system. Back in 2003, there was an outbreak of SARS and that made China hurry to spread HIS or Hospital Information System and more than 80% of hospitals had HIS. China had been comparing itself to Korea's healthcare system and figuring out how it can better its own system. There was a study done that surveyed six hospitals in China that had HIS. The results were that doctors didn't use computers as much so it was concluded that it wasn't used as much for clinical practice than it was for administrative purposes. The survey asked if the hospitals created any websites and it was concluded that only four of them had created websites and that three had a third-party company create it for them and one was created by the hospital staff. In conclusion, all of them agreed or strongly agreed that providing health information on the Internet should be utilized.*[63]

Health Informatics Standards in China Collected information at different times, by different participants or systems could frequently lead to issues of misunderstanding, dis-comparing or dis-exchanging. To design an issues-minor system, healthcare providers realised that certain standards were the basis for sharing information and interoperability, however a system lacking standards

would be a large impediment to interfere the improvement of corresponding information systems. Given that the standardisation for health informatics depends on the authorities, standardisation events must be involved with government and the subsequently relevant funding and supports were critical. In 2003, the Ministry of Health released the Development Lay-out of National Health Informatics (2003–2010)*[64] indicating the identification of standardisation for health informatics which is 'combining adoption of international standards and development of national standards'.

In China, the establishment of standardisation was initially facilitated with the development of vocabulary, classification and coding, which is conducive to reserve and transmit information for premium management at national level. By 2006, 55 international/ domestic standards of vocabulary, classification and coding have served in hospital information system. In 2003, the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) and the ICD-10 Clinical Modification (ICD-10-CM) were adopted as standards for diagnostic classification and acute care procedure classification. Simultaneously, the International Classification of Primary Care (ICPC) were translated and tested in China's local applied environment.*[65] Another coding standard, named Logical Observation Identifiers Names and Codes (LOINC), was applied to serve as general identifiers for clinical observation in hospitals. Personal identifier codes were widely employed in different information systems, involving name, sex, nationality, family relationship, educational level and job occupation. However, these codes within different systems are inconsistent, when sharing between different regions. Considering this large quantity of vocabulary, classification and coding standards between different jurisdictions, the healthcare provider realised that using multiple systems could generate issues of resource wasting and a non-conflicting national level standard was beneficial and necessary. Therefore, in late 2003, the health informatics group in Ministry of Health released three projects to deal with issues of lacking national health information standards, which were the Chinese National Health Information Framework and Standardisation, the Basic Data Set Standards of Hospital Information System and the Basic Data Set Standards of Public Health Information System.

*[58]

Comparison between China's EHR Standard and Segments of the ASTM E 1384 Standard Recently, researchers from local universities evaluated the performance of China's Electronic Health Record(EHR) Standard compared with the American Society for Testing and Materials Standard Practice for Content and Structure of Electronic Health Records in the United States (ASTM E 1384 Standard).*[66]

The table above demonstrates details of this comparison which indicates certain domains of improvement for future revisions of EHR Standard in China. Detailedly, these deficiencies are listed in the following.

1. The lack of supporting on privacy and security. The ISO/TS 18308 specifies "The EHR must support the ethical and legal use of personal information, in accordance with established privacy principles and frameworks, which may be culturally or jurisdictionally specific" (ISO 18308: Health Informatics-Requirements for an Electronic Health Record Architecture, 2004). However this China's EHR Standard did not achieve any of the fifteen requirements in the subclass of privacy and security.

2. The shortage of supporting on different types of data and reference. Considering only ICD-9 is referenced as China's external international coding systems, other similar systems, such as SNOMED CT in clinical terminology presentation, cannot be considered as familiar for Chinese specialists, which could lead to internationally information-sharing deficiency.

3. The lack of more generic and extensible lower level data structures. China's large and complex EHR Standard was constructed for all medical domains. However, the specific and time-frequent attributes of clinical data elements, value sets and templates identified that this once-for-all purpose cannot lead to practical consequence.*[67]

Hong Kong In Hong Kong a computerized patient record system called the Clinical Management System (CMS) has been developed by the Hospital Authority since 1994. This system has been deployed at all the sites of the Authority (40 hospitals and 120 clinics), and is used by all 30,000 clinical staff on a daily basis, with a daily transaction of up to 2 millions. The comprehensive records of 7 million patients are available on-line in the Electronic Patient Record (ePR), with data integrated from all sites. Since 2004 radiology image viewing has been added to the ePR, with radiography images from any HA site being available as part of the ePR.

The Hong Kong Hospital Authority placed particular attention to the governance of clinical systems development, with input from hundreds of clinicians being incorporated through a structured process. The Health Informatics Section in Hong Kong Hospital Authority*[68] has close relationship with Information Technology Department and clinicians to develop healthcare systems for the organization to support the service to all public hospitals and clinics in the region.

The Hong Kong Society of Medical Informatics (HKSMI) was established in 1987 to promote the use of information technology in healthcare. The eHealth

Consortium has been formed to bring together clinicians from both the private and public sectors, medical informatics professionals and the IT industry to further promote IT in healthcare in Hong Kong.*[69]

India Main article: Indian Association for Medical Informatics

eHCF School of Medical Informatics http://www.ehcfsmi.edu.in eHealth-Care Foundation http://www.ehealth-care.net

Malaysia Since 2010, The Ministry of Health (MoH) working on the Malaysian Health Data Warehouse (MyHDW) project. MyHDW aims to meet the diverse needs of timely health information provision and management, and acts as a platform for the standardization and integration of health data from a variety of sources (Health Informatics Centre, 2013). The Ministry has embarked on introducing the electronic Hospital Information Systems (HIS) in several public hospitals including Serdang Hospital, Selayang Hospital and University Kebangsaan Malaysia Medical Centre (UKMMC) under the Ministry of Higher Education (MOHE).

A Hospital Information System (HIS) is a comprehensive, integrated information system designed to manage the administrative, financial and clinical aspects of a hospital. As an area of Medical Informatics, the aim of hospital information system is to achieve the best possible support of patient care and administration by electronic data processing. HIS plays a vital role in planning, initiating, organizing and controlling the operations of the subsystems of the hospital and thus provides a synergistic organization in the process.

New Zealand Health Informatics is taught at five New Zealand universities. The most mature and established is the Otago programme which has been offered for over a decade.*[70] Health Informatics New Zealand (HINZ), is the national organisation that advocates for Health Informatics. HINZ organises a conference every year and also publishes an online journal- Healthcare Informatics Review Online.

Saudi Arabia The Saudi Association for Health Information (SAHI) was established in 2006*[71] to work under direct supervision of King Saud bin Abdulaziz University for Health Sciences to practice public activities, develop theoretical and applicable knowledge, and provide scientific and applicable studies.*[72]

Post Soviet Countries

The Russian Federation Russian healthcare system mainly consists of the principles based on the principles of the soviet healthcare system that was oriented on mass prophylaxis, prevention of infection and epidemic diseases, vaccination and immunization of the Soviet population on socially protected basis. Current government Healthcare system consists of several directions:

- Preventive health care
- Primary health care
- Specialized medical care
- Obstetrical and gynecologic medical care
- Pediatric medical care
- Surgery
- Rehabilitation/ Health resort treatment

One of the main issues of the post-soviet medical health care system was the absence of the united system providing optimization of work for medical institutes with one, single database and structured appointment schedule and hence hours-long lines. Efficiency of medical workers might have been also doubtful because of the paperwork administrating or lost book records.

Along with the development of the information systems IT and Healthcare departments of Moscow agreed on designing a system that would improve public services of health care institutes. Tackling with the issues appearing in the current system, Moscow Government ordered the designing of the system that would provide simplified electronic booking to public clinics and automatize work of medical workers on the first level.

The system designed for that purposes was called EMIAS (United Medical Information and Analysis System) and presents EHR (Electronic Health Record) with the majority of other services set in the system that allow managing flows of patients, contains outpatient card integrated in the system, and provides an opportunity to manage consolidated managerial accounting and personalized list of medical help. Besides that, the system contains information about availability of the medical institutions and various doctors.

The beginning of the implementation of the system started in 2013 with the organization of one computerized database for all patients in the city, including convenient front-end for the users. EMIAS is implemented in Moscow and Moscow region and it is planned that the project should embrace most parts of the country.

1.2.9 Health Informatics Law

For more details on this topic, see Health law.

Health informatics law deals with evolving and sometimes complex legal principles as they apply to information technology in health-related fields. It addresses the privacy, ethical and operational issues that invariably arise when electronic tools, information and media are used in health care delivery. Health Informatics Law also applies to all matters that involve information technology, health care and the interaction of information. It deals with the circumstances under which data and records are shared with other fields or areas that support and enhance patient care.

As many healthcare systems are making an effort to have patient records more readily available to them via the internet, it is important that providers be sure that there are a few security standards in place in order to make sure that the patients information is safe. They have to be able to assure confidentiality and the security of the people, process, and technology. Since there is also the possibility of payments being made through this system, it is vital that this aspect of their private information will also be protected through cryptography.

1.2.10 History

Worldwide use of computer technology in medicine began in the early 1950s with the rise of the computers.*[31] In 1949, Gustav Wagner established the first professional organization for informatics in Germany.*[73] The prehistory, history, and future of medical information and health information technology are discussed in reference.*[74] Specialized university departments and Informatics training programs began during the 1960s in France, Germany, Belgium and The Netherlands. Medical informatics research units began to appear during the 1970s in Poland and in the U.S.*[73] Since then the development of high-quality health informatics research, education and infrastructure has been a goal of the U.S. and the European Union.*[73]

Early names for health informatics included medical computing, biomedical computing, medical computer science, computer medicine, medical electronic data processing, medical automatic data processing, medical information processing, medical information science, medical software engineering, and medical computer technology.

The health informatics community is still growing, it is by no means a mature profession, but work in the UK by the voluntary registration body, the UK Council of Health Informatics Professions has suggested eight key constituencies within the domain - information management, knowledge management, portfolio/programme/project management, ICT, education and research, clinical informatics, health records(service and business-related), health informatics service management. These constituencies accommodate professionals in and for the NHS, in academia and commercial service and solution providers.

Since the 1970s the most prominent international coordinating body has been the International Medical Informatics Association (IMIA).*[75]

1.2.11 Leading health informatics and medical informatics journals

Main article: List of medical and health informatics journals

1.2.12 See also

Related concepts

- Bioinformatics
- Clinical coder
- Clinical documentation improvement
- Continuity of care record (CCR)
- Diagnosis-related groups
- eHealth
- Electronic health record (EHR)
- Electronic medical record (EMR)
- Health information exchange (HIE)
- Health information management (HIM)
- Hospital information system
- Human resources for health (HRH) information system
- International Classification of Diseases (ICD)
- Medical coding
- Neuroinformatics
- Nosology
- Personal health record (PHR)
- Public health informatics

Standards/frameworks and governance

- DICOM
- Health Metrics Network
- HL7
- Fast Healthcare Interoperability Resources (FHIR)

- LOINC
- Omaha System
- openEHR
- SNOMED
- xDT

Algorithms

- Datafly algorithm

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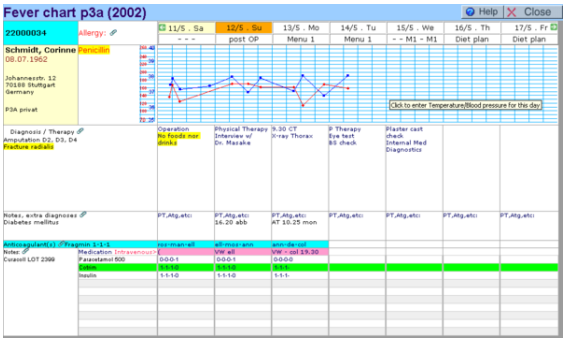
1.2.14 External links

- Health informatics at DMOZ
- Article about informatics
- Willison, Brian. Advancing Meaningful Use: Simplifying Complex Clinical Metrics Through Visual Representation.
- Clinfowiki
- Global Health Informatics Partnership

1.3 Clinical Informatics



Electronic patient chart from a health information system

Health informatics (also called **health care informatics**, **healthcare informatics**, **medical informatics**, **nursing informatics**, **clinical informatics**, or **biomedical informatics**) is informatics in health care. It is a multidisciplinary field that uses health information technology (HIT) to improve health care via any combination of higher quality, higher efficiency (spurring lower cost and thus greater availability), and new opportunities. The disciplines involved include information science, computer science, social science, behavioral science, management science, and others. The NLM defines health informatics as "the interdisciplinary study of the design, development, adoption and application of IT-based innovations in healthcare services delivery, management and planning." *[1] It deals with the resources, devices, and methods required to optimize the acquisition, storage, retrieval, and use of information in health and biomedicine. Health informatics tools include amongst others computers, clinical guidelines, formal medical terminologies, and information and communication systems.*[2]*[3] It is applied to the areas of nursing, clinical care, dentistry, pharmacy, public health, occupational therapy, physical therapy and (bio)medical

research, and alternative medicine.*[4] All of which are designed to improve the overall of effectiveness of patient care delivery by ensuring that the data generated is of a high quality e.g. an mHealth based early warning scorecard.*[5]

- The international standards on the subject are covered by ICS 35.240.80*[6] in which ISO 27799:2008 is one of the core components.*[7]
- Molecular bioinformatics and clinical informatics have converged into the field of translational bioinformatics.

1.3.1 Sub Specialities

- Healthcare Informatics
  - Clinical Informatics
  - Pathology Informatics
  - Pharmacy Informatics*[8]*[9]*[10]*[11]*[12]*[13]
  - Public Health Informatics
  - Community Health Informatics
    - Home Health Informatics
  - Nursing Informatics
  - Medical Informatics
- Consumer Health Informatics
- Clinical Bioinformatics
- Informatics for Education & Research in Health & Medicine

1.3.2 Healthcare Informatics

Clinical Informatics

Clinical Informatics is concerned with the use of information in health care by and for clinicians.*[14]*[15]

Clinical informaticians transform health care by analyzing, designing, implementing, and evaluating information and communication systems that enhance individual and population health outcomes, improve [patient] care, and strengthen the clinician-patient relationship. Clinical informaticians use their knowledge of patient care combined with their understanding of informatics concepts, methods, and health informatics tools to:

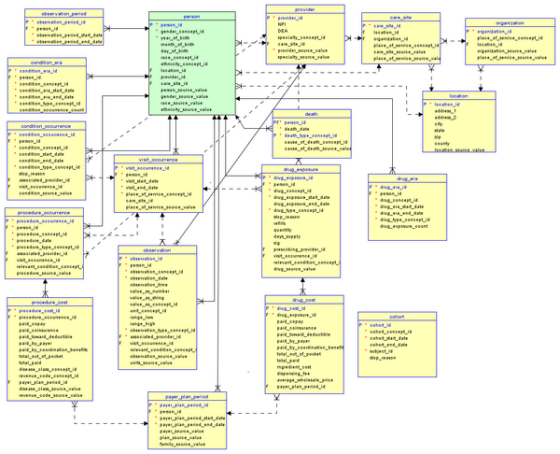
- assess information and knowledge needs of health care professionals and patients,
- characterize, evaluate, and refine clinical processes,
- develop, implement, and refine clinical decision support systems, and
- lead or participate in the procurement, customization, development, implementation, management, evaluation, and continuous improvement of clinical information systems.

Clinicians collaborate with other health care and information technology professionals to develop health informatics tools which promote patient care that is safe, efficient, effective, timely, patient-centered, and equitable.

In October 2011 American Board of Medical Specialties (ABMS), the organization overseeing the certification of physician specialists (MD Physicians only) in the United States, announced the creation of physician (MD physicians only) certification in Clinical Informatics. The first examination for board certification in the subspecialty of Clinical Informatics was offered in October 2013 by American Board of Preventive Medicine with 432 passing to become the 2014 inaugural class of Diplomates (ABPM) in Clinical Informatics.*[16]

Fellowship programs exist for physicians who wish to become board-certified in Clinical Informatics. Physicians must have graduated from a medical school in the United States or Canada, or a school located elsewhere that is approved by the ABPM. In addition, they must complete a primary residency program such as Internal Medicine (or any of the 24 subspecialties recognized by the ABMS) and be eligible to become licensed to practice medicine in the state where their fellowship program is located.*[17] The fellowship program is 24 months in length, with fellows dividing their time between Informatics rotations, didactics, research, and clinical work in their primary specialty.

Integrated data repository



example IDR schema

Development of the field of clinical informatics lead to creation of large data sets with electronic health record data integrated with other data (such as genomic data). Large data warehouses are often described as clinical data

warehouses (also known as clinical data repositories). In research, deidentified CDWs can be used by researchers with less complex ethical oversight. CDWs with data of deceased patients were also suggested as a research resource that does not require IRB approval.*[18]*[19]

1.3.3 Human Bioinformatics

Translational bioinformatics

With the completion of the human genome and the recent advent of high throughput sequencing and genome-wide association studies of single nucleotide polymorphisms, the fields of molecular bioinformatics, biostatistics, statistical genetics and clinical informatics are converging into the emerging field of translational bioinformatics.*[20]*[21]*[22]
The relationship between bioinformatics and health informatics, while conceptually related under the umbrella of biomedical informatics,*[23] has not always been very clear. The TBI community is specifically motivated with the development of approaches to identify linkages between fundamental biological and clinical information.
Along with complementary areas of emphasis, such as those focused on developing systems and approaches within clinical research contexts,*[24] insights from TBI may enable a new paradigm for the study and treatment of disease.

1.3.4 Computational Health Informatics

Computational Health Informatics

Computational health informatics is a branch of Computer Science that deals specifically with computational techniques that are relevant in healthcare. Computational health informatics is also a branch of Health Informatics, but is orthogonal to much of the work going on in health informatics because computer scientist's interest is mainly in understanding fundamental properties of computation. Health informatics, on the other hand, is primarily concerned with understanding fundamental properties of medicine that allow for the intervention of computers. The health domain provides an extremely wide variety of problems that can be tackled using computational techniques, and computer scientists are attempting to make a difference in medicine by studying the underlying principles of computer science that will allow for meaningful (to medicine) algorithms and systems to be developed. Thus, computer scientists working in computational health informatics and health scientists working in medical health informatics combine to develop the next generation of healthcare technologies.

Using computers to analyze health data has been around since the 1950s, but it wasn't until the 1990s that the first sturdy models appeared. The development of the internet has helped develop computational health informatics over the past decade. Computer models are used to examine various topics such as how exercise affects obesity, healthcare costs, and many more.*[25]

Examples of projects in computational health informatics include the COACH project.*[26]*[27]

1.3.5 Informatics for Education & Research in Health & Medicine

Clinical Research Informatics

Clinical Research Informatics (or, CRI) takes the core foundations, principles, and technologies related to Health Informatics, and applies these to clinical research contexts.*[28] As such, CRI is a sub-discipline of Health Informatics, and interest and activities in CRI have increased greatly in recent years given the overwhelming problems associated with the explosive growth of clinical research data and information.*[29] There are a number of activities within clinical research that CRI supports, including:

- more efficient and effective data collection and acquisition
- improved recruitment into clinical trials
- optimal protocol design and efficient management
- patient recruitment and management
- adverse event reporting
- regulatory compliance
- data storage, transfer,*[30] processing and analysis
- repositories of data from completed clinical trials (for secondary analyses)

1.3.6 Medical informatics in the United States

Even though the idea of using computers in medicine emerged as technology advanced in the early 20th century, it was not until the 1950s that informatics began to have an effect in the United States.*[31]

The earliest use of electronic digital computers for medicine was for dental projects in the 1950s at the United States National Bureau of Standards by Robert Ledley.*[32] During the mid-1950s, the United States Air Force (USAF) carried out several medical projects on its computers while also encouraging civilian agencies such as the National Academy of Sciences - National Research Council (NAS-NRC) and the National Institutes of Health (NIH) to sponsor such work.*[33] In 1959, Ledley and Lee B. Lusted published "Reasoning

Foundations of Medical Diagnosis," a widely read article in *Science*, which introduced computing (especially operations research) techniques to medical workers. Ledley and Lusted's article has remained influential for decades, especially within the field of medical decision making.*[34]

Guided by Ledley's late 1950s survey of computer use in biology and medicine (carried out for the NAS-NRC), and by his and Lusted's articles, the NIH undertook the first major effort to introduce computers to biology and medicine. This effort, carried out initially by the NIH's Advisory Committee on Computers in Research (ACCR), chaired by Lusted, spent over $40 million between 1960 and 1964 in order to establish dozens of large and small biomedical research centers in the US.*[33]

One early (1960, non-ACCR) use of computers was to help quantify normal human movement, as a precursor to scientifically measuring deviations from normal, and design of prostheses.*[35] The use of computers (IBM 650, 1620, and 7040) allowed analysis of a large sample size, and of more measurements and subgroups than had been previously practical with mechanical calculators, thus allowing an objective understanding of how human locomotion varies by age and body characteristics. A study co-author was Dean of the Marquette University College of Engineering; this work led to discrete Biomedical Engineering departments there and elsewhere.

The next steps, in the mid-1960s, were the development (sponsored largely by the NIH) of expert systems such as MYCIN and Internist-I. In 1965, the National Library of Medicine started to use MEDLINE and MEDLARS. Around this time, Neil Pappalardo, Curtis Marble, and Robert Greenes developed MUMPS (Massachusetts General Hospital Utility Multi-Programming System) in Octo Barnett's Laboratory of Computer Science *[36] at Massachusetts General Hospital in Boston, another center of biomedical computing that received significant support from the NIH.*[37] In the 1970s and 1980s it was the most commonly used programming language for clinical applications. The MUMPS operating system was used to support MUMPS language specifications. As of 2004, a descendent of this system is being used in the United States Veterans Affairs hospital system. The VA has the largest enterprise-wide health information system that includes an electronic medical record, known as the Veterans Health Information Systems and Technology Architecture (VistA). A graphical user interface known as the Computerized Patient Record System (CPRS) allows health care providers to review and update a patient's electronic medical record at any of the VA's over 1,000 health care facilities.

During the 1960s, Morris Collen, a physician working for Kaiser Permanente's Division of Research, developed computerized systems to automate many aspects of multiphasic health checkups. These system became the basis the larger medical databases Kaiser Permanente developed during the 1970s and 1980s.*[38] The American College of Medical Informatics (ACMI) has since 1993 annually bestowed the Morris F. Collen, MD Medal for Outstanding Contributions to the Field of Medical Informatics.*[39]

In the 1970s a growing number of commercial vendors began to market practice management and electronic medical records systems. Although many products exist, only a small number of health practitioners use fully featured electronic health care records systems.

Homer R. Warner, one of the fathers of medical informatics,*[40] founded the Department of Medical Informatics at the University of Utah in 1968. The American Medical Informatics Association (AMIA) has an award named after him on application of informatics to medicine.

Informatics Certifications

Like other IT training specialties, there are Informatics certifications available to help informatics professionals stand out and be recognized. The American Nurses Credentialing Center (ANCC) offers a board certification in Nursing Informatics. For Radiology Informatics, the CIIP (Certified Imaging Informatics Professional) certification was created by ABII (The American Board of Imaging Informatics) which was founded by SIIM (the Society for Imaging Informatics in Medicine) and ARRT (the American Registry of Radiologic Technologists) in 2005. The CIIP certification requires documented experience working in Imaging Informatics, formal testing and is a limited time credential requiring renewal every five years. The exam tests for a combination of IT technical knowledge, clinical understanding, and project management experience thought to represent the typical workload of a PACS administrator or other radiology IT clinical support role. Certifications from PARCA (PACS Administrators Registry and Certifications Association) are also recognized. The five PARCA certifications are tiered from entry level to architect level.

1.3.7 Medical informatics in the UK

The broad history of health informatics has been captured in the book *UK Health Computing : Recollections and reflections*, Hayes G, Barnett D (Eds.), BCS (May 2008) by those active in the field, predominantly members of BCS Health and its constituent groups. The book describes the path taken as 'early development of health informatics was unorganized and idiosyncratic'. In the early −1950s it was prompted by those involved in NHS finance and only in the early 1960s did solutions including those in pathology (1960), radiotherapy (1962), immunization (1963), and primary care (1968) emerge. Many of these solutions, even in the early 1970s were developed in-house by pioneers in the field to meet their own

requirements. In part this was due to some areas of health services (for example the immunization and vaccination of children) still being provided by Local Authorities. Interesting, this is a situation which the coalition government propose broadly to return to in the 2010 strategy Equity and Excellence: Liberating the NHS (July 2010); stating:

"We will put patients at the heart of the NHS, through an information revolution and greater choice and control' with shared decision-making becoming the norm: 'no decision about me without me' and patients having access to the information they want, to make choices about their care. They will have increased control over their own care records."

These types of statements present a significant opportunity for health informaticians to come out of the back-office and take up a front-line role supporting clinical practice, and the business of care delivery. The UK health informatics community has long played a key role in international activity, joining TC4 of the International Federation of Information Processing (1969) which became IMIA (1979). Under the aegis of BCS Health, Cambridge was the host for the first EFMI Medical Informatics Europe (1974) conference and London was the location for IMIA' s tenth global congress (MEDINFO2001).

1.3.8 Current state of health informatics and policy initiatives

Argentina

Since 1997, the Buenos Aires Biomedical Informatics Group, a nonprofit group, represents the interests of a broad range of clinical and non-clinical professionals working within the Health Informatics sphere. Its purposes are:

- Promote the implementation of the computer tool in the healthcare activity, scientific research, health administration and in all areas related to health sciences and biomedical research.
- Support, promote and disseminate content related activities with the management of health information and tools they used to do under the name of Biomedical informatics.
- Promote cooperation and exchange of actions generated in the field of biomedical informatics, both in the public and private, national and international level.
- Interact with all scientists, recognized academic stimulating the creation of new instances that have the same goal and be inspired by the same purpose.
- To promote, organize, sponsor and participate in events and activities for training in computer and information and disseminating developments in this area that might be useful for team members and health related activities.

The Argentinian health system is heterogeneous in its function, and because of that the informatics developments show a heterogeneous stage. Many private Health Care center have developed systems, such as the Hospital Aleman of Buenos Aires, or the Hospital Italiano de Buenos Aires that also has a residence program for health informatics.

Brazil

Main article: Brazilian Society of Health Informatics

The first applications of computers to medicine and healthcare in Brazil started around 1968, with the installation of the first mainframes in public university hospitals, and the use of programmable calculators in scientific research applications. Minicomputers, such as the IBM 1130 were installed in several universities, and the first applications were developed for them, such as the hospital census in the School of Medicine of Ribeirão Preto and patient master files, in the Hospital das Clínicas da Universidade de São Paulo, respectively at the cities of Ribeirão Preto and São Paulo campuses of the University of São Paulo. In the 1970s, several Digital Corporation and Hewlett Packard minicomputers were acquired for public and Armed Forces hospitals, and more intensively used for intensive-care unit, cardiology diagnostics, patient monitoring and other applications. In the early 1980s, with the arrival of cheaper microcomputers, a great upsurge of computer applications in health ensued, and in 1986 the Brazilian Society of Health Informatics was founded, the first Brazilian Congress of Health Informatics was held, and the first *Brazilian Journal of Health Informatics* was published. In Brazil, two universities are pioneers in teaching and research in Medical Informatics, both the University of Sao Paulo and the Federal University of Sao Paulo offer undergraduate programs highly qualified in the area as well as extensive graduate programs (MSc and PhD). In 2015 the Universidade Federal de Ciências da Saúde de Porto Alegre, Rio Grande do Sul, also started to offer undergraduate program.

Canada

Health Informatics projects in Canada are implemented provincially, with different provinces creating different systems. A national, federally funded, not-for-profit organization called Canada Health Infoway was created in 2001 to foster the development and adoption of electronic health records across Canada. As of December 31, 2008

there were 276 EHR projects under way in Canadian hospitals, other health-care facilities, pharmacies and laboratories, with an investment value of $1.5-billion from Canada Health Infoway.*[41]

Provincial and territorial programmes include the following:

- **eHealth Ontario** was created as an Ontario provincial government agency in September 2008. It has been plagued by delays and its CEO was fired over a multimillion-dollar contracts scandal in 2009.*[42]
- **Alberta Netcare** was created in 2003 by the Government of Alberta. Today the netCARE portal is used daily by thousands of clinicians. It provides access to demographic data, prescribed/dispensed drugs, known allergies/intolerances, immunizations, laboratory test results, diagnostic imaging reports, the diabetes registry and other medical reports. netCARE interface capabilities are being included in electronic medical record products which are being funded by the provincial government.

United States

In 2004, President George W. Bush signed Executive Order 13335, creating the Office of the National Coordinator for Health Information Technology (ONCHIT) as a division of the U.S. Department of Health and Human Services (HHS). The mission of this office is widespread adoption of interoperable electronic health records (EHRs) in the US within 10 years. See quality improvement organizations for more information on federal initiatives in this area.

In 2014 The Department of Education approved an advanced Health Informatics Undergraduate program that was submitted by The University of South Alabama. The program is designed to provide specific Health Informatics education, and is the only program in the country with a Health Informatics Lab. The program is housed in The School of Computing in Shelby Hall, a recently completed $50 million state of the art teaching facility. The University of South Alabama awarded David L. Loeser on May 10, 2014 with the first Health Informatics degree. The program currently is scheduled to have 100+ students awarded by 2016.

The Certification Commission for Healthcare Information Technology (CCHIT), a private nonprofit group, was funded in 2005 by the U.S. Department of Health and Human Services to develop a set of standards for electronic health records (EHR) and supporting networks, and certify vendors who meet them. In July 2006, CCHIT released its first list of 22 certified ambulatory EHR products, in two different announcements.*[43]

Harvard Medical School added a department of biomedical informatics in 2015.*[44]

Europe

For more details on this topic, see European Federation for Medical Informatics.

The European Union's Member States are committed to sharing their best practices and experiences to create a European eHealth Area, thereby improving access to and quality health care at the same time as stimulating growth in a promising new industrial sector. The European eHealth Action Plan plays a fundamental role in the European Union's strategy. Work on this initiative involves a collaborative approach among several parts of the Commission services.*[45]*[46] The European Institute for Health Records is involved in the promotion of high quality electronic health record systems in the European Union.*[47]

UK There are different models of health informatics delivery in each of the home countries (England, Scotland, Northern Ireland and Wales) but some bodies like UKCHIP (see below) operate for those 'in and for' all the home countries and beyond.

England NHS informatics in England was contracted out to several vendors for national health informatics solutions under the National Programme for Information Technology (NPfIT) label in the early to mid-2000's, under the auspices of NHS Connecting for Health (part of the Health and Social Care Information Centre as of 1 April 2013). NPfIT originally divided the country into five regions, with strategic 'systems integration' contracts awarded to one of several Local Service Providers (LSP). The various specific technical solutions were required to connect securely with the NHS 'Spine', a system designed to broker data between different systems and care settings.[16] NPfIT fell significantly behind schedule and its scope and design were being revised in real time, exacerbated by media and political lambasting of the Programme's spend (past and projected) against proposed budget. In 2010 a consultation was launched as part of the new Conservative/Liberal Democrat Coalition Government's White Paper 'Liberating the NHS'. This initiative provided little in the way of innovative thinking, primarily re-stating existing strategies within the proposed new context of the Coalition's vision for the NHS. The degree of computerisation in NHS secondary care was quite high before NPfIT, and the programme stagnated further development of the install base - the original NPfIT regional approach provided neither a single, nationwide solution nor local health community agility or autonomy to purchase systems, but instead tried to deal with a hinterland in the middle. Almost all general practices in England and Wales are computerised under the 'GP Systems of Choice' (GPSoC) programme, and patients have relatively extensive computerised primary care clinical

records. System choice is the responsibility of individual general practices and while there is no single, standardised GP system, GPSoC sets relatively rigid minimum standards of performance and functionality for vendors to adhere to. Interoperation between primary and secondary care systems is rather primitive. It is hoped that a focus on interworking (for interfacing and integration) standards will stimulate synergy between primary and secondary care in sharing necessary information to support the care of individuals. Notable successes to date are in the electronic requesting and viewing of test results, and in some areas GPs have access to digital X-ray images from secondary care systems. Scotland has an approach to central connection under way which is more advanced than the English one in some ways. Scotland has the GPASS system whose source code is owned by the State, and controlled and developed by NHS Scotland. GPASS was accepted in 1984. It has been provided free to all GPs in Scotland but has developed poorly. Discussion of open sourcing it as a remedy is occurring.

Wales Wales has a dedicated Health Informatics function that supports NHS Wales in leading on the new integrated digital information services and promoting Health Informatics as a career.

Emerging Directions (European R&D) The European Commission's preference, as exemplified in the 5th Framework*[48] as well as currently pursued pilot projects,*[49] is for Free/Libre and Open Source Software (FLOSS) for healthcare. Another stream of research currently focuses on aspects of "big data" in health information systems. For background information on data-related aspects in health informatics see, e.g., the book "Biomedical Informatics" *[50] by Andreas Holzinger.

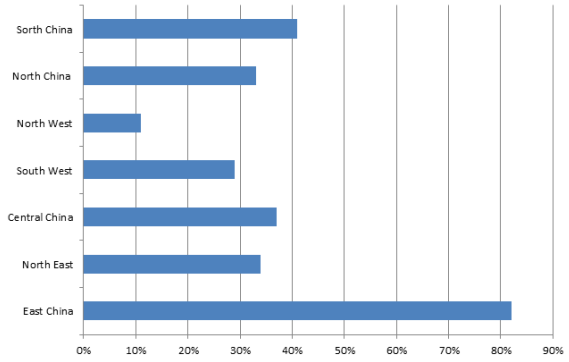
Asia and Oceania

In Asia and Australia-New Zealand, the regional group called the Asia Pacific Association for Medical Informatics (APAMI)*[51] was established in 1994 and now consists of more than 15 member regions in the Asia Pacific Region.

Australia The Australasian College of Health Informatics (ACHI) is the professional association for health informatics in the Asia-Pacific region. It represents the interests of a broad range of clinical and non-clinical professionals working within the health informatics sphere through a commitment to quality, standards and ethical practice.*[52] ACHI is an academic institutional member of the International Medical Informatics Association (IMIA)*[53] and a full member of the Australian Council of Professions.*[54] ACHI is a sponsor of the "e-Journal for Health Informatics" ,*[55] an indexed and peer-reviewed professional journal. ACHI has also supported the "Australian Health Informatics Education Council" (AHIEC) since its founding in 2009.*[56]

Although there are a number of health informatics organisations in Australia, the Health Informatics Society of Australia*[57] (HISA) is regarded as the major umbrella group and is a member of the International Medical Informatics Association (IMIA). Nursing informaticians were the driving force behind the formation of HISA, which is now a company limited by guarantee of the members. The membership comes from across the informatics spectrum that is from students to corporate affiliates. HISA has a number of branches (Queensland, New South Wales, Victoria and Western Australia) as well as special interest groups such as nursing (NIA), pathology, aged and community care, industry and medical imaging (Conrick, 2006).

China At last 20 years, China performed a successful transition from its planned economy to a socialist market economy. Along this great and earth-shaking change, China's healthcare system also experienced a significant reform to follow and adapt to this historical revolution. In 2003, the data (released from Ministry of Health of the People's Republic of China (MoH)), indicated that the national healthcare-involved expenditure was up to RMB 662.33 billion totally, which accounted for about 5.56% of nationwide gross domestic products. Before the 1980s, the entire healthcare costs were covered in central government annual budget. Since that, the construct of healthcare-expended supporters started to change gradually. Most of the expenditure was contributed by health insurance schemes and private spending, which corresponded to 40% and 45% of total expenditure, respectively. Meanwhile, the financially governmental contribution was decreased to 10% only. On the other hand, by 2004, up to 296,492 healthcare facilities were recorded in statistic summary of MoH, and an average of 2.4 clinical beds per 1000 people were mentioned as well.*[58]



Proportion of Nationwide Hospitals with HIS in China by 2004

Health Informatics in China Along with the development of information technology since the 1990s, health-

care providers realised that the information could generate significant benefits to improve their services by computerised cases and data, for instance of gaining the information for directing patient care and assessing the best patient care for specific clinical conditions. Therefore, substantial resources were collected to build China's own health informatics system. Most of these resources were arranged to construct Hospital Information System (HIS), which was aimed to minimise unnecessary waste and repetition, subsequently to promote the efficiency and quality-control of healthcare.*[59] By 2004, China had successfully spread HIS through approximately 35-40% of nationwide hospitals.*[60] However, the dispersion of hospital-owned HIS varies critically. In the east part of China, over 80% of hospitals constructed HIS, in northwest of China the equivalent was no more than 20%. Moreover, all of the Centers for Disease Control and Prevention (CDC) above rural level, approximately 80% of healthcare organisations above the rural level and 27% of hospitals over town level have the ability to perform the transmission of reports about real-time epidemic situation through public health information system and to analysis infectious diseases by dynamic statistics.*[61]

China has four tiers in its healthcare system. The first tier is street health and workplace clinics and these are cheaper than hospitals in terms of medical billing and act as prevention centers. The second tier is district and enterprise hospitals along with specialist clinics and these provide the second level of care. The third tier is provisional and municipal general hospitals and teaching hospitals which provided the third level of care. In a tier of its own is the national hospitals which are governed by the Ministry of Health. China has been greatly improving its health informatics since it finally opened its doors to the outside world and joined the World Trade Organization (WTO). In 2001, it was reported that China had 324,380 medical institutions and the majority of those were clinics. The reason for that is that clinics are prevention centers and Chinese people like using traditional Chinese medicine as opposed to Western medicine and it usually works for the minor cases. China has also been improving its higher education in regards to health informatics. At the end of 2002, there were 77 medical universities and medical colleges. There were 48 university medical colleges which offered bachelor, master, and doctorate degrees in medicine. There were 21 higher medical specialty institutions that offered diploma degrees so in total, there were 147 higher medical and educational institutions. Since joining the WTO, China has been working hard to improve its education system and bring it up to international standards.*[62] SARS played a large role in China quickly improving its healthcare system. Back in 2003, there was an outbreak of SARS and that made China hurry to spread HIS or Hospital Information System and more than 80% of hospitals had HIS. China had been comparing itself to Korea's healthcare system and figuring out how it can better its own system. There was a study done that surveyed six hospitals in China that had HIS. The results were that doctors didn't use computers as much so it was concluded that it wasn't used as much for clinical practice than it was for administrative purposes. The survey asked if the hospitals created any websites and it was concluded that only four of them had created websites and that three had a third-party company create it for them and one was created by the hospital staff. In conclusion, all of them agreed or strongly agreed that providing health information on the Internet should be utilized.*[63]

Health Informatics Standards in China Collected information at different times, by different participants or systems could frequently lead to issues of misunderstanding, dis-comparing or dis-exchanging. To design an issues-minor system, healthcare providers realised that certain standards were the basis for sharing information and interoperability, however a system lacking standards would be a large impediment to interfere the improvement of corresponding information systems. Given that the standardisation for health informatics depends on the authorities, standardisation events must be involved with government and the subsequently relevant funding and supports were critical. In 2003, the Ministry of Health released the Development Lay-out of National Health Informatics (2003–2010)*[64] indicating the identification of standardisation for health informatics which is 'combining adoption of international standards and development of national standards'.

In China, the establishment of standardisation was initially facilitated with the development of vocabulary, classification and coding, which is conducive to reserve and transmit information for premium management at national level. By 2006, 55 international/ domestic standards of vocabulary, classification and coding have served in hospital information system. In 2003, the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) and the ICD-10 Clinical Modification (ICD-10-CM) were adopted as standards for diagnostic classification and acute care procedure classification. Simultaneously, the International Classification of Primary Care (ICPC) were translated and tested in China's local applied environment.*[65] Another coding standard, named Logical Observation Identifiers Names and Codes (LOINC), was applied to serve as general identifiers for clinical observation in hospitals. Personal identifier codes were widely employed in different information systems, involving name, sex, nationality, family relationship, educational level and job occupation. However, these codes within different systems are inconsistent, when sharing between different regions. Considering this large quantity of vocabulary, classification and coding standards between different jurisdictions, the healthcare provider realised that using multiple systems could generate issues of resource wasting and a non-conflicting national level standard was beneficial and necessary. Therefore, in late 2003, the health

informatics group in Ministry of Health released three projects to deal with issues of lacking national health information standards, which were the Chinese National Health Information Framework and Standardisation, the Basic Data Set Standards of Hospital Information System and the Basic Data Set Standards of Public Health Information System.

*[58]

Comparison between China's EHR Standard and Segments of the ASTM E 1384 Standard Recently, researchers from local universities evaluated the performance of China's Electronic Health Record(EHR) Standard compared with the American Society for Testing and Materials Standard Practice for Content and Structure of Electronic Health Records in the United States (ASTM E 1384 Standard).*[66]

The table above demonstrates details of this comparison which indicates certain domains of improvement for future revisions of EHR Standard in China. Detailedly, these deficiencies are listed in the following.

1. The lack of supporting on privacy and security. The ISO/TS 18308 specifies "The EHR must support the ethical and legal use of personal information, in accordance with established privacy principles and frameworks, which may be culturally or jurisdictionally specific" (ISO 18308: Health Informatics-Requirements for an Electronic Health Record Architecture, 2004). However this China's EHR Standard did not achieve any of the fifteen requirements in the subclass of privacy and security.

2. The shortage of supporting on different types of data and reference. Considering only ICD-9 is referenced as China's external international coding systems, other similar systems, such as SNOMED CT in clinical terminology presentation, cannot be considered as familiar for Chinese specialists, which could lead to internationally information-sharing deficiency.

3. The lack of more generic and extensible lower level data structures. China's large and complex EHR Standard was constructed for all medical domains. However, the specific and time-frequent attributes of clinical data elements, value sets and templates identified that this once-for-all purpose cannot lead to practical consequence.*[67]

Hong Kong In Hong Kong a computerized patient record system called the Clinical Management System (CMS) has been developed by the Hospital Authority since 1994. This system has been deployed at all the sites of the Authority (40 hospitals and 120 clinics), and is used by all 30,000 clinical staff on a daily basis, with a daily transaction of up to 2 millions. The comprehensive records of 7 million patients are available on-line in the Electronic Patient Record (ePR), with data integrated from all sites. Since 2004 radiology image viewing has been added to the ePR, with radiography images from any HA site being available as part of the ePR.

The Hong Kong Hospital Authority placed particular attention to the governance of clinical systems development, with input from hundreds of clinicians being incorporated through a structured process. The Health Informatics Section in Hong Kong Hospital Authority*[68] has close relationship with Information Technology Department and clinicians to develop healthcare systems for the organization to support the service to all public hospitals and clinics in the region.

The Hong Kong Society of Medical Informatics (HKSMI) was established in 1987 to promote the use of information technology in healthcare. The eHealth Consortium has been formed to bring together clinicians from both the private and public sectors, medical informatics professionals and the IT industry to further promote IT in healthcare in Hong Kong.*[69]

India Main article: Indian Association for Medical Informatics

eHCF School of Medical Informatics http://www.ehcfsmi.edu.in eHealth-Care Foundation http://www.ehealth-care.net

Malaysia Since 2010, The Ministry of Health (MoH) working on the Malaysian Health Data Warehouse (MyHDW) project. MyHDW aims to meet the diverse needs of timely health information provision and management, and acts as a platform for the standardization and integration of health data from a variety of sources (Health Informatics Centre, 2013). The Ministry has embarked on introducing the electronic Hospital Information Systems (HIS) in several public hospitals including Serdang Hospital, Selayang Hospital and University Kebangsaan Malaysia Medical Centre (UKMMC) under the Ministry of Higher Education (MOHE).

A Hospital Information System (HIS) is a comprehensive, integrated information system designed to manage the administrative, financial and clinical aspects of a hospital. As an area of Medical Informatics, the aim of hospital information system is to achieve the best possible support of patient care and administration by electronic data processing. HIS plays a vital role in planning, initiating, organizing and controlling the operations of the subsystems of the hospital and thus provides a synergistic organization in the process.

New Zealand Health Informatics is taught at five New Zealand universities. The most mature and established is

the Otago programme which has been offered for over a decade.* [70] Health Informatics New Zealand (HINZ), is the national organisation that advocates for Health Informatics. HINZ organises a conference every year and also publishes an online journal- Healthcare Informatics Review Online.

Saudi Arabia The Saudi Association for Health Information (SAHI) was established in 2006* [71] to work under direct supervision of King Saud bin Abdulaziz University for Health Sciences to practice public activities, develop theoretical and applicable knowledge, and provide scientific and applicable studies.* [72]

Post Soviet Countries

The Russian Federation Russian healthcare system mainly consists of the principles based on the principles of the soviet healthcare system that was oriented on mass prophylaxis, prevention of infection and epidemic diseases, vaccination and immunization of the Soviet population on socially protected basis. Current government Healthcare system consists of several directions:

- Preventive health care
- Primary health care
- Specialized medical care
- Obstetrical and gynecologic medical care
- Pediatric medical care
- Surgery
- Rehabilitation/ Health resort treatment

One of the main issues of the post-soviet medical health care system was the absence of the united system providing optimization of work for medical institutes with one, single database and structured appointment schedule and hence hours-long lines. Efficiency of medical workers might have been also doubtful because of the paperwork administrating or lost book records.

Along with the development of the information systems IT and Healthcare departments of Moscow agreed on designing a system that would improve public services of health care institutes. Tackling with the issues appearing in the current system, Moscow Government ordered the designing of the system that would provide simplified electronic booking to public clinics and automatize work of medical workers on the first level.

The system designed for that purposes was called EMIAS (United Medical Information and Analysis System) and presents EHR (Electronic Health Record) with the majority of other services set in the system that allow managing flows of patients, contains outpatient card integrated in the system, and provides an opportunity to manage consolidated managerial accounting and personalized list of medical help. Besides that, the system contains information about availability of the medical institutions and various doctors.

The beginning of the implementation of the system started in 2013 with the organization of one computerized database for all patients in the city, including convenient front-end for the users. EMIAS is implemented in Moscow and Moscow region and it is planned that the project should embrace most parts of the country.

1.3.9 Health Informatics Law

For more details on this topic, see Health law.

Health informatics law deals with evolving and sometimes complex legal principles as they apply to information technology in health-related fields. It addresses the privacy, ethical and operational issues that invariably arise when electronic tools, information and media are used in health care delivery. Health Informatics Law also applies to all matters that involve information technology, health care and the interaction of information. It deals with the circumstances under which data and records are shared with other fields or areas that support and enhance patient care.

As many healthcare systems are making an effort to have patient records more readily available to them via the internet, it is important that providers be sure that there are a few security standards in place in order to make sure that the patients information is safe. They have to be able to assure confidentiality and the security of the people, process, and technology. Since there is also the possibility of payments being made through this system, it is vital that this aspect of their private information will also be protected through cryptography.

1.3.10 History

Worldwide use of computer technology in medicine began in the early 1950s with the rise of the computers.* [31] In 1949, Gustav Wagner established the first professional organization for informatics in Germany.* [73] The prehistory, history, and future of medical information and health information technology are discussed in reference.* [74] Specialized university departments and Informatics training programs began during the 1960s in France, Germany, Belgium and The Netherlands. Medical informatics research units began to appear during the 1970s in Poland and in the U.S.* [73] Since then the development of high-quality health informatics research, education and infrastructure has been a goal of the U.S. and the European Union.* [73]

Early names for health informatics included medical

computing, biomedical computing, medical computer science, computer medicine, medical electronic data processing, medical automatic data processing, medical information processing, medical information science, medical software engineering, and medical computer technology.

The health informatics community is still growing, it is by no means a mature profession, but work in the UK by the voluntary registration body, the UK Council of Health Informatics Professions has suggested eight key constituencies within the domain - information management, knowledge management, portfolio/programme/project management, ICT, education and research, clinical informatics, health records(service and business-related), health informatics service management. These constituencies accommodate professionals in and for the NHS, in academia and commercial service and solution providers.

Since the 1970s the most prominent international coordinating body has been the International Medical Informatics Association (IMIA).* [75]

1.3.11 Leading health informatics and medical informatics journals

Main article: List of medical and health informatics journals

1.3.12 See also

Related concepts

- Bioinformatics
- Clinical coder
- Clinical documentation improvement
- Continuity of care record (CCR)
- Diagnosis-related groups
- eHealth
- Electronic health record (EHR)
- Electronic medical record (EMR)
- Health information exchange (HIE)
- Health information management (HIM)
- Hospital information system
- Human resources for health (HRH) information system
- International Classification of Diseases (ICD)
- Medical coding
- Neuroinformatics
- Nosology
- Personal health record (PHR)
- Public health informatics

Standards/frameworks and governance

- DICOM
- Health Metrics Network
- HL7
- Fast Healthcare Interoperability Resources (FHIR)
- LOINC
- Omaha System
- openEHR
- SNOMED
- xDT

Algorithms

- Datafly algorithm

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1.3.14 External links

- Health informatics at DMOZ
- Article about informatics
- Willison, Brian. Advancing Meaningful Use: Simplifying Complex Clinical Metrics Through Visual Representation.
- Clinfowiki
- Global Health Informatics Partnership

1.4 eHealth

eHealth (also written **e-health**) is a relatively recent term for healthcare practice supported by electronic processes and communication, dating back to at least 1999.*[1] Usage of the term varies. A study in 2005 found 51 unique definitions *[2] . Some argue that it is interchangeable with health informatics with a broad definition covering electronic/digital processes in health*[3] while others use it in the narrower sense of healthcare practice using the Internet.*[4]*[5]*[6] It can also include health applications and links on mobile phones, referred to as m-health or mHealth. Since about 2011, the increasing recognition of the need for better cyber-security and regulation may result in the need for these specialized resources to develop safer eHealth solutions that can withstand these growing threats.

1.4.1 Forms of e-health

The term can encompass a range of services or systems that are at the edge of medicine/healthcare and information technology, including:

- Electronic health records: enabling the communication of patient data between different healthcare professionals (GPs, specialists *etc.*);
- Computerized Physician Order Entry: a means of requesting diagnostic tests and treatments electronically and receiving the results
- ePrescribing: access to prescribing options, printing prescriptions to patients and sometimes electronic transmission of prescriptions from doctors to pharmacists
- Clinical Decision Support: providing information electronically about protocols and standards for healthcare professionals to use in diagnosing and treating patients
- Telemedicine: physical and psychological diagnosis and treatments at a distance, including telemonitoring of patients functions;
- Consumer health informatics: use of electronic resources on medical topics by healthy individuals or patients;
- Health knowledge management: *e.g.* in an overview of latest medical journals, best practice guidelines or epidemiological tracking (examples include physician resources such as Medscape and MDLinx);
- Virtual healthcare teams: consisting of healthcare professionals who collaborate and share information on patients through digital equipment (for transmural care);
- mHealth or m-Health: includes the use of mobile devices in collecting aggregate and patient level health data, providing healthcare information to practitioners, researchers, and patients, real-time monitoring of patient vitals, and direct provision of care (via mobile telemedicine);
- Medical research using Grids: powerful computing and data management capabilities to handle large amounts of heterogeneous data.*[7]
- Health Informatics / Healthcare Information Systems: also often refer to software solutions for appointment scheduling, patient data management, work schedule management and other administrative tasks surrounding health

1.4.2 Contested definition

Several authors have noted the variable usage in the term, from being specific to the use of the Internet in healthcare to being generally around any use of computers in healthcare.*[8] Various authors have considered the evolution of the term and its usage and how this maps to changes in health informatics and healthcare generally.*[1]*[9]*[10] Oh *et al.*, in a 2005 systematic review of the term's usage, offered the definition of eHealth as a set of technological themes in health today, more specifically based on commerce, activities, stakeholders, outcomes, locations, or perspectives.*[11] One thing that all sources seem to agree on is that e-Health initiatives do not originate with the patient, though the patient may be a member of a patient organization that seeks to do this (see e-Patient).

1.4.3 E-Health data exchange

One of the factors blocking the use of e-Health tools from widespread acceptance is the concern about privacy issues regarding patient records, most specifically the EPR (Electronic patient record). This main concern has to do with the confidentiality of the data. There is also concern about non-confidential data however. Each medical practise has its own jargon and diagnostic tools. To standardize the exchange of information, various coding schemes may be used in combination with international medical standards. Systems that deal with these transfers are often referred to as Health Information Exchange (HIE). Of the forms of e-Health already mentioned, there are roughly two types; front-end data exchange and back-end exchange.

Front-end exchange typically involves the patient, while back-end exchange does not. A common example of a rather simple front-end exchange is a patient sending a photo taken by mobile phone of a healing wound and sending it by email to the family doctor for control. Such an actions may avoid the cost of an expensive visit to the hospital.

A common example of a back-end exchange is when a patient on vacation visits a doctor who then may request access to the patient's health records, such as medicine prescriptions, x-ray photographs, or blood test results. Such an action may reveal allergies or other prior conditions that are relevant to the visit.

Thesaurus

Successful e-Health initiatives such as e-Diabetes have shown that for data exchange to be facilitated either at the front-end or the back-end, a common thesaurus is needed for terms of reference.*[12] Various medical practises in chronic patient care (such as for diabetic patients) already have a well defined set of terms and actions, which makes standard communication exchange easier, whether the exchange is initiated by the patient or the caregiver.

In general, explanatory diagnostic information (such as the standard ICD-10) may be exchanged insecurely, and private information (such as personal information from the patient) must be secured. E-health manages both flows of information, while ensuring the quality of the data exchange.

1.4.4 Early adopters

Patients living with long term conditions (also called Chronic conditions) over time often acquire a high level of knowledge about the processes involved in their own care, and often develop a routine in coping with their condition. For these types of routine patients, front-end e-Health solutions tend to be relatively easy to implement.

1.4.5 E-Mental Health

E-mental health is frequently used to refer to internet based interventions and support for mental health conditions.*[13] However, it can also refer to the use of information and communication technologies that also includes the use of social media, landline and mobile phones.*[14] E-mental health services can include information; peer support services, computer and internet based programs, virtual applications and games as well as real time interaction with trained clinicians.*[15] Programs can also be delivered using telephones and interactive voice response (IVR) *[16]

Mental disorders includes a range of conditions such as alcohol and drug use disorders, mood disorders such as depression, dementia and Alzheimer's disease, delusional disorders such as schizophrenia and anxiety disorders.*[17] The majority of e-mental health interventions have focused on the treatment of depression and anxiety.*[15] There are, however, programs also for problems as diverse as smoking cessation *[18] gambling *[19] and post-disaster mental health.*[20]

Advantages and Disadvantages

E-mental health has a number of advantages such as being low cost, easily accessible and providing anonymity to users.*[21] However, there are also a number of disadvantages such as concerns regarding treatment credibility, user privacy and confidentiality.*[22] Online security involves the implementation of appropriate safeguards to protect user privacy and confidentiality. This includes appropriate collection and handling of user data, the protection of data from unauthorized access and modification and the safe storage of data.*[23]

E-mental health has been gaining momentum in the academic research as well as practical arenas in a wide variety of disciplines such as psychology, clinical social work,

family and marriage therapy, and mental health counseling. Testifying to this momentum, the E-Mental Health movement has its own international organization, **The International Society for Mental Health Online**.*[24]

Programs

There are at least four programs currently available to treat anxiety and depression. Two programs have been identified by the UK National Institute for Health and Care Excellence*[25] as cost effective for use in primary care. The first is *Fearfighter*[26] which is a text based cognitive behavioral therapy program to treat people with phobias and the second is *Beating the Blues*,*[27] an interactive text, cartoon and video CBT program for anxiety and depression. Two programs have been supported for use in primary care by the Australian Government. The first is *Anxiety Online*,*[28] a text based program for the anxiety, depressive and eating disorders, and the second is *THIS WAY UP*,*[29] a set of interactive text, cartoon and video programs for the anxiety and depressive disorders.

There are a number of online programs relating to smoking cessation. *QuitCoach*[30] is a personalised quit plan based on the users response to questions regarding giving up smoking and tailored individually each time the user logs in to the site. *Freedom From Smoking*[31] takes users through lessons that are grouped into modules that provide information and assignments to complete. The modules guide participants through steps such as preparing to quit smoking, stopping smoking and preventing relapse.

Other internet programs have been developed specifically as part of research into treatment for specific disorders. For example, an online self-directed therapy for problem gambling was developed to specifically test this as a method of treatment.*[19] All participants were given access to a website. The treatment group was provided with behavioural and cognitive strategies to reduce or quit gambling. This was presented in the form of a workbook which encouraged participants to self-monitor their gambling by maintaining an online log of gambling and gambling urges. Participants could also use a smartphone application to collect self-monitoring information. Finally participants could also choose to receive motivational email or text reminders of their progress and goals.

An internet based intervention was also developed for use after Hurricane Ike in 2009.*[20] During this study, 1,249 disaster-affected adults were randomly recruited to take part in the intervention. Participants were given a structured interview then invited to access the web intervention using a unique password. Access to the website was provided for a four-month period. As participants accessed the site they were randomly assigned to either the intervention. those assigned to the intervention were provided with modules consisting of information regarding effective coping strategies to manage mental health and health risk behaviour.

1.4.6 Cybermedicine

Cybermedicine is the use of the Internet to deliver medical services, such as medical consultations and drug prescriptions. It is the successor to telemedicine, wherein doctors would consult and treat patients remotely via telephone or fax.

Cybermedicine is already being used in small projects where images are transmitted from a primary care setting to a medical specialist, who comments on the case and suggests which intervention might benefit the patient. A field that lends itself to this approach is dermatology, where images of an eruption are communicated to a hospital specialist who determines if referral is necessary.

The field has also expanded to include online "ask the doctor" services that allow patients direct, paid access to consultations (with varying degrees of depth) with medical professionals (examples include, Bundoo.com, DoctorSpring.com, Teladoc, and Ask The Doctor).

A Cyber Doctor,*[32] known in the UK as a Cyber Physician,*[33] is a medical professional who does consultation via the internet, treating virtual patients, who may never meet face to face. This is a new area of medicine which has been utilized by the armed forces and teaching hospitals offering online consultation to patients before making their decision to travel for unique medical treatment only offered at a particular medical facility.*[32]

1.4.7 Self-Monitoring Healthcare Devices

Self-monitoring is the use of sensors or tools which are readily available to the general public to track and record personal data. The sensors are usually wearable devices and the tools are digitally available through mobile device applications. Self-monitoring devices were created for the purpose of allowing personal data to be instantly available to the individual to be analyzed. As of now, fitness and health monitoring are the most popular applications for self-monitoring devices.*[34] The biggest benefit to self-monitoring devices is the elimination of the necessity for third party hospitals to run tests, which are both expensive and lengthy. These devices are an important advancement in the field of personal health management.

Currently, self-monitoring healthcare devices exist in many forms. An example is the Nike+ Fuelband, which is a modified version of the original pedometer.*[34] This device is wearable on the wrist and allows one to set a personal goal for a daily energy burn. It records the calories burned and the number of steps taken for each day while simultaneously functioning as a watch. To add to the ease of the user interface, it includes both numeric

and visual indicators of whether or not the individual has achieved his or her daily goal. Finally, it is also synced to an iPhone app which allows for tracking and sharing of personal record and achievements.

Other monitoring devices have more medical relevance. A well-known device of this type is the blood glucose monitor. The use of this device is restricted to diabetic patients and allows users to measure the blood glucose levels in their body. It is extremely quantitative and the results are available instantaneously.*[35] However, this device is not as independent of a self-monitoring device as the Nike+ Fuelband because it requires some patient education before use. One needs to be able to make connections between the levels of glucose and the effect of diet and exercise. In addition, the users must also understand how the treatment should be adjusted based on the results. In other words, the results are not just static measurements.

The demand for self-monitoring health devices is skyrocketing, as wireless health technologies have become especially popular in the last few years. In fact, it is expected that by 2016, self-monitoring health devices will account for 80% of wireless medical devices.*[36] The key selling point for these devices is the mobility of information for consumers. The accessibility of mobile devices such as smartphones and tablets has increased significantly within the past decade. This has made it easier for users to access real-time information in a number of peripheral devices.

There are still many future improvements for self-monitoring healthcare devices. Although most of these wearable devices have been excellent at providing direct data to the individual user, the biggest task which remains at hand is how to effectively use this data. Although the blood glucose monitor allows the user to take action based on the results, measurements such as the pulse rate, EKG signals, and calories do not necessarily serve to actively guide an individual's personal healthcare management. Consumers are interested in qualitative feedback in addition to the quantitative measurements recorded by the devices.*[37]

1.4.8 Evaluating eHealth

Knowledge of the socio-economic performance of eHealth is limited, and findings from evaluations are often challenging to transfer to other settings. Socio-economic evaluations of some narrow types of mHealth can rely on health economic methodologies, but larger scale eHealth may have too many variables, and tortuous, intangible cause and effect links may need a wider approach. Why Do Evaluations of eHealth Programs Fail? An Alternative Set of Guiding Principles describes one way to do this.

1.4.9 eHealth in Developing Countries

eHealth in general, and telemedicine in particular, is a vital resource to remote regions of emerging and developing countries but is often difficult to establish because of the lack of communications infrastructure.*[38] For example, in Benin, hospitals often can become inaccessible due to flooding during the rainy season*[39] and across Africa, the low population density, along with severe weather conditions and the difficult financial situation in many African states, has meant that the majority of the African people are badly disadvantaged in medical care. In many regions there is not only a significant lack of facilities and trained health professionals, but also no access to eHealth because there is also no internet access in remote villages, or even a reliable electricity supply.*[40]

Internet connectivity, and the benefits of eHealth, can be brought to these regions using satellite broadband technology, and satellite is often the only solution where terrestrial access may be limited, or poor quality, and one that can provide a fast connection over a vast coverage area.*[40]

1.4.10 See also

- e-Patient
- Electronic health record
- eHealthInsurance
- EUDRANET
- European Institute for Health Records
- Health 2.0
- Health blog
- Health Informatics
- mHealth
- Technology and mental health issues
- Telemedicine

1.4.11 Notes

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1.4.12 Further reading

- Slack, Warner V. (2001). *Cybermedicine* (Second ed.). Jossey Bass. ISBN 0787956317.
- Magdalene Rosenmöller Diane Whitehouse Petra Wilson; et al. (2014). *Managing eHealth From Vision to Reality*. Basingstoke: Palgrave Macmillan. ISBN 978-1-137-37942-9.

1.4.13 External links

- NorthWest EHealth
- *The Medicalisation of Cyberspace*, by Dr Andy Miah & Dr Emma Rich
- *The eHeatlhQ Seal*, by Internet Medical Society
- Virtual Healthcare Trends, by Anna Maria College
- The Digital Health Care Environment *Why Do Evaluations of eHealth Programs Fail? An Alternative Set of Guiding Principles*, Greenhalgh T, Russell J (2010)
- GOSH Child Health Portal Project 2001 to 2003 Key Documents. ISBN 978-0-9920217-8-8.

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Several authors have noted the variable usage in the term, from being specific to the use of the Internet in healthcare to being generally around any use of computers in healthcare.*[8] Various authors have considered the evolution of the term and its usage and how this maps to changes in health informatics and healthcare generally.*[1]*[9]*[10] Oh *et al.*, in a 2005 systematic review of the term's usage, offered the definition of eHealth as a set of technological themes in health today, more specifically based on commerce, activities, stakeholders, outcomes, locations, or perspectives.*[11] One thing that all sources seem to agree on is that e-Health initiatives do not originate with the patient, though the patient may be a member of a patient organization that seeks to do this (see e-Patient).

1.5.3 E-Health data exchange

One of the factors blocking the use of e-Health tools from widespread acceptance is the concern about privacy issues regarding patient records, most specifically the EPR (Electronic patient record). This main concern has to do with the confidentiality of the data. There is also concern about non-confidential data however. Each medical practise has its own jargon and diagnostic tools. To standardize the exchange of information, various coding schemes may be used in combination with international medical standards. Systems that deal with these transfers are often referred to as Health Information Exchange (HIE). Of the forms of e-Health already mentioned, there are roughly two types; front-end data exchange and back-end exchange.

Front-end exchange typically involves the patient, while back-end exchange does not. A common example of a rather simple front-end exchange is a patient sending a photo taken by mobile phone of a healing wound and sending it by email to the family doctor for control. Such an actions may avoid the cost of an expensive visit to the hospital.

A common example of a back-end exchange is when a patient on vacation visits a doctor who then may request access to the patient's health records, such as medicine prescriptions, x-ray photographs, or blood test results. Such an action may reveal allergies or other prior conditions that are relevant to the visit.

Thesaurus

Successful e-Health initiatives such as e-Diabetes have shown that for data exchange to be facilitated either at the front-end or the back-end, a common thesaurus is needed for terms of reference.*[12] Various medical practises in chronic patient care (such as for diabetic patients) already have a well defined set of terms and actions, which makes standard communication exchange easier, whether the exchange is initiated by the patient or the caregiver.

In general, explanatory diagnostic information (such as the standard ICD-10) may be exchanged insecurely, and private information (such as personal information from the patient) must be secured. E-health manages both flows of information, while ensuring the quality of the data exchange.

1.5.4 Early adopters

Patients living with long term conditions (also called Chronic conditions) over time often acquire a high level of knowledge about the processes involved in their own care, and often develop a routine in coping with their condition. For these types of routine patients, front-end e-Health solutions tend to be relatively easy to implement.

1.5.5 E-Mental Health

E-mental health is frequently used to refer to internet based interventions and support for mental health conditions.*[13] However, it can also refer to the use of information and communication technologies that also includes the use of social media, landline and mobile phones.*[14] E-mental health services can include information; peer support services, computer and internet based programs, virtual applications and games as well as real time interaction with trained clinicians.*[15] Programs can also be delivered using telephones and interactive voice response (IVR) *[16]

Mental disorders includes a range of conditions such as alcohol and drug use disorders, mood disorders such as depression, dementia and Alzheimer's disease, delusional disorders such as schizophrenia and anxiety disorders.*[17] The majority of e-mental health interventions have focused on the treatment of depression and anxiety.*[15] There are, however, programs also for problems as diverse as smoking cessation *[18] gambling *[19] and post-disaster mental health.*[20]

Advantages and Disadvantages

E-mental health has a number of advantages such as being low cost, easily accessible and providing anonymity to users.*[21] However, there are also a number of disadvantages such as concerns regarding treatment credibility, user privacy and confidentiality.*[22] Online security involves the implementation of appropriate safeguards to protect user privacy and confidentiality. This includes appropriate collection and handling of user data, the protection of data from unauthorized access and modification and the safe storage of data.*[23]

E-mental health has been gaining momentum in the academic research as well as practical arenas in a wide variety of disciplines such as psychology, clinical social work, family and marriage therapy, and mental health counseling. Testifying to this momentum, the E-Mental Health movement has its own international organization, **The International Society for Mental Health Online**.*[24]

Programs

There are at least four programs currently available to treat anxiety and depression. Two programs have been identified by the UK National Institute for Health and Care Excellence*[25] as cost effective for use in primary care. The first is *Fearfighter**[26] which is a text based cognitive behavioral therapy program to treat people with phobias and the second is *Beating the Blues*,*[27] an interactive text, cartoon and video CBT program for anxiety and depression. Two programs have been supported for use in primary care by the Australian Government. The first is *Anxiety Online*,*[28] a text based program for the anxiety, depressive and eating disorders, and the second is *THIS WAY UP*,*[29] a set of interactive text, cartoon and video programs for the anxiety and depressive disorders.

There are a number of online programs relating to smoking cessation. *QuitCoach**[30] is a personalised quit plan based on the users response to questions regarding giving up smoking and tailored individually each time the user logs in to the site. *Freedom From Smoking**[31] takes users through lessons that are grouped into modules that provide information and assignments to complete. The modules guide participants through steps such as preparing to quit smoking, stopping smoking and preventing relapse.

Other internet programs have been developed specifically as part of research into treatment for specific disorders. For example, an online self-directed therapy for problem gambling was developed to specifically test this as a method of treatment.*[19] All participants were given access to a website. The treatment group was provided with behavioural and cognitive strategies to reduce or quit gambling. This was presented in the form of a workbook which encouraged participants to self-monitor their gambling by maintaining an online log of gambling and gambling urges. Participants could also use a smartphone application to collect self-monitoring information. Finally participants could also choose to receive motivational email or text reminders of their progress and goals.

An internet based intervention was also developed for use after Hurricane Ike in 2009.*[20] During this study, 1,249 disaster-affected adults were randomly recruited to take part in the intervention. Participants were given a structured interview then invited to access the web intervention using a unique password. Access to the website was provided for a four-month period. As participants accessed the site they were randomly assigned to either the intervention. those assigned to the intervention were provided with modules consisting of information regarding effective coping strategies to manage mental health and health risk behaviour.

1.5.6 Cybermedicine

Cybermedicine is the use of the Internet to deliver medical services, such as medical consultations and drug prescriptions. It is the successor to telemedicine, wherein doctors would consult and treat patients remotely via telephone or fax.

Cybermedicine is already being used in small projects where images are transmitted from a primary care setting to a medical specialist, who comments on the case and suggests which intervention might benefit the patient. A field that lends itself to this approach is dermatology, where images of an eruption are communicated to a hospital specialist who determines if referral is necessary.

The field has also expanded to include online "ask the doctor" services that allow patients direct, paid access to consultations (with varying degrees of depth) with medical professionals (examples include, Bundoo.com, DoctorSpring.com, Teladoc, and Ask The Doctor).

A Cyber Doctor,*[32] known in the UK as a Cyber Physician,*[33] is a medical professional who does consultation via the internet, treating virtual patients, who may never meet face to face. This is a new area of medicine which has been utilized by the armed forces and teaching hospitals offering online consultation to patients before making their decision to travel for unique medical treatment only offered at a particular medical facility.*[32]

1.5.7 Self-Monitoring Healthcare Devices

Self-monitoring is the use of sensors or tools which are readily available to the general public to track and record personal data. The sensors are usually wearable devices and the tools are digitally available through mobile device applications. Self-monitoring devices were created for the purpose of allowing personal data to be instantly avail-

able to the individual to be analyzed. As of now, fitness and health monitoring are the most popular applications for self-monitoring devices.*[34] The biggest benefit to self-monitoring devices is the elimination of the necessity for third party hospitals to run tests, which are both expensive and lengthy. These devices are an important advancement in the field of personal health management.

Currently, self-monitoring healthcare devices exist in many forms. An example is the Nike+ Fuelband, which is a modified version of the original pedometer.*[34] This device is wearable on the wrist and allows one to set a personal goal for a daily energy burn. It records the calories burned and the number of steps taken for each day while simultaneously functioning as a watch. To add to the ease of the user interface, it includes both numeric and visual indicators of whether or not the individual has achieved his or her daily goal. Finally, it is also synced to an iPhone app which allows for tracking and sharing of personal record and achievements.

Other monitoring devices have more medical relevance. A well-known device of this type is the blood glucose monitor. The use of this device is restricted to diabetic patients and allows users to measure the blood glucose levels in their body. It is extremely quantitative and the results are available instantaneously.*[35] However, this device is not as independent of a self-monitoring device as the Nike+ Fuelband because it requires some patient education before use. One needs to be able to make connections between the levels of glucose and the effect of diet and exercise. In addition, the users must also understand how the treatment should be adjusted based on the results. In other words, the results are not just static measurements.

The demand for self-monitoring health devices is skyrocketing, as wireless health technologies have become especially popular in the last few years. In fact, it is expected that by 2016, self-monitoring health devices will account for 80% of wireless medical devices.*[36] The key selling point for these devices is the mobility of information for consumers. The accessibility of mobile devices such as smartphones and tablets has increased significantly within the past decade. This has made it easier for users to access real-time information in a number of peripheral devices.

There are still many future improvements for self-monitoring healthcare devices. Although most of these wearable devices have been excellent at providing direct data to the individual user, the biggest task which remains at hand is how to effectively use this data. Although the blood glucose monitor allows the user to take action based on the results, measurements such as the pulse rate, EKG signals, and calories do not necessarily serve to actively guide an individual's personal healthcare management. Consumers are interested in qualitative feedback in addition to the quantitative measurements recorded by the devices.*[37]

1.5.8 Evaluating eHealth

Knowledge of the socio-economic performance of eHealth is limited, and findings from evaluations are often challenging to transfer to other settings. Socio-economic evaluations of some narrow types of mHealth can rely on health economic methodologies, but larger scale eHealth may have too many variables, and tortuous, intangible cause and effect links may need a wider approach. Why Do Evaluations of eHealth Programs Fail? An Alternative Set of Guiding Principles describes one way to do this.

1.5.9 eHealth in Developing Countries

eHealth in general, and telemedicine in particular, is a vital resource to remote regions of emerging and developing countries but is often difficult to establish because of the lack of communications infrastructure.*[38] For example, in Benin, hospitals often can become inaccessible due to flooding during the rainy season*[39] and across Africa, the low population density, along with severe weather conditions and the difficult financial situation in many African states, has meant that the majority of the African people are badly disadvantaged in medical care. In many regions there is not only a significant lack of facilities and trained health professionals, but also no access to eHealth because there is also no internet access in remote villages, or even a reliable electricity supply.*[40]

Internet connectivity, and the benefits of eHealth, can be brought to these regions using satellite broadband technology, and satellite is often the only solution where terrestrial access may be limited, or poor quality, and one that can provide a fast connection over a vast coverage area.*[40]

1.5.10 See also

- e-Patient
- Electronic health record
- eHealthInsurance
- EUDRANET
- European Institute for Health Records
- Health 2.0
- Health blog
- Health Informatics
- mHealth
- Technology and mental health issues
- Telemedicine

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1.5.12 Further reading

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- Magdalene Rosenmöller Diane Whitehouse Petra Wilson; et al. (2014). *Managing eHealth From Vision to Reality*. Basingstoke: Palgrave Macmillan. ISBN 978-1-137-37942-9.

1.5.13 External links

- NorthWest EHealth
- *The Medicalisation of Cyberspace*, by Dr Andy Miah & Dr Emma Rich
- *The eHeatlhQ Seal*, by Internet Medical Society
- Virtual Healthcare Trends, by Anna Maria College
- The Digital Health Care Environment *Why Do Evaluations of eHealth Programs Fail? An Alternative Set of Guiding Principles*, Greenhalgh T, Russell J (2010)
- GOSH Child Health Portal Project 2001 to 2003 Key Documents. ISBN 978-0-9920217-8-8.

1.6 Health 2.0

"Health 2.0" is a term introduced in the mid-2000s, as the subset of health technologies mirroring the wider Web 2.0 movement.

1.6.1 History

Health 2.0 built on the possibilities for changing health care, which started with the introduction of eHealth in the mid-1990s following the emergence of the World Wide Web. In the mid-2000s, following the widespread adoption both of the Internet and of easy to use tools for communication, social networking, and self-publishing, there was spate of media attention to and increasing interest from patients, clinicians, and medical librarians in using these tools for health care and medical purposes [*][1][*][2]

Early examples of **Health 2.0** were the use of a specific set of Web tools (blogs, email list-servs, online communities, podcasts, search, tagging, Twitter, videos, wikis, and more) by actors in health care including doctors, patients, and scientists, using principles of open source and user generated content, and the power of networks and social netwotks in order to personalize health care, to collaborate, and to promote health education.[*][3] Possible explanations why health care has generated its own "2.0" term are the availability and proliferation the Health 2.0 applications across health care in general, and the potential for improving public health in particular.[*][4]

1.6.2 Current use

While the "2.0" moniker was originally associated with concepts like collaboration, openness, participation, and social networking,[*][5] in recent years the term "Health 2.0" has evolved to mean the role of Saas and cloud-based technologies, and their associated applications on multiple devices. Health 2.0 describes the integration of these into much of general clinical and administrative workflow in health care. As of 2014, approximately 3,000 companies were offering products and services matching this definition, with venture capital funding in the sector exceeding $2.3 billion in 2013.[*][6]

1.6.3 Definitions

The "traditional" definition of "Health 2.0" focused on technology as an enabler for care **collaboration**: "The use of social software t-weight tools to promote collaboration between patients, their caregivers, medical professionals, and other stakeholders in health" [*][7] An expanded version of the traditional definition breaks this construct into component factors, which collectively allow patients to increasingly guide their own care.[*][8]

In 2011, Indu Subaiya (who co-founded the Health 2.0 Conference with Matthew Holt) redefined Health 2.0 *[9] as the use in health care of new cloud, Saas, mobile, and device technologies that are:

1. Adaptable technologies which easily allow other tools and applications to link and integrate with them, primarily through use of accessible APIs
2. Focused on the user experience, bringing in the principles of user-center design
3. Data driven, in that they both create data and present data to the user in order to help improve decision making

This wider definition allows recognition of what is or what isn't a Health 2.0 technology. Typically, enterprise-based, customized client-server systems are not, while more open, cloud based systems fit the definition. However, this line was blurring by 2011-2 as more enterprise vendors started to introduce cloud-based systems and native applications for new devices like smartphones and tablets.

In addition, Health 2.0 has several competing terms, each with its own followers—if not exact definitions—including Connected Health, Digital Health, Medicine 2.0, and mHealth. All of these support a goal of wider change to the health care system, using technology-enabled system reform—usually changing the relationship between patient and professional.:

1. Personalized search that looks into the long tail but cares about the user experience
2. Communities that capture the accumulated knowledge of patients, caregivers, and clinicians, and explains it to the world
3. Intelligent tools for content delivery—and transactions
4. Better integration of data with content

1.6.4 Wider health system definitions

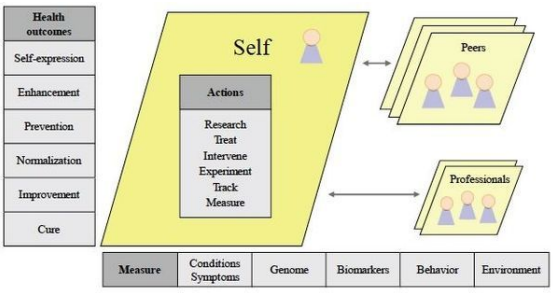
In the late 2000s, several commentators used Health 2.0 as a moniker for a wider concept of system reform, seeking a participatory process between patient and clinician: "New concept of health care wherein all the constituents (patients, physicians, providers, and payers) focus on health care value (outcomes/price) and use competition at the medical condition level over the full cycle of care as the catalyst for improving the safety, efficiency, and quality of health care" *[10]

Health 2.0 defines the combination of health data and health information with (patient) experience, through the use of ICT, enabling the citizen to become an active and responsible partner in his/her own health and care pathway.*[11]

Health 2.0 is participatory healthcare. Enabled by information, software, and communities that we collect or create, we the patients can be effective partners in our own healthcare, and we the people can participate in reshaping the health system itself.*[12]

Definitions of Medicine 2.0 appear to be very similar but typically include more scientific and research aspects—Medicine 2.0: "Medicine 2.0 applications, services and tools are Web-based services for health care consumers, caregivers, patients, health professionals, and biomedical researchers, that use Web 2.0 technologies as well as semantic web and virtual reality tools, to enable and facilitate specifically social networking, participation, apomediation, collaboration, and openness within and between these user groups.*[13]*[14] Published in JMIR Tom Van de Belt, Lucien Engelen *et al.* systematic review found 46 (!) unique definitions of health 2.0*[15]

1.6.5 Overview



A model of Health 2.0

Health 2.0 refers to the use of a diverse set of technologies including Connected Health, electronic medical records, mHealth, telemedicine, and the use of the Internet by patients themselves such as through blogs, messageboards, online communities, patient to physician communication systems, and other more advanced systems. A key concept is that patients themselves should have greater insight and control into information generated about them. Additionally Health 2.0 relies on the use of modern cloud and mobile-based technologies.

Much of the potential for change from Health 2.0 is facilitated by combining technology driven trends such as Personal Health Records with social networking —[which] may lead to a powerful new generation of health applications, with which people share parts of their electronic health records with other consumers and "crowdsource" the collective wisdom of other patients and professionals." .*[5] Traditional models of medicine had patient records (held on paper or a proprietary computer system) that could only be accessed by a physician or other medical professional. Physicians acted as gatekeepers to this information, telling patients test results when and if

they deemed it necessary. Such a model operates relatively well in situations such as acute care, where information about specific blood results would be of little use to a lay person, or in general practice where results were generally benign. However, in the case of complex chronic diseases, psychiatric disorders, or diseases of unknown etiology patients were at risk of being left without well-coordinated care because data about them was stored in a variety of disparate places and in some cases might contain the opinions of healthcare professionals which were not to be shared with the patient. Increasingly, medical ethics deems such actions to be medical paternalism, and they are discouraged in modern medicine.

A hypothetical example demonstrates the increased engagement of a patient operating in a Health 2.0 setting: a patient goes to see their primary care physician with a presenting complaint, having first ensured their own medical record was up to date via the Internet. The treating physician might make a diagnosis or send for tests, the results of which could be transmitted directly to the patient's electronic medical record. If a second appointment is needed, the patient will have had time to research what the results might mean for them, what diagnoses may be likely, and may have communicated with other patients who have had a similar set of results in the past. On a second visit a referral might be made to a specialist. The patient might have the opportunity to search for the views of other patients on the best specialist to go to, and in combination with their primary care physician decides who to see. The specialist gives a diagnosis along with a prognosis and potential options for treatment. The patient has the opportunity to research these treatment options and take a more proactive role in coming to a joint decision with their healthcare provider. They can also choose to submit more data about themselves, such as through a personalized genomics service to identify any risk factors that might improve or worsen their prognosis. As treatment commences, the patient can track their health outcomes through a data-sharing patient community to determine whether the treatment is having an effect for them, and they can stay up to date on research opportunities and clinical trials for their condition. They also have the social support of communicating with other patients diagnosed with the same condition throughout the world.

1.6.6 Level of use of Web 2.0 in health care

Partly due to weak definitions, the novelty of the endeavor and its nature as an entrepreneurial (rather than academic) movement, little empirical evidence exists to explain how much Web 2.0 is being used in general. While it has been estimated that nearly one-third of the 100 million Americans who have looked for health information online say that they or people they know have been significantly helped by what they found,*[16] this study considers only the broader use of the Internet for health management.

A study examining physician practices has suggested that a segment of 245,000 physicians in the U.S are using Web 2.0 for their practice, indicating that use is beyond the stage of the early adopter with regard to physicians and Web 2.0.*[17]

1.6.7 Types of Web 2.0 technology in health care

Web 2.0 is commonly associated with technologies such as podcasts, RSS feeds, social bookmarking, weblogs (health blogs), wikis, and other forms of many-to-many publishing; social software; and web application programming interfaces (APIs) (see main article Web 2.0).

1.6.8 Types of Web 2.0 use in health care

The following are examples of uses that have been documented in academic literature.

1.6.9 Criticism of the use of Web 2.0 in health care

Several criticisms have been raised about the use of Web 2.0 in health care. Firstly, the limitations for Medical Doctors (MDs) to use Google as a diagnostic tool, which may be effective only for conditions with unique symptoms and signs that can easily be used as search term.*[21] Secondly, long-held concerns exist about the effects of patients obtaining information online, such as the idea that patients may delay seeking medical advice.*[24] Finally concerns exist about the quality of user generated content leading to misinformation, though one study has suggested that in certain support groups only 6% of information is factually wrong and that only 3% reported that online advice had caused serious harm.*[25] Other venues of information are likely to be less useful to the general public.

1.6.10 Tensions in Health 2.0

Hughes *et al.* (2009) argue there are four major tensions represented in the literature on Health/Medicine 2.0: these concern:*[3]

1. the lack of clear definitions
2. issues around the loss of control over information that doctors perceive
3. safety and the dangers of inaccurate information
4. issues of ownership and privacy

1.6.11 Conferences and trademarks

- Medicine 2.0 is an annual conference with a focus on the science and evidence behind Health 2.0. Medicine 2.0 is a registered trademark of JMIR Publications, the producer of the conference and publisher of the leading peer-reviewed ehealth journal Journal of Medical Internet Research
- Health 2.0 is a conference with a focus on the business of Health 2.0. Health 2.0 is a registered trademark of Matthew Holt, the producer of that conference
- Doctors 2.0 & You is an annual international conference in Paris, dedicated to web 2.0, social media, and mobile applications, with a focus on disease conditions. Doctors 2.0 is a registered trademark of Basil Strategies, conference producers.

1.6.12 See also

- e-Patient
- Health 3.0
- Patient opinion leader

1.6.13 References

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1.6.14 External links

- The term Health 2.0 is trademarked by this conference series
- A set of useful resource on the Health 2.0 Wiki including a list of Health 2.0 companies
- A list of medical wiki websites including links to more than 40 medical wikis
- Medicine 2.0 Congress, which is similar or identical to the Health 2.0 concept, but also includes "Science 2.0"
- "Web Site Harnesses Power of Social Networks", The Washington Post, October 19, 2009

1.7 Public health informatics

Public Health Informatics has been defined as the systematic application of information and computer science and technology to public health practice, research, and learning. It is one of the subdomains of Health informatics.

1.7.1 What is Public Health Informatics?

Public health informatics is defined as the use of computers, clinical guidelines, communication and information systems, which apply to vast majority of public health, related professions, such as nursing, clinical/ hospital care/ public health and medical research*[1]

1.7.2 United States

In developed countries like the United States, public health informatics is practiced by individuals in public health agencies at the federal and state levels and in the larger local health jurisdictions. Additionally, research and training in public health informatics takes place at a variety of academic institutions.

At the federal Centers for Disease Control and Prevention in US states like Atlanta, Georgia, the Public Health Surveillance and Informatics Program Office (PHSIPO) focuses on advancing the state of information science and applies digital information technologies to aid in the detection and management of diseases and syndromes in individuals and populations.

The bulk of the work of public health informatics in the United States, as with public health generally, takes place at the state and local level, in the state departments of health and the county or parish departments of health. At a state health department the activities may include: collection and storage of *vital statistics* (birth and death records); collection of reports of communicable disease cases from doctors, hospitals, and laboratories, used for infectious disease surveillance; display of infectious disease statistics and trends; collection of child immunization and lead screening information; daily collection and analysis of emergency room data to detect early evidence of biological threats; collection of hospital capacity information to allow for planning of responses in case of emergencies. Each of these activities presents its own information processing challenge.

Collection of public health data

(TODO: describe CDC-provided DOS/desktop-based systems like TIMSS (TB), STDMIS (Sexually transmitted diseases); Epi-Info for epidemiology investigations; and others)

Since the beginning of the World Wide Web, public health agencies with sufficient information technology resources have been transitioning to web-based collection of public health data, and, more recently, to automated messaging of the same information. In the years roughly 2000 to 2005 the Centers for Disease Control and Prevention, under its National Electronic Disease Surveillance System (NEDSS), built and provided free to states a comprehensive web and message-based reporting system called the NEDSS Base System (NBS). Due to the funding being limited and it not being wise to have fiefdom-based systems, only a few states and larger counties have built their own versions of electronic disease surveillance systems, such as Pennsylvania's PA-NEDSS. These do not provide timely full intestate notification services causing an increase in disease rates versus the NEDSS federal product.

To promote interoperability, the CDC has encouraged the adoption in public health data exchange of several standard vocabularies and messaging formats from the health care world. The most prominent of these are: the Health Level 7 (HL7) standards for health care messaging; the LOINC system for encoding laboratory test and result information; and the Systematized Nomenclature of Medicine (SNOMED) vocabulary of health care concepts.

Since about 2005, the CDC has promoted the idea of the Public Health Information Network to facilitate the transmission of data from various partners in the health care industry and elsewhere (hospitals, clinical and environmental laboratories, doctors' practices, pharmacies) to local health agencies, then to state health agencies, and then to the CDC. At each stage the entity must be capable of receiving the data, storing it, aggregating it appropriately, and transmitting it to the next level. A typical example

would be infectious disease data, which hospitals, labs, and doctors are legally required to report to local health agencies; local health agencies must report to their state public health department; and which the states must report in aggregate form to the CDC. Among other uses, the CDC publishes the Morbidity and Mortality Weekly Report (MMWR) based on these data acquired systematically from across the United States.

Major issues in the collection of public health data are: awareness of the need to report data; lack of resources of either the reporter or collector; lack of interoperability of data interchange formats, which can be at the purely syntactic or at the semantic level; variation in reporting requirements across the states, territories, and localities.

Public health informatics can be thought or divided into three categories.

Study models of different systems

The first category is to discover and study models of complex systems, such as disease transmission. This can be done through different types of data collections, such as hospital surveys, or electronic surveys submitted to the organization (such as the CDC). Transmission rates or disease incidence rates/surveillance can be obtained through government organizations, such as the CDC, or global organizations, such as WHO. Not only disease transmission/rates can be looked at. Public health informatics can also delve into people with/without health insurance and the rates at which they go to the doctor. Before the advent of the internet, public health data in the United States, like other healthcare and business data, were collected on paper forms and stored centrally at the relevant public health agency. If the data were to be computerized they required a distinct data entry process, were stored in the various file formats of the day and analyzed by mainframe computers using standard batch processing.*[2]

Storage of public health data

The second category is to find ways to improve the efficiency of different public health systems. This is done through various collections methods, storage of data and how the data is used to improve current health problems. In order to keep everything standardized, vocabulary and word usage needs to be consistent throughout all systems. Finding new ways to link together and share new data with current systems is important to keep everything up to date. *[3]

Storage of public health data shares the same data management issues as other industries. And like other industries, the details of how these issues play out are affected by the nature of the data being managed.

Due to the complexity and variability of public health data, like health care data generally, the issue of data modeling presents a particular challenge. While a generation ago flat data sets for statistical analysis were the norm, today's requirements of interoperability and integrated sets of data across the public health enterprise require more sophistication. The relational database is increasingly the norm in public health informatics. Designers and implementers of the many sets of data required for various public health purposes must find a workable balance between very complex and abstract data models such as HL7's Reference Information Model (RIM) or CDC's Public Health Logical Data Model, and simplistic, ad hoc models that untrained public health practitioners come up with and feel capable of working with.

Due to the variability of the incoming data to public health jurisdictions, data quality assurance is also a major issue.

Analysis of public health data

Finally, the last category can be thought as maintaining and enriching current systems and models to adapt to overflow of data and storing/sorting of this new data. This can be as simple as connecting directly to an electronic data collection source, such as health records from the hospital, or can go public information (CDC) about disease rates/transmission. Finding new algorithms that will sort through large quantities of data quickly and effectively is necessary as well.*[4]

The need to extract usable public health information from the mass of data available requires the public health informaticist to become familiar with a range of analysis tools, ranging from business intelligence tools to produce routine or ad hoc reports, to sophisticated statistical analysis tools such as DAP/SAS and PSPP/SPSS, to Geographical Information Systems (GIS) to expose the geographical dimension of public health trends.Such analyses usually require methods that appropriately secure the privacy of the health data. One approach is to separate the individually identifiable variables of the data from the rest*[5]

Applications in health surveillance and epidemiology

There are a few organizations out there that provide useful information for those professionals that want to be more involved in public health informatics. Such as the American Medical Informatics Association (AMIA). AMIA is for professions that are involved in health care, informatics research, biomedical research, including physicians, scientists, researchers, and students. The main goals of AMIA are to move from ‘bench to bedside’, help improve the impact of health innovations and advance the public health informatics field. They hold annual conferences, online classes and webinars, which are free to their members. There is also a career center specific for the biomedical and health informatics community.*[6]

Many jobs or fellowships in public health informatics

are offered. The CDC (Center for Disease Control) has various fellowship programs, while multiple colleges/companies offer degree programs or training in this field.[*] [7]

For more information on these topics, follow the links below:

http://www.jhsph.edu/departments/health-policy-and-management/certificates/public-health-informatics/what-is-health-informatics.html

http://www.phii.org/what-we-do

- SAPPHIRE (Health care) or *Situational Awareness and Preparedness for Public Health Incidences and Reasoning Engines* is a semantics-based health information system capable of tracking and evaluating situations and occurrences that may affect public health.

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Chapter 2

Applications in Healthcare Management

2.1 Health Administration Informatics

The emerging field of **Health administration informatics** is concerned with the evaluation, acquisition, implementation and day-to-day operation of information technology systems in support of all administration and clinical functions within the health care industry. The closely related field of biomedical informatics is primarily focused on the use of information systems for acquisition and application of patients' medical data, whereas nursing informatics deals with the delivery, administration and evaluation of patient care and disease prevention. What remains unclear, however, is how this emerging discipline should relate to the myriad of previously existing sub specializations within the broad umbrella of health informatics - including clinical informatics (which itself includes sub areas such as oncology informatics), bioinformatics and healthcare management informatics - particularly in light of the proposed "fundamental theorem" of biomedical informatics posed by Friedman in early 2009.

The field of health administration informatics is emerging as attention continues to focus on the costly mistakes made by some health care organizations whilst implementing electronic medical records.

2.1.1 Relevance within the health care industry

In a recent survey of health care CIOs and Information System (IS) directors, increasing patient safety and reducing medical errors was reported as among the top business issues. Two other key findings were that:

- two-thirds of respondents indicated that the number of FTEs in their IT department will increase in the next 12 months;
- and three-quarters of respondents indicated that their IT budgets would be increasing.

The most likely staffing needs reported by the health care executives are network and architecture support (HIMMS, 2005).

"The government and private insurers are beginning to pay hospitals more for higher quality care–and the only way to measure quality, and then improve it, is with more information technology. Hospital spending on such gear is expected to climb to $30.5 billion next year, from $25.8 billion in 2004, according to researcher Dorenfest Group" (Mullaney and Weintraub, 2005).

This fundamental change in health care (pay for performance) means that hospitals and other health care providers will need to develop, adapt and maintain all of the technology necessary to measure and improve on quality. Physicians have traditionally lagged behind in their use of technology (i.e., electronic patient records). Only 7% of physicians work for hospitals, and so the task of "wooing them is an extremely delicate task" (Mullaney and Weintraub, 2005).

2.1.2 Careers

The market demand for a specialized advanced degree that integrates Health Care Administration and Informatics is growing as the concept has gained support from the academic and professional communities. Recent articles in Health Management Technology cite the importance of integrating information technology with health care administration to meet the unique needs of the health care industry. The health care industry has been estimated to be around 10 years behind other industries in the application of technology and at least 10 to 15 years behind in leadership capability from the technology and perhaps the business perspective (Seliger, 2005; Thibault, 2005). This means there is quantifiable demand in the work force for health care administrators who are also prepared to lead in the field of health care administration informatics.

In addition, the increasing costs and difficulties involved in evaluating the projected benefits from IT investments are requiring health care administrators to learn more about IT and how it affects business processes. The health care Chief Information Officer (CIO) must be able to build enterprise wide systems that will help reduce the administrative cost and streamline the automation of administrative processes and patient record keeping. In-

creasingly, the CIO is relied upon for specialized analytical and collaborative skills that will enable him/her to build systems that health care clinicians will use. A recent well-publicized debacle (shelving of a $34 million computer system after three months) at a top U. S. hospital underlines the need for leaders who understand the health care industry information technology requirements (Connolly, 2005).

Several professional organizations have also addressed the need for academic preparation that integrates the two specializations addressed by UMUC's MSHCAI degree. In the collaborative response to the Office of the National Coordinator for Health Information Technology (ONCHIT) request for information regarding future IT needs, thirteen major health and technology organizations endorsed a "Common Framework" to support health information exchange in the United States, while protecting patient privacy. The response cited the need for continuing education of health information management professionals as a significant barrier to implementation of a National Health Information Network (NHIN) (The Collaborative Response, 2005).

2.1.3 See also

- Consumer health informatics
- Medical informatics
- Nursing informatics

2.1.4 References

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2.2 Medical integration environment

Medical integration environment (MIE) are specialised tools designed to simplify the sharing of medical and related data between medical equipment and electronic health records. Technically, they are similar to an Enterprise Service Bus but with several extra features allowing for legacy systems that do not use web services messaging. Typically, they use Java Message Service; most Enterprise Application Integration systems can be modified to be used as an MIE but may lack the crucial HL7 and Arden syntax for storing medical knowledge.

2.3 Health information exchange

Not to be confused with Health insurance exchange (HIX).

Health information exchange (**HIE**) is the mobilization of health care information electronically across organizations within a region, community or hospital system. In practice the term HIE may also refer to the organization that facilitates the exchange.

HIE provides the capability to electronically move clinical information among different health care information systems. The goal of HIE is to facilitate access to and retrieval of clinical data to provide safer and more timely, efficient, effective, and equitable patient-centered care. HIE is also useful to public health authorities to assist in analyses of the health of the population.

HIE systems facilitate the efforts of physicians and clinicians to meet high standards of patient care through electronic participation in a patient's continuity of care with multiple providers. Secondary health care provider benefits include reduced expenses associated with:

- the manual printing, scanning and faxing of documents, including paper and ink costs, as well as the maintenance of associated office machinery
- the physical mailing of patient charts and records, and phone communication to verify delivery of traditional communications, referrals, and test results
- the time and effort involved in recovering missing patient information, including any duplicate tests required to recover such information

According to an internal study at Sushoo Health Information Exchange, the current method of exchanging patients' health information accounts for approximately $17,160 of expenses annually for a single-clinician practice.

Formal organizations are now emerging to provide both form and function for health information exchange efforts, both on independent and governmental or regional levels. These organizations are, in many cases, enabled and supported financially by statewide health information exchange grants from the Office of the National Coordinator for Health Information Technology. These grants were legislated into the HITECH components of the American Reinvestment and Recovery Act in 2009.*[1] The latter organizations (often called Regional Health Information Organizations, or RHIOs) are ordinarily geographically defined entities which develop and manage a set of contractual conventions and terms, arrange for the means of electronic exchange of information, and develop and maintain HIE standards.*[2]

In the United States, federal and state regulations regarding HIEs and HIT (health information technology) are still being defined. Federal regulations and incentive programs such as "Meaningful Use", which is formally known as the EHR Incentive Program,*[3]*[4] are rapidly changing the face of this relatively new industry. In addition to changes driven by federal activities, the lessons learned in the ongoing implementation of some state-sponsored HIEs (such as the North Carolina HIE*[5]) and the fluctuating nature of health care regulations at the level of the state governments themselves are leading to additional refinement. However, HIEs and RHIOs continue to struggle to achieve self-sustainability and the vast majority remain tied to federal, state, or independent grant funding in order to remain operational. Some exceptions exist, such as the Indiana HIE.*[6]*[7]

2.3.1 Storage and gathering of information

Data architecture models

There are two main models for the data architecture of health information exchanges. One is a federated, or decentralized model, and the second is a centralized one. There is also a hybrid model that contains elements of both. In a centralized HIE there is a central (or master) database which holds a complete copy of all of the records of every patient contained in the HIE. In a federated HIE there is no master database.

In a federated model each health care provider is responsible for maintaining the records of their individual patients. In this model the main function of the HIE is to facilitate providers with exchanging patient records among themselves as the need arises. For example, if a physician in a federated HIE requests the records of Patient Y a query is sent to each server in the system asking to return any records that they have pertaining to Patient Y. Each federated HIE may accomplish this in a slightly different way, but the salient distinction is that in a federated model there is no central database from which a previously compiled comprehensive medical record is stored and can be downloaded.

In short, in a federated HIE records are exchanged electronically among providers when they need them. In a centralized model all patient information is uploaded to a single database from which any provider in the HIE can download a patient's full medical record.*[8]*[9]

Patient consent

Exchanges in the US must operate with patient consent to comply with not only the Health Insurance Portability and Accountability Act (HIPAA), but a variety of state and federal laws and regulations. This was clarified by the Office of Civil Rights in the January 2013 Final Omnibus Rule Update to HIPAA.*[10]

There are two methods for gaining patient consent. One is explicit consent and is termed *opt-in*. With this method a patient is not automatically enrolled into the HIE by default and generally must submit a written request to join the exchange.

The other method is implicit patient consent and is termed *opt-out*. In this method patients give implicit consent to join an HIE when they agree to use the services of a health care provider who is submitting data into an HIE and sign the provider's Notice Of Privacy Practices. In this model patients can request to opt out of the HIE, generally with a written form.*[11]

2.3.2 List of health information exchanges

Chesapeake Regional Information System for our Patients
: CRISP is a non-profit corporation that is implementing health information exchange in the state of Maryland. The organization also serves as the Health IT Extension Center for Maryland. CRISP was created by Johns Hopkins Medicine, MedStar Health, the University of Maryland Medical System and Erickson Retirement Communities.*[12] Audacious Inquiry, a health information system consulting firm, serves as the technical architect and strategic partner for the health information exchange while Dynamed Solutions provides operational, project management and organizational support under CRISP.

CORHIO - the Colorado Regional Health Information Organization
: CORHIO is one of the United States' largest public health information exchange networks and the state designated entity for HIE in Colorado.*[13] As of November 1, 2014, 38 Colorado hospitals and more than 2,200 doctors, and 130 long-term and post-acute care centers were connected to the CORHIO HIE.*[14]*[15]

Delaware Health Information Network DHIN is a non-profit public-private partnership enacted by the Delaware General Assembly in 1997, for the benefit of all citizens of Delaware to advance the creation of a statewide health information network and to address Delaware's needs for timely, reliable and relevant health care information. DHIN has adopted regulations to govern its operations and has policies and procedures in place to support privacy and security of patient information. DHIN enhances a health care information exchange started in May 2007. In February 2012, The Delaware Health Information Network announced full participation of all acute care hospitals and skilled nursing facilities in the state, along with the vast majority of Delaware providers, in the first statewide community health record. As of June 2013, DHIN has attracted the participation of 97 percent of Delaware providers, tracks nearly 88 percent of Delaware's population, and delivers more than 10 million clinical results and reports to participating providers annually.* [16]

Frysian Health Information Exchange The Friesland Regional Cardiology Network speeds up the referral process, improves both diagnosis and the clinical decision process, and on average reduces by one or two days the length-of-stay for patients in hospitals. From their office workstations, cardiologists are able to consult the advanced clinical images provided by any hospital linked to the network. The distributed storage of records eliminates the duplication of records across multiple sites. Once uploaded to the cardiology network, records remain available for consultation at any time so that previous episodes of a patient's care can be consulted in detail no matter where the care was provided in the region.

Great Lakes Health Connect Great Lakes Health Connect (GLHC), based in Grand Rapids, is the largest provider of Health Information Exchange (HIE) services in Michigan. GLHC was founded in 2009 as Michigan Health Connect (MHC) when several health systems in West Michigan (including Spectrum Health, Trinity Health, Metro Health, Lakeland Health, and Northern Michigan Regional Health System) agreed to collaborate and not compete on clinical data exchange. In March of 2010 MHC was formally launched as a charitable [509(a)2] non-profit corporation in Michigan. In June of 2014 Michigan Health Connect merged with Great Lakes Health Information Exchange (GLHIE) to form Great Lakes Health Connect. Today, GLHC is among the leading providers of health information exchange services in the nation. GLHC seamlessly and securely facilitates the transmission of more than a billion messages a year across 129 health systems and nearly 4,000 primary, secondary and allied care provider offices across the state. The community-based nonprofit is dedicated to improving the quality and accessibility of healthcare information by creating care-connected communities across Michigan and beyond.

Harvard Pilgrim Health Care HPHC is a non-profit insurance provider which serves members throughout Massachusetts, New Hampshire, and Maine. The provider offers variety health insurance options for companies, families and individuals. Customers health insurance expectations are met through a tailored options from preferred provider organization (PPO), point-of-sale (POS), and health maintenance organization (HMO). HPHC implements CRM, Master Data Management and is now implementing Oracle Policy Automation to support integrated call center and online self-service for plan purchase and management across their various customer groups additionally, HPHC is using their platform to support recruitment and to better analyze and improve service levels in a heavily competitive market.* [17]

HealthShare Exchange of Southeastern Pennsylvania, Inc. HealthShare Exchange of Southeastern Pennsylvania, Inc. is a non-profit health information exchange organization serving the Delaware valley. Founded in 2009, HealthShare Exchange of Southeastern PA, (or HSX) facilitates the exchange of patient data between hospitals, insurers and physicians within the region.

Idaho Health Data Exchange The Idaho Health Data Exchange (IHDE) is the state designated Health Information Exchange (HIE) for Idaho. Health Information Exchange enables doctors, nurses, labs, and other medical providers to securely access their patient's electronic health information quickly, 24/7/365, to improve the speed, quality, safety, and cost of patient care. IHDE is a non-profit 501(c)(6) company. The IHDE is Idaho created, based, and managed. Located in Boise, ID, the staff consists of an Executive Director, Executive Assistant, Sr. Marketing Coordinator, Business Analysts (Implementations), Training/Support Specialists, and IT systems support. The IHDE's mission is to create, and maintain a collaborative effort to improve the coordination and quality of healthcare through the use of Health Information Exchange and Health Information Technology. The IHDE is governed by a voluntary Board of Directors and voluntary Privacy and Security Committee which provides oversight of compliance and best practices. Members of the Board of Directors and Privacy and Security Committee represent the private and public sectors, and health care delivery systems, with a passionate interest in Health Information Exchange.* [18]

Indiana Health Information Exchange The Indiana Health Information Exchange (IHIE) operates the U.S.'s largest HIE and one of the oldest with data on more than 7 million patients, connecting hospitals, rehabilitation centers, long term care facilities, laboratories, imaging centers, clinics, community health centers and other healthcare organizations. Created by the Regenstrief Institute, a medical informatics think tank, the Indiana Network for Patient Care (INPC) is a secure network that provides a patient records to participating doctors. The IHIE provides current data about admissions, discharges, and transfers to help health plans and accountable care organizations reduce nonurgent emergency department visits.*[19] This HIE grew over time from 12 hospitals in the center of the state with approximately 5,000 physicians, to 106 hospitals out of 126 in the state and more than 14,000 physicians in Indiana.*[20]

Keystone Health Information Exchange KeyHIE was founded by Geisinger Health System in April 2005, via a memorandum of understanding signed by 8 hospitals throughout Central Pennsylvania. One of the nation's largest and most advanced health information exchanges, KeyHIE connects 18 hospitals, 251 physician practices, 95 long-term care facilities, 30 home health agencies and other healthcare organizations such as EMS agencies, pharmacies, and federally qualified health centers (FQHCs). It serves 4.3 million patients over a 53-county presence in Pennsylvania to ensure health information follows patients, regardless of where they receive care. KeyHIE offers a wide range of services to doctor's offices, hospitals, nursing homes and other healthcare organizations in Pennsylvania and surrounding areas.

Michiana Health Information Network MHIN is one of the first HIEs in the United States and offers unprecedented levels of integration and connectivity to healthcare professionals and providers. In 1998, MHIN was incorporated, and the team went right to work improving, securing, and facilitating communication among providers. Today, MHIN continues to assist communities throughout the Midwest to establish a regionally based HIE. Organizations across the healthcare spectrum - from hospitals to specialty groups to medical labs and diagnostic centers - find solutions in MHIN's diverse service platform. MHIN's core applications provide an efficient, secure way for providers to exchange information and facilitate high-quality, coordinated care.

Missouri Health Connection Missouri Health Connection(MHC) is a nonprofit organization that operates Missouri's statewide health information network. Established in 2009, MHC's mission is to enable Missouri healthcare providers-from small, rural clinics to large hospital systems-to securely share a patient's medical data. With our wide network of hospitals, clinics, and community health centers, MHC's network will connect inpatient and outpatient care in Missouri. MHC's network covers two-thirds of the inpatient care in Missouri and enables physicians to access more complete patient records.

MHC provides the technological infrastructure for health care providers to coordinate care for their patients through a secure health information network.The services provided by MHC are designed to support all health care provider organizations, from the largest multi-hospital health system to a solo physician practice. Coordinating care, reducing preventable errors, and avoiding treatment duplication are among MHC's primary goals. MHC's network will improve patient care and help save lives in emergencies by securely delivering more complete and accurate information at the point of care, or wherever it is needed. MHC is a nonprofit 501(c)(3) organization and is governed by a board of directors that includes representatives from both public and private organizations such as hospital systems, health care providers, state agencies and consumer groups.

Ohio Health Information Partnership CliniSync HIE

The Ohio Health Information Partnership, a nonprofit, public/private partnership initially funded with $14.8 million in federal HITECH funds under the Office of the National Coordinator for HIT, is the state-designated statewide health information exchange founded by the Ohio State Medical Association, the Ohio Osteopathic Association,the Ohio Hospital Association, BioOhio and the Ohio Department of Insurance.

Federal funds paid for the creation of the technological infrastructure, powered by Medicity, as well as discounted implementation fees for hospitals in Ohio. The CliniSync Health Information Exchange has 149 hospitals contracted to join the network. CliniSync now has 122 hospitals "live" on the network with thousands of physicians receiving results and reports directly from live hospitals or waiting to do so when hospitals go live.

The CliniSync HIE continues to grow each day, with more and more physicians connecting. In 2015, CliniSync enabled practices and other authorized users to look up and find (query and retrieve) a longitudinal Community Health

Record on a patient that gives clinician a full picture of a patients health, including recent visits to various hospitals hospital, allergies, tests and reports, care summaries and other useful information. Patients in Ohio automatically are enrolled in the CliniSync HIE unless they wish to opt out.

Along with results and reports delivery and the Community Health Record, CliniSync members will receive notifications when a patient is discharged or admitted to the hospital or Emergency Department in late 2016. The CliniSync base has extended to 400 plus long-term and post-acute care facilities, behavioral health facilities, and even to social service agencies whose patients need the resources of the community beyond medical care. The nonprofit is now fiscally independent of any federal funds. CliniSync's website is www.clinisync.org.

Pennsylvania eHealth Partnership Authority Taking over the work of the PA eHealth Collaborative, the Pennsylvania eHealth Partnership Authority (PAeHealth) provides leadership and strategic direction for public and private, federally funded and state-funded investments in health information technology initiatives, including health information exchange capabilities and other related health information technology efforts. The Authority's direction has considered the stakeholder community's needs and will complement commonwealth agency operations. It also will ensure ongoing interagency cooperation.

Utah Health Information Network The Utah Health Information Network (UHIN) is a broad-based coalition of Utah healthcare insurers, providers, and other interested parties, including the Utah State government. Since 1993, UHIN members have come together for the common goal of reducing healthcare costs and improving the quality of care through the use of electronic data interchange (EDI) for healthcare transactions. Exchanging information electronically rather than by phone, fax or surface mail means that data can get to those who need it securely, economically and efficiently. UHIN currently serves nearly all the hospitals, ambulatory surgery centers, national laboratories, insurers, and approximately 90% of the medical providers in Utah as well as the Utah State government. As a community organization the focus is on creating data exchange solutions that work for the entire healthcare community, from large integrated networks to single-provider offices. The Clinical Health Information Exchange (cHIE) is a secure electronic way for medical professionals to share and view patient information that is needed at the point of care. The cHIE makes this information accessible, with patient consent, to authorized users while maintaining the highest standards of patient privacy.

2.3.3 See also

- DICOM (Digital Imaging and Communications in Medicine)
- LOINC (Logical Observation Identifiers Names and Codes)
- Health informatics
- Health Level 7 (HL7)
- Integrating the Healthcare Enterprise (IHE)
- Medical imaging
- Regional Health Information Organization (RHIO)

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2.4 Hospital information system

A **hospital information system** (**HIS**) is an element of health informatics that focuses mainly on the administrational needs of hospitals. In many implementations, a HIS is a comprehensive, integrated information system designed to manage all the aspects of a hospital's operation, such as medical, administrative, financial, and legal issues and the corresponding processing of services.

2.4.1 Architecture

Hospital Information System architecture has three main levels, Central Government Level, Territory Level, and Patient Carrying Level. Generally all types of hospital information system (HIS) are supported in client-server architectures for networking and processing. Most work positions for HIS are currently resident types. Mobile computing began with wheeled PC stands. Now tablet computers and smartphone applications are used.

Enterprise HIS with Internet architectures have been successfully deployed in Public Healthcare Territories and have been widely adopted by further entities.*[1] The Hospital Information System (HIS) is a province-wide initiative designed to improve access to patient information through a central electronic information system. HIS's goal is to streamline patient information flow and its accessibility for doctors and other health care providers. These changes in service will improve patient care quality and patient safety over time.

The patient carries system record patient information, patient laboratory test results, and patient's doctor information. Doctors can access easily person information, test results, and previous prescriptions. Patient schedule organization and early warning systems can provide by related systems.

Functional split

HIS has data warehousing as the main topic, hence a more static model of information management. HIS is often composed of one or several software components with specialty-specific extensions, as well as of a large variety of sub-systems in medical specialties from a multi-vendor market. Specialized implementations name for example Laboratory Information System (**LIS**), Policy and Procedure Management System,*[2] Radiology Information System (**RIS**) or Picture archiving and communication system (**PACS**).

Architecture is based on a distributed approach and on the utilization of standard software products complying with the industrial and market standards must be utilized (such as: UNIX operating systems, MS-Windows, local area network based on Ethernet and TCP/IP protocols, relational database management systems based on SQL language or Oracle databases, C programming language).

Portable devices such as smartphones and table computers may be used at the bedside.

2.4.2 Aim

Hospital Information Systems provide a common source of information about a patient's health history. The system have to keep data in secure place and controls who can reach the data in certain circumstances. These systems enhance the ability of health care professionals to coordinate care by providing a patient's health information and visit history at the place and time that it is needed. Patient's laboratory test information also visual results such as X-ray may reachable from professionals. HIS provide internal and external communication among health care providers.

The HIS may control organizations, which is Hospital in these case, official documentations, financial situation reports, personal data, utilities and stock amounts, also keeps in secure place patients information, patients medical history, prescriptions, operations and laboratory test results.

The HIS may protect organizations, handwriting error, overstock problems, conflict of scheduling personnel, official documentation errors like tax preparations errors.

Systems administrator/database administrator

IT Administrators

The systems administrator-database administrator is responsible for systems administration to ensure the high uptime of the system and for handling all database back-up and restoration activities.

Application specialist and trainer

The hospital's application specialist together with the software vendor is involved in all the activities required for implementing the application software. Trainers train and retrain new employees in the hospital.

Hardware/network engineers

Hardware/Network engineers are responsible for maintaining the hardware and network systems in the hospital. They undertake all troubleshooting activities that may be required to keep the system online and patient data available to doctors and nurses.

2.4.3 Standardization

There is no standardization but for data formats and for data interchange, as with the HL7 initiative supported by ISO.

- Efficient and accurate administration of finance, diet of patient, engineering, and distribution of medical aid. It helps to view a broad picture of hospital growth
- Improved monitoring of drug usage, and study of effectiveness. This leads to the reduction of adverse drug interactions while promoting more appropriate pharmaceutical utilization.
- Enhances information integrity, reduces transcription errors, and reduces duplication of information entries.*[3]
- Hospital software is easy to use and eliminates error caused by handwriting. New technology computer systems give perfect performance to pull up information from server or cloud servers.

2.4.4 See also

- Clinical documentation improvement
- Cloud computing
- DICOM
- Electronic health record (EHR)
- eMix
- European Institute for Health Records (EuroRec)
- Health care
- Health information management
- List of open source healthcare software
- Medical imaging
- Medical record
- Personal health record

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2.5 Computer physician order entry

Computerized Physician Order Entry (CPOE), sometimes referred to as **Computerized Provider Order Entry** or **Computerized Provider Order Management (CPOM)**, is a process of electronic entry of medical practitioner instructions for the treatment of patients (particularly hospitalized patients) under his or her care. Basically this acronym is a tautology, as order entry always requires some computerised facility.

The entered orders are communicated over a computer network to the medical staff or to the departments (pharmacy, laboratory, or radiology) responsible for fulfilling the order. CPOE decreases delay in

- order distribution,
- resource allocation,

- order completion,

and shall

- reduce errors related to handwriting or transcription,
- allow order entry at the point of care or off-site,
- provide error-checking for duplicate or incorrect doses or tests, and
- simplify inventory and posting of charges.

CPOE is a form of patient management software.*[1]

2.5.1 Terminology related to order entry

Filler

The application responding to, *i.e.*, performing, a request for services (orders) or producing an observation. The filler can also originate requests for services (new orders), add additional services to existing orders, replace existing orders, put an order on hold, discontinue an order, release a held order, or cancel existing orders.

Order

A request for a service from one application to a second application. In some cases an application is allowed to place orders with itself.

Order detail segment

One of several segments that can carry order information. Future ancillary specific segments may be defined in subsequent releases of the Standard if they become necessary.

Placer

The application or individual originating a request for services (order).

Placer order group

A list of associated orders coming from a single location regarding a single patient.

Order Set

A grouping of orders used to standardize and expedite the ordering process for a common clinical scenario. (Typically, these orders are started, modified, and stopped by a licensed physician.)

Protocol

A grouping of orders used to standardize and automate a clinical process on behalf of a physician. (Typically, these orders are started, modified, and stopped by a nurse, pharmacist, or other licensed health professional.)

2.5.2 Features of CPOE systems

Features of the ideal computerized physician order entry system (CPOE) include:

Ordering Physician orders are standardized across the organization, yet may be individualized for each doctor or specialty by using order sets. Orders are communicated to all departments and involved caregivers, improving response time and avoiding scheduling problems and conflict with existing orders.

Patient-centered decision support The ordering process includes a display of the patient's medical history and current results and evidence-based clinical guidelines to support treatment decisions. Often uses medical logic module and/or Arden syntax to facilitate fully integrated Clinical Decision Support Systems (CDSS).

Patient safety features The CPOE system allows real-time patient identification, drug dose recommendations, adverse drug reaction reviews, and checks on allergies and test or treatment conflicts. Physicians and nurses can review orders immediately for confirmation.

Intuitive Human interface The order entry workflow corresponds to familiar "paper-based" ordering to allow efficient use by new or infrequent users.

Regulatory compliance and security Access is secure, and a permanent record is created, with electronic signature.

Portability The system accepts and manages orders for all departments at the point-of-care, from any location in the health system (physician's office, hospital or home) through a variety of devices, including wireless PCs and tablet computers.

Management The system delivers statistical reports online so that managers can analyze patient census and make changes in staffing, replace inventory and audit utilization and productivity throughout the organization. Data is collected for training, planning, and root cause analysis for patient safety events.

Billing Documentation is improved by linking diagnoses (ICD-9-CM or ICD-10-CM codes) to orders at the time of order entry to support appropriate charges.

2.5.3 Patient safety benefits of CPOE

In the past, physicians have traditionally hand-written or verbally communicated orders for patient care, which are then transcribed by various individuals (such as unit clerks, nurses, and ancillary staff) before being carried out. Handwritten reports or notes, manual order entry, non-standard abbreviations and poor legibility lead to errors and injuries to patients, .*[2] A follow up IOM report in 2001 advised use of electronic medication ordering, with computer- and internet-based information systems to support clinical decisions.*[3] Prescribing errors are the largest identified source of preventable hospital medical error. A 2006 report by the Institute of Medicine estimated that a hospitalized patient is exposed to a medication error each day of his or her stay.*[4] While further studies have estimated that CPOE implementation at all nonrural hospitals in the United States could prevent over 500,000 serious medication errors each year.*[5] Studies of computerized physician order entry (CPOE) has yielded evidence that suggests the medication error rate can be reduced by 80%, and errors that have potential for serious harm or death for patients can be reduced by 55%,*[6] and other studies have also suggested benefits.*[7] Further, in 2005, CMS and CDC released a report that showed only 41 percent of prophylactic antibacterials were correctly stopped within 24 hours of completed surgery. The researchers conducted an analysis over an eight-month period, implementing a CPOE system designed to stop the administration of prophylactic antibacterials. Results showed CPOE significantly improved timely discontinuation of antibacterials from 38.8 percent of surgeries to 55.7 percent in the intervention hospital.*[8] CPOE/e-Prescribing systems can provide automatic dosing alerts (for example, letting the user know that the dose is too high and thus dangerous) and interaction checking (for example, telling the user that 2 medicines ordered taken together can cause health problems). In this way, specialists in pharmacy informatics work with the medical and nursing staffs at hospitals to improve the safety and effectiveness of medication use by utilizing CPOE systems.

2.5.4 Risks of CPOE

CPOE presents several possible dangers by introducing new types of errors.*[9]*[10] Prescriber and staff inexperience may cause slower entry of orders at first, use more staff time, and is slower than person-to-person communication in an emergency situation. Physician to nurse communication can worsen if each group works alone at their workstations. Automation causes a false sense of security, a misconception that when technology suggests a course of action, errors are avoided. These factors contributed to an *increased* mortality rate in the Children's Hospital of Pittsburgh's Pediatric ICU when a CPOE systems was introduced.*[11] In other settings, shortcut or default selections can override non-standard medication regimens for elderly or underweight patients, resulting in toxic doses. Frequent alerts and warnings can interrupt work flow, causing these messages to be ignored or overridden due to alert fatigue. CPOE and automated drug dispensing was identified as a cause of error by 84% of over 500 health care facilities participating in a surveillance system by the United States Pharmacopoeia.*[12] Introducing CPOE to a complex medical environment requires ongoing changes in design to cope with unique patients and care settings, close supervision of overrides caused by automatic systems, and training, testing and retraining all users.

2.5.5 Implementation

CPOE systems can take years to install and configure. Despite ample evidence of the potential to reduce medication errors, adoption of this technology by doctors and hospitals in the United States has been slowed by resistance to changes in physician's practice patterns, costs and training time involved, and concern with interoperability and compliance with future national standards.*[13] According to a study by RAND Health, the US healthcare system could save more than 81 billion dollars annually, reduce adverse medical events and improve the quality of care if it were to widely adopt CPOE and other health information technology.*[14] As more hospitals become aware of the financial benefits of CPOE, and more physicians with a familiarity with computers enter practice, increased use of CPOE is predicted. Several high profile failures of CPOE implementation have occurred,*[15] so a major effort must be focused on change management, including restructuring workflows, dealing with physicians' resistance to change, and creating a collaborative environment.

An early success with CPOE by the United States Department of Veterans Affairs (VA) is the Veterans Health Information Systems and Technology Architecture or VistA. A graphical user interface known as the Computerized Patient Record System (CPRS) allows health care providers to review and update a patient's record at any computer in the VA's over 1,000 healthcare facilities. CPRS includes the ability to place orders by CPOE, including medications, special procedures, x-rays, patient care nursing orders, diets and laboratory tests.

The world's first successful implementation of a CPOE system was at El Camino Hospital in Mountain View, California in the early 1970s. The Medical Information System (MIS) was originally developed by a software and hardware team at Lockheed in Sunnyvale, California, which became the TMIS group at Technicon Instruments Corporation. The MIS system used a light pen to allow physicians and nurses to quickly point and click items to be ordered.

As of 2005, one of the largest projects for a national EHR

is by the National Health Service (NHS) in the United Kingdom. The goal of the NHS is to have 60,000,000 patients with a centralized electronic health record by 2010. The plan involves a gradual roll-out commencing May 2006, providing general practices in England access to the National Programme for IT (NPfIT). The NHS component, known as the "Connecting for Health Programme",*[16] includes office-based CPOE for medication prescribing and test ordering and retrieval, although some concerns have been raised about patient safety features.*[17]

In 2008, the Massachusetts Technology Collaborative and the New England Healthcare Institute (NEHI) published research showing that 1 in 10 patients admitted to a Massachusetts community hospital suffered a preventable medication error. The study argued that Massachusetts hospitals could prevent 55,000 adverse drug events per year and save $170 million annually if they fully implemented CPOE. The findings prompted the Commonwealth of Massachusetts to enact legislation requiring all hospitals to implement CPOE by 2012 as a condition of licensure.*[18]*[19]

In addition, the study*[20] also concludes that it would cost approximately $2.1 million to implement a CPOE system, and a cost of $435,000 to maintain it in the state of Massachusetts while it saves annually about $2.7 million per hospital. The hospitals will still see payback within 26 months through reducing hospitalizations generated by error. Despite the advantages and cost savings, the CPOE is still not well adapted by many hospitals in the US.

The Leapfrog's 2008 Survey*[21] showed that most hospitals are still not complying with having a fully implemented, effective CPOE system. The CPOE requirement became more challenging to meet in 2008 because the Leapfrog introduced a new requirement: Hospitals must test their CPOE systems with Leapfrog's CPOE Evaluation Tool. So the number of hospitals in the survey considered to be fully meeting the standard dropped to 7% in 2008 from 11% the previous year. Though the adoption rate seems very low in 2008, it is still an improvement from 2002 when only 2% of hospitals met this Leapfrog standard.

2.5.6 See also

- Electronic prescribing
- Continuity of Care Record
- Electronic health record
- Electronic medical record
- Health informatics
- Pharmacy informatics
- VistA - Veterans Health Information Systems and Technology Architecture

2.5.7 External links

- Certification Commission for Healthcare Information Technology (CCHIT)
- AHRQ National Resource Center for Health IT
- Nationwide Electronic Requisition Network™

2.5.8 Notes

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2.6 ICU quality and management tools

The intensive care unit (ICU) is one of the major components of the current health care system. The advances in supportive care and monitoring resulted in significant improvements in the care of surgical and clinical patients. Nowadays aggressive surgical therapies as well as transplantation are made safer by the monitoring in a closed environment, the surgical ICU, in the post-operative period. Moreover, the care and full recovery of many severely ill clinical patients as those with life-threatening infections occurs as a result of medical intensive care unit.

However, despite many significant advances in various fields as mechanical ventilation, renal replacement therapy, antimicrobial therapy and hemodynamic monitoring this increased knowledge and the wise use of such technology is not available for all patients. Shortage of ICU beds are an important issue, however even when ICU beds are available significant variability in treatment and in the adherence to evidence-based interventions do not occur.

2.6.1 Tools for ICU quality monitoring

Several measures of ICU performance have been proposed in the past 30 years. It is intuitive, and correct, to assume that ICU mortality may be a useful marker of quality. However, crude mortality rates does not take into consideration the singular aspects of each specific patient population that is treated in a certain geographic region, hospital or ICU. Therefore approaches looking for standardized mortality ratios that are adjusted for disease severity, comorbidities and other clinical aspects are often sought. Severity of illness is usually evaluated by scoring systems that integrates clinical, physiologic and demographic variables. Scoring systems are interesting tools to describe ICU populations and explain their different outcomes. The most frequently used are the APACHE II, SAPS II and MPM. The APACHE II, for example, provides an estimate of ICU mortality based on a number of laboratory values and patient signs taking both acute and chronic disease into account. The data used should be from the initial 24 hours in the ICU, and the worst value (furtherest from baseline/normal) should be used. The APACHE II can also define "chronic organ insufficiency" - including liver, cardiovascular, respiratory and renal- as well as defining when a patient is immunocompromised. However, newer scores as APACHE IV and SAPS III have been recently introduced in clinical practice. More than only using scoring systems, one should search for a high rate of adherence to clinically effective interventions. Adherence to interventions as deep venous thrombosis prophylaxis, reduction of ICU-acquired infections, adequate sedation regimens and decreasing and reporting serious adverse events are essential and have been accepted as benchmarking of quality.

The complex task of collecting and analyzing data on performance measures are made easier when clinical information systems are available. Although several clinical information systems focus on important aspects as computerized physician order entry systems and individual patient tracking information, few have attempted to gather clinical information generating full reports that provide a panorama of the ICU performance and detailed data on several domains as mortality, length of stay, severity of illness, clinical scores, nosocomial infections, adverse events and adherence to good clinical practice. Through implementing quality initiatives, increasing the quality of care and patient safety are major and feasible goals. Such systems (for example: Epimed Monitor) are available for clinical use and may facilitate the process of care on a daily basis and provide data for an in-depth analysis of ICU performance.

2.6.2 See Also

- APACHE II
- SAPS III
- Intensive care unit

2.6.3 References

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2.6.4 External Links

- APACHE II Score online
- SAPS II Scoring Sheets and Database

2.7 Laboratory information system

This article is about the laboratory software system. For other uses of "LIMS", see LIMS (disambiguation).

A **laboratory information management system** (**LIMS**), sometimes referred to as a **laboratory information system** (**LIS**) or **laboratory management system** (**LMS**), is a software-based laboratory and information management system with features that support a modern laboratory's operations. Key features include —but are not limited to —workflow and data tracking support, flexible architecture, and data exchange interfaces, which fully "support its use in regulated environments." *[1] The features and uses of a LIMS have evolved over the years from simple sample tracking to an enterprise resource planning tool that manages multiple aspects of laboratory informatics.*[2]

Laboratories around the world depend on a LIMS to manage data, assign rights, manage inventory, and more.

The definition of a LIMS is somewhat controversial: LIMSs are dynamic because the laboratory's requirements are rapidly evolving and different labs often have different needs. Therefore, a working definition of a LIMS ultimately depends on the interpretation by the individuals or groups involved.*[1] Dr. Alan McLelland of the Institute of Biochemistry, Royal Infirmary, Glasgow highlighted this problem in the late 1990s by explaining how a LIMS is perceived by an analyst, a laboratory manager, an information systems manager, and an accountant, "all of them correct, but each of them limited by the users' own perceptions." *[3]

Historically the LIMS, LIS, and process development execution system (PDES) have all performed similar functions. The term "LIMS"has tended to refer to informatics systems targeted for environmental, research, or commercial analysis such as pharmaceutical or petrochemical work. "LIS" has tended to refer to laboratory informatics systems in the forensics and clinical markets, which often required special case management tools. "PDES" has generally applied to a wider scope, including, for example, virtual manufacturing techniques, while not necessarily integrating with laboratory equipment.

In recent times LIMS functionality has spread even farther beyond its original purpose of sample management. Assay data management, data mining, data analysis, and electronic laboratory notebook (ELN) integration have been added to many LIMS,*[4] enabling the realization of translational medicine completely within a single software solution. Additionally, the distinction between

LIMS and LIS has blurred, as many LIMS now also fully support comprehensive case-centric clinical data.*[4]

2.7.1 History

Up until the late 1970s, the management of laboratory samples and the associated analysis and reporting were time-consuming manual processes often riddled with transcription errors. This gave some organizations impetus to streamline the collection of data and how it was reported. Custom in-house solutions were developed by a few individual laboratories, while some enterprising entities at the same time sought to develop a more commercial reporting solution in the form of special instrument-based systems.*[5]

In 1982 the first generation of LIMS was introduced in the form of a single centralized minicomputer, which offered laboratories the first opportunity to utilize automated reporting tools. As the interest in these early LIMS grew, industry leaders like Gerst Gibbon of the Federal Energy Technology Center in Pittsburgh began planting the seeds through LIMS-related conferences. By 1988 the second-generation commercial offerings were tapping into relational databases to expand LIMS into more application-specific territory, and International LIMS Conferences were in full swing. As personal computers became more powerful and prominent, a third generation of LIMS emerged in the early 1990s. These new LIMS took advantage of client/server architecture, allowing laboratories to implement better data processing and exchanges.*[5]

By 1995 the client/server tools had developed to the point of allowing processing of data anywhere on the network. Web-enabled LIMS were introduced the following year, enabling researchers to extend operations outside the confines of the laboratory. From 1996 to 2002 additional functionality was included in LIMS, from wireless networking capabilities and georeferencing of samples, to the adoption of XML standards and the development of Internet purchasing.*[5]

As of 2012, some LIMS have added additional characteristics that continue to shape how a LIMS is defined. Additions include clinical functionality, electronic laboratory notebook (ELN) functionality, as well a rise in the software as a service (SaaS) distribution model.*[4]*[6]

2.7.2 Technology

Operations

The LIMS is an evolving concept, with new features and functionality being added often. As laboratory demands change and technological progress continues, the functions of a LIMS will likely also change. Despite these changes, a LIMS tends to have a base set of functionality that defines it. That functionality can roughly be divided into five laboratory processing phases, with numerous software functions falling under each:*[7] (1) the reception and log in of a sample and its associated customer data, (2) the assignment, scheduling, and tracking of the sample and the associated analytical workload, (3)the processing and quality control associated with the sample and the utilized equipment and inventory, (4) the storage of data associated with the sample analysis, (5) the inspection, approval, and compilation of the sample data for reporting and/or further analysis

There are several pieces of core functionality associated with these laboratory processing phases that tend to appear in most LIMS:

A lab worker matches blood samples to documents. With a LIMS, this sort of sample management is made more efficient.

Sample management The core function of LIMS has traditionally been the management of samples.*[5] This typically is initiated when a sample is received in the laboratory, at which point the sample will be registered in the LIMS. Some LIMS will allow the customer to place an "order" for a sample directly to the LIMS at which point the sample is generated in an "unreceived" state. The processing could then include a step where the sample container is registered and sent to the customer for the sample to be taken and then returned to the lab. The registration process may involve accessioning the sample and producing barcodes to affix to the sample container. Various other parameters such as clinical or phenotypic information corresponding with the sample are also often recorded. The LIMS then tracks chain of custody as well as sample location. Location tracking usually involves assigning the sample to a particular freezer location, often down to the granular level of shelf, rack, box, row, and column. Other event tracking such as freeze and thaw cycles that a sample undergoes in the laboratory may be required.

Modern LIMS have implemented extensive configurability, as each laboratory's needs for tracking additional

data points can vary widely. LIMS vendors cannot typically make assumptions about what these data tracking needs are, and therefore vendors must create LIMS that are adaptable to individual environments. LIMS users may also have regulatory concerns to comply with such as CLIA, HIPAA, GLP, and FDA specifications, affecting certain aspects of sample management in a LIMS solution.*[8] One key to compliance with many of these standards is audit logging of all changes to LIMS data, and in some cases a full electronic signature system is required for rigorous tracking of field-level changes to LIMS data.

Instrument and application integration Modern LIMS offer an increasing amount of integration with laboratory instruments and applications. A LIMS may create control files that are "fed" into the instrument and direct its operation on some physical item such as a sample tube or sample plate. The LIMS may then import instrument results files to extract data for quality control assessment of the operation on the sample. Access to the instrument data can sometimes be regulated based on chain of custody assignments or other security features if need be.

Modern LIMS products now also allow for the import and management of raw assay data results.*[9] Modern targeted assays such as qPCR and deep sequencing can produce tens of thousands of data points per sample. Furthermore, in the case of drug and diagnostic development as many as 12 or more assays may be run for each sample. In order to track this data, a LIMS solution needs to be adaptable to many different assay formats at both the data layer and import creation layer, while maintaining a high level of overall performance. Some LIMS products address this by simply attaching assay data as BLOBs to samples, but this limits the utility of that data in data mining and downstream analysis.

Electronic data exchange The exponentially growing volume of data created in laboratories, coupled with increased business demands and focus on profitability, have pushed LIMS vendors to increase attention to how their LIMS handles electronic data exchanges. Attention must be paid to how an instrument's input and output data is managed, how remote sample collection data is imported and exported, and how mobile technology integrates with the LIMS. The successful transfer of data files in spreadsheet and other formats, as well as the import and export of data to MySQL, PostgreSQL, and other databases is a pivotal aspect of the modern LIMS.*[4] In fact, the transition "from proprietary databases to standardized database management systems such as MySQL" has arguably had one of the biggest impacts on how data is managed and exchanged in laboratories.*[10] In addition to mobile and database electronic data exchange, many LIMS support real-time data exchange with Electronic Health Records used in core hospital or clinic operations.*[11]

Additional functions Aside from the key functions of sample management, instrument and application integration, and electronic data exchange, there are numerous additional operations that can be managed in a LIMS. This includes but is not limited to:*[2]*[4]*[12]

audit management fully track and maintain an audit trail

barcode handling assign one or more data points to a barcode format; read and extract information from a barcode

chain of custody assign roles and groups that dictate access to specific data records and who is managing them

compliance follow regulatory standards that affect the laboratory

customer relationship management handle the demographic information and communications for associated clients

document management process and convert data to certain formats; manage how documents are distributed and accessed

instrument calibration and maintenance schedule important maintenance and calibration of lab instruments and keep detailed records of such activities

inventory and equipment management measure and record inventories of vital supplies and laboratory equipment

manual and electronic data entry provide fast and reliable interfaces for data to be entered by a human or electronic component

method management provide one location for all laboratory process and procedure (P&P) and methodology to be housed and managed as well as connecting each sample handling step with current instructions for performing the operation

personnel and workload management organize work schedules, workload assignments, employee demographic information, training, and financial information

quality assurance and control gauge and control sample quality, data entry standards, and workflow

reports create and schedule reports in a specific format; schedule and distribute reports to designated parties

time tracking calculate and maintain processing and handling times on chemical reactions, workflows, and more

traceability show audit trail and/or chain of custody of a sample

workflows track a sample, a batch of samples, or a "lot" of batches through its lifecycle

Client-side options

A LIMS has utilized many architectures and distribution models over the years. As technology has changed, how a LIMS is installed, managed, and utilized has also changed with it. The following represents architectures which have been utilized at one point or another.

Thick-client A thick-client LIMS is a more traditional client/server architecture, with some of the system residing on the computer or workstation of the user (the client) and the rest on the server. The LIMS software is installed on the client computer, which does all of the data processing. Later it passes information to the server, which has the primary purpose of data storage. Most changes, upgrades, and other modifications will happen on the client side.

This was one of the first architectures implemented into a LIMS, having the advantage of providing higher processing speeds (because processing is done on the client and not the server). Additionally, thick-client systems have also provided more interactivity and customization, though often at a greater learning curve. The disadvantages of client-side LIMS include the need for more robust client computers and more time-consuming upgrades, as well as a lack of base functionality through a web browser. The thick-client LIMS can become web-enabled through an add-on component.*[13]

Although there is a claim of improved security through the use of a thick-client LIMS,*[13] this is based on the misconception that "only users with the client application installed on their PC can access server side information". This secrecy-of-design reliance is known as security through obscurity and ignores an adversary's ability to mimic client-server interaction through, for example, reverse engineering, network traffic interception, or simply purchasing a thick-client license. Such a view is in contradiction of the "Open Design" principle of the National Institute of Standards and Technology's *Guide to General Server Security* which states that "system security should not depend on the secrecy of the implementation or its components",*[14] which can be considered as a reiteration of Kerckhoffs's principle.

Thin-client A thin-client LIMS is a more modern architecture which offers full application functionality accessed through a device's web browser. The actual LIMS software resides on a server (host) which feeds and processes information without saving it to the user's hard disk. Any necessary changes, upgrades, and other modifications are handled by the entity hosting the server-side LIMS software, meaning all end-users see all changes made. To this end, a true thin-client LIMS will leave no "footprint" on the client's computer, and only the integrity of the web browser need be maintained by the user. The advantages of this system include significantly lower cost of ownership and fewer network and client-side maintenance expenses. However, this architecture has the disadvantage of requiring real-time server access, a need for increased network throughput, and slightly less functionality. A sort of hybrid architecture that incorporates the features of thin-client browser usage with a thick client installation exists in the form of a web-based LIMS.

Some LIMS vendors are beginning to rent hosted, thin-client solutions as "software as a service" (SaaS). These solutions tend to be less configurable than on-premises solutions and are therefore considered for less demanding implementations such as laboratories with few users and limited sample processing volumes.

Another implementation of the thin client architecture is the maintenance, warranty, and support (MSW) agreement. Pricing levels are typically based on a percentage of the license fee, with a standard level of service for 10 concurrent users being approximately 10 hours of support and additional customer service, at a roughly $200 per hour rate.*[4] Though some may choose to opt out of an MSW after the first year, it's often more economical to continue the plan in order to receive updates to the LIMS, giving it a longer life span in the laboratory.

Web-enabled A web-enabled LIMS architecture is essentially a thick-client architecture with an added web browser component. In this setup, the client-side software has additional functionality that allows users to interface with the software through their device's browser. This functionality is typically limited only to certain functions of the web client. The primary advantage of a web-enabled LIMS is the end-user can access data both on the client side and the server side of the configuration. As in a thick-client architecture, updates in the software must be propagated to every client machine. However, the added disadvantages of requiring always-on access to the host server and the need for cross-platform functionality mean that additional overhead costs may arise.

Web-based A web-based LIMS architecture is a hybrid of the thick- and thin-client architectures. While much of the client-side work is done through a web browser, the LIMS may also require the support of desktop software installed on the client device. The end result is a process that is apparent to the end-user through a web browser, but perhaps not so apparent as it runs thick-client-like processing in the background. In this case, web-based architecture has the advantage of providing more functionality through a more friendly web

interface. The disadvantages of this setup are more sunk costs in system administration and reduced functionality on mobile platforms.

The disadvantage of a thick client is in the installation and update phases of the applications. Users who want the security, high speed and functionality of a thick client may use Microsoft ClickOnce Technology. This enables the user to install and run a Windows-based smart client application by clicking a link in a web page. The software does not to be installed at each user workstation one by one. ClickOnce applications can be self-updating; they can check for newer versions as they become available and automatically replace any updated files.

Configurability

LIMS implementations are notorious for often being lengthy and costly.[*][15] This is due in part to the diversity of requirements within each lab, but also to the inflexible nature of LIMS products for adapting to these widely varying requirements. Newer LIMS solutions are beginning to emerge that take advantage of modern techniques in software design that are inherently more configurable and adaptable —particularly at the data layer —than prior solutions. This means not only that implementations are much faster, but also that the costs are lower and the risk of obsolescence is minimized.

2.7.3 Distinction between a LIMS and a LIS

Until recently, the LIMS and laboratory information system (LIS) have exhibited a few key differences, making them noticeably separate entities.

A LIMS traditionally has been designed to process and report data related to batches of samples from biology labs, water treatment facilities, drug trials, and other entities that handle complex batches of data. A LIS has been designed primarily for processing and reporting data related to individual patients in a clinical setting.[*][16][*][17]

A LIMS may need to satisfy good manufacturing practice (GMP) and meet the reporting and audit needs of the regulatory bodies and research scientists in many different industries. A LIS, however, must satisfy the reporting and auditing needs of health service agencies e.g. the hospital accreditation agency, HIPAA in the US, or other clinical medical practitioners.[*][16]

A LIMS is most competitive in group-centric settings (dealing with "batches" and "samples") that often deal with mostly anonymous research-specific laboratory data, whereas a LIS is usually most competitive in patient-centric settings (dealing with "subjects" and "specimens") and clinical labs.

2.7.4 Standards

A LIMS covers standards such as 21 CFR Part 11 from the Food and Drug Administration (United States), ISO/IEC 17025, ISO 15189, good laboratory practice, and Good Automated Manufacturing Practice (GAMP)

2.7.5 See also

- List of LIMS software packages
- Virtual research environment
- Laboratory informatics
- Electronic lab notebook
- Title 21 CFR Part 11
- Data management
- Scientific management
- Process development execution system

2.7.6 Further reading

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Thick-client A thick-client LIMS is a more traditional client/server architecture, with some of the system residing on the computer or workstation of the user (the client) and the rest on the server. The LIMS software is installed on the client computer, which does all of the data processing. Later it passes information to the server, which has the primary purpose of data storage. Most changes, upgrades, and other modifications will happen on the client side.

This was one of the first architectures implemented into a LIMS, having the advantage of providing higher processing speeds (because processing is done on the client and not the server). Additionally, thick-client systems have also provided more interactivity and customization, though often at a greater learning curve. The disadvantages of client-side LIMS include the need for more robust client computers and more time-consuming upgrades, as well as a lack of base functionality through a web browser. The thick-client LIMS can become web-enabled through an add-on component.*[13]

Although there is a claim of improved security through the use of a thick-client LIMS,*[13] this is based on the misconception that "only users with the client application installed on their PC can access server side information". This secrecy-of-design reliance is known as security through obscurity and ignores an adversary's ability to mimic client-server interaction through, for example, reverse engineering, network traffic interception, or simply purchasing a thick-client license. Such a view is in contradiction of the "Open Design" principle of the National Institute of Standards and Technology's *Guide to General Server Security* which states that "system security should not depend on the secrecy of the implementation or its components",*[14] which can be considered as a reiteration of Kerckhoffs's principle.

Thin-client A thin-client LIMS is a more modern architecture which offers full application functionality accessed through a device's web browser. The actual LIMS software resides on a server (host) which feeds and processes information without saving it to the user's hard disk. Any necessary changes, upgrades, and other modifications are handled by the entity hosting the server-side LIMS software, meaning all end-users see all changes made. To this end, a true thin-client LIMS will leave no "footprint" on the client's computer, and only the integrity of the web browser need be maintained by the user. The advantages of this system include significantly lower cost of ownership and fewer network and client-side maintenance expenses. However, this architecture has the disadvantage of requiring real-time server access, a need for increased network throughput, and slightly less functionality. A sort of hybrid architecture that incorporates the features of thin-client browser usage with a thick client installation exists in the form of a web-based LIMS.

Some LIMS vendors are beginning to rent hosted, thin-client solutions as "software as a service" (SaaS). These solutions tend to be less configurable than on-premises solutions and are therefore considered for less demanding implementations such as laboratories with few users and limited sample processing volumes.

Another implementation of the thin client architecture is the maintenance, warranty, and support (MSW) agreement. Pricing levels are typically based on a percentage of the license fee, with a standard level of service for 10 concurrent users being approximately 10 hours of support and additional customer service, at a roughly $200 per hour rate.*[4] Though some may choose to opt out of an MSW after the first year, it's often more economical to continue the plan in order to receive updates to the LIMS, giving it a longer life span in the laboratory.

Web-enabled A web-enabled LIMS architecture is essentially a thick-client architecture with an added web browser component. In this setup, the client-side software has additional functionality that allows users to interface with the software through their device's browser. This functionality is typically limited only to certain functions of the web client. The primary advantage of a web-enabled LIMS is the end-user can access data both on the client side and the server side of the configuration. As in a thick-client architecture, updates in the software must be propagated to every client machine. However, the added disadvantages of requiring always-on access to the host server and the need for cross-platform functionality mean that additional overhead costs may arise.

Web-based A web-based LIMS architecture is a hybrid of the thick- and thin-client architectures. While

much of the client-side work is done through a web browser, the LIMS may also require the support of desktop software installed on the client device. The end result is a process that is apparent to the end-user through a web browser, but perhaps not so apparent as it runs thick-client-like processing in the background. In this case, web-based architecture has the advantage of providing more functionality through a more friendly web interface. The disadvantages of this setup are more sunk costs in system administration and reduced functionality on mobile platforms.

The disadvantage of a thick client is in the installation and update phases of the applications. Users who want the security, high speed and functionality of a thick client may use Microsoft ClickOnce Technology. This enables the user to install and run a Windows-based smart client application by clicking a link in a web page. The software does not to be installed at each user workstation one by one. ClickOnce applications can be self-updating; they can check for newer versions as they become available and automatically replace any updated files.

Configurability

LIMS implementations are notorious for often being lengthy and costly.*[15] This is due in part to the diversity of requirements within each lab, but also to the inflexible nature of LIMS products for adapting to these widely varying requirements. Newer LIMS solutions are beginning to emerge that take advantage of modern techniques in software design that are inherently more configurable and adaptable —particularly at the data layer —than prior solutions. This means not only that implementations are much faster, but also that the costs are lower and the risk of obsolescence is minimized.

2.8.3 Distinction between a LIMS and a LIS

Until recently, the LIMS and laboratory information system (LIS) have exhibited a few key differences, making them noticeably separate entities.

A LIMS traditionally has been designed to process and report data related to batches of samples from biology labs, water treatment facilities, drug trials, and other entities that handle complex batches of data. A LIS has been designed primarily for processing and reporting data related to individual patients in a clinical setting.*[16]*[17]

A LIMS may need to satisfy good manufacturing practice (GMP) and meet the reporting and audit needs of the regulatory bodies and research scientists in many different industries. A LIS, however, must satisfy the reporting and auditing needs of health service agencies e.g. the hospital accreditation agency, HIPAA in the US, or other clinical medical practitioners.*[16]

A LIMS is most competitive in group-centric settings (dealing with "batches" and "samples") that often deal with mostly anonymous research-specific laboratory data, whereas a LIS is usually most competitive in patient-centric settings (dealing with "subjects" and "specimens") and clinical labs.

2.8.4 Standards

A LIMS covers standards such as 21 CFR Part 11 from the Food and Drug Administration (United States), ISO/IEC 17025, ISO 15189, good laboratory practice, and Good Automated Manufacturing Practice (GAMP)

2.8.5 See also

- List of LIMS software packages
- Virtual research environment
- Laboratory informatics
- Electronic lab notebook
- Title 21 CFR Part 11
- Data management
- Scientific management
- Process development execution system

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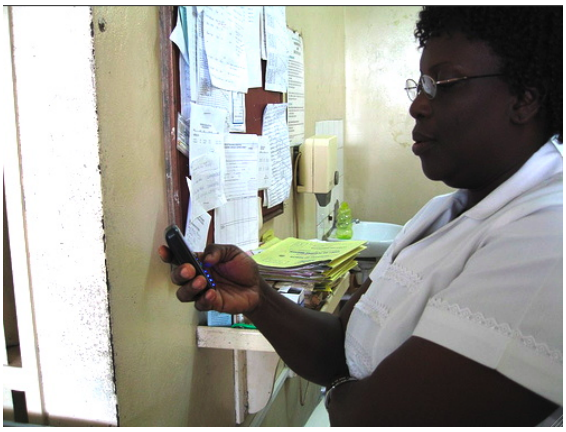
2.9 mHealth



Nurse using a mobile phone in Accra, Ghana

mHealth (also written as **m-health**) is an abbreviation for **mobile health**, a term used for the practice of medicine and public health supported by mobile devices.*[1] The term is most commonly used in reference to using mobile communication devices, such as mobile phones, tablet computers and PDAs, for health services and information, but also to affect emotional states.*[2] The mHealth field has emerged as a subsegment of eHealth, the use of information and communication technology (ICT), such as computers, mobile phones, communications satellite, patient monitors, etc., for health services and information.*[3] mHealth applications include the use of mobile devices in collecting community and clinical health data, delivery of healthcare information to practitioners, researchers, and patients, real-time monitoring of patient vital signs, and direct provision of care (via mobile telemedicine).*[4]

While mHealth certainly has application for industrialized nations, the field has emerged in recent years as largely an application for developing countries, stemming from the rapid rise of mobile phone penetration in low-income nations. The field, then, largely emerges as a means of providing greater access to larger segments of a population in developing countries, as well as improving the capacity of health systems in such countries to provide quality healthcare.*[5] Within the mHealth space, projects operate with a variety of objectives, including increased access to healthcare and health-related information (particularly for hard-to-reach populations); improved ability to diagnose and track diseases; timelier, more actionable public health information; and expanded access to ongoing medical education and training for health workers.*[3]

According to an analyst firm, around 2.8 million patients worldwide were using a home monitoring service based on equipment with integrated connectivity at the end of 2012. The figure does not include patients that use monitoring devices connected to a PC or mobile phone. It only includes systems that rely on monitors with integrated

connectivity or systems that use monitoring hubs with integrated cellular or fixed-line modems. It forecast that the number of home monitoring systems with integrated communication capabilities will grow at a compound annual growth rate (CAGR) of 26.9 percent between 2011 and 2017 reaching 9.4 million connections globally by the end of the forecast period. The number of these devices that have integrated cellular connectivity increased from 0.73 million in 2011 to about 1.03 million in 2012, and is projected to grow at a CAGR of 46.3 percent to 7.10 million in 2017.*[6]

A growing percentage of health-related smartphone apps are available, and some estimates predict 500 million patients will be using such apps by the year 2015.*[1]*[7]

There are concerns about the accuracy and unregulated status of health apps.*[7]*[8]

2.9.1 Definitions

Malaria Clinic in Tanzania helped by SMS for Life program that uses cell phones to efficiently deliver malaria vaccine

mHealth broadly encompasses the use of mobile telecommunication and multimedia technologies as they are integrated within increasingly mobile and wireless health care delivery systems. The field broadly encompasses the use of mobile telecommunication and multimedia technologies in health care delivery. The term mHealth was coined by Robert Istepanian as use of "emerging mobile communications and network technologies for healthcare".*[9] A definition used at the 2010 mHealth Summit of the Foundation for the National Institutes of Health (FNIH) was "the delivery of healthcare services via mobile communication devices".*[10]

While there are some projects that are considered solely within the field of mHealth, the linkage between mHealth and eHealth is unquestionable. For example, an mHealth project that uses mobile phones to access data on HIV/AIDS rates would require an eHealth system in order to manage, store, and assess the data. Thus, eHealth projects many times operate as the backbone of mHealth projects.*[3]

In a similar vein, while not clearly bifurcated by such a definition, eHealth can largely be viewed as technology that supports the functions and delivery of healthcare, while mHealth rests largely on providing healthcare access.*[10] Because mHealth is by definition based on mobile technology such as smartphones, healthcare, through information and delivery, can better reach areas, people, and/or healthcare practitioners with previously limited exposure to certain aspects of healthcare.

2.9.2 Motivation of mHealth

mHealth is one aspect of eHealth that is pushing the limits of how to acquire, transport, store, process, and secure the raw and processed data to deliver meaningful results. mHealth offers the ability of remote individuals to participate in the health care value matrix, which may not have been possible in the past. Participation does not imply just consumption of health care services. In many cases remote users are valuable contributors to gather data regarding disease and public health concerns such as outdoor pollution, drugs and violence.

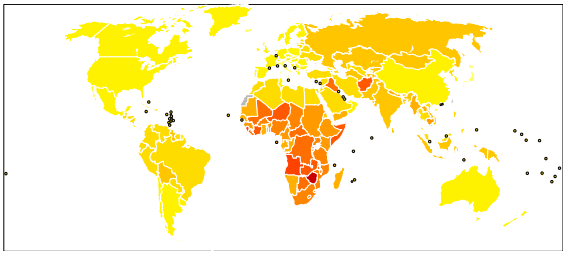
The motivation behind the development of the mHealth field arises from two factors. The first factor concerns the myriad constraints felt by healthcare systems of developing nations. These constraints include high population growth, a high burden of disease prevalence,*[11] low health care workforce, large numbers of rural inhabitants, and limited financial resources to support healthcare infrastructure and health information systems. The second factor is the recent rapid rise in mobile phone penetration in developing countries to large segments of the healthcare workforce, as well as the population of a country as a whole.*[12] With greater access to mobile phones to all segments of a country, including rural areas, the potential of lowering information and transaction costs in order to deliver healthcare improves.

The combination of these two factors has motivated much discussion of how greater access to mobile phone technology can be leveraged to mitigate the numerous pressures faced by developing countries' healthcare systems. Both factors are discussed here.

Healthcare and mHealth in low- and middle-income countries

Middle income and especially low-income countries face a plethora of constraints in their healthcare systems. These countries face a severe lack of human and physical resources, as well as some of the largest burdens of disease, extreme poverty, and large population growth rates. Additionally, healthcare access to all reaches of society is generally low in these countries.

According to a World Health Organization (WHO) report from June 2011, higher-income countries show more



Disability-adjusted life year for all causes per 100,000 inhabitants in 2004.[13]*
no data
less than 9,250
9,250–16,000
16,000–22,750
22,750–29,500
29,500–36,250
36,250–43,000
43,000–49,750
49,750–56,500
56,500–63,250
63,250–70,000
70,000–80,000
more than 80,000

mHealth activity than do lower-income countries (as consistent with eHealth trends in general). Countries in the European Region are currently the most active and those in the African Region the least active. The WHO report findings also included that mHealth is most easily incorporated into processes and services that historically use voice communication through conventional telephone networks. The report[14] was the result of a mHealth survey module designed by researchers at the Earth Institute's Center for Global Health and Economic Development, Columbia University.

The WHO notes an extreme deficit within the global healthcare workforce. The WHO notes critical healthcare workforce shortages in 57 countries—most of which are characterized as developing countries—and a global deficit of 2.4 million doctors, nurses, and midwives.[15] The WHO, in a study of the healthcare workforce in 12 countries of Africa, finds an average density of physicians, nurses and midwives per 1000 population of 0.64.[16] The density of the same metric is four times as high in the United States, at 2.6.[17]

The burden of disease is additionally much higher in low- and middle-income countries than high-income countries. The burden of disease, measured in disability-adjusted life year (DALY), which can be thought of as a measurement of the gap between current health status and an ideal situation where everyone lives into old age, free of disease and disability, is about five times higher in Africa than in high-income countries.[18] In addition, low- and middle-income countries are forced to face the burdens of both extreme poverty and the growing incidence of chronic diseases, such as diabetes and heart disease, an effect of new-found (relative) affluence.[3]

Considering poor infrastructure and low human resources, the WHO notes that the healthcare workforce in sub-Saharan Africa would need to be scaled up by as much as 140% to attain international health development targets such as those in the Millennium Declaration.[19]

The WHO, in reference to the healthcare condition in sub-saharan Africa, states:

> The problem is so serious that in many instances there is simply not enough human capacity even to absorb, deploy and efficiently use the substantial additional funds that are considered necessary to improve health in these countries.[19]

Mobile technology has made a recent and rapid appearance into low- and middle-income nations.[20] While, in the mHealth field, mobile technology usually refers to mobile phone technology, the entrance of other technologies into these nations to facilitate healthcare are also discussed here.

Health and development The link between health and development can be found in three of the Millennium Development Goals (MDGs), as set forth by the United Nations Millennium Declaration in 2000. The MDGs that specifically address health include reducing child mortality; improving maternal health; combating HIV and AIDS, malaria, and other diseases; and increasing access to safe drinking water.[21] A progress report published in 2006 indicates that childhood immunization and deliveries by skilled birth attendants are on the rise, while many regions continue to struggle to achieve reductions in the prevalence of the diseases of poverty including malaria, HIV and AIDS and tuberculosis.[22]

Healthcare and mHealth in developed countries

In developed countries, healthcare systems have different policies and goals in relation to the personal and population health care goals.

In US and EU many patients and consumers use their cell phones and tablets to access health information and look for healthcare services. In parallel the number of mHealth applications grew significantly the last years.

Doctors, nurses and clinicians use mobile devices to access patient information and other databases and resources.

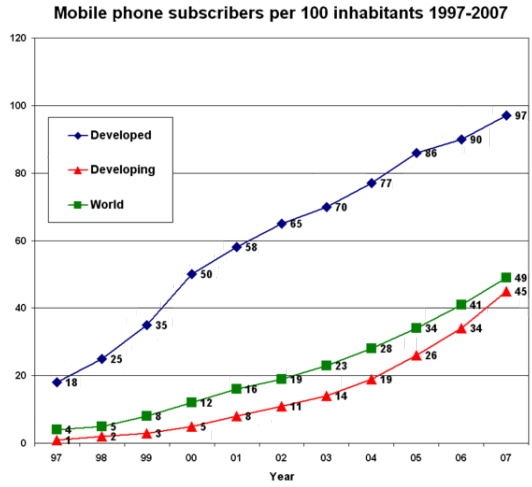
2.9.3 Technology and market

Basic SMS functions and real-time voice communication serve as the backbone and the current most common use

of mobile phone technology. The broad range of potential benefits to the health sector that the simple functions of mobile phones can provide should not be understated.*[23]

The appeal of mobile communication technologies is that they enable communication in motion, allowing individuals to contact each other irrespective of time and place.*[24]*[25] This is particularly beneficial for work in remote areas where the mobile phone, and now increasingly wireless infrastructure, is able to reach more people, faster. As a result of such technological advances, the capacity for improved access to information and two-way communication becomes more available at the point of need.

Mobile phones



Mobile phone subscribers per 100 inhabitants 1997–2007

Mobile phones have made a recent and rapid entrance into many parts of the low- and middle-income world, with the global Mobile phone penetration rate drastically increasing over the last decade. Improvements in telecommunications technology infrastructure, reduced costs of mobile handsets, and a general increase in non-food expenditure have influenced this trend. Low- and middle-income countries are utilizing mobile phones as "leapfrog technology" (see leapfrogging). That is, mobile phones have allowed many developing countries, even those with relatively poor infrastructure, to bypass 20th century fixed-line technology and jump to modern mobile technology.*[26]

The number of global mobile phone subscribers in 2007 was estimated at 3.1 billion of an estimated global population of 6.6 billion (47%).*[27] These figures are expected to grow to 4.5 billion by 2012, or a 64.7% mobile penetration rate. The greatest growth is expected in Asia, the Middle East, and Africa. In many countries, the number of mobile phone subscribers has bypassed the number of fixed-line telephones; this is particularly true in developing countries.*[28] Globally, there were 4.1 billion mobile phones in use in December 2008. See List of countries by number of mobile phones in use.

While mobile phone penetration rates are on the rise, globally, the growth within countries is not generally evenly distributed. In India, for example, while mobile penetration rates have increased markedly, by far the greatest growth rates are found in urban areas. Mobile penetration, in September 2008, was 66% in urban areas, while only 9.4% in rural areas. The all India average was 28.2% at the same time.*[29] So, while mobile phones may have the potential to provide greater healthcare access to a larger portion of a population, there are certainly within-country equity issues to consider.

Mobile phones are spreading because the cost of mobile technology deployment is dropping and people are, on average, getting wealthier in low- and middle-income nations.*[30] Vendors, such as Nokia, are developing cheaper infrastructure technologies (CDMA) and cheaper phones (sub $50–100, such as Sun's Java phone). Non-food consumption expenditure is increasing in many parts of the developing world, as disposable income rises, causing a rapid increase spending on new technology, such as mobile phones. In India, for example, consumers have become and continue to become wealthier. Consumers are shifting their expenditure from necessity to discretionary. For example, on average, 56% of Indian consumers' consumption went towards food in 1995, compared to 42% in 2005. The number is expected to drop to 34% by 2015. That being said, although total share of consumption has declined, total consumption of food and beverages increased 82% from 1985 to 2005, while per-capita consumption of food and beverages increased 24%. Indian consumers are getting wealthier and they are spending more and more, with a greater ability to spend on new technologies.*[31]

Smartphones

More advanced mobile phone technologies are enabling the potential for further healthcare delivery.*[1] Smartphone technologies are in now in the hands of a large number of physicians and other healthcare workers in low- and middle-income countries. Although far from ubiquitous, the spread of Smartphone technologies opens up doors for mHealth projects such as technology-based diagnosis support, remote diagnostics and telemedicine, web browsing, GPS navigation, access to web-based patient information, post-visit patient surveillance, and decentralized health management information systems (HMIS).

While uptake of Smartphone technology by the medical field has grown in low- and middle-income countries, it is worth noting that the capabilities of mobile phones in low- and middle-income countries has not reached the sophistication of those in high-income countries. The

infrastructure that enables web browsing, GPS navigation, and email through Smartphones is not as well developed in much of the low- and middle-income countries.*[32] Increased availability and efficiency in both voice and data-transfer systems in addition to rapid deployment of wireless infrastructure will likely accelerate the deployment of mobile-enabled health systems and services throughout the world.*[33]

Other mHealth technologies

Beyond mobile phones, wireless-enabled laptops and specialized health-related software applications are currently being developed, tested, and marketed for use in the mHealth field. Many of these technologies, while having some application to low- and middle-income nations, are developing primarily in high-income countries. However, with broad advocacy campaigns for free and open source software (FOSS), applications are beginning to be tailored for and make inroads in low- and middle-income countries.*[5]

Some other mHealth technologies include:*[1]

- Patient monitoring devices
- Mobile telemedicine/telecare devices
- MP3 players for mLearning
- Microcomputers
- Data collection software
- Mobile Operating System Technology
- Mobile applications (e.g., gamified/social wellness solutions)

Mobile device operating system technology Technologies relate to the operating systems that orchestrate mobile device hardware while maintaining confidentiality, integrity and availability are required to build trust. This may foster greater adoption of mHealth technologies and services, by exploiting lower cost multi purpose mobile devices such as tablets, PCs, and smartphones. Devices in this class may include Apple's iPad 1&2 and Motorola's Xoom. Operating systems that control these emerging classes of devices include Google's Android, Apple's iPhone OS, Microsoft's Windows Mobile, Nokia Symbian OS and RIM's BlackBerry OS.

Operating systems must be agile and evolve to effectively balance and deliver the desired level of service to an application and end user, while managing display real estate, power consumption and security posture. As advances in capabilities such as integrating voice, video and Web 2.0 collaboration tools into mobile devices, significant benefits can be achieved in the delivery of health care services. New sensor technologies*[34] such as HD video and audio capabilities, accelerometers, GPS, ambient light detectors, barometers and gyroscopes*[35] can enhance the methods of describing and studying cases, close to the patient or consumer of the health care service. This could include diagnosis, education, treatment and monitoring.

Air quality sensing technologies Environmental conditions have a significant impact to public health. Per the World Health Organization, outdoor air pollution accounts for about 1.4% of total mortality.*[36] Utilizing Participatory sensing technologies in mobile telephone, public health research can exploit the wide penetration of mobile devices to collect air measurements,*[35] which can be utilized to assess the impact of pollution. Projects such as the Urban Atmospheres are utilizing embedded technologies in mobile phones to acquire real time conditions from millions of user mobile phones. By aggregating this data, public health policy shall be able to craft initiatives to mitigate risk associated with outdoor air pollution.

Data has become an especially important aspect of mHealth. Data collection requires both the collection device (mobile phones, computer, or portable device) and the software that houses the information. Data is primarily focused on visualizing static text but can also extend to interactive decision support algorithms, other visual image information, and also communication capabilities through the integration of e-mail and SMS features. Integrating use of GIS and GPS with mobile technologies adds a geographical mapping component that is able to "tag" voice and data communication to a particular location or series of locations. These combined capabilities have been used for emergency health services as well as for disease surveillance, health facilities and services mapping, and other health-related data collection.

2.9.4 mHealth and health outcomes

The mHealth field operates on the premise that technology integration within the health sector has the great potential to promote a better health communication to achieve healthy lifestyles, improve decision-making by health professionals (and patients) and enhance healthcare quality by improving access to medical and health information and facilitating instantaneous communication in places where this was not previously possible.*[37]*[38] It follows that the increased use of technology can help reduce health care costs by improving efficiencies in the health care system and promoting prevention through behavior change communication (BCC). The mHealth field also houses the idea that there exists a powerful potential to advance clinical care and public health services by facilitating health professional practice and communication and reducing health disparities through the use of mobile technology.

Aponjon (MAMA Bangladesh) impact evaluation show that almost two-thirds (63%) of Aponjon primary clients who have completed the Aponjon service cycle from the time of registration up to the delivery of a child attended at least four antenatal care (ANC) visits. This represents a 37% increase over a 2011 national baseline of 26% attending four ANC visits. It is also important to note that 45% of the Aponjon subscribers went to a facility for delivery and 32% chose safe delivery at home. The survey results were also encouraging for subscribers in the 'new mother' category. 56% of new mothers did a postnatal care visit, 91% of new mothers fed colostrum after delivery, and 83% of new mothers practiced exclusive breast feeding. The immunization rate of BCG was 96%, and immunization rate of Pentavalet was 100%. The phone survey revealed that overall 93% of subscribers were satisfied with the service.*[39]

The growth of health-related apps and the availability of mobile device drives the growth of mHealth. In 2010, only about 4,000 health-related app available and now more than 20,000 health-related apps are available for mobile device. Revenues from remote patient monitoring services that use mobile networks will rise to $1.9 billion globally by 2014, according to Juniper Research's recent report in 2011.

Efforts are ongoing to explore how a broad range of technologies, and most recently mHealth technologies, can improve such health outcomes as well as generate cost savings within the health systems of low- and middle-income countries. In some ways, the potential of mHealth lies in its ability to offer opportunities for direct voice communication (of particular value in areas of poor literacy rates and limited local language-enable phones) and information transfer capabilities that previous technologies did not have. Overall, mobile communication technologies are tools that can be leveraged to support existing workflows within the health sector and between the health sector and the general public.*[40]

Within the mHealth space, projects operate with a variety of objectives, as stated by the UN Foundation and Vodafone Foundation's report on *mHealth for Development*:

- increased access to healthcare and health-related information (particularly for hard-to-reach populations)
- improved ability to diagnose and track diseases
- timelier, more actionable public health information
- expanded access to ongoing medical education and training for health workers*[3]

2.9.5 Applications in the mHealth field

While others exist, the UN Foundation and Vodafone Foundation*[3] report presents seven application categories within the mHealth field.*[5]

- Education and awareness
- Helpline
- Diagnostic and treatment support
- Communication and training for healthcare workers
- Disease and epidemic outbreak tracking
- Remote monitoring
- Remote data collection

Each application category as well as a specific project within the category will be described.

Education and awareness

Education and awareness programs within the mHealth field are largely about the spreading of mass information from source to recipient through short message services (SMS). In education and awareness applications, SMS messages are sent directly to users' phones to offer information about various subjects, including testing and treatment methods, availability of health services, and disease management. SMSs provide an advantage of being relatively unobtrusive, offering patients confidentiality in environments where disease (especially HIV/AIDS) is often taboo. Additionally, SMSs provide an avenue to reach far-reaching areas—such as rural areas—which may have limited access to public health information and education, health clinics, and a deficit of healthcare workers.*[3]

Helpline

Helpline typically consists of a specific phone number that any individual is able to call to gain access to a range of medical services. These include phone consultations, counseling, service complaints, and information on facilities, drugs, equipment, and/or available mobile health clinics.*[3]

Diagnostic support, treatment support, communication and training for healthcare workers

Diagnostic and treatment support systems are typically designed to provide healthcare workers in remote areas advice about diagnosis and treatment of patients. While some projects may provide mobile phone applications—such as a step-by-step medical decision tree systems—to help healthcare workers diagnosis, other projects provide direct diagnosis to patients themselves. In such cases, known as telemedicine, patients might take a photograph of a wound or illness and allow a remote physician diagnose to help treat the medical problem. Both diagnosis and treatment support projects attempt to mitigate the cost and time of travel for patients located in remote areas*[3]

mHealth projects within the communication and training for healthcare workers subset involve connecting healthcare workers to sources of information through their mobile phone. This involves connecting healthcare workers to other healthcare workers, medical institutions, ministries of health, or other houses of medical information. Such projects additionally involve using mobile phones to better organize and target in-person training. Improved communication projects attempt to increase knowledge transfer amongst healthcare workers and improve patient outcomes through such programs as patient referral processes*[3]

Disease surveillance, remote data collection, and epidemic outbreak tracking

Projects within this area operate to utilize mobile phones' ability to collect and transmit data quickly, cheaply, and relatively efficiently. Data concerning the location and levels of specific diseases (such as malaria, HIV/AIDS, TB, Avian Flu) can help medical systems or ministries of health or other organizations identify outbreaks and better target medical resources to areas of greatest need. Such projects can be particularly useful during emergencies, in order to identify where the greatest medical needs are within a country*[3]

Policymakers and health providers at the national, district, and community level need accurate data in order to gauge the effectiveness of existing policies and programs and shape new ones. In the developing world, collecting field information is particularly difficult since many segments of the population are rarely able to visit a hospital, even in the case of severe illness. A lack of patient data creates an arduous environment in which policy makers can decide where and how to spend their (sometimes limited) resources. While some software within this area is specific to a particular content or area, other software can be adapted to any data collection purpose.

Treatment support and medication compliance for patients, including chronic disease management

Remote monitoring and treatment support allows for greater involvement in the continued care of patients. Recent studies seem to show also the efficacy of inducing positive and negative affective states, using smart phones.*[2] Within environments of limited resources and beds —and subsequently a 'outpatient' culture — remote monitoring allows healthcare workers to better track patient conditions, medication regimen adherence, and follow-up scheduling. Such projects can operate through either one- or two-way communications systems. Remote monitoring has been used particularly in the area of medication adherence for AIDS and diabetes;*[3] technical process evaluations have confirmed the feasibility of deploying dynamically tailored, SMS-based interventions designed to provide ongoing behavioral reinforcement for persons living with HIV.*[41]

In conclusion, the use of the mobile phone technology (in combination with a web-based interface) in health care results in an increase in convenience and efficiency of data collection, transfer, storage and analysis management of data as compared with paper-based systems. Formal studies and preliminary project assessments demonstrate this improvement of efficiency of healthcare delivery by mobile technology.*[42] Nevertheless, mHealth should not be considered as a panacea for healthcare.*[43] Possible organizational issues include the ensuring of appropriate use and proper care of the handset, lost or stolen phones, and the important consideration of costs related to the purchase of equipment. There is therefore a difficulty in comparison in weighing up mHealth interventions against other priority and evidence-based interventions.*[44]

2.9.6 Emerging trends and areas of interest in mHealth

- Emergency response systems (e.g., road traffic accidents, emergency obstetric care)
- Human resources coordination, management, and supervision
- Mobile synchronous (voice) and asynchronous (SMS) telemedicine diagnostic and decision support to remote clinicians*[45]
- Clinician-focused, evidence-based formulary, database and decision support information available at the point-of-care*[45]
- Pharmaceutical Supply Chain Integrity & Patient Safety Systems (e.g. Sproxil and mPedigree)*[46]
- Clinical care and remote patient monitoring
- Health extension services
- Health services monitoring and reporting
- Health-related mLearning for the general public
- Training and continuing professional development for health care workers*[47]
- Health promotion and community mobilization
- Support of long-term conditions*[48] for example in diabetes self-management*[49]
- Peer-to-Peer Personal Health Management*[50] for telemedicine
- Social Mobilization for Infectious Disease Prevention*[51]
- Follow-up of major joint arthroplasty patients*[52]

- Mobile social media for global health personnel;[*] [53] for example, the capacity to facilitate professional connectedness, and to empower health workforce.[*] [54]

According to Vodafone Group Foundation on February 13, 2008, a partnership for emergency communications was created between the group and United Nations Foundation. Such partnership will increase the effectiveness of the information and communications technology response to major emergencies and disasters around the world.

2.9.7 International legal issues of mHealth

M-health has raised serious legal issues especially in developing countries that lack privacy and data protection laws. This makes medical records like the electronic health record vulnerable to third party abuses.

2.9.8 See also

- Health informatics
- Health 2.0
- Open source software packages for mHealth
- Telehealth
- Healthcare workforce information systems

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2.10 Practice management software

Practice management software may refer to software used for the management of a professional office:

- Law practice management software

- Medical practice management software

There are also practice management software for accounting, architecture, veterinary, dental, optometry and other practices.

2.11 Clinical Quality Management System

Clinical Quality Management Systems (CQMS) are systems used in the life sciences sector (primarily in the pharmaceutical, biologics and medical device industries) designed to manage quality management best practices throughout clinical research and clinical study management. A CQMS system is designed to manage all of the documents, activities, tasks, processes, quality events, relationships, audits and training that must be administered and controlled throughout the life of a clinical trial. The premise of a CQMS is to being together the activities lead by two sectors of clinical research, Clinical Quality and Clinical Operations to facilitate cross-functional activities to improve efficiencies, transparency and encourage the use of risk mitigation and risk management practices at the clinical study level.

Based on the principles of Quality management systems(QMS) which are used in many industries to create a framework for defining and delivering quality outcomes, managing risk, and continual improvement. Many guidelines and governance bodies have been established to ensure a common approach within a given industry to a set of parameters used to identify the minimally acceptable standard for that industry. The pharmaceutical industry is no exception, with several trade groups (e.g. PhRMA, EFPIA, RQA, etc.) coming together to enhance collaboration. However, as noted by the Academy of Medical Sciences, there are increasingly complex and bureaucratic legal and ethical frameworks that innovators must work within to develop new medicines for patients.

The historical pharmaceutical QMS applies primarily to good manufacturing practice as described in existing ISO (International Organization for Standardization) and ICH (International Committee on Harmonization) guidelines. "Good Manufacturing Practices (GMP) relate to quality control and quality assurance enabling companies in the pharmaceutical sector to minimize or eliminate instances of contamination, mix-ups, and errors. This in turn, protects the customer from purchasing a product which is ineffective or even dangerous." *[1]

These standards have historically been applied to the manufacturing environment, appropriate to how they have been written. However, according to FDA as well as other regulatory bodies, "Pharmaceutical Quality Systems (ICH Q10) applies to drug substance and drug product throughout product lifecycle and provide tools to facilitate continual improvement" 3, implying that the same standards that apply to the manufacturing environment should also be applied to the clinical research space, earlier in the lifecycle of an investigational or marketed product. Accordingly, a CQMS is any system developed to apply these principles to clinical operations within an organization.

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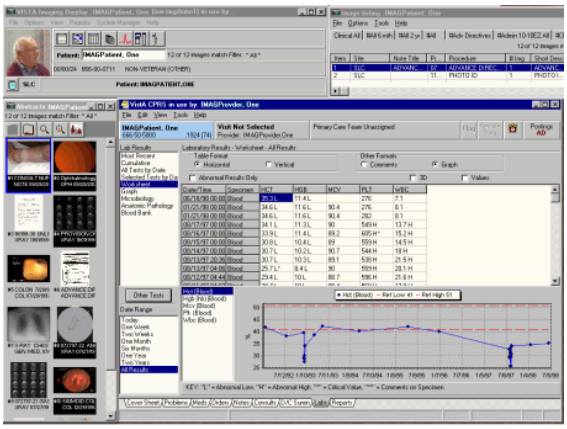
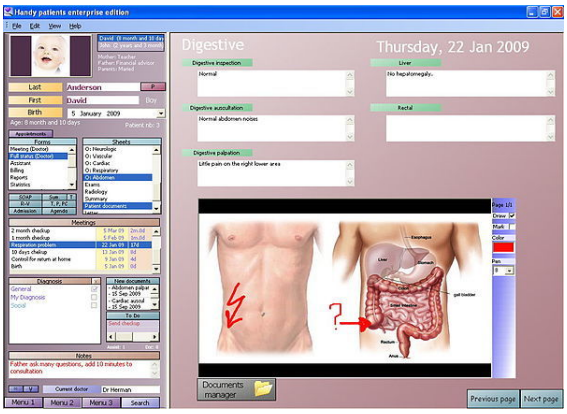
Chapter 3

Health Electronic Records

3.1 Electronic medical record



Sample view of an electronic health record based on images



Sample view of an electronic health record

An **electronic health record** (**EHR**), or **electronic medical record** (**EMR**), refers to the systematized collection of patient and population electronically-stored health information in a digital format.*[1] These records can be shared across different health care settings. Records are shared through network-connected, enterprise-wide information systems or other information networks and exchanges. EHRs may include a range of data, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and billing information.*[2]

EHR systems are designed to store data accurately and to capture the state of a patient across time. It eliminates the need to track down a patient's previous paper medical records and assists in ensuring data is accurate and legible. It can reduce risk of data replication as there is only one modifiable file, which means the file is more likely up to date, and decreases risk of lost paperwork. Due to the digital information being searchable and in a single file, EMR's are more effective when extracting medical data for the examination of possible trends and long term changes in a patient. Population-based studies of medical records may also be facilitated by the widespread adoption of EHR's and EMR's.

3.1.1 Terminology

The terms EHR, electronic patient record (EPR) and EMR have often been used interchangeably, although differences between the models are now being defined. The electronic health record (EHR) is an evolving concept defined as a more longitudinal collection of the electronic health information of individual patients or populations. (See reference 1.) The EMR is, in contrast, defined as the patient record created by providers for specific encounters in hospitals and ambulatory environments, and which can serve as a data source for an EHR.*[3]*[4] It is important to note that an "EHR" is generated and maintained within an institution, such as a hospital, integrated delivery network, clinic, or physician office, to give patients, physicians and other health care providers, employers, and payers or insurers access to a patient's medical records across facilities.*[5] (Please note that the term "EMR" would now be used for the preceding description, and that many EMR's now use cloud software maintenance and data storage rather than local networks.)

In contrast, a personal health record (PHR) is an electronic application for recording personal medical data that the individual patient controls and may make available to health providers.*[6]

3.1.2 Comparison with paper-based records

Federal and state governments, insurance companies and other large medical institutions are heavily promoting the adoption of electronic medical records. The US Congress included a formula of both incentives (up to $44,000 per physician under Medicare, or up to $65,000 over six years under Medicaid) and penalties (i.e. decreased Medicare and Medicaid reimbursements to doctors who fail to use EMRs by 2015, for covered patients) for EMR/EHR adoption versus continued use of paper records as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009.*[7]

One VA study estimates its electronic medical record system may improve overall efficiency by 6% per year, and the monthly cost of an EMR may (depending on the cost of the EMR) be offset by the cost of only a few "unnecessary" tests or admissions.*[8]*[9] Jerome Groopman disputed these results, publicly asking "how such dramatic claims of cost-saving and quality improvement could be true".*[10] A 2014 survey of the American College of Physicians member sample, however, found that family practice physicians spent 48 minutes more per day when using EMRs. 90% reported that at least 1 data management function was slower after EMRs were adopted, and 64% reported that note writing took longer. A third (34%) reported that it took longer to find and review medical record data, and 32% reported that it was slower to read other clinicians' notes.*[11]

The increased portability and accessibility of electronic medical records may also increase the ease with which they can be accessed and stolen by unauthorized persons or unscrupulous users versus paper medical records, as acknowledged by the increased security requirements for electronic medical records included in the Health Information and Accessibility Act and by large-scale breaches in confidential records reported by EMR users.*[12]*[13] Concerns about security contribute to the resistance shown to their widespread adoption.

Handwritten paper medical records may be poorly legible, which can contribute to medical errors.*[14] Preprinted forms, standardization of abbreviations and standards for penmanship were encouraged to improve reliability of paper medical records. Electronic records may help with the standardization of forms, terminology and data input. Digitization of forms facilitates the collection of data for epidemiology and clinical studies.*[15]*[16]

EMRs can be continuously updated (within certain legal limitations – see below). If the ability to exchange records between different EMR systems were perfected("interoperability" *[17]) would facilitate the co-ordination of health care delivery in non-affiliated health care facilities. In addition, data from an electronic system can be used anonymously for statistical reporting in matters such as quality improvement, resource management and public health communicable disease surveillance.*[18]

In ambulances

Ambulance services in Australia have introduced the use of EMR systems *[19] The benefits of EMR in ambulances include: better training for paramedics, review of clinical standards, better research options for pre-hospital care and design of future treatment options.*[20]

Automated handwriting recognition of ambulance medical forms has also been successful. These systems allow paper-based medical documents to be converted to digital text with substantially less cost overhead. Patient identifying information would not be converted to comply with government privacy regulations. The data can then be efficiently used for epidemiological analysis.*[21]

3.1.3 Technical features

- Digital formatting enables information to be used and shared over secure networks
- Track care (e.g. prescriptions) and outcomes (e.g. blood pressure)
- Trigger warnings and reminders
- Send and receive orders, reports, and results
- Decrease billing processing time and create more accurate billing system*[22]

Health Information Exchange*[23]

- Technical and social framework that enables information to move electronically between organizations

Using an EMR to read and write a patient's record is not only possible through a workstation but, depending on the type of system and health care settings, may also be possible through mobile devices that are handwriting capable,*[24] tablets and smartphones. Electronic Medical Records may include access to Personal Health Records (PHR) which makes individual notes from an EMR readily visible and accessible for consumers.

Some EMR systems automatically monitor clinical events, by analyzing patient data from an electronic health record to predict, detect and potentially prevent adverse events. This can include discharge/transfer orders, pharmacy orders, radiology results, laboratory results and any other data from ancillary services or provider notes.*[25] This type of event monitoring has been implemented using the Louisiana Public health information exchange linking state wide public health with electronic medical

records. This system alerted medical providers when a patient with HIV/AIDS had not received care in over twelve months. This system greatly reduced the number of missed critical opportunities.*[26]

3.1.4 Philosophical views of the EHR

Within a meta-narrative systematic review of research in the field, there exist a number of different philosophical approaches to the EHR.*[27] The health information systems literature has seen the EHR as a container holding information about the patient, and a tool for aggregating clinical data for secondary uses (billing, audit *etc.*). However, other research traditions see the EHR as a contextualised artifact within a socio-technical system. For example, actor-network theory would see the EHR as an actant in a network,*[28] while research in computer supported cooperative work (CSCW) sees the EHR as a tool supporting particular work.

Several possible advantages to EHRs over paper records have been proposed, but there is debate about the degree to which these are achieved in practice.*[29]

3.1.5 Implementation, end user and patient considerations

Quality

Several studies call into question whether EHRs improve the quality of care.*[27]*[30]*[31]*[32]*[33] However, a recent multi-provider study in diabetes care, published in the New England Journal of Medicine, found evidence that practices with EHR provided better quality care.*[34]

EMR's may eventually help improve care coordination. An article in a trade journal suggests that since anyone using an EMR can view the patient's full chart, that it cuts down on guessing histories, seeing multiple specialists, smooths transitions between care settings, and may allow better care in emergency situations.*[35] EHRs may also improve prevention by providing doctors and patients better access to test results, identifying missing patient information, and offering evidence-based recommendations for preventive services.*[36]

Costs

The steep price of EHR and provider uncertainty regarding the value they will derive from adoption in the form of return on investment has a significant influence on EHR adoption.*[37] In a project initiated by the Office of the National Coordinator for Health Information (ONC), surveyors found that hospital administrators and physicians who had adopted EHR noted that any gains in efficiency were offset by reduced productivity as the technology was implemented, as well as the need to increase information technology staff to maintain the system.*[37]

The U.S. Congressional Budget Office concluded that the cost savings may occur only in large integrated institutions like Kaiser Permanente, and not in small physician offices. They challenged the Rand Corporation's estimates of savings. "Office-based physicians in particular may see no benefit if they purchase such a product—and may even suffer financial harm. Even though the use of health IT could generate cost savings for the health system at large that might offset the EHR's cost, many physicians might not be able to reduce their office expenses or increase their revenue sufficiently to pay for it. For example, the use of health IT could reduce the number of duplicated diagnostic tests. However, that improvement in efficiency would be unlikely to increase the income of many physicians." *[38] One CEO of an EHR company has argued if a physician performs tests in the office, it might reduce his or her income.*[39]

Doubts have been raised about cost saving from EHRs by researchers at Harvard University, the Wharton School of the University of Pennsylvania, Stanford University, and others.*[33]*[40]*[41]

Time

The implementation of EMR can potentially decrease identification time of patients upon hospital admission. A research from the Annals of Internal Medicine showed that since the adoption of EMR a relative decrease in time by 65% has been recorded (from 130 to 46 hours).*[42]

Software quality and usability deficiencies

The Healthcare Information and Management Systems Society (HIMSS), a very large U.S. healthcare IT industry trade group, observed that EHR adoption rates "have been slower than expected in the United States, especially in comparison to other industry sectors and other developed countries. A key reason, aside from initial costs and lost productivity during EMR implementation, is lack of efficiency and usability of EMRs currently available." *[43] The U.S. National Institute of Standards and Technology of the Department of Commerce studied usability in 2011 and lists a number of specific issues that have been reported by health care workers.*[44] The U.S. military's EHR, AHLTA, was reported to have significant usability issues.*[45] It was observed that the efforts to improve EHR usability should be placed in the context of physician-patient communication.*[46]

However, physicians are embracing mobile technologies such as smartphones and tablets at a rapid pace. According to a 2012 survey by *Physicians Practice*, 62.6 percent of respondents (1,369 physicians, practice managers, and other healthcare providers) say they use mobile devices in the performance of their job. Mobile devices

are increasingly able to synch up with electronic health record systems thus allowing physicians to access patient records from remote locations. Most devices are extensions of desk-top EHR systems, using a variety of software to communicate and access files remotely. The advantages of instant access to patient records at any time and any place are clear, but bring a host of security concerns. As mobile systems become more prevalent, practices will need comprehensive policies that govern security measures and patient privacy regulations.*[47]

Eventually, EHR will be more secured because the cyber security professionals have never stopped pursuing better ways to protect data with an enhanced software and technology. At the same time, they need to beware that the system will be significantly complicated and not user-friendly anymore as the data is growing and technology is more advancing. While we have a better secured system, it could lead to an error-prone. Therefore, efficient and effective trainings are needed along with a well-designed user interface .*[22]

Unintended consequences

Per empirical research in social informatics, information and communications technology (ICT) use can lead to both intended and unintended consequences.*[48]*[49]*[50]

A 2008 **Sentinel Event Alert** from the U.S. Joint Commission, the organization that accredits American hospitals to provide healthcare services, states that "*As health information technology (HIT) and 'converging technologies'—the interrelationship between medical devices and HIT—are increasingly adopted by health care organizations, users must be mindful of the safety risks and preventable adverse events that these implementations can create or perpetuate. Technology-related adverse events can be associated with all components of a comprehensive technology system and may involve errors of either commission or omission. These unintended adverse events typically stem from human-machine interfaces or organization/system design.*" *[51] The Joint Commission cites as an example the United States Pharmacopeia MEDMARX database*[52] where of 176,409 medication error records for 2006, approximately 25 percent (43,372) involved some aspect of computer technology as at least one cause of the error.

The National Health Service (NHS) in the UK reports specific examples of potential and actual EHR-caused unintended consequences in their 2009 document on the management of clinical risk relating to the deployment and use of health software.*[53]

In a Feb. 2010 U.S. Food and Drug Administration (FDA) memorandum, FDA notes EHR unintended consequences include EHR-related medical errors due to (1) errors of commission (EOC), (2) errors of omission or transmission (EOT), (3) errors in data analysis (EDA), and (4) incompatibility between multi-vendor software applications or systems (ISMA) and cites examples. In the memo FDA also notes the "absence of mandatory reporting enforcement of H-IT safety issues limits the numbers of medical device reports (MDRs) and impedes a more comprehensive understanding of the actual problems and implications." *[54]

A 2010 Board Position Paper by the American Medical Informatics Association (AMIA) contains recommendations on EHR-related patient safety, transparency, ethics education for purchasers and users, adoption of best practices, and re-examination of regulation of electronic health applications.*[55] Beyond concrete issues such as conflicts of interest and privacy concerns, questions have been raised about the ways in which the physician-patient relationship would be affected by an electronic intermediary.*[56]*[57]

During the implementation phase, cognitive workload for healthcare professionals may be significantly increased as they become familiar with a new system.*[58]

Privacy and confidentiality

In the United States in 2011 there were 380 major data breaches involving 500 or more patients' records listed on the website kept by the United States Department of Health and Human Services (HHS) Office for Civil Rights.*[59] So far, from the first wall postings in September 2009 through the latest on 8 December 2012, there have been 18,059,831 "individuals affected," and even that massive number is an undercount of the breach problem. The civil rights office has not released the records of tens of thousands of breaches it has received under a federal reporting mandate on breaches affecting fewer than 500 patients per incident.*[60]

3.1.6 Governance, privacy and legal issues

Privacy concerns

In the United States, Great Britain, and Germany, the concept of a national centralized server model of healthcare data has been poorly received. Issues of privacy and security in such a model have been of concern.*[61]*[62]

Privacy concerns in healthcare apply to both paper and electronic records. According to the *Los Angeles Times*, roughly 150 people (from doctors and nurses to technicians and billing clerks) have access to at least part of a patient's records during a hospitalization, and 600,000 payers, providers and other entities that handle providers' billing data have some access also.*[63] Recent revelations of "secure" data breaches at centralized data repositories, in banking and other financial institutions, in the retail industry, and from government databases, have caused concern about storing electronic medical records in a central location.*[64] Records that are exchanged

over the Internet are subject to the same security concerns as any other type of data transaction over the Internet.

The Health Insurance Portability and Accountability Act (HIPAA) was passed in the US in 1996 to establish rules for access, authentications, storage and auditing, and transmittal of electronic medical records. This standard made restrictions for electronic records more stringent than those for paper records. However, there are concerns as to the adequacy of these standards.*[65]

In the United States, information in electronic medical records is referred to as Protected Health Information (PHI) and its management is addressed under the Health Insurance Portability and Accountability Act (HIPAA) as well as many local laws.*[66] The HIPAA protects a patient's information; the information that is protected under this act are: information doctors and nurses input into the electronic medical record, conversations between a doctor and a patient that may have been recorded, as well as billing information. Under this act there is a limit as to how much information can be disclosed, and as well as who can see a patient's information. Patients also get to have a copy of their records if they desire, and get notified if their information is ever to be shared with third parties.*[67] Covered entities may disclose protected health information to law enforcement officials for law enforcement purposes as required by law (including court orders, court-ordered warrants, subpoenas) and administrative requests; or to identify or locate a suspect, fugitive, material witness, or missing person.*[68]

Medical and health care providers experienced 767 security breaches resulting in the compromised confidential health information of 23,625,933 patients during the period of 2006–2012.*[69]

In the European Union (EU), a new directly binding instrument, a regulation of the European Parliament and of the Council, was passed in 2016 to go into effect in 2018 to protect the processing of personal data, including that for purposes of health care, the General_Data_Protection_Regulation.

Threats to health care information can be categorized under three headings:

- Human threats, such as employees or hackers
- Natural and environmental threats, such as earthquakes, hurricanes and fires.
- Technology failures, such as a system crashing

These threats can either be internal, external, intentional and unintentional. Therefore, one will find health information systems professionals having these particular threats in mind when discussing ways to protect the health information of patients. The Health Insurance Portability and Accountability Act (HIPAA) has developed a framework to mitigate the harm of these threats that is comprehensive but not so specific as to limit the options of healthcare professionals who may have access to different technology.*[70]

Personal Information Protection and Electronic Documents Act (PIPEDA) was given Royal Assent in Canada on 13 April 2000 to establish rules on the use, disclosure and collection of personal information. The personal information includes both non-digital and electronic form. In 2002, PIPEDA extended to the health sector in Stage 2 of the law's implementation.*[71] There are four provinces where this law does not apply because its privacy law was considered similar to PIPEDA: Alberta, British Columbia, Ontario and Quebec.

One major issue that has risen on the privacy of the US network for electronic health records is the strategy to secure the privacy of patients. Former US president Bush called for the creation of networks, but federal investigators report that there is no clear strategy to protect the privacy of patients as the promotions of the electronic medical records expands throughout the United States. In 2007, the Government Accountability Office reports that there is a "jumble of studies and vague policy statements but no overall strategy to ensure that privacy protections would be built into computer networks linking insurers, doctors, hospitals and other health care providers." *[72]

The privacy threat posed by the interoperability of a national network is a key concern. One of the most vocal critics of EMRs, New York University Professor Jacob M. Appel, has claimed that the number of people who will need to have access to such a truly interoperable national system, which he estimates to be 12 million, will inevitable lead to breaches of privacy on a massive scale. Appel has written that while "hospitals keep careful tabs on who accesses the charts of VIP patients," they are powerless to act against "a meddlesome pharmacist in Alaska" who "looks up the urine toxicology on his daughter's fiance in Florida, to check if the fellow has a cocaine habit." *[73] This is a significant barrier for the adoption of an EHR. Accountability among all the parties that are involved in the processing of electronic transactions including the patient, physician office staff, and insurance companies, is the key to successful advancement of the EHR in the US Supporters of EHRs have argued that there needs to be a fundamental shift in "attitudes, awareness, habits, and capabilities in the areas of privacy and security" of individual's health records if adoption of an EHR is to occur.*[74]

According to the *Wall Street Journal*, the DHHS takes no action on complaints under HIPAA, and medical records are disclosed under court orders in legal actions such as claims arising from automobile accidents. HIPAA has special restrictions on psychotherapy records, but psychotherapy records can also be disclosed without the client's knowledge or permission, according to the *Journal*. For example, Patricia Galvin, a lawyer in San Francisco, saw a psychologist at Stanford Hospital & Clinics after her fiance committed suicide. Her therapist had as-

sured her that her records would be confidential. But after she applied for disability benefits, Stanford gave the insurer her therapy notes, and the insurer denied her benefits based on what Galvin claims was a misinterpretation of the notes.*[75]*[76]

Within the private sector, many companies are moving forward in the development, establishment and implementation of medical record banks and health information exchange. By law, companies are required to follow all HIPAA standards and adopt the same information-handling practices that have been in effect for the federal government for years. This includes two ideas, standardized formatting of data electronically exchanged and federalization of security and privacy practices among the private sector.*[74] Private companies have promised to have "stringent privacy policies and procedures." If protection and security are not part of the systems developed, people will not trust the technology nor will they participate in it.*[72]

In 2013, reports based on documents released by Edward Snowden revealed that the NSA had succeeded in breaking the encryption codes protecting electronic health records, among other databases.*[77]

In 2015, 4.5 million health records were hacked at UCLA Medical Center.*[78]

Legal issues

Liability Legal liability in all aspects of healthcare was an increasing problem in the 1990s and 2000s. The surge in the per capita number of attorneys*[79] and changes in the tort system caused an increase in the cost of every aspect of healthcare, and healthcare technology was no exception.*[80]

Failure or damages caused during installation or utilization of an EHR system has been feared as a threat in lawsuits.*[81] Similarly, it's important to recognize that the implementation of electronic health records carries with it significant legal risks.*[82]

This liability concern was of special concern for small EHR system makers. Some smaller companies may be forced to abandon markets based on the regional liability climate.*[83] Larger EHR providers (or government-sponsored providers of EHRs) are better able to withstand legal assaults.

While there is no argument that electronic documentation of patient visits and data brings improved patient care, there is increasing concern that such documentation could open physicians to an increased incidence of malpractice suits. Disabling physician alerts, selecting from dropdown menus, and the use of templates can encourage physicians to skip a complete review of past patient history and medications, and thus miss important data.

Another potential problem is electronic time stamps. Many physicians are unaware that EHR systems produce an electronic time stamp every time the patient record is updated. If a malpractice claim goes to court, through the process of discovery, the prosecution can request a detailed record of all entries made in a patient's electronic record. Waiting to chart patient notes until the end of the day and making addendums to records well after the patient visit can be problematic, in that this practice could result in less than accurate patient data or indicate possible intent to illegally alter the patient's record.*[84]

In some communities, hospitals attempt to standardize EHR systems by providing discounted versions of the hospital's software to local healthcare providers. A challenge to this practice has been raised as being a violation of Stark rules that prohibit hospitals from preferentially assisting community healthcare providers.*[85] In 2006, however, exceptions to the Stark rule were enacted to allow hospitals to furnish software and training to community providers, mostly removing this legal obstacle.*[86]*[87]

Legal interoperability In cross-border use cases of EHR implementations, the additional issue of legal interoperability arises. Different countries may have diverging legal requirements for the content or usage of electronic health records, which can require radical changes to the technical makeup of the EHR implementation in question. (especially when fundamental legal incompatibilities are involved) Exploring these issues is therefore often necessary when implementing cross-border EHR solutions.*[88]

Regulatory compliance

- Health Level 7

In the United States, reimbursement for many healthcare services is based upon the extent to which specific work by healthcare providers is documented in the patient's medical record. Enforcement authorities in the United States have become concerned that functionality available in many electronic health records, especially copy-and-paste, may enable fraudulent claims for reimbursement. The authorities are concerned that healthcare providers may easily use these systems to create documentation of medical care that did not actually occur. These concerns came to the forefront in 2012, in a joint letter from the U.S. Departments of Justice and Health and Human Services to the American hospital community.*[89] The American Hospital Association responded, focusing on the need for clear guidance from the government regarding permissible and prohibited conduct using electronic health records.*[90] In a December 2013 audit report, the U.S. HHS Office of the Inspector General (OIG) issued an audit report reiterating that vulnerabilities continue to exist in the operation of electronic health records.*[91] The OIG's 2014 Workplan indicates an enhanced focus on providers' use of electronic health records.*[92]

3.1.7 Contribution under UN administration and accredited organizations

The United Nations World Health Organization (WHO) administration intentionally does not contribute to an internationally standardized view of medical records nor to personal health records. However, WHO contributes to minimum requirements definition for developing countries.* [93]

The United Nations accredited standardisation body International Organization for Standardization (ISO) however has settled thorough word for standards in the scope of the HL7 platform for health care informatics. Respective standards are available with ISO/HL7 10781:2009 Electronic Health Record-System Functional Model, Release 1.1* [94] and subsequent set of detailing standards.* [95]

3.1.8 Medical data breach

The Security Rule, according to Health and Human Services (HHS), establishes a security framework for small practices as well as large institutions. All covered entities must have a written security plan. The HHS identifies three components as necessary for the security plan: administrative safeguards, physical safeguards, and technical safeguards.

However, medical and healthcare providers have experienced 767 security breaches resulting in the compromised confidential health information of 23,625,933 patients during the period of 2006–2012.* [96]

The majority of the countries in Europe have made a strategy for the development and implementation of the Electronic Health Record Systems. This would mean greater access to health records by numerous stakeholders, even from countries with lower levels of privacy protection. The forthcoming implementation of the Cross Border Health Directive and the EU Commission's plans to centralize all health records are of prime concern to the EU public who believe that the health care organizations and governments cannot be trusted to manage their data electronically and expose them to more threats.

The idea of a centralized electronic health record system has been poorly received by the public who are wary that the governments may extend the use of the system beyond its purpose. There is also the risk for privacy breaches that could allow sensitive health care information to fall into the wrong hands. Some countries have enacted laws requiring safeguards to be put in place to protect the security and confidentiality of medical information as it is shared electronically and to give patients some important rights to monitor their medical records and receive notification for loss and unauthorized acquisition of health information. The United States and the EU have imposed mandatory medical data breach notifications.* [97]

The Health Insurance Portability and Accessibility Act (HIPAA) requires safeguards to limit the number of people who have access to personal information. However, given the number of people who may have access to your information as part of the operations and business of the health care provider or plan, there is no realistic way to estimate the number of people who may come across your records.* [98]

Additionally, law enforcement access is authorized under HIPAA. In some cases, medical information may be disclosed without a warrant or court order.

Breach notification

The purpose of a personal data breach notification is to protect individuals so that they can take all the necessary actions to limit the undesirable effects of the breach and to motivate the organization to improve the security of the infrastructure to protect the confidentiality of the data. The US law requires the entities to inform the individuals in the event of breach while the EU Directive currently requires breach notification only when the breach is likely to adversely affect the privacy of the individual. Personal health data is valuable to individuals and is therefore difficult to make an assessment whether the breach will cause reputational or financial harm or cause adverse effects on one's privacy.

The Security Rule that was adopted in 2005 did not require breach notification. However, notice might be required by state laws that apply to a variety of industries, including health care providers. In California, a law has been in place since 2003 requiring that a HIPAA covered organization's breach could have triggered a notice even though notice was not required by the HIPAA Security Rule.* [99] Since 1 January 2009, California residents are required to receive notice of a health information breach.

Federal law and regulations now provide rights to notice of a breach of health information. The Health Information Technology for Economic and Clinical Health (HITECH) Act requires HHS and the Federal Trade Commission (FTC) to jointly study and report on privacy and data security of personal health information. HITECH also requires the agencies to issue breach notification rules that apply to HIPAA covered entities and Web-based vendors that store health information electronically. The FTC has adopted rules regarding breach notification for internet-based vendors.* [100]

The Breach notification law in the EU provides better privacy safeguards with fewer exemptions, unlike the US law which exempts unintentional acquisition, access, or use of protected health information and inadvertent disclosure under a good faith belief.* [97]

3.1.9 Technical issues

Standards

- ASC X12 (EDI) - transaction protocols used for transmitting patient data. Popular in the United States for transmission of billing data.
- CEN's TC/251 provides EHR standards in Europe including:
  - EN 13606, communication standards for EHR information
  - CONTSYS (EN 13940), supports continuity of care record standardization.
  - HISA (EN 12967), a services standard for inter-system communication in a clinical information environment.
- Continuity of Care Record - ASTM International Continuity of Care Record standard
- DICOM - an international communications protocol standard for representing and transmitting radiology (and other) image-based data, sponsored by NEMA (National Electrical Manufacturers Association)
- HL7 - a standardized messaging and text communications protocol between hospital and physician record systems, and between practice management systems
- Fast Healthcare Interoperability Resources (FHIR) - a modernized proposal from HL7 designed to provide open, granular access to medical information
- ISO - ISO TC 215 provides international technical specifications for EHRs. ISO 18308 describes EHR architectures
- xDT - a family of data exchange formats for medical purposes that is used in the German public health system.

The U.S. federal government has issued new rules of electronic health records.*[101]

Open specifications

- openEHR: an open community developed specification for a shared health record with web-based content developed online by experts. Strong multilingual capability.
- Virtual Medical Record: HL7's proposed model for interfacing with clinical decision support systems.
- SMART (Substitutable Medical Apps, reusable technologies): an open platform specification to provide a standard base for healthcare applications.*[102]

Customization Each healthcare environment functions differently, often in significant ways. It is difficult to create a "one-size-fits-all" EHR system. Many first generation EHRs were designed to fit the needs of primary care physicians, leaving certain specialties significantly less satisfied with their EHR system.

An ideal EHR system will have record standardization but interfaces that can be customized to each provider environment. Modularity in an EHR system facilitates this. Many EHR companies employ vendors to provide customization.

This customization can often be done so that a physician's input interface closely mimics previously utilized paper forms.*[103]

At the same time they reported negative effects in communication, increased overtime, and missing records when a non-customized EMR system was utilized.*[104] Customizing the software when it is released yields the highest benefits because it is adapted for the users and tailored to workflows specific to the institution.*[105]

Customization can have its disadvantages. There is, of course, higher costs involved to implementation of a customized system initially. More time must be spent by both the implementation team and the healthcare provider to understand the workflow needs.

Development and maintenance of these interfaces and customizations can also lead to higher software implementation and maintenance costs.*[106]*[107]

Long-term preservation and storage of records

An important consideration in the process of developing electronic health records is to plan for the long-term preservation and storage of these records. The field will need to come to consensus on the length of time to store EHRs, methods to ensure the future accessibility and compatibility of archived data with yet-to-be developed retrieval systems, and how to ensure the physical and virtual security of the archives.

Additionally, considerations about long-term storage of electronic health records are complicated by the possibility that the records might one day be used longitudinally and integrated across sites of care. Records have the potential to be created, used, edited, and viewed by multiple independent entities. These entities include, but are not limited to, primary care physicians, hospitals, insurance companies, and patients. Mandl et al. have noted that "choices about the structure and ownership of these records will have profound impact on the accessibility and privacy of patient information." *[108]

The required length of storage of an individual electronic health record will depend on national and state regulations, which are subject to change over time. Ruotsalainen and Manning have found that the typical preservation time of patient data varies between 20 and 100

years. In one example of how an EHR archive might function, their research "describes a co-operative trusted notary archive (TNA) which receives health data from different EHR-systems, stores data together with associated meta-information for long periods and distributes EHR-data objects. TNA can store objects in XML-format and prove the integrity of stored data with the help of event records, timestamps and archive e-signatures." *[109]

In addition to the TNA archive described by Ruotsalainen and Manning, other combinations of EHR systems and archive systems are possible. Again, overall requirements for the design and security of the system and its archive will vary and must function under ethical and legal principles specific to the time and place.

While it is currently unknown precisely how long EHRs will be preserved, it is certain that length of time will exceed the average shelf-life of paper records. The evolution of technology is such that the programs and systems used to input information will likely not be available to a user who desires to examine archived data. One proposed solution to the challenge of long-term accessibility and usability of data by future systems is to standardize information fields in a time-invariant way, such as with XML language. Olhede and Peterson report that "the basic XML-format has undergone preliminary testing in Europe by a Spri project and been found suitable for EU purposes. Spri has advised the Swedish National Board of Health and Welfare and the Swedish National Archive to issue directives concerning the use of XML as the archive-format for EHCR (Electronic Health Care Record) information." *[110]

Synchronization of records

When care is provided at two different facilities, it may be difficult to update records at both locations in a coordinated fashion.

Two models have been used to satisfy this problem: a centralized data server solution, and a peer-to-peer file synchronization program (as has been developed for other peer-to-peer networks).

Synchronization programs for distributed storage models, however, are only useful once record standardization has occurred.

Merging of already existing public healthcare databases is a common software challenge. The ability of electronic health record systems to provide this function is a key benefit and can improve healthcare delivery.*[111]*[112]*[113]

3.1.10 eHealth and teleradiology

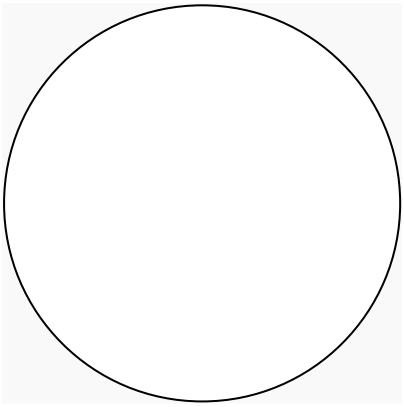
The sharing of patient information between health care organizations and IT systems is changing from a "point to point" model to a "many to many" one. The European Commission is supporting moves to facilitate cross-border interoperability of e-health systems and to remove potential legal hurdles, as in the project www.epsos.eu/. To allow for global shared workflow, studies will be locked when they are being read and then unlocked and updated once reading is complete. Radiologists will be able to serve multiple health care facilities and read and report across large geographical areas, thus balancing workloads. The biggest challenges will relate to interoperability and legal clarity. In some countries it is almost forbidden to practice teleradiology. The variety of languages spoken is a problem and multilingual reporting templates for all anatomical regions are not yet available. However, the market for e-health and teleradiology is evolving more rapidly than any laws or regulations.*[114]

3.1.11 European Union: Directive 2011/24/EU on patients' rights in cross-border healthcare

The European Commission wants to boost the digital economy by enabling all Europeans to have access to online medical records anywhere in Europe by 2020. With the newly enacted Directive 2011/24/EU on patients' rights in cross-border healthcare due for implementation by 2013, it is inevitable that a centralised European health record system will become a reality even before 2020. However, the concept of a centralised supranational central server raises concern about storing electronic medical records in a central location. The privacy threat posed by a supranational network is a key concern. Cross-border and Interoperable electronic health record systems make confidential data more easily and rapidly accessible to a wider audience and increase the risk that personal data concerning health could be accidentally exposed or easily distributed to unauthorised parties by enabling greater access to a compilation of the personal data concerning health, from different sources, and throughout a lifetime.*[115]

3.1.12 National contexts

United States



EHR adoption of all physicians in the US. Source: DesRoches et al. (2008).

Fully functional EHR system (4%)
Basic EHR system (13%)
Bought but not implemented yet (13%)
EHR purchase planned in 2 years (22%)
No EHR system (48%)

Usage Even though EMR systems with a computerized provider order entry (CPOE) have existed for more than 30 years, fewer than 10 percent of hospitals as of 2006 had a fully integrated system.*[116]

In a 2008 survey by DesRoches et al. of 4484 physicians (62% response rate), 83% of all physicians, 80% of primary care physicians, and 86% of non-primary care physicians had no EHRs. "Among the 83% of respondents who did not have electronic health records, 16%" had bought, but not implemented an EHR system yet.*[117] The 2009 National Ambulatory Medical Care Survey of 5200 physicians (70% response rate) by the National Center for Health Statistics showed that 51.7% of office-based physicians did not use any EMR/EHR system.*[118]

In the United States, the CDC reported that the EMR adoption rate had steadily risen to 48.3 percent at the end of 2009.*[119] This is an increase over 2008, when only 38.4% of office-based physicians reported using fully or partially electronic medical record systems (EMR) in 2008.*[120] However, the same study found that only 20.4% of all physicians reported using a system described as minimally functional and including the following features: orders for prescriptions, orders for tests, viewing laboratory or imaging results, and clinical progress notes. As of 2013, 78 percent of office physicians are using basic electronic medical records. As of 2014, more than 80 percent of hospitals in the U.S.have adopted some type of EHR. Though within a hospital, the type of EHR data and mix varies significantly. Types of EHR data used in hospitals include structured data (e.g., medication information) and unstructured data (e.g., clinical notes).*[121]

The healthcare industry spends only 2% of gross revenues on HIT, which is low compared to other information intensive industries such as finance, which spend upwards of 10%.*[122]*[123]

The usage of electronic medical records can vary depending on who the user is and how they are using it. Electronic medical records can help improve the quality of medical care given to patients. Many doctors and office-based physicians refuse to get rid of the traditional paper records. Harvard University has conducted an experiment in which they tested how doctors and nurses use electronic medical records to keep their patients' information up to date. The studies found that electronic medical records were very useful; a doctor or a nurse was able to find a patient's information fast and easy just by typing their name; even if it was misspelled. The usage of electronic medical records increases in some work places due to the ease of use of the system; whereas the president of the Canadian Family Practice Nurses Association says that using electronic medical records can be time consuming, and it isn't very helpful due to the complexity of the system.*[124] Beth Israel Deaconess Medical Center reported that doctors and nurses prefer to use a much more friendly user software due to the difficulty and time it takes for a medical staff to input the information as well as to find a patients information. A study was done and the amount of information that was recorded in the EMRs was recorded; about 44% of the patients information was recorded in the EMRs. This shows that EMRs are not very efficient most of the time.*[125]

The cost of implementing an EMR system for smaller practices has also been criticized; data produced by the Robert Wood Johnson Foundation demonstrates that the first year investment for an average five person practice is $162,000 followed by about $85,000 in maintenance fees.*[126] Despite this, tighter regulations regarding meaningful use criteria and national laws (Health Information Technology for Economic and Clinical Health Act and the Affordable Care Act)*[127] have resulted in more physicians and facilities adopting EMR systems:

- Software, hardware and other services for EMR system implementation are provided for cost by various companies including Dell.*[128]
- Open source EMR systems exist, but have not seen widespread adoption of open-source EMR system software.

Beyond financial concerns there are a number of legal and ethical dilemmas created by increasing EMR use, including the risk of medical malpractice due to user error, server glitches that result in the EMR not being accessible, and increased vulnerability to hackers.*[129]*[130]

Legal status Electronic medical records, like other medical records, must be kept in unaltered form and au-

thenticated by the creator.[*][131] Under data protection legislation, the responsibility for patient records (irrespective of the form they are kept in) is always on the creator and custodian of the record, usually a health care practice or facility. This role has been said to require changes such that the sole medico-legal record should be held elsewhere.[*][132] The physical medical records are the property of the medical provider (or facility) that prepares them. This includes films and tracings from diagnostic imaging procedures such as X-ray, CT, PET, MRI, ultrasound, etc. The patient, however, according to HIPAA, has a right to view the originals, and to obtain copies under law.[*][133]

The Health Information Technology for Economic and Clinical Health Act (HITECH) (Pub.L. 111–5,§2.A.III & B.4) (a part of the 2009 stimulus package) set meaningful use of interoperable EHR adoption in the health care system as a critical national goal and incentivized EHR adoption.[*][134][*][135] The "goal is not adoption alone but 'meaningful use' of EHRs —that is, their use by providers to achieve significant improvements in care."[*][136]

Title IV of the act promises maximum incentive payments for Medicaid to those who adopt and use "certified EHRs" of $63,750 over 6 years beginning in 2011. Eligible professionals must begin receiving payments by 2016 to qualify for the program. For Medicare the maximum payments are $44,000 over 5 years. Doctors who do not adopt an EHR by 2015 will be penalized 1% of Medicare payments, increasing to 3% over 3 years. In order to receive the EHR stimulus money, the HITECH Act requires doctors to show "meaningful use" of an EHR system. As of June 2010, there are no penalty provisions for Medicaid.[*][3]

Health information exchange (HIE) has emerged as a core capability for hospitals and physicians to achieve "meaningful use" and receive stimulus funding. Healthcare vendors are pushing HIE as a way to allow EHR systems to pull disparate data and function on a more interoperable level.

Starting in 2015, hospitals and doctors will be subject to financial penalties under Medicare if they are not using electronic health records.[*][101]

Goals and objectives

- Improve care quality, safety, efficiency, and reduce health disparities
  - Quality and safety measurement
  - Clinical decision support (automated advice) for providers
  - Patient registries (e.g., "a directory of patients with diabetes")
- Improve care coordination
- Engage patients and families in their care
- Improve population and public health
  - Electronic laboratory reporting for reportable conditions (hospitals)
  - Immunization reporting to immunization registries
  - Syndromic surveillance (health event awareness)
- Ensure adequate privacy and security protections

Quality Studies call into question whether, in real life, EMRs improve the quality of care.[*][30][*][31] 2009 produced several articles raising doubts about EMR benefits.[*][32][*][33][*][137] A major concern is the reduction of physician-patient interaction due to formatting constraints. For example, some doctors have reported that the use of check-boxes has led to fewer open-ended questions.[*][138]

Meaningful use The main components of Meaningful Use are:

- The use of a certified EHR in a meaningful manner, such as e-prescribing.
- The use of certified EHR technology for electronic exchange of health information to improve quality of health care.
- The use of certified EHR technology to submit clinical quality and other measures.

In other words, providers need to show they're using certified EHR technology in ways that can be measured significantly in quality and in quantity.[*][139]

The meaningful use of EHRs intended by the US government incentives is categorized as follows:

- Improve care coordination
- Reduce healthcare disparities
- Engage patients and their families
- Improve population and public health[*][140][*][141]
- Ensure adequate privacy and security

The Obama Administration's Health IT program intends to use federal investments to stimulate the market of electronic health records:

- Incentives: to providers who use IT

- Strict and open standards: To ensure users and sellers of EHRs work towards the same goal
- Certification of software: To provide assurance that the EHRs meet basic quality, safety, and efficiency standards

The detailed definition of "meaningful use" is to be rolled out in 3 stages over a period of time until 2017. Details of each stage are hotly debated by various groups.*[142]

Meaningful use Stage 1

The first steps in achieving meaningful use are to have a certified electronic health record (EHR) and to be able to demonstrate that it is being used to meet the requirements. Stage 1 contains 25 objectives/measures for Eligible Providers (EPs) and 24 objectives/measures for eligible hospitals. The objectives/measures have been divided into a core set and menu set. EPs and eligible hospitals must meet all objectives/measures in the core set (15 for EPs and 14 for eligible hospitals). EPs must meet 5 of the 10 menu-set items during Stage 1, one of which must be a public health objective.*[143]

Full list of the Core Requirements and a full list of the Menu Requirements.

Core Requirements:

1. Use computerized order entry for medication orders.
2. Implement drug-drug, drug-allergy checks.
3. Generate and transmit permissible prescriptions electronically.
4. Record demographics.
5. Maintain an up-to-date problem list of current and active diagnoses.
6. Maintain active medication list.
7. Maintain active medication allergy list.
8. Record and chart changes in vital signs.
9. Record smoking status for patients 13 years old or older.
10. Implement one clinical decision support rule.
11. Report ambulatory quality measures to CMS or the States.
12. Provide patients with an electronic copy of their health information upon request.
13. Provide clinical summaries to patients for each office visit.
14. Capability to exchange key clinical information electronically among providers and patient authorized entities.
15. Protect electronic health information (privacy & security)

Menu Requirements:

1. Implement drug-formulary checks.
2. Incorporate clinical lab-test results into certified EHR as structured data.
3. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach.
4. Send reminders to patients per patient preference for preventive/ follow-up care
5. Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies)
6. Use certified EHR to identify patient-specific education resources and provide to patient if appropriate.
7. Perform medication reconciliation as relevant
8. Provide summary care record for transitions in care or referrals.
9. Capability to submit electronic data to immunization registries and actual submission.
10. Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission.

To receive federal incentive money, CMS requires participants in the Medicare EHR Incentive Program to "attest" that during a 90-day reporting period, they used a certified EHR and met Stage 1 criteria for meaningful use objectives and clinical quality measures. For the Medicaid EHR Incentive Program, providers follow a similar process using their state's attestation system.*[144]

Meaningful use Stage 2

The government released its final ruling on achieving Stage 2 of meaningful use in August 2012. Eligible providers will need to meet 17 of 20 core objectives in Stage 2, and fulfill three out of six menu objectives. The required percentage of patient encounters that meet each objective has generally increased over the Stage 1 objectives.

While Stage 2 focuses more on information exchange and patient engagement, many large EHR systems have this type of functionality built into their software, making it easier to achieve compliance. Also, for those eligible providers who have successfully attested to Stage 1, meeting Stage 2 should not be as difficult, as it builds incrementally on the requirements for the first stage.*[145]*[146]

Meaningful use Stage 3

On March 20, CMS released its proposed rule for Stage 3 meaningful use.*[147] These new rules focus on some of the tougher aspects of Stage 2 and require healthcare providers to vastly improve their EHR adoption and care delivery by 2018.*[148]

Barriers to adoption

Costs The steep price of EMR and provider uncertainty regarding the value they will derive from adoption in the form of return on investment have a significant influence on EMR adoption.*[37] In a project initiated by the Office of the National Coordinator for Health Information (ONC), surveyors found that hospital administrators and physicians who had adopted EMR noted that any gains in efficiency were offset by reduced productivity as the technology was implemented, as well as the need to increase information technology staff to maintain the system.*[37]

The U.S. Congressional Budget Office concluded that the cost savings may occur only in large integrated institutions like Kaiser Permanente, and not in small physician offices. They challenged the Rand Corporation's estimates of savings. "Office-based physicians in particular may see no benefit if they purchase such a product—and may even suffer financial harm. Even though the use of health IT could generate cost savings for the health system at large that might offset the EMR's cost, many physicians might not be able to reduce their office expenses or increase their revenue sufficiently to pay for it. For example. the use of health IT could reduce the number of duplicated diagnostic tests. However, that improvement in efficiency would be unlikely to increase the income of many physicians." *[38] "Given the ease at which information can be exchanged between health IT systems, patients whose physicians use them may feel that their privacy is more at risk than if paper records were used." *[38]

Doubts have been raised about cost saving from EMRs by researchers at Harvard University, the Wharton School of the University of Pennsylvania, Stanford University, and others.*[33]*[40]*[41]

Start-up costs In a survey by DesRoches et al. (2008), 66% of physicians without EHRs cited capital costs as a barrier to adoption, while 50% were uncertain about the investment. Around 56% of physicians without EHRs stated that financial incentives to purchase and/or use EHRs would facilitate adoption.*[117] In 2002, initial costs were estimated to be $50,000–70,000 per physician in a 3-physician practice. Since then, costs have decreased with increasing adoption.*[149] A 2011 survey estimated a cost of $32,000 per physician in a 5-physician practice during the first 60 days of implementation.*[150] One case study by Miller et al. (2005) of 14 small primary-care practices found that the average practice paid for the initial and ongoing costs within 2.5 years.*[151] A 2003 cost-benefit analysis found that using EMRs for 5 years created a net benefit of $86,000 per provider.*[152]

Some physicians are skeptical of the positive claims and believe the data is skewed by vendors and others with an interest in EHR implementation.

Brigham and Women's Hospital in Boston, Massachusetts, estimated it achieved net savings of $5 million to $10 million per year following installation of a computerized physician order entry system that reduced serious medication errors by 55 percent. Another large hospital generated about $8.6 million in annual savings by replacing paper medical charts with EHRs for outpatients and about $2.8 million annually by establishing electronic access to laboratory results and reports.*[153]

Maintenance costs Maintenance costs can be high.*[149] Miller et al. found the average estimated maintenance cost was $8500 per FTE health-care provider per year.*[151]

Furthermore, software technology advances at a rapid pace. Most software systems require frequent updates, often at a significant ongoing cost. Some types of software and operating systems require full-scale re-implementation periodically, which disrupts not only the budget but also workflow. Costs for upgrades and associated regression testing can be particularly high where the applications are governed by FDA regulations (e.g. Clinical Laboratory systems). Physicians desire modular upgrades and ability to continually customize, without large-scale reimplementation.

Training costs Training of employees to use an EHR system is costly, just as for training in the use of any other hospital system. New employees, permanent or temporary, will also require training as they are hired.*[154]

In the United States, a substantial majority of healthcare providers train at a VA facility sometime during their career. With the widespread adoption of the Veterans Health Information Systems and Technology Architecture (VistA) electronic health record system at all VA facilities, fewer recently-trained medical professionals will be inexperienced in electronic health record systems. Older practitioners who are less experienced in the use of electronic health record systems will retire over time.

Software quality and usability deficiencies The Healthcare Information and Management Systems Society (HIMSS), a very large U.S. health care IT industry trade group, observed that EMR adoption rates "have been slower than expected in the United States, especially

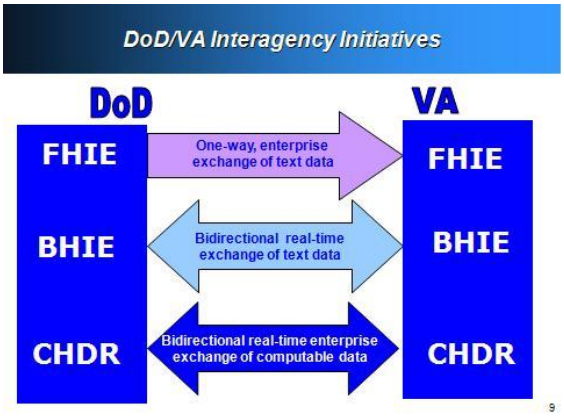
in comparison to other industry sectors and other developed countries. A key reason, aside from initial costs and lost productivity during EMR implementation, is lack of efficiency and usability of EMRs currently available." *[43] The U.S. National Institute of Standards and Technology of the Department of Commerce studied usability in 2011 and lists a number of specific issues that have been reported by health care workers.*[44] The U.S. military's EMR "AHLTA" was reported to have significant usability issues.*[45]

Lack of semantic interoperability In the United States, there are no standards for semantic interoperability of health care data; there are only syntactic standards. This means that while data may be packaged in a standard format (using the pipe notation of HL7, or the bracket notation of XML), it lacks definition, or linkage to a common shared dictionary. The addition of layers of complex information models (such as the HL7 v3 RIM) does not resolve this fundamental issue.

Implementations In the United States, the Department of Veterans Affairs (VA) has the largest enterprise-wide health information system that includes an electronic medical record, known as the Veterans Health Information Systems and Technology Architecture (VistA). A key component in VistA is their VistA imaging System which provides a comprehensive multimedia data from many specialties, including cardiology, radiology and orthopedics. A graphical user interface known as the Computerized Patient Record System (CPRS) allows health care providers to review and update a patient's electronic medical record at any of the VA's over 1,000 healthcare facilities. CPRS includes the ability to place orders, including medications, special procedures, X-rays, patient care nursing orders, diets, and laboratory tests.

The 2003 National Defense Authorization Act (NDAA) ensured that the VA and DoD would work together to establish a bidirectional exchange of reference quality medical images. Initially, demonstrations were only worked in El Paso, Texas, but capabilities have been expanded to six different locations of VA and DoD facilities. These facilities include VA polytrauma centers in Tampa and Richmond, Denver, North Chicago, Biloxi, and the National Capitol Area medical facilities. Radiological images such as CT scans, MRIs, and x-rays are being shared using the BHIE. Goals of the VA and DoD in the near future are to use several image sharing solutions (VistA Imaging and DoD Picture Archiving & Communications System (PACS) solutions).*[155]

Clinical Data Repository/Health Data Repository (CDHR) is a database that allows for sharing of patient records, especially allergy and pharmaceutical information, between the Department of Veteran Affairs (VA) and the Department of Defense (DoD) in the United States. The program shares data by translating



Electronic health records flow chart

the various vocabularies of the information being transmitted, allowing all of the VA facilities to access and interpret the patient records.*[156] The Laboratory Data Sharing and Interoperability (LDSI) application is a new program being implemented to allow sharing at certain sites between the VA and DoD of "chemistry and hematology laboratory tests." Unlike the CHDR, the LDSI is currently limited in its scope.*[157]

One attribute for the start of implementing EHRs in the States is the development of the Nationwide Health Information Network which is a work in progress and still being developed. This started with the North Carolina Healthcare Information and Communication Alliance founded in 1994 and who received funding from Department of Health and Human Services.*[158]

The Department of Veterans Affairs and Kaiser Permanente has a pilot program to share health records between their systems VistA and HealthConnect, respectively.*[159] This software called 'CONNECT' uses Nationwide Health Information Network standards and governance to make sure that health information exchanges are compatible with other exchanges being set up throughout the country. CONNECT is an open source software solution that supports electronic health information exchange.*[160] The CONNECT initiative is a Federal Health Architecture project that was conceived in 2007 and initially built by 20 various federal agencies and now comprises more than 500 organizations including federal agencies, states, healthcare providers, insurers, and health IT vendors.*[161]

The US Indian Health Service uses an EHR similar to Vista called RPMS. VistA Imaging is also being used to integrate images and co-ordinate PACS into the EHR system. In Alaska, use of the EHR by the Kodiak Area Native Association has improved screening services and helped the organization reach all 21 clinical performance measures defined by the Indian Health Service as required by the Government Performance and Results Act.*[162]

UK

See also: NHS Connecting for Health

In 2005 the National Health Service (NHS) in the United Kingdom began deployment of EHR systems in NHS Trusts. The goal was to have all patients with a centralized electronic health record by 2010.*[163] Lorenzo patient record systems were adopted in a number of NHS trusts While many hospitals acquired electronic patient records systems in this process, there was no national healthcare information exchange.*[29]*[164]*[165]*[166]*[167] Ultimately, the program was dismantled after a cost to the UK taxpayer was over $24 Billion (12 Billion GPB), and is considered one of the most expensive healthcare IT failures.*[168] The UK Government is now considered open-source healthcare platform from the United States Veterans Affairs following on the success of the VistA EHR deployment in Jordan.

In November 2013 NHS England launched a clinical digital maturity index to measure the digital maturity of NHS providers*[169] but 40% of NHS managers surveyed by the Health Service Journal did not know their ranking, and the same proportion said improving their ranking was of low or very low priority.*[170]

Electronic palliative care coordination systems have been developed by Marie Curie Cancer Care and the Royal College of General Practitioners which mean that terminally ill patients no longer have to explain their circumstances afresh to every new professional they meet and are less likely to be inappropriately taken to hospital.*[171]

Personalised Health and Care 2020 The publication of *Personalised Health and Care 2020* by the Department of Health elaborated a new attempt to integrate patient records.*[172] Its stated ambition is that every citizen will be able securely to access their health records online by 2018 and make real time data available to paramedics, doctors and nurses.*[173] A real time record across health and social care is seen as the key to the provision of integrated care.*[174]

GP Systems GP2GP is an NHS Connecting for Health project in the United Kingdom. It enables GPs to transfer a patient's electronic medical record to another practice when the patient moves onto the list.*[175] In General Practice in the UK the medical record has been computerized for many years, in fact the UK is probably one of the world leaders in this field. There are very few General Practices in the UK which are not computerized. Unlike the USA GP's have not had to deal with billing and have been able to concentrate on clinical care. The GP record is separate from the national Care Record and contains far more data. Shaun O'Hanlon, EMIS's Chief Clinical Officer says that the legal framework around data sharing is the main problem in integrating patient data because the Data Protection Act 1998 puts responsibilities on GPs to protect the confidentiality of patient data, but at the same time they have a "duty to share" when it is in the best interests of the patient. He says the quickest, easiest route to large scale record sharing is to put patients in the driving seat using smartphone technology. He quotes a YouGov poll which found that 85% of the population wanted any medical professional directly responsible for their treatment to have secure electronic access to key data from their GP record, such as long term conditions, medication history or allergies.*[176]

Clinical IT suppliers are moving towards greater interoperability, already achieved with the GP2GP project allowing different systems to exchange complete medical records between practices. There are projects allowing access between hospitals & GP practices. The main Primary Care systems are EMIS Health, SystmOne, iSOFT, and INPS Vision. The NHS in Scotland widely used GPASS until 2012. From April 2014 practices are contractually required to promote and offer patients the opportunity to book appointments online, order repeat prescriptions online and provide online Patient record access.*[177]

Patient access It has been possible for patients to access their own GP records online for some time, and Dr Amir Hannan pioneered this using EMIS software. He says "there are some doctors and nurses who have genuine concerns about patients suddenly being let loose to access their records without any controls in place or without clinicians having to do anything and a feeling of irresponsibility that that raises." *[178]

See Patient record access

Australia

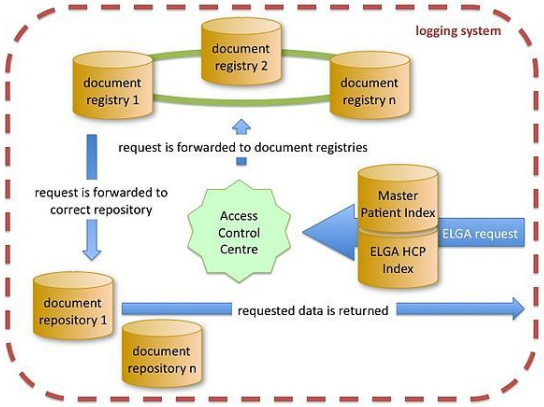
Australia is dedicated to the development of a lifetime electronic health record for all its citizens. PCEHR - the Personally Controlled Electronic Health Record - is the major national EHR initiative in Australia, being delivered through territory, state, and federal governments. This electronic health record was initially deployed in July 2012, and is under active development and extension.*[179]

MediConnect is an earlier program that provides an electronic medication record to keep track of patient prescriptions and provide stakeholders with drug alerts to avoid errors in prescribing.*[180]

Within Australia, there is a not-for-profit organisation called Standards Australia, which has created an electronic health website relating to information not only about Australia and what is currently going on about EHRs but also globally. There is a large number of key stakeholders that contribute to the process of integrat-

ing EHRs within Australia,they range from each States Departments of Health to Universities around Australia and National E-Health Transition Authority to name a few.*[181]*[182]*[183]

Austria



Structure and basic components of the Austrian EHR (ELGA)

In December 2012 Austria introduced an Electronic Health Records Act (EHR-Act).*[184] These provisions are the legal foundation for a national EHR system based upon a substantial public interest according to Art 8(4) of the Data Protection Directive 95/46/EC.*[185] In compliance to the Data Protection Directive (DPD) national electronic health records could be based upon explicit consent (Art 8(2)(a) DPD), the necessity for healthcare purposes (Art 8(3) DPD) or substantial public interests (Art 8(4) DPD).*[186]

The Austrian EHR-Act pursues an opt-out approach in order to harmonize the interests of public health and privacy in the best possible manner.

The 4th Part of the Austrian Health Telematics Act 2012 (HTA 2012) - these are the EHR provisions - are one of the most detailed data protection rules within Austrian legislation. Numerous safeguards according to Art 8(4) DPD guarantee a high level of data protection. For example:

- personal health data needs to be encrypted prior to transmission (§ 6 HTA 2012), or
- strict rules on data usage allow personal health data only to be used for treatment purposes or exercising patients' rights (§ 14 HTA 2012), or
- patients may declare their right to opt out from the national EHR at any time (§ 15 HTA 2012), or
- the implementation of an EHR-Ombudsman, to support the patients in exercising their rights (§ 17 HTA 2012), or
- the Access Control Center provides EHR-participants with full control over their data (§ 21 HTA 2012), or
- judicial penalties for privacy breaches (Art 7 of the EHR-Act).

Canada

Canadian provinces have launched a number of EHR projects and there are ongoing discussions about interoperability.

Jordan

In 2009, the Jordanian Government made a strategic decision to address quality and cost challenges in their healthcare system by investing in an effective, national e-health infrastructure. Following a period of detailed consultation and investigation, Jordan adopted the electronic health record system of the US Veterans Health Administration VistA EHR because it was a proven, national-scale enterprise system capable of scaling to hundreds of hospitals and millions of patients. In 2010 three of the country's largest hospitals went live with VistA EHR. It is anticipated that all further hospital deployments based on this 'gold' version will require less than 20% effort and cost of the original hospitals, enabling rapid national coverage. The implementation of VistA EHR was estimated at 75% less cost than proprietary products, with the greatest savings related to reduced costs of configuration, customization, implementation and support. When completed, Jordan will be the largest country in the world with a single, comprehensive, national electronic health care delivery network to care for the country's entire population in a single electronic network of over 850 hospitals and clinics.

Denmark

Denmark does not have nationwide EHR. It is mandatory for primary care practices and hospitals to use EHRs. The Danish Health Data Network (Medcom) acts as a data integrator to ensure interoperability. Unfortunately, non-interoperability is an issue despite the high adoption rate.*[187] The five regions are attempting to address this problem by each setting up their own electronic health record systems for public hospitals. However, all patient data will still be registered in the national e-journal.

Estonia

Estonia is the first country in the world that has implemented a nationwide EHR system, registering virtually all residents' medical history from birth to death.*[188] It was launched on 17 December 2008 *[189]

India

The Government of India, while unveiling of National Health Portal, has come out with guidelines for E.H.R standards in India. The document recommends set of standards to be followed by different healthcare service providers in India, so that medical data becomes portable and easily transferable.*[190]

India is considering to set up a National eHealth Authority (NeHA) for standardisation, storage and exchange of electronic health records of patients as part of the government's Digital India programme. The authority, to be set up by an Act of Parliament will work on the integration of multiple health IT systems in a way that ensures security, confidentiality and privacy of patient data. A centralised electronic health record repository of all citizens which is the ultimate goal of the authority will ensure that the health history and status of all patients would always be available to all health institutions. Union Health Ministry has circulated a concept note for the setting up of **NeHa**, inviting comments from stakeholders.*[191]

Netherlands

The vast majority of GP's *[192] and all pharmacies and hospitals use EHR's. In hospitals, computerized order management and medical imaging systems (PACS) are widely accepted. Whereas healthcare institutions continue to upgrade their EHR's functionalities, the national infrastructure is still far from being generally accepted.

In 2012 the national EHR restarted under the joined ownership of GPs, pharmacies and hospitals. A major change is that, as of January 2013, patients have to give their explicit permission that their data may be exchanged over the national infrastructure. The national EHR is a virtual EHR and is a reference server which "knows" in which local EHR what kind of patient record is stored. EDIFACT still is the most common way to exchange patient information electronically between hospitals and GP's.

UAE

Abu Dhabi is leading the way in using national EHR data as a live longitudinal cohort in the assessment of risk of cardiovascular disease.*[193]

Saudi Arabia

In 2010, Saudi Arabian National Guard Health Affairs was recognized with the Arab Health Award for "Excellence in Electronic Health Records" .*[194]

Switzerland

In 2007, the Swiss Federal Government has approved a national strategy for adoption of e-health.*[195] A central element of this strategy is a nationwide EHR. Following the federal tradition of Switzerland, it is planned that the nationwide EHR infrastructure is implemented with a decentralized approach, i.e. using access and control mechanism for federating existing records. In order to govern legal and financial aspects of the future nationwide EHR implementation, a bill is currently under development by the Swiss Federal Government.*[196] Besides the current discussions about a nation-wide implementation, EHR are widely used in both private and public healthcare organizations.*[197]

3.1.13 In veterinary medicine

In UK veterinary practice, the replace of paper recording systems with electronic methods of storing animal patient information escalated from the 1980s and the majority of clinics now use electronic medical records. In a sample of 129 veterinary practices, 89% used a Practice Management System (PMS) for data recording.*[198] There are more than ten PMS providers currently in the UK. Collecting data directly from PMSs for epidemiological analysis abolishes the need for veterinarians to manually submit individual reports per animal visit and therefore increases the reporting rate.*[199]

Veterinary electronic medical record data are being used to investigate antimicrobial efficacy; risk factors for canine cancer; and inherited diseases in dogs and cats, in the small animal disease surveillance project 'VetCOMPASS' (Veterinary Companion Animal Surveillance System) at the Royal Veterinary College, London, in collaboration with the University of Sydney (the VetCOMPASS project was formerly known as VEctAR).*[200]

3.1.14 See also

- Clinical documentation improvement
- eMix
- European Institute for Health Records (EuroRec)
- Health informatics
- Health information management
- Hospital information system
- List of open source healthcare software
- Medical imaging
- Medical record

- Personally Controlled Electronic Health Record, the Australian government's shared electronic health summary system*[201]
- Personal health record
- Picture archiving and communication system
- Radiology Information System

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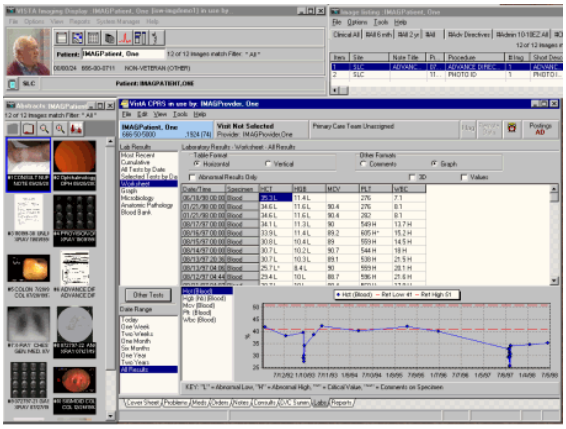
3.1.16 External links

- Can Electronic Health Record Systems Transform Health Care?
- Maryland Health Care Commission EHR Product Portfolio is a resource to compare and evaluate EHR products along with information on product vendors.
- Open-Source EHR Systems for Ambulatory Care: A Market Assessment (California HealthCare Foundation, January 2008)
- US Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology (ONC)
- US Department of Health and Human Services (HHS), Agency for Healthcare Research and Quality (AHRQ), National Resource Center for Health Information Technology
- Security Aspects in Electronic Personal Health Record: Data Access and Preservation - a briefing paper at Digital Preservation Europe

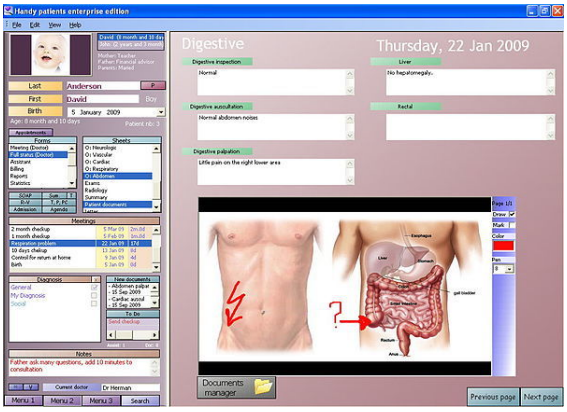
3.2 Electronic medical record



Sample view of an electronic health record based on images

An **electronic health record** (**EHR**), or **electronic medical record** (**EMR**), refers to the systematized collection of patient and population electronically-stored health information in a digital format.*[1] These records can be shared across different health care settings. Records are shared through network-connected, enterprise-wide information systems or other information networks and exchanges. EHRs may include a range of data, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and billing information.*[2]

EHR systems are designed to store data accurately and to capture the state of a patient across time. It eliminates



Sample view of an electronic health record

the need to track down a patient's previous paper medical records and assists in ensuring data is accurate and legible. It can reduce risk of data replication as there is only one modifiable file, which means the file is more likely up to date, and decreases risk of lost paperwork. Due to the digital information being searchable and in a single file, EMR's are more effective when extracting medical data for the examination of possible trends and long term changes in a patient. Population-based studies of medical records may also be facilitated by the widespread adoption of EHR's and EMR's.

3.2.1 Terminology

The terms EHR, electronic patient record (EPR) and EMR have often been used interchangeably, although differences between the models are now being defined. The electronic health record (EHR) is an evolving concept defined as a more longitudinal collection of the electronic health information of individual patients or populations. (See reference 1.) The EMR is, in contrast, defined as the patient record created by providers for specific encounters in hospitals and ambulatory environments, and which can serve as a data source for an EHR.*[3]*[4] It is important to note that an "EHR" is generated and maintained within an institution, such as a hospital, integrated delivery network, clinic, or physician office, to give patients, physicians and other health care providers, employers, and payers or insurers access to a patient's medical records across facilities.*[5] (Please note that the term "EMR" would now be used for the preceding description, and that many EMR's now use cloud software maintenance and data storage rather than local networks.)

In contrast, a personal health record (PHR) is an electronic application for recording personal medical data that the individual patient controls and may make available to health providers.*[6]

3.2.2 Comparison with paper-based records

Federal and state governments, insurance companies and other large medical institutions are heavily promoting the adoption of electronic medical records. The US Congress included a formula of both incentives (up to $44,000 per physician under Medicare, or up to $65,000 over six years under Medicaid) and penalties (i.e. decreased Medicare and Medicaid reimbursements to doctors who fail to use EMRs by 2015, for covered patients) for EMR/EHR adoption versus continued use of paper records as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009.*[7]

One VA study estimates its electronic medical record system may improve overall efficiency by 6% per year, and the monthly cost of an EMR may (depending on the cost of the EMR) be offset by the cost of only a few "unnecessary" tests or admissions.*[8]*[9] Jerome Groopman disputed these results, publicly asking "how such dramatic claims of cost-saving and quality improvement could be true".*[10] A 2014 survey of the American College of Physicians member sample, however, found that family practice physicians spent 48 minutes more per day when using EMRs. 90% reported that at least 1 data management function was slower after EMRs were adopted, and 64% reported that note writing took longer. A third (34%) reported that it took longer to find and review medical record data, and 32% reported that it was slower to read other clinicians' notes.*[11]

The increased portability and accessibility of electronic medical records may also increase the ease with which they can be accessed and stolen by unauthorized persons or unscrupulous users versus paper medical records, as acknowledged by the increased security requirements for electronic medical records included in the Health Information and Accessibility Act and by large-scale breaches in confidential records reported by EMR users.*[12]*[13] Concerns about security contribute to the resistance shown to their widespread adoption.

Handwritten paper medical records may be poorly legible, which can contribute to medical errors.*[14] Preprinted forms, standardization of abbreviations and standards for penmanship were encouraged to improve reliability of paper medical records. Electronic records may help with the standardization of forms, terminology and data input. Digitization of forms facilitates the collection of data for epidemiology and clinical studies.*[15]*[16]

EMRs can be continuously updated (within certain legal limitations – see below). If the ability to exchange records between different EMR systems were perfected("interoperability" *[17]) would facilitate the co-ordination of health care delivery in non-affiliated health care facilities. In addition, data from an electronic system can be used anonymously for statistical reporting

in matters such as quality improvement, resource management and public health communicable disease surveillance.*[18]

In ambulances

Ambulance services in Australia have introduced the use of EMR systems *[19] The benefits of EMR in ambulances include: better training for paramedics, review of clinical standards, better research options for pre-hospital care and design of future treatment options.*[20]

Automated handwriting recognition of ambulance medical forms has also been successful. These systems allow paper-based medical documents to be converted to digital text with substantially less cost overhead. Patient identifying information would not be converted to comply with government privacy regulations. The data can then be efficiently used for epidemiological analysis.*[21]

3.2.3 Technical features

- Digital formatting enables information to be used and shared over secure networks
- Track care (e.g. prescriptions) and outcomes (e.g. blood pressure)
- Trigger warnings and reminders
- Send and receive orders, reports, and results
- Decrease billing processing time and create more accurate billing system*[22]

Health Information Exchange*[23]

- Technical and social framework that enables information to move electronically between organizations

Using an EMR to read and write a patient's record is not only possible through a workstation but, depending on the type of system and health care settings, may also be possible through mobile devices that are handwriting capable,*[24] tablets and smartphones. Electronic Medical Records may include access to Personal Health Records (PHR) which makes individual notes from an EMR readily visible and accessible for consumers.

Some EMR systems automatically monitor clinical events, by analyzing patient data from an electronic health record to predict, detect and potentially prevent adverse events. This can include discharge/transfer orders, pharmacy orders, radiology results, laboratory results and any other data from ancillary services or provider notes.*[25] This type of event monitoring has been implemented using the Louisiana Public health information exchange linking state wide public health with electronic medical records. This system alerted medical providers when a patient with HIV/AIDS had not received care in over twelve months. This system greatly reduced the number of missed critical opportunities.*[26]

3.2.4 Philosophical views of the EHR

Within a meta-narrative systematic review of research in the field, there exist a number of different philosophical approaches to the EHR.*[27] The health information systems literature has seen the EHR as a container holding information about the patient, and a tool for aggregating clinical data for secondary uses (billing, audit *etc.*). However, other research traditions see the EHR as a contextualised artifact within a socio-technical system. For example, actor-network theory would see the EHR as an actant in a network,*[28] while research in computer supported cooperative work (CSCW) sees the EHR as a tool supporting particular work.

Several possible advantages to EHRs over paper records have been proposed, but there is debate about the degree to which these are achieved in practice.*[29]

3.2.5 Implementation, end user and patient considerations

Quality

Several studies call into question whether EHRs improve the quality of care.*[27]*[30]*[31]*[32]*[33] However, a recent multi-provider study in diabetes care, published in the New England Journal of Medicine, found evidence that practices with EHR provided better quality care.*[34]

EMR's may eventually help improve care coordination. An article in a trade journal suggests that since anyone using an EMR can view the patient's full chart, that it cuts down on guessing histories, seeing multiple specialists, smooths transitions between care settings, and may allow better care in emergency situations.*[35] EHRs may also improve prevention by providing doctors and patients better access to test results, identifying missing patient information, and offering evidence-based recommendations for preventive services.*[36]

Costs

The steep price of EHR and provider uncertainty regarding the value they will derive from adoption in the form of return on investment has a significant influence on EHR adoption.*[37] In a project initiated by the Office of the National Coordinator for Health Information (ONC), surveyors found that hospital administrators and physicians who had adopted EHR noted that any gains in efficiency were offset by reduced productivity as the technology was

implemented, as well as the need to increase information technology staff to maintain the system.*[37]

The U.S. Congressional Budget Office concluded that the cost savings may occur only in large integrated institutions like Kaiser Permanente, and not in small physician offices. They challenged the Rand Corporation's estimates of savings. "Office-based physicians in particular may see no benefit if they purchase such a product—and may even suffer financial harm. Even though the use of health IT could generate cost savings for the health system at large that might offset the EHR's cost, many physicians might not be able to reduce their office expenses or increase their revenue sufficiently to pay for it. For example, the use of health IT could reduce the number of duplicated diagnostic tests. However, that improvement in efficiency would be unlikely to increase the income of many physicians." *[38] One CEO of an EHR company has argued if a physician performs tests in the office, it might reduce his or her income.*[39]

Doubts have been raised about cost saving from EHRs by researchers at Harvard University, the Wharton School of the University of Pennsylvania, Stanford University, and others.*[33]*[40]*[41]

Time

The implementation of EMR can potentially decrease identification time of patients upon hospital admission. A research from the Annals of Internal Medicine showed that since the adoption of EMR a relative decrease in time by 65% has been recorded (from 130 to 46 hours).*[42]

Software quality and usability deficiencies

The Healthcare Information and Management Systems Society (HIMSS), a very large U.S. healthcare IT industry trade group, observed that EHR adoption rates "have been slower than expected in the United States, especially in comparison to other industry sectors and other developed countries. A key reason, aside from initial costs and lost productivity during EMR implementation, is lack of efficiency and usability of EMRs currently available." *[43] The U.S. National Institute of Standards and Technology of the Department of Commerce studied usability in 2011 and lists a number of specific issues that have been reported by health care workers.*[44] The U.S. military's EHR, AHLTA, was reported to have significant usability issues.*[45] It was observed that the efforts to improve EHR usability should be placed in the context of physician-patient communication.*[46]

However, physicians are embracing mobile technologies such as smartphones and tablets at a rapid pace. According to a 2012 survey by *Physicians Practice*, 62.6 percent of respondents (1,369 physicians, practice managers, and other healthcare providers) say they use mobile devices in the performance of their job. Mobile devices are increasingly able to synch up with electronic health record systems thus allowing physicians to access patient records from remote locations. Most devices are extensions of desk-top EHR systems, using a variety of software to communicate and access files remotely. The advantages of instant access to patient records at any time and any place are clear, but bring a host of security concerns. As mobile systems become more prevalent, practices will need comprehensive policies that govern security measures and patient privacy regulations.*[47]

Eventually, EHR will be more secured because the cyber security professionals have never stopped pursuing better ways to protect data with an enhanced software and technology. At the same time, they need to beware that the system will be significantly complicated and not user-friendly anymore as the data is growing and technology is more advancing. While we have a better secured system, it could lead to an error-prone. Therefore, efficient and effective trainings are needed along with a well-designed user interface .*[22]

Unintended consequences

Per empirical research in social informatics, information and communications technology (ICT) use can lead to both intended and unintended consequences.*[48]*[49]*[50]

A 2008 **Sentinel Event Alert** from the U.S. Joint Commission, the organization that accredits American hospitals to provide healthcare services, states that "*As health information technology (HIT) and 'converging technologies'—the interrelationship between medical devices and HIT—are increasingly adopted by health care organizations, users must be mindful of the safety risks and preventable adverse events that these implementations can create or perpetuate. Technology-related adverse events can be associated with all components of a comprehensive technology system and may involve errors of either commission or omission. These unintended adverse events typically stem from human-machine interfaces or organization/system design.*" *[51] The Joint Commission cites as an example the United States Pharmacopeia MEDMARX database*[52] where of 176,409 medication error records for 2006, approximately 25 percent (43,372) involved some aspect of computer technology as at least one cause of the error.

The National Health Service (NHS) in the UK reports specific examples of potential and actual EHR-caused unintended consequences in their 2009 document on the management of clinical risk relating to the deployment and use of health software.*[53]

In a Feb. 2010 U.S. Food and Drug Administration (FDA) memorandum, FDA notes EHR unintended consequences include EHR-related medical errors due to (1) errors of commission (EOC), (2) errors of omission or transmission (EOT), (3) errors in data analysis (EDA),

and (4) incompatibility between multi-vendor software applications or systems (ISMA) and cites examples. In the memo FDA also notes the "absence of mandatory reporting enforcement of H-IT safety issues limits the numbers of medical device reports (MDRs) and impedes a more comprehensive understanding of the actual problems and implications." *[54]

A 2010 Board Position Paper by the American Medical Informatics Association (AMIA) contains recommendations on EHR-related patient safety, transparency, ethics education for purchasers and users, adoption of best practices, and re-examination of regulation of electronic health applications.*[55] Beyond concrete issues such as conflicts of interest and privacy concerns, questions have been raised about the ways in which the physician-patient relationship would be affected by an electronic intermediary.*[56]*[57]

During the implementation phase, cognitive workload for healthcare professionals may be significantly increased as they become familiar with a new system.*[58]

Privacy and confidentiality

In the United States in 2011 there were 380 major data breaches involving 500 or more patients' records listed on the website kept by the United States Department of Health and Human Services (HHS) Office for Civil Rights.*[59] So far, from the first wall postings in September 2009 through the latest on 8 December 2012, there have been 18,059,831 "individuals affected," and even that massive number is an undercount of the breach problem. The civil rights office has not released the records of tens of thousands of breaches it has received under a federal reporting mandate on breaches affecting fewer than 500 patients per incident.*[60]

3.2.6 Governance, privacy and legal issues

Privacy concerns

In the United States, Great Britain, and Germany, the concept of a national centralized server model of healthcare data has been poorly received. Issues of privacy and security in such a model have been of concern.*[61]*[62]

Privacy concerns in healthcare apply to both paper and electronic records. According to the *Los Angeles Times*, roughly 150 people (from doctors and nurses to technicians and billing clerks) have access to at least part of a patient's records during a hospitalization, and 600,000 payers, providers and other entities that handle providers' billing data have some access also.*[63] Recent revelations of "secure" data breaches at centralized data repositories, in banking and other financial institutions, in the retail industry, and from government databases, have caused concern about storing electronic medical records in a central location.*[64] Records that are exchanged over the Internet are subject to the same security concerns as any other type of data transaction over the Internet.

The Health Insurance Portability and Accountability Act (HIPAA) was passed in the US in 1996 to establish rules for access, authentications, storage and auditing, and transmittal of electronic medical records. This standard made restrictions for electronic records more stringent than those for paper records. However, there are concerns as to the adequacy of these standards.*[65]

In the United States, information in electronic medical records is referred to as Protected Health Information (PHI) and its management is addressed under the Health Insurance Portability and Accountability Act (HIPAA) as well as many local laws.*[66] The HIPAA protects a patient's information; the information that is protected under this act are: information doctors and nurses input into the electronic medical record, conversations between a doctor and a patient that may have been recorded, as well as billing information. Under this act there is a limit as to how much information can be disclosed, and as well as who can see a patient's information. Patients also get to have a copy of their records if they desire, and get notified if their information is ever to be shared with third parties.*[67] Covered entities may disclose protected health information to law enforcement officials for law enforcement purposes as required by law (including court orders, court-ordered warrants, subpoenas) and administrative requests; or to identify or locate a suspect, fugitive, material witness, or missing person.*[68]

Medical and health care providers experienced 767 security breaches resulting in the compromised confidential health information of 23,625,933 patients during the period of 2006–2012.*[69]

In the European Union (EU), a new directly binding instrument, a regulation of the European Parliament and of the Council, was passed in 2016 to go into effect in 2018 to protect the processing of personal data, including that for purposes of health care, the General_Data_Protection_Regulation.

Threats to health care information can be categorized under three headings:

- Human threats, such as employees or hackers
- Natural and environmental threats, such as earthquakes, hurricanes and fires.
- Technology failures, such as a system crashing

These threats can either be internal, external, intentional and unintentional. Therefore, one will find health information systems professionals having these particular threats in mind when discussing ways to protect the health information of patients. The Health Insurance Portability and Accountability Act (HIPAA) has developed a framework to mitigate the harm of these threats that is comprehensive but not so specific as to limit the options of

healthcare professionals who may have access to different technology.*[70]

Personal Information Protection and Electronic Documents Act (PIPEDA) was given Royal Assent in Canada on 13 April 2000 to establish rules on the use, disclosure and collection of personal information. The personal information includes both non-digital and electronic form. In 2002, PIPEDA extended to the health sector in Stage 2 of the law's implementation.*[71] There are four provinces where this law does not apply because its privacy law was considered similar to PIPEDA: Alberta, British Columbia, Ontario and Quebec.

One major issue that has risen on the privacy of the US network for electronic health records is the strategy to secure the privacy of patients. Former US president Bush called for the creation of networks, but federal investigators report that there is no clear strategy to protect the privacy of patients as the promotions of the electronic medical records expands throughout the United States. In 2007, the Government Accountability Office reports that there is a "jumble of studies and vague policy statements but no overall strategy to ensure that privacy protections would be built into computer networks linking insurers, doctors, hospitals and other health care providers." *[72]

The privacy threat posed by the interoperability of a national network is a key concern. One of the most vocal critics of EMRs, New York University Professor Jacob M. Appel, has claimed that the number of people who will need to have access to such a truly interoperable national system, which he estimates to be 12 million, will inevitable lead to breaches of privacy on a massive scale. Appel has written that while "hospitals keep careful tabs on who accesses the charts of VIP patients," they are powerless to act against "a meddlesome pharmacist in Alaska" who "looks up the urine toxicology on his daughter's fiance in Florida, to check if the fellow has a cocaine habit." *[73] This is a significant barrier for the adoption of an EHR. Accountability among all the parties that are involved in the processing of electronic transactions including the patient, physician office staff, and insurance companies, is the key to successful advancement of the EHR in the US Supporters of EHRs have argued that there needs to be a fundamental shift in "attitudes, awareness, habits, and capabilities in the areas of privacy and security" of individual's health records if adoption of an EHR is to occur.*[74]

According to the *Wall Street Journal*, the DHHS takes no action on complaints under HIPAA, and medical records are disclosed under court orders in legal actions such as claims arising from automobile accidents. HIPAA has special restrictions on psychotherapy records, but psychotherapy records can also be disclosed without the client's knowledge or permission, according to the *Journal*. For example, Patricia Galvin, a lawyer in San Francisco, saw a psychologist at Stanford Hospital & Clinics after her fiance committed suicide. Her therapist had assured her that her records would be confidential. But after she applied for disability benefits, Stanford gave the insurer her therapy notes, and the insurer denied her benefits based on what Galvin claims was a misinterpretation of the notes.*[75]*[76]

Within the private sector, many companies are moving forward in the development, establishment and implementation of medical record banks and health information exchange. By law, companies are required to follow all HIPAA standards and adopt the same information-handling practices that have been in effect for the federal government for years. This includes two ideas, standardized formatting of data electronically exchanged and federalization of security and privacy practices among the private sector.*[74] Private companies have promised to have "stringent privacy policies and procedures." If protection and security are not part of the systems developed, people will not trust the technology nor will they participate in it.*[72]

In 2013, reports based on documents released by Edward Snowden revealed that the NSA had succeeded in breaking the encryption codes protecting electronic health records, among other databases.*[77]

In 2015, 4.5 million health records were hacked at UCLA Medical Center.*[78]

Legal issues

Liability Legal liability in all aspects of healthcare was an increasing problem in the 1990s and 2000s. The surge in the per capita number of attorneys*[79] and changes in the tort system caused an increase in the cost of every aspect of healthcare, and healthcare technology was no exception.*[80]

Failure or damages caused during installation or utilization of an EHR system has been feared as a threat in lawsuits.*[81] Similarly, it's important to recognize that the implementation of electronic health records carries with it significant legal risks.*[82]

This liability concern was of special concern for small EHR system makers. Some smaller companies may be forced to abandon markets based on the regional liability climate.*[83] Larger EHR providers (or government-sponsored providers of EHRs) are better able to withstand legal assaults.

While there is no argument that electronic documentation of patient visits and data brings improved patient care, there is increasing concern that such documentation could open physicians to an increased incidence of malpractice suits. Disabling physician alerts, selecting from dropdown menus, and the use of templates can encourage physicians to skip a complete review of past patient history and medications, and thus miss important data.

Another potential problem is electronic time stamps. Many physicians are unaware that EHR systems produce

an electronic time stamp every time the patient record is updated. If a malpractice claim goes to court, through the process of discovery, the prosecution can request a detailed record of all entries made in a patient's electronic record. Waiting to chart patient notes until the end of the day and making addendums to records well after the patient visit can be problematic, in that this practice could result in less than accurate patient data or indicate possible intent to illegally alter the patient's record.*[84]

In some communities, hospitals attempt to standardize EHR systems by providing discounted versions of the hospital's software to local healthcare providers. A challenge to this practice has been raised as being a violation of Stark rules that prohibit hospitals from preferentially assisting community healthcare providers.*[85] In 2006, however, exceptions to the Stark rule were enacted to allow hospitals to furnish software and training to community providers, mostly removing this legal obstacle.*[86]*[87]

Legal interoperability In cross-border use cases of EHR implementations, the additional issue of legal interoperability arises. Different countries may have diverging legal requirements for the content or usage of electronic health records, which can require radical changes to the technical makeup of the EHR implementation in question. (especially when fundamental legal incompatibilities are involved) Exploring these issues is therefore often necessary when implementing cross-border EHR solutions.*[88]

Regulatory compliance

- Health Level 7

In the United States, reimbursement for many healthcare services is based upon the extent to which specific work by healthcare providers is documented in the patient's medical record. Enforcement authorities in the United States have become concerned that functionality available in many electronic health records, especially copy-and-paste, may enable fraudulent claims for reimbursement. The authorities are concerned that healthcare providers may easily use these systems to create documentation of medical care that did not actually occur. These concerns came to the forefront in 2012, in a joint letter from the U.S. Departments of Justice and Health and Human Services to the American hospital community.*[89] The American Hospital Association responded, focusing on the need for clear guidance from the government regarding permissible and prohibited conduct using electronic health records.*[90] In a December 2013 audit report, the U.S. HHS Office of the Inspector General (OIG) issued an audit report reiterating that vulnerabilities continue to exist in the operation of electronic health records.*[91] The OIG's 2014 Workplan indicates an enhanced focus on providers' use of electronic health records.*[92]

3.2.7 Contribution under UN administration and accredited organizations

The United Nations World Health Organization (WHO) administration intentionally does not contribute to an internationally standardized view of medical records nor to personal health records. However, WHO contributes to minimum requirements definition for developing countries.*[93]

The United Nations accredited standardisation body International Organization for Standardization (ISO) however has settled thorough word for standards in the scope of the HL7 platform for health care informatics. Respective standards are available with ISO/HL7 10781:2009 Electronic Health Record-System Functional Model, Release 1.1*[94] and subsequent set of detailing standards.*[95]

3.2.8 Medical data breach

The Security Rule, according to Health and Human Services (HHS), establishes a security framework for small practices as well as large institutions. All covered entities must have a written security plan. The HHS identifies three components as necessary for the security plan: administrative safeguards, physical safeguards, and technical safeguards.

However, medical and healthcare providers have experienced 767 security breaches resulting in the compromised confidential health information of 23,625,933 patients during the period of 2006–2012.*[96]

The majority of the countries in Europe have made a strategy for the development and implementation of the Electronic Health Record Systems. This would mean greater access to health records by numerous stakeholders, even from countries with lower levels of privacy protection. The forthcoming implementation of the Cross Border Health Directive and the EU Commission's plans to centralize all health records are of prime concern to the EU public who believe that the health care organizations and governments cannot be trusted to manage their data electronically and expose them to more threats.

The idea of a centralized electronic health record system has been poorly received by the public who are wary that the governments may extend the use of the system beyond its purpose. There is also the risk for privacy breaches that could allow sensitive health care information to fall into the wrong hands. Some countries have enacted laws requiring safeguards to be put in place to protect the security and confidentiality of medical information as it is shared electronically and to give patients some important rights to monitor their medical records and receive notification for loss and unauthorized acquisition of health information. The United States and the EU have imposed mandatory medical data breach notifications.*[97]

The Health Insurance Portability and Accessibility Act (HIPAA) requires safeguards to limit the number of people who have access to personal information. However, given the number of people who may have access to your information as part of the operations and business of the health care provider or plan, there is no realistic way to estimate the number of people who may come across your records.*[98]

Additionally, law enforcement access is authorized under HIPAA. In some cases, medical information may be disclosed without a warrant or court order.

Breach notification

The purpose of a personal data breach notification is to protect individuals so that they can take all the necessary actions to limit the undesirable effects of the breach and to motivate the organization to improve the security of the infrastructure to protect the confidentiality of the data. The US law requires the entities to inform the individuals in the event of breach while the EU Directive currently requires breach notification only when the breach is likely to adversely affect the privacy of the individual. Personal health data is valuable to individuals and is therefore difficult to make an assessment whether the breach will cause reputational or financial harm or cause adverse effects on one's privacy.

The Security Rule that was adopted in 2005 did not require breach notification. However, notice might be required by state laws that apply to a variety of industries, including health care providers. In California, a law has been in place since 2003 requiring that a HIPAA covered organization's breach could have triggered a notice even though notice was not required by the HIPAA Security Rule.*[99] Since 1 January 2009, California residents are required to receive notice of a health information breach.

Federal law and regulations now provide rights to notice of a breach of health information. The Health Information Technology for Economic and Clinical Health (HITECH) Act requires HHS and the Federal Trade Commission (FTC) to jointly study and report on privacy and data security of personal health information. HITECH also requires the agencies to issue breach notification rules that apply to HIPAA covered entities and Web-based vendors that store health information electronically. The FTC has adopted rules regarding breach notification for internet-based vendors.*[100]

The Breach notification law in the EU provides better privacy safeguards with fewer exemptions, unlike the US law which exempts unintentional acquisition, access, or use of protected health information and inadvertent disclosure under a good faith belief.*[97]

3.2.9 Technical issues

Standards

- ASC X12 (EDI) - transaction protocols used for transmitting patient data. Popular in the United States for transmission of billing data.
- CEN's TC/251 provides EHR standards in Europe including:
  - EN 13606, communication standards for EHR information
  - CONTSYS (EN 13940), supports continuity of care record standardization.
  - HISA (EN 12967), a services standard for inter-system communication in a clinical information environment.
- Continuity of Care Record - ASTM International Continuity of Care Record standard
- DICOM - an international communications protocol standard for representing and transmitting radiology (and other) image-based data, sponsored by NEMA (National Electrical Manufacturers Association)
- HL7 - a standardized messaging and text communications protocol between hospital and physician record systems, and between practice management systems
- Fast Healthcare Interoperability Resources (FHIR) - a modernized proposal from HL7 designed to provide open, granular access to medical information
- ISO - ISO TC 215 provides international technical specifications for EHRs. ISO 18308 describes EHR architectures
- xDT - a family of data exchange formats for medical purposes that is used in the German public health system.

The U.S. federal government has issued new rules of electronic health records.*[101]

Open specifications

- openEHR: an open community developed specification for a shared health record with web-based content developed online by experts. Strong multilingual capability.
- Virtual Medical Record: HL7's proposed model for interfacing with clinical decision support systems.
- SMART (Substitutable Medical Apps, reusable technologies): an open platform specification to provide a standard base for healthcare applications.*[102]

Customization Each healthcare environment functions differently, often in significant ways. It is difficult to create a "one-size-fits-all" EHR system. Many first generation EHRs were designed to fit the needs of primary care physicians, leaving certain specialties significantly less satisfied with their EHR system.

An ideal EHR system will have record standardization but interfaces that can be customized to each provider environment. Modularity in an EHR system facilitates this. Many EHR companies employ vendors to provide customization.

This customization can often be done so that a physician's input interface closely mimics previously utilized paper forms.*[103]

At the same time they reported negative effects in communication, increased overtime, and missing records when a non-customized EMR system was utilized.*[104] Customizing the software when it is released yields the highest benefits because it is adapted for the users and tailored to workflows specific to the institution.*[105]

Customization can have its disadvantages. There is, of course, higher costs involved to implementation of a customized system initially. More time must be spent by both the implementation team and the healthcare provider to understand the workflow needs.

Development and maintenance of these interfaces and customizations can also lead to higher software implementation and maintenance costs.*[106]*[107]

Long-term preservation and storage of records

An important consideration in the process of developing electronic health records is to plan for the long-term preservation and storage of these records. The field will need to come to consensus on the length of time to store EHRs, methods to ensure the future accessibility and compatibility of archived data with yet-to-be developed retrieval systems, and how to ensure the physical and virtual security of the archives.

Additionally, considerations about long-term storage of electronic health records are complicated by the possibility that the records might one day be used longitudinally and integrated across sites of care. Records have the potential to be created, used, edited, and viewed by multiple independent entities. These entities include, but are not limited to, primary care physicians, hospitals, insurance companies, and patients. Mandl et al. have noted that "choices about the structure and ownership of these records will have profound impact on the accessibility and privacy of patient information." *[108]

The required length of storage of an individual electronic health record will depend on national and state regulations, which are subject to change over time. Ruotsalainen and Manning have found that the typical preservation time of patient data varies between 20 and 100 years. In one example of how an EHR archive might function, their research "describes a co-operative trusted notary archive (TNA) which receives health data from different EHR-systems, stores data together with associated meta-information for long periods and distributes EHR-data objects. TNA can store objects in XML-format and prove the integrity of stored data with the help of event records, timestamps and archive e-signatures." *[109]

In addition to the TNA archive described by Ruotsalainen and Manning, other combinations of EHR systems and archive systems are possible. Again, overall requirements for the design and security of the system and its archive will vary and must function under ethical and legal principles specific to the time and place.

While it is currently unknown precisely how long EHRs will be preserved, it is certain that length of time will exceed the average shelf-life of paper records. The evolution of technology is such that the programs and systems used to input information will likely not be available to a user who desires to examine archived data. One proposed solution to the challenge of long-term accessibility and usability of data by future systems is to standardize information fields in a time-invariant way, such as with XML language. Olhede and Peterson report that "the basic XML-format has undergone preliminary testing in Europe by a Spri project and been found suitable for EU purposes. Spri has advised the Swedish National Board of Health and Welfare and the Swedish National Archive to issue directives concerning the use of XML as the archive-format for EHCR (Electronic Health Care Record) information." *[110]

Synchronization of records

When care is provided at two different facilities, it may be difficult to update records at both locations in a coordinated fashion.

Two models have been used to satisfy this problem: a centralized data server solution, and a peer-to-peer file synchronization program (as has been developed for other peer-to-peer networks).

Synchronization programs for distributed storage models, however, are only useful once record standardization has occurred.

Merging of already existing public healthcare databases is a common software challenge. The ability of electronic health record systems to provide this function is a key benefit and can improve healthcare delivery.*[111]*[112]*[113]

3.2.10 eHealth and teleradiology

The sharing of patient information between health care organizations and IT systems is changing from a "point

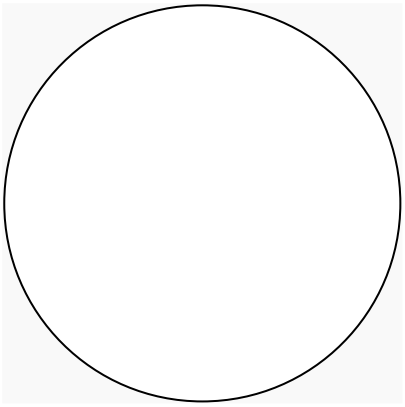
to point" model to a "many to many" one. The European Commission is supporting moves to facilitate cross-border interoperability of e-health systems and to remove potential legal hurdles, as in the project www.epsos.eu/. To allow for global shared workflow, studies will be locked when they are being read and then unlocked and updated once reading is complete. Radiologists will be able to serve multiple health care facilities and read and report across large geographical areas, thus balancing workloads. The biggest challenges will relate to interoperability and legal clarity. In some countries it is almost forbidden to practice teleradiology. The variety of languages spoken is a problem and multilingual reporting templates for all anatomical regions are not yet available. However, the market for e-health and teleradiology is evolving more rapidly than any laws or regulations.*[114]

3.2.11 European Union: Directive 2011/24/EU on patients' rights in cross-border healthcare

The European Commission wants to boost the digital economy by enabling all Europeans to have access to online medical records anywhere in Europe by 2020. With the newly enacted Directive 2011/24/EU on patients' rights in cross-border healthcare due for implementation by 2013, it is inevitable that a centralised European health record system will become a reality even before 2020. However, the concept of a centralised supranational central server raises concern about storing electronic medical records in a central location. The privacy threat posed by a supranational network is a key concern. Cross-border and Interoperable electronic health record systems make confidential data more easily and rapidly accessible to a wider audience and increase the risk that personal data concerning health could be accidentally exposed or easily distributed to unauthorised parties by enabling greater access to a compilation of the personal data concerning health, from different sources, and throughout a lifetime.*[115]

3.2.12 National contexts

United States



EHR adoption of all physicians in the US. Source: DesRoches et al. (2008).

Fully functional EHR system (4%)
Basic EHR system (13%)
Bought but not implemented yet (13%)
EHR purchase planned in 2 years (22%)
No EHR system (48%)

Usage Even though EMR systems with a computerized provider order entry (CPOE) have existed for more than 30 years, fewer than 10 percent of hospitals as of 2006 had a fully integrated system.*[116]

In a 2008 survey by DesRoches et al. of 4484 physicians (62% response rate), 83% of all physicians, 80% of primary care physicians, and 86% of non-primary care physicians had no EHRs. "Among the 83% of respondents who did not have electronic health records, 16%" had bought, but not implemented an EHR system yet.*[117] The 2009 National Ambulatory Medical Care Survey of 5200 physicians (70% response rate) by the National Center for Health Statistics showed that 51.7% of office-based physicians did not use any EMR/EHR system.*[118]

In the United States, the CDC reported that the EMR adoption rate had steadily risen to 48.3 percent at the end of 2009.*[119] This is an increase over 2008, when only 38.4% of office-based physicians reported using fully or partially electronic medical record systems (EMR) in 2008.*[120] However, the same study found that only 20.4% of all physicians reported using a system described as minimally functional and including the following features: orders for prescriptions, orders for tests, viewing laboratory or imaging results, and clinical progress notes. As of 2013, 78 percent of office physicians are using basic electronic medical records. As of 2014, more than 80 percent of hospitals in the U.S.have adopted some type of EHR. Though within a hospital, the type of EHR data and mix varies significantly. Types of EHR data used in hospitals include structured data (e.g., medication information) and unstructured data (e.g., clinical notes).*[121]

The healthcare industry spends only 2% of gross revenues on HIT, which is low compared to other information intensive industries such as finance, which spend upwards of 10%.*[122]*[123]

The usage of electronic medical records can vary depending on who the user is and how they are using it. Electronic medical records can help improve the quality of medical care given to patients. Many doctors and office-based physicians refuse to get rid of the traditional paper records. Harvard University has conducted an experiment in which they tested how doctors and nurses use electronic medical records to keep their patients' information up to date. The studies found that electronic medical records were very useful; a doctor or a nurse was able to find a patient's information fast and easy just by typing their name; even if it was misspelled. The usage of electronic medical records increases in some work places due to the ease of use of the system; whereas the president of the Canadian Family Practice Nurses Association says that using electronic medical records can be time consuming, and it isn't very helpful due to the complexity of the system.*[124] Beth Israel Deaconess Medical Center reported that doctors and nurses prefer to use a much more friendly user software due to the difficulty and time it takes for a medical staff to input the information as well as to find a patients information. A study was done and the amount of information that was recorded in the EMRs was recorded; about 44% of the patients information was recorded in the EMRs. This shows that EMRs are not very efficient most of the time.*[125]

The cost of implementing an EMR system for smaller practices has also been criticized; data produced by the Robert Wood Johnson Foundation demonstrates that the first year investment for an average five person practice is $162,000 followed by about $85,000 in maintenance fees.*[126] Despite this, tighter regulations regarding meaningful use criteria and national laws (Health Information Technology for Economic and Clinical Health Act and the Affordable Care Act)*[127] have resulted in more physicians and facilities adopting EMR systems:

- Software, hardware and other services for EMR system implementation are provided for cost by various companies including Dell.*[128]
- Open source EMR systems exist, but have not seen widespread adoption of open-source EMR system software.

Beyond financial concerns there are a number of legal and ethical dilemmas created by increasing EMR use, including the risk of medical malpractice due to user error, server glitches that result in the EMR not being accessible, and increased vulnerability to hackers.*[129]*[130]

Legal status Electronic medical records, like other medical records, must be kept in unaltered form and authenticated by the creator.*[131] Under data protection legislation, the responsibility for patient records (irrespective of the form they are kept in) is always on the creator and custodian of the record, usually a health care practice or facility. This role has been said to require changes such that the sole medico-legal record should be held elsewhere.*[132] The physical medical records are the property of the medical provider (or facility) that prepares them. This includes films and tracings from diagnostic imaging procedures such as X-ray, CT, PET, MRI, ultrasound, etc. The patient, however, according to HIPAA, has a right to view the originals, and to obtain copies under law.*[133]

The Health Information Technology for Economic and Clinical Health Act (HITECH) (Pub.L. 111–5,§2.A.III & B.4) (a part of the 2009 stimulus package) set meaningful use of interoperable EHR adoption in the health care system as a critical national goal and incentivized EHR adoption.*[134]*[135] The "goal is not adoption alone but 'meaningful use' of EHRs —that is, their use by providers to achieve significant improvements in care."*[136]

Title IV of the act promises maximum incentive payments for Medicaid to those who adopt and use "certified EHRs" of $63,750 over 6 years beginning in 2011. Eligible professionals must begin receiving payments by 2016 to qualify for the program. For Medicare the maximum payments are $44,000 over 5 years. Doctors who do not adopt an EHR by 2015 will be penalized 1% of Medicare payments, increasing to 3% over 3 years. In order to receive the EHR stimulus money, the HITECH Act requires doctors to show "meaningful use" of an EHR system. As of June 2010, there are no penalty provisions for Medicaid.*[3]

Health information exchange (HIE) has emerged as a core capability for hospitals and physicians to achieve "meaningful use" and receive stimulus funding. Healthcare vendors are pushing HIE as a way to allow EHR systems to pull disparate data and function on a more interoperable level.

Starting in 2015, hospitals and doctors will be subject to financial penalties under Medicare if they are not using electronic health records.*[101]

Goals and objectives

- Improve care quality, safety, efficiency, and reduce health disparities

  Quality and safety measurement
  Clinical decision support (automated advice) for providers
  Patient registries (e.g., "a directory of patients with diabetes")

- Improve care coordination

- Engage patients and families in their care
- Improve population and public health

  Electronic laboratory reporting for reportable conditions (hospitals)
  Immunization reporting to immunization registries
  Syndromic surveillance (health event awareness)

- Ensure adequate privacy and security protections

Quality Studies call into question whether, in real life, EMRs improve the quality of care.*[30]*[31] 2009 produced several articles raising doubts about EMR benefits.*[32]*[33]*[137] A major concern is the reduction of physician-patient interaction due to formatting constraints. For example, some doctors have reported that the use of check-boxes has led to fewer open-ended questions.*[138]

Meaningful use The main components of Meaningful Use are:

- The use of a certified EHR in a meaningful manner, such as e-prescribing.
- The use of certified EHR technology for electronic exchange of health information to improve quality of health care.
- The use of certified EHR technology to submit clinical quality and other measures.

In other words, providers need to show they're using certified EHR technology in ways that can be measured significantly in quality and in quantity.*[139]

The meaningful use of EHRs intended by the US government incentives is categorized as follows:

- Improve care coordination
- Reduce healthcare disparities
- Engage patients and their families
- Improve population and public health*[140]*[141]
- Ensure adequate privacy and security

The Obama Administration's Health IT program intends to use federal investments to stimulate the market of electronic health records:

- Incentives: to providers who use IT
- Strict and open standards: To ensure users and sellers of EHRs work towards the same goal
- Certification of software: To provide assurance that the EHRs meet basic quality, safety, and efficiency standards

The detailed definition of "meaningful use" is to be rolled out in 3 stages over a period of time until 2017. Details of each stage are hotly debated by various groups.*[142]

Meaningful use Stage 1

The first steps in achieving meaningful use are to have a certified electronic health record (EHR) and to be able to demonstrate that it is being used to meet the requirements. Stage 1 contains 25 objectives/measures for Eligible Providers (EPs) and 24 objectives/measures for eligible hospitals. The objectives/measures have been divided into a core set and menu set. EPs and eligible hospitals must meet all objectives/measures in the core set (15 for EPs and 14 for eligible hospitals). EPs must meet 5 of the 10 menu-set items during Stage 1, one of which must be a public health objective.*[143]

Full list of the Core Requirements and a full list of the Menu Requirements.

Core Requirements:

1. Use computerized order entry for medication orders.
2. Implement drug-drug, drug-allergy checks.
3. Generate and transmit permissible prescriptions electronically.
4. Record demographics.
5. Maintain an up-to-date problem list of current and active diagnoses.
6. Maintain active medication list.
7. Maintain active medication allergy list.
8. Record and chart changes in vital signs.
9. Record smoking status for patients 13 years old or older.
10. Implement one clinical decision support rule.
11. Report ambulatory quality measures to CMS or the States.
12. Provide patients with an electronic copy of their health information upon request.
13. Provide clinical summaries to patients for each office visit.
14. Capability to exchange key clinical information electronically among providers and patient authorized entities.

15. Protect electronic health information (privacy & security)

Menu Requirements:

1. Implement drug-formulary checks.
2. Incorporate clinical lab-test results into certified EHR as structured data.
3. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach.
4. Send reminders to patients per patient preference for preventive/ follow-up care
5. Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies)
6. Use certified EHR to identify patient-specific education resources and provide to patient if appropriate.
7. Perform medication reconciliation as relevant
8. Provide summary care record for transitions in care or referrals.
9. Capability to submit electronic data to immunization registries and actual submission.
10. Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission.

To receive federal incentive money, CMS requires participants in the Medicare EHR Incentive Program to "attest" that during a 90-day reporting period, they used a certified EHR and met Stage 1 criteria for meaningful use objectives and clinical quality measures. For the Medicaid EHR Incentive Program, providers follow a similar process using their state's attestation system.*[144]

Meaningful use Stage 2

The government released its final ruling on achieving Stage 2 of meaningful use in August 2012. Eligible providers will need to meet 17 of 20 core objectives in Stage 2, and fulfill three out of six menu objectives. The required percentage of patient encounters that meet each objective has generally increased over the Stage 1 objectives.

While Stage 2 focuses more on information exchange and patient engagement, many large EHR systems have this type of functionality built into their software, making it easier to achieve compliance. Also, for those eligible providers who have successfully attested to Stage 1, meeting Stage 2 should not be as difficult, as it builds incrementally on the requirements for the first stage.*[145]*[146]

Meaningful use Stage 3

On March 20, CMS released its proposed rule for Stage 3 meaningful use.*[147] These new rules focus on some of the tougher aspects of Stage 2 and require healthcare providers to vastly improve their EHR adoption and care delivery by 2018.*[148]

Barriers to adoption

Costs The steep price of EMR and provider uncertainty regarding the value they will derive from adoption in the form of return on investment have a significant influence on EMR adoption.*[37] In a project initiated by the Office of the National Coordinator for Health Information (ONC), surveyors found that hospital administrators and physicians who had adopted EMR noted that any gains in efficiency were offset by reduced productivity as the technology was implemented, as well as the need to increase information technology staff to maintain the system.*[37]

The U.S. Congressional Budget Office concluded that the cost savings may occur only in large integrated institutions like Kaiser Permanente, and not in small physician offices. They challenged the Rand Corporation's estimates of savings. "Office-based physicians in particular may see no benefit if they purchase such a product—and may even suffer financial harm. Even though the use of health IT could generate cost savings for the health system at large that might offset the EMR's cost, many physicians might not be able to reduce their office expenses or increase their revenue sufficiently to pay for it. For example. the use of health IT could reduce the number of duplicated diagnostic tests. However, that improvement in efficiency would be unlikely to increase the income of many physicians." *[38] "Given the ease at which information can be exchanged between health IT systems, patients whose physicians use them may feel that their privacy is more at risk than if paper records were used." *[38]

Doubts have been raised about cost saving from EMRs by researchers at Harvard University, the Wharton School of the University of Pennsylvania, Stanford University, and others.*[33]*[40]*[41]

Start-up costs In a survey by DesRoches et al. (2008), 66% of physicians without EHRs cited capital costs as a barrier to adoption, while 50% were uncertain about the investment. Around 56% of physicians without EHRs stated that financial incentives to purchase and/or use EHRs would facilitate adoption.*[117] In 2002, initial costs were estimated to be $50,000–70,000 per physician in a 3-physician practice. Since then, costs have decreased with increasing adoption.*[149] A 2011 survey estimated a cost of $32,000 per physician in a 5-physician practice during the first 60 days of implementation.*[150]

One case study by Miller et al. (2005) of 14 small primary-care practices found that the average practice paid for the initial and ongoing costs within 2.5 years.*[151] A 2003 cost-benefit analysis found that using EMRs for 5 years created a net benefit of $86,000 per provider.*[152]

Some physicians are skeptical of the positive claims and believe the data is skewed by vendors and others with an interest in EHR implementation.

Brigham and Women's Hospital in Boston, Massachusetts, estimated it achieved net savings of $5 million to $10 million per year following installation of a computerized physician order entry system that reduced serious medication errors by 55 percent. Another large hospital generated about $8.6 million in annual savings by replacing paper medical charts with EHRs for outpatients and about $2.8 million annually by establishing electronic access to laboratory results and reports.*[153]

Maintenance costs Maintenance costs can be high.*[149] Miller et al. found the average estimated maintenance cost was $8500 per FTE health-care provider per year.*[151]

Furthermore, software technology advances at a rapid pace. Most software systems require frequent updates, often at a significant ongoing cost. Some types of software and operating systems require full-scale re-implementation periodically, which disrupts not only the budget but also workflow. Costs for upgrades and associated regression testing can be particularly high where the applications are governed by FDA regulations (e.g. Clinical Laboratory systems). Physicians desire modular upgrades and ability to continually customize, without large-scale reimplementation.

Training costs Training of employees to use an EHR system is costly, just as for training in the use of any other hospital system. New employees, permanent or temporary, will also require training as they are hired.*[154]

In the United States, a substantial majority of healthcare providers train at a VA facility sometime during their career. With the widespread adoption of the Veterans Health Information Systems and Technology Architecture (VistA) electronic health record system at all VA facilities, fewer recently-trained medical professionals will be inexperienced in electronic health record systems. Older practitioners who are less experienced in the use of electronic health record systems will retire over time.

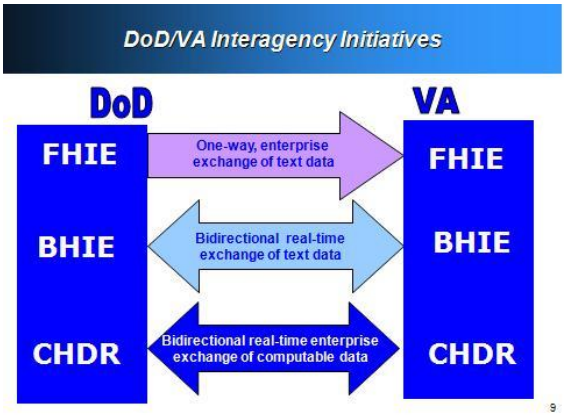
Software quality and usability deficiencies The Healthcare Information and Management Systems Society (HIMSS), a very large U.S. health care IT industry trade group, observed that EMR adoption rates "have been slower than expected in the United States, especially in comparison to other industry sectors and other developed countries. A key reason, aside from initial costs and lost productivity during EMR implementation, is lack of efficiency and usability of EMRs currently available."*[43] The U.S. National Institute of Standards and Technology of the Department of Commerce studied usability in 2011 and lists a number of specific issues that have been reported by health care workers.*[44] The U.S. military's EMR "AHLTA" was reported to have significant usability issues.*[45]

Lack of semantic interoperability In the United States, there are no standards for semantic interoperability of health care data; there are only syntactic standards. This means that while data may be packaged in a standard format (using the pipe notation of HL7, or the bracket notation of XML), it lacks definition, or linkage to a common shared dictionary. The addition of layers of complex information models (such as the HL7 v3 RIM) does not resolve this fundamental issue.

Implementations In the United States, the Department of Veterans Affairs (VA) has the largest enterprise-wide health information system that includes an electronic medical record, known as the Veterans Health Information Systems and Technology Architecture (VistA). A key component in VistA is their VistA imaging System which provides a comprehensive multimedia data from many specialties, including cardiology, radiology and orthopedics. A graphical user interface known as the Computerized Patient Record System (CPRS) allows health care providers to review and update a patient's electronic medical record at any of the VA's over 1,000 healthcare facilities. CPRS includes the ability to place orders, including medications, special procedures, X-rays, patient care nursing orders, diets, and laboratory tests.

The 2003 National Defense Authorization Act (NDAA) ensured that the VA and DoD would work together to establish a bidirectional exchange of reference quality medical images. Initially, demonstrations were only worked in El Paso, Texas, but capabilities have been expanded to six different locations of VA and DoD facilities. These facilities include VA polytrauma centers in Tampa and Richmond, Denver, North Chicago, Biloxi, and the National Capitol Area medical facilities. Radiological images such as CT scans, MRIs, and x-rays are being shared using the BHIE. Goals of the VA and DoD in the near future are to use several image sharing solutions (VistA Imaging and DoD Picture Archiving & Communications System (PACS) solutions).*[155]

Clinical Data Repository/Health Data Repository (CDHR) is a database that allows for sharing of patient records, especially allergy and pharmaceutical information, between the Department of Veteran Affairs (VA) and the Department of Defense (DoD) in the United States. The program shares data by translating



Electronic health records flow chart

the various vocabularies of the information being transmitted, allowing all of the VA facilities to access and interpret the patient records.*[156] The Laboratory Data Sharing and Interoperability (LDSI) application is a new program being implemented to allow sharing at certain sites between the VA and DoD of "chemistry and hematology laboratory tests." Unlike the CHDR, the LDSI is currently limited in its scope.*[157]

One attribute for the start of implementing EHRs in the States is the development of the Nationwide Health Information Network which is a work in progress and still being developed. This started with the North Carolina Healthcare Information and Communication Alliance founded in 1994 and who received funding from Department of Health and Human Services.*[158]

The Department of Veterans Affairs and Kaiser Permanente has a pilot program to share health records between their systems VistA and HealthConnect, respectively.*[159] This software called 'CONNECT' uses Nationwide Health Information Network standards and governance to make sure that health information exchanges are compatible with other exchanges being set up throughout the country. CONNECT is an open source software solution that supports electronic health information exchange.*[160] The CONNECT initiative is a Federal Health Architecture project that was conceived in 2007 and initially built by 20 various federal agencies and now comprises more than 500 organizations including federal agencies, states, healthcare providers, insurers, and health IT vendors.*[161]

The US Indian Health Service uses an EHR similar to Vista called RPMS. VistA Imaging is also being used to integrate images and co-ordinate PACS into the EHR system. In Alaska, use of the EHR by the Kodiak Area Native Association has improved screening services and helped the organization reach all 21 clinical performance measures defined by the Indian Health Service as required by the Government Performance and Results Act.*[162]

UK

See also: NHS Connecting for Health

In 2005 the National Health Service (NHS) in the United Kingdom began deployment of EHR systems in NHS Trusts. The goal was to have all patients with a centralized electronic health record by 2010.*[163] Lorenzo patient record systems were adopted in a number of NHS trusts While many hospitals acquired electronic patient records systems in this process, there was no national healthcare information exchange.*[29]*[164]*[165]*[166]*[167] Ultimately, the program was dismantled after a cost to the UK taxpayer was over $24 Billion (12 Billion GPB), and is considered one of the most expensive healthcare IT failures.*[168] The UK Government is now considered open-source healthcare platform from the United States Veterans Affairs following on the success of the VistA EHR deployment in Jordan.

In November 2013 NHS England launched a clinical digital maturity index to measure the digital maturity of NHS providers*[169] but 40% of NHS managers surveyed by the Health Service Journal did not know their ranking, and the same proportion said improving their ranking was of low or very low priority.*[170]

Electronic palliative care coordination systems have been developed by Marie Curie Cancer Care and the Royal College of General Practitioners which mean that terminally ill patients no longer have to explain their circumstances afresh to every new professional they meet and are less likely to be inappropriately taken to hospital.*[171]

Personalised Health and Care 2020 The publication of *Personalised Health and Care 2020* by the Department of Health elaborated a new attempt to integrate patient records.*[172] Its stated ambition is that every citizen will be able securely to access their health records online by 2018 and make real time data available to paramedics, doctors and nurses.*[173] A real time record across health and social care is seen as the key to the provision of integrated care.*[174]

GP Systems GP2GP is an NHS Connecting for Health project in the United Kingdom. It enables GPs to transfer a patient's electronic medical record to another practice when the patient moves onto the list.*[175] In General Practice in the UK the medical record has been computerized for many years, in fact the UK is probably one of the world leaders in this field. There are very few General Practices in the UK which are not computerized. Unlike the USA GP's have not had to deal with billing and have been able to concentrate on clinical care. The GP record is separate from the national Care Record and contains far more data. Shaun O'Hanlon, EMIS's Chief Clinical Officer says that the legal framework around data shar-

ing is the main problem in integrating patient data because the Data Protection Act 1998 puts responsibilities on GPs to protect the confidentiality of patient data, but at the same time they have a "duty to share" when it is in the best interests of the patient. He says the quickest, easiest route to large scale record sharing is to put patients in the driving seat using smartphone technology. He quotes a YouGov poll which found that 85% of the population wanted any medical professional directly responsible for their treatment to have secure electronic access to key data from their GP record, such as long term conditions, medication history or allergies.*[176]

Clinical IT suppliers are moving towards greater interoperability, already achieved with the GP2GP project allowing different systems to exchange complete medical records between practices. There are projects allowing access between hospitals & GP practices. The main Primary Care systems are EMIS Health, SystmOne, iSOFT, and INPS Vision. The NHS in Scotland widely used GPASS until 2012. From April 2014 practices are contractually required to promote and offer patients the opportunity to book appointments online, order repeat prescriptions online and provide online Patient record access.*[177]

Patient access It has been possible for patients to access their own GP records online for some time, and Dr Amir Hannan pioneered this using EMIS software. He says "there are some doctors and nurses who have genuine concerns about patients suddenly being let loose to access their records without any controls in place or without clinicians having to do anything and a feeling of irresponsibility that that raises." *[178]

See Patient record access

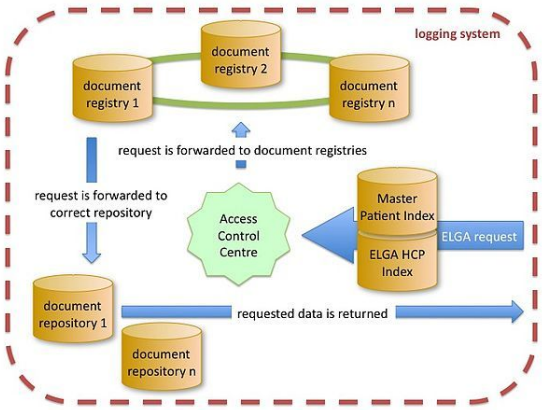
Australia

Australia is dedicated to the development of a lifetime electronic health record for all its citizens. PCEHR - the Personally Controlled Electronic Health Record - is the major national EHR initiative in Australia, being delivered through territory, state, and federal governments. This electronic health record was initially deployed in July 2012, and is under active development and extension.*[179]

MediConnect is an earlier program that provides an electronic medication record to keep track of patient prescriptions and provide stakeholders with drug alerts to avoid errors in prescribing.*[180]

Within Australia, there is a not-for-profit organisation called Standards Australia, which has created an electronic health website relating to information not only about Australia and what is currently going on about EHRs but also globally. There is a large number of key stakeholders that contribute to the process of integrating EHRs within Australia,they range from each States Departments of Health to Universities around Australia and National E-Health Transition Authority to name a few.*[181]*[182]*[183]

Austria



Structure and basic components of the Austrian EHR (ELGA)

In December 2012 Austria introduced an Electronic Health Records Act (EHR-Act).*[184] These provisions are the legal foundation for a national EHR system based upon a substantial public interest according to Art 8(4) of the Data Protection Directive 95/46/EC.*[185] In compliance to the Data Protection Directive (DPD) national electronic health records could be based upon explicit consent (Art 8(2)(a) DPD), the necessity for healthcare purposes (Art 8(3) DPD) or substantial public interests (Art 8(4) DPD).*[186]

The Austrian EHR-Act pursues an opt-out approach in order to harmonize the interests of public health and privacy in the best possible manner.

The 4th Part of the Austrian Health Telematics Act 2012 (HTA 2012) - these are the EHR provisions - are one of the most detailed data protection rules within Austrian legislation. Numerous safeguards according to Art 8(4) DPD guarantee a high level of data protection. For example:

- personal health data needs to be encrypted prior to transmission (§ 6 HTA 2012), or
- strict rules on data usage allow personal health data only to be used for treatment purposes or exercising patients' rights (§ 14 HTA 2012), or
- patients may declare their right to opt out from the national EHR at any time (§ 15 HTA 2012), or
- the implementation of an EHR-Ombudsman, to support the patients in exercising their rights (§ 17 HTA 2012), or

- the Access Control Center provides EHR-participants with full control over their data (§ 21 HTA 2012), or
- judicial penalties for privacy breaches (Art 7 of the EHR-Act).

Canada

Canadian provinces have launched a number of EHR projects and there are ongoing discussions about interoperability.

Jordan

In 2009, the Jordanian Government made a strategic decision to address quality and cost challenges in their healthcare system by investing in an effective, national e-health infrastructure. Following a period of detailed consultation and investigation, Jordan adopted the electronic health record system of the US Veterans Health Administration VistA EHR because it was a proven, national-scale enterprise system capable of scaling to hundreds of hospitals and millions of patients. In 2010 three of the country's largest hospitals went live with VistA EHR. It is anticipated that all further hospital deployments based on this 'gold' version will require less than 20% effort and cost of the original hospitals, enabling rapid national coverage. The implementation of VistA EHR was estimated at 75% less cost than proprietary products, with the greatest savings related to reduced costs of configuration, customization, implementation and support. When completed, Jordan will be the largest country in the world with a single, comprehensive, national electronic health care delivery network to care for the country's entire population in a single electronic network of over 850 hospitals and clinics.

Denmark

Denmark does not have nationwide EHR. It is mandatory for primary care practices and hospitals to use EHRs. The Danish Health Data Network (Medcom) acts as a data integrator to ensure interoperability. Unfortunately, non-interoperability is an issue despite the high adoption rate.*[187] The five regions are attempting to address this problem by each setting up their own electronic health record systems for public hospitals. However, all patient data will still be registered in the national e-journal.

Estonia

Estonia is the first country in the world that has implemented a nationwide EHR system, registering virtually all residents' medical history from birth to death.*[188] It was launched on 17 December 2008 *[189]

India

The Government of India, while unveiling of National Health Portal, has come out with guidelines for E.H.R standards in India. The document recommends set of standards to be followed by different healthcare service providers in India, so that medical data becomes portable and easily transferable.*[190]

India is considering to set up a National eHealth Authority (NeHA) for standardisation, storage and exchange of electronic health records of patients as part of the government's Digital India programme. The authority, to be set up by an Act of Parliament will work on the integration of multiple health IT systems in a way that ensures security, confidentiality and privacy of patient data. A centralised electronic health record repository of all citizens which is the ultimate goal of the authority will ensure that the health history and status of all patients would always be available to all health institutions. Union Health Ministry has circulated a concept note for the setting up of **NeHa**, inviting comments from stakeholders.*[191]

Netherlands

The vast majority of GP's *[192] and all pharmacies and hospitals use EHR's. In hospitals, computerized order management and medical imaging systems (PACS) are widely accepted. Whereas healthcare institutions continue to upgrade their EHR's functionalities, the national infrastructure is still far from being generally accepted.

In 2012 the national EHR restarted under the joined ownership of GPs, pharmacies and hospitals. A major change is that, as of January 2013, patients have to give their explicit permission that their data may be exchanged over the national infrastructure. The national EHR is a virtual EHR and is a reference server which "knows" in which local EHR what kind of patient record is stored. EDIFACT still is the most common way to exchange patient information electronically between hospitals and GP's.

UAE

Abu Dhabi is leading the way in using national EHR data as a live longitudinal cohort in the assessment of risk of cardiovascular disease.*[193]

Saudi Arabia

In 2010, Saudi Arabian National Guard Health Affairs was recognized with the Arab Health Award for "Excellence in Electronic Health Records" .*[194]

Switzerland

In 2007, the Swiss Federal Government has approved a national strategy for adoption of e-health.*[195] A central element of this strategy is a nationwide EHR. Following the federal tradition of Switzerland, it is planned that the nationwide EHR infrastructure is implemented with a decentralized approach, i.e. using access and control mechanism for federating existing records. In order to govern legal and financial aspects of the future nationwide EHR implementation, a bill is currently under development by the Swiss Federal Government.*[196] Besides the current discussions about a nation-wide implementation, EHR are widely used in both private and public healthcare organizations.*[197]

3.2.13 In veterinary medicine

In UK veterinary practice, the replace of paper recording systems with electronic methods of storing animal patient information escalated from the 1980s and the majority of clinics now use electronic medical records. In a sample of 129 veterinary practices, 89% used a Practice Management System (PMS) for data recording.*[198] There are more than ten PMS providers currently in the UK. Collecting data directly from PMSs for epidemiological analysis abolishes the need for veterinarians to manually submit individual reports per animal visit and therefore increases the reporting rate.*[199]

Veterinary electronic medical record data are being used to investigate antimicrobial efficacy; risk factors for canine cancer; and inherited diseases in dogs and cats, in the small animal disease surveillance project 'VetCOMPASS' (Veterinary Companion Animal Surveillance System) at the Royal Veterinary College, London, in collaboration with the University of Sydney (the VetCOMPASS project was formerly known as VEctAR).*[200]

3.2.14 See also

- Clinical documentation improvement
- eMix
- European Institute for Health Records (EuroRec)
- Health informatics
- Health information management
- Hospital information system
- List of open source healthcare software
- Medical imaging
- Medical record
- Personally Controlled Electronic Health Record, the Australian government's shared electronic health summary system*[201]
- Personal health record
- Picture archiving and communication system
- Radiology Information System

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3.2.16 External links

- Can Electronic Health Record Systems Transform Health Care?
- Maryland Health Care Commission EHR Product Portfolio is a resource to compare and evaluate EHR products along with information on product vendors.
- Open-Source EHR Systems for Ambulatory Care: A Market Assessment (California HealthCare Foundation, January 2008)
- US Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology (ONC)
- US Department of Health and Human Services (HHS), Agency for Healthcare Research and Quality (AHRQ), National Resource Center for Health Information Technology
- Security Aspects in Electronic Personal Health Record: Data Access and Preservation - a briefing paper at Digital Preservation Europe

3.3 Personal health record

A **personal health record**, or PHR, is a health record where health data and information related to the care of a patient is maintained by the patient.*[1] This stands in contrast to the more widely used electronic medical record, which is operated by institutions (such as hospitals) and contains data entered by clinicians or billing data to support insurance claims. The intention of a PHR is to provide a complete and accurate summary of an individual's medical history which is accessible online. The health data on a PHR might include patient-reported outcome data, lab results, data from devices such as wireless electronic weighing scales or collected passively from a smartphone.

3.3.1 Definition

The term "personal health record" is not new. The earliest mention of the term was in an article indexed by PubMed dated June 1978,*[2] and even earlier in 1956 reference is made to a personal health log.*[3] However, most scientific articles written about PHRs have been published since 2000.

The term "PHR" has been applied to both paper-based and computerized systems; current usage usually implies an electronic application used to collect and store health data. In recent years, several formal definitions of the term have been proposed by various organizations.*[4]*[5]*[6]

It is important to note that PHRs are not the same as electronic health records (EHRs). The latter are software systems designed for use by health care providers. Like the data recorded in paper-based medical records, the data in EHRs are legally mandated notes on the care provided by clinicians to patients. There is no legal mandate that compels a consumer or patient to store her personal health information in a PHR.

PHRs can contain a diverse range of data, including but not limited to:

- allergies and adverse drug reactions
- chronic diseases
- family history
- illnesses and hospitalizations
- imaging reports (e.g. X-ray)
- laboratory test results
- medications and dosing
- prescription record
- surgeries and other procedures
- vaccinations
- and Observations of Daily Living (ODLs)

There are two methods by which data can arrive in a PHR.*[1] A patient may enter it directly, either by typing into fields or uploading/transmitting data from a file or another website. The second is when the PHR is tethered to an electronic health record, which automatically updates the PHR. Not all PHRs have the same capabilities, and individual PHRs may support one or all of these methods.*[1]

In addition to storing an individual's personal health information, some PHRs provide added-value services such as drug-drug interaction checking, electronic messaging between patients and providers, managing appointments, and reminders.*[7]

3.3.2 Benefits

PHRs grant patients access to a wide range of health information sources, best medical practices and health knowledge. All of an individual's medical records are stored in one place instead of paper-based files in various doctors' offices. Upon encountering a medical condition, a patient's health information is only a few clicks away.

Moreover, PHRs can benefit clinicians. PHRs offer patients the opportunity to submit their data to their clinicians' EHRs. This helps clinicians make better treatment decisions by providing more continuous data.*[1]

PHRs have the potential to help analyze an individual's health profile and identify health threats and improvement opportunities based on an analysis of drug interaction, current best medical practices, gaps in current medical care plans, and identification of medical errors. Patient illnesses can be tracked in conjunction with healthcare providers and early interventions can be promoted upon encountering deviation of health status. PHRs also make it easier for clinicians to care for their patients by facilitating continuous communication as opposed to episodic. Eliminating communication barriers and allowing documentation flow between patients and clinicians in a timely fashion can save time consumed by face-to-face meetings and telephone communication. Improved communication can also ease the process for patients and caregivers to ask questions, to set up appointments, to request refills and referrals, and to report problems. Additionally, in the case of an emergency a PHR can quickly provide critical information to proper diagnosis or treatment.

3.3.3 Architecture

Like other health information technology, PHR architecture of has three main components:

Data The information collected, stored, analyzed, and exchanged by the PHR.

Examples: medical history, laboratory results, imaging studies, medications

Infrastructure The platform that handles data storage, processing, and exchange.

Examples: stand-alone software programs or websites, provider- or payer-connected (tethered) websites

Applications The information exchange, data analysis, and content delivery capabilities of the system.

Examples: scheduling appointments, medication refill or renewal, decision aids, and patient education materials.*[8]

Various architectural models have different costs and benefits. Likewise, stand-alone, provider-tethered, and payer-tethered PHRs have different advantages and disadvantages for patients related to their individual circumstances. Such differences are among the priority areas in PHR research.*[8] As PHRs may play key role in advancing health information exchange, interoperability with other health IT systems is an important consideration for PHR architecture.*[8] If PHRs serve only as a repository for an individual's health information, it is unlikely that individuals who are not highly motivated will maintain their health records and find PHRs to be useful.

3.3.4 Delivery platforms

One of the principal distinguishing features of a PHR is the platform by which it is delivered. The types of platforms include: paper, electronic device, and web.

Paper

Personal health information is recorded and stored in paper format. Printed laboratory reports, copies of clinic notes, and health histories created by the individual may be parts of a paper-based PHR. This method is low cost, reliable, and accessible without the need for a computer or any other hardware. Probably the most successful paper PHR is the hand-held pregnancy record, developed in Milton Keynes in the mid-1980s*[9] and now in use throughout the United Kingdom. These include the Scottish Woman-Held Maternity Record,*[10] All Wales Maternity Record,*[11] and Perinatal Institute notes.*[12]

Paper-based PHRs may be difficult to locate, update, and share with others. Paper-based PHRs are subject to physical loss and damage, such as can occur during a natural disaster. Paper records can also be printed from most electronic PHRs. However, Fawdry *et al.* have shown that paper records are extremely flexible and do have distinct advantages over rigid electronic systems.*[13]

Electronic devices

Personal health information is recorded and stored in personal computer-based software that may have the capability to print, backup, encrypt, and import data from other sources such as a hospital laboratory. The most basic form of a PC-based PHR would be a health history created in a word-processing program. The health history created in this way can be printed, copied, and shared with anyone with a compatible word processor.

PHR software can provide more sophisticated features such as data encryption, data importation, and data sharing with health care providers. Some PHR products allow the copying of health records to a mass-storage device such as a CD-ROM, DVD, smart card,*[14] or USB flash drive.*[15]*[16]

PC-based PHRs are subject to physical loss and damage of the personal computer and the data that it contains. Some other methods of device solution may entail cards with embedded chips containing health information that may or may not be linked to a personal computer application or a web solution.

Web applications

Web-based PHR solutions are essentially the same as electronic device PHR solutions, however, web-based solutions have the advantage of being easily integrated with

other services. For example, some solutions allow for import of medical data from external sources. Solutions including HealthVault, and PatientsLikeMe allow for data to be shared with other applications or specific people. Mobile solutions often integrate themselves with web solutions and use the web-based solution as the platform.

A large number of companies have emerged to provide consumers the opportunity to develop online PHRs. Some have been developed by non-profit organizations, while others have been developed by commercial ventures. These web-based applications allow users to directly enter their information such as diagnosis, medications, laboratory tests, immunizations and other data associated with their health. They generate records that can be displayed for review or transmitted to authorized receivers.

Despite the need for PHRs and the availability of various online PHR providers, there has not been wide adoption of PHR services. In fact, Google, being among the most innovative companies in the world, discontinued its PHR service called Google Health on January 12, 2012. The reason cited for shutting down Google Health was that the service did not translate from its limited usage into widespread usage in the daily health routines of millions of people.*[17]

An emerging standard from HL7, Fast Healthcare Interoperability Resources (FHIR), is designed to make it easier for developers of personal health record applications to access relevant medical records.*[18]

3.3.5 EHRs, PHRs, patient portals and UHRs

The terms electronic health records, personal health records, and patient portals are not always used correctly. The generally agreed upon definition of these terms relates mainly to the *ownership* of the data. Once data is in a PHR it usually owned and controlled by the patient. Most EHRs, however, are the property of the provider, although the content can be co-created by both the provider and patient. A patient has a legal right in most states to request their healthcare data and under recent USA legislation those providers using a certified EHR will be required to provide an electronic copy as well. In the UK, according to the governments's information strategy for the NHS every primary care practice in England will have to offer patients online access to their care records by 2015.*[19] In 2012, only 1% did so.*[20] Electronic health records and electronic medical records contain clinical data created by and for health professionals in the course of providing care. The data is about the patient but the data resides in a health care provider's system. The patient portal is typically defined as a view into the electronic medical records. In addition, ancillary functions that support a health care provider's interaction with a patient are also found in those systems e.g. prescription refill requests, appointment requests, electronic case management, etc. Finally, PHRs are data that resides with the patient, in a system of the patient's choosing. This data may have been exported directly from an EMR, but the point is it now resides in a location of the patient's choosing. Access to that information is controlled entirely by the patient.

A new concept being discussed is the UHR or "universal health record",*[21] which would be a patient-centered and patient-controlled body of information that could be shared in a granular way with particular health care providers at the patient's discretion in support of the patient's work with health care providers. This project would enlist open source contributions and enhancements from developers, with particular emphasis on supporting patient expectations of privacy and responsible patient control of private health information (PHI). It is anticipated that effective implementation of one or more "open source" approaches to the UHR would benefit both providers and patients, including providing more cost-effective solutions to currently difficult problems including entry/verification/update of personal health data, enabling responsible patient-controlled granular release of PHI, and supporting interoperability and effective collaboration of patients and physicians across disparate EHR/PHR platforms.

While PHRs can help patients keep track of their personal health information, the value of PHRs to healthcare organizations is still unclear.*[22]

3.3.6 In public health

PHRs have the ability to benefit the public health sector by providing health monitoring, outbreak monitoring, empowerment, linking to services, and research. PHRs can give consumers the potential to play a large role in protecting and promoting the public's health.*[23]

3.3.7 Barriers to adoption

Barriers to the adoption of PHRs include economic, technological, behavioral, and organizational issues, and barriers exist at both the environmental and individual levels.*[1] Limited access to computers and Internet access among low-income populations, known as the digital divide, is one such barrier.*[24]

Functional limitations

Despite the need to centralize patient information, PHR adoption has been very low. A study was carried out in an effort to assess the functionality and utility of online PHRs. An abstraction from real-life case of a patient suffering from a thyroid condition was utilized to create various online PHRs. The outputs generated were examined

for accuracy and completeness of clinical information. A team of researchers identified 19 websites offering different versions of PHRs. To evaluate the PHRs, researchers identified criteria based on their promotional advertisements. Ideally, centralized PHRs should help patients relate accurate history during clinical encounters, check for drug interactions, eliminate unnecessary duplication of laboratory tests and diagnostic studies, and serve as an information hub for patients' health management.*[25] An analysis of web-based PHR applications showed that most websites did provide access to personal medical information, however each demonstrated limited capacity in a different way:

From the 19 sites examined, four were found to be specific to certain diseases only and were therefore excluded from the study. Another four were excluded for reasons such as recurrent technical problems or connections to a specific hospital's information system. The remaining 11 sites did not provide patients with sufficient guidance as to how they should enter personal data. Some of the sites allowed patients to select medical conditions from categorized lists which did not cover the patients' complete health condition while others allowed free text entry. To formulate medication history, sites that required patients to choose medication from lists requested them to enter a wide range of descriptive information for each medication such as prescribed dose, administration frequency, start date, name of pharmacy that issued the medication and name of provider that prescribed the medication. With respect to laboratory tests, only two allowed patients to import results from outside sources. From these two sites, only one was functional. Not every site allowed patients to enter insurance coverage information. Majority of the sites required patients to enter date and results of diagnostic tests.*[25]

Most people do not keep record of minute details of their healthcare experiences and therefore find it difficult to make use of web-based PHRs. Overall, the sites selected for evaluation offered limited functionality to the general public. Low adoption of web-based PHRs can be a direct result of limitations in these applications' data entry, validation and information display methods. PHR development should be guided by ample patient-oriented research in future.

3.3.8 Promotion

There are instances where the use of a PHR would be beneficial to patients and may, therefore, override privacy concerns. Stage 1 of meaningful use of certified EHR systems requires that practices provide at least 50 percent of their patients with a copy of their health records upon request. While this can be accomplished through a patient portal, this function can also be part of a larger system such as Kaiser Permanente's My Health Manager —a PHR that is integrated into the health system's patient portal. By June 2012, 3.9 million Kaiser members were enrolled in this program. For the first half of 2012, members viewed 2.5 million lab results, sent 1 million e-mails to physicians, and scheduled 230,000 appointments monthly, demonstrating ease of use and convenience.*[26]

3.3.9 Privacy and security

One of the most controversial issues for PHRs is how the technology could threaten the privacy of patient information. Network computer break-ins are becoming more common,*[27] thus storing medical information online can cause fear of the exposure of health information to unauthorized individuals. In addition to height, weight, blood pressure and other quantitative information about a patient's physical body, medical records can reveal very sensitive information, including fertility, surgical procedures, emotional and psychological disorders, and diseases, etc. Various threats exist to patient information confidentiality, some of which are listed below:

- *Accidental disclosure*: During multiple electronic transfers of data to various entities, medical personnel can make innocent mistakes to cause disclosure of data.
- *Insider curiosity*: Medical personnel may misuse their access to patient information out of curiosity or for another purpose.
- *Insider subordination*: Medical personnel may leak out personal medical information for spite, profit, revenge, or other purposes.
- *Uncontrolled secondary usage*: Those who are granted access to patient information solely for the purpose of supporting primary care can exploit that permission for reasons not listed in the contract, such as research.
- *Outsider intrusion*: Former employees, network intruders, hackers, or others may access information, damage systems or disrupt operations

Unlike paper-based records that require manual control, digital health records are secured by technological tools.*[28] identifies three general classes of technological interventions that can improve system security:

- *Deterrents* – These depend on the ethical behavior of people and include controls such as alerts, reminders, and education of users. Another useful form of deterrents has been Audit Trails. The system records identity, times, and circumstances of users accessing information. If system users are aware of such a record keeping system, it will discourage them from taking ethically inappropriate actions

- *Technological obstacles* – These directly control the ability of a user to access information and ensure that users only access information they need to know according to their job requirements. Examples of technological obstacles include authorization, authentication, encryption, firewalls, and more.

- *System management precautions* – This involves proactively examining the information system to ensure that known sources of vulnerability are eliminated. Examples of this would be the use of encryption or installing antivirus software in the system

Information security concerns surrounding PHRs extend beyond technological issues. There are also ethical issues affecting the transfer of personally identifiable information in the treatment process. Only gradually are architectural requirements and information use policies becoming available such as the Privacy Rule under the U.S. Health Insurance Portability and Accountability Act (HIPAA).

3.3.10 See also

- Electronic health record
- mHealth
- Personal health application

3.3.11 References

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3.3.13 External links

- MedlinePlus - Personal Health Records - The U.S. National Library of Medicine & National Institutes of Health.
- Personal Health Records: What Physicians Need to Know
- Difference between Electronic Health Record (EHR). Electronic Medical Record (EMR) and Personal Health Record (PHR)

3.4 COmputer STored Ambulatory Record

COmputer STored Ambulatory Record (COSTAR) is an electronic medical record using the MUMPS programming language. It was developed by the Laboratory of Computer Science at Massachusetts General Hospital between 1968 and 1971 for Harvard Community Health Plan by Octo Barnett and Jerome Grossman.

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3.5 ProRec

The **ProRec** initiative of 1996 is a network of national non-profit organisations (the "ProRec centres"). The initiative was a consequence of the conclusions of the Concerted Action MEDIREC (1994-1995) regarding the reasons why Electronic Health Record (EHR) systems were not used more widely in any of the European Union. As part of the Lisbon Declaration suggestions were made to remedy this situation.

The ProRec initiative is supported by the DG Information Society of the European Union. The DG Information Society supported the ProRec initiative with the ProRec Support Action (1996-1998), and the WIDENET Accompanying Measure (2000-2003).

The goal of the initiative is to build awareness of the limitations, shortcomings and obstacles on the way towards widespread development, implementation and use of quality Electronic Health Records (EHRs) and pointing them out. Especially significant for implementing Electronic Health Record systems is the ability to communicate and interoperate.

3.5.1 See also

- CEN/TC 251
- EHRcom
- European Institute for Health Records (EuroRec)
- European Health Telematics Association (EHTEL)
- European Health Telematics Observatory (EHTO)
- Health Informatics Service Architecture (HISA)

3.5.2 External links

- ProRec-BE
- ProRec-RO

3.6 Health record trust

A **health record trust** (also **independent health record trust** or **health record data bank**) provides a secure and protected place for individuals to create, use, and maintain their lifetime electronic health record (EHR). The health record trust takes personal health records one step further by combining an individual's electronic health record with the personal health record. A health record trust protects patient privacy by establishing that the patient is the owner of his or her health care records. It gives patients authority to access and review the entire record at any time as well as the authority to allow health care professionals, facilities, and organizations to view all of the records or a limited portion of the records. Currently a record is left at each facility a patient seeks care. The health record trust allows for all of the information to be in one central document.[*][1] Patients cannot alter their health records but instead add notes and request corrections. They can also view every provider who downloads their EHR.

Legislation was introduced in the 110th Congress to establish a regulatory framework for the establishment of health record trusts. The Independent Health Record

Trust Act of 2007 (H.R. 2991) was introduced by Rep. Dennis Moore (D-KS) and Rep. Paul Ryan (R-WI) on July 11, 2007. The legislation seeks to give people control over their lifetime health records, with the broader goal of reducing health care costs that result from inefficiency, medical errors, inappropriate care, and incomplete information. This legislation provides standards for the use of health record trusts, including certifications and interoperability of independent health record trusts. HR 2991 was referred to the House Committee on Energy and Commerce and the House Committee on Ways and Means. The bill died in committee and has not been reintroduced.*[2] With the availability of a longitudinal health record protected by a health record trust, patients receive better quality of care and are able to pass along their medical records to future generations. Health record trusts promote wellness and improve patient care through quick and easy access to critical health information.

3.6.1 References

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3.6.2 Sources

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3.6.3 External links

- HR 2991
- Health Banking information

3.7 ClearHealth

ClearHealth is an Open Source practice management (PM) and electronic medical records (EMR/EHR/PHR) system available under the GNU General Public License. It has received attention as a possible open source option for FQHC and CHC sites.*[2] It is currently deployed at approximately 600 sites worldwide including commercially supported and self-supported open source installations. There are number of high profile installations in non-profit health settings including the Primary Care Coalition network, powering the Community Healthlink System, in Maryland, USA, which includes approximately 50 sites and 1,500 users*[3] and Operation Samahan,*[4] a Federally Qualified Health Center (FQHC-Look alike)look alike facility in National City, CA with 5 locations. OsNews provides an introduction to the system.*[5]

3.7.1 History

ClearHealth began when the core developers of several other Open Source healthcare software systems including OpenEMR and FreeMed. ClearHealth released the first version in 2003, supporting mainly scheduling capabilities. Its 1.0 release was in October 2005 and included additions to the original scheduling capabilities, including support for patient registration/demographics, and electronic billing. In July 2007, its 2.0 version was released which added electronic medical records capabilities and an integrated SQL based reporting system.

In 2006, the Tides Foundation provided a grant which funded the development of a set of feature additions to support the specialized needs of Federally Qualified Health Centers (FQHC) and other CHC/RNC facilities.

Written in the PHP language and capable of running on most server configurations, Windows, Linux or Mac OS X, under Apache and MySQL (LAMP), ClearHealth is compliant with the expectations of most Open Source web-based systems.

Amongst several open source solutions for the healthcare industry, the California Healthcare Foundation identified ClearHealth specifically as a viable solution based on its evaluation of sites and support in its Open Source Primer on healthcare software.*[6]

3.7.2 Features

ClearHealth is a comprehensive practice management and EMR system incorporating the key categories of functionality for scheduling, patient registration, electronic medical records and CPOE, electronic and paper billing, and SQL reporting. As an open source reference implementation of several interoperability protocols, ClearHealth has support for working with data in HL7*[7] and Continuity of Care Record (CCR) formats.

The ClearHealth system is fully compliant with HIPAA security provisions.*[8]

3.7.3 References

[1] See Archived April 2, 2015, at the Wayback Machine.

[2] CHCF Market Assessment California Healthcare Foundation

[3] VistA and Open Healthcare News May/June 2008

[4] Operation Samahan LinuxMedNews Coverage of Operation Samahan

[5] OsNews OsNews Introduction

[6] CHCF CHCF Open Source Primer

[7] Fred Trotter Interview HL7 Support

[8] CHCF Open Source Healthcare Market Assessment California Healthcare Foundation

3.7.4 External links

- Clearhealth on GitHub
- ClearHealth User Forums
- Primary Care Coalition

3.8 Laika

Laika is an open source Electronic Health Record (EHR) testing framework. Laika analyzes and reports on the interoperability capabilities of EHR systems. This includes the testing for certification of EHR software products and networks. Laika is designed to verify the input and output of EHR data against the standards and criteria identified by the Certification Commission for Healthcare Information Technology (CCHIT).

Since June 2008, Laika has been used by CCHIT to perform the machine-automated testing of EHR systems for interoperability.

3.8.1 Laika interoperability packages

- **Laika C32**: Laika C32 was the first tool to be created in the Laika framework suite, and supports testing of the HL7/ASTM Continuity of Care Document (CCD) constrained by the HITSP C32 version 2.1 specification.
- **Laika ORU**: was released in September 2008 to test the interoperability of HL7 2.5.1 lab messages. Laika ORU can be used with Mirth, an open source health informatics messaging package, to manage the routing of HL7 2.5.1 lab messages with Laika.
- **Laika XDS**: is scheduled to be released in March 2009 to test EHR systems and Health Information Exchange systems with XDS registries and repositories.

3.8.2 CCHIT and MITRE collaboration

Laika is an active collaborative effort between CCHIT and The MITRE Corporation. CCHIT is leading the functional requirements definition of the Laika testing framework. MITRE is leading the technical software design and is prototyping the software service.

The Certification Commission is a private, not-for-profit organization whose mission is to accelerate adoption of health information technology in the United States. MITRE is a 501(c)(3) not-for-profit corporation that manages three Federally Funded Research and Development Centers (FFRDCs) and works in partnership with the US government applying systems engineering and advanced technology to address issues of critical national importance in the USA.

3.8.3 Deployment in virtual environments

Laika has been deployed in virtual environments using, for example, the Amazon cloud environment. This allows centralized testing of multiple EHRs in segmented environments. It also allows portable implementations, so that field testing can be achieved.

3.8.4 Technical details

Laika is licensed under an Apache 2.0 open source license. Laika uses the Ruby on Rails framework, the Java programming language, the open source PostgreSQL database, and several Web 2.0 JavaScript libraries including Scriptaculous and Prototype.

3.8.5 Laika and popHealth

In 2010, the core Laika software infrastructure, consisting of the Laika database and Rails controllers, was forked to support the open source popHealth project. The popHealth project was developed from resources provided by the Federal Health Architecture within the Office of the National Coordinator. popHealth integrates with a healthcare provider's electronic health record (EHR) system to produce summary quality measures on the provider's patient population. The MITRE Corporation was also tasked as the technical lead team for the popHealth activity.

3.8.6 Background of project name *Laika*

Laika is named after the dog and first living animal to enter earth orbit, paving the way for human space flight.

3.8.7 External links

- Laika project on SourceForge
- The Certification Commission for Healthcare Information Technology website
- The MITRE Corporation website

3.9 openEHR

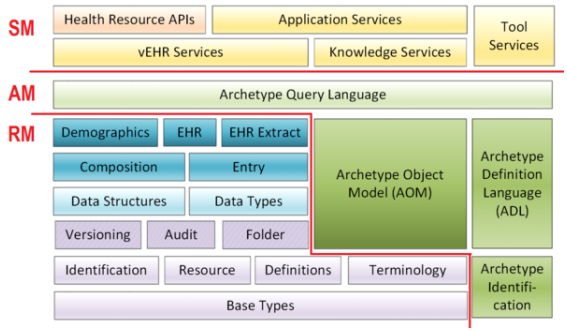
openEHR is an open standard specification in health informatics that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs). In openEHR, all health data for a person is stored in a "one lifetime", vendor-independent, person-centred EHR. The openEHR specifications include an EHR Extract specification*[1] but are otherwise

not primarily concerned with the exchange of data between EHR-systems as this is the focus of other standards such as EN 13606 and HL7.

The openEHR specifications are maintained by the openEHR Foundation, a not for profit foundation supporting the open research, development, and implementation of openEHR EHRs. The specifications are based on a combination of 15 years of European and Australian research and development into EHRs and new paradigms, including what has become known as the archetype methodology*[2]*[3] for specification of content.

The openEHR specifications*[4] include information and service models for the EHR, demographics, clinical workflow and archetypes. They are designed to be the basis of a medico-legally sound, distributed, versioned EHR infrastructure.

3.9.1 Architecture



Block diagram of openEHR specification components.

The architecture of the openEHR specifications as a whole consists of the following key elements:

- information models (aka 'Reference Model');
- the archetype formalism;
- the portable archetype query language;
- service models / APIs.

The use of the first two enable the development of 'archetypes' and 'templates', which are formal models of clinical and related content, and constitute a layer of *de facto* standards of their own, far more numerous than the base specifications on which they are built. The query language enables queries to be built based on the archetypes, rather than physical database schemata, thus decoupling queries from physical persistence details. The service models define access to key back-end services, including the EHR Service and Demographics Service, while a growing set of lightweight REST-based APIs based on archetype paths are used for application access.

The openEHR Architecture Overview provides a summary of the architecture and the detailed specifications.*[5]

3.9.2 Reference model

A central part of the openEHR specifications is the set of information models, known in openEHR as 'reference models'.*[6] The models constitute the base information models for openEHR systems, and define the invariant semantics of the Electronic Health Record (EHR), EHR Extract, and Demographics model, as well as supporting data types, data structures, identifiers and useful design patterns.

Some of the key classes in the EHR component are the ENTRY classes, whose subtypes include OBSERVATION, EVALUATION, INSTRUCTION, ACTION and ADMIN_ENTRY, as well as the Instruction State Machine, a state machine defining a standard model of the lifecycle of interventions, including medication orders, surgery and other therapies.

3.9.3 Archetypes and multi-level modelling

A key innovation in the openEHR framework is to leave all specification of clinical information out of the information model (also known as "reference model") and instead to provide a powerful means of expressing definitions of the content clinicians and patients need to record that can be directly consumed at runtime by systems built on the Reference Model. This is justified by the need to deal scalably with the generic problem in health of a very large, growing, and ever-changing set of information types.*[7]

Clinical content is specified in terms of two types of artefact which exist outside the information model. The first, known as "archetypes" provides a place to formally define re-usable data point and data group definitions, i.e. content items that will be re-used in numerous contexts. Typical examples include "systemic arterial blood pressure measurement" and "serum sodium". Many such data points occur in logical groups, e.g. the group of data items to document an allergic reaction, or the analytes in a liver function test result. Some archetypes contain numerous data points, e.g. 50, although a more common number is 10-20. A collection of archetypes can be understood as a "library" of re-usable domain content definitions, with each archetype functioning as a "governance unit", whose contents are co-designed, reviewed and published.

The second kind of artefact is known in openEHR as a "template", and is used to logically represent a use case-specific data-set, such as the data items making up a patient discharge summary, or a radiology report.*[8] A template is constructed by referencing rel-

evant items from a number of archetypes. A template might only require one or two data points or groups from each archetype. In terms of the technical representation, openEHR templates cannot violate the semantics of the archetypes from which they are constructed. Templates are almost always developed for local use by software developers and clinical analysts. Templates are typically defined for GUI screen forms, message definitions and document definitions, and as such, correspond to "operational" content definitions.

The justification for the two layers of models over and above the information model is that if data set definitions consist of pre-defined data points from a library of such definitions, then all recorded data (i.e. instances of templates) will ultimately just be instances of the standard content definitions. This provides a basis for standardised querying to work. Without the archetype "library" level, every data set (i.e. chunk of operational content) is uniquely defined and a standard approach to querying is difficult.

Accordingly, openEHR defines a method of querying based on archetypes, known as AQL (Archetype Querying Language).*[9]

Notably, openEHR has been used to model shared care plan. The archetypes have been designed to accommodate the concepts of the shared care plan.*[10]

While individual health records may be vastly different in content, the core information in openEHR data instances always complies to archetypes. The way this works is by creating archetypes which express clinical information in a way that is highly reusable, even universal in some cases.*[11]

Archetype formalism

openEHR archetypes are expressed in "Archetype Definition Language", an openEHR public specification. Two versions are available: ADL 1.4,*[12] and ADL 2,*[13] a new release with better support for specialisation, redefinition and annotations, among other improvements.*[14] The 1.4 release of ADL and its "object model" counterpart Archetype Object Model (AOM) are the basis for the CEN and ISO "Archetype Definition Language" standard (ISO standard 13606-2).

Templates have historically been developed in a simple, de facto industry-developed XML format, known as ".oet", after the file extension.*[15] ADL 2 defines a way to express templates seamlessly with archetypes, using extensions of the ADL language.*[16]

Quality assurance of archetypes

Various principles for developing archetypes have been identified.*[17] For example, a set of openEHR archetypes needs to be quality managed to conform to a number of axioms such as being mutually exclusive. The archetypes can be managed independently from software implementations and infrastructure, in the hands of clinician groups to ensure they meet the real needs on the ground. Archetypes are designed to allow the specification of clinical knowledge to evolve and develop over time. Challenges in implementation of information designs expressed in openEHR centre on the extent to which actual system constraints are in harmony with the information design.

In the field of Electronic health records there are a number of existing information models with overlaps in their scope which are difficult to manage, such as between HL7 V3 and SNOMED CT. The openEHR approach faces harmonisation challenges unless used in isolation.

3.9.4 International collaboration

Following the openEHR approach, the use of shared and governed archetypes globally would ensure openEHR health data could be consistently manipulated and viewed, regardless of the technical, organisational and cultural context. This approach also means the actual data models used by any EHR are flexible, given that new archetypes may be defined to meet future needs of clinical record keeping. Recently work in Australia has demonstrated how archetypes and templates may be used to facilitate the use of legacy health record and message data in an openEHR health record system, and output standardised messages and CDA documents.

The prospect of gaining agreement on design and on forms of governance at the international level remains speculative, with influences ranging from the diverse medico-legal environments to cultural variations, to technical variations such as the extent to which a reference clinical terminology is to be integral.

The openEHR Framework is consistent with the new Electronic Health Record Communication Standard (EN 13606). It is being used in parts of the UK NHS Connecting for Health Programme and has been selected as the basis for the national program in Sweden. It is also under evaluation in a number of countries including Denmark, Slovakia, Chile and Brazil. It is beginning to be utilised in commercial systems throughout the world.

3.9.5 Clinical Knowledge Manager

One of the outcomes of openEHR modelling approach is the open development of archetypes, templates and terminology subsets to represent health data. Due to the open nature of openEHR, these structures are publicly available to be used and implemented in health information systems. Community users are able to share, discuss and approve these structures in a collaborative repository known as the Clinical Knowledge Manager (CKM).

Some currently used openEHR CKMs:

- openEHR Clinical Knowledge Manager
- NEHTA Clinical Knowledge Manager
- UK Clinical Knowledge Manager
- Norwegian National ICT Clinical Knowledge Manager
- Slovenian MoH Clinical Knowledge Manager

3.9.6 See also

- Archetype (information science)
- European Institute for Health Records
- Electronic Health Record Communication (ISO/CEN EN 13606 - EHRcom)
- Health Level 7
- Health Informatics Service Architecture (HISA)
- HIPAA
- ProRec
- SNOMED CT

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3.9.8 External links

- openEHR Foundation website
- openEHR specifications
- openEHR 2015 white paper

3.10 OpenEMR

OpenEMR[*][2] is a medical practice management software which also supports Electronic Medical Records (EMR). It is **ONC Complete Ambulatory EHR certified**[*][3][*][4][*][5] and it features fully integrated electronic medical records, practice management for a medical practice, scheduling, and electronic billing.

The server side is written in PHP and can be employed in conjunction with a LAMP "stack", though any operating system with PHP support is supported.

OpenEMR is free and open-source software subject to the terms of the GNU General Public License (GPL). OpenEMR is subject to ongoing efforts of internationalization and localization in multiple languages, and there is free support available in various forums over the world. At the time of writing, commercial support is offered by more than 30 vendors in more than 10 countries.[*][6]

OpenEMR is one of the most popular free electronic medical records in use today with over 3,700 downloads per month.[*][7]

3.10.1 Features*[8]

- ONC Complete Ambulatory EHR Certified
- Patient Demographics
- Patient Scheduling
- Electronic Medical Records
- Prescriptions
- Medical Billing
- Clinical Decision Rules
- Patient Portal
- Reports
- Advantages and benefits of free and open-source software
- Security
- Multilanguage Support
- Free Support

3.10.2 Adoption

The market share of a software can be estimated based on sales numbers, but since most free and open-source software is not sold but installed via the package management system of the Linux distribution of choice, the term "installed base" seems rather popular. It is very difficult to estimate the number of practitioners that are using this software.

In the US, it has been estimated that there are more than 5,000 installations of OpenEMR in physician offices and other small healthcare facilities serving more than 30 million patients.*[9] Internationally, it has been estimated that OpenEMR is installed in over 15,000 healthcare facilities, translating into more than 45,000 practitioners using the system which are serving greater than 90 million patients.*[9] The Peace Corps plan to incorporate OpenEMR into their EHR system.*[10]*[11]*[12]*[13]*[14] Siaya District Hospital, a 220-bed hospital in rural Kenya, is using OpenEMR.*[15]*[16]*[17]*[18]*[19] HP India is planning to utilize OpenEMR for their Mobile Health Centre Project.*[20] There are also articles describing single clinician deployments*[21]*[22]*[23] and a free clinic deployment.*[24] Internationally, it is known that there are practitioners in Pakistan,*[25] Puerto Rico, Australia, Sweden, the Netherlands, Israel, India,*[20]*[26] Malaysia, Nepal, Indonesia, Bermuda, Armenia, Kenya,*[15]*[16]*[17]*[18]*[19]*[27] and Greece that are either testing or actively using OpenEMR for use as a free electronic medical records program in the respective languages.*[28]

3.10.3 Awards

OpenEMR has received a Bossie Award in the "The Best Open Source Applications" category in both 2012 and 2013.*[29]*[30]*[31]

3.10.4 Development

The official OpenEMR code repository was migrated from CVS to git on 20 October 2010.*[32] As of early 2016, the project's main code repository is on Sourceforge.*[33] There are also official mirrored code repositories on Github,*[34] Google Code,*[35] Gitorious,*[36] Bitbucket,*[37] Assembla,*[38] CodePlex*[39] and Repo.or.cz.*[40]

OpenEMR has a vibrant open-source development community with over 98 developers having contributed to the project.*[41]*[42] There are 205 developers with personal OpenEMR code repositories on Github.*[34] Open Hub (formerly Ohloh) says OpenEMR has "a relatively large team, in the top 10% of all project teams on Open Hub".*[42]

OEMR

OEMR*[43] is a 501(c)(3) tax exempt entity that was organized in July, 2010 to support the OpenEMR project.*[44] OEMR is the entity that holds the ONC EHR Certifications with ICSA and InfoGard Labs.*[4]*[45]*[46]

Certification

OpenEMR versions 4.1.0 (released on 9/23/2011), 4.1.1 (released on 8/31/2012) and 4.1.2 (released on 8/17/2013) have 2011 ONC Complete Ambulatory EHR Certification by ICSA Labs.*[45]*[3]*[4]*[5]*[47]

OpenEMR version 4.2.0 (released 12/28/2014) and 4.2.1 (released 3/25/2016) has 2014 ONC Modular Ambulatory EHR Certification by InfoGard Laboratories.*[46]*[48]*[49]

The OEMR*[43] organization is a non-profit entity that manages/provides the ONC certifications.*[4]

3.10.5 History

OpenEMR was originally developed by Synitech and version 1.0 was released in June 2001 as MP Pro (Medical-Practice Professional).*[50] Much of the code was then reworked to comply with the Health Insurance Portability and Accountability Act (HIPAA) and to improve security, and the product was reintroduced as OpenEMR version 1.3 a year later, in July 2002.*[51] On 13 August 2002 OpenEMR was released to the public under

the GNU General Public License (GPL), i.e. it became a free and open-source project and was registered on SourceForge.*[52] The project evolved through version 2.0 and the Pennington Firm (Pennfirm) took over as its primary maintainer in 2003.*[50] Walt Pennington transferred the OpenEMR software repository to SourceForge in March 2005, where it remains today.*[53] Mr. Pennington also established Rod Roark, Andres Paglayan and James Perry, Jr. as administrators of the project.*[50] Walt Pennington, Andres Paglayan and James Perry eventually took other directions and were replaced by Brady Miller in August 2009.*[54] So at this time Rod Roark and Brady Miller are the project's co-administrators.*[54]

Releases

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3.10.7 External links

- Official website
- Source code repository
- OEMR.org: A non-profit organization that supports OpenEMR

3.11 OpenMRS

OpenMRS logo

OpenMRS is a collaborative open source project to develop software to support the delivery of health care in developing countries.*[1] It grew out of the critical need to scale up the treatment of HIV in Africa but from the start was conceived as a general purpose electronic medical record system that could support the full range of medical treatments. The first ideas and prototype of OpenMRS were conceived by Paul Biondich and Burke Mamlin from the Regenstrief Institute, Indiana on a visit to the AMPATH project in Eldoret, Kenya in February 2004. Around the same time the EMR team at Partners

In Health led by Hamish Fraser and Darius Jazayeri were looking at ways to scale up the PIH-EMR*[2]*[3] web-based medical record system developed to manage drug resistant tuberculosis in Peru, and HIV in rural Haiti. Paul, Burke and Hamish met in September 2004 at the Medinfo conference in San Francisco, and recognized they had a common approach to medical information systems and a similar philosophy for healthcare and development and OpenMRS was born. Later, Chris Seebregts of the South African Medical Research Council (MRC) became the fourth founding member.

OpenMRS is founded on the principles of openness and sharing of ideas, software and strategies for deployment and use. The system is designed to be usable in very resource poor environments and can be modified with the addition of new data items, forms and reports without programming. It is intended as a platform that many organizations can adopt and modify avoiding the need to develop a system from scratch.

OpenMRS, Inc. is a registered non-profit that is the owner of all OpenMRS materials and the maintainer of the software's Public License. This entity will represent the OpenMRS project in legal and financial matters.*[4]

The software is licensed under version 2 of the Mozilla Public License. It requires that recipients are entitled to freely access the source code, but allows binary distribution, modification of the code (under the same license) and bundling into larger products that are under different licenses.*[5]

3.11.1 Design

The OpenMRS code is based on a "concept dictionary" that describes all the data items that can be stored in the system such as clinical findings, laboratory test results or socio-economic data. This approach avoids the need to modify the database structure to add new diseases, for example, and facilitates sharing of data dictionaries between projects and sites. An important feature of OpenMRS is its modular construction which allows the programming of new functions without modifying the core code. OpenMRS is web based but can be deployed on a single laptop or on a large server and runs on Linux, Windows or Mac OS X. There is also a demonstration version available that allows users to experience OpenMRS using hypothetical patient data. The latest version of OpenMRS is OpenMRS 2.2 released in April 2015.

Other key features of OpenMRS:

- Built on the MySQL database (but uses Hibernate allowing it to be ported to other databases)
- Programmed in Java
- Includes tools for data export and reporting
- Versions currently exist for HIV/AIDS, Drug resistant TB, primary care and oncology
- Supports open standards for medical data exchange including HL7, LOINC and IXF
- Form-based tools, such as the Form Entry module and XForms module
- Provides access to between-release code through Continuous Deployment
- Bidirectional synchronization with systems such as MoTeCH and TRACnet
- The Atlas module, which gives information on all OpenMRS facilities using a visual map
- Can be integrated with SMS messaging

New features (OpenMRS 1.9 and later):

- Allows older versions to run without upgrading
- Tools to link to hand held devices and cell phones (JavaROSA project)
- Research data collection tools for clinical trials and community data collection projects
- New CIEL dictionary entries
- Patient dashboard tab-loading rendered on-demand via AJAX to decrease lag

Currently being tested/developed:

- API support for order entry that provides support of orders within the system
- HL7 FHIR support for OpenMRS
- Anatomical drawing tool with pre-loads image and blank canvas options
- User interface improvements
- Ebola treatment unit electronic medical record as a response to the 2014 Ebola epidemic
- Message delivery triggered by a trend in data entry

3.11.2 Deployments

The first deployment was in Eldoret, Kenya in February 2006*[6] followed by the PIH-supported hospital in Rwinkwavu, Rwanda*[7] in August 2006 and Richmond Hospital in the KwaZulu-Natal province of South Africa later that year. As of March 2010, OpenMRS is in use in at least 23 developing countries (mostly in Africa) and it has been used to record over 1 million patient records

around the world. Most deployments are run by independent groups who carry out the work on the ground with technical support and training provided by the core team of OpenMRS developers, and other implementers. There have been four annual OpenMRS meetings in South Africa, organized by Chris Seebregts, who also leads the OpenMRS implementers community. Shorter meetings were held in Boston in May 2009, and a developer training in Indianapolis in February 2010. There are five known deployments supporting clinical care in the US - three in Indianapolis, one in Los Angeles, and one in Maryland. OpenMRS use will be expanded in Haiti to assist with the patients recovering from the January 2010 earthquake. In Nigeria, Institute of Human Virology is pushing for OpenMRS penetration in public and private clinics. The institute had a pilot of OpenMRS in 2011 to manage HIV/AIDs patients' records in 27 health facilities, the outcome of the pilot was overwhelming. In 2013, the institute decided to scale-up on OpenMRS and scale-down paper-based systems in all its over 400 health facilities and sub-partners' facilities. There has been tremendous progress in this scale-up.

3.11.3 Support

OpenMRS is supported by core teams from Partners In Health, Regenstrief Institute, and the South African Medical Research Council. Other organizations that collaborate on OpenMRS are the Millennium Villages Project, based at Columbia University, and Baobab Health Systems in Malawi. Some institutes have extended financial and consulting support as well, including The United States Center for Disease Control, the Rockefeller Foundation, and the World Health Organization. A variety of organizations, such as Atlassian, Blueberry Software, and YourKit, have also donated licenses to OpenMRS developers. There are several groups of programmers working on OpenMRS in developing countries including Kenya, Rwanda, Uganda, South Africa, Pakistan, Chile, and India. In Rwanda, Partners In Health started local training program called E-Health Software Development and Implementation (EHSDI). The nine-month course was designed to train students in medical information systems, and it focused highly in using the OpenMRS platform.

3.11.4 Community

The OpenMRS community includes developers, implementers, and users from multiple countries who collaborate through mailing lists, #openmrs *connect, and annual conferences.*[8] There is currently an OpemMRS Implementers Meeting planned for January 27, 2015 in Maputo, Mozambique. The theme of the meeting is "Building Quality Systems, Delivering Useful Data." The objectives include strengthening the partnership between OpenMRS and DHIS2 and expanding the OpenMRS community. OpenMRS also has its own Ask and Talk pages that allow those involved to communicate freely with the OpenMRS core team.

OpenMRS has participated annually in Google Summer of Code since 2007; according to that program's manager, it receives more student applications than the Apache Software Foundation. In the summer of 2013, OpenMRS participated as a mentoring organization in the Outreach Program for Women. OpenMRS also held a three-day leadership retreat, OpenMRS Camp 2014, at Bradford Woods. The focus of the camp was to build strategies for growing the OpenMRS community and ensuring its success. OpenMRS held its first OpenMRS Code Jam on November 19, 2014 in Toronto, where it was hosted by ThoughtWorks. OpenMRS is a mentoring organization in Google Code-in 2015.

3.11.5 See also

- eHealth
- Electronic medical record
- Health informatics

3.11.6 References

[1] Mamlin, BW; Biondich, PG; Wolfe, BA; Fraser, H; Jazayeri, D; Allen, C; Miranda, J; Tierney, WM (2006). "Cooking up an open source EMR for developing countries: OpenMRS - a recipe for successful collaboration". *AMIA Annual Symposium Proceedings*: 529–33. PMC 1839638. PMID 17238397.

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[5] "OpenMRS License FAQ". Retrieved 21 March 2015.

[6] Mamlin, BW; Biondich, PG (2005). "AMPATH Medical Record System (AMRS): collaborating toward an EMR for developing countries". *AMIA Annual Symposium Proceedings*: 490–4. PMC 1560633. PMID 16779088.

[7] Allen, C; Jazayeri, D; Miranda, J; Biondich, PG; Mamlin, BW; Wolfe, BA; Seebregts, C; Lesh, N; et al. (2007). "Experience in implementing the OpenMRS medical record system to support HIV treatment in Rwanda". *Studies in health technology and informatics* **129** (Pt 1): 382–6. PMID 17911744.

[8] Seebregts, CJ; Mamlin, BW; Biondich, PG; Fraser, HS; Wolfe, BA; Jazayeri, D; Allen, C; Miranda, J; et al. (2009). "The OpenMRS Implementers Network". *International journal of medical informatics* **78** (11): 711–20. doi:10.1016/j.ijmedinf.2008.09.005. PMID 19157968.

3.11.7 External links

- OpenMRS
- Regenstrief Institute
- Partners In Health
- Podcast/MP3 of an episode of the BBC radioprogramme Digital Planet. Described OpenMRS on 2008-06-23; 07m 02s - 14 m 23s.
- OpenMRS presentation for Google Tech Talks. August 23, 2007
- Lecture slides on OpenMRS from the May 2009 meeting, Boston, MA, USA

3.12 Summarized Electronic Health Record

KMEHR or **Kind Messages for Electronic Healthcare Record** is a proposed Belgian medical data standard introduced in 2002, designed to enable the exchange of structured clinical information. It is funded by the Belgian federal Ministry of public health and assessed in collaboration with Belgian industry.

The initiative lead to the specification of about 20 specific XML messages (the Kind Messages for Electronic Healthcare Records - Belgian implementation standard or KMEHR-bis).

3.12.1 Structure

The KMEHR standard consists of an XML (eXtensible Markup Language) message format defined by the KMEHR XML Schema and a set of reference tables.

Message structure

A KMEHR XML message is composed of two components a header and at least one folder. The header of the message describes the sender, the recipient(s) and a few technical statuses.

The folder itself gathers the information about a patient, where each folder identifies the subject of care (patient) and contains at least one medical transaction.

The medical transaction item gathers the information reported by one healthcare professional at a given instance. Its attributes are type, author, date and time.

3.12.2 Summarized Electronic Health Record

Summarized Electronic Health Record (SumEHR) is a KMEHR message, used for the exchange of medical information. It summarizes the minimal set of data that a physician needs in order to understand the medical status of the patient in a few minutes and to ensure the continuity of care. The SumEHR standard was introduced by the Belgian government in 2005 and an EMD software package used by a physician (GP) should be capable of exporting a SumEHR message (KMEHR message level 4) for any given patient.

Coding

The KMEHR-bis standard comprises a set of dictionaries which define the transaction types, heading types, item types, severity levels and administration routes.

3.12.3 Object linkage

The KMEHR-bis standard supports links to either internal or external objects, e.g. an image or another KMEHR-message.

Services

The KMEHR-Bis specification is extended with web services (based on SOAP), which define request and response elements to offer standard web services.

3.12.4 See also

- Belgian Health Telematics Commission (BHTC)
- FLOW
- Electronic health record (EHR)
- Health Level 7
- Clinical Document Architecture (CDA)
- Clinical Data Interchange Standards Consortium (CDISC)

3.12.5 Source

- KMEHR: Kind Messages for Electronic Healthcare Record, Belgian Implementation Standard

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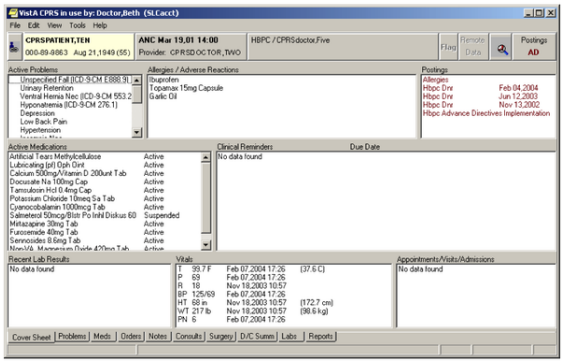
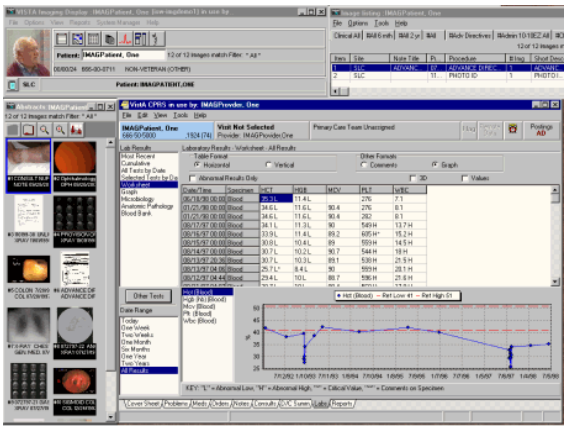
3.14 VistA

This article is about the health information system developed by the US Department of Veterans Affairs . For other uses, see Vista (disambiguation).

The **Veterans Information Systems and Technology Architecture (VISTA)** is a nationwide information system and Electronic Health Record (EHR) developed by the U.S. Department of Veterans Affairs (VA)



The VistA Computerized Patient Record System (CPRS) cover sheet view



Sample patient record view from VistA Imaging

throughout the U.S. to all 1200+ healthcare sites of the Veterans Health Administration (VHA).*[1] The VHA manages the largest integrated healthcare network in the United States,*[2] providing care to over 8 million veterans, employing 180,000 medical personnel and operating 163 hospitals, over 800 clinics, and 135 nursing homes throughout the continental U.S., Alaska, and Hawaii on a single electronic healthcare information network.*[3]

VISTA consists of nearly 180 applications for clinical, financial, administrative, and infrastructure needs in VA integrated into a single, common database, permitting all VA applications to share one single, authoritative data source for all veteran-related care and services. The U.S. Congress has mandated the VA keep all veterans health information in one single authoritative system, and has mandated VISTA as this role.

Over 60% of all physicians trained in the U.S. rotate through the VHA on clinical electives, making VistA the most familiar and widely used EHR in the U.S. Nearly half of all U.S. hospitals that have a complete inpatient/outpatient enterprise-wide implementation of an EHR are VA hospitals using VistA.*[4]*[5]

3.14.1 Features

The Department of Veterans Affairs (VA) has had automated data processing systems, including extensive clinical and administrative capabilities, within its medical facilities since before 1985.*[6] Initially called the Decentralized Hospital Computer Program (DHCP) information system, DHCP was enshrined as a recipient of the Computerworld Smithsonian Award for best use of Information Technology in Medicine in 1995.

VistA supports both ambulatory and inpatient care, and includes several significant enhancements to the original DHCP system. The most significant is a graphical user interface for clinicians known as the Computerized Patient Record System (CPRS), which was released in 1997. In addition, VistA includes computerized order entry, bar code medication administration, electronic prescribing, and clinical guidelines.

CPRS provides a client–server interface that allows health care providers to review and update a patient's electronic medical record. This includes the ability to place orders, including those for medications, special procedures, X-rays, nursing interventions, diets, and laboratory tests. CPRS provides flexibility in a wide variety of settings so that a consistent, event-driven, Windows-style interface is presented to a broad spectrum of health care workers.

Clinical Functions

- Admission Discharge Transfer (ADT)
- Ambulatory Care Reporting
- Anticoagulation Management Tool (AMT)
- Automated Service Connected Designation (ASCD)
- Beneficiary Travel
- Blind Rehabilitation
- Care Management
- Clinical Case Registries
- Clinical Procedures
- Clinical/Health Data Repository (CHDR)
- Computerized Patient Record System (CPRS)
- CPRS: Adverse Reaction Tracking (ART)
- CPRS: Authorization Subscription Utility (ASU)
- CPRS: Clinical Reminders
- CPRS: Consult/Request Tracking
- CPRS: Health Summary
- CPRS: Problem List
- CPRS: Text Integration Utility (TIU)
- Dentistry
- Electronic Wait List Pharm: National Drug File (NDF)
- Emergency Department Integration Software (EDIS)
- Functional Independence Measurement (FIM)
- Group Notes Primary Care Management Module (PCMM)
- HDR – Historical (HDR-Hx)
- Home Based Primary Care (HBPC)

- Home Telehealth
- Immunology Case Registry (ICR)
- Incomplete Records Tracking (IRT)
- Intake and Output Scheduling
- Laboratory Shift Handoff Tool
- Laboratory: Anatomic Pathology
- Laboratory: Blood Bank
- Laboratory: Blood Bank Workarounds
- Laboratory: Electronic Data Interchange (LEDI)
- Laboratory: Emerging Pathogens Initiative (EPI)
- Laboratory: Howdy Computerized Phlebotomy Login Process
- Laboratory: National Laboratory Tests (NLT) Documents and LOINC Request Form
- Laboratory: Point of Care (POC)
- Laboratory: Universal Interface
- Laboratory: VistA Blood Establishment Computer Software (VBECS)
- Lexicon Utility
- Medicine
- Mental Health (YS)
- Methicillin Resistant Staph Aurerus (MRSA)
- Mobile Electronic Documentation (MED)
- Nationwide Health Information Network Adapter (NHIN)
- Nursing
- Nutrition and Food Service (NFS)
- Oncology
- Patient Appointment Info. Transmission (PAIT)
- Patient Assessment Documentation Package (PADP)
- Patient Care Encounter (PCE)
- Patient Record Flags
- Pharm: Automatic Replenish / Ward Stock (AR/WS)
- Pharm: Bar Code Medication Administration (BCMA)
- Pharm: Benefits Management (PBM)
- Pharm: Consolidated Mail Outpatient Pharmacy
- Pharm: Consolidated Mail Outpatient Pharmacy
- Pharm: Controlled Substances
- Pharm: Data Management (PDM)
- Pharm: Drug Accountability
- Pharm: Inpatient Medications
- Pharm: Outpatient Pharmacy
- Pharm: Prescription Practices (PPP)
- Prosthetics
- Quality Audiology and Speech Analysis and Reporting (QUASAR)
- Radiology / Nuclear Medicine
- RAI/MDS
- Remote Order Entry System (ROES)
- Social Work
- Spinal Cord Dysfunction
- Standards & Terminology Services (STS)
- Surgery
- Traumatic Brain Injury (TBI)
- Virtual Patient Record
- VistA Imaging System
- VistAWeb
- Visual Impairment Service Team (VIST)
- Vitals / Measurements
- Women's Health

Financial-Administrative Functions

- Accounts Receivable (AR)
- Auto Safety Incident Surv Track System (ASISTS)
- Automated Information Collection System (AICS)
- Automated Medical Information Exchange (AMIE)
- Clinical Monitoring System Integrated Billing (IB)
- Compensation Pension Record Interchange (CAPRI)
- Current Procedural Terminology (CPT) Library
- Decision Support System (DSS) Extracts
- Diagnostic Related Group (DRG) Grouper

- Electronic Claims Management Engine (ECME)
- Engineering (AEMS / MERS) Police and Security
- Enrollment Application System Quality Management Integration Module
- Equipment / Turn-In Request
- Event Capture Release of Information (ROI) Manager
- Fee Basis
- Fugitive Felon Program (FFP)
- Generic Code Sheet (GCS)
- Health Eligibility Center (HEC)
- Hospital Inquiry (HINQ)
- ICD-9-CM
- Incident Reporting
- Income Verification Match (IVM)
- Integrated Patient Funds
- Occurrence Screen
- Patient Representative
- Personnel and Accounting Integrated Data (PAID)
- Record Tracking
- Veterans Identification Card (VIC/PICS)
- Voluntary Service System (VSS)
- WebHR
- Wounded Injured and Ill Warriors

Infrastructure Functions

- Capacity Management Tools
- Duplicate Record Merge: Patient Merge Name Standardization
- Electronic Error and Enhancement Reporting (E3R)
- Enterprise Exception Log Service (EELS)
- FatKAAT
- FileMan
- FileMan Delphi Components (FMDC)
- Health Data Informatics
- Health Level 7 (HL7) (VistA Messaging)
- Institution File Redesign (IFR)
- KAAJEE
- Kernel
- Kernel Delphi Components (KDC)
- Kernel Toolkit
- Kernel Unwinder
- List Manager
- M-to-M Broker
- MailMan
- Master Patient Index (MPI)
- Medical Domain Web Services (MDWS) (MWVS*2)
- National Online Information Sharing (NOIS)
- National Patch Module
- Network Health Exchange (NHE)
- Patient Data Exchange (PDX)
- Remote Procedure Call (RPC) Broker
- Resource Usage Monitor
- Single Signon/User Context (SSO/UC)
- SlotMaster (Kernel ZSLOT)
- SQL Interface (SQLI)
- Standard Files and Tables
- Statistical Analysis of Global Growth (SAGG)
- Survey Generator
- System Toolkit (STK)
- VistA Data Extraction Framework (VDEF)
- VistALink
- XML Parser (VistA)

Patient Web Portal Functions

- Clinical Information Support System (CISS)
- Electronic Signature (ESig) Person Services
- HealtheVet Web Services Client (HWSC) Registries
- My HealtheVet Spinal Cord Injury and Disorders Outcomes (SCIDO)
- National Utilization Management Integration (NUMI)

- Occupational Health Record-keeping System (OHRS)
- Patient Advocate Tracking System (PATS)
- VA Enrollment System (VES)
- Veterans Personal Finance System (VPFS)

3.14.2 Achievements

For its development of VistA, the United States Department of Veterans Affairs (VA) / Veterans Health Administration (VHA) was named the recipient of the prestigious Innovations in American Government Award presented by the Ash Institute of the John F. Kennedy School of Government at Harvard University in July, 2006. The VistA electronic medical records system is estimated to improve efficiency by 6% per year, and the monthly cost of the EHR is offset by eliminating the cost of even a few unnecessary tests or admissions.*[7]*[8]

The adoption of VistA has allowed the VA to achieve a pharmacy prescription accuracy rate of 99.997%, and the VA outperforms most public sector hospitals on a variety of criteria, enabled by the implementation of VistA.*[9]

VA hospitals using VistA are one of only thirteen hospital systems that have achieved the qualifications for HIMSS stage 7, the highest level of electronic health record integration,*[10]*[11] while a non-VA hospital using VistA is one of only 42 US hospitals that has achieved HIMSS stage 6.*[12]*[13]

3.14.3 Licensing and dissemination

The VistA system is public domain software, available through the Freedom Of Information Act directly from the VA website*[14] or through a growing network of distributors, such as the OSEHRA VistA-M.git tree.

3.14.4 VistA modules and projects

Database backend

VistA was developed using the M or MUMPS language/database. The VA currently runs a majority of VistA systems on the proprietary InterSystems Caché version of MUMPS, but an open source MUMPS database engine, called GT.M, for Linux and Unix computers has also been developed. Although initially separate releases, publicly available VistA distributions are now often bundled with the GT.M database in an integrated package. This has considerably eased installation. The free, open source nature of GT.M allows redundant and cost-effective failsafe database implementations, increasing reliability for complex installations of VistA.

Database projections

An open source project called EsiObjects has also allowed the (ANSI- Standard) MUMPS language and database technology to evolve into a modern object-oriented language (and persistent-object store) that can be integrated into mainstream, state-of-the-art technologies. For the Caché MUMPS database, a similar object-oriented extension to MUMPS called Caché ObjectScript has been developed. Both of these have allowed development of the MUMPS database environment (by programmers) using modern object-oriented tools.

M2Web is an open source web gateway to MUMPS for use with VistA.

A free open source module from M/Gateway called MGWSI has been developed to act as a gateway between GT.M, Cache, or M21 MUMPS databases and programming tools such as PHP, ASP.NET, or Java, in order to create a web-based interface.

Patient Web Portal

MyHealtheVet is a web portal that allows veterans to access and update their personal health record, refill prescriptions, and schedule appointments. This also allows veterans to port their health records to institutions outside the VA health system or keep a personal copy of their health records, a Personal Health Record (PHR).

VistA Imaging

The Veterans Administration has also developed VistA Imaging, a coordinated system for communicating with PACS (radiology imaging) systems and for integrating others types of image-based information, such as EKGs, pathology slides, and scanned documents, into the VistA electronic medical records system. This type of integration of information into a medical record is critical to efficient utilization.*[15]

It can be used independently or integrated into the VistA electronic health record system (as is done in VA health facilities).

3.14.5 Deployments and uses

Role in development of a national healthcare network

The VistA electronic healthcare record has been widely credited for reforming the VA healthcare system, improving safety and efficiency substantially. The results have spurred a national impetus to adopt electronic medical records similar to VistA nationwide.

VistA Web collectively describes a set of protocols that in 2007 was being developed and used by the VHA to transfer data (from VistA) between hospitals and clinics

within the pilot project. This is the first effort to view a single patient record so that VistA becomes truly interoperable among the more than 128 sites running VistA today.

BHIE enables real-time sharing of electronic health information between DoD and VA for shared patients of allergy, outpatient pharmacy, demographic, laboratory, and radiology data. This became a priority during the Second Iraq War, when a concern for the transition of healthcare for soldiers as they transferred from active military status to veteran status became a national focus of attention.*[16]

A Clinical Data Repository/Health Data Repository (CHDR) allows interoperability between the DoD's Clinical Data Repository (CDR) & the VA's Health Data Repository (HDR). Bidirectional real time exchange of computable pharmacy, allergy, demographic and laboratory data occurred in phase 1. Phase 2 involved additional drug–drug interaction and allergy checking. Initial deployment of the system was completed in March 2007 at the El Paso, Augusta, Pensacola, Puget Sound, Chicago, San Diego, and Las Vegas facilities.

The combination of VistA and the interoperable projects listed above in the VA/DoD systems will continue to expand to meet the objectives that all citizens will have an electronic record by 2014.

Because of the success of these programs, a national move to standardize healthcare data transmission across the country was started. Text-based information exchange is standardized using a protocol called HL7 (Health Level 7), which is approved by the American National Standards Institute. DICOM is an international image communications protocol standard. VistA is compliant with both.

VistA has been interfaced with commercial off-the-shelf products, as well. Standards and protocols used by VA are consistent with current industry standards and include HL7, DICOM, and other protocols.

Tools for CCR/CCD support have been developed for VistA, allowing VistA to communicate with other EHRs using these standardized information exchange protocols.*[17] This includes the Mirth open source cross platform HL7 interface and NHIN Connect, the open source health information exchange adaptor.

In 2009, a project was undertaken to facilitate EHR communication between the VA (using VistA) and Kaiser Permanente (using Epic) using NHIN Connect.*[18] (Both VistA and the commercial EHR Epic use a derivative of the MUMPS database, thereby facilitating data exchange.) When completed, two of the largest medical record systems in the US will be able to exchange health data. Public-domain VistA derivatives are also expected to be able to use NHIN Connect.

The VistA EHR has been used by the VA in combination with Telemedicine to provide surgical care to rural areas in Nebraska and Western Iowa over a 400,000-square-mile (1,000,000 km^2) area.*[19]

Usage in non-governmental hospitals

Under the Freedom of Information Act (FOIA), the VistA system, the CPRS graphical interface, and unlimited ongoing updates (500–600 per year) are provided as public domain software.*[20]

This was done by the US government in an effort to make VistA available as a low cost Electronic Health Record (EHR) for non-governmental hospitals and other healthcare entities.

With funding from The Pacific Telehealth & Technology Hui, the Hui 7 produced a version of VistA that ran on GT.M in a Linux operating system, and that was suitable for use in private settings. VistA has since been adapted by companies such as Blue Cliff, DSS, Inc., Medsphere, and Sequence Managers Software to a variety of environments, from individual practices to clinics to hospitals, to regional healthcare co-ordination between far-flung islands. In addition, VistA has been adopted within similar provider environments worldwide. Universities, such as UC Davis and Texas Tech implemented these systems. A non-profit organization, WorldVistA, has also been established to extend and collaboratively improve the VistA electronic health record and health information system for use outside of its original setting.

VistA (and other derivative EMR/EHR systems) can be interfaced with healthcare databases not initially used by the VA system, including billing software, lab databases, and image databases (radiology, for example).

VistA implementations have been deployed (or are currently being deployed) in non-VA healthcare facilities in Texas,*[21] Arizona,*[22] Florida, Hawaii,*[23] New Jersey,*[24] Oklahoma,*[23] West Virginia,*[25]*[26] California,*[27]*[28] New York,*[29] and Washington, D.C.*[23]*[30]

In one state, the cost of a multiple hospital VistA-based EHR network was implemented for one tenth the price of a commercial EHR network in another hospital network in the same state ($9 million versus $90 million for 7–8 hospitals each). (Both VistA and the commercial system used the MUMPS database).*[31]

VistA has even been adapted into a Health Information System (VMACS) at the veterinary medical teaching hospital at UC Davis.*[32]

International deployments

VistA software modules have been installed around the world, or are being considered for installation, in healthcare institutions such as the World Health Organization,*[25] and in countries such as Mex-

ico,*[23]*[25]*[33] Samoa,*[23] Finland, Jordan,*[34] Germany,*[35] Kenya,*[25] Nigeria,*[36] Egypt,*[23] Malaysia, India,*[37] Brazil, Pakistan,*[30] and Denmark.*[38]

In September 2009, Dell Computer bought Perot Systems, the company installing VistA in Jordan (the Hakeem project).*[39]

3.14.6 History

The concept that eventually became VistA was initiated and planned at the beginning of the 1970s by the National Center for Health Services Research and Development of the U.S. Public Health Service (NCHSR&D/PHS). (The NCHSR&D is now known as the Agency for Healthcare Research and Quality (AHRQ).)

As a proof of concept, the U.S. Navy's clinic at the Brunswick Naval Air Station had used an early version of the system software to develop an operational, automated, clinic-management and medical-record system that was "paperless".

The National Center for Health Sciences Research and Development then turned to an agency of the U.S. Department of Commerce, the National Bureau of Standards (NBS, reorganized in 1988 as the National Institute of Standards and Technology), to turn the systems-technology strategy into a systems-architecture design.

Under the farsighted leadership of the VA's Chief Medical Director, Dr. John Chase, the VA's Department of Medicine and Surgery (now known as the Veterans Health Administration (VHA)), then agreed to deploy the system at the largest medical system of that time, the VA hospitals.

Both Dr. Robert Kolodner (National Health Information Technology Coordinator)*[40] and George Timson (an architect of VistA who has been involved with it since the early years) date VistA's actual architecture genesis, then, to 1977.*[41]*[42] The program was launched in 1978 with the deployment of the initial modules in about twenty VA Medical Centers. The program was named the Decentralized Hospital Computer Program (DHCP) in 1981.

The physicians in VA Medical Centers, with leadership from the National Association of VA Physicians (NAVAP, renamed NAVAPD in 1989 when Dentists were added) and its Executive Director, Dr. Paul Shafer, made sure that the VA understood the importance of clinician-directed development and refinement of this new clinical-information system.

In December 1981, Congressman Sonny Montgomery of Mississippi arranged for the Decentralized Hospital Computer Program (DHCP) to be written into law as the medical-information systems development program of the VA. VA Administrator Robert P. Nimmo signed an Executive Order in February 1982 describing how the DHCP was to be organized and managed within the VA's Department of Medicine and Surgery.

In consultation with F. Whitten Peters and Vincent Fuller of the Williams and Connolly law firm, it was established at the beginning of the 1980s that the software existing in the VA (derived from the PHS projects) was legally in the public domain and must be made available without proprietary or other restrictions to other government and private-sector organizations for their use.

In conjunction with the VA's DHCP development, the (IHS) Indian Health Service deployed a system built on and augmenting DHCP throughout its Federal and Tribal facilities as the Resource and Patient Management System (RPMS). This implementation emphasized the integration of outpatient clinics into the system, and many of its elements were soon re-incorporated into the VA system (through a system of technology sharing). Subsequent VistA systems therefore included elements from both RPMS and DHCP. Health IT sharing between VA and IHS continues to the present day.

The U.S. Department of Defense (DoD) then contracted with Science Applications International Corporation (SAIC) for a heavily modified and extended form of the DHCP system for use in DoD healthcare facilities, naming it the Composite Health Care System (CHCS).

Meanwhile, in the early 1980s, major hospitals in Finland*[43] were the first institutions outside of the United States to adopt and adapt the VistA system to their language and institutional processes, creating a suite of applications called MUSTI and Multilab. (Since then, institutions in Germany, Egypt,*[23] Nigeria,*[36] and other nations abroad have adopted and adapted this system for their use, as well.)

The name "VistA" (Veterans Health Information System and Technology Architecture) was adopted by the VA in 1994, when the Under Secretary for Health of the U.S. Department of Veterans Affairs (VA), Dr. Ken Kizer, renamed what had previously been known as the Decentralized Hospital Computer Program (DHCP).

The four major adopters of VistA – VA (VistA), DoD (CHCS), IHS (RPMS), and the Finnish Musti consortium – each took VistA in a different direction, creating related but distinct "dialects" of VistA. VA VistA and RPMS exchanged ideas and software repeatedly over the years, and RPMS periodically folded back into its code base new versions of the VA VistA packages. These two dialects are therefore the most closely related. The Musti software drifted further away from these two but retained compatibility with the infrastructure of RPMS and VA VistA (while adding additional GUI and web capabilities to improve function). Meanwhile, the CHCS code base diverged from that of the VA's VistA in the mid-eighties and has never been reintegrated. The VA and the DoD had been instructed for years to improve the sharing of medical information between the two systems, but

for political reasons made little progress toward bringing the two dialects back together. More recently, CHCS's development was brought to a complete stop by continued political opposition within the DoD, and it has now been supplanted by a related, but different, system called AHLTA. While AHLTA is the new system for DoD, the core systems beneath AHLTA (for Computerized Physician Order Entry, appointing, referral management, and creation of new patient registrations) remain those of the underlying CHCS system. (While some ongoing development has occurred for CHCS, the majority of funds are consumed by the AHLTA project.) Thus, the VistA code base was split four ways.

Many VistA professionals then informally banded together as the "Hardhats" (a name the original VistA programmers used for themselves) to promote that the FOIA (Freedom of Information Act) release of VA VistA (that allows it to be in the public domain) be standardized for universal usage.

WorldVistA was formed from this group and was incorporated in March 2003 as a non-profit corporation. This allowed the WorldVistA board of directors to pursue certain activities (obtaining grants, creating contracts, and making formal alliances) that they otherwise could not pursue as an informal organization. It is, however, an organization independent of the VA system and its version of VistA therefore differs from that of the VA's. Nevertheless, it maintains as an objective that its public version be compatible (interoperable) with the VA's official version. It has developed packages of WorldVistA for multiple operating systems, including Linux (Debian/Ubuntu and Red Hat) -based and Microsoft Windows-based operating systems. Co-operation with the maintainers and vendors of OpenVistA, another widely deployed open source public version of VistA, helps maintain interoperability and a standardized framework.

In 2011 the Open Source Electronic Health Record Agent (OSEHRA) project was started (in cooperation with the Department of Veterans Affairs) to provide a common code repository for VistA (and other EHR and health IT) software.*[44]

Therefore, it is through the joint achievement of thousands of clinicians and professional systems experts from the United States and other nations, many of them volunteers, that the VistA system has developed.

3.14.7 Supporters of VistA

There have been many champions of VistA as the electronic healthcare record system for a universal healthcare plan. VistA can act as a standalone system, allowing self-contained management and retention of healthcare data within an institution. Combined with BHIE (or other data exchange protocol) it can be part of a peer-to-peer model of universal healthcare. It is also scalable to be used as a centralized system (allowing regional or even national centralization of healthcare records). It is, therefore, the electronic records system most adaptable to a variety of healthcare models.

In addition to the unwavering support of congressional representatives such as Congressman Sonny Montgomery of Mississippi, numerous IT specialists, physicians, and other healthcare professionals have donated significant amounts of time in adapting the VistA system for use in non-governmental healthcare settings.

The ranking member of the House Veterans Affairs Committee's Oversight and Investigation Subcommittee, Rep. Ginny Brown-Waite of Florida, recommended that the Department of Defense (DOD) adopt VA's VistA system following accusations of inefficiencies in the DOD healthcare system. The DOD hospitals use Armed Forces Health Longitudinal Technology Application (AHLTA) which has not been as successful as VistA and has not been adapted to non-military environments (as has been done with VistA).*[16]

In November 2005, the U.S. Senate passed the Wired for Health Care Quality Act, introduced by Sen. Enzi of Wyoming with 38 co-sponsors, that would require the government to use the VA's technology standards as a basis for national standards allowing all health care providers to communicate with each other as part of a nationwide health information exchange. The legislation would also authorize $280 million in grants, which would help persuade reluctant providers to invest in the new technology.*[45] There has been no action on the bill since December 2005. Two similar House bills were introduced in late 2005 and early 2006; no action has been taken on either of them, either.*[46]

In late 2008, House Ways and Means Health Subcommittee Chair Congressman Pete Stark (D-CA) introduced the Health-e Information Technology Act of 2008 (H.R. 6898) that calls for the creation of a low-cost public IT system for those providers who do not want to invest in a proprietary one.*[47]

In April 2009, Sen. John D. Rockefeller of West Virginia introduced the Health Information Technology Public Utility Act of 2009 calling for the government to create an open source electronic health records solution and offer it at little or no cost to safety-net hospitals and small rural providers.*[48]*[49]

3.14.8 VistA Derivatives

- Astronaut VistA – an installer suite for different versions of VistA, with multiple enhancements and bug fixes.
- WorldVistA or WorldVistA EHR
- OpenVistA (Medsphere)
- Osehra-Vista (OSEHRA)

- vxVistA (Document Storage Systems, Inc.)

An effort has been made by the Astronaut team, WorldVistA team, members of the VistA Software Alliance, and the OSEHRA to standardize structure between the platform derivatives to allow for future interoperability, as part of the vision for a national healthcare network record system.

3.14.9 See also

- Electronic health record
- Health informatics
- MUMPS
- Veterans Health Administration
- United States Department of Veterans Affairs
- FileMan
- VA Kernel
- GNUmed
- GNU Health

3.14.10 References

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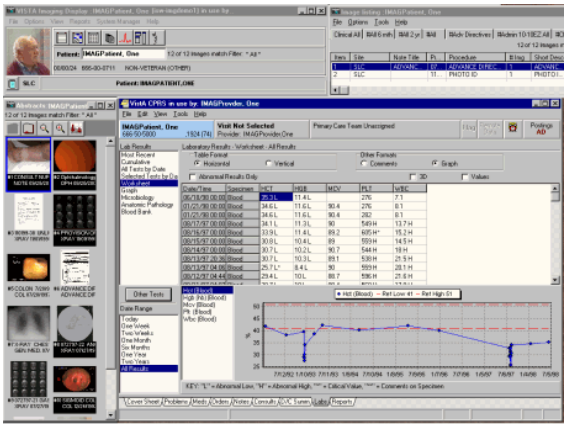
3.14.11 External links

- Vistapedia: the WorldVistA Wiki
- Hardhats – a VistA user community
- Hardhats Google Group – a forum to discuss installation of WorldVistA
- VISTA Monograph (Veterans Administration)
- VistA Monograph wiki (OLPC project)
- VistA Software Alliance (VistA Software Vendor Trade Organization)
- OSEHRA – Open Source Electronic Health Record Agent, a code repository for VistA
- VistA / CPRS Demo site (Department of Veterans Affairs)
- VA VistA software FTP site (Department of Veterans Affairs)
- The Pacific Telehealth & Technology Hui
- VistA Imaging overview (Department of Veterans Affairs)
- BHIE – Bidirectional Health Information Exchange protocols of the Department of Veterans Affairs
- Why is VistA good?
- "Innovations Award" (PDF). Retrieved July 25, 2006. – Ash Institute News Release
- VistA Glossary LiuTiu Medical Administrative Lexicon (Brokenly translated into English from Russian)
- Ubuntu Doctors Guild Information about implementing VistA and other open source medical applications in Ubuntu Linux

Videos about VistA:

- VistA at the VA
- History of Vista Architecture Interview with Tom Munnecke
- Interview with Rob Kolodner regarding VistA's potential for the National Health Information Network
- Impact of VistA Interview with Dr. Ross Fletcher
- Interview with Philip Longman
- Events leading up to the development of VistA Interview with Henry Heffernan
- History of Vista Interview with Ruth Dayhoff
- Early development of the Decentralized Hospital Computer Program Interview with Marty Johnson
- Early days of the VA "Underground Railroad" Interview with Tom Munnecke

3.15 VistA imaging



Sample patient record view from VistA Imaging

VistA Imaging is an FDA-listed Image Management system used in the Department of Veterans Affairs healthcare facilities nationwide. It is one of the most widely used image management systems in routine healthcare use, and is used to manage many different varieties of images associated with a patient's medical record.

3.15.1 Hardware requirements

The VistA Imaging System uses hardware components to provide short- and long-term storage. It takes advantage of network servers for storage. It uses a DICOM gateway system to communicate with commercial Picture Archiving and Communication Systems (PACS) and modalities such as CT, MR, and Computed Radiography (x-ray) devices for image capture. It utilizes a background processor for moving the images to the proper storage device and for managing storage space.

3.15.2 Types of data managed

The system not only manages radiologic images, but also is able to capture and manage EKGs, pathology images, gastroenterology (endoscopic) images, laparoscopic images, scanned paperwork, or essentially any type of health care image.

3.15.3 Integration with Electronic Health Record systems

VistA Imaging is currently integrated into the VistA EMR (electronic medical record) system used nationwide in Department of Veterans Affairs hospitals. This integration is able to provide increased efficiency of retrieval of images.* [1] It has also been used as a separate software package and can be used with EHRs other than VistA.

VistA Imaging now connects to a nationwide backbone that allows clinicians to access the 350 million images stored in the VA system via Remote Image View software.* [2]

The VA has developed interfaces for more than 250 medical devices in VistA Imaging, the images from which can be accessed through the desktop VistA Imaging Viewer. The Department of Defense will use the VistA Imaging Viewer to enhance its own EHR.* [2]

3.15.4 Usage in a National Network of Healthcare Records

As part of the US national mandate to co-ordinate care between Department of Defense and the VA, VistA Imaging is forming a cornerstone of the effort to exchange medical imagery between the two systems. "When soldiers come back from Iraq and Afghanistan and eventually enter the VA system, images will be able to move from DOD to VA seamlessly." Eventually, DOD and VA should be able to share all image file types from all sites. Additional enhancements to VistA Imaging include development of a central archive for all VA images (whether acquired through VistA or a commercial system) and new indexing and search capabilities.* [3]

3.15.5 Availability

The software for VistA Imaging has been made available through the Freedom of Information Act so that it is in the public domain. Due to its designation as a medical device, however, it can not be designated as free open source software and therefore can not be altered or implemented without FDA approval.

Although it can be used in healthcare facilities that are outside the Department of Veterans Affairs, this is possible only if the proprietary modules that have been integrated into it are also licensed and implementation is registered with the FDA. This has effectively limited its use to government institutions who have licensed the proprietary modules.

The source code can be downloaded from the OSEHRA VistA-M.git tree.

3.15.6 Proprietary modules required

VistA Imaging uses proprietary modules not in the public domain. This makes its public domain use limited.

3.15.7 Information retrieval after a natural disaster

The VistA Imaging system was robust enough to be restored after Hurricane Katrina damaged the data facility

at the New Orleans VA.*[4] This type of backup proved superior to a paper record system.

3.15.8 References

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- "DICOM devices approved for use with VistA Imaging" (PDF).
- "VistA Imaging in the IHS RPMS EHR". Nov 2009.

3.16 VistA Web

VistAWeb is a portal accessible through CPRS (Computerized Patient Recordkeeping System), the graphical user interface for the *Veterans Health Information Systems and Technology Architecture* (VistA), the electronic health record used throughout the United States Department of Veterans Affairs (VA) medical system (known as the Veterans Health Administration (VHA)).

This portal has been implemented throughout the VA system, allowing healthcare providers at remote VA facilities to view records contained within the VistA electronic health record system at the patient's primary facility.

As originally created, the VA health systems has 21 regional data systems (VISN), each with some differences in data collection and storage. The usage of VistA throughout the VA has helped to standardize records, but there has until recently not been an easy way for accessing records from a different VISN service area.

If a patient travels or is injured or sick and visits a VA facility far from their home, VistAWeb will allow the physician or other healthcare provider access to the records at that patient's home institution.

3.16.1 Introduction

Veterans Health Information Systems and Technology Architecture (VistA) VistAWeb is an intranet web application used to review remote patient information found in VistA, the Federal Health Information Exchange (FHIE) system, and the Health Data Repository (HDR) databases. To a large extent, VistAWeb mirrors the reports behavior of the Computerized Patient Record System (CPRS) and Remote Data View (RDV). However, by permitting a more robust and timely retrieval of remote-site patient data, VistAWeb is also an enhancement to CPRS/RDV.

There are three ways to access VistAWeb. VistAWeb can be made available by adding it to the CPRS Tools Menu, and it can be selected as the default method of retrieving data from the Remote Data Available button in CPRS. These two methods are referred to as CPRS-spawned versions of VistAWeb. They are compliant with the Health Level 7 (HL7) Clinical Context Object Workgroup (CCOW) standards and therefore maintain context with the patient selected in CPRS. As a third option, VistAWeb can be accessed in a standalone mode from its website at https://vistaweb.med.va.gov/.

The standalone version of VistAWeb is connected to neither CPRS nor the clinical context management application. Standalone VistAWeb serves an important function for users who have been granted special access to multiple sites, such as for National Programs, Veterans Administration (VA) researchers, and others.

3.16.2 Usage for record access following natural disaster

VistAWeb was also made available broadly, though temporarily, to assist clinical staff with the retrieval of patient information from the sites affected by damage caused by hurricane Katrina.

*[1]

3.16.3 Usage for record access from DoD

VistAWeb was also expanded for to access patient records from the DoD AHLTA patient record system in 2009. This relied on mapping data from AHLTA via a bidirectional data exchange system to VistA. Due to errors in the bidirectional exchange system, erroneous data was transmitted to the VA, causing this remote viewer function from DoD sites to be closed.*[2]*[3]

3.16.4 Availability

The VistAWeb package is distributed in the public domain as a module of the VistA software package under

the Freedom of Information Act (FOIA). It is therefore available from the VA FTP site, from the VA software distribution office, and in bundled packages. Its capabilities, therefore, can be achieved by a healthcare institution that installs the VistA electronic health record.

3.16.5 See also

- Electronic health record
- Health informatics
- MUMPS
- Veterans Health Administration
- United States Department of Veterans Affairs

3.16.6 References

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3.16.7 External links

- "VISTA Monograph". *Veterans Administration*.
- "VistA / CPRS Demo site". (Department of Veterans Affairs)
- "VA VistA software FTP site". (Department of Veterans Affairs)
- "VistA Software Alliance". (VistA Software Vendor Trade Organization)
- "The Pacific Telehealth & Technology Hui".
- "WorldVistA". - Home of the WorldVistA EHR
- "WorldVistA Wiki".
- "Hardhats". - a VistA user community
- "Innovations Award" (PDF). Retrieved July 25, 2006. - Ash Institute News Release
- "Sequence Managers Software". Retrieved June 11, 2007.—provides a VistA-based EMR package, based in Raleigh, North Carolina
- "VistA Imaging overview". *Department of Veterans Affairs*.
- "BHIE". Bidirectional Health Information Exchange protocols of the Department of Veterans Affairs

3.17 WorldVistA

WorldVistA is an open source implementation of the Veteran Administration's Electronic Health Record system intended for use in health care facilities outside the VA.

3.17.1 Background

The US Veterans Administration developed the most widely distributed electronic health record used in the US, the Veterans Health Information Systems and Technology Architecture (VistA). In an effort to make the system widely available to institutions outside the Veterans Administration health system, the software code was placed in the Public Domain under the Freedom of Information Act.

The foundation for the WorldVistA EHR was formed to extend and collaboratively improve the VistA electronic health record and health information system for use outside of its original setting. It was originally developed as part of the VistA-Office project, a collaborative effort funded by the United States Centers for Medicare and Medicaid Services (CMS), an agency of the US Department of Health and Human Services (DHHS).

WorldVistA EHR VOE/ 1.0 is based on and compatible with the U.S. Department of Veterans Affairs (VA) world-renowned EHR, Veterans Health Information Systems and Technology Architecture (VistA). A fully open-source (GPL v2 licensed) project, WorldVistA has also developed software modules (such as pediatrics, obstetrics, and other functions) not used in the veterans' healthcare setting.

In 2006, WorldVistA EHR VOE/ 1.0 was the only open source EHR that met Certification Commission for Healthcare Information Technology (CCHITSM) ambulatory electronic health record (EHR) criteria, and in January 2008, it was released with full CCHITSM EHR.

As a free product developed in co-operation with the US government, WorldVistA is not marketed in a similar fashion to commercial EHRs.

3.17.2 Core VistA functions

- patient registration
- clinical reminders for chronic disease management

- clinical order entry
- progress note templates
- results reporting

3.17.3 Customizable functions

The structure of WorldVistA is modular, and a wide variety of customization is possible. Because it is fully open source, this can be done without restriction (although CCHIT certification is granted only to the officially maintained package).

- ability to interface to existing practice management / billing systems, lab services and other applications
- scanning and inclusion of scanned documents into the medical record
- prescription finishing and faxing
- clinical quality measure reporting capabilities
- support for disease management, using clinical reminders
- templates for obstetrics/gynecology (OB/GYN) and pediatrics care

3.17.4 Server platforms

For Linux-based servers, WorldVistA server uses the (free open source) Fidelity GT.M MUMPS database, available as an integrated package along with WorldVistA Server. This software is part of the VistA Public Domain software, and does not require licensing.

For Windows-based servers, WorldVistA can be implemented used the commercial Caché MUMPS database, which requires a database license and software from Intersystems Corporation.

For Mac OS-X-based servers, a development effort to port GT.M (and the Server software) to that platform has begun.

3.17.5 Client platforms

The Client software is an implementation of CPRS, which is Windows-based. This allows Windows terminals to access the central server database. This software is part of the VistA Public Domain software, and does not require licensing.

For Linux terminals, CPRS can be run as a Wine package or from within a virtual machine.

A separate (Windows-based) module is available to capture and view vital signs as well as graphing of other clinical data. This is meant to be used on client terminals.

A separate (Windows-based) module allows the scanning, capture and integration of paper documents as part of an individuals medical record. It can also be used to add a variety of non-diagnostic quality images to the medical record. This is meant to be used on client terminals.

3.17.6 Development history

WorldVistA is developed by a series of physicians (and other medical professionals) and software professionals that donate their efforts as volunteers. This group loosely referred to themselves as Hardhats (and continues to do so) before the name of the project was officially changed to WorldVistA.

WorldVistA has developed and distributes a "toaster" version of VistA, which is a self-contained software package that integrates both the MUMPS database (GT.M version) and the VistA software.

In 2009, the self-installing Linux toaster version was enhanced with a GUI-based patient registration module, web interface, and other enhancements, and incorporated into a self-installing package for both Debian/Ubuntu and Red Hat Linux. This freely available version of WorldVistA is known as Astronaut VistA. This version is packaged with both an enhanced GUI as well as a web interface (which allows connection through an intranet or through the Internet). An introduction to this package is here in a PDF slide presentation.

A similar package for Windows-based servers is in alpha (early development) stage.

3.17.7 Grants opportunities to help further development

- NIH grants -- Supported by the American Recovery & Reinvestment Act of 2009 (ARRA), NIH grants can be used efforts to further technology that advances the goals of the NIH
- Robert Woods Johnson Foundation -- This foundation has a goal of helping integrate personal access to electronic health records nationwide, similar to the VA's HealtheVet project.

3.17.8 Adoption

- Clinica Adelante implemented the open source version of VistA for its 30,000 member community health clinic, and has testified before the US Congress regarding its success.
- Oroville Hospital is installing the WorldVistA version into a co-ordinated hospital and clinic system.

3.17.9 References

3.17.10 External links

- "WorldVistA" . - Home of the WorldVistA EHR
- "Vistapedia: the WorldVistA Wiki" .
- "Hardhats" . - a WorldVistA user community
- "Astronaut WorldVistA on Ubuntu" . - Tips for installation of the Astronaut WorldVistA server on Ubuntu/Kubuntu Linux (from Ubuntu Doctors Guild)

3.18 ZEPRS

The **Zambia Electronic Perinatal Record System** (**ZEPRS**) is an Electronic Medical Record (EMR) system used by public obstetric clinics and a hospital (the University Teaching Hospital) in Lusaka, Zambia.

3.18.1 Background

In early 2001 a team of physicians at the University of Alabama at Birmingham (UAB) and visiting Zambian physician Dr. Moses Sinkala conceived the idea based on a successful electronic perinatal record system that the UAB had developed and proven in clinics in Birmingham. in July 2001 the Bill & Melinda Gates Foundation awarded a grant to the UAB to develop a similar system to serve public obstetric clinics in Lusaka, Zambia.*[1]

The UAB team solicited proposals for the technical design and implementation of the system from several private sector information technology firms, including Electronic Data Systems, before awarding a contract to RTI International (RTI), a large 501(c)3 not-for-profit research organization based in Research Triangle Park, North Carolina. Other project partners included the Center for Infectious Disease Research in Zambia (CIDRZ) and the Lusaka District Health Management Team of the Zambian Central Board of Health.

3.18.2 Objectives

ZEPRS was designed to improve maternal and perinatal outcomes by:

1. Improving perinatal care for women and postnatal care for neonates by:
   (a) Promoting adherence to good standard of care practices
   (b) Identifying and document potential medical/obstetrical problems so that effective therapies can be administered
   (c) Improving communication and referrals among providers
   (d) Enhancing monitoring and evaluation of outcomes, clinics, and providers
2. Improving efficiency, completeness, accuracy of documentation and reporting

3.18.3 Major components

ZEPRS achieves these objectives by providing the following:

- An electronic patient record system with patient record database shared among facilities
- A system that guides clinicians through the Zambian standard of care
- Intelligent rules that alert clinicians to problems and recommend patient referral when appropriate
- Standard & ad hoc reporting for supportive supervision, surveillance, and analysis
- An electronic-first system used by clinicians during the course of patient care
- An electronic referral system to improve the efficiency and effectiveness of referrals

ZEPRS components include a high-speed point-to-point voice and data wireless network that interconnects facilities; wired and wireless networks within facilities; a data center managed by CIDRZ; and an electronic perinatal record system with integrated patient referral system.

ZEPRS uses a tabbed user interface and role-based access control system to enable several clinicians to share the same computer to retrieve and enter data for different patients.

3.18.4 Software architecture

ZEPRS has been developed using the Java programming language. Other technologies used include AJAX, Quartz , MySQL, and others. ZEPRS has its own content management system called DynaSite, that makes it easy to add forms, fields, form flows, and business rules without programming. RTI has developed a locally installable version of the software using the Eclipse Rich Client Platform (RCP) and the Apache Derby embedded database. This version uses the free and open source zcore platform, which uses an implementation of RSS to transmit data over intermittent networks, such as mobile phone networks.

3.18.5 Development history

RTI worked with South African firm Communications Solutions (Comsol) to conduct a wireless site survey of all facilities, and to design a line-of-sight wireless network to connect them. By March 2003 this network was operational. Before the end of 2003 RTI had worked with Comsol to add Voice over Internet Protocol (VoIP) to provide voice communication between facilities, and had extended the network to connect multiple buildings in clinic compounds and to multiple wards of the University Teaching Hospital.

Three to nine networked PCs and one laser printer were installed in each clinic, as well as additional PCs and printers in the University Teaching Hospital and administrative offices. The ZEPRS data center was installed at CIDRZ, which housed the combined ZEPRS technical support team.

Approximately 800 clinicians, many of whom had never used a computer, were trained in basic computer literacy. Standard clinical protocol reference works and email were made available to clinicians electronically over the ZEPRS network.

By early May 2004 RTI had completed an open source electronic patient referral system. This was launched into production use in clinics on 22 June 2004. Clinicians adopted this component readily and the system was soon rolled out to all 24 clinics and the University Teaching Hospital.

Also in May 2004, CIDRZ asked RTI whether the ZEPRS software could be adapted to help in managing antiretroviral therapy (ART) to treat patients infected with the Human immunodeficiency virus (HIV). Version 1.0 of this software, the ART Patient Tracking System (ART/PTS), was launched into use at Kalingalinga Clinic on 1 June 2004.*[2]

RTI reviewed the completed Beta version of the fully integrated perinatal record system with the UAB team in July 2005, and released Version 1.0 on 21 November 2005. This version was pilot tested in a limited number of clinics in Lusaka from December 2005 through January 2006. ZEPRS was launched into production use in two clinics in February 2006. The system was rolled out to all clinics at the average rate of one clinic each month until the roll out was completed in August 2007.

3.18.6 Current status

Since roll out was completed in August 2007, ZEPRS has been used by 24 public obstetrics clinics, as well as six wards (blocks A-D, adult ARV ward, and pediatric ARV ward) within the University Teaching Hospital in Lusaka. The ZEPRS patient record database has been used since February 2006 for routine health surveillance, monitoring, and supervision of health care. A 2006 study cited the use of a ZEPRS-based patient record system as one of four key factors in the successful rapid scale-up of antiretroviral therapy at primary care sites in Zambia.*[2]

By September 2011 ZEPRS contained medical records for more than 510,000 patients and ZEPRS had been used to manage multiple pregnancies for more than 20,000 mothers. In 2011 an average of more than 8,000 new antenatal patients were being registered in the system each month and the system was being used by 278 individual users.*[3] Clinicians in 25 facilities have used ZEPRS to manage perinatal care during more than 7.7 million patient encounters with more than 770,000 patients and during more than 335,000 deliveries.*[4]

Information regarding the impact of ZEPRS on the quality of health care and health outcomes can be obtained by contacting the Center for Infectious Disease Research in Zambia or the Zambian Central Board of Health.

3.18.7 Ongoing development

Since ZEPRS was launched in February 2006 it has been continually refined and enhanced based on input from clinicians and emerging needs. In 2008 RTI worked with CIDRZ to implement an interface with the Laboratory Information Management System (LMIS) at Kalingalinga Clinic, enabling lab test results such as CD4 counts to be transferred to patient records automatically twice daily. RTI has developed a version of the software that can be installed locally, be used within a facility in the absence of network connectivity, and can synchronize records automatically when connectivity is detected. This version is based on the free and open source Zcore platform, which can transmit data automatically over intermittent networks, such as mobile phone networks.

3.18.8 Adaptability

The Zcore software platform that emerged from ZEPRS has been used for managing pharmaceutical supplies in health centers in Nairobi, Kenya, managing malaria indoor residual spraying operations in Kenya, and managing medical and legal care for rape survivors in South Africa.

3.18.9 Availability

ZEPRS has been released by RTI as free and open source software under the Apache Software License (Version 2.0). RTI has released ZEPRS documentation under a Creative Commons Attribution-NonCommercial-ShareAlike 2.5 License.

3.18.10 See also

- OpenMRS

- OpenEMR
- SmartCare
- WorldVistA

3.18.11 Footnotes

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3.18.13 External links

- ZEPRS ZEPRS source code on GitHub
- ZEPRS project website
- ZEPRS wireless network on Google Earth Community
- ZEPRS overview presentation

Chapter 4

Decision Support Applications

4.1 Clinical decision support system

A **clinical decision support system** (**CDSS**) is a health information technology system that is designed to provide physicians and other health professionals with **clinical decision support** (**CDS**), that is, assistance with clinical decision-making tasks. A working definition has been proposed by Robert Hayward of the Centre for Health Evidence: "Clinical Decision Support systems link health observations with health knowledge to influence health choices by clinicians for improved health care". CDSSs constitute a major topic in artificial intelligence in medicine.

4.1.1 Effectiveness

The evidence of the effectiveness of CDSS is mixed. A 2014 systematic review did not find a benefit in terms of risk of death when the CDSS was combined with the electronic health record.*[1] There may be some benefits, however, in terms of other outcomes.*[1]

A 2005 systematic review concluded that CDSSs improved practitioner performance in 64% of the studies. The CDSSs improved patient outcomes in 13% of the studies. Sustainable CDSSs features associated with improved practitioner performance include the following:

- automatic electronic prompts rather than requiring user activation of the system

Both the number and the methodological quality of studies of CDSSs increased from 1973 through 2004.*[2]

Another 2005 systematic review found... "*Decision support systems significantly improved clinical practice in 68% of trials.*" The CDSS features associated with success include the following:*[3]

- the CDSS is integrated into the clinical workflow rather than as a separate log-in or screen.
- the CDSS is electronic rather than paper-based templates.
- the CDSS provides decision support at the time and location of care rather than prior to or after the patient encounter.
- the CDSS provides (active voice) recommendations for care, not just assessments.

However, other systematic reviews are less optimistic about the effects of CDS, with one from 2011 stating "*There is a large gap between the postulated and empirically demonstrated benefits of [CDSS and other] eHealth technologies ... their cost-effectiveness has yet to be demonstrated*".*[4]

A 5-year evaluation of the effectiveness of a CDSS in implementing rational treatment of bacterial infections was published in 2014; according to the authors, it was the first long term study of a CDSS.*[5]

4.1.2 Characteristics

A clinical decision support system has been defined as an "active knowledge systems, which use two or more items of patient data to generate case-specific advice."*[6] This implies that a CDSS is simply a decision support system that is focused on using knowledge management in such a way so as to achieve clinical advice for patient care based on multiple items of patient data.

Purpose

The main purpose of modern CDSS is to assist clinicians at the point of care.*[7] This means that clinicians interact with a CDSS to help to analyse, and reach a diagnosis based on, patient data.

In the early days, CDSSs were conceived of as being used to literally make decisions for the clinician. The clinician would input the information and wait for the CDSS to output the "right" choice and the clinician would simply act on that output. However, the modern methodology of using CDSSs to assist means that the clinician interacts with the CDSS, utilizing both their own knowledge and the CDSS, to make a better analysis of the patient's data than either human or CDSS could make on their own.

Typically, a CDSS makes suggestions for the clinician to look through, and the clinician is expected to pick out useful information from the presented results and discount erroneous CDSS suggestions.*[6]

There are two main types of CDSS:*[7]

- Knowledge-based
- Non-knowledge-based

as detailed below.

An example of how a CDSS might be used by a clinician is a specific type of Clinical Decision Support System, a DDSS (Diagnosis Decision Support Systems). A DDSS requests some of the patients data and in response, proposes a set of appropriate diagnoses. The doctor then takes the output of the DDSS and determines which diagnoses might be relevant and which are not,*[7] and if necessary orders further tests to narrow down the diagnosis.

Another important classification of a CDSS is based on the timing of its use. Doctors use these systems at point of care to help them as they are dealing with a patient, with the timing of use being either pre-diagnosis, during diagnosis, or post diagnosis. Pre-diagnosis CDSS systems are used to help the physician prepare the diagnoses. CDSS used during diagnosis help review and filter the physician's preliminary diagnostic choices to improve their final results. Post-diagnosis CDSS systems are used to mine data to derive connections between patients and their past medical history and clinical research to predict future events.*[7] It has been claimed that decision support will begin to replace clinicians in common tasks in the future.*[8]

Another approach, used by the National Health Service in England, is to use a DDSS (either, in the past, operated by the patient, or, today, by a phone operative who is not medically-trained) to triage medical conditions out of hours by suggesting a suitable next step to the patient (e.g. call an ambulance, or see a general practitioner on the next working day). The suggestion, which may be disregarded by either the patient or the phone operative if common sense or caution suggests otherwise, is based on the known information and an implicit conclusion about what the *worst-case* diagnosis is likely to be (which is not always revealed to the patient, because it might well be incorrect and is not based on a medically-trained person's opinion - it is only used for initial triage purposes).

Knowledge-based CDSS

Most CDSSs consist of three parts: the knowledge base, an inference engine, and a mechanism to communicate. The knowledge base contains the rules and associations of compiled data which most often take the form of IF-THEN rules. If this was a system for determining drug interactions, then a rule might be that IF drug X is taken AND drug Y is taken THEN alert user. Using another interface, an advanced user could edit the knowledge base to keep it up to date with new drugs. The inference engine combines the rules from the knowledge base with the patient's data. The communication mechanism allows the system to show the results to the user as well as have input into the system.*[6]*[7]

Non-knowledge-based CDSS

CDSSs that do not use a knowledge base use a form of artificial intelligence called machine learning,*[9] which allow computers to learn from past experiences and/or find patterns in clinical data. This eliminates the need for writing rules and for expert input. However, since systems based on machine learning cannot *explain* the reasons for their conclusions (they are so-called "black boxes", because no meaningful information about how they work can be discerned by human inspection), most clinicians do not use them directly for diagnoses, for reliability and accountability reasons.*[6]*[7] Nevertheless, they can be useful as post-diagnostic systems, for suggesting patterns for clinicians to look into in more depth.

Three types of non-knowledge-based systems are support vector machines, artificial neural networks and genetic algorithms.*[10]

Artificial neural networks use nodesBased and weighted connections between them to analyse the patterns found in patient data to derive associations between symptoms and a diagnosis.

Genetic Algorithms are based on simplified evolutionary processes using directed selection to achieve optimal CDSS results. The selection algorithms evaluate components of random sets of solutions to a problem. The solutions that come out on top are then recombined and mutated and run through the process again. This happens over and over until the proper solution is discovered. They are functionally similar to neural networks in that they are also "black boxes" that attempt to derive knowledge from patient data.

Non-knowledge-based networks often focus on a narrow list of symptoms, such as symptoms for a single disease, as opposed to the knowledge based approach which cover the diagnosis of many different diseases.*[6]*[7]

4.1.3 Regulations

United States

With the enactment of the American Recovery and Reinvestment Act of 2009 (ARRA), there is a push for widespread adoption of health information technology through the Health Information Technology for Economic and Clinical Health Act (HITECH). Through these

initiatives, more hospitals and clinics are integrating Electronic Medical Records (EMRs) and Computerized physician order entry (CPOE) within their health information processing and storage. Consequently, the Institute of Medicine (IOM) promoted usage of health information technology including Clinical Decision Support Systems to advance quality of patient care. The IOM had published a report in 1999, *To Err Is Human*, which focused on the patient safety crisis in the United States, pointing to the incredibly high number of deaths. This statistic attracted great attention to the quality of patient care.

With the enactment of the HITECH Act included in the ARRA, encouraging the adoption of health IT, more detailed case laws for CDSS and EMRs are still being defined by the Office of National Coordinator for Health Information Technology (ONC) and approved by Department of Health and Human Services (HHS). A definition of "Meaningful use" is yet to be polished.

Despite the absence of laws, the CDSS vendors would almost certainly be viewed as having a legal duty of care to both the patients who may adversely be affected due to CDSS usage and the clinicians who may use the technology for patient care. However, duties of care legal regulations are not explicitly defined yet.

With recent effective legislations related to performance shift payment incentives, CDSS are becoming more attractive.

4.1.4 Challenges to adoption

Clinical challenges

Much effort has been put forth by many medical institutions and software companies to produce viable CDSSs to support all aspects of clinical tasks. However, with the complexity of clinical workflows and the demands on staff time high, care must be taken by the institution deploying the support system to ensure that the system becomes a fluid and integral part of the clinical workflow. Some CDSSs have met with varying amounts of success, while others have suffered from common problems preventing or reducing successful adoption and acceptance.

Two sectors of the healthcare domain in which CDSSs have had a large impact are the pharmacy and billing sectors. There are commonly used pharmacy and prescription ordering systems that now perform batch-based checking of orders for negative drug interactions and report warnings to the ordering professional. Another sector of success for CDSS is in billing and claims filing. Since many hospitals rely on Medicare reimbursements to stay in operation, systems have been created to help examine both a proposed treatment plan and the current rules of Medicare in order to suggest a plan that attempts to address both the care of the patient and the financial needs of the institution.

Other CDSSs that are aimed at diagnostic tasks have found success, but are often very limited in deployment and scope. The Leeds Abdominal Pain System went operational in 1971 for the University of Leeds hospital, and was reported to have produced a correct diagnosis in 91.8% of cases, compared to the clinicians' success rate of 79.6%.

Despite the wide range of efforts by institutions to produce and use these systems, widespread adoption and acceptance has still not yet been achieved for most offerings. One large roadblock to acceptance has historically been workflow integration. A tendency to focus only on the functional decision making core of the CDSS existed, causing a deficiency in planning for how the clinician will actually use the product in situ. Often CDSSs were standalone applications, requiring the clinician to cease working on their current system, switch to the CDSS, input the necessary data (even if it had already been inputted into another system), and examine the results produced. The additional steps break the flow from the clinician's perspective and cost precious time.

Technical challenges and barriers to implementation

Clinical decision support systems face steep technical challenges in a number of areas. Biological systems are profoundly complicated, and a clinical decision may utilize an enormous range of potentially relevant data. For example, an electronic evidence-based medicine system may potentially consider a patient's symptoms, medical history, family history and genetics, as well as historical and geographical trends of disease occurrence, and published clinical data on medicinal effectiveness when recommending a patient's course of treatment.

Clinically, a large deterrent to CDSS acceptance is workflow integration, as mentioned above.

Another source of contention with many medical support systems is that they produce a massive number of alerts. When systems produce high volume of warnings (especially those that do not require escalation), aside from the annoyance, clinicians may pay less attention to warnings, causing potentially critical alerts to be missed.

Maintenance

One of the core challenges facing CDSS is difficulty in incorporating the extensive quantity of clinical research being published on an ongoing basis. In a given year, tens of thousands of clinical trials are published.[*][11] Currently, each one of these studies must be manually read, evaluated for scientific legitimacy, and incorporated into the CDSS in an accurate way. In 2004, it was stated that the process of gathering clinical data and medical knowledge and putting them into a form that computers can manipulate to assist in clinical decision-support is "still in its infancy".[*][12]

Nevertheless, it is more feasible for a business to do this centrally, even if incompletely, than for each individual doctor to try to keep up with all the research being published.

In addition to being laborious, integration of new data can sometimes be difficult to quantify or incorporate into the existing decision support schema, particularly in instances where different clinical papers may appear conflicting. Properly resolving these sorts of discrepancies is often the subject of clinical papers itself (see meta-analysis), which often take months to complete.

Evaluation

In order for a CDSS to offer value, it must demonstrably improve clinical workflow or outcome. Evaluation of CDSS is the process of quantifying its value to improve a system's quality and measure its effectiveness. Because different CDSSs serve different purposes, there is no generic metric which applies to all such systems; however, attributes such as consistency (with itself, and with experts) often apply across a wide spectrum of systems.*[13]

The evaluation benchmark for a CDSS depends on the system's goal: for example, a diagnostic decision support system may be rated based upon the consistency and accuracy of its classification of disease (as compared to physicians or other decision support systems). An evidence-based medicine system might be rated based upon a high incidence of patient improvement, or higher financial reimbursement for care providers.

4.1.5 Combining CDSS with Electronic Health Records

Implementing Electronic Health Records (EHR) was an inevitable challenge. The reasons behind this challenge are that it is a relatively uncharted area, and there are many issues and complications during the implementation phase of an EHR. This can be seen in the numerous studies that have been undertaken. However, challenges in implementing electronic health records (EHRs) have received some attention, but less is known about the process of transitioning from legacy EHRs to newer systems.*[14]

With all of that said, electronic health records are the way of the future for healthcare industry. They are a way to capture and utilise real-time data to provide high-quality patient care, ensuring efficiency and effective use of time and resources. Incorporating EHR and CDSS together into the process of medicine has the potential to change the way medicine has been taught and practiced.*[15] It has been said that "the highest level of EHR is a CDSS".*[16]

Since "clinical decision support systems (CDSS) are computer systems designed to impact clinician decision making about individual patients at the point in time that these decisions are made",*[15] it is clear that it would be beneficial to have a fully integrated CDSS and EHR.

Even though the benefits can be seen, to fully implement a CDSS that is integrated with an EHR has historically required significant planning by the healthcare facility/organisation, in order for the purpose of the CDSS to be successful and effective. The success and effectiveness can be measured by the increase in patient care being delivered and reduced adverse events occurring. In addition to this, there would be a saving of time and resources, and benefits in terms of autonomy and financial benefits to the healthcare facility/organisation.*[17]

Benefits of CDSS combined with EHR

A successful CDSS/EHR integration will allow the provision of best practice, high quality care to the patient, which is the ultimate goal of healthcare.

Errors have always occurred in healthcare, so trying to minimise them as much as possible is important in order to provide quality patient care. Three areas that can be addressed with the implementation of CDSS and Electronic Health Records (EHRs), are:

1. Medication prescription errors
2. Adverse drug events
3. Other medical errors

CDSSs will be most beneficial in the future when healthcare facilities are "100% electronic" in terms of real-time patient information, thus simplifying the number of modifications that have to occur to ensure that all the systems are up to date with each other.

The measurable benefits of clinical decision support systems on physician performance and patient outcomes remain the subject of ongoing research, as noted in the "Effectiveness" section above.

Barriers to CDSS combined with EHR

Implementing electronic health records (EHR) in healthcare settings incurs challenges; none more important than maintaining efficiency and safety during rollout,*[18] but in order for the implementation process to be effective, an understanding of the EHR users' perspectives is key to the success of EHR implementation projects.*[19] In addition to this, adoption needs to be actively fostered through a bottom-up, clinical-needs-first approach.*[20] The same can be said for CDSS.

The main areas of concern with moving into a fully integrated EHR/CDSS system are:

1. Privacy
2. Confidentiality
3. User-friendliness
4. Document accuracy and completeness
5. Integration
6. Uniformity
7. Acceptance
8. Alert desensitisation

*[21] as well as the key aspects of data entry that need to be addressed when implementing a CDSS to avoid potential adverse events from occurring. These aspects include whether:

- correct data is being used
- all the data has been entered into the system
- current best practice is being followed
- the data is evidence-based

A Service oriented architecture has been proposed as a technical means to address some of these barriers.*[22]

Status in Australia

As of July 2015, the planned transition to EHRs in Australia is facing difficulties. The majority of healthcare facilities are still running completely paper-based systems, and some are in a transition phase of scanned EHRs, or are moving towards such a transition phase.

Victoria has attempted to implement EHR across the state with its HealthSMART program, but due to unexpectedly high costs it has cancelled the project.*[23]

South Australia (SA) however is slightly more successful than Victoria in the implementation of an EHR. This may be due to all public healthcare organisations in SA being centrally run. (However, on the other hand, the UK's National Health Service is also centrally administered, and its National Programme for IT in the 2000s, which included EHRs in its remit, was an expensive disaster.)

SA is in the process of implementing "Enterprise patient administration system (EPAS)". This system is the foundation for all public hospitals and health care sites for an EHR within SA and it was expected that by the end of 2014 all facilities in SA will be connected to it. This would allow for successful integration of CDSS into SA and increase the benefits of the EHR.*[24] By July 2015 it was reported that only 3 out of 75 indented health care facilities implemented EPAS.*[25]

4.1.6 See also

- Clinical Informatics
- Gello Expression Language
- International Health Terminology Standards Development Organisation
- Personal Health Information Protection Act (a law in force in Ontario)

4.1.7 References

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4.1.8 External links

- Decision support chapter from Coiera's Guide to Health Informatics
- OpenClinical maintains an extensive archive of Artificial Intelligence systems in routine clinical use.
- Robert Trowbridge/ Scott Weingarten. Chapter 53. Clinical Decision Support Systems
- Stanford CDSS

4.2 Computer-aided diagnosis

For computer aid in other medical fields, see Clinical decision support system.

In radiology, **computer-aided detection (CADe)**, also called **computer-aided diagnosis (CADx)**, are procedures in medicine that assist doctors in the interpretation of medical images. Imaging techniques in X-ray, MRI, and Ultrasound diagnostics yield a great deal of information, which the radiologist has to analyze and evaluate comprehensively in a short time. CAD systems help scan digital images, *e.g.* from computed tomography, for typical appearances and to highlight conspicuous sections, such as possible diseases.

CAD is an interdisciplinary technology combining elements of artificial intelligence and computer vision with radiological image processing. A typical application is the detection of a tumor. For instance, some hospitals use CAD to support preventive medical check-ups in mammography (diagnosis of breast cancer), the detection of polyps in the colon, and lung cancer.

Computer-aided detection (CADe) systems are usually confined to marking conspicuous structures and sections.

Computer-aided diagnosis (CADx) systems evaluate the conspicuous structures. For example, in mammography CAD highlights micro calcification clusters and hyperdense structures in the soft tissue. This allows the radiologist to draw conclusions about the condition of the pathology. Another application is CADq, which quantifies, e.g., the size of a tumor or the tumor's behavior in contrast medium uptake. Computer-aided simple triage (CAST) is another type of CAD, which performs a fully automatic initial interpretation and triage of studies into some meaningful categories (e.g. negative and positive). CAST is particularly applicable in emergency diagnostic imaging, where a prompt diagnosis of critical, life-threatening condition is required.

Although CAD has been used in clinical environments for over 40 years, CAD cannot and may not substitute the doctor, but rather plays a supporting role.*[1] The doctor (generally a radiologist) is always responsible for the final interpretation of a medical image.

4.2.1 Computer-aided diagnosis topics

Methodology

CAD is fundamentally based on highly complex pattern recognition. X-ray images are scanned for suspicious structures. Normally a few thousand images are required to optimize the algorithm. Digital image data are copied to a CAD server in a DICOM-format and are prepared and analyzed in several steps.

1. Preprocessing for

- Reduction of artifacts (bugs in images)
- Image noise reduction
- Leveling (harmonization) of image quality for clearing the image's different basic conditions e.g. different exposure parameter.

2. Segmentation for

- Differentiation of different structures in the image, e.g. heart, lung, ribcage, possible round lesions
- Matching with anatomic databank

3. Structure/ROI (Region of Interest) Analyze Every detected region is analyzed individually for special characteristics:

- Compactness
- Form, size and location
- Reference to close-by structures / ROIs
- Average greylevel value analyze within a ROI
- Proportion of greylevels to border of the structure inside the ROI

4. Evaluation / classification After the structure is analyzed, every ROI is evaluated individually (scoring) for the probability of a TP. Therefore, the procedures are:

- Nearest-Neighbor Rule
- Minimum distance classifier
- Cascade Classifier
- Bayesian Classifier
- Artificial Neural Network
- Radial basis function network (RBF)
- SVM

If the detected structures have reached a certain threshold level, they are highlighted in the image for the radiologist. Depending on the CAD system these markings can be permanently or temporary saved. The latter's advantage is that only the markings which are approved by the radiologist are saved. False hits should not be saved, because an examination at a later date becomes more difficult then.

Sensitivity and specificity

CAD systems seek to highlight suspicious structures. Today's CAD systems cannot detect 100% of pathological changes. The hit rate (sensitivity) can be up to 90% depending on system and application.*[2] A correct hit is termed a True Positive (TP), while the incorrect marking of healthy sections constitutes a False Positive (FP). The less FPs indicated, the higher the specificity is. A low specificity reduces the acceptance of the CAD system because the user has to identify all of these wrong hits. The FP-rate in lung overview examinations (CAD Chest) could be reduced to 2 per examination. In other segments (*e.g.* CT lung examinations) the FP-rate could be 25 or more. In CAST systems the FP rate must be extremely low (less than 1 per examination) to allow a meaningful study triage.

Absolute detection rate

The absolute detection rate of the radiologist is an alternative metric to sensitivity and specificity. Overall, results of clinical trials about sensitivity, specificity, and the absolute detection rate can vary markedly. Each study result depends on its basic conditions and has to be evaluated on those terms. The following facts have a strong influence:

- Retrospective or prospective design

- Quality of the used images
- Condition of the x-ray examination
- Radiologist's experience and education
- Type of lesion
- Size of the considered lesion

4.2.2 Applications

CAD is used in the diagnosis of Pathological Brain Detection (PBD), breast cancer, lung cancer, colon cancer, prostate cancer, bone metastases, coronary artery disease, congenital heart defect, and Alzheimer's disease.

Pathological Brain Detection (PBD)

Chaplot et al. was the first to use Discrete Wavelet Transform (DWT) coefficients to detect pathological brains.*[3] Maitra and Chatterjee employed the Slantlet transform, which is an improved version of DWT. Their feature vector of each image is created by considering the magnitudes of Slantlet transform outputs corresponding to six spatial positions chosen according to a specific logic.*[4]

In 2010, Wang and Wu presented a forward neural network (FNN) based method to classify a given MR brain image as normal or abnormal. The parameters of FNN were optimized via adaptive chaotic particle swarm optimization (ACPSO). Results over 160 images showed that the classification accuracy was 98.75%.*[5]

In 2011, Wu and Wang proposed using DWT for feature extraction, PCA for feature reduction, and FNN with scaled chaotic artificial bee colony (SCABC) as classifier.*[6]

In 2013, Saritha et al. were the first to apply wavelet entropy (WE) to detect pathological brains. Saritha also suggested to use spider-web plots.*[7] Later, Zhang et al. proved removing spider-web plots did not influence the performance.*[8] Genetic pattern search method was applied to identify abnormal brain from normal controls. Its classification accuracy was reported as 95.188%.*[9] Das et al. proposed to use Ripplet transform.*[10] Zhang et al. proposed to use particle swarm optimization (PSO).*[11] Kalbkhani et al. suggested to use GARCH model.*[12]

In 2014, El-Dahshan et al. suggested to use pulse coupled neural network.*[13]

In 2015, Zhou et al. suggested to apply naive Bayes classifier to detect pathological brains.*[14]

Breast cancer

CAD is used in screening mammography (X-ray examination of the female breast). Screening mammography is used for the early detection of breast cancer. CAD is especially established in US and the Netherlands and is used in addition to human evaluation, usually by a radiologist. The first CAD system for mammography was developed in a research project at the University of Chicago. Today it is commercially offered by iCAD and Hologic. There are currently some non-commercial projects being developed, such as Ashita Project, a gradient-based screening software by Alan Hshieh, as well. However, while achieving high sensitivities, CAD systems tend to have very low specificity and the benefits of using CAD remain uncertain. Some studies suggest a positive impact on mammography screening programs,*[15]*[16] but others show no improvement.*[17]*[18] A 2008 systematic review on computer-aided detection in screening mammography concluded that CAD does not have a significant effect on cancer detection rate, but does undesirably increase recall rate (*i.e.* the rate of false positives). However, it noted considerable heterogeneity in the impact on recall rate across studies.*[19]

Procedures to evaluate mammography based on magnetic resonance imaging exist too.

Lung cancer (bronchial carcinoma)

In the diagnosis of lung cancer, computed tomography with special three-dimensional CAD systems are established and considered as gold standard. At this a volumetric dataset with up to 3,000 single images is prepared and analyzed. Round lesions (lung cancer, metastases and benign changes) from 1 mm are detectable. Today all well-known vendors of medical systems offer corresponding solutions.

Early detection of lung cancer is valuable. The 5-year-survival-rate of lung cancer has stagnated in the last 30 years and is now at approximately just 15%. Lung cancer takes more victims than breast cancer, prostate cancer and colon cancer together. This is due to the asymptomatic growth of this cancer. In the majority of cases it is too late for a successful therapy if the patient develops first symptoms (*e.g.* chronic croakiness or hemoptysis). But if the lung cancer is detected early (mostly by chance), there is a survival rate at 47% according to the American Cancer Society.*[20] At the same time the standard x-ray-examination of the lung is the most frequently x-ray examination with a 50% share. Indeed, the random detection of lung cancer in the early stage (stage 1) in the x-ray image is difficult. It is a fact that round lesions vary from 5–10 mm are easily overlooked.*[21] The routine application of CAD Chest Systems may help to detect small changes without initial suspicion. Philips was the first vendor to present a CAD for early detection of round lung lesions on x-ray images.*[22]

Colon cancer

CAD is available for detection of colorectal polyps in the colon. Polyps are small growths that arise from the inner lining of the colon. CAD detects the polyps by identifying their characteristic "bump-like" shape. To avoid excessive false positives, CAD ignores the normal colon wall, including the haustral folds. In early clinical trials, CAD helped radiologists find more polyps in the colon than they found prior to using CAD.*[23]*[24]

Coronary artery disease

CAD is available for the automatic detection of significant (causing more than 50% stenosis) coronary artery disease in coronary CT angiography (CCTA) studies. A low false positives rate (60-70% specificity per patient)*[25]*[26]*[27] allows using it as a computer-aided simple triage (CAST) tool distinguishing between positive and negative studies and yielding a preliminary report. This, for example, can be used for chest pain patients' triage in an emergency setting.

Congenital heart defect

Early detection of pathology can be the difference between life and death. CADe can be done by auscultation with a digital stethoscope and specialized software, also known as Computer-aided auscultation. Murmurs, irregular heart sounds, caused by blood flowing through a defective heart, can be detected with high sensitivity and specificity. Computer-aided auscultation is sensitive to external noise and bodily sounds and requires an almost silent environment to function accurately.

Alzheimer's disease

CADs can be used to identify subjects with Alzheimer's and mild cognitive impairment from normal elder controls.

In 2014, Padma et al. used combined wavelet statistical texture features to segment and classify AD benign and malignant tumor slices.*[28] Zhang et al. found kernel support vector machine decision tree had 80% classification accuracy, with an average computation time of 0.022s for each image classification.*[29]

Eigenbran is a novel brain feature that can help to detect AD. The results showed polynomial kernel SVM achieved accuracy of 92.36±0.94, sensitivity of 83.48±3.27, specificity of 94.90±1.09, and precision of 82.28±2.78. The polynomial KSVM performs better than linear SVM and RBF kernel SVM.*[30]

In 2015, Anika Cheerla, world finalist of the Google Science Fair, developed an automated tool based on artificial neural networks which lead her to obtain an overall testing accuracy of 97% in Alzheimer's disease diagnosis. Her automated system is based on the analysis of MRI images and patient's basic information which need to be provided by the doctor through a simple GUI.*[31]

Nuclear medicine

CADx is available for nuclear medicine images. Commercial CADx systems for the diagnosis of bone metastases in whole-body bone scans and coronary artery disease in myocardial perfusion images exist.*[32]

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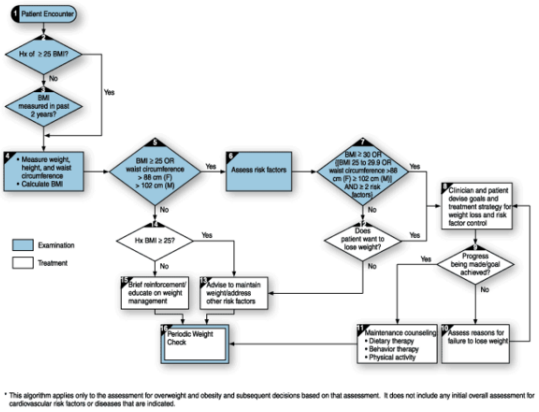
4.3 Medical algorithm

A **medical algorithm** is any computation, formula, statistical survey, nomogram, or look-up table, useful in



A medical algorithm for assessment and treatment of overweight and obesity.

healthcare. Medical algorithms include decision tree approaches to healthcare treatment (e.g., if symptoms A, B, and C are evident, then use treatment X) and also less clear-cut tools aimed at reducing or defining uncertainty.

4.3.1 Scope

Medical algorithms are part of a broader field which is usually fit under the aims of medical informatics and medical decision making. Medical decisions occur in several areas of medical activity including medical test selection, diagnosis, therapy and prognosis, and automatic control of medical equipment.

In relation to logic-based and artificial neural network-based clinical decision support system, which are also computer applications to the medical decision making field, algorithms are less complex in architecture, data structure and user interface. Medical algorithms are not necessarily implemented using digital computers. In fact, many of them can be represented on paper, in the form of diagrams, nomographs, etc.

4.3.2 Examples

A wealth of medical information exists in the form of published medical algorithms. These algorithms range from simple calculations to complex outcome predictions. Most clinicians use only a small subset routinely.

Examples of medical algorithms are:

- **Calculators,**. e.g., an on-line or stand-alone calculator for body mass index (BMI) when stature and body weight are given;
- **Flowcharts,** e.g., a binary decision tree for deciding what is the etiology of chest pain
- **Look-up tables,** e.g., for looking up food energy and nutritional contents of foodstuffs
- **Nomograms,** e.g., a moving circular slide to calculate body surface area or drug dosages.

A common class of algorithms are embedded in guidelines on the choice of treatments produced by many national, state, financial and local healthcare organisations and provided as knowledge resources for day to day use and for induction of new physicians. A field which has gained particular attention is the choice of medications for psychiatric conditions. In the United Kingdom, guidelines or algorithms for this have been produced by most of the circa 500 primary care trusts, substantially all of the circa 100 secondary care psychiatric units and many of the circa 10 000 general practices. In the US, there is a national (federal) initiative to provide them for all states, and by 2005 six states were adapting the approach of the Texas Medication Algorithm Project or otherwise working on their production.

A grammar—the Arden syntax—exists for describing algorithms in terms of medical logic modules. An approach such as this should allow exchange of MLMs between doctors and establishments, and enrichment of the common stock of tools.

4.3.3 Purpose

The intended purpose of medical algorithms is to improve and standardize decisions made in the delivery of medical care. Medical algorithms assist in standardizing selection and application of treatment regimens, with algorithm automation intended to reduce potential introduction of errors. Some attempt to predict the outcome, for example critical care scoring systems.

Computerized health diagnostics algorithms can provide timely clinical decision support, improve adherence to evidence-based guidelines, and be a resource for education and research.

Medical algorithms based on best practice can assist everyone involved in delivery of standardized treatment via a wide range of clinical care providers. Many are presented as protocols and it is a key task in training to ensure people step outside the protocol when necessary. In our present state of knowledge, generating hints and producing guidelines may be less satisfying to the authors, but more appropriate.

4.3.4 Cautions

In common with most science and medicine, algorithms whose contents are not wholly available for scrutiny and open to improvement should be regarded with suspicion.

Computations obtained from medical algorithms should be compared with, and tempered by, clinical knowledge and physician judgment.

4.3.5 See also

- Consensus (medical)
- Evidence-based medicine
- Journal Club
- Medical decision making
- Medical guideline
- Medical informatics
- Odds algorithm
- *Treatment Guidelines from The Medical Letter*

4.3.6 Further reading

- Johnson, Kathy A.; Svirbely, John R.; Sriram, M.G.; Smith, Jack W.; Kantor, Gareth; Rodriguez, Jorge Raul (November 2002). "Automated Medical Algorithms: Issues for Medical Errors". *Journal of the American Medical Informatics Association* **9** (6 Suppl 1): s56–s57. doi:10.1197/jamia.M1228. PMC 419420.

4.3.7 External links

- AlternativeMentalHealth.com - 'Alternative Health Medical Evaluation Field Manual', Lorrin M. Koran, MD, Stanford University Medical Center (1991)

4.4 Medical logic module

A **medical logic module (MLM)** is an independent unit in a healthcare knowledge base that represents the knowledge published on a requirement for treating a patient according to a single medical decision.

Possible usage is with an event monitor program in an intensive care ward or with hospital information system on occurrence of defined conditions. See Arden syntax reference for examples. Early introduction is given with monographs.*[1]

4.4.1 Implementation

The Arden syntax has been defined as a grammar which could make MLMs swappable between various platforms. XML representation of Arden (ArdenML) can be transformed by Extensible Stylesheet Language Transformations (XSLTs) to other forms.*[2]

There is no reference stated for general implementation as a transfer method between different information systems.

4.4.2 See also

- Arden syntax
- Health Level 7

4.4.3 References

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4.5 Arden syntax

Arden syntax is a markup language used for representing and sharing medical knowledge.*[1] This clinical and scientific knowledge language is used in an executable format by clinical decision support systems*[2] to generate alerts, interpretations, and to screen and manage messages to clinicians. This syntax is used to share medical knowledge within and across many health service institutions. *[2] Rule sets, called Medical Logic Modules, comprise enough logic to make a single medical decision.*[1] Medical logic modules are written in Arden syntax, and are called by a program - an event monitor - when the condition they are written to help with occurs.

Arden syntax was formerly a standard under ASTM, published in 1992, and is now part of Health Level Seven International.*[2] Arden syntax version 2.0 was published by HL7 in 1999. Arden syntax version 2.9 is the current version.

4.5.1 Rationale

The syntax offers potential users help deciding if the standard is appropriate for their purposes. It offers users and implementors knowledge of how parts of the standard were designed to be used. It also provides authors of other standards an insight that might be helpful in their own attempts in future designing of new languages.*[3]

4.5.2 History

The name, "Arden Syntax", was adopted from Arden House, located about 90 minutes north of Manhattan in Orange County, New York. Originally purchased by Edward Henry (E. H.) Harriman in 1885, the estate was given to Columbia University by his son W. Averell Harriman in 1950 following its use by the Navy in World War II. The house and grounds became a National Historic Landmark in 1966, and it is now a conference center. During the five-year IBM/CPMC R&D program,

conferences and working sessions were hosted and led by CPMC at Arden House and attended by medical informaticians from several leading universities and hospitals, IBM personnel, and others directly or indirectly involved in the program. The "Arden Syntax" name was chosen in recognition of important milestones achieved at Arden House in the development and refinement of the syntax and its implementation.*[4]

4.5.3 Structure of Arden syntax

The unit of representation in the Arden syntax is the Medical Logic Module (MLM).*[5] A Medical logic Module is composed of four categories, namely maintenance, library, knowledge and resources, with appropriate slots.*[2] Arden Syntax is an instance of a Knowledge Resource-Centric Knowledge Integration Architecture, where the knowledge resources command the delivery mechanisms of clinical decision support system.*[6]

Maintenance Category

This category contains metadata about the MLM. The maintenance category consists of slots that indicate maintenance information unrelated to the medical knowledge in the module.*[7] The first slot is the title which gives a brief description of the module followed by a file name, a distinct identifier used to specify the MLM. The third slot is the version which specifies the version used. It also maintains a track of updates to the MLMs. A version slot is followed by institution and author slots that specify where the MLM is written and the person who wrote it.*[1] The sixth slot is the specialist slot that names the person in the institution liable for validating and installing the MLM in the institution. This slot is always meant to be blank when transferring information from one institution to another.*[8] This slot is followed by date and validation slots which show the date at which MLM was last updated. The validation level is set by the specialist, it indicates that the MLM is only used for testing.*[1] These slots are used for knowledge base maintenance and change control.*[9]

Library Category

This category contains five slots called purpose, explanation, keywords, citations and links. The purpose slot explains what a particular MLM is used for, whereas the explanation slot illustrates how an MLM works. Terms that can be used to search through a knowledge base of MLM is supplied by a keyword slot. The citation and link slots are optional. References to literature that support MLM's medical behaviour are included in the citation slot. Institution specific links to other sources of information such as electronic textbooks and educational modules are contained in the links slot.*[1]

Knowledge Category

This category contains the actual medical knowledge of the MLM. It consists of type, data, priority, evoke, logic and action slots. The way in which MLM is used is known by type slot. Terms used in the rest of the MLM are defined by the data slot. Its goal is to separate those parts of the MLM that are specific to an institution from the more generic parts of the MLM. The order in which the MLM must be invoked are indicated by the priority, which can be a number from 1 (Last) to 99(first). It is a rarely used optional slot. An MLM can be activated by an event, or by a direct call from an MLM or an application programme which is specified by the evoke slot.*[1] A real medical condition or rule to test for is contained in the logic slot which may include compound calculations.*[8] The action slot creates a message that is sent to the health care provider, such as sending an alert to the destination, evoking other MLMs and returning values. The urgency slot is optional; it can be a number from 1 to 99 which indicates the importance of an MLMs action or message.*[1]

Resources Category

To be added

4.5.4 Functions of Arden Syntax

- When a clinically important situation such as a medication interaction or dangerous laboratory result arises, the provider is warned by an alert message.*[1]
- An interpretation is a nonemergency message designed to supply a provider with supportive information such as an interpretation of liver function tests.
- A Screen is a message sent to clinical research when patients meeting certain characteristics either for a clinical trial or quality assurance concern are admitted to the hospital.*[1]
- Management messages are used for administrative purposes such as managing bed assignments, same day admissions and discharges from the hospital.

4.5.5 Testing

Arden syntax is tested for reliability and imprecision using tools lex and Yacc that, when used together, create a compiler or interpreter. Source file is split into tokens by lex and the hierarchical structure of the programme is found by Yacc. These tools reduce ambiguities in the syntax.*[8]

4.5.6 Implementation

Several developers have used yacc-based compilers or similar tools to translate the MLMs to an intermediate form which is executed later. Other developers use Prolog for both parsing and interpretation and optimising MLMs by converting them to single-assignment declarative form.*[3]

4.5.7 Advantages

- It is a part of the Health Level Seven International standards organization and is well known by many healthcare providers.
- It allows easy encoding of several important medical concepts.*[10]
- It is more appropriate for practical implementation of Clinical decision support system.
- Every data element and event has date/time stamp that is clinically significant. The time functions help users specify data and time in MLMs.
- The code is written in a way close to natural language and easily readable, with several syntactic features such as flexible list handling that can be filtered with ease.*[2]
- Easier to handle patient data created at different times by two components, namely the value and the primary time.
- Developers are encouraged to document and annotate MLMs for producing large metadata by the standard, which is vital for making large collections of MLMs manageable.*[2]

4.5.8 Limitations

- Problems related to adoption of Arden syntax are the curly braces problem and the compiler problem, which may be resolved in the future by the introduction of XML-based techniques like Virtual Medical Record (vMR).*[9]
- Since it is divided into various categories, it allows usage of various operators and statements at the same time, leading to inconsistencies.
- Standard might be written in two separate documents, one for users to develop Arden syntax MLMs and the other for developers of Arden syntax compilers.*[2]

4.5.9 Uses of Arden Syntax

Arden syntax is used in computerized care plans for the management of patients following Coronary artery bypass surgery*[11]

The Regenstrief Institute, Inc. uses Arden Syntax MLMs in its CARE system to deliver reminders or hints to clinicians regarding patient treatment recommendations (e.g. the next clinic appointment, based on rules applied to the digitized notes and pertinent patient data stored in the system). Regenstrief Institute is an international nonprofit medical research organization"recognized for its role in improving quality of care, increasing efficiency of healthcare delivery, preventing medical errors and enhancing patient safety" *[12] as well as Health Services Researchers. Additionally, LDS hospital in Salt Lake City (HELP System...) has contributed much to this standard as well as body of knowledge. Indiana University's section of Children's Health Services Research within the School of Medicine extensively uses Arden Syntax MLMs to control clinical decision support within the CHICA (Child Health Improvement through Computer Automation) pediatric clinical decision support system, an ambulatory CDS that has been running within Indianapolis area health systems for 11 years.*[13]

4.5.10 Fuzzy Arden Syntax

The main aim of fuzzy Arden syntax is to provide easy method in processing of uncertain data which routinely appears in medicine. New concepts are incorporated into Arden Syntax by fuzzy Arden syntax in order to assist in processing information that may not be completely defined.*[14] For example a fuzzy logic has been used in knowledge base in Moni–ICU system at clinical institute of hospital hygiene of the Vienna general hospital. It is a system that detects and constantly checks Hospital-acquired infections.*[2] Use of fuzzy logic in knowledge base provide physicians with more precise information on the degree of the presence of nosocomial infections, that aids to recognize borderline cases and allows former detection of an infection onset and its decline.*[2]

4.5.11 Applications

Arden Syntax and its first applications were conceived and developed as the primary deliverables of a multimillion-dollar joint research and development (R&D) program between Columbia Presbyterian Medical Center (CPMC) in New York City and IBM Health Industry Marketing in Atlanta, Georgia from 1989-1993. IBM provided program funding, S/370 mainframe hardware, software, peripheral equipment, and other materials for the work, and program management oversight of the collaborative effort.

At Columbia-Presbyterian Medical center, 40 Arden syn-

tax MLMs have been implemented in which eighteen of those are clinical MLMs, including four interpretations and fourteen alerts. For example, a user is alerted by three MLMs to the presence of hypokalemia and digoxin use that might lead to cardiac dysrhythmia. One MLM is activated by storage of a pharmacy order by digoxin,a second MLM is activated by the storage of a blood potassium result and the third activated by the storage of blood digoxin level. Twelve are research MLM examples, which include the ability to identify patients with abnormal cervical pathology, etc. that notify the researcher of the details of the patient's medical record and their inpatient location to enrol the patient in a study, and the remaining ten are administrative MLMs. Arden syntax is implemented at LDS hospital, Salt Lake City, Utah, using the HELP system.*[8]

A medical decision support system at Linkoping University, Linkoping, Sweden comprises a clinical data base, Medical database dictionary, and a knowledge base component. Syntax for the knowledge base is Arden syntax.*[15] Samwald et al. group developed many Clinical decision support system using Arden syntax standard ranging from a few to several dozens of MLMs. These systems are Hepaxpert,*[16] Thyrexpert,*[17] Toxopert*[18] and RHEUMexpert.*[19] The Hepaxpert system helps in interpretation of Hepatitis A, B and C serology test results, whereas the Thyrexpert system helps in interpretation of thyroid hormone test results. The Toxopert system helps in interpretation of time sequences of toxoplasmosis serology test results. Differential diagnosis decision support in rheumatology is offered by RHEUMexpert.*[2]

IBM's artificial intelligence product, KnowledgeTool, provided the original basis for MLM syntax representation and processing, as enhanced and applied by CPMC researchers Drs. James J. Cimino, George Hripcsak, Steve Johnson, Carol Friedman, and others at CPMC, under the leadership of Dr. Paul D. Clayton. In a related effort under the same program, another prototype implementation of the syntax was developed by Peter Ludemann using Quintus Prolog. IBM program management and AI technology services were provided by Terry Rankin, Pete Smith, and Eddie Sanders.

4.5.12 Arden Syntax Example

maintenance: title: To check the diastolic blood pressure of the patient;; mlmname: Hypotension;; arden: version 2.7;; version: 1.00;; institution: Latrobe University Bundoora;; author: Lakshmi Devineni;; specialist: ;; date: 2013-06-02;; validation: testing;; library: purpose: check if the diastolic blood pressure of the patient is within limits;; explanation: This MLM is an example for reading data and writing a message;; keywords: hypotension; categorization;; citations: ;; links: http://en.wikipedia.org/wiki/Hypotension;; knowledge: type: data_driven;; data: /* read the diastolic blood pressure */ diastolic_blood_pressure := read last {diastolic blood pressure}; /* the value in braces is specific to your runtime environment */ /* If the height is lower than height_threshold, output a message */ diastolic_pressure_threshold := 60; stdout_dest := destination {stdout}; ;; evoke: null_event;; logic: if (diastolic_blood_pressure is not number) then conclude false; endif; if (diastolic_blood_pressure >= diastolic_pressure_threshold) then conclude true; else conclude false; endif; ;; action: write "Your Diastolic Blood Pressure is too low (hypotension)" at stdout_dest; ;; resources: default: de ;; language: en 'msg' : "The normal range from 60 to 90"; ;; language: de 'msg' : "Der Normalbereich von 60 bis 90"; ;; end:

4.5.13 See also

- Electronic health record
- Clinical decision support system
- Compiler
- Virtual Medical Record (vMR)
- Health Level Seven International
- Lex and Yacc

4.5.14 References

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4.5.15 External links

- Introduction to the HL7 Standards
- Open Source Arden Syntax compiler implementation

4.6 Concept Processing

Concept Processing is a technology that uses an artificial intelligence engine to provide flexible user interfaces. This technology is used in some Electronic Medical Record (EMR) software applications, as an alternative to the more rigid template-based technology.

4.6.1 Some methods of data entry in electronic medical records

The most widespread methods of data entry into an EMR are templates, voice recognition, transcription, and concept processing.

Templates

The physician selects either a general, symptom-based or diagnosis-based template pre-fabricated for the type of case at that moment, making it specific through use of forms, pick-lists, check-boxes and free-text boxes. This method became predominant especially in Emergency Room Medicine during the late 1990s.

Voice recognition

The physician dictates into a computer voice recognition device that enters the data directly into a free-text area of the EMR.

Transcription

The physician dictates the case into a recording device, which is then sent to a transcriptionist for entry into the EMR, usually into free text areas.

Concept Processing

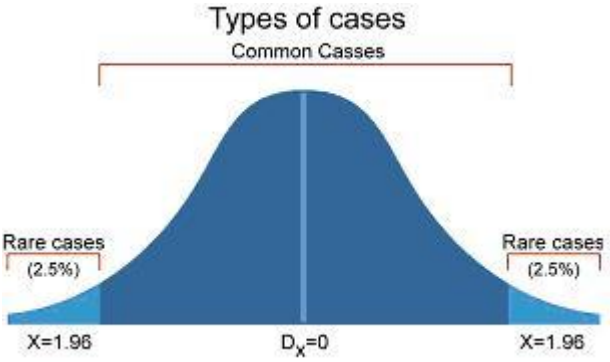
Based on artificial intelligence technology and Boolean logic, Concept Processing attempts to mirror the mind of each physician by recalling elements from past cases that are the same or similar to the case being seen at that moment.

4.6.2 How Concept Processing works

For every physician the bell-shaped curve effect is found, representing a frequency distribution of case types. Some cases are so rare that physicians will have never handled them before. The majority of other cases become repetitive, and are found on top of this bell shape curve.

A Concept Processor brings forward the closest previous encounter in relation to the one being seen at that moment, putting that case in front of the physician for fine-tuning.

There are only three possibilities of cases : The closest encounter could be identical to the current encounter (not an impossible event). It could be similar to the current note, or it could be a rare new case.



If the closest encounter is identical to your present one, the physician has effectively completed charting. A Concept Processor will pull through all the related information needed.

If the encounter is similar but not identical, the physician modifies the differences from the closest case using hand-writing recognition, voice recognition, or keyboard. A Concept Processor then memorizes all the changes, so that when the next encounter falls between two similar cases, the editing is cut in half, and then by a quarter for the next case, and then by an eighth....and so on. In fact, the more a Concept Processor is used, the faster and smarter it becomes.

Concept Processing also can be used for rare cases. These are usually combinations of SOAP note elements, which in themselves are not rare. If the text of each element is saved for a given type of case, there will be elements available to use with other cases, even though the other cases may not be similar overall.

The role of a concept processor is simply to reflect that thinking process accurately in a doctor's own words.

4.6.3 See also

- Electronic health record
- Electronic medical record
- Health informatics
- Medical record

4.7 Guideline execution engine

A **Guideline Execution Engine** is a computer program which can interpret a clinical guideline represented in a computerized format and perform actions towards the user of an electronic medical record.

A Guideline Execution Engine needs to communicate with a host Clinical information system. vMR is one possible interface which can be used.

The engine's main function is to manage instances of executed guidelines of individual patients.

Delivering the inferred engine recommendations or impacts to the host Clinical information system has to carefully respect current workflow of the clinicians (physicians, nurses, clerks, etc.)

4.7.1 Architecture of Guideline Execution Engine

The following modules are generally needed for any engine

- interface to Clinical Information System
- new guidelines loading module
- guideline interpreter module
- clinical events parser
- alert/recommendations dispatch

4.7.2 Guideline Interchange Format

The *Guideline Interchange Format (GLIF)* is computer representation format for clinical guidelines.*[1] Represented guidelines can be executed using a guideline execution engine.

The format has several versions as it has been improved. In 2003 GLIF3 was introduced.

4.7.3 Use of third party workflow engine as a guideline execution engine

Some commercial Electronic Health Record systems use a workflow engine to execute clinical guidelines. RetroGuide*[2] and HealthFlow*[3] are examples of such an approach.

4.7.4 See also

- Electronic medical record
- Clinical practice guideline
- Medical algorithm
- Arden syntax
- Healthcare workflow
- Glif
- RetroGuide

4.7.5 References

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4.7.6 External links

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4.8 CADUCEUS

CADUCEUS was a medical expert system finished in the mid-1980s (first begun in the 1970s- it took a long time to build the knowledge base) by Harry Pople (of the University of Pittsburgh), building on Pople's years of interviews with Dr. Jack Meyers, one of the top internal medicine diagnosticians and a professor at the University of Pittsburgh. Their motivation was an intent to improve on MYCIN - which focused on blood-borne infectious bacteria - to focus on more comprehensive issues than a narrow field like blood poisoning (though it would do it in a similar manner); instead embracing all internal medicine. CADUCEUS eventually could diagnose up to 1000 different diseases.

While CADUCEUS worked using an inference engine similar to MYCIN's, it made a number of changes (like incorporating abductive reasoning) to deal with the additional complexity of internal disease- there can be a number of simultaneous diseases, and data is generally flawed and scarce.

CADUCEUS has been described as the "most knowledge-intensive expert system in existence".*[1]

4.8.1 See also

- Internist-I

4.8.2 References

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4.9 DXplain

DXplain is a Clinical decision support system (CDSS) available through the World Wide Web that assists clinicians by generating stratified diagnoses based on user input of patient signs and symptoms, laboratory results, and other clinical findings.*[1] Evidential support for each differential diagnosis is presented, along with recommended follow-up that may be conducted by the clinician to arrive at a more definitive diagnosis. The system also serves as a clinician reference with a searchable database of diseases and clinical manifestations.

4.9.1 History

Designed by the Laboratory of Computer Science at the Massachusetts General Hospital, work on DXplain began in 1984 with a first version being released in 1986.*[2] .*[2]

4.9.2 Educational tool

Use of DXplain as a tool for medical consultation has been common to some institutions since it fills a gap, particularly for medical students in clinical rotations, that is not adequately covered by textbook literature.*[3] The system's large knowledge base combined with its ability to formulate diagnostic hypotheses have made it a popular education tool for US-based medical schools; by 2005, **DXplain** was supporting more than 33,189 total users.*[4]

4.9.3 Methodology

DXplain generates ranked differential diagnoses using a pseudo-probabilistic algorithm.*[5] Each clinical finding entered into DXplain is assessed by determining the importance of the finding and how strongly the finding supports a given diagnosis for each disease in the knowledge base. Using this criterion, DXplain generates ranked differential diagnoses with the most likely diseases yielding the lowest rank. Using stored information regarding each disease' s prevalence and significance, the system differentiates between common and rare diseases.

4.9.4 Accuracy

Analysis of accuracy has shown promise in DXplain and similar clinical decision support systems. In a preliminary trial investigation of 46 benchmark cases with a variety of diseases and clinical manifestations, the ranked differential diagnoses generated by DXplain were shown to be in alignment with a panel of five board-certified physicians.*[6] In another study investigating how well decision support systems work at responding to a bioterrorism event, an evaluation of 103 consecutive internal medicine cases showed that Dxplain correctly identified the diagnosis in 73% of cases, with the correct diagnosis averaging a rank of 10.7.*[7]

4.9.5 Clinical usage

Despite its usage in clinician training, similar to other clinical decision support systems, DXplain has not expanded beyond the research laboratory or medical training setting, due in part to a lack of support by clinicians in real-world settings.*[8]

4.9.6 References

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4.9.7 See also

- QMR
- INTERNIST-1
- Iliad
- Isabel
- VisualDx

4.9.8 External links

- DXplain at the MGH Lab of Computer Science

4.10 Internist-I

INTERNIST-I was a broad-based computer-assisted diagnostic tool developed in the early 1970s at the University of Pittsburgh as an educational experiment. The system was designed to capture the expertise of just one man, Jack D. Myers, MD, chairman of internal medicine in the University of Pittsburgh School of Medicine. The Division of Research Resources and the National Library of Medicine funded INTERNIST-I. Other major collaborators on the project included Randolph A. Miller and Harry E. Pople.

4.10.1 Development

INTERNIST-I is the successor of the DIALOG system. For ten years, INTERNIST-I was the centerpiece of a Pittsburgh course entitled "The Logic of Problem-Solving in Clinical Diagnosis." In consultation with faculty experts, much responsibility for data entry and updating of the system fell to the fourth-year medical students enrolled in the course. These students encoded the findings of standard clinicopathological reports. By 1982, the INTERNIST-I project represented fifteen person-years of work, and by some reports covered 70-80% of all the possible diagnoses in internal medicine.

Data input into the system by operators included signs and symptoms, laboratory results, and other items of patient history. The principal investigators on INTERNIST-I did not follow other medical expert systems designers in adopting Bayesian statistical models or pattern recognition. This was because, as Myers explained, "The method used by physicians to arrive at diagnoses requires complex information processing which bears little resemblance to the statistical manipulations of most computer-based systems." INTERNIST-I instead used a powerful ranking algorithm to reach diagnoses in the domain of internal medicine. The heuristic rules that drove INTERNIST-I relied on a partitioning algorithm to create problems areas, and exclusion functions to eliminate diagnostic possibilities.

These rules, in turn, produce a list of ranked diagnoses based on disease profiles existing in the system's memory. When the system was unable to make a determination of diagnosis it asked questions or offered recommendations for further tests or observations to clear up the mystery. INTERNIST-I worked best when only a single disease was expressed in the patient, but handled complex cases poorly, where more than one disease was present. This was because the system exclusively relied on hierarchical or taxonomic decision-tree logic, which linked each disease profile to only one "parent" disease class.

4.10.2 Use of INTERNIST-I

By the late 1970s, INTERNIST-I was in experimental use as a consultant program and educational "quizmaster" at Presbyterian-University Hospital in Pittsburgh. INTERNIST-I's designers hoped that the system could one day become useful in remote environments—rural areas, outer space, and foreign military bases, for instance—where experts were in short supply or unavailable. Still, physicians and paramedics wanting to use INTERNIST-I found the training period lengthy and the interface unwieldy. An average consultation with INTERNIST-I required about thirty to ninety minutes, too long for most clinics. To meet this challenge, researchers at nearby Carnegie Mellon University wrote a program called ZOG that allowed those unfamiliar with the system to master it more rapidly. INTERNIST-I never moved beyond its original status as a research tool. In one instance, for example, a failed attempt to extract "synthetic" case studies of "artificial patients" from the system's knowledge base in the mid-1970s overtly demonstrated its "shallowness" in practice.

4.10.3 INTERNIST-I and QMR

In the first version of INTERNIST-I (completed in 1974) the computer program "treated the physician as unable to solve a diagnostic problem," or as a "passive observer" who merely performed data entry. Miller and his collaborators came to see this function as a liability in the 1980s, referring to INTERNIST-I derisively as an example of the outmoded "Greek Oracle" model for medical expert systems. In the mid-1980s INTERNIST-I was succeeded by a powerful microcomputer-based consultant developed at the University of Pittsburgh called Quick Medical Reference (QMR). QMR, meant to rectify the technical and philosophical deficiencies of INTERNIST-I, still remained dependent on many of the same algorithms developed for INTERNIST-I, and the systems are often referred to together as INTERNIST-I/QMR. The main competitors to INTERNIST-I included CASNET, MYCIN, and PIP.

4.10.4 References

- Gregory Freiherr, The Seeds of Artificial Intelligence: SUMEX-AIM (NIH Publication 80-2071, Washington, D.C.: National Institutes of Health, Division of Research Resources, 1979).

- Randolph A. Miller, et al., "INTERNIST-1: An Experimental Computer-Based Diagnostic Consultant for General Internal Medicine," New England Journal of

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- Jack D. Myers, "The Background of INTERNIST-I and QMR," in A History of Medical Informatics, eds. Bruce I. Blum and Karen Duncan (New York: ACM Press, 1990), 427-33.
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- Harry E. Pople, Jr., "Presentation of the INTERNIST System," in Proceedings of the AIM Workshop (New Brunswick, N.J.: Rutgers University, 1976).

4.10.5 See also

- Transcript of an INTERNIST-I Consultation
- CADUCEUS (expert system)

4.11 Mycin

MYCIN was an early expert system that used artificial intelligence to identify bacteria causing severe infections, such as bacteremia and meningitis, and to recommend antibiotics, with the dosage adjusted for patient's body weight —the name derived from the antibiotics themselves, as many antibiotics have the suffix "-mycin" . The Mycin system was also used for the diagnosis of blood clotting diseases.

MYCIN was developed over five or six years in the early 1970s at Stanford University. It was written in Lisp as the doctoral dissertation of Edward Shortliffe under the direction of Bruce G. Buchanan, Stanley N. Cohen and others. It arose in the laboratory that had created the earlier Dendral expert system.

MYCIN was never actually used in practice but research indicated that it proposed an acceptable therapy in about 69% of cases, which was better than the performance of infectious disease experts who were judged using the same criteria.

4.11.1 Method

MYCIN operated using fairly simple inference engine, and a knowledge base of ~600 rules. It would query the physician running the program via a long series of simple yes/no or textual questions. At the end, it provided a list of possible culprit bacteria ranked from high to low based on the probability of each diagnosis, its confidence in each diagnosis' probability, the reasoning behind each diagnosis (that is, MYCIN would also list the questions and rules which led it to rank a diagnosis a particular way), and its recommended course of drug treatment.

Despite MYCIN's success, it sparked debate about the use of its ad hoc, but principled, uncertainty framework known as "certainty factors". The developers performed studies showing that MYCIN's performance was minimally affected by perturbations in the uncertainty metrics associated with individual rules, suggesting that the power in the system was related more to its knowledge representation and reasoning scheme than to the details of its numerical uncertainty model. Some observers felt that it should have been possible to use classical Bayesian statistics. MYCIN's developers argued that this would require either unrealistic assumptions of probabilistic independence, or require the experts to provide estimates for an unfeasibly large number of conditional probabilities.*[1]*[2]

Subsequent studies later showed that the certainty factor model could indeed be interpreted in a probabilistic sense, and highlighted problems with the implied assumptions of such a model. However the modular structure of the system would prove very successful, leading to the development of graphical models such as Bayesian networks.*[3]

4.11.2 Results

Research conducted at the Stanford Medical School found MYCIN to propose an acceptable therapy in about 69% of cases, which was better than the performance of infectious disease experts who were judged using the same criteria. This study is often cited as showing the potential for disagreement about thereapeutic decisions, even among experts, when there is no "gold standard" for correct treatment.*[4]

4.11.3 Practical use

MYCIN was never actually used in practice. This wasn't because of any weakness in its performance. As mentioned, in tests it outperformed members of the Stanford medical school faculty. Some observers raised ethical and legal issues related to the use of computers in medicine —if a program gives the wrong diagnosis or recommends the wrong therapy, who should be held responsible? However, the greatest problem, and the reason that MYCIN was not used in routine practice, was the state of technologies for system integration, especially at the time it was developed. MYCIN was a stand-alone system that required a user to enter all relevant information about a patient by typing in responses to questions MYCIN posed. The program ran on a large time-shared system, available over the early Internet (ARPANet), before personal computers were developed. In the modern era, such a system would be integrated with medical record systems, would extract answers to questions from patient databases, and would be much less dependent on physician entry of information. In the 1970s, a session

with MYCIN could easily consume 30 minutes or more —an unrealistic time commitment for a busy clinician.

MYCIN's greatest influence was accordingly its demonstration of the power of its representation and reasoning approach. Rule-based systems in many non-medical domains were developed in the years that followed MYCIN's introduction of the approach. In the 1980s, expert system "shells" were introduced (including one based on MYCIN, known as E-MYCIN (followed by KEE)) and supported the development of expert systems in a wide variety of application areas.

A difficulty that rose to prominence during the development of MYCIN and subsequent complex expert systems has been the extraction of the necessary knowledge for the inference engine to use from the human expert in the relevant fields into the rule base (the so-called "knowledge acquisition bottleneck").

4.11.4 See also

- CADUCEUS (expert system)
- Internist-I
- Clinical decision support system

4.11.5 References

[1] Shortliffe, E.H.; Buchanan, B.G. (1975). "A model of inexact reasoning in medicine". *Mathematical Biosciences* **23** (3–4): 351–379. doi:10.1016/0025-5564(75)90047-4. MR 381762.

[2] Buchanan, B.G.; Shortliffe, E.H. (1984). *Rule Based Expert Systems: The MYCIN Experiments of the Stanford Heuristic Programming Project*. Reading, MA: Addison-Wesley. ISBN 978-0-201-10172-0.

[3] Heckerman, D.; Shortliffe, E. (1992). "From certainty factors to belief networks" (PDF). *Artificial Intelligence in Medicine* **4** (1): 35–52. doi:10.1016/0933-3657(92)90036-O.

[4] Yu, V.L.; et al. (1979). "Antimicrobial selection by a computer: a blinded evaluation by infectious disease experts" (PDF). *Journal of the American Medical Association* **242** (12): 1279–1282. doi:10.1001/jama.1979.03300120033020. PMID 480542.

- *The AI Business: The commercial uses of artificial intelligence*, ed. Patrick Winston and Karen A. Prendergast. ISBN 0-262-23117-4.

4.11.6 External links

- *Rule-Based Expert Systems: The MYCIN Experiments of the Stanford Heuristic Programming Project* -(edited by Bruce G. Buchanan and Edward H. Shortlife; ebook version)
- TMYCIN, system based on MYCIN
- "Mycin Expert System: A Ruby Implementation"
- "MYCIN: A Quick Case Study"
- " SOME EXPERT SYSTEM NEED COMMON SENSE" -(by John McCarthy)
- "Expert Systems"

4.12 Physicians' Information and Education Resource

ACP Smart Medicine is an electronic, evidence-based, decision-support tool designed for point-of-care use by internists and other physicians. It is developed and supported by the American College of Physicians.

4.12.1 History

The Physicians' Information and Education Resource (PIER) was launched in 2002. It was replaced with ACP Smart Medicine in 2013.

4.12.2 External links

ACP Smart Medicine official website

Chapter 5

Medical Imaging Applications

5.1 Digital radiography

Digital radiography is a form of X-ray imaging, where digital X-ray sensors are used instead of traditional photographic film. Advantages include time efficiency through bypassing chemical processing and the ability to digitally transfer and enhance images. Also, less radiation can be used to produce an image of similar contrast to conventional radiography.

Instead of X-ray film, digital radiography uses a digital image capture device. This gives advantages of immediate image preview and availability; elimination of costly film processing steps; a wider dynamic range, which makes it more forgiving for over- and under-exposure; as well as the ability to apply special image processing techniques that enhance overall display quality of the image.

5.1.1 Detectors

There are two major variants of digital image capture devices: flat panel detectors (FPDs) and high-density line-scan solid state detectors. (Baes, 2015)

Flat Panel Detectors

FPDs are further classified in two main categories:

1. **Indirect FPDs** Amorphous silicon (a-Si) is the most common material of commercial FPDs. Combining a-Si detectors with a scintillator in the detector's outer layer, which is made from caesium iodide (CsI) or gadolinium oxysulfide (Gd_2O_2S), converts X-rays to light. Because of this conversion the a-Si detector is considered an indirect imaging device. The light is channeled through the a-Si photodiode layer where it is converted to a digital output signal. The digital signal is then read out by thin film transistors (TFTs) or fiber-coupled CCDs. The image data file is sent to a computer for display.

2. **Direct FPDs**. Amorphous selenium (a-Se) FPDs are known as "direct" detectors because X-ray photons are converted directly into charge. The outer layer of the flat panel in this design is typically a high-voltage bias electrode. X-ray photons create electron-hole pairs in a-Se, and the transit of these electrons and holes depends on the potential of the bias voltage charge. As the holes are replaced with electrons, the resultant charge pattern in the selenium layer is read out by a TFT array, active matrix array, electrometer probes or microplasma line addressing.

High-density Line-scan Detectors

A **high-density line-scan solid state detector** is composed of a photostimulable barium fluorobromide doped with europium (BaFBr:Eu) or caesium bromide (CsBr) phosphor. The phosphor detector records the X-ray energy during exposure and is scanned by a laser diode to excite the stored energy which is released and read out by a digital image capture array of a CCD.

5.1.2 Radiological examinations

Medical

Digital Radiography

(This is an expanding and changing field of science, and subject to revision)

Digital Radiography is replacement of the former Analog methods of detection, with the almost instantaneous development of images on a digital display, instead of the former methods of film and the associated delay in time and chemistry consumption.

At present there are two distinct methods of Digital Radiography.

Computed radiography (CR); This resembles the old analogue system of a light sensitive film sandwiched between two x-ray sensitive screens, the difference being the analogue film has been replaced by an imaging plate, which records the image to be read by an image reading device, which transfers the image usually to a Picture archiving and communication system (PACS)

Direct radiography (confusingly also abbreviated to DR). A direct radiography system has a sealed imaging cassette, this contains an imaging system not entirely un-

like the CCD in a digital camera. the image is recorded then transmitted wirelessly direct to the PACS (hence the name Direct Radiography)

CR vs DR

Initially CR was the system of choice; early DR systems were prohibitively expensive (each cassette costs £40-£50K), and as the 'technology was being taken to the patient', prone to damage.

Therefore, CR system were initially cheaper, less likely to critical failure, and more akin to previous analogue systems...but as newer DR systems have been developed the cassettes have become cheaper more durable and now incorporate wireless technology. Also manufacturers of the x-ray equipment are now producing integrated DR x-ray systems. These integrated systems cost no more than the x-ray equipment alone, and often include warranties for replacement of the DR cassettes. As a result, the CR is becoming the 'old' technology, and as x-ray equipment is replaced the DR systems are proving faster, more efficient and producing higher quality radiographs

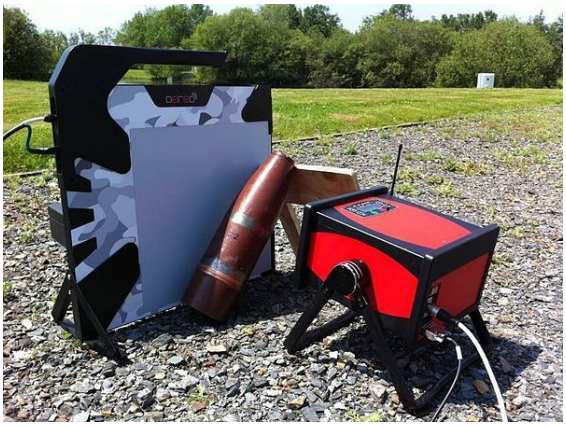
Dental Main article: Dental radiography

The radiological examinations in dentistry may be classified into *intraoral* – where the film or sensor is placed in the mouth, the purpose being to focus on a small region of the oral-maxillofacial region and *extraoral* where the film or sensor is placed outside the mouth aiming to visualize the entire oral maxillofacial region. Extraoral imaging is further divided into orthopantomogram, showing a section, curved following more or less mandible shape, of the whole maxillofacial block and cephalometric analysis showing a projection, as parallel as possible, of the whole skull.

Digital radiography in dentistry provides the clinician with the ability to store their images on a computer. This provides two key advantages over film in the form of full screen images that can be enhanced and zoomed in on, aiding diagnostics and providing easier patient communication, as well as allowing dental offices to communicate images electronically, allowing for simpler referrals and, where applicable, easier insurance claim submission.

Industrial Usage of X-Rays

Aerospace Aerospace is an industry that has experienced great growth in recent decades. Non Destructive Testing (NDT) in aerospace has a special driver of its own due to the high levels of human traffic involved; the crash of a civil or military airliner has the ability to cause loss of life reaching catastrophic proportions. Therefore, strict NDT specifications have been set to detect very small cracks and defects in engine turbo discs, blades and airframe structures, in both production and ongoing maintenance.



EOD training and material testing. A 105 mm shell is radiographied with battery powered portable X-ray generator and flat panel detector.

Security Digital Radiography (DR) has existed in various forms (for example, CCD and amorphous Silicon imagers) in the security X-ray inspection field for over 20 years and is rapidly replacing the use of film for inspection X-rays in the Security and NDT fields. DR has opened a window of opportunity for the security NDT industry due to several key advantages including excellent image quality, high POD, portability, environmental friendliness and immediate imaging.*[1]

5.1.3 Digital radiographic systems

Digital dental radiography comes in two forms: direct, that connect directly to the computer via USB and provides immediate images, and indirect (photostimulable phosphor plates, or PSP) which uses plates that are radiated and then digitally scanned.

Direct digital sensors represent a significant initial investment, but in addition to the convenience of digital images, provide instant images that can reduce the time the patient spends in the dental chair. They also reduce the need for the constant purchase of film and the necessary development chemicals. Early systems used CCD sensor technology, but changed to Amorphous Silicon (aSi:H) sensors following their introduction in early 1998-9.

Indirect digital imaging (also termed Computed Radiography) utilizes a reusable plate in place of the film. After X-ray exposure the plate (sheet) is placed in a special scanner where the latent formed image is retrieved point by point and digitized, using laser light scanning. The digitized images are stored and displayed on the computer screen. This method is halfway between old film-based technology and current direct digital imaging technology. It is similar to the film process because it involves the same image support handling but differs in that the chemical development process is replaced by scanning. This is not much faster than film processing and the resolution and sensitivity performances are contested. PSP has been described as having an advantage of fitting within any

pre-existing equipment without modification because it replaces the existing film; however, it includes extra costs for the scanner and replacement of scratched plates.

5.1.4 Invention

In the early 1960s, while developing compact, lightweight, portable equipment for the onboard nondestructive testing (NDT) of naval aircraft, Frederick G. Weighart*[2]*[3] and James F. McNulty (U.S. radio engineer)*[4] at Automation Industries, Inc., then, in El Segundo, California co-invented the apparatus, which produced the world's first image to be digitally generated with x-rays. Square wave signals were detected on the fluorescent screen of a fluoroscope to create the image.

5.1.5 Historical milestones for digital intraoral sensors

- **1987 – RVG** (*radiovisiography*), Trophy Radiology (France) introduced the world's first intraoral X-rays imaging sensor. Trophy Radiology patented it under the restricted name *radiovisiography* (other companies use the phrase *digital radiography*) and continues to produce intraoral sensors today under the Carestream Dental name, which is used under license by Carestream Health. Carestream Dental has released a wireless version of their RVG intraoral sensor named the RVG 6500.
- **1992 – Sens-a-Ray** of *Regam Medical System AB* (Sundsvall, Sweden) is introduced. The company went out of business and their technology was purchased by Dent-X, recently renamed to ImageWorks (USA). First distributor in North America was Video Dental Concepts 1992
- **1993 – VisualX** of *Gendex*-Italy (subsidiary of USA company).
- **1994 – CDR** of *Schick Technologies*, USA. Schick were the first company to offer three film-like sizes of sensor, as well providing the significant breakthroughs of CMOS-APS technology (1998), USB connectivity (1999), the first sensors without cables (2003) and the first sensors with replaceable cables (2008). They launched their second generation of CMOS-APS chips in 2009. Schick merged with Sirona (Germany) in 2006 and is now part of Sirona Dental Systems, LLC.
- **1995 – SIDEXIS** of *Sirona*, **DEXIS** of *ProVison Dental Systems, Inc.* (renamed DEXIS, LLC following its acquisition by Danaher Corp.), **DIGORA** (PSP solution) of *Soredex* (Finland)
- **2011 - Sodium Dental (Sodium Systems llc)** were the first to offer digital intraoral x-ray sensor repair to dental practitioners and dental equipment companies.

Today there are many other products available under a lot of different names (rebranding is quite usual for this type of product).

5.1.6 Historical milestones for digital panoramic systems

DXIS - real time display

- **1995 – DXIS**, the first dental digital panoramic X-rays system available on the market, created by Catalin Stoichita at Signet (France). DXIS targeted to retrofit all the panoramic models.
- **1997 – SIDEXIS**, of *Siemens* (currently Sirona, Germany) offered for Ortophos Plus panoramic unit, **DigiPan** of *Trophy Radiology* (France) offered for the OP100 panoramic made by Instrumentarium (Finland).
- **1998–2004** – many panoramic manufacturers offered their own digital system.
- **2005 – SCAN300FP**, of '**Ajat**' (Finland) is the latest innovation offered. It shows the feature to acquire many hundreds of mega bytes of image information at high frame rate and to reconstruct the panoramic layer by intensive post acquisition computing like a computed tomography. The main advantage is the ability to reconstruct focused differently. The drawback is the low signal/noise ratio of primary information which involves much software work for correction. Also the ability to reconstruct various layers raises the importance of the geometrical distortions already high in dental panoramic radiography. Since **2008** the SCAN300FP system is available in **Ajat ART PLUS** and **ART PLUS C** system.

5.1.7 See also

- Computed radiography
- Fluoroscopy

5.1.8 External links

- Digital Radiography for NDT & Security
- Applications in the field of Digital radiography

[1] "http://www.vidisco.com/node/273". *Digigital Radiography*. Vidisco. Retrieved 2012-09-27. External link in |title= (help)

[2] U.S. Patent 3,277,302, titled "X-Ray Apparatus Having Means for Supplying An Alternating Square Wave Voltage to the X-Ray Tube", granted to Weighart on October 4, 1964, showing its patent application date as May 10, 1963 and at lines 1-6 of its column 4, also, noting James F. McNulty's earlier filed co-pending application for an essential component of invention

[3] U.S. Patent 3,482,093, see also this patent, titled "Flouroscopy", referencing US Patent 3277302 to Weighart and detailing the flouroscopy procedure used for nondestructing testing.

[4] U.S. Patent 3,289,000, titled "Means for Separately Controlling the Filament Current and Voltage on a X-Ray Tube", granted to McNulty on November 29, 1966 and showing its patent application date as March 5, 1963

5.2 Imaging informatics

Imaging Informatics, also known as Radiology Informatics or Medical Imaging Informatics, is a subspecialty of Biomedical Informatics that aims to improve the efficiency, accuracy, usability and reliability of medical imaging services within the healthcare enterprise.*[1] It is devoted to the study of how information about and contained within medical images is retrieved, analyzed, enhanced, and exchanged throughout the medical enterprise.

As radiology is an inherently data-intensive and technology-driven specialty of medicine, radiologists have become leaders in Imaging Informatics. However, with the proliferation of digitized images across the practice of medicine to include fields such as cardiology, ophthalmology, dermatology, surgery, gastroenterology, obstetrics, gynecology and pathology, the advances in Imaging Informatics are also being tested and applied in other areas of medicine. Various industry players and vendors involved with medical imaging, along with IT experts and other biomedical informatics professionals, are contributing and getting involved in this expanding field.

Imaging informatics exists at the intersection of several broad fields:

- biological science - includes bench sciences such as biochemistry, microbiology, physiology and genetics
- clinical services - includes the practice of medicine, bedside research, including outcomes and cost-effectiveness studies, and public health policy
- information science - deals with the acquisition, retrieval, cataloging, and archiving of information
- medical physics / biomedical engineering - entails the use of equipment and technology for a medical purpose
- cognitive science - studying human computer interactions, usability, and information visualization
- computer science - studying the use of computer algorithms for applications such as computer assisted diagnosis and computer vision

5.2.1 Areas of Interest

Key areas relevant to Imaging informatics include:

- Picture Archiving and Communication System (PACS) and Component Systems
- Imaging Informatics for the Enterprise
- Image-Enabled Electronic Medical Records
- Radiology Information Systems (RIS) and Hospital Information Systems (HIS)
- Digital image acquisition
- Image processing and enhancement
- Image data compression
- 3D visualization and multimedia
- Speech recognition
- Computer-aided diagnosis (CAD).
- Imaging facilities design
- Imaging vocabularies and ontologies
- Data mining from medical images databases
- Transforming the Radiological Interpretation Process (TRIP)*[2]
- DICOM, HL7 and other standards
- Workflow and process modeling and process simulation
- Quality assurance
- Archive integrity and security
- Teleradiology
- Radiology informatics education
- Digital imaging

5.2.2 Training

Radiologists who wish to pursue sub-specialty training in this field can undergo fellowship training in Imaging Informatics. Medical Imaging Informatics Fellowships are done after completion of Board Certification in Diagnostic Radiology, and may be pursued concurrently with other sub-specialty radiology fellowships.

The American Board of Imaging Informatics (ABII) also administers a certification examination for Imaging Informatics Professionals. PARCA (PACS Administrators Registry and Certification Association) certifications also exist for imaging informatics professionals.

5.2.3 References

[1] Branstetter, B (2007). "Basics of Imaging Informatics". *Radiology* **243** (3): 656–67. doi:10.1148/radiol.2433060243. PMID 17431128.

[2] TRIP - an initiative between the then Society of Computer Applications in Radiology (SCAR), now known as the Society of Imaging Informatics in Medicine (SIIM)

5.2.4 External links

- The Society for Imaging Informatics in Medicine
- American Board of Imaging Informatics

5.3 Patient registration

Patient registration is the concept and set of methods needed to correlate the reference position of a virtual 3D dataset gathered by computer medical imaging with the reference position of the patient. This procedure is crucial in computer assisted surgery, in order to insure the reproducitibility of the preoperative registration and the clinical situation during surgery. The use of the term "patient registration" out of this context can lead to a confusion with the procedure of registering a patient into the files of a medical institution.

5.3.1 The larger context

In computer assisted surgery, the first step is to gather a 3D dataset that reproduces with great accuracy the geometry of the normal and pathological tissues in the region that has to be operated on. This is mainly obtained by using CT or MRI scans of that region. The role of patient registration is to obtain a close-to-ideal reference reproducitibility of the dataset – in order to correlate the position (offset) of the gathered dataset with the patient's position during the surgical intervention. Patient registration (1) eliminates the necessity of maintaining the same strict position of the patient during both preoperative scanning and surgery, and (2) provides the surgical robot the necessary reference information to act accurately on the patient, even if he has (been) moved during the intervention.

5.3.2 Evolution of the concept

Patient registration was used mostly in head surgery – oral and maxillofacial surgery, neurosurgery, otolaryngology. With the advent of marker- and markerless-registration, the concept has been extended for abdominal surgery.

Patient registration using headframes

The first attempts in 3D mapping of human tissues were made by V. Horsley and R. Clarke in 1906.*[1] They have built a rectangular stereotactic headframe that had to be fixed to the head. It was based on cartesian principles and allowed them to accurately and reproductibly guide needle-like electrodes for neurophysiological experiments. They have experimented animals and were able to contribute to the mapping of the cerebellum. Improved versions of the Horsley–Clarke apparatus are still in used today in experimental neurosurgery.

The first stereotactic device for humans was also developed in neurosurgery, by E. Spiegel and H. Wycis in 1947.*[2] It was used for surgical treatment of Parkinson's disease and, during time, its applicability was extended for the surgical treatment of tumors, vascular malformations, functional neurosurgery etc. The system was based both on headframes and X-ray images taken for all three planes of space.

Further development of stereotactic surgery was made by Brown, Roberts and Wells in 1980.*[3] They have developed a halo ring that was applied on the skull, during a CT scan and neurosurgical interventions. This method provided improved surgical guidance and was in fact the first development of computer guided surgery.

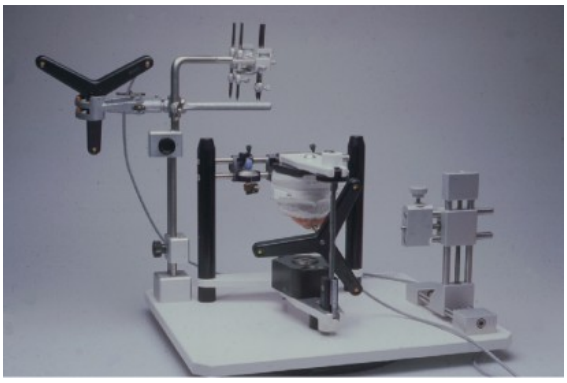
Patient registration for the head area has developed for nearly two decades on the same principle of combining CT scans with mechanical reference devices such as headframes or halo rings. But the clinical experience showed that headgear is very uncomfortable to wear and even impossible to apply on little children, because their lack of cooperation; furthermore, the headframes can create artifacts in preoperative data gathering, or during surgery.

Patient registration using reference markers

Patient registration using skin markers In 1986, a different approach was developed by Roberts und Strohbehn.*[4] They have used as landmarks several markers on the patient's skin both preoperative CT registra-

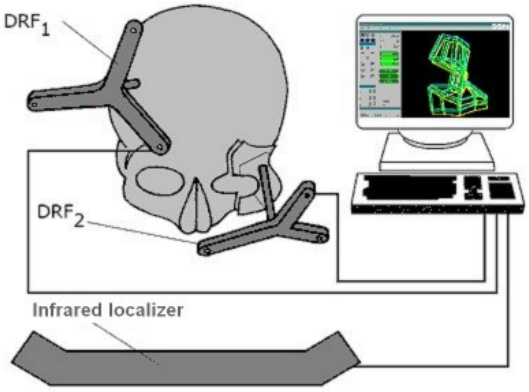
tion, and intraoperatively. This was a new current of the time in patient registration. Still, the method is time-consuming, and the exact reproducitibility of the marker positions is questionable.

Patient registration using bone markers The bony structures can provide a much better stability and reproducibility of the landmarks for patient registration. Based on this concept, a further technique was used: to implant temporary markers into bone structures that are superficial to the skin, under local anestesia.*[5] This was also combined with surface markers and CT registration.*[6] The technique has the disadvantage of a further minimal surgical procedure of placing the bone implants, with some risk of infection for the patient.

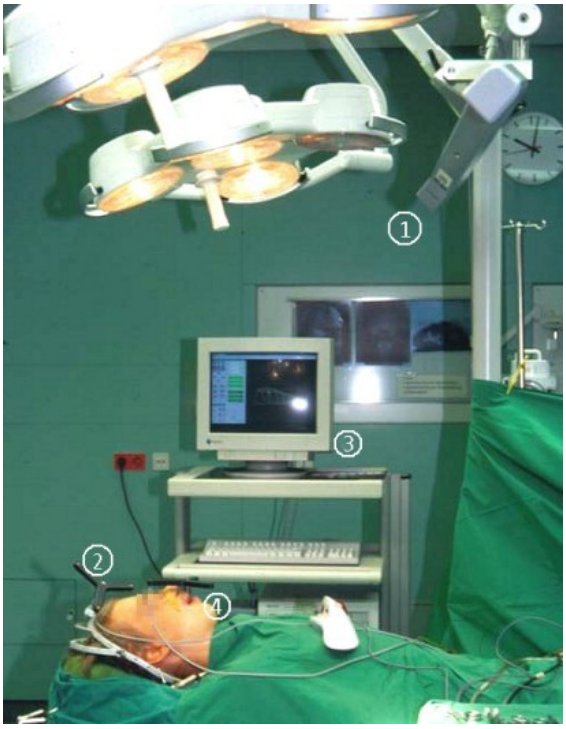


Surgical planning using bone segment navigation for the osteotomy of the jaw bones, based on models fixed into an articulator (registration based on infrared devices)

Patient registration using markers on a dental splint Dental splints have been traditionally used for transferring and reproducing 3D reference landmarks for positioning cast models in articulators – in dental prosthetics, orthodontics and orthognatic surgery. By applying several infrared markers on the splints and using an infrared camera, a better registration was obtained.*[7]



Schematic representation of the SSN system



Actual usage of the SSN system in the operating room

Markerless patient registration

Markerless patient registration using anatomical landmarks The first attempts, based on the identification of anatomical landmarks were made by Caversaccio and Zulliger.*[8] The method was based on identifying certain antropometrical points and other anatomical landmarks on the skull, in correlation with the CT registration. But the landmarks cannot be exactly pointed out and reproduced during patient dataset registration and surgery, therefore the method is not precise enough.

Markerless patient registration using surface registration Since 1998, new procedures have been developed by Marmulla and co-workers, using a different approach to the problem.*[9]*[10] Both during CT dataset gathering and surgical intervention, the patient registration was made by registering complete areas and surfaces, instead of distinctive surface markers. This was achieved by using laser scanners and a small guiding transmitter. The precision of the patient registration was significantly improved with this method.

Based on this concept, several registration and navigation systems were built by the same team. The Surgical Segment Navigator (SSN and SSN++) is such a system, developed for the first time for oral and maxillofacial surgery. This system correlates three different coordinate sets: CT data set, surface laser scan data set and the dataset produced by a small guiding transmitter, placed on the patient's head. The Laboratory Unit for Computer-

Assisted Surgery (LUCAS) is used for planning surgery in the laboratory. This technological and surgical advance has permitted the elimination of mechanical guidance systems and improved the accuracy of the determinations, and thus the surgical act.

5.3.3 References

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5.4 Radiology information system

A **radiology information system** (RIS) is a computerized database used by radiology departments to store, manipulate, and distribute patient radiological data and imagery. The system generally consists of patient tracking and scheduling, result reporting and image tracking capabilities. RIS complements HIS (Hospital Information Systems), and is critical to efficient workflow to radiology practices.

5.4.1 Basic Features

Radiology information systems commonly support the following features:

- Patient Registration and scheduling
- Patient List Management
- Interface with modality via Work-list.
- Radiology Department workflow management
- Request and document scanning
- Result(s) Entry
- Reporting and printout
- Result(s) Delivery including faxing and e-mailing of clinical reports
- Patient Tracking
- Interactive Documents
- Technical Files Creation
- Modality and Material management.

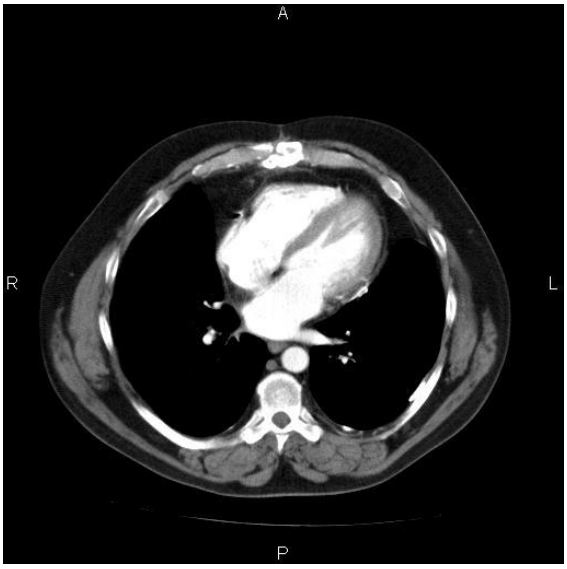
5.4.2 Additional Features

In addition a RIS often supports the following:

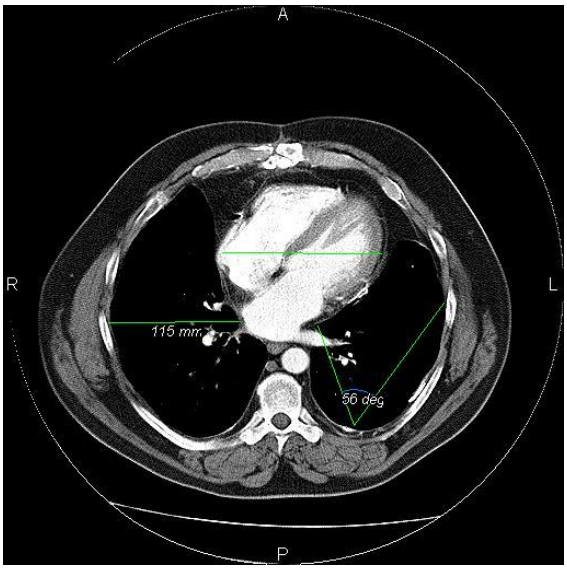
- Appointment booking
- PACS workflow
- Custom report creation
- HL7 interfaces with a PACS. HL7 also enables communication between HIS and RIS in addition to RIS and PACS.
- Billing
- Rule engines

5.4.3 See also

- Electronic health record (EHR)
- eMix
- Hospital information system (HIS)
- Picture archiving and communication system (PACS)
- Medical imaging
- Medical software



An image as stored on a picture archiving and communication system (PACS)



The same image following contrast adjustment, sharpening and measurement tags added by the system

5.5 Picture archiving and communication system

A **picture archiving and communication system** (**PACS**) is a medical imaging technology which provides economical storage and convenient access to images from multiple modalities (source machine types).[*] [1] Electronic images and reports are transmitted digitally via PACS; this eliminates the need to manually file, retrieve, or transport film jackets. The universal format for PACS image storage and transfer is DICOM (Digital Imaging and Communications in Medicine). Non-image data, such as scanned documents, may be incorporated using consumer industry standard formats like PDF (Portable Document Format), once encapsulated in DICOM. A PACS consists of four major components: The imaging modalities such as X-ray plain film (PF), computed tomography (CT) and magnetic resonance imaging (MRI), a secured network for the transmission of patient information, workstations for interpreting and reviewing images, and archives for the storage and retrieval of images and reports. Combined with available and emerging web technology, PACS has the ability to deliver timely and efficient access to images, interpretations, and related data. PACS breaks down the physical and time barriers associated with traditional film-based image retrieval, distribution, and display.

5.5.1 Types of images

Most PACSs handle images from various medical imaging instruments, including ultrasound (US), magnetic resonance (MR), Nuclear Medicine imaging, positron emission tomography (PET), computed tomography (CT), endoscopy (ES), mammograms (MG), digital radiography (DR), computed radiography (CR), Histopathology, ophthalmology, etc. Additional types of image formats are always being added. Clinical areas beyond radiology; cardiology, oncology, gastroenterology, and even the laboratory are creating medical images that can be incorporated into PACS. (see DICOM Application areas).

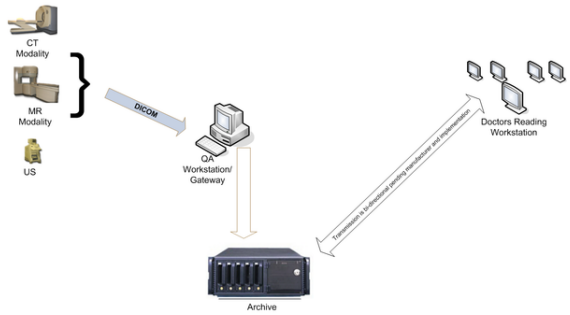
5.5.2 Uses

PACS has four main uses:

- Hard copy replacement: PACS replaces hard-copy based means of managing medical images, such as film archives. With the decreasing price of digital storage, PACSs provide a growing cost and space advantage over film archives in addition to the instant access to prior images at the same institution. Digital copies are referred to as Soft-copy.
- Remote access: It expands on the possibilities of conventional systems by providing capabilities of off-site viewing and reporting (distance education, telediagnosis). It enables practitioners in different physical locations to access the same information simultaneously for teleradiology.
- Electronic image integration platform: PACS provides the electronic platform for radiology images interfacing with other medical automation systems such as Hospital Information System (HIS), Electronic Medical Record (EMR), Practice Management Software, and Radiology Information System (RIS).
- Radiology Workflow Management: PACS is used by radiology personnel to manage the workflow of patient exams.

PACS is offered by virtually all the major medical imaging equipment manufacturers, medical IT companies and many independent software companies. Basic PACS software can be found free on the Internet.

5.5.3 Architecture



PACS workflow diagram

The architecture is the physical implementation of required functionality, or what one sees from the outside. There are different views, depending on the user. A radiologist typically sees a viewing station, a technologist a QA workstation, while a PACS administrator might spend most of their time in the climate-controlled computer room. The composite view is rather different for the various vendors.* [2]

Typically a PACS consists of a multitude of devices. The first step in typical PACS systems is the modality. Modalities are typically computed tomography (CT), ultrasound, nuclear medicine, positron emission tomography (PET), and magnetic resonance imaging (MRI). Depending on the facility's workflow most modalities send to a quality assurance (QA) workstation or sometimes called a PACS gateway. The QA workstation is a checkpoint to make sure patient demographics are correct as well as other important attributes of a study. If the study information is correct the images are passed to the archive for storage. The central storage device (archive) stores images and in some cases reports, measurements and other information that resides with the images. The next step in the PACS workflow is the reading workstations. The reading workstation is where the radiologist reviews the patient's study and formulates their diagnosis. Normally tied to the reading workstation is a reporting package that assists the radiologist with dictating the final report. Reporting software is optional and there are various ways in which doctors prefer to dictate their report. Ancillary to the workflow mentioned, there is normally CD/DVD authoring software used to burn patient studies for distribution to patients or referring physicians. The diagram above shows a typical workflow in most imaging centers and hospitals. Note that this section does not cover integration to a Radiology Information System, Hospital Information System and other such front-end system that relates to the PACS workflow.

More and more PACS include web-based interfaces to utilize the internet or a Wide Area Network as their means of communication, usually via VPN (Virtual Private Network) or SSL (Secure Sockets Layer). The clients side software may use ActiveX, JavaScript and/or a Java Applet. More robust PACS clients are full applications which can utilize the full resources of the computer they are executing on and are unaffected by the frequent unattended Web Browser and Java updates. As the need for distribution of images and reports becomes more widespread there is a push for PACS systems to support DICOM part 18 of the DICOM standard. Web Access to DICOM Objects (WADO) creates the necessary standard to expose images and reports over the web through truly portable medium. Without stepping outside the focus of the PACS architecture, WADO becomes the solution to cross platform capability and can increase the distribution of images and reports to referring physicians and patients.

PACS image backup is a critical, but sometimes overlooked, part of the PACS Architecture (see below). HIPAA requires that backup copies of patient images be made in case of image loss from the PACS. There are several methods of backing up the images, but they typically involve automatically sending copies of the images to a separate computer for storage, preferably off-site.

5.5.4 Querying (C-FIND) and Image (Instance) Retrieval (C-MOVE and C-GET)

The communication with the PACS server is done through DICOM messages that are similar to DICOM image "headers", but with different attributes. A query (C-FIND) is performed as follows:

- The client establishes the network connection to the PACS server.
- The client prepares a C-FIND request message which is a list of DICOM attributes.
- The client fills in the C-FIND request message with the keys that should be matched. E.g. to query for a patient ID, the patient ID attribute is filled with the patient's ID.
- The client creates empty (zero length) attributes for all the attributes it wishes to receive from the server. E.g. if the client wishes to receive an ID that it can use to receive images (see image retrieval) it should include a zero-length SOPInstanceUID (0008,0018) attribute in the C-FIND request messages.
- The C-FIND request message is sent to the server.
- The server sends back to the client a list of C-FIND response messages, each of which is also a list of

DICOM attributes, populated with values for each match.

- The client extracts the attributes that are of interest from the response messages objects.

Images (and other composite instances like Presentation States and Structured Reports) are then retrieved from a PACS server through either a C-MOVE or C-GET request, using the DICOM network protocol. Retrieval can be performed at the Study, Series or Image (instance) level. The C-MOVE request specifies where the retrieved instances should be sent (using separate C-STORE messages on one or more separate connections) with an identifier known as the destination Application Entity Title (AE Title). For a C-MOVE to work, the server must be configured with mapping of the AE Title to a TCP/IP address and port, and as a consequence the server must know in advance all the AE Titles that it will ever be requested to send images to. A C-GET, on the other hand, performs the C-STORE operations on the same connection as the request, and hence does not require that the "server" know the "client" TCP/IP address and port, and hence also works more easily through firewalls and with network address translation, environments in which the incoming TCP C-STORE connections required for C-MOVE may not get through. The difference between C-MOVE and C-GET is somewhat analogous to the difference between active and passive FTP. C-MOVE is most commonly used within enterprises and facilities, whereas C-GET is more practical between enterprises.

In addition to the traditional DICOM network services, particularly for cross-enterprise use, DICOM (and IHE) define other retrieval mechanisms, including WADO, WADO-WS and most recently WADO-RS.

5.5.5 Image archival and backup

Digital medical images are typically stored locally on a PACS for retrieval. It is important (and required in the USA by the Security Rule's Administrative Safeguards section of HIPAA) that facilities have a means of recovering images in the event of an error or disaster. While each facility is different, the goal in image back-up is to make it automatic and as easy to administer as possible. The hope is that the copies won't ever be needed, but, as with other disaster recovery and business continuity planning, they need to be available if needed.

Ideally, copies of images should be streamed off-site as they are created. (If using the Internet, the Security Rule's Technical Safeguards section of HIPAA requires that the images be encrypted during transmission.) Depending on upload bandwidth and image volume, this may not be practical if the back-up system cannot be configured to tune bandwidth usage and frequency of backups. Other options include removable media (hard drives,

PACS-Server with 35 Terabyte RAID Archive and high speed fiber optic switch

DVDs or other media that can hold many patients' images) that is physically transferred off-site. The content of these copies must be protected via encryption from exposure to unauthorized personnel or stiff penalties can be assessed.*[3]

Images may be stored both locally and remotely on off-line media such as tape or optical media, or partially or exclusively on hard disks ("spinning") media. The latter is becoming more common. The hard drives may be configured and attached to the PACS server in various ways, either as Direct-Attached Storage (DAS), Network-attached storage (NAS), or via a Storage Area Network (SAN).

However the storage is attached, the drives themselves are usually configured as a Redundant Array of Inexpensive (or Independent) Discs RAID, which may be configured to provide appropriate combination of faster disk access or protection against the failure of one (or even two) discs in the physical RAID array. Typically, failed drives may be physically replaced (hot swapping) without interruption of service. Since costs of computers has fallen, some sites opt for fully redundant Archives, rather than just protecting the drives through RAID. Further, RAIDs are fragile and can be rendered useless by one erroneous hit on the controller.

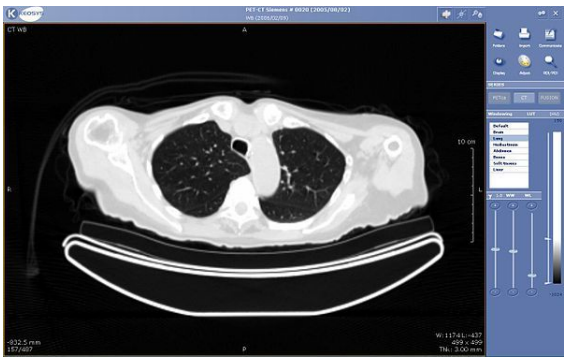
Data stored on disk may also be backed up to tape or optical media or copied, in real time, to a slower, inexpensive disc in another machine at another location. Some sites make two such backups and remove them from the site

on a rotating basis.

In the event that it is necessary to reconstruct a PACS partially or completely from the back-up images, some means of rapidly transferring all of its images back to the PACS is required, preferably whilst the PACS continues to receive and provide current images.

The back-up infrastructure may also be capable of supporting the migration of images to a new PACS. Due to the high volume of images that need to be archived many rad centers are migrating their systems to a Cloud-based PACS.

5.5.6 Integration



A chest image displayed via a PACS

A full PACS should provide a single point of access for images and their associated data. That is, it should support all digital modalities, in all departments, throughout the enterprise.

However, until PACS penetration is complete, individual islands of digital imaging not yet connected to a central PACS may exist. These may take the form of a localized, modality-specific network of modalities, workstations and storage (a so-called "mini-PACS"), or may consist of a small cluster of modalities directly connected to reading workstations without long term storage or management. Such systems are also often not connected to the departmental information system. Historically, Ultrasound, Nuclear Medicine and Cardiology Cath Labs are often departments that adopt such an approach.

More recently, Full Field digital mammography (FFDM) has taken a similar approach, largely because of the large image size, highly specialized reading workflow and display requirements, and intervention by regulators. The rapid deployment of FFDM in the US following the DMIST study has led to the integration of Digital Mammography and PACS becoming more commonplace.

All PACS, whether they span the entire enterprise or are localized within a department, should also interface with existing hospital information systems: Hospital information system (HIS) and Radiology Information System (RIS). There are several data flowing into PACS as inputs for next procedures and back to HIS as results corresponding inputs:

> **In:** Patient Identification and Orders for examination. These data are sent from HIS to RIS via integration interface, in most of hospital, via HL7 protocol. Patient ID and Orders will be sent to Modality (CT,MR,etc) via DICOM protocol (Worklist). Images will be created after images scanning and then forwarded to PACS Server. Diagnosis Report is created based on the images retrieved for presenting from PACS Server by physician/radiologist and then saved to RIS System.
> **Out:** Diagnosis Report and Images created accordingly. Diagnosis Report is sent back to HIS via HL7 usually and Images are sent back to HIS via DICOM usually if there is a DICOM Viewer integrated with HIS in hospitals (In most of cases, Clinical Physician gets reminder of Diagnosis Report coming and then queries images from PACS Server).

Interfacing between multiple systems provides a more consistent and more reliable dataset:

- Less risk of entering an incorrect patient ID for a study – modalities that support DICOM worklists can retrieve identifying patient information (patient name, patient number, accession number) for upcoming cases and present that to the technologist, preventing data entry errors during acquisition. Once the acquisition is complete, the PACS can compare the embedded image data with a list of scheduled studies from RIS, and can flag a warning if the image data does not match a scheduled study.
- Data saved in the PACS can be tagged with unique patient identifiers (such as a social security number or NHS number) obtained from HIS. Providing a robust method of merging datasets from multiple hospitals, even where the different centers use different ID systems internally.

An interface can also improve workflow patterns:

- When a study has been reported by a radiologist the PACS can mark it as read. This avoids needless double-reading. The report can be attached to the images and be viewable via a single interface.
- Improved use of online storage and nearline storage in the image archive. The PACS can obtain lists of appointments and admissions in advance, allowing images to be pre-fetched from off-line storage or near-line storage onto online disk storage.

Recognition of the importance of integration has led a number of suppliers to develop fully integrated

RIS/PACS. These may offer a number of advanced features:

- Dictation of reports can be integrated into a single system. Integrated speech-to-text voice recognition software may be used to create and upload a report to the patient's chart within minutes of the patient's scan, or the reporting physician may dictate their findings into a phone system or voice recorder. That recording may be automatically sent to a transcript writer's workstation for typing, but it can also be made available for access by physicians, avoiding typing delays for urgent results, or retained in case of typing error.
- Provides a single tool for quality control and audit purposes. Rejected images can be tagged, allowing later analysis (as may be required under radiation protection legislation). Workloads and turn-around time can be reported automatically for management purposes.

5.5.7 Acceptance testing

The PACS installation process is complicated requiring time, resources, planning, and testing. Installation is not complete until the acceptance test is passed. Acceptance testing of a new installation is a vital step to assure user compliance, functionality, and especially clinical safety. Take for example the Therac-25, a radiation medical device involved in accidents in which patients were given massive overdoses of radiation, due to unverified software control.*[4]

The acceptance test determines whether the PACS is ready for clinical use and marks the warranty timeline while serving as a payment milestone. The test process varies in time requirements depending on facility size but contract condition of 30-day time limit is not unusual. It requires detailed planning and development of testing criteria prior to writing the contract. It is a joint process requiring defined test protocols and benchmarks.

Testing uncovers deficiencies. A study determined that the most frequently cited deficiencies were the most costly components.*[5] Failures ranked from most-to-least common are: Workstation; HIS/RIS/ACS broker interfaces; RIS; Computer Monitors; Web-based image distribution system; Modality interfaces; Archive devices; Maintenance; Training; Network; DICOM; Teleradiology; Security; Film digitizer.

5.5.8 History

The principles of PACS were first discussed at meetings of radiologists in 1982. Various people are credited with the coinage of the term *PACS*. Cardiovascular radiologist Dr Andre Duerinckx reported in 1983 that he had first used the term in 1981.*[6] Dr Samuel Dwyer, though, credits Dr Judith M. Prewitt for introducing the term.*[7]

Dr Harold Glass, a medical physicist working in London in the early 1990s secured UK Government funding and managed the project over many years which transformed Hammersmith Hospital in London as the first filmless hospital in the United Kingdom.*[8] Dr Glass died a few months after the project came live but is credited with being one of the pioneers of PACS.

The first large-scale PACS installation was in 1982 at the University of Kansas, Kansas City.*[2] This first installation became more of a teaching experience of what not to do rather than what to do in a PACS installation.

5.5.9 Regulatory concerns

In the US PACS are classified as Medical Devices, and hence if for sale are regulated by the USFDA. In general they are subject to Class 2 controls and hence require a 510(k), though individual PACS components may be subject to less stringent general controls.*[9] Some specific applications, such as the use for primary mammography interpretation, are additionally regulated*[10] within the scope of the Mammography Quality Standards Act.

The Society for Imaging Informatics in Medicine (SIIM) is the worldwide professional and trade organization that provides an annual meeting and a peer-reviewed journal to promote research and education about PACS and related digital topics.

5.5.10 See also

- DICOM
- Electronic Health Record (EHR)
- Electronic Medical Record (EMR)
- eMix
- Medical device
- Medical imaging
- Medical software
- Radiographer
- Radiology
- Radiology Information System
- Teleradiology
- Vendor Neutral Archive (VNA)
- X-ray

5.5.11 References

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[10] USFDA (30 May 2008). "Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions". Retrieved 11 February 2010.

5.5.12 External links

- Teleradiology, PACS and DICOM Software List of free PACS and DICOM software available on the web
- PACS History Web Site
- USC IPILab Research Article on Backup
- What is picture archiving and communication system (PACS) Definition

5.6 Analysis of Functional NeuroImages

Analysis of Functional NeuroImages (AFNI) is an open-source environment for processing and displaying functional MRI data—a technique for mapping human brain activity.

AFNI is an agglomeration of programs that can be used interactively or flexibly assembled for batch processing using shell script. The term *AFNI* refers both to the entire suite and to a particular interactive program often used for visualization. AFNI is actively developed by the NIMH Scientific and Statistical Computing Core and its capabilities are continually expanding.

AFNI runs under many Unix-like operating systems that provide X11 and Motif libraries, including IRIX, Solaris, Linux, FreeBSD and OS X. Precompiled binaries are available for some platforms. AFNI is available for research use under the GNU General Public License. AFNI now comprises over 300,000 lines of C source code, and a skilled C programmer can add interactive and batch functions to AFNI with relative ease.

5.6.1 History and development

AFNI was originally developed at the Medical College of Wisconsin beginning in 1994, largely by Robert W. Cox. Robert Cox brought development to the NIH in 2001 and development continues at the NIMH Scientific and Statistical Computing Core.

5.6.2 See also

- National Institute of Mental Health
- Neuroimaging
- Statistical parametric mapping

5.6.3 External links

- AFNI main page
- NIMH Scientific and Statistical Computing Core

5.7 3DSlicer

3D Slicer (Slicer) is a free and open source software package for image analysis*[1] and scientific visualization. Slicer is used in a variety of medical applications, including autism, multiple sclerosis, systemic lupus erythematosus, prostate cancer, schizophrenia, orthopedic biomechanics, COPD, cardiovascular disease and neurosurgery.

5.7.1 About Slicer

3D Slicer is a free open source software (BSD-style license) that is a flexible, modular platform for image anal-

ysis and visualization. 3D Slicer can be extended to enable development of both interactive and batch processing tools for a variety of applications.

3D Slicer provides image registration, processing of DTI (diffusion tractography), an interface to external devices for image guidance support, and GPU-enabled volume rendering, among other capabilities. 3D Slicer has a modular organization that allows the addition of new functionality and provides a number of generic features not available in competing tools.

The interactive visualization capabilities of 3D Slicer include the ability to display arbitrarily oriented image slices, build surface models from image labels, and hardware accelerated volume rendering. 3D Slicer also supports a rich set of annotation features (fiducials and measurement widgets, customized colormaps).

Slicer's capabilities include:* [2]

- Handling DICOM images and reading/writing a variety of other formats
- Interactive visualization of volumetric Voxel images, polygonal meshes, and volume renderings
- Manual editing
- Fusion and co-registering of data using rigid and non-rigid algorithms
- Automatic image segmentation
- Analysis and visualization of diffusion tensor imaging data
- Tracking of devices for image-guided procedures.

Slicer is compiled for use on multiple computing platforms, including Windows, Linux, and Mac OS X.

Slicer is distributed under a BSD style, free, open source license. The license has no restrictions on use of the software in academic or commercial projects. However, no claims are made on the software being useful for any particular task. It is entirely the responsibility of the user to ensure compliance with local rules and regulations. Slicer has not been formally approved for clinical use in the FDA in the US or by any other regulatory body elsewhere.

5.7.2 Image gallery

- Hardware accelerated volume rendering with nVidia drivers, (on Windows and Linux only).
- ProstateNav Module for MRI guided robot assisted biopsy of the prostate.
- Left: 3D rendering. Right: Open MR system
- Visualization of some atlas-based ROIs which correspond to major anatomical fiber tracts. The atlas was provided as part of a download of DTI studio.
- High resolution data acquired on 3-Tesla magnet and post-processed using automated tracking procedure.
- High-dimensional white matter atlas generation and group analysis: result of automatic segmentation of novel subjects.
- Patient-specific modeling in a patient with congenital heart disease.
- Left: Three-dimensional model of levator ani subdivisions including the pubic bone and pelvic viscera. Right: The same model without the pubic bone.
- Cortical parcellations derived from SPGR images obtained from a tumor patient.
- Intraoperative colocalization using iMRI images and 3-D Slicer software.

5.7.3 History

Slicer started as a masters thesis project between the Surgical Planning Laboratory at the Brigham and Women's Hospital and the MIT Artificial Intelligence Laboratory in 1998.* [3] 3D Slicer version 2 has been downloaded several thousand times. In 2007 a completely revamped version 3 of Slicer was released. The next major refactoring of Slicer was initiated in 2009, which aims to transition the GUI of Slicer from using KWWidgets to Qt. Qt-enabled Slicer version 4 has been released in 2011.* [4]

Slicer software has enabled a variety of research publications, all aimed at improving image analysis.* [5]

This significant software project has been enabled by the participation of several large-scale NIH funded efforts, including the NA-MIC, NAC, BIRN, CIMIT, Harvard Catalyst and NCIGT communities. The funding support comes from several federal funding sources, including NCRR, NIBIB, NIH Roadmap, NCI, NSF and the DOD.

5.7.4 Users

Slicer's platform provides functionalities for segmentation, registration and three-dimensional visualization of multimodal image data, as well as advanced image analysis algorithms for diffusion tensor imaging, functional magnetic resonance imaging and image-guided radiation therapy. Standard image file formats are supported, and the application integrates interface capabilities to biomedical research software.

Slicer has been used in a variety of clinical research. In image-guided therapy research, Slicer is frequently used to construct and visualize collections of MRI data that are available pre- and intra-operatively to allow for the acquiring of spatial coordinates for instrument tracking.* [6] In fact, Slicer has already played such a pivotal role in image-guided therapy, it can be considered as growing

up alongside that field, with over 200 publications referencing Slicer since 1998.*[7]

In addition to producing 3D models from conventional MRI images, Slicer has also been used to present information derived from fMRI (using MRI to assess blood flow in the brain related to neural or spinal cord activity),*[8] DTI (using MRI to measure the restricted diffusion of water in imaged tissue),*[9] and electrocardiography.*[10] For example, Slicer's DTI package allows the conversion and analysis of DTI images. The results of such analysis can be integrated with the results from analysis of morphologic MRI, MR angiograms and fMRI. Other uses of Slicer include paleontology*[11] and neurosurgery planning.*[12]

5.7.5 Developers

The Slicer Developer Orientation offers resources for developers new to the platform. Slicer development is coordinated on the slicer-devel mailing list, and a summary of development statistics is available on Ohloh.

3D Slicer is built on VTK, a pipeline-based graphical library that is widely used in scientific visualization. In version 4, the core application is implemented in C++, and the API is available through a Python wrapper to facilitate rapid, iterative development and visualization in the included Python console. The user interface is implemented in Qt, and may be extended using either C++ or Python.

Slicer supports several types of modular development. Fully interactive, custom interfaces may be written in C++ or Python. Command-line programs in any language may be wrapped using a light-weight XML specification, from which a graphical interface is automatically generated.

For modules that are not distributed in the Slicer core application, a system is available to automatically build and distribute for selective download from within Slicer. This mechanism facilitates the incorporation of code with different license requirements from the permissive BSD-style license used for the Slicer core.

The Slicer build process utilizes CMake to automatically build prerequisite and optional libraries (excluding Qt). The core development cycle incorporates automatic testing, as well as incremental and nightly builds on all platforms, monitored using an online dashboard.

5.7.6 Criticism

With development still in progress, Slicer is sometimes accused by users of being poorly documented and a lacking in automation facilities (which is useful in batch processing). Other users report that Slicer has excellent documentation and training materials. Also Slicer's user interface and internal processing logic is fully scriptable. Although bugs can be reported to the mailing list and issue tracker, they are addressed based on developer availability. Updated versions are periodically released with updated features, while the development version with the latest source code is available daily.

5.7.7 External dependencies

- VTK
- ITK
- CMake
- CPack
- Python
- Tcl
- Nrrd
- MRML
- IGSTK
- KWWidgets
- Qt

5.7.8 See also

- Analyze
- GIMIAS
- Mimics

5.7.9 References

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[11] http://openpaleo.blogspot.com/2009/03/3d-slicer-tutorial-part-vi.html

[12] http://picasaweb.google.com/107065747472066371420

5.7.10 External links

- Slicer

5.8 Analyze

Analyze is a software package developed by the Biomedical Imaging Resource (BIR) at Mayo Clinic for multi-dimensional display, processing, and measurement of multi-modality biomedical images. It is a commercial program and is used for medical tomographic scans from magnetic resonance imaging, computed tomography and positron emission tomography.

The Analyze 7.5 file format*[1] has been widely used in the functional neuroimaging field, and other programs such as SPM, FreeSurfer, AIR, MRIcro and Mango are able to read and write the format. The files can be used to store voxel-based volumes. One data item consists of two files: One file with the actual data in a binary format with the filename extension .img and another file (*header* with filename extension .hdr) with information about the data such as voxel size and number of voxels in each dimension. SPM has defined changes to this format, among other things the voxel ordering within the file.

5.8.1 References

[1] "The Mayo Clinic" (PDF). Archived from the original (PDF) on September 27, 2007. Retrieved 2009-08-28.

5.8.2 External links

- AnalyzeDirect - homepage for Analyze.
- Biomedical Imaging Resource - Mayo Clinic.
- Graham Wideman, Mayo/SPM "Analyze" Format Spec Compilation. Explains voxel ordering.

5.9 CARET

For other uses, see Caret (disambiguation).

CARET (Computerized Anatomical Reconstruction Toolkit) is a software application for the structural and functional analysis of the cerebral and cerebellar cortex. CARET is developed in the Van Essen Laboratory in the Department of Anatomy and Neurobiology at the Washington University School of Medicine in St. Louis, Missouri.

CARET is a free, open-source application distributed in both binary and source formats under the GNU General Public License. CARET runs on FreeBSD, Linux, Mac OS X, and Microsoft Windows.

- Image of CARET main window with functional and foci data on surface

5.9.1 CARET's capabilities

- Analysis of group anatomical differences using sulcal depth morphometry.

- Display of activation foci.
- Generation of flat, inflated, spherical surfaces.
- Mapping of fMRI volumes onto surfaces.
- Surface reconstruction from anatomical MRI volumes using the SureFit algorithm.
- Surface reconstruction from contours.
- Surface-based registration.
- Visualization of contours, surfaces, and volumes.

5.9.2 Related Software

SuMS Database and WebCaret provided on-line storage of surface and volume-based data along with web-based visualization of the data.

5.9.3 See also

- AFNI
- FMRIB Software Library
- FreeSurfer
- Neuroimaging
- Neuroinformatics
- SPM

5.9.4 References

- Steven H. Koslow and Shankar Subramaniam. *Databasing the Brain: From Data to Knowledge, (Neuroinformatics)*. Wiley. ISBN 0-471-30921-4.

5.9.5 External links

- CARET Home Page

5.10 CAVEman

CAVEman is a 4D high-resolution model of a functioning human elaborated by University of Calgary. It resides in a cube-shaped virtual reality room, like a cave, also known as the "research holodeck", in which the human model floats in space, projected from three walls and the floor below.*[1]

5.10.1 References

[1] http://www.trendhunter.com/trends/caveman-3-d-virtual-patient

5.10.2 External links

- University of Calgary Unveils the CAVEman Virtual Human
- CAVEman unveiled
- Meet the CAVEman of the future

5.11 FreeSurfer

FreeSurfer is a brain imaging software package developed by the Athinoula A. Martinos Center for Biomedical Imaging at Massachusetts General Hospital for analyzing magnetic resonance imaging (MRI) scan data. It is an important tool in functional brain mapping and facilitates the visualization of the functional regions of the highly folded cerebral cortex. It contains tools to conduct both volume based and surface based analysis, which primarily use the white matter surface.*[2] FreeSurfer includes tools for the reconstruction of topologically correct and geometrically accurate models of both the gray/white and pial surfaces, for measuring cortical thickness, surface area and folding, and for computing inter-subject registration based on the pattern of cortical folds. In addition, an automated labeling of 35 non-cortical regions is included in the package.

5.11.1 Usage

The FreeSurfer processing stream is controlled by a shell script called *recon-all*.*[3] The script calls component programs that organize raw MRI images into formats easily usable for morphometric and functional MRI statistical analysis with the FreeSurfer Functional Analysis Stream (FS-FAST) package.*[4] Freesurfer uses a morphed spherical method to average across subjects for statistical (general linear model) analysis with the QDEC*[5] tool. Two editing and visualization tools, Tkmedit and Tksurfer, respectively, are included in the package, with an additional visualization tool called Freeview in development. FreeSurfer automatically segments the volume and parcellates the surface into standardized regions of interest (ROIs). The package has a broad spectrum of other uses, including retinotopy, brain morphometry, and other data analysis tools. Freesurfer can also do interhemispheric registration*[6] and can also calcluate the degree of folding or localGI.*[7] Freesurfer also include a Matlab toolbox for linear mixed effects models*[8]

5.11.2 Interoperation

FreeSurfer interoperates easily with the FMRIB Software Library (FSL), which is a comprehensive library for image analysis, written by the Functional MRI of the Brain

(FMRIB) group at Oxford, UK. The functional activation results obtained using either the FreeSurfer Functional Analysis Stream (FS-FAST) or the FSL tools can be overlaid onto inflated, sphered or flattened cortical surfaces using FreeSurfer. FreeSurfer also uses toolkits from MNI MINC, VXL, Tcl/Tk/Tix/BLT, VTK., KWWidgets and Qt,*[9] which are all available with the distribution. Other neuroimaging programs like Caret, AFNI/SUMA, MNE, and 3D Slicer can also import data processed by FreeSurfer.

5.11.3 Download

FreeSurfer runs on Mac OS and Linux. Free registration and binary installation are available without a cost, but a license key (text file) is necessary to run the FreeSurfer binaries.*[10] Documentation can be found on the FreeSurfer Wiki*[11] and limited support is available from the developers and community through the FreeSurfer mailing list.

5.11.4 See also

- Analysis of Functional NeuroImages
- Caret Van Essen Lab, Washington University in St. Louis
- Laboratory of Neuro Imaging, UCLA
- Statistical parametric mapping (SPM)

See also

5.11.5 References

[1] FreeSurfer Software License page

[2] Dale, A. M., B. Fischl, et al. (1999). "Cortical surface-based analysis: Segmentation and surface reconstruction." Neuroimage 9(2): 179-94.

[3] recon-all script usage

[4] FS-FAST Documentation

[5] QDEC Tutorial

[6] https://surfer.nmr.mgh.harvard.edu/fswiki/Xhemi

[7] https://surfer.nmr.mgh.harvard.edu/fswiki/LGI

[8] https://surfer.nmr.mgh.harvard.edu/fswiki/LinearMixedEffectsModels

[9] Developer's Guide

[10] Download notes

[11] FreeSurfer Wiki

5.11.6 External links

- FreeSurfer Home

5.12 ImageJ

ImageJ is a public domain, Java-based image processing program developed at the National Institutes of Health.*[1]*[2] ImageJ was designed with an open architecture that provides extensibility via Java plugins and recordable macros.*[3] Custom acquisition, analysis and processing plugins can be developed using ImageJ's built-in editor and a Java compiler. User-written plugins make it possible to solve many image processing and analysis problems, from three-dimensional live-cell imaging*[4] to radiological image processing,*[5] multiple imaging system data comparisons*[6] to automated hematology systems.*[7] ImageJ's plugin architecture and built-in development environment has made it a popular platform for teaching image processing.*[8]*[9]

ImageJ can be run as an online applet, a downloadable application, or on any computer with a Java 5 or later virtual machine. Downloadable distributions are available for Microsoft Windows, Mac OS, OS X, Linux, and the Sharp Zaurus PDA. The source code for ImageJ is freely available.*[10]

The project developer, Wayne Rasband, retired from the Research Services Branch of the National Institute of Mental Health in 2010, but continues to develop the software.

5.12.1 Features

ImageJ can display, edit, analyze, process, save, and print 8-bit color and grayscale, 16-bit integer, and 32-bit floating point images. It can read many image file formats, including TIFF, PNG, GIF, JPEG, BMP, DICOM, and FITS, as well as raw formats. ImageJ supports image *stacks*, a series of images that share a single window, and it is multithreaded, so time-consuming operations can be performed in parallel on multi-CPU hardware. ImageJ can calculate area and pixel value statistics of user-defined selections and intensity-thresholded objects. It can measure distances and angles. It can create density histograms and line profile plots. It supports standard image processing functions such as logical and arithmetical operations between images, contrast manipulation, convolution, Fourier analysis, sharpening, smoothing, edge detection, and median filtering. It does geometric transformations such as scaling, rotation, and flips. The program supports any number of images simultaneously, limited only by available memory.

5.12.2 History

Prior to the release of ImageJ in 1997, a similar freeware image analysis program known as *NIH Image* had been developed in Object Pascal for Macintosh computers running pre-OS X operating systems. Further development of this code continues in the form of Image SXM, a variant tailored for physical research of scanning microscope images. A Windows version – ported by Scion Corporation (now defunct), so-called *Scion Image for Windows* – was also developed. Both versions are still available but – in contrast to NIH Image – closed-source.*[11]

5.12.3 See also

- Microscope image processing
- Fiji (Fiji Is Just ImageJ), an image processing package based on ImageJ
- CellProfiler, a software package for high-throughput image analysis by interactive construction of workflow. The workflow could include ImageJ macro
- Bitplane - producers of image processing software with ImageJ compatibility
- CoLocalizer Pro - software application for quantification of colocalization in fluorescence microscopy images
- CVIPtools A complete open-source GUI-based Computer Vision and Image Processing software, with C functions libraries COM based dll along with two utilities program for algorithm development and batch processing.
- KNIME - an open-source data mining environment supporting image analysis developed in close collaboration with the next generation of ImageJ
- Bio7 - an Integrated Development Environment for Ecological Modeling, Scientific Image Analysis and Statistical Analysis embedding ImageJ as an Eclipse view.

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5.12.5 External links

- Official website
- NIH Image Official
- Imaging Science at DMOZ

5.13 InVesalius

InVesalius is a free medical software used to generate virtual reconstructions of structures in the human body. Based on two-dimensional images, acquired using computed tomography or magnetic resonance imaging equipment, the software generates virtual three-dimensional models correspondent to anatomical parts of the human body. After constructing three-dimensional DICOM images, the software allows the generation of STL (stereolithography) files. These files can be used for rapid prototyping.

InVesalius was developed at **CTI** (Renato Archer Information Technology Center), a research institute of the Brazilian Science and Technology Center and is available at no cost at the homepage of Public Software Portal

homepage. The software license is CC-GPL 2. It is available in English, Brazilian Portuguese, Italian, French, Spanish, Chinese, German, Czech, Greek and Catalan.

InVesalius was developed using Python and works under Linux, Windows and Mac OS X. It also uses graphic libraries VTK, wxPython, Numpy, Scipy and GDCM.

The software's name is a tribute to Belgian physician Andreas Vesalius (1514–1564), considered the "father of modern anatomy". Developed since 2001 for attending Brazilian Public Hospitals demands, InVesalius development was directed for promoting social inclusion of individuals with severe facial deformities. Since then, however, it has been employed in various research areas of dentistry, medicine, veterinary medicine, paleontology and anthropology. It has been used not only in public hospitals, but also in private clinics and hospitals.

Until 2013, the software had already been used for generating more than 2500 rapid prototyping models of anatomical structures at Promed project.

5.13.1 External links

- Official InVesalius website
- InVesalius source code
- InVesalius Translation page at Transifex
- InVesalius at Ohloh
- InVesalius at Twitter
- Public Software Portal (Portuguese)
- Rapid Prototyping for Medicine(Portuguese)

5.13.2 Related works

- Confex.com (in English)

5.14 ITK-SNAP

ITK-SNAP is an interactive software application that allows users to navigate three-dimensional medical images, manually delineate anatomical regions of interest, and perform automatic image segmentation. The software was designed with the audience of clinical and basic science researchers in mind, and emphasis has been placed on having a user-friendly interface and maintaining a limited feature set to prevent feature creep. ITK-SNAP is most frequently used to work with magnetic resonance imaging (MRI) and computed tomography (CT) data sets.

5.14.1 Features

The purpose of the tool is to make it easy for researchers to delineate anatomical structures and regions of interest in imaging data. The set of features is kept to a minimum. The main features of the program are

Image navigation three orthogonal cut planes through the image volume are shown at all times. The cut planes are linked by a common cursor, so that moving the cursor in one cut plane updates the other cut planes. The cursor is moved by dragging the mouse over the cut planes, making for smooth navigation. The linked cursor also works across ITK-SNAP sessions, making it possible to navigate multimodality imaging data (e.g., two MRI scans of a subject from a single session).

Manual segmentation ITK-SNAP provides tools for manual delineation of anatomical structures in images. Labeling can take place in all three orthogonal cut planes and results can be visualized as a three-dimensional rendering. This makes it easier to ensure that the segmentation maintains reasonable shape in 3D.

Automatic segmentation ITK-SNAP provides automatic functionality segmentation using the level set method. This makes it possible to segment structures that appear somewhat homogeneous in medical images using very little human interaction. For example, the lateral ventricles in MRI can be segmented reliably, as can some types of tumors in CT and MRI.

ITK-SNAP is open source software distributed under the GNU General Public License. It is written in C++ and it leverages the Insight Segmentation and Registration Toolkit (ITK) library. ITK-SNAP can read and write a variety of medical image formats, including DICOM, NIfTI, and Mayo Analyze. It also offers limited support for multi-component (e.g., diffusion tensor imaging) and multi-variate imaging data.

5.14.2 Applications

ITK-SNAP has been applied in the following areas

- Carotid artery segmentation *[1]
- Diffusion MRI Analysis *[2]
- Target definition for cancer radiotherapy
  - lung cancer radiotherapy *[3]
- Prenatal Image Analysis

- Diagnosis of spina bifida <ref name=D'addario2007>D'addario, V.; Pinto, V.; Pintucci, A.; Di Cagno, L. (2007). "OP13. 04: Accuracy of six sonographic signs in the prenatal dignosis of spina bifida". *Ultrasound in Obstetrics and Gynecology* **30** (4): 498–498. doi:10.1002/uog.4534. Retrieved 2007-11-08. Cite uses deprecated parameter |coauthors= (help)</ref>

- Virtual Reality in Medicine*[4]

- Orthodontics*[5]

- Brain morphometry

  - Corpus callosum and ventricle analysis in 22q11.2 deletion syndrome *[6]

  - Hippocampus size and shape measurement in neurodegenerative disorders.*[7]*[8]

5.14.3 References

[1] Spangler, E.L.; Brown, C.; Roberts, J.A.; Chapman, B.E. (2007). "Evaluation of internal carotid artery segmentation by InsightSNAP". *Proceedings of SPIE* **6512** (5): 65123F. Bibcode:2007SPIE.6512E.120S. doi:10.1117/12.709954. Retrieved 2007-11-08.

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5.14.4 External links

- Main ITK-SNAP website (downloads, bugs, mailing lists)

- ITK-SNAP on Sourceforge

5.15 Mango

This article is about the medical visualisation software. For other uses, see Mango (disambiguation).

Mango (**M**ulti-Image **An**alysis **G**UI) is a non-commercial software for viewing, editing and analyzing volumetric medical images. Mango is written in Java, and distributed freely in precompiled versions for Linux, Mac OS and Microsoft Windows. It supports NIFTI , ANALYZE, NEMA and DICOM formats, and is able to load and save 2D, 3D and 4D images.

Mango provides tools for creation and editing of regions of interest (ROI) within the images, surface rendering, image stacking (overlaying), filtering in space domain and histogram analysis, among other functions that can be used in neuroimaging analysis*[1]*[2] for scientific (non-clinical) purposes.

The software can be extended with user-defined functions (plug-ins), which can be created using the Java language and the Mango API.

5.15.1 See also

- List of neuroimaging software

5.15.2 References

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Speech Changes following Deep Brain Stimulation in Parkinson's Disease". *Am J Speech Lang Pathol* **18** (2): 146–61. doi:10.1044/1058-0360(2008/08-0004). PMC 2779712. PMID 19029533.

5.15.3 External links

- Mango website

5.16 OsiriX

OsiriX is an image processing application for Mac dedicated to DICOM images (".dcm" / ".DCM" extension) produced by medical equipment (MRI, CT, PET, PET-CT, ...). Osirix is complementary to existing viewers, in particular to nuclear medicine viewers. It can also read many other file formats: TIFF (8,16, 32 bits), JPEG, PDF, AVI, MPEG and QuickTime. It is fully compliant with the DICOM standard for image communication and image file formats. OsiriX is able to receive images transferred by DICOM communication protocol from any PACS or medical imaging modality (STORE SCP - Service Class Provider, STORE SCU - Service Class User, and Query/Retrieve) .

5.16.1 History

The OsiriX project started in 2004 at UCLA with Dr Antoine Rosset and Prof. Osman Ratib.*[1]*[2] OsiriX has been developed by Rosset, working in LaTour Hospital (Geneva, Switzerland) and Joris Heuberger, a computer scientist from Geneva.

In 2010, a version of OsiriX for iPhone and iPod touch was released.

5.16.2 Features

OsiriX has been specifically designed for navigation and visualization of multimodality and multidimensional images: 2D Viewer, 3D Viewer, 4D Viewer (3D series with temporal dimension, for example: Cardiac-CT) and 5D Viewer (3D series with temporal and functional dimensions, for example: Cardiac-PET-CT). The 3D Viewer offers all modern rendering modes: Multiplanar reconstruction (MPR), Surface Rendering, Volume Rendering and Maximum intensity projection (MIP). All these modes support 4D data and are able to produce image fusion between two different series (for example: PET-CT).

Osirix is simultaneously a DICOM PACS workstation for medical imaging and an image processing software package for medical research (radiology and nuclear imaging), functional imaging, 3D imaging, confocal microscopy and molecular imaging.

Osirix supports a complete plug-in architecture that allows one to expand the capabilities of OsiriX for personal needs. OsiriX is released under a free software licence and runs under Mac OS X.

Osirix source code makes heavy use of Apple idioms such as Cocoa. The source is almost entirely in Objective-C.

5.16.3 OsiriX Foundation

In 2008, the OsiriX Foundation was founded.*[3] OsiriX Foundation will promote research and development and distribution of software tools for scientific and medical applications. It will host and help to promote research projects in Open Source software development for medical applications.

5.16.4 Pixmeo Company

In 2010, the OsiriX Team created the company Pixmeo*[4] to promote and distribute a special version of OsiriX: OsiriX MD. This version is certified for medical imaging. OsiriX MD is a FDA cleared 510k class II medical device, according to US Food And Drug Regulation CFR21 part 820. OsiriX MD complies with European Directive 93/42/EEC concerning medical devices. Under this directive, it is regarded as a class IIa.

5.16.5 See also

5.16.6 References

[1] Journal of Digital Imaging: OsiriX: An Open-Source Software for Navigating in Multidimensional DICOM Images

[2] http://www.osirix-viewer.com/UserManualIntroduction.pdf

[3] OsiriX Foundation - Excerpt of the Commercial Register of the State of Geneva, Switzerland

[4]

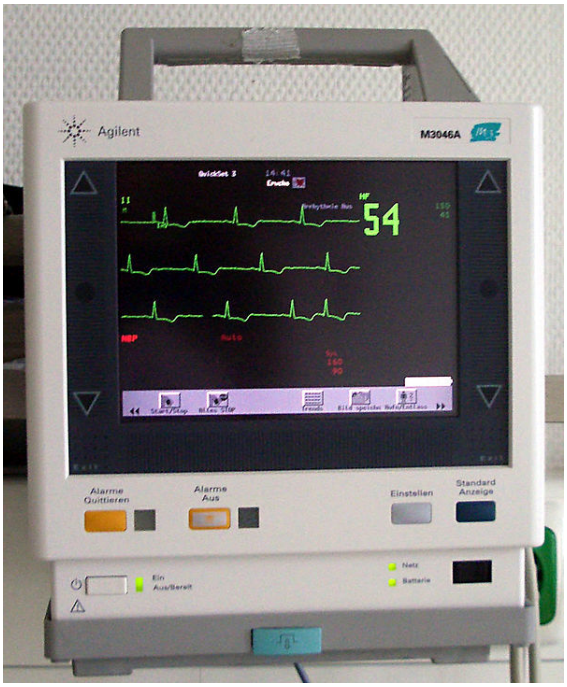
5.16.7 External links

- Official website
- Radiographics: Navigating the Fifth Dimension: Innovative Interface for Multidimensional Multimodality Image Navigation

Chapter 6

Medical and biological signal applications

6.1 Medical monitor



Display device of a medical monitor as used in anesthesia.

In medicine, **monitoring** is the observation of a disease, condition or one or several medical parameters over time.

It can be performed by continuously measuring certain parameters by using a **medical monitor** (for example, by continuously measuring vital signs by a bedside monitor), and/or by repeatedly performing medical tests (such as blood glucose monitoring with a glucose meter in people with diabetes mellitus).

Transmitting data from a monitor to a distant monitoring station is known as telemetry or biotelemetry.

6.1.1 Classification by target parameter

Monitoring can be classified by the target of interest, including:

- **Cardiac monitoring**, which generally refers to continuous electrocardiography with assessment of the patients condition relative to their cardiac rhythm. A small monitor worn by an ambulatory patient for this purpose is known as a Holter monitor. Cardiac monitoring can also involve cardiac output monitoring via an invasive Swan-Ganz catheter.
- **Hemodynamic monitoring**, which monitors the blood pressure and blood flow within the circulatory system. Blood pressure can be measured either invasively through an inserted blood pressure transducer assembly, or noninvasively with an inflatable blood pressure cuff.
- **Respiratory monitoring**, such as:
  - Pulse oximetry which involves measurement of the saturated percentage of oxygen in the blood, referred to as SpO2, and measured by an infrared finger cuff
  - Capnography, which involves CO_2 measurements, referred to as EtCO2 or end-tidal carbon dioxide concentration. The respiratory rate monitored as such is called AWRR or airway respiratory rate)
  - Respiratory rate monitoring through a thoracic transducer belt, an ECG channel or via capnography
- **Neurological monitoring**, such as of intracranial pressure. Also, there are special patient monitors which incorporate the monitoring of brain waves (electroencephalography), gas anesthetic concentrations, bispectral index (BIS), etc. They are usually incorporated into anesthesia machines. In neurosurgery intensive care units, brain EEG monitors have a larger multichannel capability and can monitor other physiological events, as well.
- **Blood glucose monitoring**
- **Childbirth monitoring**
- **Body temperature monitoring** through an adhesive pad containing a thermoelectric transducer.

Vital parameters

An anesthetic machine with integrated systems for monitoring of several vital parameters, including blood pressure and heart rate.

Monitoring of vital parameters can include several of the ones mentioned above, and most commonly include at least blood pressure and heart rate, and preferably also pulse oximetry and respiratory rate. Multimodal monitors that simultaneously measure and display the relevant vital parameters are commonly integrated into the bedside monitors in critical care units, and the anesthetic machines in operating rooms. These allow for continuous monitoring of a patient, with medical staff being continuously informed of the changes in general condition of a patient. Some monitors can even warn of pending fatal cardiac conditions before visible signs are noticeable to clinical staff, such as atrial fibrillation or premature ventricular contraction (PVC).

6.1.2 Medical monitor

A *medical monitor* or *physiological monitor* is a medical device used for monitoring. It can consist of one or more sensors, processing components, display devices (which are sometimes in themselves called "monitors"), as well as communication links for displaying or recording the results elsewhere through a monitoring network.

Components

Sensor Sensors of medical monitors include biosensors and mechanical sensors.

Translating component The translating component of medical monitors is responsible for converting the signals from the sensors to a format that can be shown on the display device or transferred to an external display or recording device.

Display device Physiological data are displayed continuously on a CRT, LED or LCD screen as data channels along the time axis, They may be accompanied by numerical readouts of computed parameters on the original data, such as maximum, minimum and average values, pulse and respiratory frequencies, and so on.

Besides the tracings of physiological parameters along time (X axis), digital medical displays have automated numeric readouts of the peak and/or average parameters displayed on the screen.

Modern medical display devices commonly use digital signal processing (DSP), which has the advantages of miniaturization, portability, and multi-parameter displays that can track many different vital signs at once.

Old analog patient displays, in contrast, were based on oscilloscopes, and had one channel only, usually reserved for electrocardiographic monitoring (ECG). Therefore, medical monitors tended to be highly specialized. One monitor would track a patient's blood pressure, while another would measure pulse oximetry, another the ECG. Later analog models had a second or third channel displayed in the same screen, usually to monitor respiration movements and blood pressure. These machines were widely used and saved many lives, but they had several restrictions, including sensitivity to electrical interference, base level fluctuations and absence of numeric readouts and alarms.

Communication links Several models of multi-parameter monitors are networkable, i.e., they can send their output to a central ICU monitoring station, where a single staff member can observe and respond to several bedside monitors simultaneously. Ambulatory telemetry can also be achieved by portable, battery-operated models which are carried by the patient and which transmit their data via a wireless data connection.

Digital monitoring has created the possibility, which is being fully developed, of integrating the physiological data from the patient monitoring networks into the emerging hospital electronic health record and digital charting systems, using appropriate health care standards which have been developed for this purpose by organizations such as IEEE and HL7. This newer method of charting patient data reduces the likelihood of human documentation error and will eventually reduce overall paper consumption. In addition, automated ECG interpretation incorporates diagnostic codes automatically into the charts. Medical monitor's embedded software can take care of the data coding according to these standards and

send messages to the medical records application, which decodes them and incorporates the data into the adequate fields.

Long-distance connectivity can avail for telemedicine, which involves provision of clinical health care at a distance.

Other components A medical monitor can also have the function to produce an alarm (such as using audible signals) to alert the staff when certain criteria are set, such as when some parameter exceeds of falls the level limits.

Mobile appliances

An entirely new scope is opened with mobile carried monitors, even such in sub-skin carriage. This class of monitors delivers information gathered in body-area networking (BAN) to e.g. smart phones and implemented autonomous agents.

6.1.3 Interpretation of monitored parameters

Monitoring of clinical parameters is primarily intended to detect changes (or absence of changes) in the clinical status of an individual. For example, the parameter of oxygen saturation is usually monitored to detect changes in respiratory capability of an individual.

Change in status versus test variability

When monitoring a clinical parameters, differences between test results (or values of a continuously monitored parameter after a time interval) can reflect either (or both) an actual change in the status of the condition or a test-retest variability of the test method.

In practice, the possibility that a difference is due to test-retest variability can almost certainly be excluded if the difference is larger than a predefined "critical difference". This "critical difference" (CD) is calculated as:*[1]

$$CD = K \times \sqrt{CV_a^2 + CV_i^2}$$

, where:*[1]

- K, is a factor dependent on the preferred probability level. Usually, it is set at 2.77, which reflects a 95% prediction interval, in which case there is less than 5% probability that a test result would become higher or lower than the critical difference by test-retest variability in the absence of other factors.
- CV_a is the anaytical variation
- CV_i is the intra-individual variability

For example, if a patient has a hemoglobin level of 100 g/L, the anaytical variation (CV_a) is 1.8% and the intra-individual variability CV_i is 2.2%, then the critical difference is 8.1 g/L. Thus, for changes of less than 8 g/L since a previous test, the possibility that the change is completely caused by test-retest variability may need to be considered in addition to considering effects of, for example, diseases or treatments.

Critical differences for other tests include early morning urinary albumin concentration, with a critical difference of 40%.*[1]

6.1.4 Techniques in development

The development of new techniques for monitoring is an advanced and developing field in smart medicine, biomedical-aided integrative medicine, alternative medicine, self-tailored preventive medicine and predictive medicine that emphasizes monitoring of comprehensive medical data of patients, people at risk and healthy people using advanced, smart, minimally invasive biomedical devices, biosensors, lab-on-a-chip (in the future nanomedicine*[3]*[4] devices like nanorobots) and advanced computerized medical diagnosis and early warning tools over a short clinical interview and drug prescription.

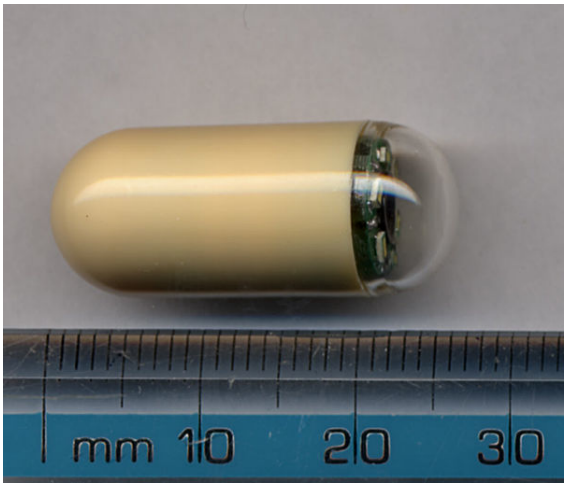
As biomedical research, nanotechnology and nutrigenomics advances, realizing the human body's self-healing capabilities and the growing awareness of the limitations of medical intervention by chemical drugs-only approach of old school medical treatment, new researches that shows the enormous damage medications can cause,*[5]*[6] researchers are working to fulfill the need for a comprehensive further study and personal continuous clinical monitoring of health conditions while keeping legacy medical intervention as a last resort.

In many medical problems, drugs offer temporary relief of symptoms while the root of a medical problem remains unknown without enough data of all our biological systems*[7] . Our body is equipped with sub-systems for the purpose of maintaining balance and self healing functions. Intervention without sufficient data might damage those healing sub systems.*[7] Monitoring medicine fills the gap to prevent diagnosis errors and can assist in future medical research by analyzing all data of many patients.

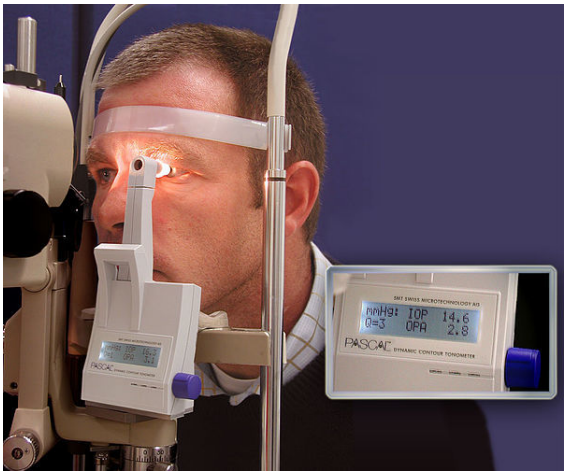
Examples and applications

The development cycle in medicine is extremely long, up to 20 years, because of the need for U.S. Food and Drug Administration (FDA) approvals, therefore many of monitoring medicine solutions are not available today in conventional medicine.

Blood glucose monitoring In vivo blood glucose monitoring devices can transmit data to a computer that



Given Imaging Capsule endoscopy



The PASCAL Dynamic Contour Tonometer. A monitor for detection of increased intraocular pressure.

can assist with daily life suggestions for lifestyle or nutrition and with the physician can make suggestions for further study in people who are at risk and help prevent diabetes mellitus type 2 .*[8]

Stress monitoring Bio sensors may provide warnings when stress levels signs are rising before human can notice it and provide alerts and suggestions.*[9]

Serotonin biosensor Future serotonin biosensors may assist with mood disorders and depression.*[10]

Continuous blood test based nutrition In the field of evidence-based nutrition, a lab-on-a-chip implant that can run 24/7 blood tests may provide a continuous results and a coumputer can provide nutritaion suggestions or alerts.

Psychiatrist-on-a-chip In clinical brain sciences drug delivery and in vivo Bio-MEMS based biosensors may assist with preventing and early treatment of mental disorders

Epilepsy monitoring In epilepsy, next generations of long-term video-EEG monitoring may predict epileptic seizure and prevent them with changes of daily life activity like sleep, stress, nutrition and mood management.*[11]

Toxicity monitoring Smart biosensors may detect toxic materials such mercury and lead and provide alerts.*[12]

6.1.5 See also

- Medical equipment
- Medical test
- Nanoelectromechanical system (NEMS)
- Functional medicine

6.1.6 References

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[3] "Healthcare 2030: disease-free life with home monitoring nanomedince". Positivefuturist.com.

[4] "Nanosensors for Medical Monitoring.". Technologyreview.com.

[5] "Brain Damage Caused by Neuroleptic Psychiatric Drugs". Mindfreedom.org.

[6] "Medications That Can Cause Nerve Damage". Livestrong.com.

[7] Hyman, Mark (December 2008). *The UltraMind Solution: Fix Your Broken Brain by Healing Your Body First.* Scribner. ISBN 978-1-4165-4971-0.

[8] "Blood glucose testing and primary prevention of diabetes mellitus type 2 - evaluation of the effect of evidence based patient information.". BMC Public health.

[9] ""Stress monitoring using a distributed wireless intelligent sensor system".". IEEE.

[10] "Using biosensors to detect the release of serotonin from taste buds during taste stimulation.". Archives Italiennes de Biologie.

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[12] "Multiarray Biosensors for Toxicity Monitoring and Bacterial Pathogens". CRC.

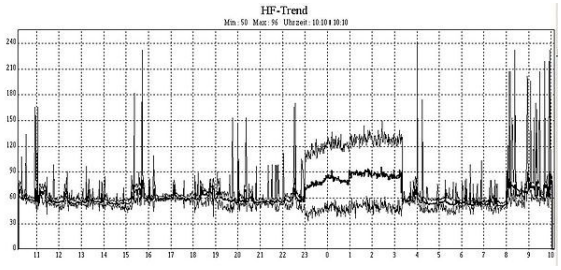
6.1.7 Further reading

- *Monitoring Level of Consciousness During Anesthesia & Sedation* , Scott D. Kelley, M.D., ISBN 978-0-9740696-0-9
- *Healthcare Sensor Networks: Challenges Toward Practical Implementation*, Daniel Tze Huei Lai (Editor), Marimuthu Palaniswami (Editor), Rezaul Begg (Editor), ISBN 978-1-4398-2181-7
- *Blood Pressure Monitoring in Cardiovascular Medicine and Therapeutics (Contemporary Cardiology)*, William B. White, ISBN 978-0-89603-840-0
- *Physiological Monitoring and Instrument Diagnosis in Perinatal and Neonatal Medicine*, Yves W. Brans, William W. Hay Jr, ISBN 978-0-521-41951-2
- *Medical Nanotechnology and Nanomedicine (Perspectives in Nanotechnology)*, Harry F. Tibbals, ISBN 978-1-4398-0874-0

6.1.8 External links

- *Monitoring medicine intake in the networked home: The iCabiNET solution*, IEEE Xplore, Issue Date: Jan. 30 2008-Feb. 1 2008, pp. 116 – 117
- *Personal Medical Monitoring Devices*, The University of Maryland

6.2 Holter monitor



Atrial fibrillation recorded by a Holter monitor.

In medicine, a **Holter monitor** (often simply "Holter" or occasionally **ambulatory electrocardiography device**) is a portable device for continuously monitoring various electrical activity of the cardiovascular system for at least 24 hours (often for two weeks at a time).

The Holter's most common use is for monitoring heart activity (electrocardiography or ECG). Its extended recording period is sometimes useful for observing occasional cardiac arrhythmias which would be difficult to identify in a shorter period of time. For patients having more transient symptoms, a cardiac event monitor which can be worn for a month or more can be used.

The Holter monitor was developed at the Holter Research Laboratory in Helena Montana by experimental physicists Norman J. Holter and Bill Glasscock,*[1] who started work on radio telemetry in 1949. Inspired by a suggestion from cardiologist Paul Dudley White in the early 1950s, they redirected their efforts toward development of a wearable cardiac monitoring device.*[2] The Holter monitor was released for commercial production in 1962.*[2]

When used to study the heart, much like standard electrocardiography, the Holter monitor records electrical signals from the heart via a series of electrodes attached to the chest. Electrodes are placed over bones to minimize artifacts from muscular activity. The number and position of electrodes varies by model, but most Holter monitors employ between three and eight. These electrodes are connected to a small piece of equipment that is attached to the patient's belt or hung around the neck, keeping a log of the heart's electrical activity throughout the recording period.

6.2.1 Data storage

Older devices used reel to reel tapes or a standard C90 or C120 audio cassette and ran at a 1.7 mm/s or 2 mm/s speed to record the data. Once a recording was made, it could be played back and analyzed at 60x speed so 24 hours of recording could be analyzed in 24 minutes. More modern units record an EDF-file onto digital flash memory devices. The data is uploaded into a computer which then automatically analyzes the input, counting ECG complexes, calculating summary statistics such as average heart rate, minimum and maximum heart rate, and finding candidate areas in the recording worthy of further study by the technician.

6.2.2 Components

Each Holter system consists of two basic parts – the hardware (called monitor or recorder) for recording the signal, and software for review and analysis of the record. Advanced Holter recorders are able to display the signal, which is very useful for checking the signal quality. Very often there is also a "patient button" located on the front site allowing the patient to press it in specific cases such as sickness, going to bed, taking pills···. A special mark will be then placed into the record so that the doctors or technicians can quickly pinpoint these areas when analyzing the signal.

Recorder

The size of the recorder differs depending on the manufacturer of the device. The average dimensions of today's Holter monitors are about 110x70x30 mm but some are

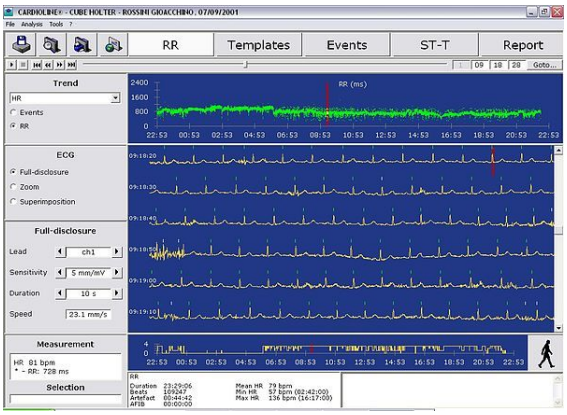
only 61x46x20 mm and weigh 99 g.* [3] Most of the devices operate with two AA batteries. In case the batteries are depleted, some Holters allow their replacement even during monitoring.

Most of the Holters monitor the ECG just in two or three channels. Depending on the model (manufacturer), different counts of leads and lead systems are used. Today's trend is to minimize the number of leads to ensure the patient's comfort during recording. Although 2/3 channel recording has been used for a long time in the Holter monitoring history, recently 12 channel Holters have appeared. These systems use the classic Mason-Likar lead system, thus producing the signal in the same representation as during the common rest ECG and/or stress test measurement. These Holters then allow to substitute stress test examination in cases the stress test is not possible for the current patient. They are also suitable when analyzing patients after myocardial infarction. Recordings from these 12-lead monitors are of a significantly lower resolution than those from a standard 12-lead ECG and in some cases have been shown to provide misleading ST segment representation, even though some devices allow setting the sampling frequency up to 1000 Hz for special-purpose exams like the late potential.

Another interesting innovation is the presence of a triaxial movement sensor, which records the patient physical activity, and later shows in the software three different statuses: sleeping, standing up, or walking. This helps the cardiologist to better analyze the recorded events belonging to the patient activity and diary. Holter monitoring is a very useful part of an ECG.

Some modern devices also have the ability to record a vocal patient diary entry that can be later listened to by the doctor.

Analyzing software



Screenshot of Holter ECG software

When the recording of ECG signal is finished (usually after 24 or 48 hours), it is up to the physician to perform the signal analysis. Since it would be extremely time demanding to browse through such a long signal, there is an integrated automatic analysis process in the software of each Holter device which automatically determines different sorts of heart beats, rhythms, etc. However the success of the automatic analysis is very closely associated with the signal quality. The quality itself mainly depends on the attachment of the electrodes to the patient body. If these are not properly attached, electromagnetic disturbance can influence the ECG signal resulting in a very noisy record. If the patient moves rapidly, the distortion will be even bigger. Such record is then very difficult to process. Besides the attachment and quality of electrodes, there are other factors affecting the signal quality, such as muscle tremors, sampling rate and resolution of the digitized signal (high quality devices offer higher sampling frequency).

The automatic analysis commonly provides the physician with information about heart beat morphology, beat interval measurement, heart rate variability, rhythm overview and patient diary (moments when the patient pressed the patient button). Advanced systems also perform spectral analysis, ischemic burden evaluation, graph of patient's activity or PQ segment analysis. Another requirement is the ability of pacemaker detection and analysis. Such ability is useful when one wants to check the correct pacemaker function.

6.2.3 History

The cardiac event monitor has been used for over twenty years. At first, these devices were not portable and had to be used only in hospital buildings. Advances resulted in these devices becoming smaller but were still being used only in hospitals for twenty four to forty eight hours. Soon portable monitors were developed weighing at first thirty pounds, then 10 pounds, and 1 pound. Modern devices are much easier to wear, weighing only a fraction of a pound.

6.2.4 Procedure

Although some patients may feel uncomfortable about a Holter examination, there is nothing to worry about. No hazards are involved, and it should have little effect on one's normal daily life.

The recording device can be worn in a case on a belt or on a strap across the chest. The device may be visible under light clothing, and those wearing a Holter monitor may wish to avoid shirts with a low neckline.

Persons being monitored should not limit normal daily activities,since its purpose is to record how a heart works under various actual conditions over an extended period. It is an electrical device, however, and should be kept dry; showering or swimming should probably be avoided. Monitors can be removed for a few minutes without inval-

idating collected data, but proper reattachment is critical to avoid degradation of its signals. Beyond changing batteries, one should leave its handling to trained personnel.

6.2.5 Gallery

- A 5-electrode Holter
- A 7-electrode Holter
- A Holter monitor can be worn for many days without causing significant discomfort.
- Canine Holter Monitor with DogLeggs Vest
- A Holter monitor with a US quarter dollar coin to show scale
- Holter monitor can be worn with bra, with no discomfort.

6.2.6 References

[1] Meldrum, Stuart J (1993). "Obituary for Wilford "Bill" Glasscock". *Journal of Ambulatory Monitoring* **6** (3): 243. with the passing of Bill Glasscock, we have lost the second half of one of the most successful partnerships ever to exist in the field of biomedical engineering

[2] Hilbel, Thomas; Thomas M Helms; Gerd Mikus; Hugo A Katus; Christian Zugck (Jan 10, 2008). "Telemetry in the clinical setting". *Herzschrittmachertherapie & Elektrophysiologie* **19** (3): 146–64. doi:10.1007/s00399-008-0017-2. ISSN 0938-7412. Retrieved Aug 4, 2009.

[3] HeartBug technical specifications

6.2.7 External links

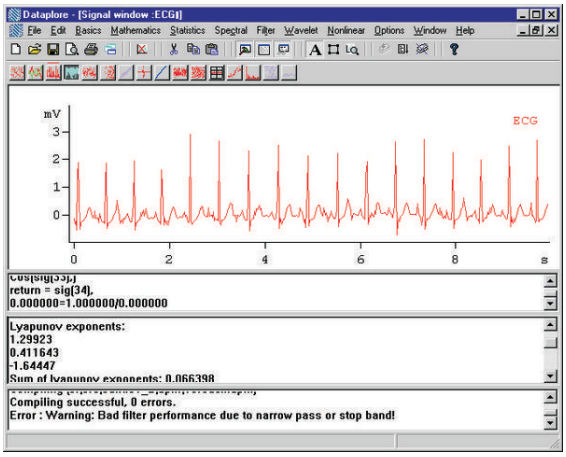
- Holter monitor - MedLine Plus

6.3 Automated ECG interpretation

Automated ECG interpretation is the use of artificial intelligence and pattern recognition software and knowledge bases to carry out automatically the interpretation, test reporting, and computer-aided diagnosis of electrocardiogram tracings obtained usually from a patient.

6.3.1 History

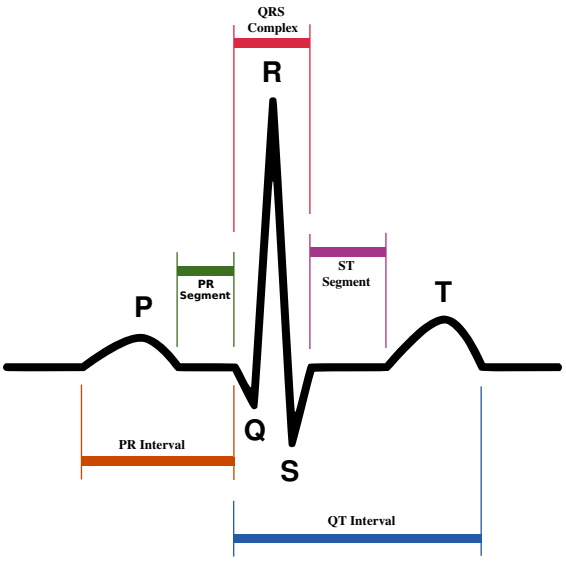
The first automated ECG programs were developed in the 1970s, when digital ECG machines became possible by third generation digital signal processing boards. Commercial models, such as those developed by Hewlett-Packard, incorporated these programs into clinically used devices.



Screenshot of a software for digital ECG processing

During the 1980s and 1990s, extensive research was carried out by companies and by university labs in order to improve the accuracy rate, which was not very high in the first models. For this purpose, several signal databases with normal and abnormal ECGs were built by institutions such as MIT and used to test the algorithms and their accuracy.

6.3.2 Phases



Basic signal features of time and amplitude which are measured and form the basis for automated ECG analysis

1. A digital representation of each recorded ECG channel is obtained, by means of an analog-digital conversion device and a special data acquisition software or a digital signal processing (DSP) chip.
2. The resulting digital signal is processed by a series of specialized algorithms, which start by conditioning it, e.g., removal of noise, baselevel variation, etc.

3. Feature extraction: mathematical analysis is now performed on the clean signal of all channels, to identify and measure a number of features which are important for interpretation and diagnosis, this will constitute the input to AI-based programs, such as the peak amplitude, area under the curve, displacement in relation to baseline, etc., of the P, Q, R, S and T waves,* [1] the time delay between these peaks and valleys, heart rate frequency (instantaneous and average), and many others. Some sort of secondary processing such as Fourier analysis and wavelet analysis* [2] may also be performed in order to provide input to pattern recognition-based programs.

4. Logical processing and pattern recognition, using rule-based expert systems,* [3] probabilistic Bayesian analysis or fuzzy logics algorithms, cluster analysis,* [4] artificial neural networks,* [5] genetic algorithms and others techniques are used to derive conclusions, interpretation and diagnosis.

5. A reporting program is activated and produces a proper display of original and calculated data, as well as the results of automated interpretation.

6. In some applications, such as automatic defibrillators, an action of some sort may be triggered by results of the analysis, such as the occurrence of an atrial fibrillation or a cardiac arrest, the sounding of alarms in a medical monitor in intensive-care unit applications, and so on.

6.3.3 Applications

The manufacturing industries of ECG machines is now entirely digital, and many models incorporate embedded software for analysis and interpretation of ECG recordings with 3 or more leads. Consumer products, such as home ECG recorders for simple, 1-channel heart arrhythmia detection, also use basic ECG analysis, essentially to detect abnormalities. Some application areas are:

- Incorporation into automatic defibrillators, so that autonomous decision can be reached whether there is a cause for administering the electrical shock on basis of an atrial or ventricular arryhtmia;

- Portable ECG used in telemedicine. These machines are used to send ECG recordings via a telecommunications link, such as telephone, cellular data communication or Internet

- Conventional ECG machines to be used in primary healthcare settings where a trained cardiologist is not available

6.3.4 Implications and limitations

The automated ECG interpretation is a useful tool when access to a specialist is not possible. Although considerable effort has been made to improve automated ECG algorithms, the sensitivity of the automated ECG interpretation is of limited value in the case of STEMI equivalent* [6]* [7] as for example with "hyperacute T waves",* [8] de Winter ST-T complex,* [9] Wellens phenomenon, Left ventricular hypertrophy, left bundle branch block or in presence of a pacemaker. Automated monitoring of ST-segment during patient transport is increasingly used and improves STEMI detection sensitivity, as ST elevation is a dynamical phenomenon.

6.3.5 See also

- Medical monitor
- Holter monitor
- Open ECG project
- SCP-ECG

6.3.6 References

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[2] Al-Fahoum, AS; Howitt,I. Combined wavelet transformation and radial basis neural networks for classifying life threatening cardiac arrhythmias, Med. Biol. Eng. Comput. 37 (1999), pp. 566–573.

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Translated and reproduced by permission of the author.

6.3.8 External links

- ecgAUTO in-depth ECG analysis software for pre-clinical research
- Kligfield, P. Automated Analysis of ECG Rhythm
- Physionet
- Telemedical ECG Interpretation training module

6.4 MECIF Protocol

The **MECIF Protocol** (*Medical Computer Interface* Protcol), is a rare communications protocol originally developed by Hewlett-Packard to allow external devices (e.g. computers) to communicate with certain Hewlett-Packard patient monitors. It is a client–server based protocol that uses a modified RS-232 cable to allow a client (e.g. a computer) to send commands to a server (e.g. patient monitor).*[1] The protocol can be used to retrieve vital data from patient monitors, such as ECG, blood pressure and heart-rate signals.

Ownership of the protocol has changed hands many times and was most recently supported by Philips.*[2]

Due to the complexity of the protocol, very few software applications currently support it.

6.4.1 References

[1] , A Macintosh Client for the Hewlett-Packard Component Monitoring System

[2] , RS232 Computer Interface Programming Guide

6.4.2 External links

- MECIFView - Software application for acquiring data from patient monitors using the MECIF protocol
- MediCollector - Software application for collecting data from patient monitors
- record - Software tools for communicating using the MECIF protocol

6.5 SCP-ECG

SCP-ECG, which stands for *Standard communications protocol for computer assisted electrocardiography*, is a standard for ECG traces, annotations, and metadata, that specifies the interchange format and a messaging procedure for ECG cart-to-host communication and for retrieval of SCP-ECG records from the host to the ECG cart. It is defined in the joint ANSI/AAMI standard EC71:2001 and in the CEN standard EN 1064:2005.

6.5.1 History

The SCP Standard was first developed between 1989 to 1991 during a European AIM R&D project.

6.5.2 External links

- "*OpenECG*" —The [OpenECG] Group supports SCP-ECG by providing and supporting open source implementations and consistent application the standard.

6.5.3 Other ECG data formats

DICOM, HL7 aECG

6.5.4 References

6.6 European Data Format

European Data Format (**EDF**) is a standard file format designed for exchange and storage of medical time series. Being an open and non-proprietary format, EDF(+) is commonly used to archive, exchange and analyse data from commercial devices in a format that is independent of the acquisition system. In this way, the data can be retrieved and analyzed by independent software. EDF(+) software (browsers, checkers, ...) and example files are freely available.

EDF was published in 1992 and stores multichannel data, allowing different sample rates for each signal. Internally it includes a header and one or more data records. The header contains some general information (patient identification, start time...) and technical specs of each signal (calibration, sampling rate, filtering, ...), coded as ASCII characters. The data records contain samples as little-endian 16-bit integers. EDF is a popular format for polysomnography (PSG) recordings.

EDF+ was published in 2003 and is largely compatible to EDF: all existing EDF viewers also show EDF+ signals. But EDF+ files also allow coding discontinuous recordings as well as annotations,

stimuli and events in UTF-8 format. EDF+ has applications in PSG, electroencephalography (EEG), electrocardiography (ECG), electromyography (EMG), and Sleep scoring. EDF+ can also be used for nerve conduction studies, evoked potentials and other data acquisition studies.

6.6.1 References

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- Kemp B, Olivan J (September 2003). "European data format 'plus' (EDF+), an EDF alike standard format for the exchange of physiological data". *Clin Neurophysiol* **114** (9): 1755–61. doi:10.1016/S1388-2457(03)00123-8. PMID 12948806.
- EDF specification, examples and tools

6.6.2 External links

- The EDFgroup
- A sample of normal sleep recordings in EDF format

6.7 OpenXDF

The Open eXchange Data Format, or **OpenXDF**, is an open, XML-based standard for the digital storage and exchange of time-series physiological signals and metadata. OpenXDF primarily focuses on electroencephalography and polysomnography.

6.7.1 History

Neurotronics began work on OpenXDF in 2003 with the goal of providing a modern, open, and extensible file format with which clinicians and researchers can share physiological data and metadata, such as signal data, signal montages, patient demographics, and event logs.

Neurotronics released the first draft of the OpenXDF Specification just before the 18th meeting of the Associated Professional Sleep Societies in 2004. Neurotronics has since relinquished control of the format to the OpenXDF Consortium.

As of version 1.0, OpenXDF is 100% backward compatible with the European Data Format (EDF), the current defacto standard format for physiological data exchange.

6.7.2 Features

Tiered structure

OpenXDF is a tiered framework designed to allow standardized and custom specializations of the format while enforcing a common foundation that provides a high-level of compatibility between unrelated systems.

Metadata

OpenXDF expands on EDF by providing standardized support for extensive patient information, display montages, annotations, and scoring information.

Unicode support

OpenXDF requires the use of a XML 1.0 compliant parser that supports UTF-8 and UTF-16.

Signal configuration

OpenXDF supports fully and independently configurable data signals. Each signal specifies its byte order, whether its samples are signed, the size of its samples, and its sampling rate.

Security

OpenXDF supports encryption of the XML file using TwoFish in Cipher Feedback (CFB) mode with a 256-bit key created from a UTF-8 encoded password hashed with SHA-256. In addition, OpenXDF supports integrity verification using a SHA-512 hash of the original XML file.

6.7.3 See also

- European Data Format (EDF)

6.7.4 References

- OpenXDF Web Site
- OpenXDF Specification

6.7.5 External links

- European Data Format (EDF) Specifications

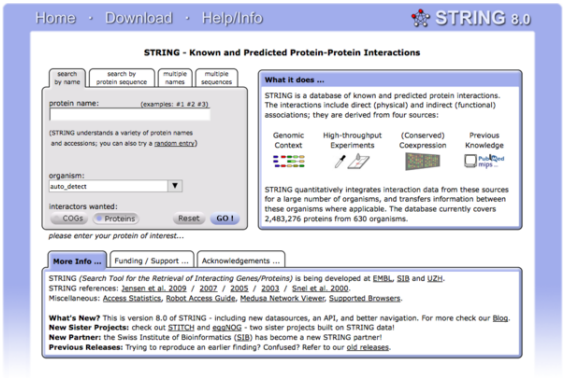
Chapter 7

Databases, Digital Libraries and Literature Retrieval

7.1 Biological database

For Gene Disease Databases, see Gene Disease Database.

Biological databases are libraries of life sci-



Home page of a biological database called STRING which characterises functional links between proteins.[*] *[1]*

ences information, collected from scientific experiments, published literature, high-throughput experiment technology, and computational analysis.[*] [2] They contain information from research areas including genomics, proteomics, metabolomics, microarray gene expression, and phylogenetics.[*] [3] Information contained in biological databases includes gene function, structure, localization (both cellular and chromosomal), clinical effects of mutations as well as similarities of biological sequences and structures.

Biological databases can be broadly classified into sequence and structure databases. Nucleic acid and protein sequences are stored in sequence databases and structure database only store proteins. These databases are important tools in assisting scientists to analyze and explain a host of biological phenomena from the structure of biomolecules and their interaction, to the whole metabolism of organisms and to understanding the evolution of species. This knowledge helps facilitate the fight against diseases, assists in the development of medications, predicting certain genetic diseases and in discovering basic relationships among species in the history of life.

Biological knowledge is distributed among many different general and specialized databases. This sometimes makes it difficult to ensure the consistency of information. Integrative bioinformatics is one field attempting to tackle this problem by providing unified access. One solution is how biological databases cross-reference to other databases with accession numbers to link their related knowledge together.

Relational database concepts of computer science and Information retrieval concepts of digital libraries are important for understanding biological databases. Biological database design, development, and long-term management is a core area of the discipline of bioinformatics.[*] [4] Data contents include gene sequences, textual descriptions, attributes and ontology classifications, citations, and tabular data. These are often described as semi-structured data, and can be represented as tables, key delimited records, and XML structures.

7.1.1 Nucleic Acids Research Database Issue

An important resource for finding biological databases is a special yearly issue of the journal *Nucleic Acids Research* (NAR). The Database Issue of NAR is freely available, and categorizes many of the publicly available on line databases related to biology and bioinformatics. A companion database to the issue called the Online Molecular Biology Database Collection lists 1,380 online databases.[*] [5] Other collections of databases exist such as MetaBase and the Bioinformatics Links Collection.[*] [6][*] [7]

7.1.2 Access

Most biological databases are available through web sites that organise data such that users can browse through the data online. In addition the underlying data is usually

available for download in a variety of formats. Biological data comes in many formats. These formats include text, sequence data, protein structure and links. Each of these can be found from certain sources, for example:

- Text formats are provided by PubMed and OMIM.
- Sequence data is provided by GenBank, in terms of DNA, and UniProt, in terms of protein.
- Protein structures are provided by PDB, SCOP, and CATH.

7.1.3 Species-specific databases

Species-specific databases are available for some species, mainly those that are often used in research. For example, Colibase is an *E. coli* database. Other popular species specific databases include Mouse Genome Informatics for the laboratory mouse, *Mus musculus*, the Rat Genome Database for *Rattus*, ZFIN for *Danio Rerio* (zebrafish), FlyBase for *Drosophila*, WormBase for the nematodes *Caenorhabditis elegans* and *Caenorhabditis briggsae*, and Xenbase for Xenopus tropicalis and Xenopus laevis frogs.

7.1.4 See also

- Gene Disease Database
- Biobank
- Biological data
- Chemical database
- European Bioinformatics Institute
- Integrative bioinformatics
- List of biological databases
- MetaBase (a database of biological databases)
- NCBI
- PubMed (a database of biomedical literature)

7.1.5 References

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7.1.6 External links

- Wiki of biological databases
- Interactive list of biological databases, classified by categories, from Nucleic Acids Research, 2010
- DBD: Database of Biological Databases
- Lecture notes for Databases in bioinformatics course

7.2 Medical literature retrieval

For a broader coverage related to this topic, see Medical literature.

Medical literature retrieval or **medical document retrieval** is an activity that uses professional methods for medical research papers retrieval, report and other data to improve medicine research and practice.

7.2.1 Medical search engine

Professional medical search engine

- Pubmed
- GoPubMed*[1]

- Pubget
- Scopus
- eTBLAST
- Cochrane Reviews, The Cochrane Library

Meta-search tools

- Trip
- NLM Gateway
- Entrez, NLM's cross-database search
- SUMSearch

Consumer health search engine

- MedlinePlus by the U.S. NLM
- Healthfinder by the U.S. HHS
- Mednar
- Healthline
- Medstory
- Healia

7.2.2 Search strategy

7.2.3 References

[1] http://www.transinsight.com/peopleAbout

7.2.4 See also

- Health informatics
- Medical Subject Headings
- Evidence-based medicine
- International Medical Informatics Association
- European Federation for Medical Informatics
- List of search engines#Medical

7.2.5 External links

- MEDLINE/PubMed
- William R. Hersh. Information Retrieval: A Health and Biomedical Perspective. 2003, Springer-Verlag. ISBN 0-387-95522-4
- Vincenta B. Vincentb M. Ferreira CG. Making PubMed Searching Simple: Learning to Retrieve Medical Literature Through Interactive Problem Solving. 2005, The Oncologist, Vol. 11 No. 3 243-251
- The Top Five Medical Search Engines on the Web at About.com by Wendy Boswell
- 25 Search Engines Every Medical Professional Should Bookmark
- PubMed Alternative Engines at American University of Beirut University Libraries

7.3 MEDLINE

For other uses, see Medline (disambiguation).

MEDLINE (Medical Literature Analysis and Retrieval System Online, or MEDLARS Online) is a bibliographic database of life sciences and biomedical information. It includes bibliographic information for articles from academic journals covering medicine, nursing, pharmacy, dentistry, veterinary medicine, and health care. MEDLINE also covers much of the literature in biology and biochemistry, as well as fields such as molecular evolution.

Compiled by the United States National Library of Medicine (NLM), MEDLINE is freely available on the Internet and searchable via PubMed and NLM's National Center for Biotechnology Information's Entrez system.

7.3.1 History

MEDLARS (Medical Literature Analysis and Retrieval System) is a computerised biomedical bibliographic retrieval system. It was launched by the National Library of Medicine in 1964 and was the first large scale, computer based, retrospective search service available to the general public.*[1]

Initial development of MEDLARS

Since 1879, the National Library of Medicine had published *Index Medicus*, a monthly guide to medical articles in thousands of journals. The huge volume of bibliographic citations were manually compiled. In 1957 the

staff of the NLM started to plan the mechanization of the *Index Medicus*, prompted by a desire for a better way to manipulate all this information, not only for *Index Medicus* but also to produce subsidiary products. By 1960 a detailed specification was prepared and by the spring of 1961 a request for proposals was sent out to 72 companies to develop the system. As a result, a contract was awarded to the General Electric Company. The computer (a Minneapolis-Honeywell 800) which was to run MEDLARS was delivered to the NLM in March 1963, and Frank Bradway Rogers (Director of the NLM 1949 to 1963) said at the time "..If all goes well, the January 1964 issue of *Index Medicus* will be ready to emerge from the system at the end of this year. It may be that this will mark the beginning of a new era in medical bibliography."

MEDLARS cost $3 million to develop and at the time of its completion in 1964, no other publicly available, fully operational electronic storage and retrieval system of its magnitude existed. The original computer configuration operated from 1964 until its replacement by MEDLARS II in January 1975.*[2]*[3]

MEDLARS Online

In late 1971, an online version called MEDLINE ("MEDLARS Online") became available as a way to do online searching of MEDLARS from remote medical libraries.*[4] This early system covered 239 journals and boasted that it could support as many as 25 simultaneous online users (remotely logged-in from distant medical libraries) at one time.*[5] However, this system remained primarily in the hands of libraries, with researchers able to submit pre-programmed search tasks to librarians and obtain results on printouts, but rarely able to interact with the NLM computer output in real-time. This situation continued through the beginning of the 1990s and the rise of the World Wide Web.

In 1996, soon after most home computers began automatically bundling efficient web browsers, a free public version of MEDLINE was instigated. This system, called PubMed, was offered to the general online user in June, 1997, when MEDLINE searches via the Web were demonstrated, in a public ceremony, by Vice President Al Gore.*[5]

7.3.2 Database

The database contains more than 21.6 million records*[6] from 5,639 selected publications*[7] covering biomedicine and health from 1950 to the present. Originally the database covered articles starting from 1965, but this has been enhanced, and records as far back as 1950/51 are now available within the main index. The database is freely accessible on the Internet via the PubMed interface and new citations are added Tuesday through Saturday. For citations added during 1995-2003: about 48% are for cited articles published in the U.S., about 88% are published in English, and about 76% have English abstracts written by authors of the articles.

7.3.3 Retrieval

MEDLINE uses Medical Subject Headings (MeSH) for information retrieval. Engines designed to search MEDLINE (such as Entrez and PubMed) generally use a Boolean expression combining MeSH terms, words in abstract and title of the article, author names, date of publication, etc. Entrez and PubMed can also find articles similar to a given one based on a mathematical scoring system that takes into account the similarity of word content of the abstracts and titles of two articles.*[8]

7.3.4 Importance

MEDLINE functions as an important resource for biomedical researchers and journal clubs from all over the world. Along with the Cochrane Library and a number of other databases, MEDLINE facilitates evidence-based medicine. Most systematic review articles published presently build on extensive searches of MEDLINE to identify articles that might be useful in the review. MEDLINE influences researchers in their choice of journals in which to publish.

7.3.5 Inclusion of journals

More than 5,500 biomedical journals are indexed in MEDLINE. New journals are not included automatically or immediately. Selection is based on the recommendations of a panel, the Literature Selection Technical Review Committee, based on scientific scope and quality of a journal.*[9] The Journals Database (one of the Entrez databases) contains information, such as its name abbreviation and publisher, about all journals included in Entrez, including PubMed.*[10]

7.3.6 Usage

PubMed usage has been on the rise since 2008. In 2011, PubMed/MEDLINE was searched 1.8 billion times, up from 1.6 billion searches in the previous year.*[11]

A service such as MEDLINE strives to balance usability with power and comprehensiveness. In keeping with the fact that MEDLINE's primary user community is professionals (medical scientists, health care providers), searching MEDLINE effectively is a learned skill; untrained users are sometimes frustrated with the large numbers of articles returned by simple searches. Counterintuitively,

a search that returns thousands of articles is not guaranteed to be comprehensive. Unlike using a typical Internet search engine, PubMed searching of MEDLINE requires a little investment of time. Using the MeSH database to define the subject of interest is one of the most useful ways to improve the quality of a search. Using MeSH terms in conjunction with limits (such as publication date or publication type), qualifiers (such as adverse effects or prevention and control), and text-word searching is another. Finding one article on the subject and clicking on the "Related Articles" link to get a collection of similarly classified articles can expand a search that otherwise yields few results.

For lay users who are trying to learn about health and medicine topics, the NIH offers MedlinePlus; thus, although such users are still free to search and read the medical literature themselves (via PubMed), they also have some help with curating it into something comprehensible and practically applicable for patients and family members.

7.3.7 See also

- LILACS
- GoPubMed - explore PubMed/MEDLINE with Gene Ontology
- HubMed - an alternative interface to the PubMed medical literature database.
- eTBLAST - a natural language text similarity engine for MEDLINE and other text databases.
- Medscape
- Twease - an open-source biomedical search engine

7.3.8 References

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7.4 Entrez

The Entrez logo

The **Entrez** Global Query Cross-Database Search System is a federated search engine, or web portal that allows users to search many discrete health sciences databases at the National Center for Biotechnology Information (NCBI) website.*[1] The NCBI is a part of the National Library of Medicine (NLM), which is itself a department of the National Institutes of Health (NIH), which in turn is a part of the United States Department of Health and Human Services. The name "Entrez"(a greeting meaning "Come in!" in French) was chosen to reflect the spirit of welcoming the public to search the content available from the NLM.

Entrez Global Query is an integrated search and retrieval system that provides access to all databases simultaneously with a single query string and user interface. Entrez can efficiently retrieve related sequences, structures, and references. The Entrez system can provide views of gene and protein sequences and chromosome maps. Some textbooks are also available online through the Entrez system.

7.4.1 Features

The Entrez front page provides, by default, access to the global query. All databases indexed by Entrez can be searched via a single query string, supporting boolean operators and search term tags to limit parts of the search statement to particular fields. This returns a unified results page, that shows the number of hits for the search in each of the databases, which are also links to actual search results for that particular database.

Entrez also provides a similar interface for searching each particular database and for refining search results. The Limits feature allows the user to narrow a search a web forms interface. The History feature gives a numbered list of recently performed queries. Results of previous queries can be referred to by number and combined via boolean operators. Search results can be saved temporarily in a Clipboard. Users with a MyNCBI account can save queries indefinitely and also choose to have updates with new search results e-mailed for saved queries of most databases. It is widely used in the field of biotechnology as a reference tool for students and professionals alike.

7.4.2 Databases

Entrez searches the following databases:

- PubMed: biomedical literature citations and abstracts, including Medline - articles from (mainly medical) journals, often including abstracts. Links to PubMed Central and other full-text resources are provided for articles from the 1990s.
- PubMed Central: free, full-text journal articles
- Site Search: NCBI web and FTP web sites
- Books: online books
- Online Mendelian Inheritance in Man (OMIM)
- *Nucleotide*: sequence database (GenBank)
- *Protein*: sequence database
- *Genome*: whole genome sequences and mapping
- *Structure*: three-dimensional macromolecular structures
- *Taxonomy*: organisms in GenBank Taxonomy
- *SNP*: single nucleotide polymorphism
- *Gene*: gene-centered information
- *HomoloGene*: eukaryotic homology groups
- PubChem Compound: unique small molecule chemical structures
- PubChem Substance: deposited chemical substance records
- Genome Project: genome project information
- UniGene: gene-oriented clusters of transcript sequences
- *CDD*: conserved protein domain database
- *PopSet*: population study data sets (epidemiology)
- *GEO Profiles*: expression and molecular abundance profiles
- *GEO DataSets*: experimental sets of GEO data
- *Sequence read archive*: high-throughput sequencing data
- *Cancer Chromosomes*: cytogenetic databases
- *PubChem BioAssay*: bioactivity screens of chemical substances
- *Probe*: sequence-specific reagents
- *NLM Catalog*: NLM bibliographic data for over 1.2 million journals, books, audiovisuals, computer software, electronic resources, and other materials resident in LocatorPlus (updated every weekday).

7.4.3 Access

In addition to using the search engine forms to query the data in Entrez, NCBI provides the Entrez Programming Utilities (eUtils) for more direct access to query results. The eUtils are accessed by posting specially formed URLs to the NCBI server, and parsing the XML response. There is also an eUtils SOAP interface.

7.4.4 History

In 1991, entrez was introduced in CD form. In 1993, a client-server version of the software provided connectivity with the internet. In 1994, NCBI established a website, and Entrez was a part of this initial release. In 2001, Entrez bookshelf was released and in 2003, the Entrez Gene database was developed.*[2]

7.4.5 References

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[2] Smith, Kent. "A Brief History of NCBI's Formation and Growth". *The NCBI Handbook [Internet]. 2nd edition*. Retrieved 3 May 2014.

7.4.6 External links

- Entrez search engine form
- Entrez Help

7.5 eTBLAST

eTBLAST is a free text similarity service search engine currently offering access to the MEDLINE database, the National Institutes of Health (NIH) CRISP database, the Institute of Physics (IOP) database, Wikipedia, arXiv, the NASA technical reports database, Virginia Tech class descriptions and a variety of databases of clinical interest. It is continuously expanding with additional text-based databases. eTBLAST searches citation databases*[1]*[2] and databases containing full text,*[3] such as PUBMED. The eTBLAST server compares a user's natural text query to target databases using a hybrid search algorithm consisting of a low-sensitivity weighted keyword-based first pass followed by a novel sentence-alignment based second pass. eTBLAST is a free web-based service of The Innovation Laboratory at the Virginia Bioinformatics Institute.

eTBLAST, as a text similarity engine, made possible a large study of duplicate publications and potential plagiarisms in the biomedical literature. Thousands of random samples of Medline abstracts were submitted to eTBLAST, and those with the highest similarity were studied and entered into an on-line database. This study is on-going, with the database maturing as the entries are manually inspected and classified. This work revealed several trends, including an increasing rate of duplication in the biomedical literature, as reported in the journals *Bioinformatics*,*[4]*[5] *Anaesthesia and Intensive Care*,*[6] *Clinical Chemistry*,*[7] *Urologic Oncology*,*[8] *Nature*,*[9] and *Science*.*[10]

7.5.1 Interface

Because eTBLAST is a text-similarity engine rather than a simple keyword-based search tool, it is claimed that the user need not identify and manipulate query keywords and Boolean operators, as must be done for other search engines.

eTBLAST aims to help the user rapidly to find references, evaluate novelty, find experts and journals in a given topical area*[11] and track the popularity of the topic as defined by the user's query. There also is information found within the results as a set, in addition to those found within individual 'hits'. eTBLAST can also infer possible hypothese from inspection of implicit keywords found within the top most similar 'hits'. A matrix of similarity and a heat map are also displayed for the most similar 'hits'.

A typical query of 120 words takes less than 10 seconds to return results after a comparison to MEDLINE that as of 8/1/2011 contains over 20 million records.

7.5.2 See also

- BLAST (Basic Local Alignment Search Tool)
- Natural language processing
- Medical literature retrieval

7.5.3 References

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[11] Errami, M; Wren, JD; Hicks, JM; Garner, HR (2007). "ETBLAST: A web server to identify expert reviewers, appropriate journals and similar publications" . *Nucleic Acids Research* **35** (Web Server issue): W12–5. doi:10.1093/nar/gkm221. PMC 1933238. PMID 17452348.

7.5.4 External links

- eTBLAST
- "NetWatch" . *Science* **304** (5673): 935. 2004. doi:10.1126/science.304.5673.935b.

7.6 PubMed

Not to be confused with PubMed Central.

PubMed is a free search engine accessing primarily the MEDLINE database of references and abstracts on life sciences and biomedical topics. The United States National Library of Medicine (NLM) at the National Institutes of Health maintains the database as part of the Entrez system of information retrieval.

From 1971 to 1997, MEDLINE online access to the MEDLARS Online computerized database had been primarily through institutional facilities, such as university libraries. PubMed, first released in January 1996, ushered in the era of private, free, home- and office-based MEDLINE searching.*[1] The PubMed system was offered free to the public in June 1997, when MEDLINE searches via the Web were demonstrated, in a ceremony, by Vice President Al Gore.*[2]

7.6.1 Content

PubMed provides quality control in scientific publishing. Only journals that meet PubMed's scientific standards are indexed.*[3]

In addition to MEDLINE, PubMed provides access to:

- older references from the print version of *Index Medicus* back to 1951 and earlier;
- references to some journals before they were indexed in Index Medicus and MEDLINE, for instance *Science*, *BMJ*, and *Annals of Surgery*;
- very recent entries to records for an article before it is indexed with Medical Subject Headings (MeSH) and added to MEDLINE; and
- a collection of books available full-text and other subsets of NLM records.*[4]
- PMC citations

Many PubMed records contain links to full text articles, some of which are freely available, often in PubMed Central*[5] and local mirrors such as UK PubMed Central.*[6]

Information about the journals indexed in PubMed is found in the NLM Catalog.*[7]

As of 8 February 2015, PubMed has over 24.6 million records going back to 1966, selectively to the year 1865, and very selectively to 1809; about 500,000 new records are added each year. As of the same date, 13.1 million of PubMed's records are listed with their abstracts, and 14.2 million articles have links to full-text (of which 3.8 million articles are available full-text for free for any user).

7.6.2 Characteristics

Standard searches

Simple searches on PubMed can be carried out by entering key aspects of a subject into PubMed's search window.

PubMed translates this initial search formulation and automatically adds field names, relevant MeSH (Medical Subject Headings) terms, synonyms, Boolean operators, and 'nests' the resulting terms appropriately, enhancing the search formulation significantly, in particular by routinely combining (using the OR operator) textwords and MeSH terms.

The examples given in a PubMed tutorial*[8] demonstrate how this automatic process works:

> **Causes Sleep Walking** is translated as ("etiology"[Subheading] OR "etiology"[All Fields] OR "causes"[All Fields] OR "causality"[MeSH Terms] OR "causality"[All Fields]) **AND** ("somnambulism"[MeSH Terms] OR "somnambulism"[All Fields] OR ("sleep"[All Fields] AND "walking"[All Fields]) OR "sleep walking"[All Fields])

Likewise,

> **Heart Attack Aspirin Prevention** is translated as ("myocardial infarction"[MeSH Terms] OR ("myocardial"[All Fields] AND "infarction"[All Fields]) OR "myocardial infarction"[All Fields] OR ("heart"[All Fields] AND "attack"[All Fields]) OR "heart attack"[All Fields]) **AND** ("aspirin"[MeSH Terms] OR "aspirin"[All Fields]) **AND** ("prevention and control"[Subheading] OR ("prevention"[All Fields] AND "control"[All Fields]) OR "prevention and control"[All Fields] OR "prevention"[All Fields])

The new PubMed interface, launched in October 2009, encourages the use of such quick, Google-like search formulations; they have also been described as 'telegram' searches.*[9]

Comprehensive searches

For comprehensive, optimal searches in PubMed, it is necessary to have a thorough understanding of its core component, MEDLINE, and especially of the MeSH (Medical Subject Headings) controlled vocabulary used to index MEDLINE articles. They may also require complex search strategies, use of field names (tags), proper use of limits and other features, and are best carried out by PubMed search specialists or librarians,*[10] who are able to select the right type of search and carefully adjust it for precision and recall.*[11]

Journal article parameters

When a journal article is indexed, numerous article parameters are extracted and stored as structured information. Such parameters are: Article Type (MeSH terms, e.g., "Clinical Trial"), Secondary identifiers, (MeSH terms), Language, Country of the Journal or publication history (e-publication date, print journal publication date).

Publication Type: Clinical queries/systematic reviews Publication type parameter enables many special features. A special feature of PubMed is its "Clinical Queries" section, where "Clinical Categories", "Systematic Reviews", and "Medical Genetics" subjects can be searched, with study-type 'filters' automatically applied to identify substantial, robust studies.*[12] As these 'clinical girish' can generate small sets of robust studies with considerable precision, it has been suggested that this PubMed section can be used as a 'point-of-care' resource.*[13]

Secondary ID Since July 2005, the MEDLINE article indexing process extracts important identifiers from the article abstract and puts those in a field called Secondary Identifier (SI). The secondary identifier field is to store accession numbers to various databases of molecular sequence data, gene expression or chemical compounds and clinical trial IDs. For clinical trials, PubMed extracts trial IDs for the two largest trial registries: ClinicalTrials.gov (NCT identifier) and the International Standard Randomized Controlled Trial Number Register (IRCTN identifier).*[14]

See also

A reference which is judged particularly relevant can be marked and "related articles" can be identified. If relevant, several studies can be selected and related articles to all of them can be generated (on PubMed or any of the other NCBI Entrez databases) using the 'Find related data' option. The related articles are then listed in order of "relatedness". To create these lists of related articles, PubMed compares words from the title and abstract of each citation, as well as the MeSH headings assigned, using a powerful word-weighted algorithm.*[15] The 'related articles' function has been judged to be so precise that some researchers suggest it can be used instead of a full search.*[16]

Mapping to MeSH headings and subheadings

A strong feature of PubMed is its ability to automatically link to MeSH terms and subheadings. Examples would be: "bad breath" links to (and includes in the search) "halitosis", "heart attack" to "myocardial infarction", "breast cancer" to "breast neoplasms". Where appropriate, these MeSH terms are automatically "expanded", that is, include more specific terms. Terms like "nursing" are automatically linked to "Nursing [MeSH]" or "Nursing [Subheading]". This important feature makes PubMed searches automatically more sensitive and avoids false-negative (missed) hits by compensating for the diversity of medical terminology.

My NCBI

The PubMed optional facility "My NCBI" (with free registration) provides tools for

- saving searches
- filtering search results
- setting up automatic updates sent by e-mail
- saving sets of references retrieved as part of a PubMed search
- configuring display formats or highlighting search terms

and a wide range of other options.*[17] The "My NCBI" area can be accessed from any computer with web-access. An earlier version of "My NCBI" was called "PubMed Cubby".*[18]

LinkOut

LinkOut, a NLM facility to link (and make available full-text) local journal holdings.*[19] Some 3,200 sites

(mainly academic institutions) participate in this NLM facility (as of March 2010), from Aalborg University in Denmark to ZymoGenetics in Seattle.*[20] Users at these institutions see their institutions logo within the PubMed search result (if the journal is held at that institution) and can access the full-text.

PubMed for handhelds/mobiles

PubMed/MEDLINE can be accessed via handheld devices, using for instance the "PICO" option (for focused clinical questions) created by the NLM.*[21] A "PubMed Mobile" option, providing access to a mobile friendly, simplified PubMed version, is also available.*[22]

askMEDLINE

askMEDLINE, a free-text, natural language query tool for MEDLINE/PubMed, developed by the NLM, also suitable for handhelds.*[23]

PubMed identifier

For help using PubMed identifiers within Wikipedia, see Wikipedia:PMID.

A **PMID** (PubMed identifier or PubMed unique identifier)*[24] is a unique number assigned to each PubMed record. A PMID is not the same as a PMCID which is the identifier for all works published in the free-to-access PubMed Central.*[25]

The assignment of a PMID or PMCID to a publication tells the reader nothing about the type or quality of the content. PMIDs are assigned to letters to the editor, editorial opinions, op-ed columns, and any other piece that the editor chooses to include in the journal, as well as peer-reviewed papers. The existence of the identification number is also not proof that the papers have not been retracted for fraud, incompetence, or misconduct. The announcement about any corrections to original papers may be assigned a PMID.

7.6.3 Alternative interfaces

The National Library of Medicine leases the MEDLINE information to a number of private vendors such as Ovid, Dialog, EBSCO, Knowledge Finder and many other commercial, non-commercial, and academic providers.*[26] As of October 2008, more than 500 licenses had been issued, more than 200 of them to providers outside the United States. As licenses to use MEDLINE data are available for free, the NLM in effect provides a free testing ground for a wide range*[27] of alternative interfaces and 3rd party additions to PubMed, one of a very few large, professionally curated databases which offers this option.

Lu*[27] identifies a sample of 28 current and free Web-based PubMed versions, requiring no installation or registration, which are grouped into four categories:

- Ranking search results, for instance: eTBLAST; Hakia; MedlineRanker;*[28] MiSearch;*[29]
- Clustering results by topics, authors, journals etc., for instance: Anne O'Tate;*[30] ClusterMed;*[31]
- Enhancing semantics and visualization, for instance: EBIMed;*[32] MedEvi;*[33] (Note: *CiteXplore* was withdrawn from service on 15 February 2013,*[34] replaced by Europe PubMed Central.*[35])
- Improved search interface and retrieval experience, for instance, askMEDLINE*[36]*[37] BabelMeSH;*[38] and PubCrawler.*[39]
- GoPubMed is a knowledge-based (Gene Ontology and MeSH) search engine for **PubMed**. GoPubMed claims to be a semantic search engine, but searches return exactly the same results as PubMed itself.
- Expertscape provides search and ranking of medical and biomedical expertise by specific diagnosis, technique, or other terminology. Results are based on analysis derived from most recent ten years of PubMed data.*[40]
- Search term forwarders like "OssiPubMed online". O. Groth., which runs searches on multiple external platforms derived from the original boolean search terms.
- Reference-to-PubMed transcriptors like "OssiPubMed online". O. Groth., which retrieves the PMID from one-letter coded journal abbreviations to get the full-text articles.
- Link-Out arborizers "OssiPubMed online". O. Groth., which tries to retrieve available PDF's from additional hosts.

As most of these and other alternatives rely essentially on PubMed/MEDLINE data leased under license from the NLM/PubMed, the term "PubMed derivatives" has been suggested.*[27] Without the need to store about 90 GB of original PubMed Datasets, anybody can write PubMed applications using the eutils-application program interface as described in "The E-utilities In-Depth: Parameters, Syntax and More", by Eric Sayers, PhD.*[41]

7.6.4 See also

- JournalReview.org
- Arrowsmith System

7.6.5 References

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7.6.6 External links

- Official website
- PubMed Mobile
- PubMed Online Tutorials
- PubMed Help
- Other PubMed Search Engines Resource Guide
- Comparison of PubMed mobile apps
- PubMed Customizable Email Alerts

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Publication Type: Clinical queries/systematic reviews Publication type parameter enables many special features. A special feature of PubMed is its "Clinical Queries" section, where "Clinical Categories", "Systematic Reviews", and "Medical Genetics" subjects can be searched, with study-type 'filters' automatically applied to identify substantial, robust studies.*[12] As these 'clinical girish' can generate small sets of robust studies with considerable precision, it has been suggested that this PubMed section can be used as a 'point-of-care' resource.*[13]

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- Clustering results by topics, authors, journals etc., for instance: Anne O'Tate;*[30] ClusterMed;*[31]
- Enhancing semantics and visualization, for instance: EBIMed;*[32] MedEvi;*[33] (Note: *CiteXplore* was withdrawn from service on 15 February 2013,*[34] replaced by Europe PubMed Central.*[35])
- Improved search interface and retrieval experience, for instance, askMEDLINE*[36]*[37] BabelMeSH;*[38] and PubCrawler.*[39]
- GoPubMed is a knowledge-based (Gene Ontology and MeSH) search engine for **PubMed**.

GoPubMed claims to be a semantic search engine, but searches return exactly the same results as PubMed itself.

- Expertscape provides search and ranking of medical and biomedical expertise by specific diagnosis, technique, or other terminology. Results are based on analysis derived from most recent ten years of PubMed data.*[40]
- Search term forwarders like "OssiPubMed online". O. Groth., which runs searches on multiple external platforms derived from the original boolean search terms.
- Reference-to-PubMed transcriptors like "OssiPubMed online". O. Groth., which retrieves the PMID from one-letter coded journal abbreviations to get the full-text articles.
- Link-Out arborizers "OssiPubMed online". O. Groth., which tries to retrieve available PDF's from additional hosts.

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7.7.4 See also

- JournalReview.org
- Arrowsmith System

7.7.5 References

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7.7.6 External links

- Official website
- PubMed Mobile
- PubMed Online Tutorials
- PubMed Help
- Other PubMed Search Engines Resource Guide
- Comparison of PubMed mobile apps
- PubMed Customizable Email Alerts

7.8 GoPubMed

GoPubMed is a knowledge-based search engine for biomedical texts.*[1] The Gene Ontology (GO) and Medical Subject Headings (MeSH) serve as "Table of contents" in order to structure the millions of articles of the MEDLINE database. **MeshPubMed** was at one point a separate project, but now the two have been merged.

The technologies used in GoPubMed are generic and can in general be applied to any kind of texts and any kind of knowledge bases.The system was developed at the Technische Universität Dresden by Michael Schroeder and his team at Transinsight.

GoPubMed.com, the semantic search engine for the life sciences, has been recognized with the 2009 red dot: best of the best award in the category communication design – graphical user interfaces and interactive tool. Transinsight has been recognized with the German Innovation Prize IT for its outstanding developments in Enterprise Semantic Intelligence at CeBIT 2011.

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7.8.2 External links

- GoPubMed

7.9 Pubget

Pubget Corp is a wholly owned subsidiary of Copyright Clearance Center that develops cloud-based search and content access tools for scientists. It provides advertising services, enterprise search services, and a public search engine.*[1] The company was founded in 2007 by Beth Israel Hospital clinical pathologist, Ramy Arnaout, out of his own need to find papers.*[2]*[3]*[4] Pubget moved its headquarters from Cambridge, Massachusetts to Boston's Innovation District in 2011.*[4]*[5]

Pubget.com is a free service for non-profit institutions and their libraries and researchers. The site provides direct access to full-text content from 450 libraries around the world. It was announced in January 2012 that Pubget was acquired by Copyright Clearance Center.*[6]

7.9.1 Products and Services

Search Engine
Pubget's search engine retrieves article citations and full text PDFs from PubMed, ArXiv, Karger, American Society for Microbiology, IEEE, RSS feeds, XML from publishers, and Open Archive sources.*[7] The company's search engine contains over 28 million scientific documents and adds 10,000 papers each day. Pubget creates a link directly from the article citation to the paper itself via a continuously updated database of links.*[8] Because of this database, users are directly linked from a citation to the full-text paper.

Access to closed full-text PDFs is granted through the institution's subscriptions. Pubget does not bypass copyright laws and will display only the abstract of restricted papers if the end user does not have institutional access.

PaperStats
Pubget PaperStats is a usage and spend analysis tool for libraries. PaperStats automatically harvests serials usage statistics delivering consolidated usage, cost, and other reports directly from publishers. Content performance can be assessed through cost-per-view analysis. Upon introduction, PaperStats was beta tested with the USC Norris Medical Library and yielded positive results for Pubget, USC and the library community.*[7]*[9]

PaperStore
The Pubget PaperStore provides Pubget.com users the option of purchasing full text papers from thousands of journals on the search engine results page. Content rights and delivery is provided by document delivery vendor, Reprints Desk.*[10]

Advertising
Pubget provides several advertising solutions. Customers include Bio-Rad, Agilent, and other scientific brands. Ads are matched with paper content via contextual targeting. For example, manufacturers of a piece of scientific equipment will pay to advertise alongside a paper that mentions using said product.*[2]*[11] Pubget, however, does not reveal data on individual users and their searches.*[2]

Textmining
Pubget's textmining technology allows research and development teams to uncover specific text strings across large groups of papers.*[12]

PaperStream
PaperStream is a web app that allows lab teams to share, store, and find documents all in one place.*[13] PaperStream organizes companies' subscriptions, purchased papers, and internal documents into an automated library database.*[14]*[15]

API
Pubget's API provides access to its search and linking technology from third-party websites.*[16]*[17]

7.9.2 References

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7.9.3 External links

- Official website
- Got PubMed? Pubget Searches and Delivers Scientific PDFs
- UCSF Pubget page
- PubMed Portuguese
- Pubget Speeds Up Science Journal Searches, Provides Marketing Tools
- Pubget RSS and Firefox Download Extension
- Reprints Desk

7.10 PubMed Central

PubMed Central (**PMC**) is a free digital repository that archives publicly accessible full-text scholarly articles that have been published within the biomedical and life sciences journal literature. As one of the major research databases within the suite of resources that have been developed by the National Center for Biotechnology Information (NCBI), PubMed Central is much more than just a document repository. Submissions into PMC undergo an indexing and formatting procedure which results in enhanced metadata, medical ontology, and unique identifiers which all enrich the XML structured data for each article on deposit.*[1] Content within PMC can easily be interlinked to many other NCBI databases and accessed via Entrez search and retrieval systems, further enhancing the public's ability to freely discover, read and build upon this portfolio of biomedical knowledge.*[2]

PubMed Central should not be confused with PubMed. These are two very different services at their core.*[3] While PubMed is a searchable database of biomedical citations and abstracts, the full-text article referenced in the PubMed record will physically reside elsewhere. (Sometimes in print, sometimes online, sometimes free, sometimes behind a toll-wall accessible only to paying subscribers). PubMed Central is a free digital archive of articles, accessible to anyone from anywhere via a basic web browser. The full text of all PubMed Central articles is free to read, with varying provisions for reuse.

As of February 2014, the PMC archive contained over 2.9 million articles, with contributions coming directly from publishers or authors depositing their own manuscripts into the repository per the NIH Public Access Policy. Recent data shows that in the past year (Jan 2013 – Jan 2014) author initiated deposits exceeded 103,000 papers during just this 12-month period.*[4] PMC also identifies about 4,000 journals which now participate in some capacity to automatically deposit their published content into the PMC repository.*[5] Some participating publishers will delay the release of their articles on PubMed Central for a set time after publication, this is often referred to as an "embargo period", and can range from a few months to a few years depending on the journal. (Embargoes of six to twelve months are the most common).

7.10.1 Adoption

See also: NIH Public Access Policy

Launched in February 2000, the repository has grown rapidly as the NIH Public Access Policy is designed to make all research funded by the National Institutes of Health (NIH) freely accessible to anyone, and, in addition, many publishers are working cooperatively with the NIH to provide free access to their works. In late 2007, the Consolidated Appropriations Act of 2008 (H.R. 2764) was signed into law and included a provision requiring the NIH to modify its policies and require inclusion into PubMed Central complete electronic copies of their peer-reviewed research and findings from NIH-funded research. These articles are required to be included within 12 months of publication. This is the first time the US government has required an agency to provide open access to research and is an evolution from the 2005 policy, in which the NIH asked researchers to voluntarily add their research to PubMed Central.*[6]

A UK version of the PubMed Central system, UK PubMed Central (UKPMC), has been developed by the

Wellcome Trust and the British Library as part of a nine-strong group of UK research funders. This system went live in January 2007. On 1 November 2012, it became Europe PubMed Central. The Canadian member of the PubMed Central International network, PubMed Central Canada, was launched in October 2009.

The National Library of Medicine "NLM Journal Publishing Tag Set" journal article markup language is freely available.*[7] The Association of Learned and Professional Society Publishers comments that "it is likely to become the standard for preparing scholarly content for both books and journals".*[8] A related DTD is available for books.*[9] The Library of Congress and the British Library have announced support for the NLM DTD.*[10] It has also been popular with journal service providers.*[11]

7.10.2 Technology

Articles are sent to PubMed Central by publishers in XML or SGML, using a variety of article DTDs. Older and larger publishers may have their own established in-house DTDs, but many publishers use the NLM Journal Publishing DTD (see above).

Received articles are converted via XSLT to the very similar NLM Archiving and Interchange DTD. This process may reveal errors that are reported back to the publisher for correction. Graphics are also converted to standard formats and sizes. The original and converted forms are archived. The converted form is moved into a relational database, along with associated files for graphics, multimedia, or other associated data. Many publishers also provide PDF of their articles, and these are made available without change.*[12]

Bibliographic citations are parsed and automatically linked to the relevant abstracts in PubMed, articles in PubMed Central, and resources on publishers' Web sites. PubMed links also lead to PubMed Central. Unresolvable references, such as to journals or particular articles not yet available at one of these sources, are tracked in the database and automatically come "live" when the resources become available.

An in-house indexing system provides search capability, and is aware of biological and medical terminology, such as generic vs. proprietary drug names, and alternate names for organisms, diseases and anatomical parts.

When a user accesses a journal issue, a table of contents is automatically generated by retrieving all articles, letters, editorials, etc. for that issue. When an actual item such as an article is reached, PubMed Central converts the NLM markup to HTML for delivery, and provides links to related data objects. This is feasible because the variety of incoming data has first been converted to standard DTDs and graphic formats.

In a separate submission stream, NIH-funded authors may deposit articles into PubMed Central using the NIH Manuscript Submission (NIHMS). Articles thus submitted typically go through XML markup in order to be converted to NLM DTD.

7.10.3 Reception

Reactions to PubMed Central among the scholarly publishing community range between a genuine enthusiasm by some,*[13] to cautious concern by others.*[14] While PMC is a welcome partner to open access publishers in its ability to augment the discovery and dissemination of biomedical knowledge, that same truth causes others to worry about traffic being diverted from the published version-of-record, the economic consequences of less readership, as well as the effect on maintaining a community of scholars within learned societies.*[15] Libraries, universities, open access supporters, consumer health advocacy groups, and patient rights organizations have applauded PubMed Central, and hope to see similar public access repositories developed by other federal funding agencies so to freely share any research publications that were the result of taxpayer support.*[16]

The Antelman study of open access publishing found that in philosophy, political science, electrical and electronic engineering and mathematics, open access papers had a greater research impact.*[17] A randomised trial found an increase in content downloads of open access papers, with no citation advantage over subscription access one year after publication.*[18]

The change in procedure has received criticism.*[19] The American Physiological Society has expressed reservations about the implementation of the policy.*[20]

7.10.4 See also

- JATS (technology)
- MEDLINE, an international literature database of life sciences and biomedical information
- PMID (PubMed Identifier)
- SciELO (similar service)
- PubMed Central Canada
- Europe PubMed Central
- Redalyc (similar project focused on Latin America)

7.10.5 Notes

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[18] Open access publishing, article downloads, and citations: randomised controlled trial

[19] C&RL News: Scholarly Communication in Flux: Entrenchment and Opportunity Kate Thomes, Science & Technology Libraries 22, no. 3/4 (220): 104 "Many faculty see the current system of scholarly communication as an effective, known, and reliable system that is not broken and therefore does not need to be fixed".

[20] The American Physiological Society "Although the American Physiological Society (APS) supports the principle of public access, the NIH approach is a mallet rather than a scalpel. It is likely to harm publishers, which will in turn harm the dissemination of science through the literature".

7.10.6 External links

- PubMed Central
- National Institutes of Health Submission System (NIHMS)
- NIH Public Access Policy

7.11 UK PubMed Central

Europe PubMed Central (Europe PMC) is an on-line database that offers free access to a large and growing collection of biomedical research literature. It was known as **UK PubMed Central** until 1 November 2012.*[2] The Europe PMC project was originally launched in 2007 as the first 'mirror' site to PMC, which aims to provide international preservation of the open and free-access biomedical and life sciences literature. It forms part of a network of PMC International*[3] (PMCI) repositories that includes PubMed Central Canada. Europe PMC is not an exact "mirror" of the PMC database but has developed some different features.*[1]*[4] On February 15, 2013, *CiteXplore* was subsumed under Europe PubMed Central.*[5]

The resource is managed and developed by the European Molecular Biology Laboratory-European Bioinformatics Institute (EMBL-EBI), on behalf of an alliance of 27 biomedical and life sciences research funders, led by the Wellcome Trust. The Europe PMC funders group requires that articles describing the results of biomedical and life sciences research they have supported be made freely available in Europe PMC within 6 months of publication to maximise the impact of the work that they fund.*[6]

7.11.1 Service

Europe PMC provides free access to more than 3.7 million full-text biomedical and life sciences research articles and over 31 million citations.*[7] Europe PMC contains some citation information and includes text-mining based marked up text that links to external molecular and medical datasets.*[1]*[4] The Grant Lookup facility allows users to search for information on over 56,700 grants awarded by the Europe PMC funders.

Europe PMC offers a manuscript submission system, Europe PMC plus, which allows scientists to submit their peer-reviewed research articles for inclusion in the Europe PMC collection.

7.11.2 Support

Europe PMC is supported by 26 organisations: Action on Hearing Loss, Alzheimer's Society, Arthritis Research

UK, Austrian Science Fund (FWF), the Biotechnology and Biological Sciences Research Council, Bloodwise, Breast Cancer Now, the British Heart Foundation, Cancer Research UK, the Chief Scientist Office of the Scottish Executive Health Department, Diabetes UK, the Department of Health, the Dunhill Medical Trust, the European Research Council, Marie Curie, the Medical Research Council, the Motor Neurone Disease Association, the Multiple Sclerosis Society, the Myrovlytis Trust, the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), Parkinson's UK, Prostate Cancer UK, Telethon Italy, the Wellcome Trust, the World Health Organization and Worldwide Cancer Research (formerly Association for International Cancer Research).*[8]

7.11.3 See also

- PubMed Central
- Hyper Articles en Ligne
- Isidore (platform)
- arXiv

7.11.4 References

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7.11.5 External links

- Official website
- Fact-sheet

7.12 Trip

Trip is a free clinical search engine. Its primary function is to help clinicians identify the best available evidence with which to answer clinical questions. Its roots are firmly in the world of evidence-based medicine.

7.12.1 History

The site was created in 1997 as a search tool to help the staff of ATTRACT*[1] answer clinical questions for GPs in Gwent, South Wales. Shortly afterwards *Bandolier* highlighted the Trip Database and this helped establish the site. In 2003, after a period of steady growth, Trip became a subscription-only service. This was abandoned In September 2006 and since then the growth in usage has been significant. Originally "Trip" stood for Turning Research Into Practice, but the system is now simply called Trip.*[2]

7.12.2 Process

The core to Trip's system is the identification and incorporation of new evidence. The people behind Trip are heavily involved in clinical question answering systems (e.g., NLH Q&A Service). Therefore, if resources are identified that are useful in the Q&A process they tend to be added to Trip.

7.12.3 Users

A site survey (September 2007) showed that the site was searched over 500,000 times per month, with 69% from health professionals and 31% from members of the public. Of the health professionals around 43% are doctors. Most users come from either the United Kingdom or the USA. In September 2008 the site was searched 1.4 million times. To date the site has been searched over 100 millions times.

7.12.4 Recent updates

At the end of 2012 Trip had a major upgrade which saw significant new enhancements:

- New content - widening the coverage
- New design
- Advanced search
- PICO search - to help users formulate focused searches
- Improved filtering

- Search history/timeline - recording all a user activity on the site
- Related articles

7.12.5 Education tracker

Trip has an education tracker which allows users to record their activity on Trip which can then be used, subject to local regulations, for revalidation/re-licensing.

7.12.6 Future areas of work

Trip is exploring numerous innovative technologies to improve the site, these include:

- Link out to full-text articles via Trip.
- RCT database.
- Rapid (within a week) systematic review quality reviews.
- Learning from users prior use of the site and that of similar users to improve search results.

7.12.7 Trip Answers

In November 2008, Trip released a new website, Trip Answers. This is a repository of clinical Q&As from a variety of Q&A services. At launch it had over 5,000 Q&As and currently has over 6,300. This content has been integrated into Trip.

7.12.8 References

[1] ATTRACT

[2] "About". *Trip*. Trip Database Ltd. Retrieved 3 April 2013.

7.12.9 External links

- Trip
- Using the Turning Research Into Practice (TRIP) database: how do clinicians really search? an evaluation of the website.
- Reviews: From Systematic to Narrative review of the site
- Evidence Based Pyramid a pictorial representation of TRIP's approach to the evidence

7.13 Twease

Twease is an open source biomedical web search engine which searches MEDLINE.

It provides searches based on relevance or chronology; highlights text passages that match the query; collects and exports references seamlessly to RefWorks, EndNote, BibTex; searches for articles similar to a group of articles; and offers a slider to control query expansion with common synonyms, word variants, mesh terms, etc. Its content is updated weekly and can be downloaded and set up locally to run unlimited searches against Medline.

7.13.1 External links

- Twease home page

7.14 SciELO

SciELO (**Sci**entific **E**lectronic **L**ibrary **O**nline) is a bibliographic database, digital library, and cooperative electronic publishing model of open access journals. SciELO was created to meet the scientific communication needs of developing countries and provides an efficient way to increase visibility and access to scientific literature [*][2] Originally established in Brazil in 1997, today there are 14 countries in the SciELO network and its journal collections: Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Mexico, Peru, Portugal, South Africa, Spain, Uruguay, and Venezuela. Paraguay is developing a journal collection.[*][3]

SciELO was initially supported by the São Paulo Research Foundation (FAPESP) and the Brazilian National Council for Scientific and Technological Development (CNPq), along with the Latin American and Caribbean Center on Health Sciences Information (BIREME). SciELO provides a portal that integrates and provides access to all of the SciELO network sites. Users can search across all SciELO collections or limit by a single country collection, or browse by subject area, publisher, or journal title.

7.14.1 Database and projects

By October 2015 the database contained:

- 1,249 journals
- 39,651 issues (journal numbers)
- 573,525 research articles
- 13,005,080 citations (sum of the number of items in each article's reference list)

from different countries, universally accessible for free open access, in full-text format.*[4] The SciELO Project's stated aims are to "envisage the development of a common methodology for the preparation, storage, dissemination and evaluation of scientific literature in electronic format." All journals are published by a special software suite which implements a scientific electronic virtual library accessed via several mechanisms, including a table of titles in alphabetic and subject list, subject and author indexes and a search engine.

History

Project's launch timeline:*[5]

- 1997: Beginning of the development of SciELO as a FAPESP supported project in partnership with BIREME.
- 1998: SciELO goes live.
- 2002: the CNPq also began its support for SciELO.
- 2005: Argentina joined as regional collection, project supported by CONICET
- 200X: Chile joined as regional collection, project supported by CONICYT.
- 2009: South Africa joined as regional collection, project supported by ASSAf.
- 2012: the SciELO Books project is launched.
- 2013: the SciELO Citation Index is integrated into Thomson Reuters' Web of Knowledge (WoS), covering about 650 journals total, 300 more than the 350 already in the WoS.*[6]

7.14.2 Open access

In 2013 the Latin American SciELO project completed 15 years of free publishing.*[7] Open access has long emphasized access to scholarly materials. However, open access can also mean access to the means of producing visible and recognized journals. This issue is particularly important in developing and emergent countries,*[8] where are other benefits of and challenges for publishing scientific journals in and by emerging countries.*[9]

7.14.3 Technology

Articles are sent to SciELO by publishers in XML or HTML+SGML, using a variety of article DTDs. The SGML DTD was used until 2013, when SciELO started to offer the Journal Article Tag Suite (JATS) DTD standard for XML deposites.

In the SciELO portals, received JATS-articles are converted via XSLT to HTML, and "SGML+HTML pack" articles use the HTML content (in general a handmade PDF-to-HTML conversion). This process may reveal errors that are reported back to the publisher for correction. Graphics are also converted to standard formats and sizes. The original and converted forms are archived. The converted form is moved into a relational database, along with associated files for graphics, multimedia, or other associated data. Many publishers also provide PDFs of their articles, and these are made available without change.

Bibliographic citations are (SGML or XML) parsed and automatically linked to the associated articles in SciELO and resources on publishers' Web sites. Unresolvable references, such as to journals or particular articles not yet available at one of these sources, are tracked in the database and automatically come "live" when the resources become available.

An in-house indexing system provides search capability.

7.14.4 Controversy

Further information: Redalyc § Controversy

In July 2015, Jeffrey Beall, an American librarian, posted an article on his blog referring to the two largest Latin American open access databases (SciELO and Redalyc) as "favelas",*[10] which is a derogatory Portuguese term for a slum. Beall stated:

> "*Many North American scholars have never even heard of these meta-publishers or the journals they aggregate. Their content is largely hidden, the neighborhood remote and unfamiliar.*"

Among the responses is a motion passed by the Brazilian Forum of Public Health Journals Editors and the Associação Brasileira de Saúde Coletiva (Abrasco, Brazilian Public Health Association).*[11] The motion takes exception to Beall's characterization, draws attention to the underlying "*ethnocentric prejudice*", and corrects factual inaccuracies. As a counterpoint to Beall's "*neocolonial point of view*", the motion draws attention to work by Vessuri, Guedon and Cetto emphasizing the value of initiatives such as SciELO and Redalyc (also targeted by Beall) to the development of science in Latin America and globally: "*In fact, Latin America is using the OA publishing model to a far greater extent than any other region in the world⋯. Also, because the sense of public mission remains strong among Latin American universities⋯these current initiatives demonstrate that the region contributes more and more to the global knowledge exchange while positioning research literature as a public good.*"*[12]

7.14.5 See also

- List of academic databases and search engines
- PubMed Central (PMC)
- Redalyc (similar project)

7.14.6 References

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7.14.8 External links

- Official website
- SciELO South Africa

Chapter 8

Telehealth and Telemedicine

8.1 Connected Health

Connected health is a model for healthcare delivery that uses technology to provide healthcare remotely. Connected health aims to maximize healthcare resources and provide increased, flexible opportunities for consumers to engage with clinicians and better self-manage their care. It uses technology – often leveraging readily available consumer technologies – to deliver patient care outside of the hospital or doctor's office. Connected health encompasses programs in telehealth, remote care (such as home care) and disease and lifestyle management, often leverages existing technologies such as connected devices using existing cellular networks and is associated with efforts to improve chronic care.

The United States and European Union are two dominant markets for the use of connected health in home care service, in part due to the high availability of telephone and Internet service as compared to other parts of the world. Within the United States, over 260 million people have a land line connected, over 190 million are cell phone users, and approximately 200 million are Internet users. The European Union has roughly an equivalent number of people connected to land lines, but prevails over the U.S. with more than 300 million cell phone users and 230 million Internet users. More recent data collected by Pew Internet: Americans and their Gadgets suggest that 86% of US residents own a mobile phone and this number is as high as 96% among Americans aged 18 to 29 years. According to the International Communications Union, it is predicted that there will be 4 billion mobile phone users worldwide by the end of 2008.*[1]

The vision of the connected health model can be implicitly understood by contemplating the significant impact of technology on other industries, such as in banking, shopping, logistics and personal communications. Proponents of connected health believe that technology can transform healthcare delivery and address many inefficiencies especially in the area of work flow management, chronic disease management and patient compliance of the US and global healthcare systems.

8.1.1 History

Connected health has its roots in telemedicine, and its more recent relative, telehealth. The first telemedicine programs were primarily undertaken to address healthcare access and/or provider shortages. Connected health is distinguished from telemedicine by:

- A broader concern for healthcare cost, quality and efficiency, particularly as related to the chronically ill
- Concomitant interests in making healthcare more patient centric by promoting healthcare consumerism through education, and patient feedback
- Efforts in the direction of integrating of data generated outside of traditional healthcare settings such as the home with centralised, often electronic patient record

One of the first telemedicine clinics was founded by Dr. Kenneth Bird at Massachusetts General Hospital in 1967. The clinic addressed the fundamental problems of delivering occupational and emergency health services to employees and travellers at Boston's Logan International Airport, located three congested miles from the hospital. Over 1,000 patients are documented as having received remote treatment from doctors at MGH using the clinic's two-way audiovisual microwave circuit.*[2] The timing of Dr. Bird's clinic more or less coincided with NASA's foray into telemedicine through the use of physiologic monitors for astronauts.*[3] Other pioneering programs in telemedicine were designed to deliver healthcare services to people in rural settings.

8.1.2 Definition

There is no standard, accepted definition of Connected Health.*[4] On a broader note "connected health is the "umbrella term arrived to lessen the confusion over the definitions of telemedicine, telehealth and mhealth" .*[5] It is considered as the new lexicon for the term telemedicene.*[6] The technology view of connected

health focuses more on the connection methods between clients and the health care professional.

An alternative growing view is that of a socio-technical perspective in which connected health is considered as a combination of people, processes and technology. Connected health is defined as patient-centred care resulting from process-driven health care delivery undertaken by health care professionals, patients and/or carer who are supported by the use of technology (software and/or hardware).*[7]

8.1.3 In operation

Two "core platforms" are emphasized in connected health, self-care and remote care, with programs primarily focused on monitoring and feedback for the chronically ill, elderly, and those patients located at an untenable distance from primary or specialty providers. Programs designed to improve patient-provider communication within an individual medical practice (for example, the use of email to communicate with patients between office visits) also fall within the purview of connected health. There are also lifestyle coaching programs, in which an individual receives healthcare information to facilitate behavior change to improve their fitness and/or general well being, (see wellness) or to reduce or eliminate the impact of a particular behavior that presents a risk to their health status.*[8] Some of the most common types of connected health programs in operation today include:

- Home care via remote monitoring of chronically ill patients including surveillance connected devices or patient controlled monitoring of health parameters
- Traditional telehealth programs, where care is provided in remote areas by teams of local clinicians or community healthcare workers teamed up with specialists in medical centers
- Monitoring programs whose aim is to ensure the safety and quality of life of elderly parents living at a distance from their relatives
- Web-based second opinion services for patients in need of medical care
- Lifestyle and fitness coaching for wellness or health risk reduction

The Center for Connected Health is implementing a range of programs in high-risk, chronic and remotely located populations.

Inherent in the concept of connected health is flexibility in terms of technological approaches to care delivery and specific program objectives. For instance, remote monitoring programs might use a combination of cell phone and smart phone technology, online communications or biosensors and may aim to increase patient-provider communication, involve patients in their care through regular feedback, or improve upon a health outcome measure in a defined patient population or individual. Digital pen technology, global positioning, videoconferencing and environmental sensors are all playing a role in connected health today.

8.1.4 Goals

Connected health is viewed by its proponents as a critical component of change in human healthcare. They envision:

- Reductions in the cost of providing quality care to the chronically ill, estimated by the Center for Health Care Economics at the Milken Institute to be over $1 trillion per year
- Improved global and local public health surveillance, with a resultant reduction in epidemics, increased control over infectious disease and improved drug safety
- Diminished rate of medical errors
- Better "customer service" in healthcare
- Ongoing preventive health, with attendant reductions in: morbidity, mortality and the cost of care
- Consumer engagement in health and self-management
- Safer and more effective clinical trials

8.1.5 Evolution

Healthcare is consistently cited in political polls and in surveys as a chief concern for consumers, administrators, employers and clinicians alike.*[9]

The formal establishment of quality improvement organizations in 2002 and rise of independent organizations such as The National Committee for Quality Assurance, The Leapfrog Group and Bridges to Excellence - all of which are dedicated to promoting and monitoring healthcare quality - illustrate intense concern over inefficiency, safety, and customer service in healthcare.

In addition, skyrocketing costs, increases in chronic diseases, geographic dispersion of families, growing provider shortages, troubling ethnic disparities in care, better survival rates among patients fighting serious diseases, an aging U.S. population and longer lifespan are all factors pointing to a need for better ways of delivering healthcare.*[10]*[11]*[12]

Consumer demand for better service and quality in healthcare is the latest source of pressure to improve the

healthcare system. Experts speculate that, having acclimated to greater speed, efficiency and cost transparency - as well as vastly improved access to information about products and services - in other industries, consumers are calling for the same responsiveness from the healthcare system. Direct-to-consumer advertising is a demonstrated contributor to the rise in consumer demand, as is the mass availability of inexpensive technology and ubiquity of the Internet, cell phones and PDAs.*[13]*[14] Connected health experts such as Joseph C. Kvedar, M.D., believe that consumer engagement in healthcare is on its way to becoming a major force for change.

In summary, connected health has arisen from: 1) a desire on the part of individual physicians and healthcare organizations to provide better access, quality and efficiency of care 2) dynamics of the healthcare economy (such as rising costs and changing demographics) 3) consumerism in health care and a drive towards patient centric healthcare. Together, these factors are providing impetus for connected healthcare in the United States and many other industrialised nations and forcing innovation both from within and outside the system.

8.1.6 Evidence

While connected health is yet emerging, there is evidence of its benefit. For example, in a program being implemented by the Center for Connected Health and Partners Home Care, over 500 heart failure patients have now been monitored remotely through the collection of vital signs, including heart rate, blood pressure and weight, using simple devices in the patient's home. The information is sent daily to a home health nurse, who can identify early warning signs, notify the patient's primary care physician, and intervene to avert potential health crises. A pilot of this program demonstrated reduced hospitalizations.*[15] Another initiative at the Center for Connected Health uses cellular telephone technology and a "smart" pill bottle to detect when a patient has not taken their scheduled medication. A signal is then sent that lights up an ambient orb device in the patient's home to remind them to take their medication.

8.1.7 Funding and implementation

Today, it appears that connected health programs are operated and funded primarily by home care agencies and large healthcare systems. However, insurers and employers, who bear enormous cost to insure their employees, are increasingly interested in connected health for its potential to reduce direct and indirect healthcare costs. For example, EMC Corporation recently launched the first employer-sponsored connected health program, currently in the beta phase of implementation, which is aimed at improving outcomes and cost of care for patients with high blood pressure.*[16]

8.1.8 US government

Government agencies involved in connected health include:

- The Office for the Advancement of Telehealth
- The Centers for Medicare & Medicaid Services (CMS), to the extent that Medicaid reimburses for telemedicine programs, at the state's option. According to the CMS Web site, at least 18 states are allowing reimbursement for services provided via telemedicine for reasons that include improved access to specialists for rural communities and reduced transportation costs.
- The Office of the National Coordinator for Health Information Technology (ONC) is charged with creating an interoperable health information technology infrastructure for the nation. That infrastructure has been primarily defined as an electronic health records system, however, former National Coordinator David Brailer indicated his support for personal health records that are portable and controlled by consumers. It remains to be seen how his successor, Robert Kolodner, will interpret this charge.*[17]

8.1.9 Personal health records

Personal health records, or PHRS, (see personal health record) – are essentially medical records controlled and maintained by the healthcare consumer. PHRs intersect with connected health in that they attempt to increase the involvement of healthcare consumers in their care.*[18] By contrast, electronic medical records (EMRs) (see electronic medical record) are digital medical records or medical records systems maintained by hospitals or medical practices and are not part of connected health delivery.

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8.1.11 Further reading

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- Office of the National Coordinator for Health Information Technology
- Telemedicine Information Exchange
- Connected Health: How Mobiles, Cloud and Big Data Will Reinvent Healthcare

8.2 Telehealth

Telehealth is the delivery of health-related services and information via telecommunications technologies. Telehealth could be as simple as two health professionals discussing a case over the telephone or as sophisticated as doing robotic surgery between facilities at different ends of the globe.

Telehealth is an expansion of telemedicine, and unlike telemedicine (which more narrowly focuses on the curative aspect) it encompasses preventative, promotive *and* curative aspects.

The use of information and communication technology (ICT) in medicine has developed over the years (see timeline of medicine and medical technology).

Modern medicine incorporates email, electronic drug prescriptions, and home monitoring of conditions by patients. Clinical trials in the UK have shown it to reduce mortality by around 47%; however, the case for telehealth is still being actively debated, with a study on a separate US project showed remote telemonitoring was associated with increased mortality in vulnerable patients.

8.2.1 Nonclinical uses

- Distance education including continuing medical education, grand rounds, and patient education
- administrative uses including meetings among telehealth networks, supervision, and presentations
- research on telehealth
- online information and health data management
- healthcare system integration
- asset identification, listing, and patient to asset matching, and movement
- overall healthcare system management
- patient movement and remote admission

8.2.2 Benefits

Telehealth allows the patient to be monitored between physician office visits which can improve patient health. Telehealth also allows patients to access expertise which is not available in their local area.

In 2003,a study of high-risk pregnant women in rural areas of the United States reduced the state's 60-day infant mortality rate by 0.5 percent by increasing the number of low birthweight infants delivered at a medical center.*[1]

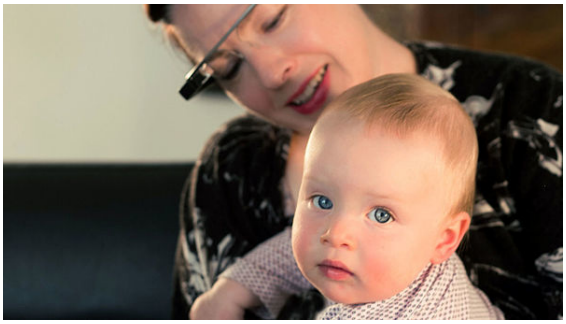
In Alaska, the Alaska Federal Health Care Access Network (AFHCAN) connects approximately 180 Alaska Native community village clinics, 25 subregional clinics, 4 multiphysician health centers, 6 regional hospitals, and the Alaska Native Medical Centerin Anchorage. More than 3,000 providers have engaged in 160,000 telehealth clinical consultations since 2001. It is estimated that in 2012, the AFHCAN telehealth program saved the state of Alaska $8.5 million in travel costs for Medicaid patients alone.*[2]

The UK's Department of Health's Whole System Demonstrator (WSD)*[3] launched in May 2008. It is the largest randomised control trial of telehealth and telecare in the world, involving 6191 patients and 238 GP practices across three sites, Newham, Kent and Cornwall. Three thousand and thirty people with one of three conditions (Diabetes, Chronic Heart Failure and COPD) were included in the telehealth trial. The trials were evaluated by several universities which foun a 45% reduction in mortality rates, 20% reduction in emergency admissions, 15% reduction in A&E visits, 14% reduction in elective admissions, 14% reduction in bed days, and8% reduction in tariff costs.

Another UK trial of telehealth, this time for patients suffering from infertility, demonstrated a reduction in the cost of care of approximately 95%. The remote patient monitoring product and service used cost $800 per patient, compared to $15,000 as the average cost of a cycle of in-vitro fertilization (IVF), and showed (for suitably selected patients) the same pregnancy rate.*[4]

There may also be some significant carbon reductions for the NHS to be gained from developing Telehealth and therefore reducing the need to travel (often, in the case of patients, by car) as well as encouraging healthy, sustainable behaviour through monitoring and improved communications and reducing the requirements to expand sites to meet increases in Healthcare demands.

In Australia, during January 2014, Melbourne tech startup Small World Social collaborated with the Australian Breastfeeding Association to create the first hands-free breastfeeding Google Glass application for new mothers.*[5] The application, named Google Glass Breastfeeding app trial, allows mothers to nurse their baby while viewing instructions about common breastfeeding issues (latching on, posture etc.) or call a lactation consultant via a secure Google Hangout, who



Baby Eve with Georgia for the Breastfeeding Support Project

can view the issue through the mother's Google Glass camera.*[6] The trial was successfully concluded in Melbourne in April 2014, and 100% of participants were breastfeeding confidently.*[7]*[8] Small World Social Breasfteeding Support Project

8.2.3 Criticism

Although several studies have demonstrated a positive impact from the use of telehealth and remote patient monitoring, there are dissenting studies.

A US study*[9] of 205 elderly patients with a high risk of hospitalization showed a significant increase in the mortality rate over 12 months, with rates over 12 months for the telemonitoring group at 14.7%, compared with 3.9% for the usual care group (Source: Arch Intern Med 2012, online 16 April, and Pulse, April 20, 2012 - Telemedicine trebles death rate in elderly patients).

As a result, there is controversy in the UK regarding the government's determination to proceed with Telehealth despite conflicting findings from the studies undertaken.

8.2.4 Reimbursement for Telehealth in the United States

Reimbursement by Medicare

Reimbursement for Medicare-covered services must satisfy federal requirements of efficiency, economy and quality of care. Since 1999, Medicare and Medicaid reimbursement for all kinds of telehealth services have expanded, requirements of providers have been reduced, and grants have been given to support telehealth program adoption.

For 2014, the Centers for Medicare and Medicaid Services (CMS) does cover telemedicine services as long as the services fall into either Category 1 or Category 2.*[10] As of now, these categories are defined as such:

- Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth ser-

vices. The request is evaluated based on the similarities between the services already eligible for reimbursement, and that of the requested service.

- Category 2: Services that are not similar to the current list of telehealth services. The assessment will be based on whether the service is accurately described by the corresponding code when delivered via telehealth, and whether the use of a telecommunications system to deliver the services produces a demonstrated clinical benefit to the patient. Supporting documentation should be included.

Medicare Telehealth Coverage Areas There are several conditions to Medicare telehealth coverage. The first being that the consumer, or individual receiving telehealth services must be physically located in an "originating site" that is eligible for Medicare coverage.*[11]

State specific Medicaid Reimbursement States have the option/flexibility to determine whether or not to cover telemedicine under the Medicaid assistance program.*[12] They may also decide:

- What types of telemedicine to cover
- Where telemedicine will be covered throughout the state
- How telemedicine services are to be covered/reimbursed
- What types of providers/practitioners can be covered/reimbursed
- How much to reimburse for telemedicine services (as long as payments do not exceed Federal Upper Limits)

Individual states are encouraged to use flexibility granted by federal law to create payment methodologies that incorporate telemedicine technology. For example, states can reimburse the practitioner at the distant site an reimburse a facility fee to the originating site. States can also reimburse support costs like technical support, transmissions charges, and equipment. Add-on costs like those can be incorporated into the fee-for services rate or separately reimbursed as an administrative cost by the state.*[13]

If a state decides to cover telemedicine, but not to cover certain areas or certain practitioners, then the state must be responsible for assuring access and covering face to face visits by recognized providers in those parts of the state where telemedicine is not available.

Reimbursement by Private Payor

Currently, 21 States have a previously enacted Legislated Mandate for Private Coverage:*[14]

8.2.5 The state of the market

The rate of adoption of telehealth services in any jurisdiction is frequently influenced by factors such as the adequacy and cost of existing conventional health services in meeting patient needs; the policies of governments and/or insurers with respect to coverage and payment for telehealth services; and medical licensing requirements that may inhibit or deter the provision of telehealth second opinions or primary consultations by physicians.

Projections for the growth of the telehealth market are optimistic, and much of this optimism is predicated upon the increasing demand for remote medical care. According to a recent survey, nearly three-quarters of U.S. consumers say they would use telehealth.*[15] At present, several major companies along with a bevy of startups are working to develop a leading presence in the field.

In the UK, the Government's Care Services minister, Paul Burstow, has stated that telehealth and telecare would be extended over the next five years (2012–2017) to reach three million people.

8.2.6 See also

- Ontario Telemedicine Network
- List of video telecommunication services and product brands
- Tele-epidemiology
- Telemedicine
- eHealth
- mHealth
- American Telemedicine Association
- National Rural Health Association
- Connected Health
- Remote therapy

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8.2.9 External links

- Office for the Advancement of Telehealth (established by the Health Resources and Services Administration)

8.3 Telemedicine

Telemedicine is the use of telecommunication and information technologies to provide clinical health care at a distance. It helps eliminate distance barriers and can improve access to medical services that would often not be consistently available in distant rural communities. It is also used to save lives in critical care and emergency situations.

Although there were distant precursors to telemedicine, it is essentially a product of 20th century telecommunication and information technologies. These technologies permit communications between patient and medical staff with both convenience and fidelity, as well as the transmission of medical, imaging and health informatics data from one site to another.

Early forms of telemedicine achieved with telephone and radio have been supplemented with videotelephony, advanced diagnostic methods supported by distributed client/server applications, and additionally with telemedical devices to support in-home care.[*][1]

8.3.1 Disambiguation

The definition of *telemedicine* is somewhat controversial. Some definitions (such as the definition given by

the World Health Organization*[2]) include all aspects of healthcare including preventive care. The American Telemedicine Association uses the terms telemedicine and telehealth interchangeably, although it acknowledges that telehealth is sometimes used more broadly for remote health not involving active clinical treatments.*[3]

eHealth is another related term, used particularly in the U.K. and Europe, as an umbrella term that includes telehealth, electronic medical records, and other components of health information technology.

8.3.2 Benefits and drawbacks

Telemedicine can be beneficial to patients in isolated communities and remote regions, who can receive care from doctors or specialists far away without the patient having to travel to visit them.*[4] Recent developments in mobile collaboration technology can allow healthcare professionals in multiple locations to share information and discuss patient issues as if they were in the same place.*[5] Remote patient monitoring through mobile technology can reduce the need for outpatient visits and enable remote prescription verification and drug administration oversight, potentially significantly reducing the overall cost of medical care.*[6] Telemedicine can also facilitate medical education by allowing workers to observe experts in their fields and share best practices more easily.*[7]

Telemedicine also can eliminate the possible transmission of infectious diseases or parasites between patients and medical staff. This is particularly an issue where MRSA is a concern. Additionally, some patients who feel uncomfortable in a doctors office may do better remotely. For example, white coat syndrome may be avoided. Patients who are home-bound and would otherwise require an ambulance to move them to a clinic are also a consideration.

The downsides of telemedicine include the cost of telecommunication and data management equipment and of technical training for medical personnel who will employ it. Virtual medical treatment also entails potentially decreased human interaction between medical professionals and patients, an increased risk of error when medical services are delivered in the absence of a registered professional, and an increased risk that protected health information may be compromised through electronic storage and transmission.*[8] There is also a concern that telemedicine may actually decrease time efficiency due to the difficulties of assessing and treating patients through virtual interactions; for example, it has been estimated that a teledermatology consultation can take up to thirty minutes, whereas fifteen minutes is typical for a traditional consultation.*[9] Additionally, potentially poor quality of transmitted records, such as images or patient progress reports, and decreased access to relevant clinical information are quality assurance risks that can compromise the quality and continuity of patient care for the reporting doctor.*[10] Other obstacles to the implementation of telemedicine include unclear legal regulation for some telemedical practices and difficulty claiming reimbursement from insurers or government programs in some fields.*[11]

Another disadvantage of telemedicine is the inability to start treatment immediately. For example, a patient suffering from a bacterial infection might be given an antibiotic hypodermic injection in the clinic, and observed for any reaction, before that antibiotic is prescribed in pill form.

8.3.3 History

In its early manifestations, African villagers used smoke signals to warn people to stay away from the village in case of serious disease.*[12]*[13] In the early 1900s, people living in remote areas of Australia used two-way radios, powered by a dynamo driven by a set of bicycle pedals, to communicate with the Royal Flying Doctor Service of Australia.

The first interactive telemedicine system, operating over standard telephone lines, designed to remotely diagnose and treat patients requiring cardiac resuscitation (defibrillation) was developed and launched by an American company, MedPhone Corporation, in 1989. A year later under the leadership of its President/CEO S Eric Wachtel, MedPhone introduced a mobile cellular version, the MDPhone. Twelve hospitals in the U.S. served as receiving and treatment centers.*[14]

8.3.4 Types

Categories

Telemedicine can be broken into three main categories: store-and-forward, remote patient monitoring and (real-time) interactive services.

Store and forward Store-and-forward telemedicine involves acquiring medical data (like medical images, biosignals etc.) and then transmitting this data to a doctor or medical specialist at a convenient time for assessment offline.*[3] It does not require the presence of both parties at the same time.*[1] Dermatology (cf: teledermatology), radiology, and pathology are common specialties that are conducive to asynchronous telemedicine. A properly structured medical record preferably in electronic form should be a component of this transfer. A key difference between traditional in-person patient meetings and telemedicine encounters is the omission of an actual physical examination and history. The 'store-and-forward' process requires the clinician to rely on a history report

and audio/video information in lieu of a physical examination.

Telehealth Blood Pressure Monitor

Remote monitoring Remote monitoring, also known as self-monitoring or testing, enables medical professionals to monitor a patient remotely using various technological devices. This method is primarily used for managing chronic diseases or specific conditions, such as heart disease, diabetes mellitus, or asthma. These services can provide comparable health outcomes to traditional in-person patient encounters, supply greater satisfaction to patients, and may be cost-effective. Examples include home-based nocturnal dialysis*[15] and improved joint management.*[16]

Real-time interactive Electronic consultations are possible through interactive telemedicine services which provide real-time interactions between patient and provider.*[1] Many activities such as history review, physical examination, psychiatric evaluations and ophthalmology assessments can be conducted comparably to those done in traditional face-to-face visits. In addition, "clinician-interactive" telemedicine services may be less costly than in-person clinical visit.

Emergency telemedicine

U.S. Navy medical staff being trained in the use of handheld telemedical devices (2006).

Common daily emergency telemedicine is performed by SAMU Regulator Physicians in France, Spain, Chile and Brazil. Aircraft and maritime emergencies are also handled by SAMU centres in Paris, Lisbon and Toulouse.*[17]

A recent study identified three major barriers to adoption of telemedicine in emergency and critical care units. They include:

- **regulatory** challenges related to the difficulty and cost of obtaining licensure across multiple states, malpractice protection and privileges at multiple facilities
- Lack of acceptance and reimbursement by government payers and some commercial insurance carriers creating a major **financial** barrier, which places the investment burden squarely upon the hospital or healthcare system.
- **Cultural** barriers occurring from the lack of desire, or unwillingness, of some physicians to adapt clinical paradigms for telemedicine applications.*[18]

Telemedicine system. Federal Center of Neurosurgery in Tyumen, 2013

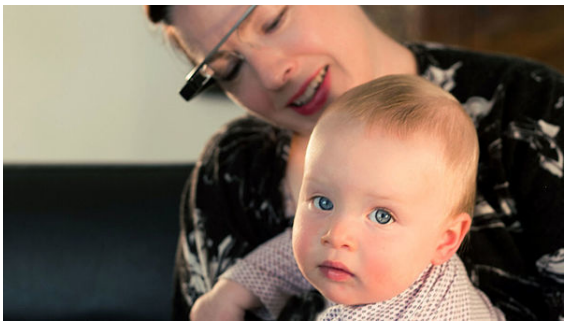
Telenursing

Main article: Telenursing

Telenursing refers to the use of telecommunications and information technology in order to provide nursing services in health care whenever a large physical distance exists between patient and nurse, or between any number of nurses. As a field it is part of telehealth, and has many points of contacts with other medical and non-medical applications, such as telediagnosis, teleconsultation, telemonitoring, etc.

Telenursing is achieving significant growth rates in many countries due to several factors: the preoccupation in reducing the costs of health care, an increase in the number of aging and chronically ill population, and the increase in coverage of health care to distant, rural, small or sparsely

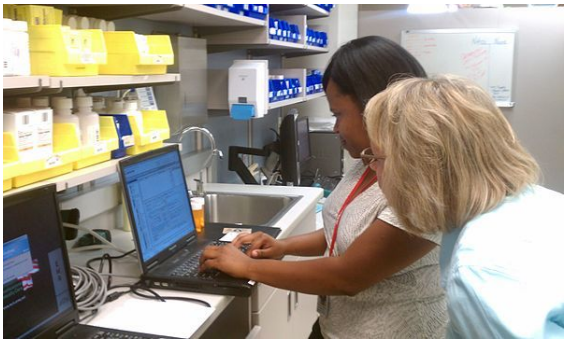
populated regions. Among its benefits, telenursing may help solve increasing shortages of nurses; to reduce distances and save travel time, and to keep patients out of hospital. A greater degree of job satisfaction has been registered among telenurses.*[19]



Baby Eve with Georgia for the Breastfeeding Support Project

In Australia, during January 2014, Melbourne tech startup Small World Social collaborated with the Australian Breastfeeding Association to create the first hands-free breastfeeding Google Glass application for new mothers.*[20] The application, named Google Glass Breastfeeding app trial, allows mothers to nurse their baby while viewing instructions about common breastfeeding issues (latching on, posture etc.) or call a lactation consultant via a secure Google Hangout, who can view the issue through the mother's Google Glass camera.*[21] The trial was successfully concluded in Melbourne in April 2014, and 100% of participants were breastfeeding confidently.*[22]*[23] Small World Social Breasfteeding Support Project

Telepharmacy



Pharmacy personnel deliver medical prescriptions electronically; remote delivery of pharmaceutical care is an example of ***telemedicine****.*

Main article: Telepharmacy

Telepharmacy is the delivery of pharmaceutical care via telecommunications to patients in locations where they may not have direct contact with a pharmacist. It is an instance of the wider phenomenon of telemedicine, as implemented in the field of pharmacy. Telepharmacy services include drug therapy monitoring, patient counseling, prior authorization and refill authorization for prescription drugs, and monitoring of formulary compliance with the aid of teleconferencing or videoconferencing. Remote dispensing of medications by automated packaging and labeling systems can also be thought of as an instance of telepharmacy. Telepharmacy services can be delivered at retail pharmacy sites or through hospitals, nursing homes, or other medical care facilities.

The term can also refer to the use of videoconferencing in pharmacy for other purposes, such as providing education, training, and management services to pharmacists and pharmacy staff remotely.*[11]

Telerehabilitation

Main article: Telerehabilitation

Telerehabilitation (or *e-rehabilitation*[*][24][*][25]) is the delivery of rehabilitation services over telecommunication networks and the Internet. Most types of services fall into two categories: clinical assessment (the patient's functional abilities in his or her environment), and clinical therapy. Some fields of rehabilitation practice that have explored telerehabilitation are: neuropsychology, speech-language pathology, audiology, occupational therapy, and physical therapy. Telerehabilitation can deliver therapy to people who cannot travel to a clinic because the patient has a disability or because of travel time. Telerehabilitation also allows experts in rehabilitation to engage in a clinical consultation at a distance.

Most telerehabilitation is highly visual. As of 2014, the most commonly used mediums are webcams, videoconferencing, phone lines, videophones and webpages containing rich Internet applications. The visual nature of telerehabilitation technology limits the types of rehabilitation services that can be provided. It is most widely used for neuropsychological rehabilitation; fitting of rehabilitation equipment such as wheelchairs, braces or artificial limbs; and in speech-language pathology. Rich internet applications for neuropsychological rehabilitation (aka cognitive rehabilitation) of cognitive impairment (from many etiologies) were first introduced in 2001. This endeavor has expanded as a teletherapy application for cognitive skills enhancement programs for school children. Tele-audiology (hearing assessments) is a growing application. Currently, telerehabilitation in the practice of occupational therapy and physical therapy is limited, perhaps because these two disciplines are more "hands on".

Two important areas of telerehabilitation research are (1) demonstrating equivalence of assessment and therapy to in-person assessment and therapy, and (2) building new

data collection systems to digitize information that a therapist can use in practice. Ground-breaking research in telehaptics (the sense of touch) and virtual reality may broaden the scope of telerehabilitation practice, in the future.

In the United States, the National Institute on Disability and Rehabilitation Research's (NIDRR)*[26] supports research and the development of telerehabilitation. NIDRR's grantees include the "Rehabilitation Engineering and Research Center" (RERC) at the University of Pittsburgh, the Rehabilitation Institute of Chicago, the State University of New York at Buffalo, and the National Rehabilitation Hospital in Washington DC. Other federal funders of research are the Veterans Health Administration, the Health Services Research Administration in the US Department of Health and Human Services, and the Department of Defense.*[27] Outside the United States, excellent research is conducted in Australia and Europe.

Only a few health insurers in the United States, and about half of Medicaid programs,*[28] reimburse for telerehabilitation services. If the research shows that teleassessments and teletherapy are equivalent to clinical encounters, it is more likely that insurers and Medicare will cover telerehabilitation services.

Teletrauma care

Telemedicine can be utilized to improve the efficiency and effectiveness of the delivery of care in a trauma environment. Examples include:

Telemedicine for trauma triage: using telemedicine, trauma specialists can interact with personnel on the scene of a mass casualty or disaster situation, via the internet using mobile devices, to determine the severity of injuries. They can provide clinical assessments and determine whether those injured must be evacuated for necessary care. Remote trauma specialists can provide the same quality of clinical assessment and plan of care as a trauma specialist located physically with the patient.*[29]

Telemedicine for intensive care unit (ICU) rounds: Telemedicine is also being used in some trauma ICUs to reduce the spread of infections. Rounds are usually conducted at hospitals across the country by a team of approximately ten or more people to include attending physicians, fellows, residents and other clinicians. This group usually moves from bed to bed in a unit discussing each patient. This aids in the transition of care for patients from the night shift to the morning shift, but also serves as an educational experience for new residents to the team. A new approach features the team conducting rounds from a conference room using a videoconferencing system. The trauma attending, residents, fellows, nurses, nurse practitioners, and pharmacists are able to watch a live video stream from the patient's bedside. They can see the vital signs on the monitor, view the settings on the respiratory ventilator, and/or view the patient's wounds. Video-conferencing allows the remote viewers two-way communication with clinicians at the bedside.*[30]

Telemedicine for trauma education: some trauma centers are delivering trauma education lectures to hospitals and health care providers worldwide using video conferencing technology. Each lecture provides fundamental principles, firsthand knowledge and evidenced-based methods for critical analysis of established clinical practice standards, and comparisons to newer advanced alternatives. The various sites collaborate and share their perspective based on location, available staff, and available resources.*[31]

Telemedicine in the trauma operating room: trauma surgeons are able to observe and consult on cases from a remote location using video conferencing. This capability allows the attending to view the residents in real time. The remote surgeon has the capability to control the camera (pan, tilt and zoom) to get the best angle of the procedure while at the same time providing expertise in order to provide the best possible care to the patient.*[32]

8.3.5 Specialist care delivery

Telemedicine can facilitate specialty care delivered by primary care physicians according to a controlled study of the treatment of hepatitis C.*[33] Various specialties are contributing to telemedicine, in varying degrees.

Telecardiology

ECGs, or electrocardiographs, can be transmitted using telephone and wireless. Willem Einthoven, the inventor of the ECG, actually did tests with transmission of ECG via telephone lines. This was because the hospital did not allow him to move patients outside the hospital to his laboratory for testing of his new device. In 1906 Einthoven came up with a way to transmit the data from the hospital directly to his lab.*[34] See above reference-General health care delivery. Remotely treating ventricular fibrillation Medphone Corporation, 1989

Teletransmission of ECG using methods indigenous to Asia One of the oldest known telecardiology systems for teletransmissions of ECGs was established in Gwalior, India in 1975 at GR Medical college by Ajai Shanker, S. Makhija, P.K. Mantri using an indigenous technique for the first time in India.

This system enabled wireless transmission of ECG from the moving ICU van or the patients home to the central station in ICU of the department of Medicine. Transmission using wireless was done using frequency modulation which eliminated noise. Transmission was also done through telephone lines. The ECG output was connected to the telephone input using a modulator which converted

ECG into high frequency sound. At the other end a demodulator reconverted the sound into ECG with a good gain accuracy. The ECG was converted to sound waves with a frequency varying from 500 Hz to 2500 Hz with 1500 Hz at baseline.

This system was also used to monitor patients with pacemakers in remote areas. The central control unit at the ICU was able to correctly interpret arrhythmia. This technique helped medical aid reach in remote areas.*[35]

In addition, electronic stethoscopes can be used as recording devices, which is helpful for purposes of telecardiology. There are many examples of successful telecardiology services worldwide.

In Pakistan three pilot projects in telemedicine was initiated by the Ministry of IT & Telecom, Government of Pakistan (MoIT) through the Electronic Government Directorate in collaboration with Oratier Technologies (a pioneer company within Pakistan dealing with healthcare and HMIS) and PakDataCom (a bandwidth provider). Three hub stations through were linked via the Pak Sat-I communications satellite, and four districts were linked with another hub. A 312 Kb link was also established with remote sites and 1 Mbit/s bandwidth was provided at each hub. Three hubs were established: the Mayo Hospital (the largest hospital in Asia), JPMC Karachi and Holy Family Rawalpindi. These 12 remote sites were connected and on average of 1,500 patients being treated per month per hub. The project was still running smoothly after two years.*[36]

Telepsychiatry

Main article: Telepsychiatry

Telepsychiatry, another aspect of telemedicine, also utilizes videoconferencing for patients residing in underserved areas to access psychiatric services. It offers wide range of services to the patients and providers, such as consultation between the psychiatrists, educational clinical programs, diagnosis and assessment, medication therapy management, and routine follow-up meetings.*[37] Most telepsychiatry is undertaken in real time (synchronous) although in recent years research at UC Davis has developed and validated the process of asynchronous telepsychiatry.*[38] Recent reviews of the literature by Hilty et al. in 2013, and by Yellowlees et al. in 2015 confirmed that telepsychiatry is as effective as in-person psychiatric consultations for diagnostic assessment, is at least as good for the treatment of disorders such as depression and post traumatic stress disorder, and may be better than in-person treatment in some groups of patients, notably children, veterans and individuals with agoraphobia.

As of 2011, the following are some of the model programs and projects which are deploying telepsychiatry in rural areas in the United States:

1. University of Colorado Health Sciences Center (UCHSC) supports two programs for American Indian and Alaskan Native populations
    a. The Center for Native American Telehealth and Tele-education (CNATT) and
    b. Telemental Health Treatment for American Indian Veterans with Post-traumatic Stress Disorder (PTSD)
1. Military Psychiatry, Walter Reed Army Medical Center.
2. In 2009, the South Carolina Department of Mental Health established a partnership with the University of South Carolina School of Medicine and the South Carolina Hospital Association to form a statewide telepsychiatry program that provides access to psychiatrists 16 hours a day, 7 days a week, to treat patients with mental health issues who present at rural emergency departments in the network.*[39]
3. Between 2007 and 2012, the University of Virginia Health System hosted a videoconferencing project that allowed child psychiatry fellows to conduct approximately 12,000 sessions with children and adolescents living in rural parts of the State.*[40]

There are a growing number of HIPAA compliant technologies for performing telepsychiatry. There is an independent comparison site of current technologies.

Links for several sites related to telemedicine, telepsychiatry policy, guidelines, and networking are available at the website for the American Psychiatric Association.*[41]*[42]

There has also been a recent trend towards Video CBT sites with the recent endorsement and support of CBT by the National Health Service (NHS) in the United Kingdom.*[43]

In April 2012, a Manchester-based Video CBT pilot project was launched to provide live video therapy sessions for those with depression, anxiety, and stress related conditions called InstantCBT*[44] The site supported at launch a variety of video platforms (including Skype, GChat, Yahoo, MSN as well as bespoke)*[45] and was aimed at lowering the waiting times for mental health patients. This is a Commercial, For-Profit business.

In the United States, the American Telemedicine Association and the Center of Telehealth and eHealth are the most respectable places to go for information about telemedicine.

The Health Insurance Portability and Accountability Act (HIPAA), is a United States Federal Law that applies to all modes of electronic information exchange such as video-conferencing mental health services. In the United States, Skype, Gchat, Yahoo, and MSN are not permitted to conduct video-conferencing services unless these companies sign a Business Associate Agreement stating that their employees are HIPAA trained. For this reason, most companies provide their own specialized videotelephony services. Violating HIPAA in the United States can result in penalties of hundreds of thousands of dollars. A similar service to Instant CBT, E Mental Health Center*[46] is a fully HIPAA compliant telemedicine platform website.

The momentum of telemental health and telepsychiatry is growing. In June 2012 the U.S. Veterans Administration announced expansion of the successful telemental health pilot. Their target was for 200,000 cases in 2012.*[47]

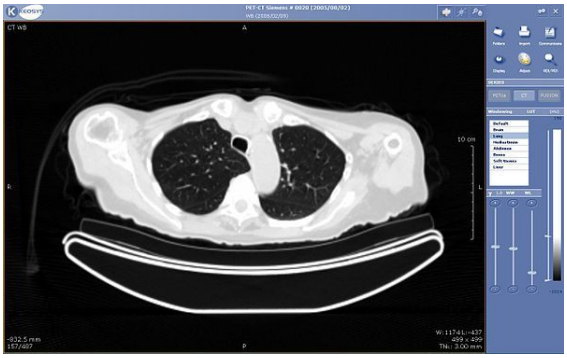
A growing number of HIPAA compliant technologies are now available. There is an independent comparison site that provides a criteria-based comparison of telemental health technologies.*[48]

The SATHI Telemental Health Support project cited above is another example of successful Telemental health support. - Also see SCARF India

Teleradiology

Main article: Teleradiology

Teleradiology is the ability to send radiographic images (x-rays, CT, MR, PET/CT, SPECT/CT, MG, US...) from one location to another.*[49] For this process to be implemented, three essential components are required, an image sending station, a transmission network, and a receiving-image review station. The most typical implementation are two computers connected via the Internet. The computer at the receiving end will need to have a high-quality display screen that has been tested and cleared for clinical purposes. Sometimes the receiving computer will have a printer so that images can be printed for convenience.



A CT exam displayed through teleradiology

The teleradiology process begins at the image sending station. The radiographic image and a modem or other connection are required for this first step. The image is scanned and then sent via the network connection to the receiving computer.

Today's high-speed broadband based Internet enables the use of new technologies for teleradiology: the image reviewer can now have access to distant servers in order to view an exam. Therefore, they do not need particular workstations to view the images; a standard personal computer (PC) and digital subscriber line (DSL) connection is enough to reach keosys central server. No particular software is necessary on the PC and the images can be reached from wherever in the world.

Teleradiology is the most popular use for telemedicine and accounts for at least 50% of all telemedicine usage.

Telepathology

Main article: Telepathology

Telepathology is the practice of pathology at a distance. It uses telecommunications technology to facilitate the transfer of image-rich pathology data between distant locations for the purposes of diagnosis, education, and research.*[50]*[51] Performance of telepathology requires that a pathologist selects the video images for analysis and the rendering diagnoses. The use of "television microscopy", the forerunner of telepathology, did not require that a pathologist have physical or virtual "hands-on" involvement is the selection of microscopic fields-of-view for analysis and diagnosis.

A pathologist, Ronald S. Weinstein, M.D., coined the term "telepathology" in 1986. In an editorial in a medical journal, Weinstein outlined the actions that would be needed to create remote pathology diagnostic services.*[52] He, and his collaborators, published the first scientific paper on robotic telepathology.*[53] Weinstein was also granted the first U.S. patents for robotic telepathology systems and telepathology diagnostic networks.*[54] Weinstein is known to many as the "father of telepathology".*[55] In Norway, Eide and Nordrum implemented the first sustainable clinical telepathology service in 1989.*[56] This is still in operation, decades later. A number of clinical telepathology services have benefited many thousands of patients in North America, Europe, and Asia.

Telepathology has been successfully used for many applications including the rendering histopathology tissue diagnoses, at a distance, for education, and for research. Although digital pathology imaging, including virtual microscopy, is the mode of choice for telepathology services in developed countries, analog telepathology imaging is still used for patient services in some developing countries.

Teledermatology

Main article: Teledermatology

Teledermatology allows dermatology consultations over a distance using audio, visual and data communication, and has been found to improve efficiency.*[57] Applications comprise health care management such as diagnoses, consultation and treatment as well as (continuing medical) education.*[58]*[59]*[60] The dermatologists Perednia and Brown were the first to coin the term "teledermatology" in 1995. In a scientific publication, they described the value of a teledermatologic service in a rural area underserved by dermatologists.*[61]

Teledentistry

Main article: Teledentistry

Teledentistry is the use of information technology and telecommunications for dental care, consultation, education, and public awareness in the same manner as telehealth and telemedicine.

Teleaudiology

Main article: Tele-audiology

Tele-audiology is the utilization of telehealth to provide audiological services and may include the full scope of audiological practice. This term was first used by Dr Gregg Givens in 1999 in reference to a system being developed at East Carolina University in North Carolina, USA.

Teleophthalmology

Main article: Teleophthalmology

Teleophthalmology is a branch of telemedicine that delivers eye care through digital medical equipment and telecommunications technology. Today, applications of teleophthalmology encompass access to eye specialists for patients in remote areas, ophthalmic disease screening, diagnosis and monitoring; as well as distant learning. Teleophthalmology may help reduce disparities by providing remote, low-cost screening tests such as diabetic retinopathy screening to low-income and uninsured patients.*[62]*[63]

8.3.6 Licensure

U.S. licensing and regulatory issues

Restrictive licensure laws in the United States require a practitioner to obtain a full license to deliver telemedicine care across state lines. Typically, states with restrictive licensure laws also have several exceptions (varying from state to state) that may release an out-of-state practitioner from the additional burden of obtaining such a license. A number of states require practitioners who seek compensation to frequently deliver interstate care to acquire a full license.

If a practitioner serves several states, obtaining this license in each state could be an expensive and time-consuming proposition. Even if the practitioner never practices medicine face-to-face with a patient in another state, he/she still must meet a variety of other individual state requirements, including paying substantial licensure fees, passing additional oral and written examinations, and traveling for interviews.

In 2008, the U.S. passed the Ryan Haight Act which required face-to-face or valid telemedicine consultations prior to receiving a prescription.*[64]

State medical licensing boards have sometimes opposed telemedicine; for example, in 2012 electronic consultations were illegal in Idaho, and an Idaho-licensed general practitioner was punished by the board for prescribing an antibiotic, triggering reviews of her licensure and board certifications across the country.*[65] Subsequently, in 2015 the state legislature legalized electronic consultations.*[65]

In 2015, Teladoc filed suit against the Texas Medical Board over a rule that required in-person consultations initially; the judge refused to dismiss the case, noting that antitrust laws apply to state medical boards.*[66]

8.3.7 Companies

In the United States, the major companies are Teladoc, American Well, and Doctor on Demand.*[67]

8.3.8 Advanced and experimental services

Telesurgery

Main article: Remote surgery

Remote surgery (also known as telesurgery) is the ability for a doctor to perform surgery on a patient even though they are not physically in the same location. It is a form of telepresence. Remote surgery combines elements of robotics, cutting edge communication technology such as high-speed data connections, haptics and elements of management information systems. While the field of robotic surgery is fairly well established, most of

these robots are controlled by surgeons at the location of the surgery.

Remote surgery is essentially advanced telecommuting for surgeons, where the physical distance between the surgeon and the patient is immaterial. It promises to allow the expertise of specialized surgeons to be available to patients worldwide, without the need for patients to travel beyond their local hospital.*[68]

Remote surgery or telesurgery is performance of surgical procedures where the surgeon is not physically in the same location as the patient, using a robotic teleoperator system controlled by the surgeon. The remote operator may give tactile feedback to the user. Remote surgery combines elements of robotics and high-speed data connections. A critical limiting factor is the speed, latency and reliability of the communication system between the surgeon and the patient, though trans-Atlantic surgeries have been demonstrated.

8.3.9 Enabling technologies

Further information: List of video telecommunication services and product brands

Videotelephony

Main article: Videotelephony

Videotelephony comprises the technologies for the reception and transmission of audio-video signals by users at different locations, for communication between people in real-time.*[69]

At the dawn of the technology, videotelephony also included *image phones* which would exchange still images between units every few seconds over conventional POTS-type telephone lines, essentially the same as slow scan TV systems.

Currently videotelephony is particularly useful to the deaf and speech-impaired who can use them with sign language and also with a video relay service, and well as to those with mobility issues or those who are located in distant places and are in need of telemedical or tele-educational services.

Health information technology

Main article: Health information technology

Health information technology (HIT) provides the umbrella framework to describe the comprehensive management of health information across computerized systems and its secure exchange between consumers, providers, government and quality entities, and insurers. Health information technology (HIT) is in general increasingly viewed as the most promising tool for improving the overall quality, safety and efficiency of the health delivery system (Chaudhry et al., 2006). Broad and consistent utilization of HIT will:

- Improve health care quality;
- Prevent medical errors;
- Reduce health care costs;
- Increase administrative efficiencies and
- Decrease paperwork; and
- Expand access to affordable care.

Interoperable HIT will improve individual patient care, but it will also bring many public health benefits including:

- Early detection of infectious disease outbreaks around the country;
- Improved tracking of chronic disease management; and
- Evaluation of health care based on value enabled by the collection of de-identified price and quality information that can be compared.

8.3.10 Developing countries

For developing countries, telemedicine and eHealth can be the only means of healthcare provision in remote areas. For example, the difficult financial situation in many African states and lack of trained health professionals has meant that the majority of the people in sub-Saharan Africa are badly disadvantaged in medical care, and in remote areas with low population density, direct healthcare provision is often very poor*[70] However, provision of telemedicine and eHealth from urban centres or from other countries is hampered by the lack of communications infrastructure, with no landline phone or broadband internet connection, little or no mobile connectivity, and often not even a reliable electricity supply.*[71]

The first Ayurvedic telemedicine center was established in India in 2007 by Partap Chauhan, an Indian Ayurvedic doctor and the Director of Jiva Ayurveda. Teledoc used Nokia phones running Javascript to link mobile ayurvedic field techs with doctors in the Jiva Institute clinic; at its peak, Teledoc reached about 1,000 villagers per month in Haryana province, primarily treating chronic diseases such as diabetes.

The Satellite African eHEalth vaLidation (SAHEL) demonstration project has shown how satellite broadband technology can be used to establish telemedicine in such

areas. SAHEL was started in 2010 in Kenya and Senegal, providing self-contained, solar-powered internet terminals to rural villages for use by community nurses for collaboration with distant health centres for training, diagnosis and advice on local health issues*[72]

In 2014, the government of Luxembourg, along with satellite operator, SES and NGOs, Archemed, Fondation Follereau, Friendship Luxembourg, German Doctors and Médecins Sans Frontières, established SATMED, a multilayer eHealth platform to improve public health in remote areas of emerging and developing countries, using the emergency.lu disaster relief satellite platform and the Astra 2G TV satellite.*[73] SATMED was first deployed in response to a report in 2014 by German Doctors of poor communications in Sierra Leone hampering the fight against Ebola, and SATMED equipment arrived in the Serabu clinic in Sierra Leone in December 2014.*[74] In June 2015 SATMED was deployed at Maternité Hospital in Ahozonnoude, Benin to provide remote consultation and monitoring, and is the only effective communication link between Ahozonnoude, the capital and a third hospital in Allada, since land routes are often inaccessible due to flooding during the rainy season.*[75]*[76]

8.3.11 See also

- American Telemedicine Association
- Connected health
- eHealth
- mHealth
- National Rural Health Association
- Ontario Telemedicine Network
- Remote therapy
- Tele-epidemiology
- Telecare
- Telehealth
- Telemental health
- Telenursing
- UNESCO Chair in Telemedicine

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8.3.13 Further reading

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8.3.14 External links

- American Telemedicine Association
- International Society for Telemedicine & eHealth (ISfTeH)
- Norwegian Centre for Integrated Care and Telemedicine
- VA Telehealth Services for Veterans
- Télémédecine 360

8.4 Telecare

For the American TV channel, see Telecare (TV channel).

Telecare is the term for offering remote care of elderly and physically less able people, providing the care and reassurance needed to allow them to remain living in their own homes. The use of sensors may be part of a package which can provide support for people with illnesses such as dementia, or people at risk of falling.

Most telecare mitigates harm by reacting to untoward events and raising a help response quickly. Some telecare, such as safety confirmation and lifestyle monitoring have a preventive function in that a deterioration in the telecare user's wellbeing can be spotted at an early stage.

Telecare is specifically different from telemedicine and telehealth. Telecare refers to the idea of enabling people to remain independent in their own homes by providing person-centred technologies to support the individual or their carers.

The meaning and usage of the term 'telecare' has not yet settled into consistent use. In the UK it is grounded in the social care framework and focuses on the meaning described above. In other countries 'telecare' may be applied to the practice of healthcare at a distance.

8.4.1 Uses of Telecare

In its simplest form, it can refer to a fixed or mobile telephone with a connection to a monitoring centre through which the user can raise an alarm. Technologically more advanced systems use sensors, whereby a range of potential risks can be monitored. These may include falls, as well as environmental changes in the home such as floods, fire and gas leaks. Carers of people with dementia may be alerted if the person leaves the house or other defined area. When a sensor is activated it sends a radio signal to a central unit in the user's home, which then automatically calls a 24-hour monitoring centre where trained operators can take appropriate action, whether it be contacting a local key holder, doctor or the emergency services.

Telecare also comprises standalone telecare which does not send signals to a response centre but supports carers through providing local (in-house) alerts in a person's home to let the carer know when a person requires attention.

It is important to note that 'telecare' is not just a warning system if someone strays from home but is also preventative measure whereby people are brought back and kept in the community through regular communication. There are now a large range of telecare services available with some of the most well known being the pendant alarm, mobile carephone system, pill dispenser, telephone prompt service the movement monitoring, fall detector and more. Multi-lingual telecare services have now been introduced opening the service up to a wider audience. All play a role in maintaining people's independence and allowing people to stay in their own homes.

8.4.2 The future of Telecare

Technological advances result in the possibility of promoting independence and for providing care from the social initiative sector, which now contemplates eCare, and navigation/positioning systems, such as GPS for people with dementia or other cognitive impairments.

8.4.3 Telecare in the UK

In 2005 the UK's Department of Health published *Building Telecare in England* to coincide with the announcement of a grant to help encourage its take up by local councils with social care responsibilities.*[1]

The UK's Department of Health's Whole System Demonstrator (WSD)*[2] launched in May 2008. It is the largest randomised control trial of telehealth and telecare in the world, involving 6191 patients and 238 GP practices across three sites, Newham, Kent and Cornwall. The trials were evaluated by: City University London, University of Oxford, University of Manchester, Nuffield Trust, Imperial College London and London School of Economics.

The WSD headline findings after the telehealth trial, involving 3154 patients, included these outcomes:*[3]

- 45% reduction in mortality rates
- 20% reduction in emergency admissions
- 15% reduction in A&E visits
- 14% reduction in elective admissions
- 14% reduction in bed days
- 8% reduction in tariff costs

The telecare findings were supposed to be published at some point in the future.*[4] In fact they have never surfaced. Some patients are still hopeful that telecare will lead to substantial improvements in the quality of services.*[5] The research showed that the telecare approach was not cost effective, with an incremental cost per QALY when added to usual care of £92,000.*[6]

The Government's Care Services minister, Paul Burstow, stated in 2012 that telehealth and telecare would be extended over the next five years (2012-2017) to reach three million people.*[7] This ambition was formally abandoned in November 2013. In September 2014 NHS England announced a replacement, but much lower profile, new "technology enabled care services" programme.*[8]

8.4.4 See also

- Assistive technology
- Wandering (dementia)

8.4.5 References

[1] Building Telecare in England

[2] Whole Systems Demonstrators: An Overview of Telecare and Telehealth

[3] Effect of telehealth on use of secondary care and mortality: findings from the Whole System Demonstrator cluster randomised trial

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8.4.6 External links

- International Society for Telemedicine & eHealth
-

8.5 Telenursing

Telenursing refers to the use of telecommunications and information technology in the provision of nursing services whenever a large physical distance exists between patient and nurse, or between any number of nurses. As a field, it is part of telehealth, and has many points of contacts with other medical and non-medical applications, such as telediagnosis, teleconsultation, telemonitoring, etc.

Telenursing is achieving a large rate of growth in many countries, due to several factors: the preoccupation in driving down the costs of health care, an increase in the number of aging and chronically ill population, and the increase in coverage of health care to distant, rural, small or sparsely populated regions. Among its many benefits, telenursing may help solve increasing shortages of nurses; to reduce distances and save travel time, and to keep patients out of hospital. A greater degree of job satisfaction has been registered among telenurses.*[1]

8.5.1 Applications

Home care

One of the most distinctive telenursing applications is home care. For example, patients who are immobilized, or live in remote or difficult to reach places, citizens who have chronic ailments, such as chronic obstructive pulmonary disease, diabetes, congestive heart disease, or debilitating diseases, such as neural degenerative diseases (Parkinson's disease, Alzheimer's disease or ALS), may stay at home and be "visited" and assisted regularly by a nurse via videoconferencing, internet or videophone. Other applications of home care are the care of patients in immediate post-surgical situations, the care of wounds, ostomies or disabled individuals. In normal home health care, one nurse is able to visit up to 5-7 patients per day. Using telenursing, one nurse can "visit" 12-16 patients in the same amount of time.

Case management

A common application of telenursing is also used by call centers operated by managed care organizations, which are staffed by registered nurses who act as case managers or perform patient triage, information and counseling as a means of regulating patient access and flow and decrease the use of emergency rooms.

Telephone triage

Telephone triage refers to symptom or clinically-based calls. Clinicians perform symptom assessment by asking detailed questions about the patient's illness or injury. The clinician's task is to estimate and/or rule out urgent symptoms. They may use pattern recognition and other problem-solving process as well. Clinicians may utilize guidelines, in paper or electronic format, to determine how urgent the symptoms are. Telephone triage requires clinicians to determine if the symptoms are life-threatening, emergency, urgent, acute or non-acute. It may involve educating and advising clients, and making safe, effective, and appropriate dispositions—all by telephone. Telephone triage takes place in settings as diverse as emergency rooms, ambulance services, large call centers, physician offices, clinics, student health centers and hospices.

8.5.2 Legal, ethical and regulatory issues

Telenursing is fraught with legal, ethical and regulatory issues, as it happens with telehealth as a whole. In

many countries, interstate and intercountry practice of telenursing is forbidden (the attending nurse must have a license both in their state/country of residence and in the state/country where the patient receiving telecare is located). The Nurse Licensure Compact helps resolve some of these jurisdiction issues. Legal issues such as accountability and malpractice, etc. are also still largely unsolved and difficult to address.

In addition, there are many considerations related to patient confidentiality and safety of clinical data.

8.5.3 References

Notes

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8.5.4 External links

- Telehealth: Issues for Nursing. American Nursing Association.
- Telenursing Fact Sheet. International Council of Nurses.
- International Society for Telemedicine & eHealth (ISfTeH) - Telenursing Working Group

8.6 Remote guidance

Remote guidance, in the medical context, refers to the supervision or guidance of a medical task, usually a procedures or test, from a remote location. This falls in the realm of real time telemedicine applications. By way of example, a radiologist may guide an ultrasound examination from a remote location. As such the proximate requisite expertise to accomplish a medical task is significantly diminished. In the previous example, a diagnostic quality ultrasound can be accomplished by non-medically trained individuals manipulating an ultrasound device located with the patient under guidance from a remote location. This is an example of teleradiology If appropriately configured, the remote guidance can originate from another room or floor in the same building, to as far away as another continent or even planet. NASA researchers have successfully demonstrated remote guidance of diagnostic level cardiac ultrasonography using an ultrasound on the space station, non-medical astronauts performing the exam as guided by a terrestrially located expert.

8.6.1 Remote diagnostics

Remote diagnostics refers to a real time telemedical application which achieves diagnostic level quality and information exchange. In this sense, it refers to an expectation for quality sufficient for making or excluding a medical diagnosis. In the tele-medical context specific to radiologic images these images often are consistent with the DICOM standard. Given bandwidth issues universally plaguing the healthcare environment imagery beyond still images and brief video has not yet become standard expectation of care environments or PACS systems. Ultrasound scanning commonly utilized for abdomen, musculoskeletal, pelvis, gynecologic, cardiac and vascular evaluations has shown potential for remote diagnosis only of late.

More general Remote Diagnostics (RD) refers to detecting which fault or faults are present in a system, body of object, from a distance. Examples of use: aeroplanes, spacecraft, Formula 1 and major assests such as ships,trains etc. In cases where also corrective actions are made, the term 'Remote Diagnostic & Maintenance' is more appropriate.

8.6.2 Technical aspects

While still imagery can be e-mailed and forwarded in a multitude of methods, video product of medical devices has typically not been available for remote interaction. Recent improvements in scanning devices, for example ultrasound machines has facilitated this new capability. The inclusion of the VGA output gives the opportunity for frame grabber devices to stream such outputs to the internet.

8.6.3 References

- see also Remote diagnostics for RD in technical systems
- http://www.remoteguidance.org/laparascopic-surgery/lights-lap-camera-tele-action/
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8.7 Tele-epidemiology

Tele-epidemiology is the application of telecommunications to epidemiological research and application, including space-based and internet-based systems.

Tele-epidemiology applies satellite communication systems to investigate or support investigations of infectious disease outbreak, including disease reemergence. In this application, space-based systems (i.e. GIS, GPS, SPOT5) use natural index and in-situ data (i.e. NDVI, Meteosat, Envisat) to assess health risk to human and animal populations. Space-based applications of tele-epidemiology extend to health surveillance and health emergency response.*[1]

Internet-based applications of tele-epidemiology include sourcing of epidemiological data in generating internet reports and real-time disease mapping. This entails gathering and structuring epidemiological data from news and social media outlets, and mapping or reporting this data for application with research or public health organizations. Examples of such applications include HealthMap and ProMED-mail, two web-based services that map and e-mail global cases of disease outbreak, respectively.*[2]

The United Nations Office for Outer Space Affairs often refers generally to telehealth for applications linking communication and information technologies such as telesurgery and telenursing, to healthcare administration.

8.7.1 Clinical Applications

- Provides real-time information about disease prevalence across populations to public health, physicians and citizens, globally.*[1]
- Diminishes communicable disease risk by mobilizing local medical efforts to respond to disease outbreaks, especially in vulnerable populations.*[1]
- Enhances the ability of managing the proliferation of communicable pathogens.*[1]
- Can be used as a management tool in public health to discover, assess, and act on epidemiological data. For example, gathering and identifying disease relevant risk factors helps to identify treatment interventions and implement the prevention strategies that could lessen the effects of the outbreak on the general population and improve clinical outcomes at the individual, patient-leve*[3]
- Could prove useful to commerce, travelers, public health agencies and federal governments, and diplomatic efforts.*[2]
- Public health agencies and federal governments might take advantage of Tele-epidemiology for predicting the propagation of communicable diseases.*[1]
- Provides users and governments with information for early warning systems.

8.7.2 Non-Clinical Applications

- Applications of tele-epidemiology are not being used frequently in clinical settings
- The use of space-based systems are important for research and public health efforts, though these activities are driven largely by secondary or tertiary organizations, not the public health agencies themselves.
- Relevant data can be used for research and is widely accessible through existing internet outlets.
- Data can be disseminated through internet reports of disease outbreak for real-time disease mapping for public use.*[2] The application of HealthMap and ProMED-mail demonstrate considerable global health utility and accessibility for users from both the public and private domains.
- Internet-based platforms can be used by the general public to determine local and international disease outbreaks. Consumers can also contribute their own epidemiologically-relevant data to these services.

8.7.3 Advantages

Space-based tele-epidemiological initiatives, using satellites, are able to gather environmental information relevant to tracking disease outbreaks. S2E, a French multidisciplinary consortium on spatial surveillance of epidemics, has used satellites to garner relevant information on vegetation, meteorology and hydrology. This information, in concert with clinical data from humans and animals, can be used to construct predictive mathematical models that may allow for the forecasting of disease outbreaks.*[1]

Web-based tele-epidemiological services are able to aggregate information from several disparate sources to provide information on disease surveillance and potential disease outbreaks. Both ProMED-mail and Healthmap collect information in several different languages to gather worldwide epidemiological information.*[4] These services are both free and allow both health care professionals and laypeople to access reliable disease outbreak information from around the world and in real-time.

8.7.4 Disadvantages

Space-based methodologies require investment of resources for the collection and management of epidemiological information; as such, these systems may not be affordable or technologically feasible for developing countries that need assistance tracking disease outbreaks. Further, the success of space-based methodologies is predicated on the collection of accurate ground-based data by qualified public health professionals. This may not be possible in developing countries because they lack basic laboratory and epidemiological resources*[5]

Web-based tele-epidemiological initiatives have a unique set of challenges that are different from those experienced by space-based methodologies. HealthMap, in an effort to provide comprehensive worldwide information, contains information from a variety of sources including eyewitness accounts, online news and validated official reports.*[4] As a result, the site necessarily relies upon third party information, the veracity of which they are not liable.

8.7.5 See also

- Telehealth
- Telenursing
- Teleophthalmology
- Telemedicine
- Telematics
- Landscape epidemiology
- Satellite imagery

8.7.6 References

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8.8 Telenursing

Telenursing refers to the use of telecommunications and information technology in the provision of nursing services whenever a large physical distance exists between patient and nurse, or between any number of nurses. As a field, it is part of telehealth, and has many points of contacts with other medical and non-medical applications, such as telediagnosis, teleconsultation, telemonitoring, etc.

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8.8.1 Applications

Home care

One of the most distinctive telenursing applications is home care. For example, patients who are immobilized, or live in remote or difficult to reach places, citizens who have chronic ailments, such as chronic obstructive pulmonary disease, diabetes, congestive heart disease, or debilitating diseases, such as neural degenerative diseases (Parkinson's disease, Alzheimer's disease or ALS), may stay at home and be "visited" and assisted regularly by a nurse via videoconferencing, internet or videophone. Other applications of home care are the care of patients in immediate post-surgical situations, the care of wounds, ostomies or disabled individuals. In normal home health care, one nurse is able to visit up to 5-7 patients per day. Using telenursing, one nurse can "visit" 12-16 patients in the same amount of time.

Case management

A common application of telenursing is also used by call centers operated by managed care organizations, which are staffed by registered nurses who act as case managers or perform patient triage, information and counseling as a means of regulating patient access and flow and decrease the use of emergency rooms.

Telephone triage

Telephone triage refers to symptom or clinically-based calls. Clinicians perform symptom assessment by asking detailed questions about the patient's illness or injury. The clinician's task is to estimate and/or rule out

urgent symptoms. They may use pattern recognition and other problem-solving process as well. Clinicians may utilize guidelines, in paper or electronic format, to determine how urgent the symptoms are. Telephone triage requires clinicians to determine if the symptoms are life-threatening, emergency, urgent, acute or non-acute. It may involve educating and advising clients, and making safe, effective, and appropriate dispositions—all by telephone. Telephone triage takes place in settings as diverse as emergency rooms, ambulance services, large call centers, physician offices, clinics, student health centers and hospices.

8.8.2 Legal, ethical and regulatory issues

Telenursing is fraught with legal, ethical and regulatory issues, as it happens with telehealth as a whole. In many countries, interstate and intercountry practice of telenursing is forbidden (the attending nurse must have a license both in their state/country of residence and in the state/country where the patient receiving telecare is located). The Nurse Licensure Compact helps resolve some of these jurisdiction issues. Legal issues such as accountability and malpractice, etc. are also still largely unsolved and difficult to address.

In addition, there are many considerations related to patient confidentiality and safety of clinical data.

8.8.3 References

Notes

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- *International Standards for Telenursing Programmes*, International Council of Nurses, 2001. 40 pg.

8.8.4 External links

- Telehealth: Issues for Nursing. American Nursing Association.
- Telenursing Fact Sheet. International Council of Nurses.
- International Society for Telemedicine & eHealth (ISfTeH) - Telenursing Working Group

8.9 Teledermatology

Teledermatology is a subspecialty in the medical field of dermatology and probably one of the most common applications of telemedicine and e-health.*[1] In teledermatology, telecommunication technologies are used to exchange medical information (concerning skin conditions and tumours of the skin) over a distance using audio, visual and data communication. Applications comprise health care management such as diagnoses, consultation and treatment as well as (continuous) education.*[2]

The dermatologists Perednia and Brown were the first to coin the term "teledermatology" in 1995. In a scientific publication, they described the value of a teledermatologic service in a rural area underserved by dermatologists.*[3]

8.9.1 Modes of data transmission

Teledermatology (as telemedicine) is practised on the basis of two concepts: **Store and forward (SAF)** and **real time/live interactive teledermatology**. Hybrid modes also exist (combining SAF and real time applications).

The SAF method is most commonly used in teledermatology: It involves sending (forwarding) digital images associated with (anonymous) medical information to the data storage unit of a consulted specialist. It can be as easy as sending an email with a digital image of a lesion to seek advice for a skin condition. Advantages of this method are that it does not demand the presence of both parties at the same time and does not usually require expensive equipment.

In real-time/ live interactive teledermatology applications, provider and individuals usually interact via live videoconferencing. It may also involve remote surgery and the use of telerobotic microscopes in dermatopathology. This mode generally requires more sophisticated and costly technology than used in the SAF mode. Both participants must be available at the same time.

A Google Glass pilot took place in an emergency room at Rhode Island Hospital in April 2014.*[4] It resulted in a peer-reviewed study published in *JAMA Dermatology* on the use of smartglasses in a healthcare environment.*[5]*[6]

8.9.2 Areas of application

Health care management

Direct consultation involves an individual with a skin condition contacting a dermatologist via telecommunication to request diagnosis and treatment. In this field, mobile applications of teledermatology gain importance.

Telediagnosis in the absence of personal contact with health care workers to the individual is complex. It requires active participation of the individual and without appropriate guidance may lead to improper management. However, as a triage tool, leading the individual directly to the appropriate specialist for his/her disease, it could be very valuable in the near future.

Specialist referral is a major area of application in teledermatology A general practitioner (or other medical professional) that sees the individual consults a specialist/ specialised centre via telecommunication in order to get a second opinion. The specialist then helps the GP in rendering a diagnosis, providing management options et cetera.*[7]

Home telehealth/telehomecare involves an individual with a chronic condition being examined and managed remotely at home. An important field of interest of telehomecare in dermatology is the follow-up treatment of individuals with skin conditions requiring regular follow-up such as crural ulcers. Crural ulcers are a common skin condition that needs follow up visits up to twice a week demanding significant time commitments by the individuals in addition to causing a financial burden on the health care system. Teledermatology can help to reduce the time and costs involved in the follow-up of such conditions.*[8]

Education and information

Medical education/continuous education are a major advantage of telemedicine/e-health. Numerous universities offer online courses, computer based training and Web applications in this field principally aimed at medical students. Specialist training courses via internet are also available, particularly in dermoscopy.*[9]

General medical/health information may be accessed by non-professionals, such as individuals affected by a skin condition, and their relatives, through the internet. They are also able to join peer support groups with others affected by the same condition.*[10]

8.9.3 Domains with special interest

Teledermoscopy

In teledermoscopy, digital dermoscopic lesion images (with or without clinical images) are transmitted electronically to a specialist for examination. This can be done on the web-based telediagnostic network Campus Medicus

Dermoscopy (dermatoscopy, epiluminescence microscopy) is the technical field of using an epiluminescence microscope for viewing skin lesions in magnification in-vivo. It is particularly useful in the early detection of malignant skin lesions (i.e., melanoma). Digital dermoscopic images can be taken with a digital camera attached to a dermatoscope or special video cameras suited for dermoscopy, e.g. the FotoFinder. Since dermoscopy is based on examination of a two-dimensional image it is very well suited for digital imaging and teledermatology.

Teledermatopathology

Teledermatopathology is the transmission of dermatopathologic images either in real-time with the aid of a robotic microscope or using a store-and-forward system (transmission as a single file). In the latter method (SAF) a rather new development is the introduction of virtual slide systems (VSS).*[11]

Virtual slides are made by digitally scanning an entire glass slide at a high resolution and then sending the images to a storage system. These can be then assessed on a computer screen similar to conventional microscopy, allowing the pathologist to maneuver around the image and view every part of the slide at any magnification.

Teledermoscopically-aided dermatopathology

This is the transmission of crucial medical data and dermoscopic as well as clinical images to a pathologist who renders the conventional histopathologic diagnosis.

In the everyday clinical setting, skin biopsies are taken by the physician directly responsible for the individual and are assessed by a dermatopathologist. This pathologist has most likely never seen the clinical aspect of the lesion and might not have any information about the person. These limitations can be overcome by teledermoscopically-aided dermatopathology whereby a patient history and clinical data may increase the sensitivity of diagnosis.*[12]

Additionally it has been shown that provision of such data may improve the level of diagnostic confidence held by the assessing dermatopathologists.

Mobile teledermatology

Mobile telemedicine is a system in which at least one participant (the person seeking advice or the doctor, for instance) uses wireless or mobile equipment*[13] (i.e. mobile phones, handheld devices), in contrast to conventional stationary telemedicine platforms. Travellers who develop skin lesions as well as doctors who are on the move in hospital/non-hospital area can benefit from this new development in teledermatology. In order to facilitate access to medical advice and enable individuals to play a more active role in managing their own health status, mobile teledermatology seems to be especially suited for patient filtering or triage. (i.e. referral based on the severity and character of their skin condition). Another

possible practical application is for follow-up of individuals with chronic skin conditions.

Suitability of cases for teledermatology

Not all cases are suitable for teledermatology.The type of cases suited for teledermatology is a topic, which requires more studies. Some studies have observed that eczema and follicular lesions were diagnosed with relatively more certainty,while in some other studies it was seen that diagnoses were made with more certainty in cases like viral warts, herpes zoster, acne vulgaris, irritant dermatitis, vitiligo, and superficial bacterial and fungal infections. Unlike in western studies where pigmented lesions suspicious of melanomas are one of the most referred cases for teledermatology (with or without teledermatoscopy), Asian studies have fewer cases referred based on the suspicion of melanoma.*[14]

8.9.4 Implemented projects by country

United Kingdom

24% of the population in England and Wales seek medical advice for a skin condition, and approximately 6% of patients presenting with a skin problem are referred for specialist advice each year.*[15]

The Department of Health encourages the use of digital technology in key areas to support delivery of the quality, innovation, productivity, and prevention (QIPP). This includes the introduction of digital or online services to deliver greater convenience for patients and to free up face-to-face clinical time for individuals who really need it.*[16]

Vantage Rego is an example of a cloud base application which enables primary care clinicians to capture images of routine dermatological conditions using high quality digital imaging equipment. These images, along with a referral letter, are sent electronically to a dermatology team. Within 3 working days, the referring GP receives a management plan recommending the most appropriate course of treatment based on local resources. Benefits of the service have been highlighted in recent audit *[17] and QIPP publications.*[18] By 2013, Rego was adopted in over 5% of GP practices in the UK.

8.9.5 See also

- List of cutaneous conditions

8.9.6 Footnotes

[1] http://www.atmeda.org/icot/sigtelederm.htm

[2] Wooton et al. 2005 Roy soc of med press; Wurm et al. 2007 JDDG; Burg et al. 2005 Teledermatology

[3] Perednia, Brown 1995 Bull Med Libr Assoc

[4] R.I. Hospital's emergency department first to test Google Glass on medical conditions/Video

[5] Feasibility and Acceptability of Google Glass for Emergency Department Dermatology Consultations

[6] Rhode Island Hospital Uses Google Glass to Diagnose Skin Conditions

[7] see http://www.telederm.org/

[8] Binder et al. 2008, Arch Derm

[9] see http://www.medunigraz.at/IDD

[10] see http://www.dermnetnz.org

[11] Massone et al. 2007 Human Pathology

[12] Bauer et al. 2006 Br J Dermatol

[13] http://www.handyscope.net

[14] Kaliyadan et al. 2009 Indian J Dermatol Venereol Leprol

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8.9.8 External links

- International Society of Teledermatology
- Telemedicine in Dermatology

8.10 Telemental Health

Telemental health (or **telebehavioral health**, **Telepsychiatry**) is the use of telecommunications technology to provide behavioral health services. Examples of telemental health services include providing health workers in remote areas with continuing education on mental health topics, videoconferencing consultations on routine and crisis behavioral health cases using a "virtual" case management team, and providing traditional psychotherapy and psychiatric consultation services through real-time videoconferencing.

Telebehavioral health services can be offered through intermediary companies that partner with facilities to increase care capacities, or by individual providers or provider groups. There are several HIPPA-compliant telebehavioral health platforms but there are many barriers in place to ensure that online services are offered at the same level of security and validity as in-person services.*[1]

While telecommunications have been used for decades to provide some behavioral health services (usually for emergencies or for experimental purposes), it was only in the 1990s that telemental health care services truly came into their own. Despite the early success of telemental health care services however, wide-scale implementation remains dependent on policy and funding initiatives. However, with many states recently passing or voting on telemedicine parity laws, the outlook for a future of widespread telemental health services remains positive.*[2]

8.10.1 Reimbursement for Telebehavioral Health in the United States

Telebehavioral health is a form of telemedicine, also known as telehealth and telepsychiatry.

Reimbursement by Medicare

Reimbursement for Medicare-covered services must satisfy federal requirements of efficiency, economy and quality of care. Since 1999, Medicare and Medicaid reimbursement for all kinds of telehealth services have expanded, requirements of providers have been reduced, and grants have been given to support telehealth program adoption.

For 2014, the Center for Medicare (CMS) services does cover telemedicine services, including telebehavioral health in many areas. Services covered by Medicare must fall into either Category 1 or Category 2. As of now, these categories are defined as such:

- Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. The request is evaluated based on the similarities between the services already eligible for reimbursement, and that of the requested service.
- Category 2: Services that are not similar to the current list of telehealth services. The assessment will be based on whether the service is accurately de-

scribed by the corresponding code when delivered via telehealth, and whether the use of a

telecommunications system to deliver the services produces a demonstrated clinical benefit to the patient. Supporting documentation should be included.

Medicare Telehealth Coverage Areas There are several conditions to Medicare telehealth coverage. The first being that the consumer, or individual receiving telehealth services must be physically located in an "originating site" that is eligible for Medicare coverage.

Those sites include:

- A Health Professional Shortage Area (HSPA).
- Outside a Metropolitan Statistical Area (MSA)
- Within a MSA rural census tract determined by HHS's Office of Rural Health Policy.
- Rural areas as defined by the department of health and human services (HRSA)

State specific Medicare Reimbursement States have the option/flexibility to determine whether or not to cover telemedicine under the Medicaid assistance program. They may also decide:

- What types of telemedicine to cover
- Where telemedicine will be covered throughout the state
- How telemedicine services are to be covered/reimbursed
- What types of providers/practitioners can be covered/reimbursed
- How much to reimburse for telemedicine services (as long as payments do not exceed Federal Upper Limits)

Individual states are encouraged to use flexibility granted by federal law to create payment methodologies that incorporate telemedicine technology. For example, sates can reimburse the practitioner at the distant site an reimburse a facility fee to the originating site. States can also reimburse support costs like technical support, transmissions charges, and equipment. Add-on costs like those can be incorporated into the fee-for services rate or separately reimbursed as an administrative cost by the state.

If a state decides to cover telemedicine, but not to cover certain areas or certain practitioners, then the state must be responsible for assuring access and covering face to face visits by recognized providers in those parts of the state where telemedicine is not available.

42 states now provide some form of Medicaid reimbursement for telehealth services. For a complete list, visit the NCSL website. There are also entities that participate in a federal telemedicine demonstration project approved by or receiving funding from the Secretary of the Department of Health and Human Services that qualify as originating sites regardless of their location. These include:

- The offices of physicians or practitioners
- Hospitals
- Critical Access Hospitals (CAH)
- Rural health clinics (RHC)
- A skilled nursing facility
- A hospital-based or critical access hospital-based dialysis facility
- A community mental health center (CMHC)
- Federally Qualified Health Centers (FQHC)

All telemedicine encounters must take place in real-time, face-to-face interactions using audio and video equipment at both consumers' and physicians' locations.

Reimbursement by Private Payor

Currently, the following states have a previously enacted Legislated Mandate for Private Coverage:[*] [3]

- Arizona
- California
- Colorado
- District of Columbia
- Georgia
- Hawaii
- Kentucky
- Louisiana
- Maine
- Maryland
- Michigan
- Mississippi
- Montana
- New Hampshire
- New Mexico
- Oklahoma

- Oregon
- Tennessee
- Texas
- Vermont
- Virginia

There are usually two types of events that are billed with a telepsychiatry visit: a provider fee and a facility fee to help offset costs. Telepsychiatry providers can panel with up to 2 major commercial payers as well as Medicare and Medicaid, if beneficial to the program.*[4]

8.10.2 See also

- Psychiatry
- Telepsychiatry
- Telehealth
- Telemedicine
- mHealth

8.10.3 References

[1] http://www.telementalhealthcomparisons.com

[2] http://www.americantelemed.org/policy/state-telemedicine-policy#.U2QRJq1dV7Y

[3] http://www.americantelemed.org/docs/default-source/policy/state-telemedicine-policy-matrix.pdf?sfvrsn=38

[4] Telepsychiatry Reimbursement

8.10.4 External links

- Telemental Health Guide
-

8.11 Telepsychiatry

Telepsychiatry is the application of telemedicine to the specialty field of psychiatry. The term typically describes the delivery of psychiatric assessment and care through telecommunications technology, usually videoconferencing.*[1] Telepsychiatry services can be offered through intermediary companies that partner with facilities to increase care capacities, or by individual providers or provider groups. Most commonly, telepsychiatry encounters take place at medical facilities under the supervision of onsite staff, though at-home models are becoming accepted*[2] as long as they are in compliance with HIPAA standards.

One of the drivers behind telepsychiatry's growth in the United States has been a national shortage of psychiatrists, particularly in specialty areas such as child and adolescent psychiatry;*[3] telepsychiatry can allow fewer doctors to serve more patients by improving utilization of the psychiatrist's time. Telepsychiatry can also make it easier for psychiatrists to treat patients in rural or underserved areas by eliminating the need for either party to travel. The most common means of insurance coverage for telehealth services among the United States is to incorporate coverage into the Medicare program. Reimbursement for Medicare-covered services must satisfy federal requirements of efficiency, economy and quality of care. Since 1999, Medicare and Medicaid reimbursement for all kinds of telehealth services have expanded, requirements of providers have been reduced, and grants have been given to support telehealth program adoption. For 2014, the Center for Medicare (CMS) services does cover telemedicine services, including telepsychiatry in many areas.

8.11.1 Sub-specialties

Telepsychiatry includes a variety of sub-specialties based on different contexts of service delivery.

In-home Telepsychiatry

Psychiatric treatment of patients who are at home or in another private setting is called home-based telepsychiatry,*[4] and it can require only a webcam and high-speed internet service. However, in order to avoid the risk of violating the patient-provider relationship, issues of security and possible HIPAA violations, providers who wish to practice in-home telepsychiatry are best served doing so from within a secure, HIPPA compliant online platform.

Led by psychiatrist Dr. Jill Afrin, South Carolina Department of Health Deaf Services Program has used home-based telepsychiatry as a part of its services since the mid-1990s.*[5]

Individual psychiatrists are adopting this method more and more with willing, interested patients,*[2] and it is an especially useful tool for consumers with limited mobility included the elderly and the disabled. Unfortunately, in-home telepsychiatry is not typically reimbursed by private payors or Medicaid, though many states are adopting measures into their legislation in the form of parity laws that would allow for it to be reimbursed in the future.

Forensic telepsychiatry

Forensic telepsychiatry is the use of a remote psychiatrist or nurse practitioner for psychiatry in a prison or correctional facility, including psychiatric assessment, medication consultation, suicide watch, pre-parole evaluations and more. Telepsychiatry can deliver significant cost savings to correctional facilities by eliminating the need for prisoners to be escorted to off-site appointments and psychiatric interventions.*[6]

On-demand telepsychiatry

As of 2008, guidelines are being developed for the provision of telepsychiatric consultation for emergency psychiatric patients, such as the evaluation of suicidal, homicidal, violent, psychotic, depressed, manic, and acutely anxious patients.*[7] However, emergency telepsychiatry services are already being provided to hospital emergency departments, jails, community mental health centers, substance abuse treatment facilities, and schools. Emergency telepsychiatry can ease staff shortages in overworked hospital emergency departments and increase patient throughput and emergency room disposition. Rather than employ expensive, short-term locum tenens doctors or have emergency room physicians evaluate the psychiatric stability of their patients, hospitals can use telepsychiatry to decrease costs and increase patient access to behavioral health evaluations by psychiatric specialists.*[8]

Crisis telepsychiatry is also an efficient means of reducing the need for psychiatric boarding. Psychiatric boarding is when a mentally ill resident is detained, often in a hospital emergency department, while waiting for proper psychiatric treatment.*[9] With the increased throughput offered by telepsychiatry, psychiatric consumers enjoy reduced wait times and faster access to care.

Scheduled Telepsychiatry

Many facilities that offer behavioral health care are turning to telepsychiatry providers to allow for an increased care capacity. With routine telepsychiatry, a consistent provider or small group of providers serve a regular caseload of consumers in previously scheduled blocks of time. Remote providers can be consulted for medication management, treatment team meetings, supervision, or to offer traditional psychiatric assessment and consultations.

Having access to remote providers allows facilities, especially those in rural areas that struggle to recruit and maintain providers, access to a greater variety of specialty care to offer their consumers.

Facilities that use routine telepsychiatry include:

Community Mental Health Centers (CMHCs) Outpatient clinics Federally Qualified Health Centers (FQHCs) Correctional Facilities Universities and Schools Residential Programs Nursing Homes Accountable Care Organizations (ACOs) Substance Use Treatment Centers Military Bases

8.11.2 HIPAA compliance in the United States

HIPAA (the Health Insurance Portability and Accountability Act) is a United States federal law that establishes security and privacy standards for electronic medical information exchange, including telemental health services. In order to comply with HIPAA guidelines, many providers develop their own specialized videoconferencing services, since common third-party consumer solutions do not include sufficient security and privacy safeguards. There are also a growing number of HIPAA-compliant technologies available for telepsychiatry.*[10]

8.11.3 Telepsychiatry in India

India's large population and relatively small number of psychiatrists makes telepsychiatric service a good option for expanding access to mental health care. Telepsychiatry in India is still a young industry, but it is gradually growing, led by institutes such as the Post Graduate Institute of Medical Education and Research in Chandigarh*[11] and the Schizophrenia Research Foundation in Chennai.*[12]

8.11.4 See also

- Psychiatry
- Telemental Health
- Telehealth
- Telemedicine
- Telebehavioral Health

8.11.5 References

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8.11.7 External links

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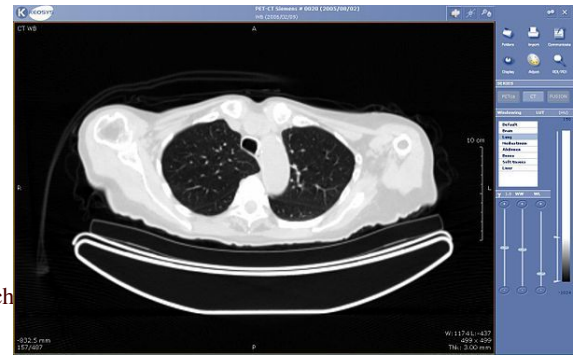
- American Association for Emergency Psychiatry
- "Look onscreen, the doctor will see you now"Focus, Illinois Public Media, April 11, 2014

8.12 Teleradiology



A CT scan of a patient's chest is displayed through ***teleradiology****.*

Teleradiology is the transmission of radiological patient images, such as x-rays, CTs, and MRIs, from one location to another for the purposes of sharing studies with other radiologists and physicians. Teleradiology is a growth technology given that imaging procedures are growing approximately 15% annually against an increase of only 2% in the radiologist population.*[1]

Teleradiology improves patient care by allowing radiologists to provide services without actually having to be at the location of the patient. This is particularly important when a sub-specialist such as a MRI radiologist, neuroradiologist, pediatric radiologist, or musculoskeletal radiologist is needed, since these professionals are generally only located in large metropolitan areas working during daytime hours. Teleradiology allows for trained specialists to be available 24/7.

Teleradiology utilizes standard network technologies such as the internet, telephone lines, wide area network, local area network (LAN) and the latest high tech being computer clouds. Specialized software is used to transmit the images and enable the radiologist to effectively analyze what can be hundreds of images for a given study. Technologies such as advanced graphics processing, voice recognition, and image compression are often used in teleradiology. Through tele radiology and mobile DICOM viewers, images can be sent to another part of the hospital, or to other locations around the world.*[2]

8.12.1 Reports

Teleradiologists can provide a Preliminary Read for emergency room cases and other emergency cases or a Final Read for the official patient record and for use in billing.

Preliminary Reports include all pertinent findings and a phone call for any critical findings. For some Teleradiology services, the turnaround time is extremely rapid with a 30-minute standard turnaround and expedited for critical and stroke studies.

Teleradiology Final Reports can be provided for emergency and non-emergency studies. Final reports include all findings and require access to prior studies and all relevant patient information for a complete diagnosis. Phone calls with any critical findings are signs of quality services.

Teleradiology Preliminary or Final Reports can be provided for all doctors and hospitals overflow studies. Teleradiology can be available for intermittent coverage as an extension of practices and will provide patients with the highest quality care.

8.12.2 Subspecialties

Some teleradiologists are fellowship trained and have a wide variety of subspecialty expertise including such difficult-to-find areas as Neuroradiology, Pediatric Neuroradiology, Thoracic Imaging, Musculoskeletal Radiology, Mammography, and Nuclear Cardiology.*[3] There are also various medical practitioners who are not radiologists that take on studies in radiology to become sub specialists in their respected fields, an example of this is dentistry where Oral and Maxillofacial Radiology (Oral & Maxillofacial Radiology) allows those in Dentistry to specialize in the acquisition and interpretation of radiographic imaging studies performed for diagnosis of treatment guidance for conditions affecting the maxillofacial region.*[4]

8.12.3 Regulations

In the United States, Medicare and Medicaid laws require the Teleradiologist to be on U.S. soil in order to qualify for reimbursement of the Final Read.

In addition, advanced teleradiology systems must also be HIPAA compliant, which helps to ensure patients' privacy. HIPAA (Health Insurance Portability and Accountability Act of 1996) is a uniform, federal floor of privacy protections for consumers. It limits the ways that entities can use patients' personal information and protects the privacy of all medical information no matter what form it is in. Quality teleradiology must abide by important HIPAA rules to ensure patients' privacy is protected.

Also State laws governing the licensing requirements and medical malpractice insurance coverage required for physicians vary from state to state. Ensuring compliance with these laws is a significant overhead expense for larger multi-state teleradiology groups.

Medicare (Australia) has identical requirements to that of the United States, where the guidelines are provided by the Department of Health and Ageing, and government based payments fall under the Health Insurance Act.*[5]

The regulations in Australia are also conducted at both federal and state levels, ensuring that strict guidelines are adhered to at all times, with regular yearly updates and amendments are introduced (usually around March and November of every year), ensuring that the legislation is kept up to date with changes in the industry.

One of the most recent changes to Medicare and Radiology / Teleradiology in Australia was the introduction of the Diagnostic Imaging Accreditation Scheme (DIAS) on the 1st of July 2008. DIAS was introduced to further improve the quality of Diagnostic Imaging and to amend the Health Insurance Act.*[6]

8.12.4 Industry growth

Until the late 1990s teleradiology was primarily used by individual radiologists to interpret occasional emergency studies from offsite locations, often in the radiologists home. The connections were made through standard analog phone lines.

Teleradiology expanded rapidly as the growth of the internet and broad band combined with new CT scanner technology to become an essential tool in trauma cases in emergency rooms throughout the country. The occasional 2-3 x ray studies a week soon became 3-10 CT scans, or more, a night. Because ER physicians are not trained to read CT scans or MRI's, radiologists went from working 8–10 hours a day, five and half days a week to a schedule of 24 hours a day, 7 days a week coverage. This became a particularly acute challenge in smaller rural facilities that only had one solo radiologist with no other to share call.

These circumstances spawned a post dot.com boom of firms and groups that provided outsourced, off-site teleradiology on-call services to hospitals and Radiology Groups around the country. As an example, a teleradiology firm might cover trauma at a hospital in Indiana with doctors based in Texas. Some firms even used overseas doctors in locations like Australia and India. Nighthawk, founded by Dr. Paul Berger, was the first to station U.S. licensed radiologists overseas (initially Australia and later Switzerland) to maximize the time zone difference to provide nightcall in U.S. hospitals.

The early innovators in this field like Teleradiology Solutions, Nighthawk Radiology, Horizon Radiology, The Radlinx Group, and Virtual Radiology Consultants (VRC or VRN most recently), became multimillion-dollar companies today. Nighthawk (symbol: NHWK) and VRC

(symbol: VRAD) ultimately went public and established almost a billion dollars in market capitalization.

However, on May 17, 2010, Providence Equity Partners acquired and took private Virtual Radiologic.*[7] Moreover, on September 27, 2010, Virtual Radiologic and NightHawk Radiology Announced their Merger.*[8] Finally, on December 23, 2010, Virtual Radiologic (vRad) and NightHawk Radiology announced the completion of their previously announced merger, with NightHawk continuing as a wholly owned subsidiary of vRad.*[9]

The Radlinx Group, founded by Greg Lowenstein and Mark Bakken, and Horizon Radiology, founded by Frank Powell, M.D. and Hans Truong, M.D., pioneered the expansion of teleradiology services beyond just night coverage to also provide coverage to hundreds of small rural hospitals and clinics, throughout the U.S., who otherwise had no on-site access to full-time radiologists. This rural coverage continues today with teleradiologists like Argus Radiology and has expanded to include 24-hour service on every day of the year regardless of location.

Currently, teleradiology firms are facing pricing pressures. Industry consolidation is likely as there are more than 500 of these firms, large and small, throughout the United States.

8.12.5 Nonprofit

Although teleradiology is flourishing in the developed world, few teleradiological links have been made to the developing world. Generally, barriers to the implementation of radiology services have also complicated setting up reliable links.*[10]

Several examples of simple, low-cost nonprofit teleradiology solutions have been employed by Satellife and the Swinfen Charitable Trust. Established in 1987 by Nobel Peace Prize laureate, Dr Bernard Lown, Satellife (Boston) was the first non-profit organization to own and use a low earth-orbit satellite as well as mobile computing devices such as handheld computers and mobile phones for medical data communication.*[11] Starting in 1998, Swinfen Charitable Trust, a U.K. based nonprofit organization founded by Lord and Lady Swinfen, gave healthcare personnel in remote places internet access and a digital camera, and also facilitated a low-cost telemedicine service linking doctors at hospitals in the developing world with medical and surgical consultants who gave advice at no cost.*[12]

More complex solutions emerged in 2007. Operated by volunteer radiologists, Téléradiologie sans Frontières (Teleradiology without Borders), a Luxembourg-based nonprofit organization founded by Dr Jean-Baptiste Niedercorn and Dr Gérald Wajnapel, started to provide teleradiology imaging services to developing countries using a professional cloud picture archiving and communications system (PACS).*[13]

Today, many established private teleradiology practices such as Virtual Radiologic (vRad) are also involved in pilot programs with NGOs, reporting radiographs from rural health centres, free of charge.*[14]

8.12.6 See also

- Radiology
- Telemedicine
- RIS
- PACS
- TelePACS
- DICOM

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8.13 Telerehabilitation

Telerehabilitation (or *e-rehabilitation*[*][1][*][2]) is the delivery of rehabilitation services over telecommunication networks and the internet. Most types of services fall into two categories: clinical assessment (the patient's functional abilities in his or her environment), and clinical therapy. Some fields of rehabilitation practice that have explored telerehabilitation are: neuropsychology, speech-language pathology, audiology, occupational therapy, and physical therapy. Telerehabilitation can deliver therapy to people who cannot travel to a clinic because the patient has a disability or because of travel time. Telerehabilitation also allows experts in rehabilitation to engage in a clinical consultation at a distance.

Most telerehabilitation is highly visual. As of 2006 the most commonly used modalities are via webcams, videoconferencing, phone lines, videophones and webpages containing rich Internet applications. The visual nature of telerehabilitation technology limits the types of rehabilitation services that can be provided. It is most widely used for neuropsychological rehabilitation; fitting of rehabilitation equipment such as wheelchairs, braces or artificial limbs; and in speech-language pathology. Rich internet applications for neuropsychological rehabilitation (aka cognitive rehabilitation) of cognitive impairment (from many etiologies) was first introduced in 2001. This endeavor has recently (2006) expanded as a teletherapy application for cognitive skills enhancement programs for school children. Tele-audiology (hearing assessments) is a growing application. As of 2006, telerehabilitation in the practice of occupational therapy and physical therapy are very limited, perhaps because these two disciplines are more "hands on".

Two important areas of telerehabilitation research are (1) demonstrating equivalence of assessment and therapy to in-person assessment and therapy, and (2) building new data collection systems to digitize information that a therapist can use in practice. Ground-breaking research in telehaptics (the sense of touch) and virtual reality may broaden the scope of telerehabilitation practice, in the future.

In the United States, the National Institute on Disability and Rehabilitation Research's (NIDRR) supports research and the development of telerehabilitation. NIDRR's grantees include the "Rehabilitation Engineering and Research Center" (RERC) at the University of Pittsburgh, the Rehabilitation Institute of Chicago, the State University of New York at Buffalo, and the National Rehabilitation Hospital in Washington DC. Other federal funders of research are the Veterans Administration, the Health Services Research Administration in the US Department of Health and Human Services, and the Department of Defense. Outside the United States, excellent research is conducted in Australia and Europe.

As of 2006, only a few health insurers in the United States will reimburse for telerehabilitation services. If the research shows that tele-assessments and tele-therapy are equivalent to clinical encounters, it is more likely that insurers and Medicare will cover telerehabilitation services.

8.13.1 History

In 1999, D.M. Angaran published "Telemedicine and Telepharmacy: Current Status and Future Implications" in the American Journal of Health-System Pharmacy. He provided a comprehensive history of telecommunications, the internet and telemedicine since the 1950s. The Department of Defense (DoD) and the National Aeronautics and Space Administration (NASA) spearheaded the technology in the United States during the Vietnam War and the space program; both agencies continue to fund advances in telemedicine.

Three early adopters of telemedicine were state penitentiary systems, rural health care systems, and the radiology profession. Telemedicine makes business sense for the states because they do not have to pay for security escorts to have a prisoner receive care outside the prison.

Rural telemedicine in the United States is heavily subsidized through federal agency grants for telecommunications operations. Most of this funding comes through the Health Services Research Administration and the Department of Commerce. Some state universities have obtained state funding to operate tele-clinics in rural areas. As of 2006, few (if any) of these programs are known to financially break-even, mostly because the Medicare program for people over age 65 (the largest payer) is very restrictive about paying for telehealth.

In contrast, the Veterans Administration is relatively active in using telemedicine for people with disabilities. There are several programs that provide annual physical exams or monitoring and consultation for veterans with spinal cord injuries. Similarly, some state Medicaid programs (for poor people and people with disabilities) have pilot programs using telecommunications to connect rural practitioners with subspecialty therapists. A few school districts in Oklahoma and Hawaii offer school-based rehabilitation therapy using therapy assistants who are directed by a remote therapist. The National Rehabilitation Hospital in Washington DC and Sister Kenny Rehabilitation Institute in Minneapolis provided assessment and evaluations to patients living in Guam and American Samoa. Cases included post-stroke, post-polio, autism, and wheel-chair fitting.

An argument can be made that "telerehabilitation" be-

gan in 1998 when NIDRR funded the first RERC on telerehabilitation. It was awarded to a consortium of biomedical engineering departments at the National Rehabilitation Hospital and The Catholic University of America, both located in Washington, DC; the Sister Kenny Rehabilitation Institute in Minnesota; and the East Carolina University in North Carolina. Some of this early research work, and its motivation, is reviewed in Winters (2002). The State of Science Conference held in 2002 convened most of military and civilian clinicians, engineers, and government officials interested in using telecommunications as a modality for rehabilitation assessment and therapy; a summary is provided in Rosen, Winters & Lauderdale (2002). The conference was attended by the incoming president of the American Telemedicine Association (ATA). This led to an invitation by ATA to the conference attendees to form a special interest group on telerehabilitation. NIDRR funded the second 5-year RERC on telerehabilitation in 2004, awarding it to the University of Pittsburgh. This RERC was renewed in 2010.

In 2001, O. Bracy, a neuropsychologist, introduced the first web based, rich internet application, for the telerehabilitation presentation of cognitive rehabilitation therapy. This system first provides the subscriber clinician with an economical means of treating their own patients over the internet. Secondly, the system then provides, directly to the patient, the therapy prescription set up and controlled by the member clinician. All applications and response data are transported via the internet in real time. The patient can login to do their therapy from home, the library or anywhere they have access to an internet computer. In 2006, this system formed the basis of a new system designed as a cognitive skills enhancement program for school children. Individual children or whole classrooms can participate in this program over the internet.

In 2006, M.J. McCue and S.E. Palsbo published an article in the Journal of Telemedicine and Telecare that explored how telemedicine can become a profitable business for hospitals. They argue that telerehabilitation should be expanded so that people with disabilities and people in pain (perhaps after hip-replacement surgery or people with arthritis) can get the rehabilitative therapy they need. It is unethical to limit paymente for telerehabilitation services only to patients in rural areas.

Research in telerehabilitation is in its infancy, with only a handful of equivalence trials. As of 2006, most peer-reviewed research in telemedicine are case reports of pilot programs or new equipment. Rehabilitation researchers need to conduct many more controlled experiments and present the evidence to clinicians (and payers) that telerehabilitation is clinically effective. The discipline of speech-language pathology is far head of occupational therapy and physical therapy in demonstrating equivalence over various types of telecommunications equipment.

8.13.2 Technologies

1. Plain old telephone service (POTS) with videophones/Phones in telerehabilitation

   There are several types of connections used with real time exchanges. Plain old telephone service (POTS) uses standard analog telephone lines. Videophones are used with POTS lines and include a camera, display screen, and telephone. Videophones use telephone lines that are available in most homes, so are easy to set up; however small display screens make them problematic for individuals with vision problems. This can be solved by using a large screen or television as a screen.

2. Videotelephony/Videotelephony in telerehabilitation

   The use of improved quality video-assisted telecommunication devices, such as videoconferencing, webcams and telepresence to assist in treatments.

3. Virtual reality/Virtual reality in telerehabilitation

   Virtual reality in telerehabilitation is one of the newest tools available in that area. This computer technology allows the development of three-dimensional virtual environments.

4. Motion technology/Motion technology in telerehabilitation

5. Web-based approaches/Web-based approaches in telerehabilitation

   Applications that run over the internet, just as if they were installed in your computer (called Rich Internet Applications), represent a new direction in software development. A person subscribes to the website rather than purchase the software. Any updates or changes to the software system are instantly available to all subscribers. The applications can be accessed from any location where one has access to an internet connected computer. Likewise, a patient's data is accessible from where ever the therapist is located. Neither the application nor the patient's data is tied to one computer.

6. Sensors and body monitoring/Sensors and body monitoring in telerehabilitation

7. Haptic technology/Haptic technology in telerehabilitation

8. Artificial intelligence/Artificial intelligence in telerehabilitation
9. Wireless technology/Wireless technology in telerehabilitation
10. PDAs/PDA in telerehabilitation
11. Mobile telephony/Mobile telephony in telerehabilitation
12. Electronic medical records/Electronic medical record telerehabilitation
13. Mobile apps/Mobile apps telerehabilitation

8.13.3 Clinical applications of telerehabilitation

1. Review of telerehabilitation research on clinical populations
2. Professional to professional (clinic to clinic applications)
3. Telehealth – Information access
4. Clinical approaches
   (a) Assessment
   (b) Monitoring
   (c) Intervention
   (d) Telesupervision (of licensed assistants)
   (e) Telementoring
   (f) Tele-education
   (g) Telementoring

Speech-language pathology

The clinical services provided by speech-language pathology readily lend themselves to telerehabilitation applications due to the emphasis on auditory and visual communicative interaction between the client and the clinician. As a result, the number of telerehabilitation applications in speech-language pathology tend to outnumber those in other allied health professions. To date, applications have been developed to assess and/or treat acquired adult speech and language disorders, stuttering, voice disorders, speech disorders in children, and swallowing dysfunction. The technology involved in these applications has ranged from the simple telephone (Plain Old Telephone System – POTS) to the use of dedicated Internet-based videoconferencing systems.

Early applications to assess and treat acquired adult speech and language disorders involved the use of the telephone to treat patients with aphasia and motor speech disorders (Vaughan, 1976, Wertz, et al., 1987), a computer controlled video laserdisc over the telephone and a closed-circuit television system to assess speech and language disorders (Wertz et al., 1987), and a satellite-based videoconferencing system to assess patients in rural areas (Duffy, Werven & Aronson, 1997). More recent applications have involved the use of sophisticated Internet-based videoconferencing systems with dedicated software which enable the assessment of language disorders (Georgeadis, Brennan, Barker, & Baron, 2004, Brennan, Georgeadis, Baron & Barker, 2004) and the assessment and treatment of motor speech disorders (Hill, Theodoros, Russell, Cahill, Ward, Clark, 2006; Theodoros, Constantinescu, Russell, Ward, Wilson & Wootton, in press) following brain impairment and Parkinson's disease. Collectively, these studies have revealed positive treatment outcomes, while assessment and diagnoses have been found to be comparable to face-to-face evaluations.

The treatment of stuttering has been adapted to a telerehabilitation environment with notable success. Two Australian studies (Harrison, Wilson & Onslow, 1999; Wilson, Onslow & Lincoln, 2004) involving the distance delivery of the Lidcombe program to children who stutter have utilized the telephone in conjunction with offline video recordings to successfully treat several children. Overall, the parents and children responded positively to the program delivered at a distant. Using a high speed videoconferencing system link, Sicotte, Lehoux, Fortier-Blanc and Leblanc (2003) assessed and treated six children and adolescents with a positive reduction in the frequency of dysfluency that was maintained six months later. In addition, a videoconferencing platform has been used successfully to provide follow-up treatment to an adult who had previously received intensive therapy (Kully, 200).

Reports of telerehabilitation applications in paediatric speech and language disorders are sparse. A recent Australian pilot study has investigated the feasibility of an Internet-based assessment of speech disorder in six children (Waite, Cahill, Theodoros, Russell, Busuttin, in press). High levels of agreement between the online and face-to-face clinicians for single-word articulation, speech intelligibility, and oro-motor tasks were obtained suggesting that the Internet-based protocol had the potential to be a reliable method for assessing paediatric speech disorders.

Voice therapy across a variety of types of voice disorders has been shown to be effectively delivered via a telerehabilitation application. Mashima et al. (2003) using PC based videoconferencing and speech analysis software compared 23 patients treated online with 28 persons treated face-to-face. The authors reported positive post treatment results with no significant difference in measures between the traditional and videoconferencing group, suggesting that the majority of traditional voice therapy techniques can be applied to distance treatment.

Although obvious limitations exist, telerehabilitation ap-

plications for the assessment of swallowing function have also been used with success. Lalor, Brown and Cranfield (2000) were able to obtain an initial assessment of the nature and extent of swallowing dysfunction in an adult via a videoconferencing link although a more complete evaluation was restricted due to the inability to physically determine the degree of laryngeal movement. A more sophisticated telerehabilitation application for the assessment of swallowing was developed by Perlman and Witthawaskul (2002) who described the use of real-time videofluoroscopic examination via the Internet. This system enabled the capture and display of images in real-time with only a three to five second delay.

There continues to be a need for ongoing research to develop and validate the use of telerehabilitation applications in speech-language pathology in a greater number and variety of adult and paediatric communication and swallowing disorders.

Physical and occupational therapy

8.13.4 Disciplines and therapies

1. (a) Speech-language pathology
   (b) Audiology
   (c) Physical therapy
   (d) Occupational therapy
   (e) Psychology
   (f) Nursing
   (g) Social work
   (h) Rehabilitation counseling/Vocational rehabilitation

8.13.5 Standards and training requirements

1. Telerehabilitation standards
2. Reimbursement policies/Reimbursement in telerehabilitation
3. Legislative activities/Legislative activities in telerehabilitation
4. Ethics and privacy issues/Ethics and privacy issues in telerehabilitation
5. Clinical and technology training issues

8.13.6 Research

8.13.7 Related organizations

- American Telemedicine Association (ATA)
- American Speech-Language-Hearing Association (ASHA)
- Association of Telehealth Service Providers (ATSP)
- National Institute on Disability and Rehabilitation Research (NIDRR)
- Rehabilitation Engineering and Assistive Technology Society of North America (RESNA)
- Special Interest Group on Telerehabilitation (SIGOT)

8.13.8 See also

- Telemedicine
- Rehabilitation (neuropsychology)

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8.13.10 External links

- Telerehabilitation at DMOZ

8.14 Virtual reality in telerehabilitation

Virtual reality in telerehabilitation is a method used first in the training of musculoskeletal patients using asynchronous patient data uploading, and an internet video link. Subsequently, therapists using virtual reality-based telerehabilitation prescribe exercise routines via the web which are then accessed and executed by patients through a web browser. Therapists then monitor the patient's progress via the web and modify the therapy asynchronously without real-time interaction or training.*[1]

8.14.1 Background

The computer technology that allows development three-dimensional virtual environments consists of both hardware and software. The current popular, technical, and scientific interest in virtual environments is inspired,

in large part, by the advent and availability of increasingly powerful and affordable visually oriented, interactive, graphical display systems and techniques lacking only sense and sensibility.

The term "virtualized reality" (VR) was coined and introduced in a paper by Kanade. The traditional virtual reality world is typically constructed using simplistic, artificially created computer-aided design (CAD) models. VR starts with the real-world scene and virtualizes it.*[2] Virtual reality is a practical, affordable technology for the practice of clinical medicine, and modern, high-fidelity virtual reality systems have practical applications in areas ranging from psychiatry to surgical planning and telemedicine.*[3] Through VR's capacity to allow the creation and control of dynamic 3-dimensional, ecologically valid stimulus environments within which behavioral response can be recorded and measured, it offers clinical assessment and rehabilitation options not available with traditional methods.*[4]

8.14.2 Application

The value of VR systems for the investigation and rehabilitation of cognitive and perceptual impairments and current and potential applications of VR technology address six neurorehabilitation issues.*[5] Korean researchers developed and assessed the value of a new rehabilitation training system to improve postural balance control by combining virtual reality technology with an unfixed bicycle. The system was effective as a training device; in addition, the technology might have a wider applicability to the rehabilitation field.*[6]

Tracy and Lathan investigated the relationship between motor tasks and participants' spatial abilities by training participants within a VR based simulator and then observing their ability to transfer training from the simulator to the real world. The study demonstrated that subjects with lower spatial abilities achieved significant positive transfer from a simulator based training task to a similar real world robotic operation task.*[7]

Virtual environments were applied to assess the training of inexperienced powered wheelchair users and demonstrated that the two virtual environments represent a potentially useful means of assessing and training novice powered wheelchair users.*[8] A recently completed project at the University of Strathclyde has resulted in the development of a wheelchair motion platform which, in conjunction with a virtual reality facility, can be used to address issues of accessibility in the built environment.*[9]

Many cases have applied virtual reality technology to telemedicine and telerehabilitation service development. Because telemedicine focuses principally on transmitting medical information, VR has potential to enhance the practice. State of the art of VR-based telemedicine applications is used in remote or augmented surgery as well as in surgical training, both of which are critically dependent on eye–hand coordination. Recently, however, different researchers have tried to use virtual environments in medical visualization and for assessment and rehabilitation in neuropsychology.*[10]

Case studies for VR applications were conducted that were internet deliverable and they identified technical, practical, and user challenges of remote VR treatment programs.*[11] To improve understanding of deficits in autism and in left visual-spatial neglect, Trepagnier et al. investigated face gaze behavior in autism and right hemisphere stroke, using virtual reality and gaze sensing technology.*[12]

An at-home stroke telerehabilitation service was developed using virtual reality haptics.*[13] Researchers from Rutgers University and Stanford University developed a virtual reality-based orthopedic telerehabilitation system.*[14]*[15]*[16]

The use of virtual reality technologies in the rehabilitation of patients with vestibular system disorders and in the provision of remote medical consultation for those patients. He stated that an appropriately designed VR experience could greatly increase the rate of adaptation in these patients.*[17]

8.14.3 See also

- Computationally Advanced Infrastructure Partnerships Center

8.14.4 References

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8.15 Wireless Medical Telemetry Service

Wireless Medical Telemetry Service (WMTS) is a wireless service specifically defined in the United States by the Federal Communications Commission (FCC) for transmission of data related to a patient's health (biotelemetry). It was created in 2000 because of interference issues due to establishment of digital television. The bands defined are 608-614 MHz, 1395-1400 MHz and 1427-1432 MHz. Devices using these bands are typically proprietary. Further, the use of these bands has not been internationally agreed to, so many times devices cannot be marketed or used freely in countries other than the United States.

Because of this, in addition to WMTS, many manufacturers have created devices that transmit data in the ISM bands such as 902-928 MHz, and, more typically, 2.4-2.5 GHz, often using IEEE 802.11 or Bluetooth radios.

8.15.1 FCC statements

There is an FCC statement on coexistence* [1] of WMTS in various frequency bands.

> Prior to the establishment of the WMTS, medical telemetry devices generally could be operated on an unlicensed basis on vacant television channels 7-13 (174-216 MHz) and 14-46 (470-668 MHz) or on a licensed but secondary basis to private land mobile radio operations in the 450-470 MHz frequency band. This meant that wireless medical telemetry operations had to accept interference from the primary users of these frequency bands, i.e., the television broadcasters and private land mobile radio licensees. Further, if a wireless medical telemetry operation caused interference to television or private land mobile radio transmissions, the user of the wireless medical telemetry equipment would be responsible for rectifying the problem, even if that meant shutting down the medical telemetry operation.
>
> The FCC was concerned that certain regulatory developments, including the advent of digital television (DTV) service, would result in more intensive use of these frequencies by the primary services, subjecting wireless medical telemetry operations to greater interference than before and perhaps precluding such operations entirely in many instances. To ensure that wireless medical telemetry devices can operate free of harmful interference, the FCC decided to establish the WMTS. In a Report and Order released on June 12, 2000, the FCC allocated a total of 14 megahertz of spectrum

to WMTS on a primary basis. At the same time, it adopted a number of regulations to ensure that the WMTS frequencies are used effectively and efficiently for their intended medical purpose. The WMTS rules took effect on October 16, 2000

8.15.2 WMTS rules by FCC

Band Plan:* [2]

> The frequencies currently allocated for WMTS are divided into three blocks: the 608-614 MHz frequency band (which corresponds to UHF TV channel 37 but is not used by any TV station because it is used for radio astronomy) and the 1395-1400 MHz and 1427-1432 MHz frequency bands (both of which had been used by the Federal Government but were reallocated to the private sector under the Omnibus Budget Reconciliation Act of 1993). The frequencies in the 1427-1432 MHz band are shared by WMTS with non-medical telemetry operations, such as utility telemetry operations, that are regulated under Part 90 of the FCC's Rules. Generally, WMTS operations are accorded primary status over non-medical telemetry operations in the 1427-1429.5 MHz band, but are treated as secondary to non-medical telemetry operations in the 1429.5-1432 MHz band. However, there are seven geographical areas in which WMTS and non-medical telemetry operations have "flipped" the bands in which each enjoys primary status. These seven areas, termed the "carve-out" areas, are (1) Pittsburgh, PA; (2) the Washington, D.C. metropolitan area; (3) Richmond/Norfolk, VA; (4) Austin/Georgetown, TX; (5) Battle Creek, MI; (6) Detroit, MI; and (7) Spokane, WA. In these seven areas, in contrast to the rest of the country, WMTS has primary status in the 1429-1431.5 MHz band, but is secondary to non-medical telemetry operations in the 1427-1429 MHz band.

8.15.3 FDA comments

Comments from US FDA,* [3] in part:

> Because of concerns for interference with the present wireless medical telemetry systems, and the introduction of the WMTS, CDRH has issued a public health advisory to hospital administrators, risk managers, directors of biomedical/clinical engineering, and nursing home directors. In general, CDRH encourages manufacturers and users of medical telemetry devices to move to the new spectrum because of its protections against interference from other intentional transmitters and because frequency coordination will be provided.

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Chapter 9

Computer-Aided Surgery, Medical Robotics and Virtual Reality

9.1 Computer assisted surgery

Computer-assisted surgery (**CAS**) represents a surgical concept and set of methods, that use computer technology for surgical planning, and for guiding or performing surgical interventions. CAS is also known as **computer-aided surgery**, **computer-assisted intervention**, **image-guided surgery** and **surgical navigation**, but these are terms that are more or less synonymous with CAS. CAS has been a leading factor in the development of robotic surgery.

9.1.1 General principles

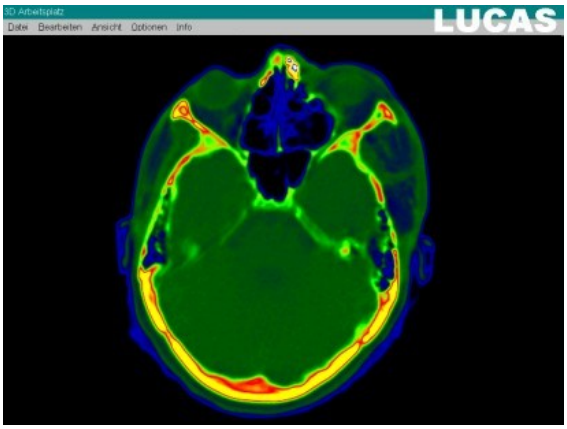

Image gathering ("segmentation") on the LUCAS workstation

Creating a virtual image of the patient

The most important component for CAS is the development of an accurate model of the patient. This can be conducted through a number of medical imaging technologies including CT, MRI, x-rays, ultrasound plus many more. For the generation of this model, the anatomical region to be operated has to be scanned and uploaded into the computer system. It is possible to employ a number of scanning methods, with the datasets combined through data fusion techniques. The final objective is the creation of a 3D dataset that reproduces the exact geometrical situation of the normal and pathological tissues and structures of that region. Of the available scanning methods, the CT is preferred,[*][1] because MRI data sets are known to have volumetric deformations that may lead to inaccuracies. An example data set can include the collection of data compiled with 180 CT slices, that are 1 mm apart, each having 512 by 512 pixels. The contrasts of the 3D dataset (with its tens of millions of pixels) provide the detail of soft vs hard tissue structures, and thus allow a computer to differentiate, and visually separate for a human, the different tissues and structures. The image data taken from a patient will often include intentional landmark features, in order to be able to later realign the virtual dataset against the actual patient during surgery. See patient registration.

Image analysis and processing

Image analysis involves the manipulation of the patients 3D model to extract relevant information from the data. Using the differing contrast levels of the different tissues within the imagery, as examples, a model can be changed to show just hard structures such as bone, or view the flow of arteries and veins through the brain.

Diagnostic, preoperative planning, surgical simulation

Using specialized software the gathered dataset can be rendered as a virtual 3D model of the patient, this model can be easily manipulated by a surgeon to provide views from any angle and at any depth within the volume. Thus the surgeon can better assess the case and establish a more accurate diagnostic. Furthermore, the surgical intervention will be planned and simulated virtually, before actual surgery takes place (computer-aided surgical simulation [CASS]). Using dedicated software, the surgical robot will be programmed to carry out the pre-planned actions during the actual surgical intervention.

Surgical navigation

In computer-assisted surgery, the actual intervention is defined as surgical navigation. Using the surgical navigation system the surgeon uses special instruments, which are tracked by the navigation system. The position of a tracked instrument in relation to the patient's anatomy is shown on images of the patient, as the surgeon moves the instrument. The surgeon thus uses the system to 'navigate' the location of an instrument. The feedback the system provides of the instrument location is particularly useful in situations where the surgeon cannot actually see the tip of the instrument, such as in minimally invasive surgeries.

Robotic surgery

Main article: Robotic surgery

Robotic surgery is a term used for correlated actions of a surgeon and a surgical robot (that has been programmed to carry out certain actions during the preoperative planning procedure). A surgical robot is a mechanical device (generally looking like a robotic arm) that is computer-controlled. Robotic surgery can be divided into three types, depending on the degree of surgeon interaction during the procedure: supervisory-controlled, telesurgical, and shared-control.*[2] In a supervisory-controlled system, the procedure is executed solely by the robot, which will perform the pre-programmed actions. A telesurgical system, also known as remote surgery, requires the surgeon to manipulate the robotic arms during the procedure rather than allowing the robotic arms to work from a predetermined program. With shared-control systems, the surgeon carries out the procedure with the use of a robot that offers steady-hand manipulations of the instrument. In most robots, the working mode can be chosen for each separate intervention, depending on the surgical complexity and the particularities of the case.

9.1.2 Applications

Computer-assisted surgery is the beginning of a revolution in surgery. It already makes a great difference in high-precision surgical domains, but it is also used in standard surgical procedures.

Computer-assisted neurosurgery

Telemanipulators have been used for the first time in neurosurgery, in the 1980s. This allowed a greater development in brain microsurgery (compensating surgeon's physiological tremor by 10-fold), increased accuracy and precision of the intervention. It also opened a new gate to minimally invasive brain surgery, furthermore reducing the risk of post-surgical morbidity by avoiding accidental damage to adjacent centers.

Computer-assisted oral and maxillofacial surgery

Bone segment navigation is the modern surgical approach in orthognathic surgery (correction of the anomalies of the jaws and skull), in temporo-mandibular joint (TMJ) surgery, or in the reconstruction of the mid-face and orbit.*[3]

It is also used in implantology where the available bone can be seen and the position, angulation and depth of the implants can be simulated before the surgery. During the operation surgeon is guided visually and by sound alerts. IGI (Image Guided Implantology) is one of the navigation systems which uses this technology.

Guided Implantology New therapeutic concepts as guided surgery are being developed and applied in the placement of dental implants. The prosthetic rehabilitation is also planned and performed parallel to the surgical procedures. The planning steps are at the foreground and carried out in a cooperation of the surgeon, the dentist and the dental technician. Edentulous patients, either one or both jaws, benefit as the time of treatment is reduced.

Regarding the edentulous patients, conventional denture support is often compromised due to moderate bone atrophy, even if the dentures are constructed based on correct anatomic morphology.

Using cone beam computed tomography, the patient and the existing prosthesis are being scanned. Furthermore, the prosthesis alone is also scanned. Glass pearls of defined diameter are placed in the prosthesis and used as reference points for the upcoming planning. The resulting data is processed and the position of the implants determined. The surgeon, using special developed software, plans the implants based on prosthetic concepts considering the anatomic morphology. After the planning of the surgical part is completed, a CAD/CAM surgical guide for dental placement is constructed. The mucosal-supported surgical splint ensures the exact placement of the implants in the patient. Parallel to this step, the new implant supported prosthesis is constructed.

The dental technician, using the data resulting from the previous scans, manufactures a model representing the situation after the implant placement. The prosthetic compounds, abutments, are already prefabricated. The length and the inclination can be chosen. The abutments are connected to the model at a position in consideration of the prosthetic situation. The exact position of the abutments is registered. The dental technician can now manufacture the prosthesis.

The fit of the surgical splint is clinically proved. After that, the splint is attached using a three-point support pin system. Prior to the attachment, irrigation with a chem-

ical disinfectant is advised. The pins are driven through defined sheaths from the vestibular to the oral side of the jaw. Ligaments anatomy should be considered, and if necessary decompensation can be achieved with minimal surgical interventions. The proper fit of the template is crucial and should be maintained throughout the whole treatment. Regardless of the mucosal resilience, a correct and stable attachment is achieved through the bone fixation. The access to the jaw can now only be achieved through the sleeves embedded in the surgical template. Using specific burs through the sleeves the mucosa is removed. Every bur used, carries a sleeve compatible to the sleeves in the template, which ensures that the final position is achieved but no further progress in the alveolar ridge can take place. Further procedure is very similar to the traditional implant placement. The pilot hole is drilled and then expanded. With the aid of the splint, the implants are finally placed. After that, the splint can be removed.

With the aid of a registration template, the abutments can be attached and connected to the implants at the defined position. No less than a pair of abutments should be connected simultaneously to avoid any discrepancy. An important advantage of this technique is the parallel positioning of the abutments. A radiological control is necessary to verify the correct placement and connection of implant and abutment.

In a further step, abutments are covered by gold cone caps, which represent the secondary crowns. Where necessary, the transition of the gold cone caps to the mucosa can be isolated with rubber dam rings.

The new prosthesis corresponds to a conventional total prosthesis but the basis contains cavities so that the secondary crowns can be incorporated. The prosthesis is controlled at the terminal position and corrected if needed. The cavities are filled with a self-curing cement and the prosthesis is placed in the terminal position. After the self-curing process, the gold caps are definitely cemented in the prosthesis cavities and the prosthesis can now be detached. Excess cement may be removed and some corrections like polishing or under filling around the secondary crowns may be necessary. The new prosthesis is fitted using a construction of telescope double cone crowns. At the end position, the prosthesis buttons down on the abutments to ensure an adequate hold.

At the same sitting, the patient receives the implants and the prosthesis. An interim prosthesis is not necessary. The extend of the surgery is kept to minimum. Due to the application of the splint, a reflection of soft tissues in not needed. The patient experiences less bleeding, swelling and discomfort. Complications such as injuring of neighbouring structures are also avoided. Using 3D imaging during the planning phase, the communication between the surgeon, dentist and dental technician is highly supported and any problems can easily detected and eliminated. Each specialist accompanies the whole treatment and interaction can be made. As the end result is already planned and all surgical intervention is carried according to the initial plan, the possibility of any deviation is kept to a minimum. Given the effectiveness of the initial planning the whole treatment duration is shorter than any other treatment procedures.

Computer-assisted ENT surgery

Image-guided surgery and CAS in ENT commonly consists of navigating preoperative image data such as CT or cone beam CT to assist with locating or avoiding anatomically important regions such as the optical nerve or the opening to the frontal sinuses.*[4] For use in middle-ear surgery there has been some application of robotic surgery due to the requirement for high-precision actions.*[5]

Computer-assisted orthopedic surgery (CAOS)

The application of robotic surgery is widespread in orthopedics, especially in routine interventions, like total hip replacement *[6] or pedicle screw insertion. *[7] It is also useful in pre-planning and guiding the correct anatomical position of displaced bone fragments in fractures, allowing a good fixation by osteosynthesis. Early CAOS systems include the HipNav, OrthoPilot, and Praxim.

Computer-assisted visceral surgery

With the advent of computer-assisted surgery, great progresses have been made in general surgery towards minimal invasive approaches. Laparoscopy in abdominal and gynecologic surgery is one of the beneficiaries, allowing surgical robots to perform routine operations, like colecystectomies, or even hysterectomies. In cardiac surgery, shared control systems can perform mitral valve replacement or ventricular pacing by small thoracotomies. In urology, surgical robots contributed in laparoscopic approaches for pyeloplasty or nephrectomy or prostatic interventions.*[8]*[9]

Computer-assisted radiosurgery

Radiosurgery is also incorporating advanced robotic systems. CyberKnife is such a system that has a lightweight linear accelerator mounted on the robotic arm. It is guided towards tumor processes, using the skeletal structures as a reference system (Stereotactic Radiosurgery System). During the procedure, real time X-ray is used to accurately position the device before delivering radiation beam. The robot can compensate for respiratory motion of the tumor in real-time.*[10]

9.1.3 Advantages

CAS starts with the premise of a much better visualization of the operative field, thus allowing a more accurate preoperative diagnostic and a well-defined surgical planning, by using surgical planning in a preoperative virtual environment. This way, the surgeon can easily assess most of the surgical difficulties and risks and have a clear idea about how to optimize the surgical approach and decrease surgical morbidity.science of designing user interaction with equipment and work places to fit the user. During the operation, the computer guidance improves the geometrical accuracy of the surgical gestures and also reduce the redundancy of the surgeon's acts. This significantly improves ergonomy in the operating theatre, decreases the risk of surgical errors and reduces the operating time.

9.1.4 Disadvantages

There are several disadvantages of computer-assisted surgery. A major disadvantage of this system is their cost. With a price tag of a million dollars, their cost is nearly prohibitive. Some people believe that improvements in technology, such as haptics, increased processor speeds, and more complex and capable software will increase the cost of these systems.*[11] Another disadvantage is the size of these systems. These systems have relatively large footprints and relatively cumbersome robotic arms. This is an important disadvantage in today's already crowded-operating rooms. It may be difficult for both the surgical team and the robot to fit into the operating room.*[11] Another factor that is stunting the development of robotic surgery is that of "latency" which is the time delay between the instructions issued by the surgeon and the movement of the robot which responds to the instructions. With the current level of technology, the surgeon must be in close proximity.*[12]

9.1.5 See also

- Advanced Simulation Library*[13] is a hardware accelerated multiphysics simulation software

9.1.6 References

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9.1.7 External links

Media related to Computer assisted surgery at Wikimedia Commons

9.2 Remote surgery

Remote surgery (also known as **telesurgery**) is the ability for a doctor to perform surgery on a patient even though they are not physically in the same location. It is a form of telepresence. A robot surgical system generally consists of one or more arms (controlled by the surgeon), a master controller (console), and a sensory system giving feedback to the user.*[1]*[2] Remote surgery combines elements of robotics, cutting edge communication technology such as high-speed data connections and elements of management information systems. While the field of robotic surgery is fairly well established, most of these robots are controlled by surgeons at the location of the surgery. Remote surgery is essentially advanced telecommuting for surgeons, where the physical distance between the surgeon and the patient is immaterial. It promises to allow the expertise of specialized surgeons to be available to patients worldwide, without the need for patients to travel beyond their local hospital.

9.2.1 Surgical systems

Surgical robot systems have been developed from the first functional telesurgery system-ZEUS-to the da Vinci Surgical System, which is currently the only commercially available surgical robotic system. In Israel a company was established by Professor Moshe Schoham, from the faculty of Mechanical Engeenering at the Technion. Used mainly for "on-site" surgery, these robots assist the surgeon visually, with better precision and less invasiveness to patients.*[1]*[2] The Da Vinci Surgical System has also been combined to form a Dual Da Vinci system which allows two surgeons to work together on a patient at the same time. The system gives the surgeons the ability to control different arms, switch command of arms at any point and communicate through headsets during the operation.*[3]

9.2.2 Costs

Marketed for $975,000, the ZEUS Robot Surgical System was less expensive than the da Vinci Surgical System, which cost $1 million. The cost of an operation through telesurgery is not precise but must pay for the surgical system, the surgeon, and contribute to paying for a year's worth of ATM technology which runs between $100,000-$200,000.*[4]

9.2.3 The Lindbergh Operation

Main article: Lindbergh Operation

The first true and complete remote surgery was conducted on 7 September 2001 across the Atlantic Ocean, with French surgeon (Dr. Jacques Marescaux) in New York performing a cholecystectomy on a 68-year-old female patient 6,230 km away in Strasbourg, France. It was named Operation Lindbergh.*[5] after Charles Lindbergh's pioneering transatlantic flight from New York to Paris. France Telecom provided the redundant fiberoptic ATM lines to minimize latency and optimize connectivity, and Computer Motion provided a modified Zeus robotic system. After clinical evaluation of the complete solution in July 2001, the human operation was successfully completed on 9/7/2001.*[6]

The success and exposure of the procedure led the robotic team to use the same technology within Canada, this time using Bell Canada's public internet between Hamilton, Ontario and North Bay, Ontario (a distance of about 400 kilometers). While operation Lindbergh used the most expensive ATM fiber optics communication to ensure reliability and success of the first telesurgery, the follow on procedures in Canada used standard public internet which was provisioned with QOS using MPLS QOS-MPLS. A series of complex laparoscopic procedures were performed where in this case, the expert clinician would support the surgeon who was less experienced, operating on his patient. This resulted in patient receiving the best care possible while remaining in their hometown, the less experienced surgeon gaining valuable experience, and the expert surgeon providing their expertise without travel. The robotic team's goal was to go from Lindbergh's proof of concept to a real-life solution. This was achieved with over 20 complex laparoscopic operations between Hamilton and North Bay.

9.2.4 Technology

The speed of remote surgery is made possible through ATM technology, or Asynchronous Transfer Mode. "Asynchronous Transfer Mode is a technology designed for the high-speed transfer of voice, video, and data through public and private networks using cell relay technology". Cell relay technology is the method of using small fixed length packets or cells to transfer data between computers or network equipment and determines the speed at which information is transferred. ATM technology has a maximum speed of 10 Gbit/s (Gigabits per second). This developed technology provides opportunities for more transatlantic surgeries similar to the Operation Lindbergh.*[7] During a surgery, the robot arm can use a different angle during a laparoscopic surgery than a tool in the surgeon's hand, providing easier movement. The da Vinci Surgical System, using "Endowrist" instruments, allows the surgeon seven degrees of rotation and a range of motion far greater than the human hand while filtering out the hand's natural tremor.*[2]*[8]

9.2.5 Applications

Since Operation Lindbergh, remote surgery has been conducted many times in numerous locations. To date Dr. Anvari, a laparoscopic surgeon in Hamilton, Canada, has conducted numerous remote surgeries on patients in North Bay, a city 400 kilometres from Hamilton.{{http://www.csii.ca/about_csii/leadership/dr_mehran_anvari}} Even though he uses a VPN over a non-dedicated fiberoptic connection that shares bandwidth with regular telecommunications data, Dr. Anvari has not had any connection problems during his procedures.

Rapid development of technology has allowed remote surgery rooms to become highly specialized. At the Advanced Surgical Technology Centre at Mt. Sinai Hospital in Toronto, Canada, the surgical room responds to the surgeon's voice commands in order to control a variety of equipment at the surgical site, including the lighting in the operating room, the position of the operating table and the surgical tools themselves. With continuing advances in communication technologies, the availability of greater bandwidth and more powerful computers, the ease and cost effectiveness of deploying remote surgery

units is likely to increase rapidly.

The possibility of being able to project the knowledge and the physical skill of a surgeon over long distances has many attractions. There is considerable research underway in the subject. The armed forces have an obvious interest since the combination of telepresence, teleoperation, and telerobotics can potentially save the lives of battle casualties by providing them with prompt attention in mobile operating theatres.

Another potential advantage of having robots perform surgeries is accuracy. A study conducted at Guy's Hospital in London, England compared the success of kidney surgeries in 304 dummy patients conducted traditionally as well as remotely and found that those conducted using robots were more successful in accurately targeting kidney stones.*[9]

9.2.6 Unassisted robotic surgery

As the techniques of expert surgeons are studied and stored in special computer systems, robots might one day be able to perform surgeries with little or no human input. Carlo Pappone, an Italian surgeon, has developed a software program that uses data collected from several surgeons and thousands of operations to perform the surgery without human intervention.*[10] This could one day make expensive, complicated surgeries much more widely available, even to patients in regions which have traditionally lacked proper medical facilities.

9.2.7 Force-feedback and time delay

The ability to carry out delicate manipulations relies greatly upon feedback. For example, it is easy to learn how much pressure is required to handle an egg. In robotic surgery, surgeons need to be able to perceive the amount of force being applied without directly touching the surgical tools. Systems known as force-feedback, or haptic technology, have been developed to simulate this. Haptics is the science of touch. Any type of Haptic feedback provides a responsive force in opposition to the touch of the hand. Haptic technology in telesurgery, making a virtual image of a patient or incision, would allow a surgeon to see what they are working on as well as feel it. This technology is designed to give a surgeon the ability to feel tendons and muscles as if it were actually the patient's body.*[8]*[11] However these systems are very sensitive to time-delays such as those present in the networks used in remote surgery.

9.2.8 Depth Perception

Being able to gauge the depth of an incision is crucial. Humans' binocular vision makes this easy in a three-dimensional environment. However this can be much more difficult when the view is presented on a flat computer screen.

9.2.9 Possible uses

One possible use of remote surgery is the Trauma-Pod project conceived by the US military under the Defense Advanced Research Agency. This system is intended to aid wounded soldiers in the battlefield by making use of the skills of remotely located medical personnel.

Another future possibility could be the use of remote surgery during long space exploration missions.

9.2.10 Limitations

For now, remote surgery is not a widespread technology in part because it does not have sponsorship by the governments.*[12] Before its acceptance on a broader scale, many issues will need to be resolved. For example, established clinical protocols, training, and global compatibility of equipment must be developed. Also, there is still the need for an anesthesiologist and a backup surgeon to be present in case there is a disruption of communications or a malfunction in the robot. Nevertheless, Operation Lindbergh proved that the technology exists today to enable delivery of expert care to remote areas of the globe.

9.2.11 See also

- Waldo (short story) by Robert A. Heinlein.

9.2.12 References

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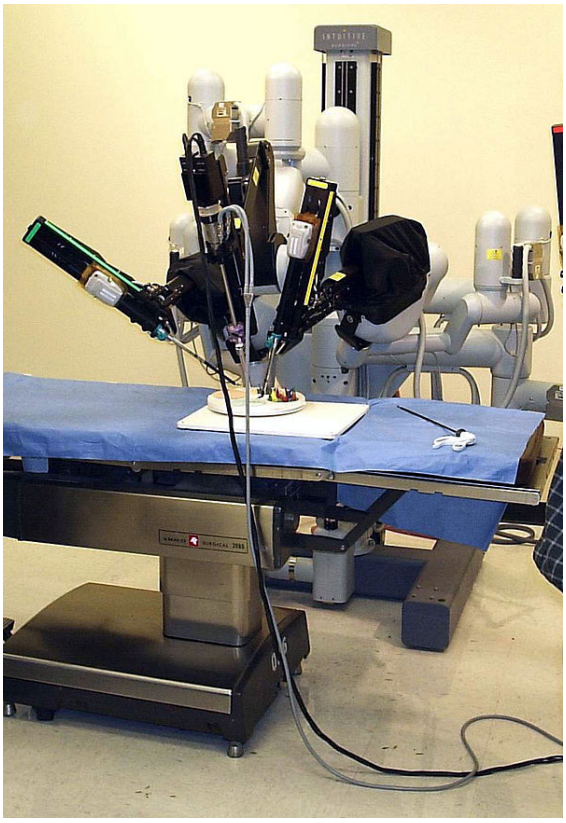
9.2.13 External links

- Article and Media Gallery for telesurgery
- PBS article on telesurgery
- Using remote surgery as a teaching tool
- How robotic surgery works
- Article in Pulse of the Planet about remote surgery
- BBC News SCI/TECH -- First transatlantic surgery
- High Performance Network Video in support of Telesurgery / NEEMO7 Mission - Revolutionary Telemedicine Techniques
- Robot Successfully Completes Unassisted Heart Surgery

9.3 Robot-assisted heart surgery

Robotic surgery, computer-assisted surgery, and robotically-assisted surgery are terms for technological developments that use robotic systems to aid in surgical procedures. Robotically-assisted surgery was developed to overcome the limitations of pre-existing minimally-invasive surgical procedures and to enhance the capabilities of surgeons performing open surgery.

In the case of robotically-assisted minimally-invasive surgery, instead of directly moving the instruments, the surgeon uses one of two methods to control the instruments; either a direct telemanipulator or through computer control. A telemanipulator is a remote manipulator that allows the surgeon to perform the normal movements associated with the surgery whilst the robotic arms carry out those movements using end-effectors and manipulators to perform the actual surgery on the patient. In computer-controlled systems the surgeon uses a computer to control the robotic arms and its end-effectors, though these systems can also still use telemanipulators for their input. One advantage of using the computerised method is that the surgeon does not have to be present, but can be anywhere in the world, leading to the possibility for remote surgery.



A robotically assisted surgical system used for prostatectomies, cardiac valve repair and gynecologic surgical procedures

In the case of enhanced open surgery, autonomous instruments (in familiar configurations) replace traditional steel tools, performing certain actions (such as rib spreading) with much smoother, feedback-controlled motions than could be achieved by a human hand. The main object of such smart instruments is to reduce or eliminate the tissue trauma traditionally associated with open surgery without requiring more than a few minutes' training on the part of surgeons. This approach seeks to improve open surgeries, particularly cardio-thoracic, that have so far not benefited from minimally-invasive techniques.

Robotic surgery has been criticized for its expense, by one estimate costing $1,500 to $2000 more per patient.*[1]

9.3.1 Comparison to traditional methods

Major advances aided by surgical robots have been remote surgery, minimally invasive surgery and un-

manned surgery. Due to robotic use, the surgery is done with precision, miniaturization, smaller incisions; decreased blood loss, less pain, and quicker healing time. Articulation beyond normal manipulation and three-dimensional magnification helps resulting in improved ergonomics. Due to these techniques there is a reduced duration of hospital stays, blood loss, transfusions, and use of pain medication.*[2] The existing open surgery technique has many flaws like limited access to surgical area, long recovery time, long hours of operation, blood loss, surgical scars and marks.*[3]

The robot normally costs $1,390,000 and while its disposable supply cost is normally $1,500 per procedure, the cost of the procedure is higher.*[4] Additional surgical training is needed to operate the system.*[5] Numerous feasibility studies have been done to determine whether the purchase of such systems are worthwhile. As it stands, opinions differ dramatically. Surgeons report that, although the manufacturers of such systems provide training on this new technology, the learning phase is intensive and surgeons must operate on twelve to eighteen patients before they adapt. During the training phase, minimally invasive operations can take up to twice as long as traditional surgery, leading to operating room tie ups and surgical staffs keeping patients under anesthesia for longer periods. Patient surveys indicate they chose the procedure based on expectations of decreased morbidity, improved outcomes, reduced blood loss and less pain.*[2] Higher expectations may explain higher rates of dissatisfaction and regret.*[5]

Compared with other minimally invasive surgery approaches, robot-assisted surgery gives the surgeon better control over the surgical instruments and a better view of the surgical site. In addition, surgeons no longer have to stand throughout the surgery and do not tire as quickly. Naturally occurring hand tremors are filtered out by the robot's computer software. Finally, the surgical robot can continuously be used by rotating surgery teams.*[6]

Critics of the system, including the American Congress of Obstetricians and Gynecologists,*[7] say there is a steep learning curve for surgeons who adopt use of the system and that there's a lack of studies that indicate long-term results are superior to results following traditional laparoscopic surgery.*[4] Articles in the newly created *Journal of Robotic Surgery* tend to report on one surgeon's experience.*[4]

A Medicare study found that some procedures that have traditionally been performed with large incisions can be converted to "minimally invasive" endoscopic procedures with the use of the Da Vinci, shortening length-of-stay in the hospital and reducing recovery times. But because of the hefty cost of the robotic system it is not clear that it is cost-effective for hospitals and physicians despite any benefits to patients since there is no additional reimbursement paid by the government or insurance companies when the system is used.*[4]

Robot-assisted pancreatectomies have been found to be associated with "longer operating time, lower estimated blood loss, a higher spleen-preservation rate, and shorter hospital stay[s]" than laparoscopic pancreatectomies; there was "no significant difference in transfusion, conversion to open surgery, overall complications, severe complications, pancreatic fistula, severe pancreatic fistula, ICU stay, total cost, and 30-day mortality between the two groups." *[8]

Robotic surgery has been criticized for its expense, by one estimate costing $1,500 to $2000 more per patient.*[1]

9.3.2 Uses

General surgery

In early 2000 the field of general surgical interventions with the daVinci device was explored by surgeons at Ohio State University. Reports were published in esophageal and pancreatic surgery for the first time in the world and further data was subsequently published by Horgan and his group at the University of Illinois and then later at the same institution by others.*[9]*[10] In 2007, the University of Illinois at Chicago medical team, led by Prof. Pier Cristoforo Giulianotti, reported a pancreatectomy and also the Midwest's first fully robotic Whipple surgery. In April 2008, the same team of surgeons performed the world's first fully minimally invasive liver resection for living donor transplantation, removing 60% of the patient's liver, yet allowing him to leave the hospital just a couple of days after the procedure, in very good condition. Furthermore, the patient can also leave with less pain than a usual surgery due to the four puncture holes and not a scar by a surgeon.*[11]

Cardiothoracic surgery

Robot-assisted MIDCAB and Endoscopic coronary artery bypass (TECAB) operations are being performed with the Da Vinci system. Mitral valve repairs and replacements have been performed. The Ohio State University, Columbus has performed CABG, mitral valve, esophagectomy, lung resection, tumor resections, among other robotic assisted procedures and serves as a training site for other surgeons. In 2002, surgeons at the Cleveland Clinic in Florida reported and published their preliminary experience with minimally invasive "hybrid" procedures. These procedures combined robotic revascularization and coronary stenting and further expanded the role of robots in coronary bypass to patients with disease in multiple vessels. Ongoing research on the outcomes of robotic assisted CABG and hybrid CABG is being done.

Cardiology and electrophysiology

The Stereotaxis Magnetic Navigation System (MNS) has been developed to increase precision and safety in ablation procedures for arrhythmias and atrial fibrillation while reducing radiation exposure for the patient and physician, and the system utilizes two magnets to remotely steerable catheters. The system allows for automated 3-D mapping of the heart and vasculature, and MNS has also been used in interventional cardiology for guiding stents and leads in PCI and CTO procedures, proven to reduce contrast usage and access tortuous anatomy unreachable by manual navigation. Dr. Andrea Natale has referred to the new Stereotaxis procedures with the magnetic irrigated catheters as "revolutionary." *[12]

The Hansen Medical Sensei robotic catheter system uses a remotely operated system of pulleys to navigate a steerable sheath for catheter guidance. It allows precise and more forceful positioning of catheters used for 3-D mapping of the heart and vasculature. The system provides doctors with estimated force feedback information and feasible manipulation within the left atrium of the heart. The Sensei has been associated with mixed acute success rates compared to manual, commensurate with higher procedural complications, longer procedure times but lower fluoroscopy dosage to the patient.*[13]*[14]*[15]

At present, three types of heart surgery are being performed on a routine basis using robotic surgery systems.*[16] These three surgery types are:

- Atrial septal defect repair – the repair of a hole between the two upper chambers of the heart,
- Mitral valve repair – the repair of the valve that prevents blood from regurgitating back into the upper heart chambers during contractions of the heart,
- Coronary artery bypass – rerouting of blood supply by bypassing blocked arteries that provide blood to the heart.

As surgical experience and robotic technology develop, it is expected that the applications of robots in cardiovascular surgery will expand.

Colon and rectal surgery

Many studies have been undertaken in order to examine the role of robotic procedures in the field of colorectal surgery.*[17]*[18]

Results to date indicate that robotic-assisted colorectal procedures outcomes are "no worse" than the results in the now "traditional" laparoscopic colorectal operations. Robotic-assisted colorectal surgery appears to be safe as well.*[19] Most of the procedures have been performed for malignant colon and rectal lesions. However, surgeons are now moving into resections for diverticulitis and non-resective rectopexies (attaching the colon to the sacrum in order to treat rectal prolapse.)

When evaluated for several variables, robotic-assisted procedures fare equally well when compared with laparoscopic, or open abdominal operations. Study parameters have looked at intraoperative patient preparation time, length of time to perform the operation, adequacy of the removed surgical specimen with respect to clear surgical margins and number of lymph nodes removed, blood loss, operative or postoperative complications and long-term results.

More difficult to evaluate are issues related to the view of the operative field, the types of procedures that should be performed using robotic assistance and the potential added cost for a robotic operation.

Many surgeons feel that the optics of the 3-dimensional, two camera stereo optic robotic system are superior to the optical system used in laparoscopic procedures. The pelvic nerves are clearly visualized during robotic-assisted procedures. Less clear however is whether or not these supposedly improved optics and visualization improve patient outcomes with respect to postoperative impotence or incontinence, and whether long-term patient survival is improved by using the 3-dimensional optic system. Additionally, there is often a need for a wider, or "larger" view of the operative field than is routinely provided during robotic operations.,*[20] The close-up view of the area under dissection may hamper visualization of the "bigger view", especially with respect to ureteral protection.

Questions remain unanswered, even after many years of experience with robotic-assisted colorectal operations. Ongoing studies may help clarify many of the issues of confusion associated with this novel surgical approach.

Gastrointestinal surgery

Multiple types of procedures have been performed with either the 'Zeus' or da Vinci robot systems, including bariatric surgery and gastrectomy*[21] for cancer. Surgeons at various universities initially published case series demonstrating different techniques and the feasibility of GI surgery using the robotic devices.*[10] Specific procedures have been more fully evaluated, specifically esophageal fundoplication for the treatment of gastroesophageal reflux*[22] and Heller myotomy for the treatment of achalasia.*[23]*[24]

Other gastrointestinal procedures including colon resection, pancreatectomy, esophagectomy and robotic approaches to pelvic disease have also been reported.

Gynecology

Robotic surgery in gynecology is of uncertain benefit with it being unclear if it affects rates of complications. Gynecologic procedures may take longer with robot-assisted surgery but may be associated with a shorter hospital stay following hysterectomy.*[25] In the United States, robotic-assisted hysterectomy for benign conditions has been shown to be more expensive than conventional laparoscopic hysterectomy, with no difference in overall rates of complications.*[26]

This includes the use of the da Vinci surgical system in benign gynecology and gynecologic oncology. Robotic surgery can be used to treat fibroids, abnormal periods, endometriosis, ovarian tumors, uterine prolapse, and female cancers. Using the robotic system, gynecologists can perform hysterectomies, myomectomies, and lymph node biopsies.

Neurosurgery

Several systems for stereotactic intervention are currently on the market. The NeuroMate was the first neurosurgical robot, commercially available in 1997.*[27] Originally developed in Grenoble by Alim-Louis_Benabid's team, it is now owned by Renishaw. With installations in the United States, Europe and Japan, the system has been used in 8000 stereotactic brain surgeries by 2009. IMRIS Inc.'s SYMBIS(TM) Surgical System*[28] will be the version of NeuroArm, the world's first MRI-compatible surgical robot, developed for world-wide commercialization. Medtech's Rosa is being used by several institutions, including the Cleveland Clinic in the U.S, and in Canada at Sherbrooke University and the Montreal Neurological Institute and Hospital in Montreal (MNI/H). Between June 2011 and September 2012, over 150 neurosurgical procedures at the MNI/H have been completed robotized stereotaxy, including in the placement of depth electrodes in the treatment of epilepsy, selective resections, and stereotaxic biopsies.

Orthopedics

The ROBODOC system was released in 1992 by Integrated Surgical Systems, Inc. which merged into CUREXO Technology Corporation.*[29] Also, The Acrobot Company Ltd. developed the "Acrobot Sculptor", a robot that constrained a bone cutting tool to a pre-defined volume. The "Acrobot Sculptor" was sold to Stanmore Implants in August 2010. Stanmore received FDA clearance in February 2013 for US surgeries but sold the Sculptor to Mako Surgical in June 2013 to resolve a patent infringement lawsuit.*[30] Another example is the CASPAR robot produced by U.R.S.-Ortho GmbH & Co. KG, which is used for total hip replacement, total knee replacement and anterior cruciate ligament reconstruction.*[31] MAKO Surgical Corp (founded 2004) produces the RIO (Robotic Arm Interactive Orthopedic System) which combines robotics, navigation, and haptics for both partial knee and total hip replacement surgery.*[32] Blue Belt Technologies received FDA clearance in November 2012 for the Navio™ Surgical System. The Navio System is a navigated, robotics-assisted surgical system that uses a CT free approach to assist in partial knee replacement surgery.*[33]

Pediatrics

Surgical robotics has been used in many types of pediatric surgical procedures including: tracheoesophageal fistula repair, cholecystectomy, nissen fundoplication, morgagni's hernia repair, kasai portoenterostomy, congenital diaphragmatic hernia repair, and others. On 17 January 2002, surgeons at Children's Hospital of Michigan in Detroit performed the nation's first advanced computer-assisted robot-enhanced surgical procedure at a children's hospital.

The Center for Robotic Surgery at Children's Hospital Boston provides a high level of expertise in pediatric robotic surgery. Specially-trained surgeons use a high-tech robot to perform complex and delicate operations through very small surgical openings. The results are less pain, faster recoveries, shorter hospital stays, smaller scars, and happier patients and families.

In 2001, Children's Hospital Boston was the first pediatric hospital to acquire a surgical robot. Today, surgeons use the technology for many procedures and perform more pediatric robotic operations than any other hospital in the world. Children's Hospital physicians have developed a number of new applications to expand the use of the robot, and train surgeons from around the world on its use.*[34]

Radiosurgery

The CyberKnife Robotic Radiosurgery System uses image guidance and computer controlled robotics to treat tumors throughout the body by delivering multiple beams of high-energy radiation to the tumor from virtually any direction. The system uses a German KUKA KR 240. Mounted on the robot is a compact X-band linac that produces 6MV X-ray radiation. Mounting the radiation source on the robot allows very fast repositioning of the source, which enables the system to deliver radiation from many different directions without the need to move both the patient and source as required by current gantry configurations.

Transplant surgery

Transplant surgery (organ transplantation) has been considered as highly technically demanding and virtually unobtainable by means of conventional laparoscopy. For

many years, transplant patients were unable to benefit from the advantages of minimally invasive surgery. The development of robotic technology and its associated high resolution capabilities, three dimensional visual system, wrist type motion and fine instruments, gave opportunity for highly complex procedures to be completed in a minimally invasive fashion. Subsequently, the first fully robotic kidney transplantations were performed in the late 2000s. After the procedure was proven to be feasible and safe, the main emerging challenge was to determine which patients would benefit most from this robotic technique. As a result, recognition of the increasing prevalence of obesity amongst patients with kidney failure on hemodialysis posed a significant problem. Due to the abundantly higher risk of complications after traditional open kidney transplantation, obese patients were frequently denied access to transplantation, which is the premium treatment for end stage kidney disease. The use of the robotic-assisted approach has allowed kidneys to be transplanted with minimal incisions, which has virtually alleviated wound complications and significantly shortened the recovery period. The University of Illinois Medical Center reported the largest series of 104 robotic-assisted kidney transplants for obese recipients (mean body mass index > 42). Amongst this group of patients, no wound infections were observed and the function of transplanted kidneys was excellent. In this way, robotic kidney transplantation could be considered as the biggest advance in surgical technique for this procedure since its creation more than half a century ago.*[35]*[36]*[37]

Urology

Robotic surgery in the field of urology has become very popular, especially in the United States.*[38] It has been most extensively applied for excision of prostate cancer because of difficult anatomical access. It is also utilized for kidney cancer surgeries and to lesser extent surgeries of the bladder.

As of 2014, there is little evidence of increased benefits compared to standard surgery to justify the increased costs.*[39] Some have found tentative evidence of more complete removal of cancer and less side effects from surgery for prostatectomy.*[40]

In 2000, the first robot-assisted laparoscopic radical prostatectomy was performed.*[5]

Vascular surgery

In September 2010, the first robotic operations with Hansen Medical's Magellan Robotic System at the femoral vasculature were performed at the University Medical Centre Ljubljana (UMC Ljubljana), Slovenia. The research was led by Borut Geršak, the head of the Department of Cardiovascular Surgery at the centre. Geršak explained that the robot used was the first true robot in the history of robotic surgery, meaning the user interface was not resembling surgical instruments and the robot was not simply imitating the movement of human hands but was guided by pressing buttons, just like one would play a video game. The robot was imported to Slovenia from the United States.*[41]*[42]

9.3.3 Miniature robotics

As scientists seek to improve the versatility and utility of robotics in surgery, some are attempting to miniaturize the robots. For example, the University of Nebraska Medical Center has led a multi-campus effort to provide collaborative research on mini-robotics among surgeons, engineers and computer scientists.*[43]

9.3.4 History

The first robot to assist in surgery was the *Arthrobot*, which was developed and used for the first time in Vancouver in 1983.*[44] Intimately involved were biomedical engineer, Dr. James McEwen, Geof Auchinleck, a UBC engineering physics grad, and Dr. Brian Day as well as a team of engineering students. The robot was used in an orthopaedic surgical procedure on 12 March 1984, at the UBC Hospital in Vancouver. Over 60 arthroscopic surgical procedures were performed in the first 12 months, and a 1985 National Geographic video on industrial robots, *The Robotics Revolution*, featured the device. Other related robotic devices developed at the same time included a surgical scrub nurse robot, which handed operative instruments on voice command, and a medical laboratory robotic arm. A YouTube video entitled *Arthrobot* illustrates some of these in operation.

In 1985 a robot, the Unimation Puma 200, was used to place a needle for a brain biopsy using CT guidance.*[45] In 1992, the PROBOT, developed at Imperial College London, was used to perform prostatic surgery by Dr. Senthil Nathan at Guy's and St Thomas' Hospital, London. This was the first pure robotic surgery in the world. Also the Robot Puma 560, a robot developed in 1985 by Kwoh et al. Puma 560 was used to perform neurosurgical biopsies with greater precision. Just like with any other technological innovation, this system led to the development of new and improved surgical robot called PROBOT. The PROBOT was specifically designed for transurethral resection of the prostate. Meanwhile, when PROBOT was being developed, ROBODOC, a robotic system designed to assist hip replacement surgeries was the first surgical robot that was approved by the FDA.*[46] The ROBODOC from Integrated Surgical Systems (working closely with IBM) was introduced in 1992 to mill out precise fittings in the femur for hip replacement.*[47] The purpose of the ROBODOC was to replace the previous method of carving out a femur for an implant, the use of a mallet and

broach/rasp.

Further development of robotic systems was carried out by SRI International and Intuitive Surgical with the introduction of the da Vinci Surgical System and Computer Motion with the *AESOP* and the ZEUS robotic surgical system.*[48] The first robotic surgery took place at The Ohio State University Medical Center in Columbus, Ohio under the direction of Robert E. Michler.*[49] Examples of using ZEUS include a fallopian tube reconnection in July 1998,*[50] a *beating heart* coronary artery bypass graft in October 1999,*[51] and the Lindbergh Operation, which was a cholecystectomy performed remotely in September 2001.*[52]

The original telesurgery robotic system that the da Vinci was based on was developed at SRI International in Menlo Park with grant support from DARPA and NASA.*[53] Although the telesurgical robot was originally intended to facilitate remotely performed surgery in battlefield and other remote environments, it turned out to be more useful for minimally invasive on-site surgery. The patents for the early prototype were sold to Intuitive Surgical in Mountain View, California. The da Vinci senses the surgeon's hand movements and translates them electronically into scaled-down micro-movements to manipulate the tiny proprietary instruments. It also detects and filters out any tremors in the surgeon's hand movements, so that they are not duplicated robotically. The camera used in the system provides a true stereoscopic picture transmitted to a surgeon's console. Examples of using the da Vinci system include the first robotically assisted heart bypass (performed in Germany) in May 1998, and the first performed in the United States in September 1999; and the first all-robotic-assisted kidney transplant, performed in January 2009.*[54] The da Vinci Si was released in April 2009, and initially sold for $1.75 million.*[55]

In May 2006 the first artificial intelligence doctor-conducted unassisted robotic surgery on a 34-year-old male to correct heart arythmia. The results were rated as better than an above-average human surgeon. The machine had a database of 10,000 similar operations, and so, in the words of its designers, was "more than qualified to operate on any patient".*[56]*[57] In August 2007, Dr. Sijo Parekattil of the Robotics Institute and Center for Urology (Winter Haven Hospital and University of Florida) performed the first robotic assisted microsurgery procedure denervation of the spermatic cord for chronic testicular pain.*[58] In February 2008, Dr. Mohan S. Gundeti of the University of Chicago Comer Children's Hospital performed the first robotic pediatric neurogenic bladder reconstruction.*[59]

On 12 May 2008, the first image-guided MR-compatible robotic neurosurgical procedure was performed at University of Calgary by Dr. Garnette Sutherland using the NeuroArm.*[60] In June 2008, the German Aerospace Centre (DLR) presented a robotic system for minimally invasive surgery, the MiroSurge.*[61] In September 2010, the Eindhoven University of Technology announced the development of the Sofie surgical system, the first surgical robot to employ force feedback.*[62] In September 2010, the first robotic operation at the femoral vasculature was performed at the University Medical Centre Ljubljana by a team led by Borut Geršak.*[41]*[42]

9.3.5 See also

- Bone segment navigation
- Computer-assisted surgery
- Computer-integrated surgery
- Minimally invasive surgery
- Patient registration
- Stereolithography (medicine)
- Surgical Segment Navigator
- Telemedicine

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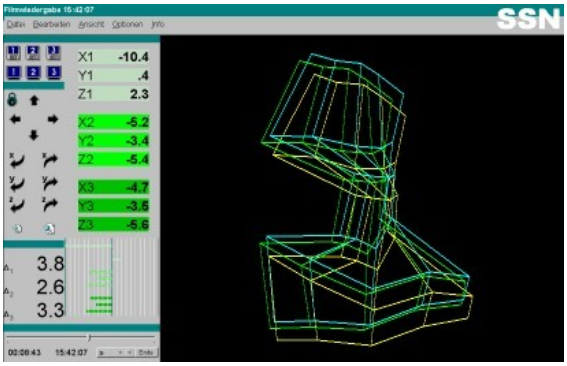
9.3.7 External links

9.4 Surgical Segment Navigator

The **surgical segment navigator (SSN)** is a computer-based system for use in surgical navigation. It is integrated into a common platform, together with the surgical tool navigator (STN), the surgical microscope navigator (SMN) and the 6DOF manipulator (MKM), developed by Carl Zeiss.



Surgical navigation for the orbit and zygoma on the SSN system (Color coding for the preoperative, predicted and goal position of the fragments, respectively)

9.4.1 SSN

The **SSN** has been developed as a computer system for bone segment navigation in oral and maxillofacial surgery. It allows a very precise repositioning of bone fragments, with the advent of preoperative simulation and surgical planning.The system has been developed since 1997 at the University of Regensburg, Germany, with the support of the Carl Zeiss Company. Its principle is based on an infrared localisation system, composed of an infrared camera and at least three infrared transmitters attached to each bony fragment. The SSN is mainly used in orthognatic surgery (surgical correction of dysgnathia), but also for the surgical reconstruction of the orbit, or other surgical interventions to the midface.

9.4.2 SSN++

Since 2001, at the University of Heidelberg, Germany, the **SSN++** has been developed, a markerless-registration navigation system, based on a native (=markerless) CT or MRI. In this case, the patient registration is obtained on the operating table, using a surface scanner. The SSN++ corelates the surface scan data (gathered on the operating table) with the skin surface reconstruction from the dataset obtained preoperatively by CT or MRI. This principle complies with the terrain contour matching principle described for flying objects. The advantage of the new method is that the registration of the patient's position becomes a simple automated procedure; on the other hand, the radiation load for the patient is reduced, compared to the method using markers.

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9.4.4 External links

- SSN Homepage

9.5 Bone segment navigation

Bone segment navigation is a surgical method used in the field to find the anatomical position of displaced bone fragments in fractures, allowing a good fixation by osteosynthesis. It has been developed for the first time in oral and maxillofacial surgery.

After an accident or injury, a fracture can be produced and the resulting bony fragments can be displaced. In the oral and maxillofacial area, such a discplacement could have a major effect both on facial aesthetics and organ function: a fracture occurring in a bone that delimits the orbit can lead to diplopia; a mandibular fracture can induce significant modifications of the dental occlusion; in the same manner, a skull (neurocranium) fracture can produce an increased intracranial pressure.

9.5.1 Surgical planning and surgical simulation

An osteotomy is a surgical intervention that consists of cutting through bone and repositioning the resulting fragments in the correct anatomical place. To insure optimal repositioning of the bony structures by osteotomy, the intervention can be planned in advance and simulated. The surgical simulation is a key factor in reducing the actual operating time. Often, during this kind of operation, the surgical access to the bone segments is very limited by the presence of the soft tissues: muscles, fat tissue and skin - thus, the correct anatomical repositioning is very difficult to assess, or even impossible. This led to the necessity of a preoperative planning and simulation on models of the bare bony structures.

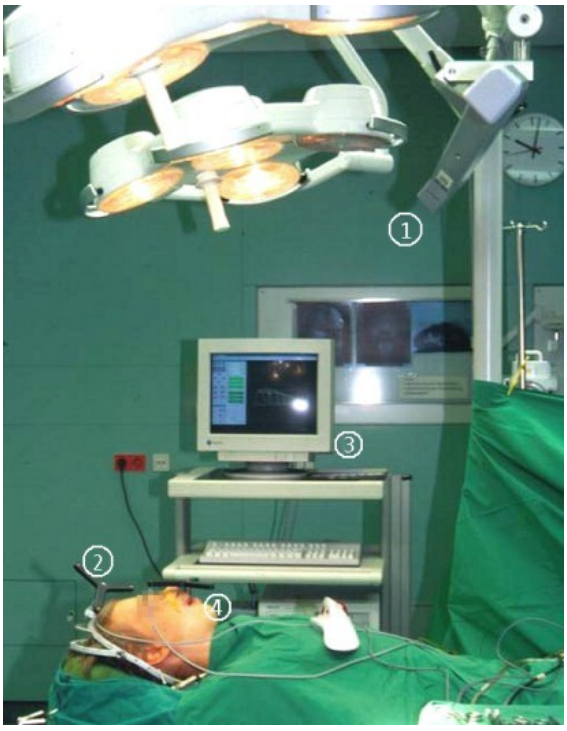
9.5.2 Materials and devices needed for preoperative planning and simulation

The osteotomies performed in orthognathic surgery are classically planned on cast models of the tooth-bearing jaws, fixed in an articulator. For edentulous patients, the surgical planning is made by using stereolithographic models. These tridimensional models are then cut along

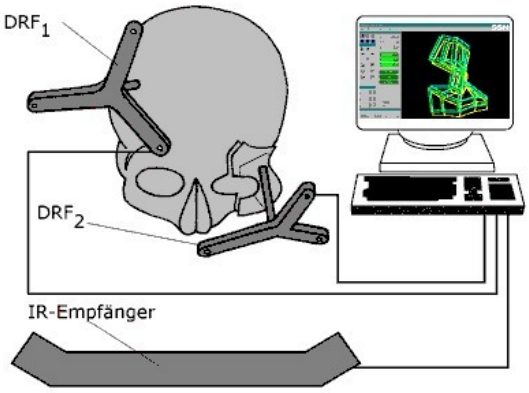
the planned osteothomy line, slid and fixed in the new position. Since the 1990s, modern techniques of presurgical planning were developed – allowing the surgeon to plan and simulate the osteotomy in a virtual environment, based on a preoperative CT or MRI; this procedure reduces the costs and the duration of creating, positioning, cutting, repositioning and refixing the cast models for each patient. The first system that allowed such a surgical simulation environment is the Laboratory Unit for Computer Assisted Surgery (LUCAS), that was developed in 1998 at the University of Regensburg, Germany, with the support of the Carl Zeiss Company.

9.5.3 Transferring the preoperative planning to the operating theatre

The usefulness of the preoperative planning, no matter how accurate, depends on the accuracy of the reproduction of the simulated osteotomy in the surgical field. The transfer of the planning was mainly based on the surgeon's visual skills. Different guiding headframes were further developed to mechanically guide bone fragment repositioning. Such a headframe is attached to the patient's head, during CT or MRI, and surgery. There are certain difficulties in using this device. First, exact reproducibility of the headframe position on the patient's head is needed, both during CT or MRI registration, and during surgery. The headframe is relatively uncomfortable to wear, and very difficult or even impossible to use on small children, who can be uncooperative during medical procedures.



Using the SSN in the operating theatre; 1=IR receiver, 2 and 4=IR Reference devices, 3=SSN-Workstation



Schematic representation of the principle of bone segment navigation; DRF1 and DRF2 = IR Reference devices

9.5.4 Surgical Segment Navigator

The first system that allowed a seamless bone segment navigation for preoperative planning was the Surgical Segment Navigator (SSN), developed in 1997 at the University of Regensburg, Germany, with the support of the Carl Zeiss Company.* [1] This new system does not need any mechanical surgical guides (such as a headframe). It is based on an infrared (IR) camera and IR transmitters attached to the skull. At least three IR transmitters are attached in the neurocranium area to compensate the movements of the patient's head. There are three or more IR transmitters are attached to the bones where the osteotomy and bone repositioning is about to be performed onto. The 3D position of each transmitter is measured by the IR camera, using the same principle as in satellite navigation. The workstation of the Surgical Segment Navigator (SSN) is constantly visualizing the actual position of the bone fragments, compared with the predetermined position, and also makes real-time spatial determinations of the free-moving bony segments resulting from the osteotomy. Thus, fragments can be very accurately positioned into the target position, predetermined by surgical simulation.

9.5.5 Indications for the hard tissue segment navigation method

The hard tissue segment navigation is more and more frequently used in orthognatic surgery (correction of the anomalies of the jaws and skull), in temporo-mandibular joint (TMJ) surgery, or in the reconstruction of the midface and orbit.

9.5.6 References

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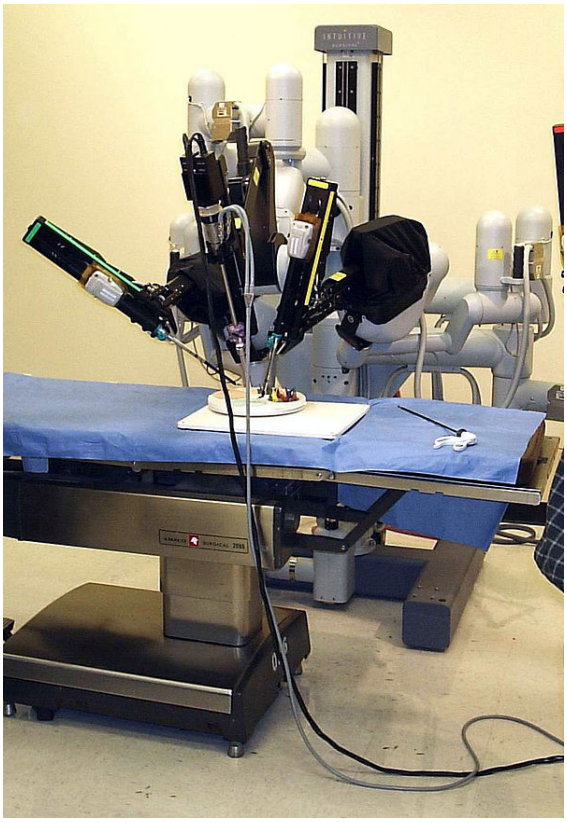
9.6 Robot-assisted heart surgery



A robotically assisted surgical system used for prostatectomies, cardiac valve repair and gynecologic surgical procedures

Robotic surgery, computer-assisted surgery, and robotically-assisted surgery are terms for technological developments that use robotic systems to aid in surgical procedures. Robotically-assisted surgery was developed to overcome the limitations of pre-existing minimally-invasive surgical procedures and to enhance the capabilities of surgeons performing open surgery.

In the case of robotically-assisted minimally-invasive surgery, instead of directly moving the instruments, the surgeon uses one of two methods to control the instruments; either a direct telemanipulator or through computer control. A telemanipulator is a remote manipulator that allows the surgeon to perform the normal movements associated with the surgery whilst the robotic arms carry out those movements using end-effectors and manipulators to perform the actual surgery on the patient. In computer-controlled systems the surgeon uses a computer to control the robotic arms and its end-effectors, though these systems can also still use telemanipulators for their input. One advantage of using the computerised method is that the surgeon does not have to be present, but can be anywhere in the world, leading to the possibility for remote surgery.

In the case of enhanced open surgery, autonomous instruments (in familiar configurations) replace traditional steel tools, performing certain actions (such as rib spreading) with much smoother, feedback-controlled motions than could be achieved by a human hand. The main object of such smart instruments is to reduce or eliminate the tissue trauma traditionally associated with open surgery without requiring more than a few minutes' training on the part of surgeons. This approach seeks to improve open surgeries, particularly cardio-thoracic, that have so far not benefited from minimally-invasive techniques.

Robotic surgery has been criticized for its expense, by one estimate costing $1,500 to $2000 more per patient.*[1]

9.6.1 Comparison to traditional methods

Major advances aided by surgical robots have been remote surgery, minimally invasive surgery and unmanned surgery. Due to robotic use, the surgery is done with precision, miniaturization, smaller incisions; decreased blood loss, less pain, and quicker healing time. Articulation beyond normal manipulation and three-dimensional magnification helps resulting in improved ergonomics. Due to these techniques there is a reduced duration of hospital stays, blood loss, transfusions, and use of pain medication.*[2] The existing open surgery technique has many flaws like limited access to surgical area, long recovery time, long hours of operation, blood loss, surgical scars and marks.*[3]

The robot normally costs $1,390,000 and while its disposable supply cost is normally $1,500 per procedure, the cost of the procedure is higher.*[4] Additional surgical training is needed to operate the system.*[5] Numerous feasibility studies have been done to determine whether the purchase of such systems are worthwhile. As it stands, opinions differ dramatically. Surgeons report that, although the manufacturers of such systems provide training on this new technology, the learning phase is intensive and surgeons must operate on twelve to eighteen patients before they adapt. During the training phase, minimally invasive operations can take up to twice as long as traditional surgery, leading to operating room tie ups and surgical staffs keeping patients under anesthesia for longer periods. Patient surveys indicate they chose the procedure based on expectations of decreased morbidity, improved outcomes, reduced blood loss and less pain.*[2] Higher expectations may explain higher rates of dissatisfaction and regret.*[5]

Compared with other minimally invasive surgery approaches, robot-assisted surgery gives the surgeon better control over the surgical instruments and a better view of the surgical site. In addition, surgeons no longer have to stand throughout the surgery and do not tire as quickly. Naturally occurring hand tremors are filtered out by the robot's computer software. Finally, the surgical robot can continuously be used by rotating surgery teams.*[6]

Critics of the system, including the American Congress of Obstetricians and Gynecologists,[*][7] say there is a steep learning curve for surgeons who adopt use of the system and that there's a lack of studies that indicate long-term results are superior to results following traditional laparoscopic surgery.[*][4] Articles in the newly created *Journal of Robotic Surgery* tend to report on one surgeon's experience.[*][4]

A Medicare study found that some procedures that have traditionally been performed with large incisions can be converted to "minimally invasive" endoscopic procedures with the use of the Da Vinci, shortening length-of-stay in the hospital and reducing recovery times. But because of the hefty cost of the robotic system it is not clear that it is cost-effective for hospitals and physicians despite any benefits to patients since there is no additional reimbursement paid by the government or insurance companies when the system is used.[*][4]

Robot-assisted pancreatectomies have been found to be associated with "longer operating time, lower estimated blood loss, a higher spleen-preservation rate, and shorter hospital stay[s]" than laparoscopic pancreatectomies; there was "no significant difference in transfusion, conversion to open surgery, overall complications, severe complications, pancreatic fistula, severe pancreatic fistula, ICU stay, total cost, and 30-day mortality between the two groups." [*][8]

Robotic surgery has been criticized for its expense, by one estimate costing $1,500 to $2000 more per patient.[*][1]

9.6.2 Uses

General surgery

In early 2000 the field of general surgical interventions with the daVinci device was explored by surgeons at Ohio State University. Reports were published in esophageal and pancreatic surgery for the first time in the world and further data was subsequently published by Horgan and his group at the University of Illinois and then later at the same institution by others.[*][9][*][10] In 2007, the University of Illinois at Chicago medical team, led by Prof. Pier Cristoforo Giulianotti, reported a pancreatectomy and also the Midwest's first fully robotic Whipple surgery. In April 2008, the same team of surgeons performed the world's first fully minimally invasive liver resection for living donor transplantation, removing 60% of the patient's liver, yet allowing him to leave the hospital just a couple of days after the procedure, in very good condition. Furthermore, the patient can also leave with less pain than a usual surgery due to the four puncture holes and not a scar by a surgeon.[*][11]

Cardiothoracic surgery

Robot-assisted MIDCAB and Endoscopic coronary artery bypass (TECAB) operations are being performed with the Da Vinci system. Mitral valve repairs and replacements have been performed. The Ohio State University, Columbus has performed CABG, mitral valve, esophagectomy, lung resection, tumor resections, among other robotic assisted procedures and serves as a training site for other surgeons. In 2002, surgeons at the Cleveland Clinic in Florida reported and published their preliminary experience with minimally invasive "hybrid" procedures. These procedures combined robotic revascularization and coronary stenting and further expanded the role of robots in coronary bypass to patients with disease in multiple vessels. Ongoing research on the outcomes of robotic assisted CABG and hybrid CABG is being done.

Cardiology and electrophysiology

The Stereotaxis Magnetic Navigation System (MNS) has been developed to increase precision and safety in ablation procedures for arrhythmias and atrial fibrillation while reducing radiation exposure for the patient and physician, and the system utilizes two magnets to remotely steerable catheters. The system allows for automated 3-D mapping of the heart and vasculature, and MNS has also been used in interventional cardiology for guiding stents and leads in PCI and CTO procedures, proven to reduce contrast usage and access tortuous anatomy unreachable by manual navigation. Dr. Andrea Natale has referred to the new Stereotaxis procedures with the magnetic irrigated catheters as "revolutionary." [*][12]

The Hansen Medical Sensei robotic catheter system uses a remotely operated system of pulleys to navigate a steerable sheath for catheter guidance. It allows precise and more forceful positioning of catheters used for 3-D mapping of the heart and vasculature. The system provides doctors with estimated force feedback information and feasible manipulation within the left atrium of the heart. The Sensei has been associated with mixed acute success rates compared to manual, commensurate with higher procedural complications, longer procedure times but lower fluoroscopy dosage to the patient.[*][13][*][14][*][15]

At present, three types of heart surgery are being performed on a routine basis using robotic surgery systems.[*][16] These three surgery types are:

- Atrial septal defect repair – the repair of a hole between the two upper chambers of the heart,
- Mitral valve repair – the repair of the valve that prevents blood from regurgitating back into the upper heart chambers during contractions of the heart,
- Coronary artery bypass – rerouting of blood supply

by bypassing blocked arteries that provide blood to the heart.

As surgical experience and robotic technology develop, it is expected that the applications of robots in cardiovascular surgery will expand.

Colon and rectal surgery

Many studies have been undertaken in order to examine the role of robotic procedures in the field of colorectal surgery.*[17]*[18]

Results to date indicate that robotic-assisted colorectal procedures outcomes are "no worse" than the results in the now "traditional" laparoscopic colorectal operations. Robotic-assisted colorectal surgery appears to be safe as well.*[19] Most of the procedures have been performed for malignant colon and rectal lesions. However, surgeons are now moving into resections for diverticulitis and non-resective rectopexies (attaching the colon to the sacrum in order to treat rectal prolapse.)

When evaluated for several variables, robotic-assisted procedures fare equally well when compared with laparoscopic, or open abdominal operations. Study parameters have looked at intraoperative patient preparation time, length of time to perform the operation, adequacy of the removed surgical specimen with respect to clear surgical margins and number of lymph nodes removed, blood loss, operative or postoperative complications and long-term results.

More difficult to evaluate are issues related to the view of the operative field, the types of procedures that should be performed using robotic assistance and the potential added cost for a robotic operation.

Many surgeons feel that the optics of the 3-dimensional, two camera stereo optic robotic system are superior to the optical system used in laparoscopic procedures. The pelvic nerves are clearly visualized during robotic-assisted procedures. Less clear however is whether or not these supposedly improved optics and visualization improve patient outcomes with respect to postoperative impotence or incontinence, and whether long-term patient survival is improved by using the 3-dimensional optic system. Additionally, there is often a need for a wider, or "larger" view of the operative field than is routinely provided during robotic operations.,*[20] The close-up view of the area under dissection may hamper visualization of the "bigger view", especially with respect to ureteral protection.

Questions remain unanswered, even after many years of experience with robotic-assisted colorectal operations. Ongoing studies may help clarify many of the issues of confusion associated with this novel surgical approach.

Gastrointestinal surgery

Multiple types of procedures have been performed with either the 'Zeus' or da Vinci robot systems, including bariatric surgery and gastrectomy*[21] for cancer. Surgeons at various universities initially published case series demonstrating different techniques and the feasibility of GI surgery using the robotic devices.*[10] Specific procedures have been more fully evaluated, specifically esophageal fundoplication for the treatment of gastroesophageal reflux*[22] and Heller myotomy for the treatment of achalasia.*[23]*[24]

Other gastrointestinal procedures including colon resection, pancreatectomy, esophagectomy and robotic approaches to pelvic disease have also been reported.

Gynecology

Robotic surgery in gynecology is of uncertain benefit with it being unclear if it affects rates of complications. Gynecologic procedures may take longer with robot-assisted surgery but may be associated with a shorter hospital stay following hysterectomy.*[25] In the United States, robotic-assisted hysterectomy for benign conditions has been shown to be more expensive than conventional laparoscopic hysterectomy, with no difference in overall rates of complications.*[26]

This includes the use of the da Vinci surgical system in benign gynecology and gynecologic oncology. Robotic surgery can be used to treat fibroids, abnormal periods, endometriosis, ovarian tumors, uterine prolapse, and female cancers. Using the robotic system, gynecologists can perform hysterectomies, myomectomies, and lymph node biopsies.

Neurosurgery

Several systems for stereotactic intervention are currently on the market. The NeuroMate was the first neurosurgical robot, commercially available in 1997.*[27] Originally developed in Grenoble by Alim-Louis_Benabid's team, it is now owned by Renishaw. With installations in the United States, Europe and Japan, the system has been used in 8000 stereotactic brain surgeries by 2009. IMRIS Inc.'s SYMBIS(TM) Surgical System*[28] will be the version of NeuroArm, the world's first MRI-compatible surgical robot, developed for world-wide commercialization. Medtech's Rosa is being used by several institutions, including the Cleveland Clinic in the U.S, and in Canada at Sherbrooke University and the Montreal Neurological Institute and Hospital in Montreal (MNI/H). Between June 2011 and September 2012, over 150 neurosurgical procedures at the MNI/H have been completed robotized stereotaxy, including in the placement of depth electrodes in the treatment of epilepsy, selective resections, and stereotaxic biopsies.

Orthopedics

The ROBODOC system was released in 1992 by Integrated Surgical Systems, Inc. which merged into CUREXO Technology Corporation.*[29] Also, The Acrobot Company Ltd. developed the "Acrobot Sculptor", a robot that constrained a bone cutting tool to a pre-defined volume. The "Acrobot Sculptor" was sold to Stanmore Implants in August 2010. Stanmore received FDA clearance in February 2013 for US surgeries but sold the Sculptor to Mako Surgical in June 2013 to resolve a patent infringement lawsuit.*[30] Another example is the CASPAR robot produced by U.R.S.-Ortho GmbH & Co. KG, which is used for total hip replacement, total knee replacement and anterior cruciate ligament reconstruction.*[31] MAKO Surgical Corp (founded 2004) produces the RIO (Robotic Arm Interactive Orthopedic System) which combines robotics, navigation, and haptics for both partial knee and total hip replacement surgery.*[32] Blue Belt Technologies received FDA clearance in November 2012 for the Navio™ Surgical System. The Navio System is a navigated, robotics-assisted surgical system that uses a CT free approach to assist in partial knee replacement surgery.*[33]

Pediatrics

Surgical robotics has been used in many types of pediatric surgical procedures including: tracheoesophageal fistula repair, cholecystectomy, nissen fundoplication, morgagni's hernia repair, kasai portoenterostomy, congenital diaphragmatic hernia repair, and others. On 17 January 2002, surgeons at Children's Hospital of Michigan in Detroit performed the nation's first advanced computer-assisted robot-enhanced surgical procedure at a children's hospital.

The Center for Robotic Surgery at Children's Hospital Boston provides a high level of expertise in pediatric robotic surgery. Specially-trained surgeons use a high-tech robot to perform complex and delicate operations through very small surgical openings. The results are less pain, faster recoveries, shorter hospital stays, smaller scars, and happier patients and families.

In 2001, Children's Hospital Boston was the first pediatric hospital to acquire a surgical robot. Today, surgeons use the technology for many procedures and perform more pediatric robotic operations than any other hospital in the world. Children's Hospital physicians have developed a number of new applications to expand the use of the robot, and train surgeons from around the world on its use.*[34]

Radiosurgery

The CyberKnife Robotic Radiosurgery System uses image guidance and computer controlled robotics to treat tumors throughout the body by delivering multiple beams of high-energy radiation to the tumor from virtually any direction. The system uses a German KUKA KR 240. Mounted on the robot is a compact X-band linac that produces 6MV X-ray radiation. Mounting the radiation source on the robot allows very fast repositioning of the source, which enables the system to deliver radiation from many different directions without the need to move both the patient and source as required by current gantry configurations.

Transplant surgery

Transplant surgery (organ transplantation) has been considered as highly technically demanding and virtually unobtainable by means of conventional laparoscopy. For many years, transplant patients were unable to benefit from the advantages of minimally invasive surgery. The development of robotic technology and its associated high resolution capabilities, three dimensional visual system, wrist type motion and fine instruments, gave opportunity for highly complex procedures to be completed in a minimally invasive fashion. Subsequently, the first fully robotic kidney transplantations were performed in the late 2000s. After the procedure was proven to be feasible and safe, the main emerging challenge was to determine which patients would benefit most from this robotic technique. As a result, recognition of the increasing prevalence of obesity amongst patients with kidney failure on hemodialysis posed a significant problem. Due to the abundantly higher risk of complications after traditional open kidney transplantation, obese patients were frequently denied access to transplantation, which is the premium treatment for end stage kidney disease. The use of the robotic-assisted approach has allowed kidneys to be transplanted with minimal incisions, which has virtually alleviated wound complications and significantly shortened the recovery period. The University of Illinois Medical Center reported the largest series of 104 robotic-assisted kidney transplants for obese recipients (mean body mass index > 42). Amongst this group of patients, no wound infections were observed and the function of transplanted kidneys was excellent. In this way, robotic kidney transplantation could be considered as the biggest advance in surgical technique for this procedure since its creation more than half a century ago.*[35]*[36]*[37]

Urology

Robotic surgery in the field of urology has become very popular, especially in the United States.*[38] It has been most extensively applied for excision of prostate cancer because of difficult anatomical access. It is also utilized for kidney cancer surgeries and to lesser extent surgeries of the bladder.

As of 2014, there is little evidence of increased benefits compared to standard surgery to justify the increased

costs.*[39] Some have found tentative evidence of more complete removal of cancer and less side effects from surgery for prostatectomy.*[40]

In 2000, the first robot-assisted laparoscopic radical prostatectomy was performed.*[5]

Vascular surgery

In September 2010, the first robotic operations with Hansen Medical's Magellan Robotic System at the femoral vasculature were performed at the University Medical Centre Ljubljana (UMC Ljubljana), Slovenia. The research was led by Borut Geršak, the head of the Department of Cardiovascular Surgery at the centre. Geršak explained that the robot used was the first true robot in the history of robotic surgery, meaning the user interface was not resembling surgical instruments and the robot was not simply imitating the movement of human hands but was guided by pressing buttons, just like one would play a video game. The robot was imported to Slovenia from the United States.*[41]*[42]

9.6.3 Miniature robotics

As scientists seek to improve the versatility and utility of robotics in surgery, some are attempting to miniaturize the robots. For example, the University of Nebraska Medical Center has led a multi-campus effort to provide collaborative research on mini-robotics among surgeons, engineers and computer scientists.*[43]

9.6.4 History

The first robot to assist in surgery was the *Arthrobot*, which was developed and used for the first time in Vancouver in 1983.*[44] Intimately involved were biomedical engineer, Dr. James McEwen, Geof Auchinleck, a UBC engineering physics grad, and Dr. Brian Day as well as a team of engineering students. The robot was used in an orthopaedic surgical procedure on 12 March 1984, at the UBC Hospital in Vancouver. Over 60 arthroscopic surgical procedures were performed in the first 12 months, and a 1985 National Geographic video on industrial robots, *The Robotics Revolution*, featured the device. Other related robotic devices developed at the same time included a surgical scrub nurse robot, which handed operative instruments on voice command, and a medical laboratory robotic arm. A YouTube video entitled *Arthrobot* illustrates some of these in operation.

In 1985 a robot, the Unimation Puma 200, was used to place a needle for a brain biopsy using CT guidance.*[45] In 1992, the PROBOT, developed at Imperial College London, was used to perform prostatic surgery by Dr. Senthil Nathan at Guy's and St Thomas' Hospital, London. This was the first pure robotic surgery in the world. Also the Robot Puma 560, a robot developed in 1985 by Kwoh et al. Puma 560 was used to perform neurosurgical biopsies with greater precision. Just like with any other technological innovation, this system led to the development of new and improved surgical robot called PROBOT. The PROBOT was specifically designed for transurethral resection of the prostate. Meanwhile, when PROBOT was being developed, ROBODOC, a robotic system designed to assist hip replacement surgeries was the first surgical robot that was approved by the FDA.*[46] The ROBODOC from Integrated Surgical Systems (working closely with IBM) was introduced in 1992 to mill out precise fittings in the femur for hip replacement.*[47] The purpose of the ROBODOC was to replace the previous method of carving out a femur for an implant, the use of a mallet and broach/rasp.

Further development of robotic systems was carried out by SRI International and Intuitive Surgical with the introduction of the da Vinci Surgical System and Computer Motion with the *AESOP* and the ZEUS robotic surgical system.*[48] The first robotic surgery took place at The Ohio State University Medical Center in Columbus, Ohio under the direction of Robert E. Michler.*[49] Examples of using ZEUS include a fallopian tube reconnection in July 1998,*[50] a *beating heart* coronary artery bypass graft in October 1999,*[51] and the Lindbergh Operation, which was a cholecystectomy performed remotely in September 2001.*[52]

The original telesurgery robotic system that the da Vinci was based on was developed at SRI International in Menlo Park with grant support from DARPA and NASA.*[53] Although the telesurgical robot was originally intended to facilitate remotely performed surgery in battlefield and other remote environments, it turned out to be more useful for minimally invasive on-site surgery. The patents for the early prototype were sold to Intuitive Surgical in Mountain View, California. The da Vinci senses the surgeon's hand movements and translates them electronically into scaled-down micro-movements to manipulate the tiny proprietary instruments. It also detects and filters out any tremors in the surgeon's hand movements, so that they are not duplicated robotically. The camera used in the system provides a true stereoscopic picture transmitted to a surgeon's console. Examples of using the da Vinci system include the first robotically assisted heart bypass (performed in Germany) in May 1998, and the first performed in the United States in September 1999; and the first all-robotic-assisted kidney transplant, performed in January 2009.*[54] The da Vinci Si was released in April 2009, and initially sold for $1.75 million.*[55]

In May 2006 the first artificial intelligence doctor-conducted unassisted robotic surgery on a 34-year-old male to correct heart arythmia. The results were rated as better than an above-average human surgeon. The machine had a database of 10,000 similar operations, and so,

in the words of its designers, was "more than qualified to operate on any patient".[*][56][*][57] In August 2007, Dr. Sijo Parekattil of the Robotics Institute and Center for Urology (Winter Haven Hospital and University of Florida) performed the first robotic assisted microsurgery procedure denervation of the spermatic cord for chronic testicular pain.[*][58] In February 2008, Dr. Mohan S. Gundeti of the University of Chicago Comer Children's Hospital performed the first robotic pediatric neurogenic bladder reconstruction.[*][59]

On 12 May 2008, the first image-guided MR-compatible robotic neurosurgical procedure was performed at University of Calgary by Dr. Garnette Sutherland using the NeuroArm.[*][60] In June 2008, the German Aerospace Centre (DLR) presented a robotic system for minimally invasive surgery, the MiroSurge.[*][61] In September 2010, the Eindhoven University of Technology announced the development of the Sofie surgical system, the first surgical robot to employ force feedback.[*][62] In September 2010, the first robotic operation at the femoral vasculature was performed at the University Medical Centre Ljubljana by a team led by Borut Geršak.[*][41][*][42]

9.6.5 See also

- Bone segment navigation
- Computer-assisted surgery
- Computer-integrated surgery
- Minimally invasive surgery
- Patient registration
- Stereolithography (medicine)
- Surgical Segment Navigator
- Telemedicine

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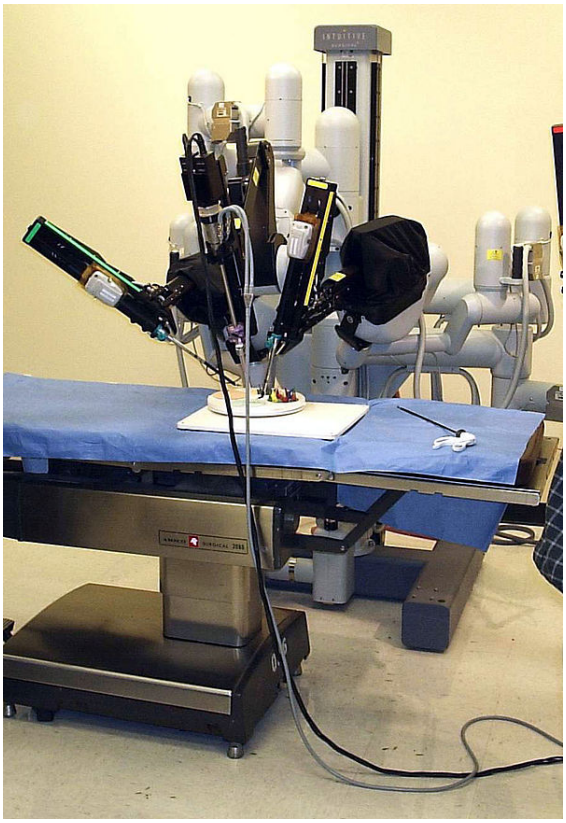
9.6.7 External links

9.7 Robot-assisted heart surgery



A robotically assisted surgical system used for prostatectomies, cardiac valve repair and gynecologic surgical procedures

Robotic surgery, computer-assisted surgery, and robotically-assisted surgery are terms for technological developments that use robotic systems to aid in surgical procedures. Robotically-assisted surgery was developed to overcome the limitations of pre-existing minimally-invasive surgical procedures and to enhance the capabilities of surgeons performing open surgery.

In the case of robotically-assisted minimally-invasive surgery, instead of directly moving the instruments, the surgeon uses one of two methods to control the instruments; either a direct telemanipulator or through computer control. A telemanipulator is a remote manipulator that allows the surgeon to perform the normal movements associated with the surgery whilst the robotic arms carry out those movements using end-effectors and manipulators to perform the actual surgery on the patient. In computer-controlled systems the surgeon uses a computer to control the robotic arms and its end-effectors, though these systems can also still use telemanipulators for their input. One advantage of using the computerised method is that the surgeon does not have to be present, but can be anywhere in the world, leading to the possibility for remote surgery.

In the case of enhanced open surgery, autonomous instruments (in familiar configurations) replace traditional steel tools, performing certain actions (such as rib spreading) with much smoother, feedback-controlled motions than could be achieved by a human hand. The main object of such smart instruments is to reduce or eliminate the tissue trauma traditionally associated with open surgery without requiring more than a few minutes' training on the part of surgeons. This approach seeks to improve open surgeries, particularly cardio-thoracic, that have so far not benefited from minimally-invasive techniques.

Robotic surgery has been criticized for its expense, by one estimate costing $1,500 to $2000 more per patient.*[1]

9.7.1 Comparison to traditional methods

Major advances aided by surgical robots have been remote surgery, minimally invasive surgery and unmanned surgery. Due to robotic use, the surgery is done with precision, miniaturization, smaller incisions; decreased blood loss, less pain, and quicker healing time. Articulation beyond normal manipulation and three-dimensional magnification helps resulting in improved ergonomics. Due to these techniques there is a reduced duration of hospital stays, blood loss, transfusions, and use of pain medication.*[2] The existing open surgery technique has many flaws like limited access to surgical area, long recovery time, long hours of operation, blood loss, surgical scars and marks.*[3]

The robot normally costs $1,390,000 and while its disposable supply cost is normally $1,500 per procedure, the cost of the procedure is higher.*[4] Additional surgical training is needed to operate the system.*[5] Numerous feasibility studies have been done to determine whether the purchase of such systems are worthwhile. As it stands, opinions differ dramatically. Surgeons report that, although the manufacturers of such systems provide training on this new technology, the learning phase is intensive and surgeons must operate on twelve to eighteen patients before they adapt. During the training phase, minimally invasive operations can take up to twice as long as traditional surgery, leading to operating room tie ups and surgical staffs keeping patients under anesthesia for longer periods. Patient surveys indicate they chose the procedure based on expectations of decreased morbidity, improved outcomes, reduced blood loss and less pain.*[2] Higher expectations may explain higher rates of dissatisfaction and regret.*[5]

Compared with other minimally invasive surgery approaches, robot-assisted surgery gives the surgeon better control over the surgical instruments and a better view of the surgical site. In addition, surgeons no longer have to stand throughout the surgery and do not tire as quickly. Naturally occurring hand tremors are filtered out by the robot's computer software. Finally, the surgical robot can continuously be used by rotating surgery teams.*[6]

Critics of the system, including the American Congress of Obstetricians and Gynecologists,*[7] say there is a steep learning curve for surgeons who adopt use of the system and that there's a lack of studies that indicate long-term results are superior to results following traditional laparoscopic surgery.*[4] Articles in the newly created *Journal of Robotic Surgery* tend to report on one surgeon's experience.*[4]

A Medicare study found that some procedures that have traditionally been performed with large incisions can be converted to "minimally invasive" endoscopic procedures with the use of the Da Vinci, shortening length-of-stay in the hospital and reducing recovery times. But because of the hefty cost of the robotic system it is not clear that it is cost-effective for hospitals and physicians despite any benefits to patients since there is no additional reimbursement paid by the government or insurance companies when the system is used.*[4]

Robot-assisted pancreatectomies have been found to be associated with "longer operating time, lower estimated blood loss, a higher spleen-preservation rate, and shorter hospital stay[s]" than laparoscopic pancreatectomies; there was "no significant difference in transfusion, conversion to open surgery, overall complications, severe complications, pancreatic fistula, severe pancreatic fistula, ICU stay, total cost, and 30-day mortality between the two groups." *[8]

Robotic surgery has been criticized for its expense, by one estimate costing $1,500 to $2000 more per patient.*[1]

9.7.2 Uses

General surgery

In early 2000 the field of general surgical interventions with the daVinci device was explored by surgeons at Ohio State University. Reports were published in esophageal and pancreatic surgery for the first time in the world and further data was subsequently published by Horgan and his group at the University of Illinois and then later at the same institution by others.*[9]*[10] In 2007, the University of Illinois at Chicago medical team, led by Prof. Pier Cristoforo Giulianotti, reported a pancreatectomy and also the Midwest's first fully robotic Whipple surgery. In April 2008, the same team of surgeons performed the world's first fully minimally invasive liver resection for living donor transplantation, removing 60% of the patient's liver, yet allowing him to leave the hospital just a couple of days after the procedure, in very good condition. Furthermore, the patient can also leave with less pain than a usual surgery due to the four puncture holes and not a scar by a surgeon.*[11]

Cardiothoracic surgery

Robot-assisted MIDCAB and Endoscopic coronary artery bypass (TECAB) operations are being performed with the Da Vinci system. Mitral valve repairs and replacements have been performed. The Ohio State University, Columbus has performed CABG, mitral valve, esophagectomy, lung resection, tumor resections, among other robotic assisted procedures and serves as a training site for other surgeons. In 2002, surgeons at the Cleveland Clinic in Florida reported and published their preliminary experience with minimally invasive "hybrid" procedures. These procedures combined robotic revascularization and coronary stenting and further expanded the role of robots in coronary bypass to patients with disease in multiple vessels. Ongoing research on the outcomes of robotic assisted CABG and hybrid CABG is being done.

Cardiology and electrophysiology

The Stereotaxis Magnetic Navigation System (MNS) has been developed to increase precision and safety in ablation procedures for arrhythmias and atrial fibrillation while reducing radiation exposure for the patient and physician, and the system utilizes two magnets to remotely steerable catheters. The system allows for automated 3-D mapping of the heart and vasculature, and MNS has also been used in interventional cardiology for guiding stents and leads in PCI and CTO procedures, proven to reduce contrast usage and access tortuous anatomy unreachable by manual navigation. Dr. Andrea Natale has referred to the new Stereotaxis procedures with the magnetic irrigated catheters as "revolutionary." *[12]

The Hansen Medical Sensei robotic catheter system uses a remotely operated system of pulleys to navigate a steerable sheath for catheter guidance. It allows precise and more forceful positioning of catheters used for 3-D mapping of the heart and vasculature. The system provides doctors with estimated force feedback information and feasible manipulation within the left atrium of the heart. The Sensei has been associated with mixed acute success rates compared to manual, commensurate with higher procedural complications, longer procedure times but lower fluoroscopy dosage to the patient.*[13]*[14]*[15]

At present, three types of heart surgery are being performed on a routine basis using robotic surgery systems.*[16] These three surgery types are:

- Atrial septal defect repair – the repair of a hole between the two upper chambers of the heart,
- Mitral valve repair – the repair of the valve that prevents blood from regurgitating back into the upper heart chambers during contractions of the heart,
- Coronary artery bypass – rerouting of blood supply by bypassing blocked arteries that provide blood to the heart.

As surgical experience and robotic technology develop, it is expected that the applications of robots in cardiovascular surgery will expand.

Colon and rectal surgery

Many studies have been undertaken in order to examine the role of robotic procedures in the field of colorectal surgery.*[17]*[18]

Results to date indicate that robotic-assisted colorectal procedures outcomes are "no worse" than the results in the now "traditional" laparoscopic colorectal operations. Robotic-assisted colorectal surgery appears to be safe as well.*[19] Most of the procedures have been performed for malignant colon and rectal lesions. However, surgeons are now moving into resections for diverticulitis and non-resective rectopexies (attaching the colon to the sacrum in order to treat rectal prolapse.)

When evaluated for several variables, robotic-assisted procedures fare equally well when compared with laparoscopic, or open abdominal operations. Study parameters have looked at intraoperative patient preparation time, length of time to perform the operation, adequacy of the removed surgical specimen with respect to clear surgical margins and number of lymph nodes removed, blood loss, operative or postoperative complications and long-term results.

More difficult to evaluate are issues related to the view of the operative field, the types of procedures that should be performed using robotic assistance and the potential added cost for a robotic operation.

Many surgeons feel that the optics of the 3-dimensional, two camera stereo optic robotic system are superior to the optical system used in laparoscopic procedures. The pelvic nerves are clearly visualized during robotic-assisted procedures. Less clear however is whether or not these supposedly improved optics and visualization improve patient outcomes with respect to postoperative impotence or incontinence, and whether long-term patient survival is improved by using the 3-dimensional optic system. Additionally, there is often a need for a wider, or "larger" view of the operative field than is routinely provided during robotic operations.,*[20] The close-up view of the area under dissection may hamper visualization of the "bigger view", especially with respect to ureteral protection.

Questions remain unanswered, even after many years of experience with robotic-assisted colorectal operations. Ongoing studies may help clarify many of the issues of confusion associated with this novel surgical approach.

Gastrointestinal surgery

Multiple types of procedures have been performed with either the 'Zeus' or da Vinci robot systems, including bariatric surgery and gastrectomy*[21] for cancer. Surgeons at various universities initially published case series demonstrating different techniques and the feasibility of GI surgery using the robotic devices.*[10] Specific procedures have been more fully evaluated, specifically esophageal fundoplication for the treatment of gastroesophageal reflux*[22] and Heller myotomy for the treatment of achalasia.*[23]*[24]

Other gastrointestinal procedures including colon resection, pancreatectomy, esophagectomy and robotic approaches to pelvic disease have also been reported.

Gynecology

Robotic surgery in gynecology is of uncertain benefit with it being unclear if it affects rates of complications. Gynecologic procedures may take longer with robot-assisted surgery but may be associated with a shorter hospital stay following hysterectomy.*[25] In the United States, robotic-assisted hysterectomy for benign conditions has been shown to be more expensive than conventional laparoscopic hysterectomy, with no difference in overall rates of complications.*[26]

This includes the use of the da Vinci surgical system in benign gynecology and gynecologic oncology. Robotic surgery can be used to treat fibroids, abnormal periods, endometriosis, ovarian tumors, uterine prolapse, and female cancers. Using the robotic system, gynecologists can perform hysterectomies, myomectomies, and lymph node biopsies.

Neurosurgery

Several systems for stereotactic intervention are currently on the market. The NeuroMate was the first neurosurgical robot, commercially available in 1997.*[27] Originally developed in Grenoble by Alim-Louis_Benabid's team, it is now owned by Renishaw. With installations in the United States, Europe and Japan, the system has been used in 8000 stereotactic brain surgeries by 2009. IMRIS Inc.'s SYMBIS(TM) Surgical System*[28] will be the version of NeuroArm, the world's first MRI-compatible surgical robot, developed for world-wide commercialization. Medtech's Rosa is being used by several institutions, including the Cleveland Clinic in the U.S, and in Canada at Sherbrooke University and the Montreal Neurological Institute and Hospital in Montreal (MNI/H). Between June 2011 and September 2012, over 150 neurosurgical procedures at the MNI/H have been completed robotized stereotaxy, including in the placement of depth electrodes in the treatment of epilepsy, selective resections, and stereotaxic biopsies.

Orthopedics

The ROBODOC system was released in 1992 by Integrated Surgical Systems, Inc. which merged into CUREXO Technology Corporation.*[29] Also, The Acrobot Company Ltd. developed the "Acrobot Sculptor", a robot that constrained a bone cutting tool to a pre-defined volume. The "Acrobot Sculptor" was sold to Stanmore Implants in August 2010. Stanmore received FDA clearance in February 2013 for US surgeries but sold the Sculptor to Mako Surgical in June 2013 to resolve a patent infringement lawsuit.*[30] Another example is the CASPAR robot produced by U.R.S.-Ortho GmbH & Co. KG, which is used for total hip replacement, total knee replacement and anterior cruciate ligament reconstruction.*[31] MAKO Surgical Corp (founded 2004) produces the RIO (Robotic Arm Interactive Orthopedic System) which combines robotics, navigation, and haptics for both partial knee and total hip replacement surgery.*[32] Blue Belt Technologies received FDA clearance in November 2012 for the Navio™ Surgical System. The Navio System is a navigated, robotics-assisted surgical system that uses a CT free approach to assist in partial knee replacement surgery.*[33]

Pediatrics

Surgical robotics has been used in many types of pediatric surgical procedures including: tracheoesophageal fistula repair, cholecystectomy, nissen fundoplication, morgagni's hernia repair, kasai portoenterostomy, congenital diaphragmatic hernia repair, and others. On 17 January 2002, surgeons at Children's Hospital of Michigan in Detroit performed the nation's first advanced computer-assisted robot-enhanced surgical procedure at a children's hospital.

The Center for Robotic Surgery at Children's Hospital Boston provides a high level of expertise in pediatric robotic surgery. Specially-trained surgeons use a high-tech robot to perform complex and delicate operations through very small surgical openings. The results are less pain, faster recoveries, shorter hospital stays, smaller scars, and happier patients and families.

In 2001, Children's Hospital Boston was the first pediatric hospital to acquire a surgical robot. Today, surgeons use the technology for many procedures and perform more pediatric robotic operations than any other hospital in the world. Children's Hospital physicians have developed a number of new applications to expand the use of the robot, and train surgeons from around the world on its use.*[34]

Radiosurgery

The CyberKnife Robotic Radiosurgery System uses image guidance and computer controlled robotics to treat tu-

mors throughout the body by delivering multiple beams of high-energy radiation to the tumor from virtually any direction. The system uses a German KUKA KR 240. Mounted on the robot is a compact X-band linac that produces 6MV X-ray radiation. Mounting the radiation source on the robot allows very fast repositioning of the source, which enables the system to deliver radiation from many different directions without the need to move both the patient and source as required by current gantry configurations.

Transplant surgery

Transplant surgery (organ transplantation) has been considered as highly technically demanding and virtually unobtainable by means of conventional laparoscopy. For many years, transplant patients were unable to benefit from the advantages of minimally invasive surgery. The development of robotic technology and its associated high resolution capabilities, three dimensional visual system, wrist type motion and fine instruments, gave opportunity for highly complex procedures to be completed in a minimally invasive fashion. Subsequently, the first fully robotic kidney transplantations were performed in the late 2000s. After the procedure was proven to be feasible and safe, the main emerging challenge was to determine which patients would benefit most from this robotic technique. As a result, recognition of the increasing prevalence of obesity amongst patients with kidney failure on hemodialysis posed a significant problem. Due to the abundantly higher risk of complications after traditional open kidney transplantation, obese patients were frequently denied access to transplantation, which is the premium treatment for end stage kidney disease. The use of the robotic-assisted approach has allowed kidneys to be transplanted with minimal incisions, which has virtually alleviated wound complications and significantly shortened the recovery period. The University of Illinois Medical Center reported the largest series of 104 robotic-assisted kidney transplants for obese recipients (mean body mass index > 42). Amongst this group of patients, no wound infections were observed and the function of transplanted kidneys was excellent. In this way, robotic kidney transplantation could be considered as the biggest advance in surgical technique for this procedure since its creation more than half a century ago.*[35]*[36]*[37]

Urology

Robotic surgery in the field of urology has become very popular, especially in the United States.*[38] It has been most extensively applied for excision of prostate cancer because of difficult anatomical access. It is also utilized for kidney cancer surgeries and to lesser extent surgeries of the bladder.

As of 2014, there is little evidence of increased benefits compared to standard surgery to justify the increased costs.*[39] Some have found tentative evidence of more complete removal of cancer and less side effects from surgery for prostatectomy.*[40]

In 2000, the first robot-assisted laparoscopic radical prostatectomy was performed.*[5]

Vascular surgery

In September 2010, the first robotic operations with Hansen Medical's Magellan Robotic System at the femoral vasculature were performed at the University Medical Centre Ljubljana (UMC Ljubljana), Slovenia. The research was led by Borut Geršak, the head of the Department of Cardiovascular Surgery at the centre. Geršak explained that the robot used was the first true robot in the history of robotic surgery, meaning the user interface was not resembling surgical instruments and the robot was not simply imitating the movement of human hands but was guided by pressing buttons, just like one would play a video game. The robot was imported to Slovenia from the United States.*[41]*[42]

9.7.3 Miniature robotics

As scientists seek to improve the versatility and utility of robotics in surgery, some are attempting to miniaturize the robots. For example, the University of Nebraska Medical Center has led a multi-campus effort to provide collaborative research on mini-robotics among surgeons, engineers and computer scientists.*[43]

9.7.4 History

The first robot to assist in surgery was the *Arthrobot*, which was developed and used for the first time in Vancouver in 1983.*[44] Intimately involved were biomedical engineer, Dr. James McEwen, Geof Auchinleck, a UBC engineering physics grad, and Dr. Brian Day as well as a team of engineering students. The robot was used in an orthopaedic surgical procedure on 12 March 1984, at the UBC Hospital in Vancouver. Over 60 arthroscopic surgical procedures were performed in the first 12 months, and a 1985 National Geographic video on industrial robots, *The Robotics Revolution*, featured the device. Other related robotic devices developed at the same time included a surgical scrub nurse robot, which handed operative instruments on voice command, and a medical laboratory robotic arm. A YouTube video entitled *Arthrobot* illustrates some of these in operation.

In 1985 a robot, the Unimation Puma 200, was used to place a needle for a brain biopsy using CT guidance.*[45] In 1992, the PROBOT, developed at Imperial College London, was used to perform prostatic surgery by Dr. Senthil Nathan at Guy's and St Thomas' Hospital, London. This was the first pure robotic surgery

in the world. Also the Robot Puma 560, a robot developed in 1985 by Kwoh et al. Puma 560 was used to perform neurosurgical biopsies with greater precision. Just like with any other technological innovation, this system led to the development of new and improved surgical robot called PROBOT. The PROBOT was specifically designed for transurethral resection of the prostate. Meanwhile, when PROBOT was being developed, ROBODOC, a robotic system designed to assist hip replacement surgeries was the first surgical robot that was approved by the FDA.*[46] The ROBODOC from Integrated Surgical Systems (working closely with IBM) was introduced in 1992 to mill out precise fittings in the femur for hip replacement.*[47] The purpose of the ROBODOC was to replace the previous method of carving out a femur for an implant, the use of a mallet and broach/rasp.

Further development of robotic systems was carried out by SRI International and Intuitive Surgical with the introduction of the da Vinci Surgical System and Computer Motion with the *AESOP* and the ZEUS robotic surgical system.*[48] The first robotic surgery took place at The Ohio State University Medical Center in Columbus, Ohio under the direction of Robert E. Michler.*[49] Examples of using ZEUS include a fallopian tube reconnection in July 1998,*[50] a *beating heart* coronary artery bypass graft in October 1999,*[51] and the Lindbergh Operation, which was a cholecystectomy performed remotely in September 2001.*[52]

The original telesurgery robotic system that the da Vinci was based on was developed at SRI International in Menlo Park with grant support from DARPA and NASA.*[53] Although the telesurgical robot was originally intended to facilitate remotely performed surgery in battlefield and other remote environments, it turned out to be more useful for minimally invasive on-site surgery. The patents for the early prototype were sold to Intuitive Surgical in Mountain View, California. The da Vinci senses the surgeon's hand movements and translates them electronically into scaled-down micro-movements to manipulate the tiny proprietary instruments. It also detects and filters out any tremors in the surgeon's hand movements, so that they are not duplicated robotically. The camera used in the system provides a true stereoscopic picture transmitted to a surgeon's console. Examples of using the da Vinci system include the first robotically assisted heart bypass (performed in Germany) in May 1998, and the first performed in the United States in September 1999; and the first all-robotic-assisted kidney transplant, performed in January 2009.*[54] The da Vinci Si was released in April 2009, and initially sold for $1.75 million.*[55]

In May 2006 the first artificial intelligence doctor-conducted unassisted robotic surgery on a 34-year-old male to correct heart arythmia. The results were rated as better than an above-average human surgeon. The machine had a database of 10,000 similar operations, and so, in the words of its designers, was "more than qualified to operate on any patient".*[56]*[57] In August 2007, Dr. Sijo Parekattil of the Robotics Institute and Center for Urology (Winter Haven Hospital and University of Florida) performed the first robotic assisted microsurgery procedure denervation of the spermatic cord for chronic testicular pain.*[58] In February 2008, Dr. Mohan S. Gundeti of the University of Chicago Comer Children's Hospital performed the first robotic pediatric neurogenic bladder reconstruction.*[59]

On 12 May 2008, the first image-guided MR-compatible robotic neurosurgical procedure was performed at University of Calgary by Dr. Garnette Sutherland using the NeuroArm.*[60] In June 2008, the German Aerospace Centre (DLR) presented a robotic system for minimally invasive surgery, the MiroSurge.*[61] In September 2010, the Eindhoven University of Technology announced the development of the Sofie surgical system, the first surgical robot to employ force feedback.*[62] In September 2010, the first robotic operation at the femoral vasculature was performed at the University Medical Centre Ljubljana by a team led by Borut Geršak.*[41]*[42]

9.7.5 See also

- Bone segment navigation
- Computer-assisted surgery
- Computer-integrated surgery
- Minimally invasive surgery
- Patient registration
- Stereolithography (medicine)
- Surgical Segment Navigator
- Telemedicine

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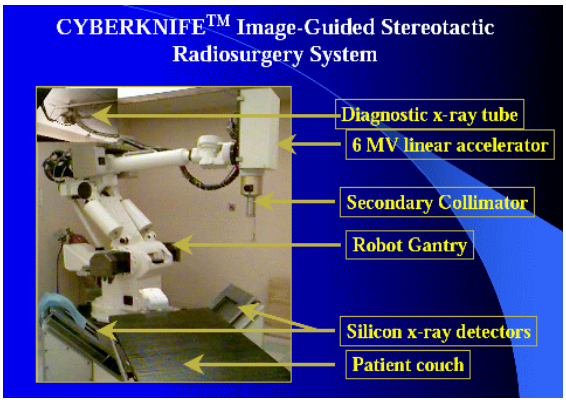
9.7.7 External links

9.8 Cyberknife

The **CyberKnife** is a frameless robotic radiosurgery system used for treating benign tumors, malignant tumors and other medical conditions.*[1]*[2] The system was invented by John R. Adler, a Stanford University professor of neurosurgery and radiation oncology, and Peter and Russell Schonberg of Schonberg Research Corporation. It is made by the Accuray company headquartered in Sunnyvale, California.

The CyberKnife system is a method of delivering radiotherapy, with the intention of targeting treatment more accurately than standard radiotherapy.*[3] The two main elements of the CyberKnife are:

1. the radiation produced from a small linear particle accelerator (linac)
2. a robotic arm which allows the energy to be directed at any part of the body from any direction



The main features of the CyberKnife system, shown on a Fanuc robot

9.8.1 Main features

Several generations of the CyberKnife system have been developed since its initial inception in 1990. There are two major features of the CyberKnife system that are different from other stereotactic therapy methods.

Robotic mounting

The first is that the radiation source is mounted on a general purpose industrial robot. The original CyberKnife used a Japanese Fanuc robot, however the more modern systems use a German KUKA KR 240. Mounted on the Robot is a compact X-band linac that produces 6MV X-ray radiation. The linac is capable of delivering approximately 600 cGy of radiation each minute – a new 800 cGy / minute model was announced at ASTRO*[4] 2007. The radiation is collimated using fixed tungsten collimators (also referred to as "cones") which produce circular radiation fields. At present the radiation field sizes are: 5, 7.5, 10, 12.5, 15, 20, 25, 30, 35, 40, 50 and 60 mm. ASTRO 2007 also saw the launch of the IRIS*[4] variable-aperture collimator which uses two offset banks of six prismatic tungsten segments to form a blurred regular dodecagon field of variable size which eliminates the need for changing the fixed collimators. Mounting the radiation source on the robot allows near-complete freedom to position the source within a space about the patient. The robotic mounting allows very fast repositioning of the source, which enables the system to deliver radiation from many different directions without the need to move both the patient and source as required by current gantry configurations.

Image guidance

The second is that the CyberKnife system uses an image guidance system. X-ray imaging cameras are located on supports around the patient allowing instantaneous X-ray images to be obtained.

6D skull The original (and still utilized) method is called 6D or skull based tracking. The X-ray camera images are compared to a library of computer generated images of the patient anatomy. Digitally Reconstructed Radiographs (or DRR's) and a computer algorithm determines what motion corrections have to be given to the robot because of patient movement. This imaging system allows the CyberKnife to deliver radiation with an accuracy of 0.5mm without using mechanical clamps attached to the patient's skull.*[5] The use of the image-guided technique is referred to as *frameless* stereotactic radiosurgery. This method is referred to as 6D because corrections are made for the 3 translational motions (X,Y and Z) and three rotational motions. It should be noted that it is necessary to use some anatomical or artificial feature to orient the robot to deliver X-ray radiation, since the tumor is never sufficiently well defined (if visible at all) on the X-ray camera images.

Xsight Additional image guidance methods are available for spinal tumors and for tumors located in the lung. For a tumor located in the spine, a variant of the image guidance called Xsight-Spine*[6] is used. The major difference here is that instead of taking images of the skull, images of the spinal processes are used. Whereas the skull is effectively rigid and non-deforming, the spinal vertebrae can move relative to each other, this means that image warping algorithms must be used to correct for the distortion of the X-ray camera images.

A recent enhancement to Xsight is Xsight-Lung*[7] which allows tracking of some lung tumors without the

6D skull tracking

need to implant fiducial markers.*[8]

Fiducial For soft tissue tumors, a method known as fiducial tracking can be utilized.*[9] Small metal markers (fiducials) made out of gold for bio-compatibility and high density to give good contrast on X-ray images are surgically implanted in the patient. This is carried out by an interventional radiologist, or neurosurgeon. The placement of the fiducials is a critical step if the fiducial tracking is to be used. If the fiducials are too far from the location of the tumor, or are not sufficiently spread out from each other it will not be possible to accurately deliver the radiation. Once these markers have been placed, they are located on a CT scan and the image guidance system is programmed with their position. When X-ray camera images are taken, the location of the tumor relative to the fiducials is determined, and the radiation can be delivered to any part of the body. Thus the fiducial tracking does not require any bony anatomy to position the radiation. Fiducials are known however to migrate and this can limit the accuracy of the treatment if sufficient time is not allowed between implantation and treatment for the fiducials to stabilize.*[10]*[11]

Synchrony Another technology of image guidance that the CyberKnife system can use is called the Synchrony system or Synchrony method. The synchrony method uses a combination of surgically placed internal fiducials (typically small gold markers, well visible in x-ray imaging), and light emitting optical fibers (LED markers) mounted on the patient skin. LED markers are tracked by an infrared tracking camera. Since the tumor is moving continuously, to continuously image its location using X-ray cameras would require prohibitive amounts of radiation to be delivered to the patient's skin. The Synchrony system overcomes this by periodically taking images of the internal fiducials, and computing a correlation model between the motion of the external LED markers and the internal fiducials. Time stamps from the two sensors (x-ray and infrared LED) are needed to synchronize the two data streams, hence the name Synchrony.

Motion prediction is used to overcome the motion latency of the robot and the latency of image acquisition. Before treatment, a computer algorithm creates a correlation model that represents how the internal fiducial markers are moving compared to the external markers. During treatment, the system continuously infers the motion of the internal fiducials, and therefore the tumor, based on the motion of the skin markers. The correlation model is updated at fixed time steps during treatment. Thus, the Synchrony tracking method makes no assumptions about the regularity or reproducibility of the patient breathing pattern.

To function properly, the Synchrony system requires that for any given correlation model there is a functional relationship between the markers and the internal fiducials. The external marker placement is also important, and the markers are usually placed on the patient abdomen so that their motion will reflect the internal motion of the diaphragm and the lungs. The synchrony method was invented in 1998.*[12]*[13] The first patients were treated at Cleveland Clinic in 2002. Synchrony is utilized primarily for tumors that are in motion while being treated, such as lung tumors and pancreatic tumors.*[14]*[15]

RoboCouch

A robotic six degree of freedom patient treatment couch called RoboCouch*[16] improves patient positioning options for treatment.

Frameless

The frameless nature of the CyberKnife also increases the clinical efficiency. In conventional frame-based radiosurgery, the accuracy of treatment delivery is determined solely by connecting a rigid frame to the patient which is anchored to the patient's skull with invasive aluminum or titanium screws. The CyberKnife is the only radiosurgery device that does not require such a frame for precise targeting.*[17] Once the frame is connected, the relative position of the patient anatomy must be determined by making a CT or MRI scan. After the CT or MRI scan has been made, a radiation oncologist must plan the delivery of the radiation using a dedicated computer program, after which the treatment can be delivered, and the frame removed. The use of the frame therefore requires a linear sequence of events that must be carried out sequentially before another patient can be treated. Staged CyberKnife radiosurgery is of particular benefit to patients who have previously received large doses of conventional radiation therapy and patients with gliomas located near critical areas of the brain. Unlike whole brain radiotherapy, which must be administered daily over several weeks, radiosurgery treatment can usually be completed in 1–5 treat-

ment sessions. Radiosurgery can be used alone to treat brain metastases, or in conjunction with surgery or whole brain radiotherapy, depending on the specific clinical circumstances.*[18]

By comparison, using a frameless system, a CT scan can be carried out on any day prior to treatment that is convenient. The treatment planning can also be carried out at any time prior to treatment. During the treatment the patient need only be positioned on a treatment table and the predetermined plan delivered. This allows the clinical staff to plan many patients at the same time, devoting as much time as is necessary for complicated cases without slowing down the treatment delivery. While a patient is being treated, another clinician can be considering treatment options and plans, and another can be conducting CT scans.

In addition, very young patients (pediatric cases) or patients with fragile heads because of prior brain surgery cannot be treated using a frame based system. Also, by being frameless the CyberKnife can efficiently re-treat the same patient without repeating the preparation steps that a frame-based system would require.

The delivery of a radiation treatment over several days or even weeks (referred to as fractionation) can also be beneficial from a therapeutic point of view. Tumor cells typically have poor repair mechanisms compared to healthy tissue, so by dividing the radiation dose into fractions the healthy tissue has time to repair itself between treatments.*[19] This can allow a larger dose to be delivered to the tumor compared to a single treatment.*[20]

9.8.2 Clinical uses

Since August 2001, the CyberKnife system has FDA clearance for treatment of tumors in any location of the body.*[21] Some of the tumors treated include: pancreas,*[15]*[22] liver,*[23] prostate,*[24]*[25] spinal lesions,*[26] head and neck cancers,*[27] and benign tumors.*[28]

None of these studies have shown any general survival benefit over conventional treatment methods. By increasing the accuracy with which treatment is delivered there is a potential for dose escalation, and potentially a subsequent increase in effectiveness, particularly in local control rates. However the studies cited are so far limited in scope, and more extensive research will need to be completed in order to show any effects on survival.*[22]

In 2008 actor Patrick Swayze was among the people to be treated with CyberKnife radiosurgery.*[29]

9.8.3 Locations

CyberKnife systems have been installed in over 150 locations,*[30] including 100 hospitals in the United States.*[31]

Recently – April 2014 – CyberKnife has been installed at Sir Charles Gairdner Hospital, Perth, Australia.*[32]

Stanford University has treated over 2,500 patients using the Cyberknife system, and worldwide over 40,000 patients have been treated.*[33]

The CyberKnife Centre at the Harley Street Clinic in London was the first in the UK to offer this treatment and to date has treated the most patients of any centre in the UK (December 2015). The Freemasons in London, UK, have paid for a CyberKnife to be placed in Barts Hospital, and it is available to all on the National Health Service, although only for certain indications that the NHS will fund. The Queen Elizabeth Hospital in Birmingham installed a CyberKnife in 2013, the first NHS hospital outside London to acquire one. The Royal Marsden NHS Foundation Trust has a CyberKnife at their Chelsea, London site.

Overlook Hospital in Summit, New Jersey was the first hospital in the New York metro area to offer the CyberKnife Stereotactic Radiosurgery System. Today, Overlook has performed the second most treatments of prostate cancer with the CyberKnife in the world. Anova Cancer Care in Denver, Colorado, has been acknowledged as the world leader in prostate cancer radiosurgery as of 2013.

CyberKnife VSI was installed in Hermitage Medical Clinic, Dublin Ireland, in 2013.

There is a CyberKnife machine in Hong Kong Adventist Hospital (private service and expensive price) in Hong Kong.

The first next generation CyberKnife VSI in Asia at BLK CyberKnife in New Delhi India.

SRS Cyberknife is also available in Pakistan at Jinnah Post-Graduate Medical Centre Karachi, the only place where it is offered free of charge.

In January 2013, the first patients were treated with the new generation CyberKnife M6 in Munich, Germany, at the European CyberKnife Center Munich.

In Malaysia, Beacon Hospital (Beacon International Specialist Centre) which specialises in oncology, provides Cybernknife treatment as one of their few treatments on cancer. It has been operating since 2005 as a boutique medical centre.*[34] Beacon Hospital also provides Corporate Social Responsibilities (CSR) programme to help underprivileged patients who cannot afford radiotherapy treatments.*[35]

9.8.4 See also

- Horsley–Clarke apparatus
- Gamma knife
- NCI-designated Cancer Centers in the United States
- Novalis radiosurgery

- Robotic surgery

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9.8.6 Further reading

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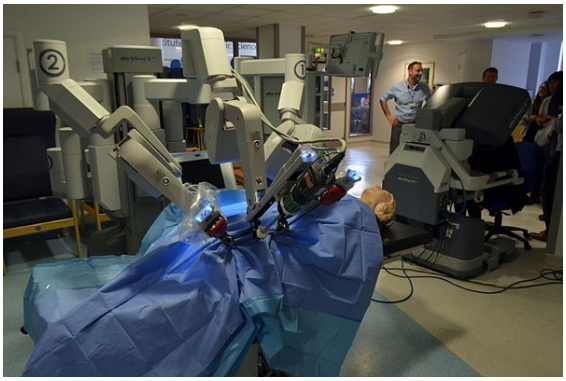
9.8.7 External links

- Official website

9.9 Da Vinci Surgical System

The **Da Vinci Surgical System** (spelled that way by the manufacturer) is a robotic surgical system made by the American company Intuitive Surgical. Approved by the Food and Drug Administration (FDA) in 2000, it is designed to facilitate complex surgery using a minimally invasive approach, and is controlled by a surgeon from a console. The system is commonly used for prostatectomies, and increasingly for cardiac valve repair and gynecologic surgical procedures.*[1]*[2] According to the manufacturer, the da Vinci System is called "da Vinci" in part because Leonardo da Vinci's "study of human anatomy eventually led to the design of the first known robot in history." *[3]

da Vinci Surgical Systems operate in hospitals worldwide, with an estimated 200,000 surgeries conducted in 2012, most commonly for hysterectomies and prostate removals.*[4] As of June 30, 2014, there was an installed base of 3,102 units worldwide, up from 2,000 units at the same time the previous year. The location of these units are as follows: 2,153 in the United States, 499 in Europe, 183 in Japan, and 267 in the rest of the world.*[5] The "Si" version of the system costs on average slightly under US$2 million, in addition to several hundred thousand dollars of annual maintenance fees.*[6] The da Vinci system has been criticised for its cost and for a number of issues with its surgical performance.*[2]*[7]



da Vinci patient-side component (left) and surgeon console (right)

A surgeon console at the treatment centre of Addenbrooke's Hospital

9.9.1 Overview

The da Vinci System consists of a surgeon's console that is typically in the same room as the patient, and a patient-side cart with four interactive robotic arms controlled from the console. Three of the arms are for tools that hold objects, and can also act as scalpels, scissors, bovies, or unipolar or hi. The surgeon uses the console's master controls to maneuver the patient-side cart's three or four robotic arms (depending on the model). The instruments' jointed-wrist design exceeds the natural range of motion of the human hand; motion scaling and tremor reduction further interpret and refine the surgeon's hand movements. The da Vinci System always requires a human operator, and incorporates multiple redundant safety features designed to minimize opportunities for human error when compared with traditional approaches.

The da Vinci System has been designed to improve upon conventional laparoscopy, in which the surgeon operates while standing, using hand-held, long-shafted instruments, which have no wrists. With conventional laparoscopy, the surgeon must look up and away from the instruments, to a nearby 2D video monitor to see an image of the target anatomy. The surgeon must also rely on a patient-side assistant to position the camera correctly. In contrast, the da Vinci System's design allows the surgeon to operate from a seated position at the console, with

eyes and hands positioned in line with the instruments and using controls at the console to move the instruments and camera.

By providing surgeons with superior visualization, enhanced dexterity, greater precision and ergonomic comfort, the da Vinci Surgical System makes it possible for more surgeons to perform minimally invasive procedures involving complex dissection or reconstruction. For the patient, a da Vinci procedure can offer all the potential benefits of a minimally invasive procedure, including less pain, less blood loss and less need for blood transfusions. Moreover, the da Vinci System can enable a shorter hospital stay, a quicker recovery and faster return to normal daily activities.*[8]

9.9.2 FDA clearance

The Food and Drug Administration (FDA) cleared the da Vinci Surgical System in 2000 for adult and pediatric use in urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures and thoracoscopically assisted cardiotomy procedures. The FDA also cleared the da Vinci System to be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization.*[9]

9.9.3 Representative clinical uses

The da Vinci System has been successfully used in the following procedures:*[9]

- Radical prostatectomy, pyeloplasty, cystectomy, nephrectomy and ureteral reimplantation;*[10]
- Hysterectomy, myomectomy and sacrocolpopexy;
- Hiatal hernia repair;
- Spleen-sparing distal pancreatectomy, cholecystectomy, Nissen fundoplication, Heller myotomy, gastric bypass, donor nephrectomy, adrenalectomy, splenectomy and bowel resection;
- Internal mammary artery mobilization and cardiac tissue ablation;
- Mitral valve repair and endoscopic atrial septal defect closure;
- Mammary to left anterior descending coronary artery anastomosis for cardiac revascularization with adjunctive mediastinotomy;
- Transoral resection of tumors of the upper aerodigestive tract (tonsil, tongue base, larynx) and transaxillary thyroidectomy
- Resection of spindle cell tumors originating in the lung

9.9.4 Future applications

Although the general term "robotic surgery" is often used to refer to the technology, this term can give the impression that the da Vinci System is performing the surgery autonomously. In contrast, the current da Vinci Surgical System cannot – in any manner – function on its own, as it was not designed as an autonomous system and lacks decision making software. Instead, it relies on a human operator for all input; however, all operations – including vision and motor functions—are performed through remote human-computer interaction, and thus with the appropriate weak AI software, the system could in principle perform partially or completely autonomously. The difficulty with creating an autonomous system of this kind is not trivial; a major obstacle is that surgery *per se* is not an engineered process – a requirement for weak AI. The current system is designed merely to replicate seamlessly the movement of the surgeon's hands with the tips of microinstruments, not to make decisions or move without the surgeon's direct input.

The possibility of long-distance operations depends on the patient having access to a da Vinci System, but technically the system could allow a doctor to perform telesurgery on a patient in another country. In 2001, Dr. Marescaux and a team from IRCAD used a combination of high-speed fiber-optic connection with an average delay of 155 ms with advanced asynchronous transfer mode (ATM) and a Zeus telemanipulator to successfully perform the first transatlantic surgical procedure, covering the distance between New York and Strasbourg. The event was considered a milestone of global telesurgery, and was dubbed "Operation Lindbergh".*[11]

9.9.5 Criticism

Main article: Robotic surgery § Advantages and disadvantages

Critics of robotic surgery assert that it is difficult for users to learn and that it has not been shown to be more effective than traditional laparoscopic surgery.*[2] The da Vinci system uses proprietary software, which cannot be modified by physicians, thereby limiting the freedom to modify the operation system.*[4] Furthermore, its $2 million cost places it beyond the reach of many institutions.*[6]

The manufacturer of the system, Intuitive Surgical, has been criticized for short-cutting FDA approval by a process known as "premarket notification," which claims the product is similar to already-approved products. Intuitive has also been accused of providing inadequate train-

ing, and encouraging health care providers to reduce the number of supervised procedures required before a doctor is allowed to use the system without supervision.*[12] There have also been claims of patient injuries caused by stray electrical currents released from inappropriate parts of the surgical tips used by the system. Intuitive counters that the same type of stray currents can occur in non-robotic laparoscopic procedures.*[13] A study published in the *Journal of the American Medical Association* found that side effects and blood loss in robotically-performed hysterectomies are no better than those performed by traditional surgery, despite the significantly greater cost of the system.*[14]*[15] As of 2013, the FDA is investigating problems with the da Vinci robot, including deaths during surgeries that used the device; a number of related lawsuits are also underway.*[7]

From a social analysis, a disadvantage is the potential for this technology to dissolve the creative freedoms of the surgeon, once hailed by scholar Timothy Lenoir as one of the most professional individual autonomous occupations to exist. Lenoir claims that in the "heroic age of medicine," the surgeon was hailed as a hero for his intuitive knowledge of human anatomy and his well-crafted techniques in repairing vital body systems. Lenoir argues that the da Vinci's 3D console and robotic arms create a mediating form of action called medialization, in which internal knowledge of images and routes within the body become external knowledge mapped into simplistic computer coding.*[16]

9.9.6 See also

- ZEUS robotic surgical system, a rival system discontinued in 2003

9.9.7 References

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9.9.8 Da Vinci Live Surgery Videos

- "Live robotic da Vinci radical prostatectomy during EAU congress" on YouTube by European Urological Association.
- "India's 1st Da vinci Robotic Live Surgery" on YouTube by Muljibhai Patel Urological Hospital.
- "da Vinci Robotic Hysterectomies / Uterine Fibroids" on YouTube.

9.9.9 External links

- Intuitive Surgical website

9.10 NeuroArm

NeuroArm is an engineering research surgical robot specifically designed for neurosurgery. It is the first image-guided, MR-compatible surgical robot that has the capability to perform both microsurgery and stereotaxy.*[1]

IMRIS, Inc. acquired NeuroArm assets in 2010, and the company is working to develop a next generation of the technology for worldwide commercialization. It will be integrated with the VISIUS(TM) Surgical Theatre under the name SYMBIS(TM) Surgical System.*[2]

9.10.1 Design

NeuroArm was designed to be image-guided and can perform procedures inside an MRI. NeuroArm includes two remote detachable manipulators on a mobile base, a workstation and a system control cabinet. For biopsy-stereotaxy, either the left or right arm is transferred to a stereotactic platform that attaches to the MR bore. The procedure is performed with image-guidance, as MR images are acquired in near real-time. The end-effectors interface with surgical tools which are based on standard neurosurgical instruments.

End-effectors are equipped with three-dimensional force-sensors, providing the sense of touch. The surgeon seated at the workstation controls the robot using force feedback hand controllers. The workstation recreates the sight and sensation of microsurgery by displaying the surgical site and 3D MRI displays, with superimposed tools. NeuroArm enables remote manipulation of the surgical tools from a control room adjacent to the surgical suite.*[3] It was designed to function within the environment of 1.5 and 3.0 tesla intraoperative MRI systems. As neuroArm is MR-compatible, stereotaxy can be performed inside the bore of the magnet with near real-time image guidance. NeuroArm possesses the dexterity to perform microsurgery, outside of the MRI system.

Telerobotic operations both inside and outside the magnet are performed using specialized tool sets based on standard neurosurgical instruments, adapted to the end effectors. Using these, NeuroArm is able to cut and manipulate soft tissue, dissect tissue planes, suture, biopsy, electrocauterize, aspirate and irrigate.*[4]

9.10.2 History

The project began in 2002 when Daryl, B.J. and Don Seaman provided $2 million to fund the design efforts. Dr. Sutherland and his group established a collaboration with the Canadian space engineering company MacDonald Dettwiler and Associates (MDA).*[5] Close collaboration between MDA's robotic engineers and University of Calgary physicians, nurses, and scientists contributed to the design and development of NeuroArm. Official launch of the project was on April 17, 2007.*[6]

NeuroArm was designed to take full advantage of the imaging environment provided by intraoperative MRI. The ability to couple near real-time, high resolution images to robotic technologies provides the surgeon with image guidance, precision, accuracy and dexterity.*[7] MDA's engineers were immersed in the operating room to study typical tool and surgeon motions in order to use biomimicry for effective design of the computer-assisted surgical device. The OR environment, personnel, surgical rhythm and instrumentation remain unchanged. The surgeon, sitting at the workstation, is provided a virtual environment that recreates the sight, sound and touch of surgery. Functions like tremor filtering and motion scaling were applied to increase precision and accuracy while functions like no-go zones and linear lock were applied to enhance safety. Surgical tools near the patient's head are incapable of fully independent movement and are slaved to the surgeon's movement at all times. Pre-planned automatic motions are used to move the robot arms away from the patient's head for manual tool exchange, and then return them to the original position and orientation.

On May 12, 2008, the first image-guided MR-compatible robotic neurosurgical procedure was performed at University of Calgary by Dr. Garnette Sutherland using the NeuroArm.*[8]

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9.10.4 External links

- Project neuroArm
- Seaman Family MR Research Centre
- SYMBIS Homepage on IMRIS Website

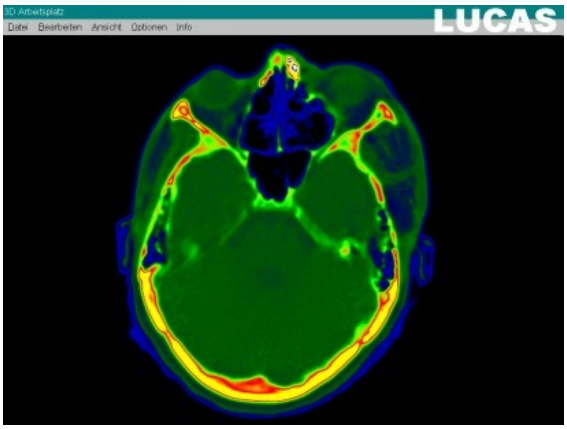
Videos

- Video in press release for NeuroArm unveiling, University of Calgary, April 17, 2007

Related patents

- Canadian Patent 2246369 Surgical procedure with magnetic resonance imaging
- US Patent 5,735,278 (at USPTO) Surgical procedure with magnetic resonance imaging
- US Patent 5,735,278 (at Google) Surgical procedure with magnetic resonance imaging

9.11 Laboratory Unit for Computer Assisted Surgery



Data gathering, based on CT "slices"

Segmentation obtained from the CT "slices"

Laboratory Unit for Computer Assisted Surgery (LUCAS) is a system used for virtual surgical planning. Starting with 1998, LUCAS was developed at the University of Regensburg, Germany, with the support of the Carl Zeiss Company. The resulting surgical planning is then reproduced onto the patient by using a navigation system. In fact, LUCAS is integrated into the same platform together with the Surgical Segment Navigator (SSN), the Surgical Tool Navigator (STN), the Surgical Microscope Navigator (SMN) and the 6DOF Manipulator (or, in German, "Mehrkoordinatenmanipulator" - MKM), also from the Carl Zeiss Company.

9.11.1 Workflow

Data from separate bidimensional slices generated by a CT or MRI scan are uploaded into the LUCAS system. The resulting dataset is then processed, in order to eliminate image noise, and to enhance the anatomical contours and also the general contrast of the images. The next step is to create a virtual 3D model from the gathered collection of 2D images. The bone segment that is to be repositioned is marked, on the 3D grid reconstructed model; then, the actual repositioning of that bone segment is done on the virtual model, until the optimal anatomical position is obtained. The criteria for the optimal position of the bone segment are: symmetry with the opposite side, the continuity of the normal bone contours, or the normal volume of an anatomical region (such as the Orbit. Afterwards, a textured final image is rendered. The calculated vectors for the bone segment repositioning, together with the whole virtual model are finally transferred to the Surgical Segment Navigator.

9.11.2 References

- Marmulla R, Niederdellmann H: *Surgical Planning of Computer Assisted Repositioning Osteotomies*, Plast Reconstr Surg 104 (4): 938-944, 1999

Chapter 10

Legislation and Regulation

10.1 Health Insurance Portability and Accountability Act

The **Health Insurance Portability and Accountability Act of 1996** (**HIPAA**; Pub.L. 104–191, 110 Stat. 1936, enacted August 21, 1996) was enacted by the United States Congress and signed by President Bill Clinton in 1996. It has been known as the Kennedy–Kassebaum Act or Kassebaum–Kennedy Act after two of its leading sponsors.*[1]*[2] Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of HIPAA, known as the Administrative Simplification (AS) provisions, requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers.*[3]

10.1.1 Title I: Health Care Access, Portability, and Renewability

Title I of HIPAA regulates the availability and breadth of group health plans and certain individual health insurance policies. It amended the Employee Retirement Income Security Act, the Public Health Service Act, and the Internal Revenue Code.

Title I requires the coverage of and also limits restrictions that a group health plan can place on benefits for preexisting conditions. Group health plans may refuse to provide benefits relating to preexisting conditions for a period of 12 months after enrollment in the plan or 18 months in the case of late enrollment.*[4] Title I allows individuals to reduce the exclusion period by the amount of time that they had "creditable coverage" prior to enrolling in the plan and after any "significant breaks" in coverage.*[5] "Creditable coverage" is defined quite broadly and includes nearly all group and individual health plans, Medicare, and Medicaid.*[6] A "significant break" in coverage is defined as any 63 day period without any creditable coverage.*[7] Along with an exception, allowing employers to tie premiums or co-payments to tobacco use, or body mass index.

Title I*[8] also requires insurers to issue policies without exclusion to those leaving group health plans with creditable coverage (see above) exceeding 18 months, and *[9] renew individual policies for as long as they are offered or provide alternatives to discontinued plans for as long as the insurer stays in the market without exclusion regardless of health condition.

Some health care plans are exempted from Title I requirements, such as long-term health plans and limited-scope plans such as dental or vision plans that are offered separately from the general health plan. However, if such benefits are part of the general health plan, then HIPAA still applies to such benefits. For example, if the new plan offers dental benefits, then it must count creditable continuous coverage under the old health plan towards any of its exclusion periods for dental benefits.

An alternate method of calculating creditable continuous coverage is available to the health plan under Title I. That is, 5 categories of health coverage can be considered separately, including dental and vision coverage. Anything not under those 5 categories must use the general calculation (e.g., the beneficiary may be counted with 18 months of general coverage, but only 6 months of dental coverage, because the beneficiary did not have a general health plan that covered dental until 6 months prior to the application date). Since limited-coverage plans are exempt from HIPAA requirements, the odd case exists in which the applicant to a general group health plan cannot obtain certificates of creditable continuous coverage for independent limited-scope plans such as dental to apply towards exclusion periods of the new plan that does include those coverages.

Hidden exclusion periods are not valid under Title I (e.g., "The accident, to be covered, must have occurred while the beneficiary was covered under this exact same health insurance contract"). Such clauses must not be acted upon by the health plan and also must be re-written so that they comply with HIPAA.

10.1.2 Title II: Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform

Title II of HIPAA defines policies, procedures and guidelines for maintaining the privacy and security of individually identifiable health information as well as outlining numerous offenses relating to health care and sets civil and criminal penalties for violations. It also creates several programs to control fraud and abuse within the health care system.*[10]*[11]*[12] However, the most significant provisions of Title II are its Administrative Simplification rules. Title II requires the Department of Health and Human Services (HHS) to draft rules aimed at increasing the efficiency of the health care system by creating standards for the use and dissemination of health care information.

These rules apply to "covered entities" as defined by HIPAA and the HHS. Covered entities include health plans, health care clearinghouses, such as billing services and community health information systems, and health care providers that transmit health care data in a way that is regulated by HIPAA.*[13]*[14]

Per the requirements of Title II, the HHS has promulgated five rules regarding Administrative Simplification: the Privacy Rule, the Transactions and Code Sets Rule, the Security Rule, the Unique Identifiers Rule, and the Enforcement Rule.

Privacy Rule

The effective compliance date of the Privacy Rule was April 14, 2003, with a one-year extension for certain "small plans". The HIPAA Privacy Rule regulates the use and disclosure of Protected Health Information (PHI) held by "covered entities" (generally, health care clearinghouses, employer sponsored health plans, health insurers, and medical service providers that engage in certain transactions.)*[15] By regulation, the Department of Health and Human Services extended the HIPAA privacy rule to independent contractors of covered entities who fit within the definition of "business associates".*[16] PHI is any information held by a covered entity which concerns health status, provision of health care, or payment for health care that can be linked to an individual.*[13] This is interpreted rather broadly and includes any part of an individual's medical record or payment history. Covered entities must disclose PHI to the individual within 30 days upon request.*[17] They also must disclose PHI when required to do so by law such as reporting suspected child abuse to state child welfare agencies.*[18]

Covered entities may disclose protected health information to law enforcement officials for law enforcement purposes as required by law (including court orders, court-ordered warrants, subpoenas) and administrative requests; or to identify or locate a suspect, fugitive, material witness, or missing person.*[19]

A covered entity may disclose PHI (Protected Health Information) to facilitate treatment, payment, or health care operations without a patient's express written authorization.*[20] Any other disclosures of PHI (Protected Health Information) require the covered entity to obtain written authorization from the individual for the disclosure.*[21] However, when a covered entity discloses any PHI, it must make a reasonable effort to disclose only the minimum necessary information required to achieve its purpose.*[22]

The Privacy Rule gives individuals the right to request that a covered entity correct any inaccurate PHI.*[23] It also requires covered entities to take reasonable steps to ensure the confidentiality of communications with individuals.*[24] For example, an individual can ask to be called at his or her work number instead of home or cell phone numbers.

The Privacy Rule requires covered entities to notify individuals of uses of their PHI. Covered entities must also keep track of disclosures of PHI and document privacy policies and procedures.*[25] They must appoint a Privacy Official and a contact person*[26] responsible for receiving complaints and train all members of their workforce in procedures regarding PHI.*[27]

An individual who believes that the Privacy Rule is not being upheld can file a complaint with the Department of Health and Human Services Office for Civil Rights (OCR).*[28]*[29] However, according to the *Wall Street Journal*, the OCR has a long backlog and ignores most complaints. "Complaints of privacy violations have been piling up at the Department of Health and Human Services. Between April of 2003 and November 2006, the agency fielded 23,886 complaints related to medical-privacy rules, but it has not yet taken any enforcement actions against hospitals, doctors, insurers or anyone else for rule violations. A spokesman for the agency says it has closed three-quarters of the complaints, typically because it found no violation or after it provided informal guidance to the parties involved." *[30] However, in July 2011, UCLA agreed to pay $865,500 in a settlement regarding potential HIPAA violations. An HHS Office for Civil Rights investigation showed that from 2005 to 2008 unauthorized employees repeatedly and without legitimate cause looked at the electronic protected health information of numerous UCLAHS patients.*[31]

2013 Final Omnibus Rule Update In January 2013, HIPAA was updated via the Final Omnibus Rule.*[32] Included in changes were updates to the Security Rule and Breach Notification portions of the HITECH Act. The greatest changes relate to the expansion of requirements to include business associates, where only covered entities had originally been held to uphold these sections of the law.

Additionally, the definition of 'significant harm' to an individual in the analysis of a breach was updated to provide more scrutiny to covered entities with the intent of disclosing more breaches which had been previously gone unreported. Previously an organization needed proof that harm had occurred whereas now they must prove the counter, that harm had not occurred.

Protection of PHI was changed from indefinite to 50 years after death. More severe penalties for violation of PHI privacy requirements were also approved.

Controversial application In compliance with HIPAA, hospitals will not reveal information over the phone to relatives of admitted patients. This has in some instances impeded the location of missing persons. In the case of the Asiana Airlines Flight 214 San Francisco crash, Asiana was unable to locate many passengers after the accident.*[33] In one instance, a man in Washington state was unable to obtain information about his injured mother.*[34]

Janlori Goldman, director of the advocacy group Health Privacy Project, said that some hospitals are being "overcautious" and misapplying the law, the Times reports. Suburban Hospital in Bethesda, Md., has interpreted a federal regulation that requires hospitals to allow patients to opt out of being included in the hospital directory as meaning that patients want to be kept out of the directory unless they specifically say otherwise. As a result, if a patient is unconscious or otherwise unable to choose to be included in the directory, relatives and friends might not be able to find them, Goldman said.*[35]

Transactions and Code Sets Rule

HIPAA was intended to make the health care system in the United States more efficient by standardizing health care transactions. HIPAA added a new Part C titled "Administrative Simplification" to Title XI of the Social Security Act. This is supposed to simplify health care transactions by requiring all health plans to engage in health care transactions in a standardized way.

The HIPAA/EDI provision was scheduled to take effect from October 16, 2003 with a one-year extension for certain "small plans". However, due to widespread confusion and difficulty in implementing the rule, CMS granted a one-year extension to all parties. On January 1, 2012 newer versions, ASC X12 005010 and NCPDP D.0 become effective, replacing the previous ASC X12 004010 and NCPDP 5.1 mandate.*[36] The ASC X12 005010 version provides a mechanism allowing the use of ICD-10-CM as well as other improvements.

After July 1, 2005 most medical providers that file electronically did have to file their electronic claims using the HIPAA standards in order to be paid.

Under HIPAA, HIPAA-covered health plans are now required to use standardized HIPAA electronic transactions. See, 42 USC § 1320d-2 and 45 CFR Part 162. Information about this can be found in the final rule for HIPAA electronic transaction standards (74 Fed. Reg. 3296, published in the Federal Register on January 16, 2009), and on the CMS website here:CMS information on HIPAA standardized electronic transactions

Key EDI(X12) transactions used for HIPAA compliance are:

EDI Health Care Claim Transaction set (837) is used to submit health care claim billing information, encounter information, or both, except for retail pharmacy claims (see EDI Retail Pharmacy Claim Transaction). It can be sent from providers of health care services to payers, either directly or via intermediary billers and claims clearinghouses. It can also be used to transmit health care claims and billing payment information between payers with different payment responsibilities where coordination of benefits is required or between payers and regulatory agencies to monitor the rendering, billing, and/or payment of health care services within a specific health care/insurance industry segment.

For example, a state mental health agency may mandate all healthcare claims, Providers and health plans who trade professional (medical) health care claims electronically must use the 837 Health Care Claim: Professional standard to send in claims. As there are many different business applications for the Health Care claim, there can be slight derivations to cover off claims involving unique claims such as for Institutions, Professionals, Chiropractors, and Dentists etc.

EDI Retail Pharmacy Claim Transaction (NCPDP Telecommunications Standard version 5.1) is used to submit retail pharmacy claims to payers by health care professionals who dispense medications, either directly or via intermediary billers and claims clearinghouses. It can also be used to transmit claims for retail pharmacy services and billing payment information between payers with different payment responsibilities where coordination of benefits is required or between payers and regulatory agencies to monitor the rendering, billing, and/or payment of retail pharmacy services within the pharmacy health care/insurance industry segment.

EDI Health Care Claim Payment/Advice Transaction Set (835) can be used to make a payment, send an Explanation of Benefits (EOB), send an Explanation of Payments (EOP) remittance advice, or make a payment and send an EOP remittance advice only from a health insurer to a health care provider either directly or via a financial institution.

EDI Benefit Enrollment and Maintenance Set (834) can be used by employers, unions, government agencies, associations or insurance agencies to enroll members to a payer. The payer is a healthcare organization that pays claims, administers insurance or benefit or product. Examples of payers include an insurance company,

health care professional (HMO), preferred provider organization (PPO), government agency (Medicaid, Medicare etc.) or any organization that may be contracted by one of these former groups.

EDI Payroll Deducted and other group Premium Payment for Insurance Products (820) is a transaction set which can be used to make a premium payment for insurance products. It can be used to order a financial institution to make a payment to a payee.

EDI Health Care Eligibility/Benefit Inquiry (270) is used to inquire about the health care benefits and eligibility associated with a subscriber or dependent.

EDI Health Care Eligibility/Benefit Response (271) is used to respond to a request inquiry about the health care benefits and eligibility associated with a subscriber or dependent.

EDI Health Care Claim Status Request (276) This transaction set can be used by a provider, recipient of health care products or services or their authorized agent to request the status of a health care claim.

EDI Health Care Claim Status Notification (277) This transaction set can be used by a health care payer or authorized agent to notify a provider, recipient or authorized agent regarding the status of a health care claim or encounter, or to request additional information from the provider regarding a health care claim or encounter. This transaction set is not intended to replace the Health Care Claim Payment/Advice Transaction Set (835) and therefore, is not used for account payment posting. The notification is at a summary or service line detail level. The notification may be solicited or unsolicited.

EDI Health Care Service Review Information (278) This transaction set can be used to transmit health care service information, such as subscriber, patient, demographic, diagnosis or treatment data for the purpose of request for review, certification, notification or reporting the outcome of a health care services review.

EDI Functional Acknowledgement Transaction Set (997) this transaction set can be used to define the control structures for a set of acknowledgments to indicate the results of the syntactical analysis of the electronically encoded documents. Although it is not specifically named in the HIPAA Legislation or Final Rule, it is necessary for X12 transaction set processing. The encoded documents are the transaction sets, which are grouped in functional groups, used in defining transactions for business data interchange. This standard does not cover the semantic meaning of the information encoded in the transaction sets.

Brief 5010 Transactions and Code Sets Rules Update Summary

1. Transaction Set (997) will be replaced by Transaction Set (999) "acknowledgement report".
2. The size of many fields {segment elements} will be expanded, causing a need for all IT providers to expand corresponding fields, element, files, GUI, paper media and databases.
3. Some segments have been removed from existing Transaction Sets.
4. Many segments have been added to existing Transaction Sets allowing greater tracking and reporting of cost and patient encounters.
5. Capacity to use both "International Classification of Diseases" versions 9 (ICD-9) and 10 (ICD-10-CM) has been added.*[37]*[38]

Security Rule

The Final Rule on Security Standards was issued on February 20, 2003. It took effect on April 21, 2003 with a compliance date of April 21, 2005 for most covered entities and April 21, 2006 for "small plans". The Security Rule complements the Privacy Rule. While the Privacy Rule pertains to all Protected Health Information (PHI) including paper and electronic, the Security Rule deals specifically with Electronic Protected Health Information (EPHI). It lays out three types of security safeguards required for compliance: administrative, physical, and technical. For each of these types, the Rule identifies various security standards, and for each standard, it names both required and addressable implementation specifications. Required specifications must be adopted and administered as dictated by the Rule. Addressable specifications are more flexible. Individual covered entities can evaluate their own situation and determine the best way to implement addressable specifications. Some privacy advocates have argued that this "flexibility" may provide too much latitude to covered entities.*[39] The standards and specifications are as follows:

- Administrative Safeguards – policies and procedures designed to clearly show how the entity will comply with the act
  - Covered entities (entities that must comply with HIPAA requirements) must adopt a written set of privacy procedures and designate a privacy officer to be responsible for developing and implementing all required policies and procedures.
  - The policies and procedures must reference management oversight and organizational buy-in to compliance with the documented security controls.
  - Procedures should clearly identify employees or classes of employees who will have access to electronic protected health information (EPHI). Access to EPHI must be restricted to

only those employees who have a need for it to complete their job function.

- The procedures must address access authorization, establishment, modification, and termination.
- Entities must show that an appropriate ongoing training program regarding the handling of PHI is provided to employees performing health plan administrative functions.
- Covered entities that out-source some of their business processes to a third party must ensure that their vendors also have a framework in place to comply with HIPAA requirements. Companies typically gain this assurance through clauses in the contracts stating that the vendor will meet the same data protection requirements that apply to the covered entity. Care must be taken to determine if the vendor further out-sources any data handling functions to other vendors and monitor whether appropriate contracts and controls are in place.
- A contingency plan should be in place for responding to emergencies. Covered entities are responsible for backing up their data and having disaster recovery procedures in place. The plan should document data priority and failure analysis, testing activities, and change control procedures.
- Internal audits play a key role in HIPAA compliance by reviewing operations with the goal of identifying potential security violations. Policies and procedures should specifically document the scope, frequency, and procedures of audits. Audits should be both routine and event-based.
- Procedures should document instructions for addressing and responding to security breaches that are identified either during the audit or the normal course of operations.

- Physical Safeguards – controlling physical access to protect against inappropriate access to protected data
  - Controls must govern the introduction and removal of hardware and software from the network. (When equipment is retired it must be disposed of properly to ensure that PHI is not compromised.)
  - Access to equipment containing health information should be carefully controlled and monitored.
  - Access to hardware and software must be limited to properly authorized individuals.
  - Required access controls consist of facility security plans, maintenance records, and visitor sign-in and escorts.
  - Policies are required to address proper workstation use. Workstations should be removed from high traffic areas and monitor screens should not be in direct view of the public.
  - If the covered entities utilize contractors or agents, they too must be fully trained on their physical access responsibilities.
- Technical Safeguards – controlling access to computer systems and enabling covered entities to protect communications containing PHI transmitted electronically over open networks from being intercepted by anyone other than the intended recipient.
  - Information systems housing PHI must be protected from intrusion. When information flows over open networks, some form of encryption must be utilized. If closed systems/networks are utilized, existing access controls are considered sufficient and encryption is optional.
  - Each covered entity is responsible for ensuring that the data within its systems has not been changed or erased in an unauthorized manner.
  - Data corroboration, including the use of check sum, double-keying, message authentication, and digital signature may be used to ensure data integrity.
  - Covered entities must also authenticate entities with which they communicate. Authentication consists of corroborating that an entity is who it claims to be. Examples of corroboration include: password systems, two or three-way handshakes, telephone callback, and token systems.
  - Covered entities must make documentation of their HIPAA practices available to the government to determine compliance.
  - In addition to policies and procedures and access records, information technology documentation should also include a written record of all configuration settings on the components of the network because these components are complex, configurable, and always changing.
  - Documented risk analysis and risk management programs are required. Covered entities must carefully consider the risks of their operations as they implement systems to comply with the act. (The requirement of risk analysis and risk management implies that the act' s security requirements are a minimum standard and places responsibility on covered entities to take all reasonable precautions necessary to prevent PHI from being used for non-health purposes.)

Unique Identifiers Rule (National Provider Identifier)

HIPAA covered entities such as providers completing electronic transactions, healthcare clearing houses, and large health plans, must use only the National Provider Identifier (NPI) to identify covered healthcare providers in standard transactions by May 23, 2007. Small health plans must use only the NPI by May 23, 2008.

Effective from May 2006 (May 2007 for small health plans), all covered entities using electronic communications (e.g., physicians, hospitals, health insurance companies, and so forth) must use a single new NPI. The NPI replaces all other identifiers used by health plans, Medicare, Medicaid, and other government programs.*[40] However, the NPI does not replace a provider's DEA number, state license number, or tax identification number. The NPI is 10 digits (may be alphanumeric), with the last digit being a checksum. The NPI cannot contain any embedded intelligence; in other words, the NPI is simply a number that does not itself have any additional meaning. The NPI is unique and national, never re-used, and except for institutions, a provider usually can have only one. An institution may obtain multiple NPIs for different "sub-parts" such as a free-standing cancer center or rehab facility.

Enforcement Rule

On February 16, 2006, HHS issued the Final Rule regarding HIPAA enforcement. It became effective on March 16, 2006. The Enforcement Rule sets civil money penalties for violating HIPAA rules and establishes procedures for investigations and hearings for HIPAA violations. For many years there were few prosecutions for violations.*[41]

> This may have changed with the fining of $50,000 to the Hospice of North Idaho (HONI) as the first entity to be fined for a potential HIPAA Security Rule breach affecting fewer than 500 people.*[42] Rachel Seeger, a spokeswoman for HHS, stated, "HONI did not conduct an accurate and thorough risk analysis to the confidentiality of ePHI as part of its security management process from 2005 through Jan. 17, 2012." This investigation was initiated with the theft from an employees vehicle of an unencrypted laptop containing 441 patient records.

As of March 2013, the U.S. Dept. of Health and Human Resources (HHS) has investigated over 19,306 cases that have been resolved by requiring changes in privacy practice or by corrective action. If noncompliance is determined by HHS, entities must apply corrective measures. Complaints have been investigated against many different types of businesses such as national pharmacy chains, major health care centers, insurance groups, hospital chains and other small providers. There were 9,146 cases where the HHS investigation found that HIPAA was followed correctly. There were 44,118 cases that HHS did not find eligible cause for enforcement; for example, a violation that started before HIPAA started; cases withdrawn by the pursuer; or an activity that does not actually violate the Rules. According to the HHS website (www.hhs.gov), the following lists the issues that have been reported according to frequency:

1. Misuse and disclosures of PHI
2. No protection in place of health information
3. Patient unable to access their health information
4. Using or disclosing more than the minimum necessary protected health information
5. No safeguards of electronic protected health information. (www.hhs.gov/enforcement, 2013)

The most common entities found to be required to take corrective action in order to be in voluntary compliance according to HHS are listed by frequency:

1. Private Practices
2. Hospitals
3. Outpatient Facilities
4. Group plans such as insurance groups
5. Pharmacies (hhs.gov/enforcement, 2013)

10.1.3 HITECH Act: Privacy Requirements

See the Privacy section of the Health Information Technology for Economic and Clinical Health Act (HITECH Act).

10.1.4 Effects on research and clinical care

The enactment of the Privacy and Security Rules has caused major changes in the way physicians and medical centers operate. The complex legalities and potentially stiff penalties associated with HIPAA, as well as the increase in paperwork and the cost of its implementation, were causes for concern among physicians and medical centers. An August 2006 article in the journal *Annals of Internal Medicine* detailed some such concerns over the implementation and effects of HIPAA.*[43]

Effects on research

HIPAA restrictions on researchers have affected their ability to perform retrospective, chart-based research as well as their ability to prospectively evaluate patients by contacting them for follow-up. A study from the University of Michigan demonstrated that implementation of the HIPAA Privacy rule resulted in a drop from 96% to 34% in the proportion of follow-up surveys completed by study patients being followed after a heart attack.*[44] Another study, detailing the effects of HIPAA on recruitment for a study on cancer prevention, demonstrated that HIPAA-mandated changes led to a 73% decrease in patient accrual, a tripling of time spent recruiting patients, and a tripling of mean recruitment costs.*[45]

In addition, informed consent forms for research studies now are required to include extensive detail on how the participant's protected health information will be kept private. While such information is important, the addition of a lengthy, legalistic section on privacy may make these already complex documents even less user-friendly for patients who are asked to read and sign them.

These data suggest that the HIPAA privacy rule, as currently implemented, may be having negative impacts on the cost and quality of medical research. Dr. Kim Eagle, professor of internal medicine at the University of Michigan, was quoted in the *Annals* article as saying, "Privacy is important, but research is also important for improving care. We hope that we will figure this out and do it right."*[43]

Effects on clinical care

The complexity of HIPAA, combined with potentially stiff penalties for violators, can lead physicians and medical centers to withhold information from those who may have a right to it. A review of the implementation of the HIPAA Privacy Rule by the U.S. Government Accountability Office found that health care providers were "uncertain about their legal privacy responsibilities and often responded with an overly guarded approach to disclosing information ... than necessary to ensure compliance with the Privacy rule".*[43] Reports of this uncertainty continue.*[46]

Costs of implementation

In the period immediately prior to the enactment of the HIPAA Privacy and Security Acts, medical centers and medical practices were charged with getting "into compliance". With an early emphasis on the potentially severe penalties associated with violation, many practices and centers turned to private, for-profit "HIPAA consultants" who were intimately familiar with the details of the legislation and offered their services to ensure that physicians and medical centers were fully "in compliance". In addition to the costs of developing and revamping systems and practices, the increase in paperwork and staff time necessary to meet the legal requirements of HIPAA may impact the finances of medical centers and practices at a time when insurance companies and Medicare reimbursement is also declining.

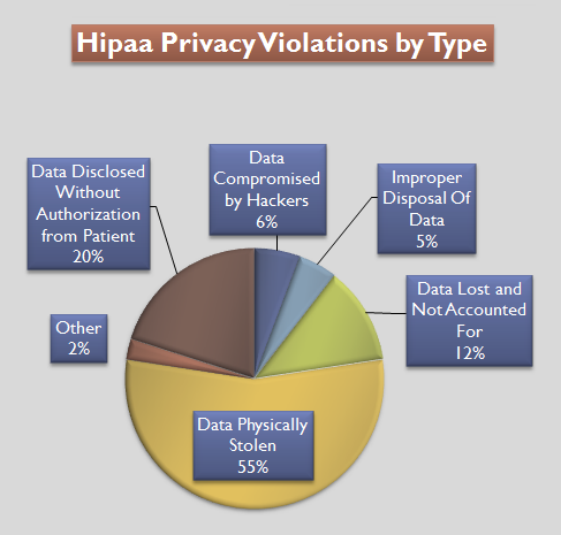
Education and training

Education and training of healthcare providers is paramount to correct implementation of the HIPAA Privacy and Security Acts. Effective training must describe the statutory and regulatory background and purpose of HIPAA and a general summary of the principles and key provisions of the Privacy Rule. Explain and define the type of entities that are covered by the Privacy Rule. The term business associate is defined, as are the requirements of the Privacy Rule when they carry out health care activities and functions on behalf of covered entities. Describes Privacy Rule provisions that address how entity organization may affect privacy functions, Describes the health information that is protected by the Privacy Rule. The presentation extensively describes the required and permitted uses and disclosures of PHI by a covered entity or its business associate, including situations where PHI may be used or disclosed without the individual's authorization and when such authorization is required. The Rule's minimum necessary provisions and its requirements are explained. Summarizes the Privacy Rule's provisions and requirements related to research. Describes when a covered entity may use and disclose PHI for research purposes and what research is affected. The presentation illustrates the relationship of the Privacy Rule's research provisions to other research rules, such as the Common Rule. Describes the Privacy Rule's administrative requirements for covered entities, such as policies and procedures, data safeguards, documentation and record retention, prohibition on retaliation, complaints to the covered entity, workforce training and sanctions.

10.1.5 HIPAA and drug and alcohol rehabilitation organizations

Special considerations for confidentiality are needed for health care organizations that offer federally funded drug or alcohol rehabilitation services.

Predating HIPAA by over a quarter century are the **Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970**[47] and language amended by the **Drug Abuse Office and Treatment Act of 1972**.*[43]*[48]



A breakdown of the HIPAA violations that resulted in the illegal exposure of personal information.

10.1.6 Violations of HIPAA

According to the US Department of Health and Human Services Office for Civil Rights, between April 2003 and January 2013 they received 91,000 complaints of HIPAA violations, in which 22,000 led to enforcement actions of varying kinds (from settlements to fines) and 521 led to referrals to the US Dept of Justice (criminal actions).*[49] Examples of significant breaches of protected information and other HIPAA violations include:

- the largest loss of data that affected 4.9 million people by Tricare Management of Virginia in 2011*[50]
- the largest fines of $4.3 million levied against Cignet Health of Maryland in 2010 for ignoring patients' requests to obtain copies of their own records and repeated ignoring of federal officials' inquiries*[51]
- the first criminal indictment was lodged in 2011 against a Virginia physician who shared information with a patient's employer "under the false pretenses that the patient was a serious and imminent threat to the safety of the public, when in fact he knew that the patient was not such a threat." *[52]

The differences between civil and criminal penalties are summarized in the following table:

10.1.7 Title III: Tax-related health provisions governing medical savings accounts

Title III standardizes the amount that may be saved per person in a pre-tax medical savings account. Beginning in 1997, medical savings account ("MSA") are available to employees covered under an employer-sponsored high deductible plan of a small employer and self-employed individuals.

10.1.8 Title IV: Application and enforcement of group health insurance requirements

Title IV specifies conditions for group health plans regarding coverage of persons with pre-existing conditions, and modifies continuation of coverage requirements. It also clarifies continuation coverage requirements and includes COBRA clarification.

10.1.9 Title V: Revenue offset governing tax deductions for employers

Title V includes provisions related to company-owned life insurance for employers providing company-owned life insurance premiums, prohibiting the tax-deduction of interest on life insurance loans, company endowments, or contracts related to the company. It also repeals the financial institution rule to interest allocation rules. Finally, it amends provisions of law relating to people who give up United States citizenship or permanent residence, expanding the expatriation tax to be assessed against those deemed to be giving up their U.S. status for tax reasons, and making ex-citizens' names part of the public record through the creation of the Quarterly Publication of Individuals Who Have Chosen to Expatriate.*[53]

10.1.10 Legislative information

- Pub.L. 104–191, 110 Stat. 1936
- H.R. 3103; H. Rept. 104-469, part 1; H. Rept. 104-736
- S. 1028; S. 1698; S. Rept. 104-156
- HHS Security Standards, 45 C.F.R. 160, 162, and 164
- HHS Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. 160 and 164

10.1.11 References

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[3] Centers for Medicare and Medicaid Services

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[5] 29 U.S.C. § 1181(a)(3)

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[7] 29 U.S.C. § 1181(c)(2)(A)

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[9] (Sub B Sec 111)

[10] 42 U.S.C. § 1320a-7c

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[16] See 45 CFR Sections 160.102 and 160.103.

[17] 45 C.F.R. 164.524(b)

[18] 45 C.F.R. 164.512

[19] Summary of the HIPAA Privacy Rule

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[21] 45 C.F.R. 164.502(a)(1)(iv)

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10.1.12 External links

- California Office of HIPAA Implementation (CalOHI)
- "HIPAA", Centers for Medicare and Medicaid Services
- Congressional Research Service (CRS) reports regarding HIPAA, University of North Texas Libraries
- Full text of the Health Insurance Portability and Accountability Act (PDF/TXT) U.S. Government Printing Office
- Full text of the Health Insurance Portability and Accountability Act (HTM) Legal Archiver
- Office for Civil Rights page on HIPAA

10.2 Certification Commission for Healthcare Information Technology

The **Certification Commission for Health Information Technology** (**CCHIT**) was an independent, 501(c)3 nonprofit organization with the public mission of accelerating the adoption of robust, interoperable health information technology. The Commission certified electronic health record technology from 2006 until 2014. It was approved by the Office of the National Coordinator for Health Information Technology (ONC) of the U.S. Department of Health and Human Services (HHS) as an Authorized Testing and Certification Body (ONC-ATCB). The **CCHIT Certified** program is an independently developed certification that includes a rigorous inspection of an EHR's integrated functionality, interoperability and security using criteria developed by CCHIT's broadly representative, expert work groups. These products may also be certified in the ONC-ATCB certification program.

10.2.1 History

CCHIT was founded in 2004 with support from three leading industry associations in healthcare information management and technology: the American Health Information Management Association (AHIMA), the Healthcare Information and Management Systems Society (HIMSS) and the National Alliance for Health Information Technology (the Alliance). In September 2005, CCHIT was awarded a 3-year contract by the U.S. Department of Health and Human Services (HHS) to develop and evaluate the certification criteria and inspection process for EHRs and the networks through which they interoperate. In October 2006, HHS officially designated CCHIT as a Recognized Certification Body (RCB).[*][1] In July 2010, HHS published new rules for recognizing testing and certification bodies, scheduled to take effect when it named the new bodies. In September 2010, the Office of the National Coordinator (ONC) of HHS named CCHIT again under these new rules. CCHIT is an ONC Authorized Testing and Certification Body (ONC-ATCB).

10.2.2 Goals

- Reduce the risk of Healthcare Information Technology (HIT) investment by physicians and other providers
- Ensure interoperability (compatibility) of HIT products
- Assure payers and purchasers providing incentives for electronic health records (EHR) adoption that the ROI will be improved quality
- Protect the privacy of patients' personal health information.

10.2.3 Operations

CCHIT focused its first efforts on ambulatory EHR products[*][2] for the office-based physician and provider and began commercial certification in May 2006.

CCHIT then developed a process of certification for inpatient EHR products[*][3] and launched that program in 2007.

CCHIT then assessed the need for, and potential benefit of, certifying EHR for specialty medicine, special care settings, and special-needs populations.[*][4][*][5]

CCHIT, in a collaboration with the MITRE Corporation, also developed an open-source program called Laika to test EHR software for compliance with federally named interoperability standards.

In January 2014, Information Week reported that CCHIT would exit the EHR certification business.[*][6]

On November 14, 2014, CCHIT ceased all operations.[*][7]

Announcements of CCHIT Certified Products

- On July 18, 2006, CCHIT released its first list of 20 certified ambulatory EMR and EHR products [*][8]
- On July 31, 2006, CCHIT announced that two additional EHR products had achieved certification.[*][9]
- On October 23, 2006, CCHIT released its second list of 11 certified vendors.[*][10]
- On April 30, 2007, CCHIT released its third list of 18 certified vendors.[*][11]
- On November 16, 2009, CCHIT released its initial draft criteria for Behavioral Health, Clinical Research, and Dermatology EHRs, with expected final publication available July 2010.

10.2.4 Commissioners

The Commission, chaired by Karen Bell, M.D., M.M.S, was composed of 21 members each serving two-year terms.

10.2.5 Stakeholders

Certified EHR products benefit many interested groups and individuals:

- Physicians, hospitals, health care systems, safety net providers, public health agencies and other purchasers of HIT products, who seek quality, interoperability, data portability and security
- Purchasers and payers – from government to the private sector – who are prepared to offer financial incentives for HIT adoption but need the assurance of having a mechanism in place to ensure that products deliver the expected benefits
- Quality improvement organizations that seek out an efficient means of measuring that criteria have been assessed and met
- Standards development and informatics experts that gain consensus on standards
- Vendors who benefit from having to meet a single set of criteria and from having a voice in the process
- Healthcare consumers, ultimately the most important stakeholders, who will benefit from a reliable, accurate and secure record of their health

CCHIT and its volunteer work groups strove to fairly represent the interests of each of these diverse groups in an open forum, communicating the progress of its work and seeking input from all quarters. CCHIT received the endorsements of a number of professional medical organizations, including the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Physicians, the Physicians' Foundation for Health Systems Excellence and Physicians' Foundation for Health Systems Innovation.

10.2.6 See also

- Electronic health record
- Electronic medical record

10.2.7 Notes

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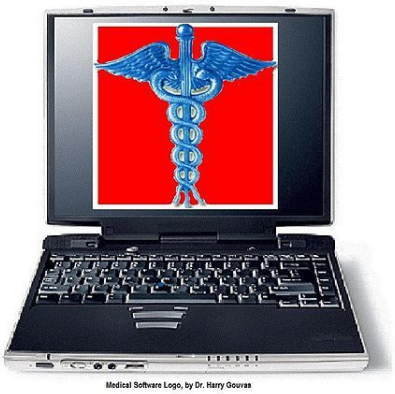
10.2.8 External links

- Official website

Chapter 11

Software Systems

11.1 Medical software



Medical software may appear on a PC, a laptop, a medical device, or even in a medical implant.

Medical software is any software item or system used within a medical context, such as:[*][1][*][2][*][3]

- standalone software used for diagnostic or therapeutic purposes;
- software embedded in a medical device (often referred to as "medical device software");
- software that drives a medical device or determines how it is used;
- software that acts as an accessory to a medical device;
- software used in the design, production, and testing of a medical device; or
- software that provides quality control management of a medical device.

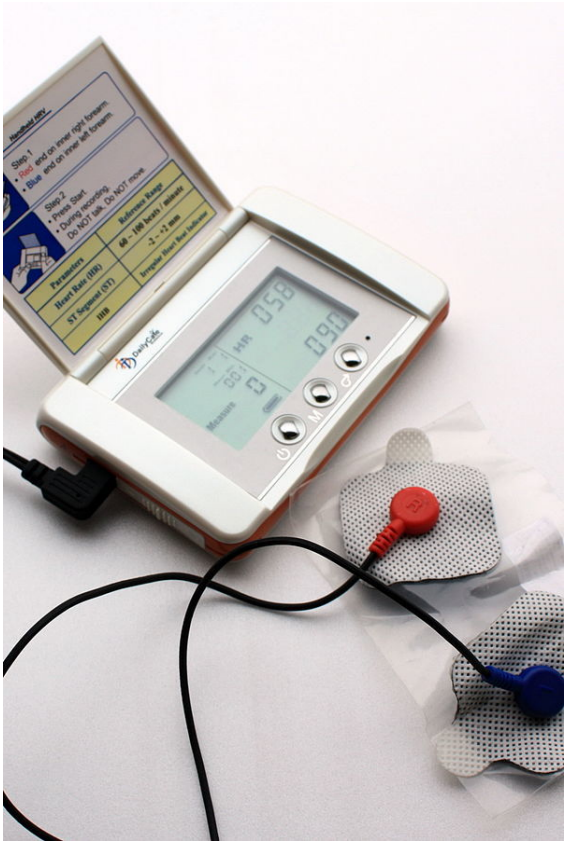
11.1.1 History

Medical software has been in use since at least since the 1960s,[*][4] a time when the first computerized information-handling system in the hospital sphere was being considered by Lockheed Martin.[*][5][*][6] As computing became more widespread and useful in the late 1970s and into the 1980s, the concept of "medical software" as a data and operations management tool in the medical industry —including in the physician's office —became more prevalent.[*][7][*][8] Medical software became more prominent in medical devices in fields such as nuclear medicine, cardiology, and medical robotics by the early 1990s, prompting additional scrutiny of the "safety-critical" nature of medical software in the research and legislative communities, in part fueled by the Therac-25 radiation therapy device scandal.[*][9][*][10] The development of the ISO 9000-3 standard[*][9] as well as the European Medical Devices Directive in 1993[*][1] helped bring some harmonization of existing laws with medical devices and their associated software, and the addition of IEC 62304 in 2006 further cemented how medical device software should be developed and tested.[*][11] The U.S. Food and Drug Administration (FDA) has also offered guidance and driven regulation on medical software, particularly embedded in and used as medical devices.[*][2][*][12][*][13]

11.1.2 Medical device software

The global IEC 62304 standard on the software life cycle processes of medical device software states it's a "software system that has been developed for the purpose of being incorporated into the medical device being developed or that is intended for use as a medical device in its own right." [*][11] In the U.S., the FDA states that "any software that meets the legal definition of a [medical] device" is considered medical device software.[*][14] A similar "software can be a medical device" interpretation was also made by the European Union in 2007 with an update to its European Medical Devices Directive, when "used specifically for diagnostic and/or therapeutic purposes." [*][15]

Due to the broad scope covered by these terms, manifold classifications can be proposed for various medical software, based for instance on their technical nature (embedded in a device or standalone), on their level of safety (from the most trivial to the most safety-critical ones), or on their primarily function (treatment, education, diag-



A portable heart rate variability device is an example of a medical device that contains medical device software.

nostics, and/or data management).

Software as a medical device

The dramatic increase in smartphone usage in the twenty-first century triggered the emergence of thousands of stand-alone health- and medical-related software apps, many falling into a gray or borderline area in terms of regulation. While software embedded into a medical device was being addressed, medical software separate from medical hardware —referred to by the International Medical Device Regulators Forum (IMDRF) as "software as a medical device" or "SaMD"[*][16] —was falling through existing regulatory cracks. In the U.S., the FDA eventually released new draft guidance in July 2011 on "mobile medical applications," with members of the legal community such as Keith Barritt speculating it should be read to imply "as applicable to all software ... since the test for determining whether a mobile application is a regulated mobile 'medical' application is the same test one would use to determine if any software is regulated." [*][17] Examples of mobile apps potentially covered by the guidance included those that regulate an installed pacemaker or those that analyze images for cancerous lesions, X-rays and MRI, graphic data such as EEG waveforms as well as bedside monitors, urine analyzers, glucometer, stethoscopes, spirometers, BMI calculators, heart rate monitors and body fat calculators.[*][18] By the time its final guidance was released in late 2013, however, members of Congress began to be concerned about the how the guidance would be used in the future, in particular with what it would mean to the SOFTWARE Act legislation that had recently been introduced.[*][19] Around the same time, the IMDRF were working on a more global perspective of SaMD with the release of its Key Definitions in December 2013, focused on "[establishing] a common framework for regulators to incorporate converged controls into their regulatory approaches for SaMD." [*][16] Aside from "not [being] necessary for a hardware medical device to achieve its intended medical purpose," the IMDRF also found that SaMD also couldn't drive a medical device, though it could be used as a module of or interfaced with one.[*][16] The group further developed quality management system principles for SaMD in 2015.[*][20]

11.1.3 International standards

IEC 62304 has become the benchmark standard for the development of medical device software, whether standalone software or otherwise, in both the E.U. and the U.S.[*][3][*][21] Leading industry innovation in software technologies has led key industry leaders and government regulators to recognize the emergence of numerous standalone medical software products that operate as medical devices. This has been reflected in regulatory changes in the E.U. (European Medical Devices Directive[*][1]) and the U.S. (various FDA guidance documents[*][2][*][12][*][13][*][19]). Additionally, quality management system requirements for manufacturing a software medical device, as is the case with any medical device, are described in the U.S. Quality Systems Regulation[*][22] of the FDA and also in ISO 13485:2003. Software technology manufacturers that operate within the software medical device space conduct mandatory development of their products in accordance with those requirements. Furthermore, though not mandatory, they may elect to obtain certification from a notified body, having implemented such quality system requirements as described within international standards such as ISO 13485:2003.

11.1.4 Further reading

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- Degoulet, P.; Fieschi, M. (2012). "Chapter 2: Medical Software Development" . *Introduction to Clinical Informatics*. New York: Springer Science & Business Media. pp. 19–34. ISBN 9781461268659.

11.1.5 See also

- Health informatics
- Health information technology
- Category:Medical software

11.1.6 External links

Media related to Medical Software at Wikimedia Commons

11.1.7 References

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11.2 Dental software

The term **dental software** is used for software used in dentistry. Computers have been used in dental medicine since the 1960s.*[1] Since then, computers and information technology have spread progressively in the dental practice. According to Atkinson, J. in the year 2000, 85.1% of all dentists in the United States were using computers.*[2]

11.2.1 Classification

Schleyer*[3] and Kirshner*[4] categorized dental software as administrative, clinical, and for the Internet. Zimmerman et al.*[5] categorized dental software functions for administration and management of patients documentation, electronic archives of the documentation, telecommunication, computer - aided education, computerizing instruments and techniques in the dental office software assisting with clinical decision making.

Patient records management dental software

Patient records management dental software is used by the dentist to organize the records of the patients in their practice. The computer patients management software is used for collecting, managing, saving, and retrieving medical information for the patients, and for creating reports for the patients. Computers in dentistry were first used to record dental archives*[1] as an alternative of paper dental documentation. Later, the term "computer based dental documentation" was replaced with the term electronic patient record (EPR) since the latter better describes the method and the environment in which the patient record is being managed.*[6] An official 1991 report of the Institute of Medicine of the National Academies in Washington, USA gave definitions about what functions must implement a computer based system for health documentation.

The American Dental Association (ADA) created specification number 1000 and number 1004*[7] concerning the structure and the content of the electronic health record. The medical data include identification and contact data, date of next visit, number of previous visits, anamnestic, clinical and paraclinical data, applied treatment, and treatment results data. Patient Records Management Dental Software is the most frequently used dental software.

Web-based dental patients records management software has been proposed. The web-based records save the information for the patients in a central web server instead in the computer in the dental office.*[8]

Dental treatment planning software

The usage of computer technologies for taking clinical decisions for the treatment of dental patients started at the end of the 1970s. The expert systems designed to enhance the treatment process, by providing the dental practitioner with a treatment plan are known as dental expert systems software. Today for more appropriate definition is supposed to be decision support systems, or DSS, and knowledge based systems (KBS). Such software products are designed for therapeutic dentistry,*[9] or prosthodontics.*[10]*[11]

Dental internet and ethernet communication software

Telecommunication technologies found application in the medicine in the 1950s, which led to the defining of a new term: telemedicine. In 1997, Cook first used the term "teledentistry" *[12] and defines it as the practice to be used videoconference technologies for diagnosis placement or consultations for the treatment from destination. Different variations of medical and dental data interchange using internet are developed.*[13] It is expected this type of software will revolutionize the way for interchanging information between medical and dental practitioners. Today teledentistry includes activities such as information interchange by phone lines, fax machines, and transfer of computer based documents via the internet. There are also special software products, designed for communication and information interchange between dentists, and software products designed to access dental information by the use of internet.

Computer-aided dental education

Computer-assisted education is an element from the remote education.*[14] The term "electronic learning" or "e-learning" defines the usage of internet and multimedia in the educational course. Schleyer*[15] describes the learning with the help of computer software as a means for overcoming the faults of the traditional forms of education. In 1997 Cook wrote about the usage of videoconference technologies by the means of their usage for dental education.*[12] Today software for computer aided dental education are made for various dental specialities: orthodontics, dental imaging, endodontics, cariesology, oral pathology, pediatric dentistry, parodontology and prosthodontics.*[14]*[15]

Software for usage of dental instruments

Instruments, used in dentistry, and needing software to operate are large number of models of digital roentgenography hardware, intraoral cameras, various diagnostic hardware products such as for early caries detec-

tion, periodontal probes, CAD/CAM systems.*[16]

11.2.2 See also

- Comparison of Dental Practice Management Software

11.2.3 References

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11.3 List of freeware health software

For health software released under a "free" open source licence, see List of open-source health software.

The following is a list of freeware software packages and applications for use in the health industry.

- Ambivu 3D Workstation, PC and Mac fast DICOM 3D/2D workstation
- VistA imaging, Public domain fully integrated PACS, image, and scanned document information system. One of the most widely used in the world, but incorporates proprietary modules not available outside the VA
- Ginkgo CADx, Cross-platform open source DICOM viewer
- MicroDicom, DICOM viewer for Windows
- IrfanView, A image viewer for Windows with DICOM support
- BioDigital

11.3.1 See also

- eHealth
- Health Informatics
- List of open-source bioinformatics software

11.3.2 References

11.4 List of open source healthcare software

The following is a list of software packages and applications licensed under an open-source license or in the public domain for use in the health care industry.

11.4.1 Public health and biosurveillance

- Epi Info is public domain statistical software for epidemiology developed by Centers for Disease Control and Prevention.
- Spatiotemporal Epidemiological Modeler is a tool, originally developed at IBM Research, for modeling and visualizing the spread of infectious diseases.

11.4.2 Dental management and patient record

- Open Dental is the first open-source dental management package with very broad capabilities on record management, patient scheduling and dental office management.

11.4.3 Electronic health or medical record

- CottageMed is a cross-platform electronic medical record system based on FileMaker. CottageMed is released under the GPL
- FreeMED is a practice management and electronic and computer records system. It allows the tracking of medical data, in detail, with preservation not just of the diagnosis but the reasons for medical encounters. FreeMED is released under the GPL
- GaiaEHR is a modern open source electronic health record developed using PHP and Ext JS
- GNUmed is a WxPython application that uses PostgreSQL
- GNU Health is a centralized, highly scalable health and hospital information system
- Hospital OS Open source hospital information system in Thai
- HOSxP is a hospital information system, including Electronic health record (EHR), in use in over 70 hospitals across Thailand.
- Mirth is an open source cross-platform HL7 interface engine that enables bi-directional sending of HL7 messages between systems and applications over multiple transports.
- openEHR is an open standard specification in health informatics that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs) following a two-level modelling paradigm.
- OpenEMR is a PHP-based *[1] electronic medical record (EMR) system.
- OpenMRS is an enterprise EMR framework. Extensible and scalable EMR based on Java.
- OSCAR McMaster is an electronic medical record (EMR) application. The billing component of the software is specialized for the needs of the Canadian health-care providers.
- THIRRA is a web-based EHR application designed primarily for narrowband. It includes communicable diseases biosurveillance feature. THIRRA uses PHP5, CodeIgniter and PostgreSQL.
- VistA – Veterans Administrations integrated electronic health record system available for non-governmental use as OSEHRA VistA or OpenVista or WorldVistA.
- ZEPRS is a web-based patient record system.
- SmartCare is a C# windows based EHR application, with working installations in Zambia, Ethiopia and South Africa. It is designed with the state of poor connectivity in developing countries in mind, making use of SmartCards to store patient level information. Its core development team is based in Zambia where the Government has adopted it as its national EHR.

11.4.4 Medical practice management software

- ClearHealth covers the five major areas of practice operations: scheduling, billing, EMR, HIPAA Security and accounts receivable.
- FreeMED is a practice management and electronic and computer records system. It allows the tracking of medical data, in detail, with preservation not just of the diagnosis but the reasons for medical encounters. FreeMED is released under the LGPL GNU license. FreeMED is an HIPAA compliant FOSS practice management system that handles billing.
- GNU Health is a centralized, highly scalable health and hospital information system
- MedinTux is a French medical practice management system, with a web interface as well as a desktop one, that has been initially to manage a hospital emergency department. Being very modular, it has been extended to run also many different smaller practices.
- Open Dental Dental practice management
- OpenEMR is a medical practice management, electronic medical records, prescription writing, and medical billing application.
- OpenHospital is an electronic medical record system meant for small rural hospitals

11.4.5 Health system management

- DHIS is a district health management information system and data warehouse
- HRHIS is a human resource for health information system for management of human resources for health developed by University of Dar es Salaam, Department of Computer Science, for Ministry of Health and Social Welfare (Tanzania) and funded by the Japan International Cooperation Agency (JICA)

11.4.6 Imaging/visualization

- Advanced Simulation Library* [2] is a hardware accelerated multiphysics simulation software
- Drishti is a volumetric visualisation package for viewing computer tomography data. Able to import DICOM image stacks.
- Endrov Image and data viewer and editor
- ITK segmentation and registration toolkit
- InVesalius 3D medical imaging reconstruction software
- ITK-SNAP Interactive software for 3D image navigation, annotation and automatic segmentation
- Ginkgo CADx Cross-platform open source DICOM viewer and dicomizer.
- MITK - Medical Imaging Interaction Toolkit for interactive medical image processing.
- Orthanc – Lightweight, RESTful DICOM server for medical imaging.
- OsiriX – 3D DICOM medical viewer for Mac OS X. Complete DICOM Viewer with DICOM network support
- ParaView large-scale visualization tool
- 3DSlicer Platform for medical image visualization and algorithm development. DICOM support, segmentation and registration, Diffusion MRI processing, and image guided surgery support.
- Voreen volume rendering engine—a library for visually exploring volume data sets. DICOM is supported and Voreen is used in medical visualization as well as for visualizing electron microscopy data.
- VTK visualization toolkit
- Xebra (medical imaging software)
- GIMIAS workflow-oriented environment focused on biomedical image computing and simulation

11.4.7 Medical information systems

- Caisis is a web-based information system for the storage and analysis of cancer patient data intended to bridge the gap between clinic and research
- cTAKES ("*clinical Text Analysis Knowledge Extraction Software*") is a natural language processing system for extracting information from electronic medical record clinical free-text, an Apache TLP since 2013, developed by the Mayo Clinic and others

11.4.8 Research

- LabKey Server is an extensible platform for integrating, analyzing and sharing all types of biomedical research data. It provides secure, web-based access to research data and includes a customizable data processing pipeline.

11.4.9 Mobile devices

- Ushahidi Allows people to submit crisis information through text messaging using a mobile phone, email or web form. Displays information in map view.
- Glucosio Allows people with diabetes to track their glucose levels while supporting diabetes research via Android or iOS mobile apps.

11.4.10 Out-of-the-box distributions

- BioLinux
- Debian-Med
- Ubuntu-Med

11.4.11 Interoperability testing

- The Office of the National Coordinator for Health Information Technology (ONC) tasked MITRE with developing an open-source program called Cypress to test EHR software for compliance with the Meaningful Use Stage 2 Clinical Quality Measures.* [3]
- The Certification Commission for Healthcare Information Technology (CCHIT) and MITRE developed an open-source program called Laika to test EHR software for compliance with CCHIT interoperability data standards, including the HITSP C32 XML and HL7 v2 Lab messages.

11.4.12 See also

- Electronic medical record
- eHealth
- Gello Expression Language
- Health informatics
- Hospital information systems
- List of freeware health software
- List of biomedical cybernetics software
- List of open-source bioinformatics software
- List of open-source health hardware
- mHealth

11.4.13 References

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[2] "ASL: Intraoperative Brain Shift".

[3] ONC: Open source CQM EHR certification tool Cypress now available | EHRintelligence.com

11.5 List of neuroimaging software

Neuroimaging software is used to study the structure and function of the brain. To see an NIH Blueprint for Neuroscience Research funded clearinghouse of many of these software applications, as well as hardware, etc. go to the NITRC web site.

- 3D Slicer Extensible, free open source multi-purpose software for visualization and analysis.
- aidScans, tumor volume estimation
- Amira 3D visualization and analysis software
- Analysis of Functional NeuroImages (AFNI)
- Analyze4D: A matlab GUI based tool designed for advanced ROI time course analysis and visualization(from Donders Institute)
- Analyze developed by the Biomedical Imaging Resource (BIR) at Mayo Clinic.
- Bioimage Suite.
- BrainMagix: Clinical neuroimaging software suite, with functional MRI, perfusion, diffusion and tractography modules, image fusion and segmentation tools.
- BESA (Brain Electrical Source Analysis)
- Bergen EEG-fMRI Toolbox plugin for EEGLab (remove fMRI gradients from simultaneous EEG-fMRI recordings)
- Brain Image Analysis Package
- BrainSuite,* [1] a collection of tools for extraction of cerebral cortex, segmentation and labeling brain volumes and surfaces, and distortion correction and coregistration of diffusion data with structural MRIs.
- BrainVISA
- BrainVoyager
- CamBA
- Camino Open-source toolkit for diffusion MRI.
- Caret Van Essen Lab, Washington University in St. Louis
- COINS (Collaborative Neuroimaging and Informatics Suite) developed by The Mind Research Network is a one stop neuroimaging/science/psychology research management toolsuite.
- CONN (functional connectivity toolbox)
- ExploreDTI * [2] is a graphical toolbox, for exploratory diffusion (tensor) MRI and fiber tractography.
- Fiasco/FIAT (from CMU)
- FMRIB Software Library (FSL)
- FMRLAB
- FreeSurfer
- IB Clinic by Imaging Biometrics
- ISAS (Ictal-Interictal SPECT Analysis by SPM)
- Leipzig Image Processing and Statistical Inference Algorithms (LIPSIA)
- LONI Pipeline, Laboratory of Neuro Imaging, USC
- Mango,* [3] developed at the Research Imaging Center, University of Texas Health Science Center at San Antonio
- Medical Image Processing, Analysis, and Visualization software (MIPAV) , developed by BIRSS at the National Institutes of Health
- MNE : Magnetoencephalography (MEG) and Electroencephalography (EEG) in Python
- MNI MINC McConnell Brain Imaging Center, Montreal Neurological Institute, McGill University
- MRIcro

- MRICloud,*[4] Center for Imaging Science, Whiting School of Engineering, The Johns Hopkins University
- MRIcron (Next generation of MRIcro)
- MRtrix, software for performing and analysing diffusion-weighted MRI white matter tractography in the presence of crossing fibres, using Constrained Spherical Deconvolution
- mrVista (from Stanford)
- MRVision
- Net Station
- Neuroimaging software installation support
- Neuroreader™*[5] - a clinical software application that analyses MR brain scans, aimed at assisting the clinician in an assessment of structural MRI's.
- NeuroLens
- NIAK, the NeuroImageing Analysis Kit
- NIfTI
- nilearn,*[6] Machine learning for Neuro-Imaging in Python
- NITRC The Neuroimaging Informatics Tools and Resources Clearinghouse. An NIH funded database of neuroimaging tools
- nordicICE
- Olea Medical: PerfScape & NeuroScape
- Prism suite
- PyMVPA
- SHAring NeurOImaging Resources (Shanoir) is a neuroinformatics platform designed to share, archive, search and visualize neuroimaging data.
- Signed differential mapping (SDM)
- The Spinal Cord Toolbox (SCT) is the first comprehensive and open-source software for processing MR images of the spinal cord.*[7]
- Statistical parametric mapping (SPM)
- Stimulate (One of the earliest fMRI software package from CMRR at University of Minnesota)
- Tortoise*[8] Tolerably Obsessive Registration and Tensor Optimization Indolent Software Ensemble. A software package is for processing diffusion MRI data

11.5.1 References

[1] D. W. Shattuck and R. M. Leahy, "BrainSuite: An automated cortical surface identification tool." Medical Image Analysis, 6 (2002): 129-142, DOI: http://dx.doi.org/10.1016/S1361-8415(02)00054-3

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[8] C. Pierpaoli, L. Walker, M. O. Irfanoglu, A. Barnett, P. Basser, L-C. Chang, C. Koay, S. Pajevic, G. Rohde, J. Sarlls, and M. Wu, 2010, TORTOISE: an integrated software package for processing of diffusion MRI data, ISMRM 18th annual meeting, Stockholm, Sweden, #1597

11.6 Mirth

Mirth Connect is a cross-platform HL7 interface engine that enables bi-directional sending of HL7 messages between systems and applications over multiple transports available under the Mozilla Public License (MPL) 1.1 license. On September 9th, 2013 Mirth Corporation announced they were acquired by Quality Systems.*[1]

11.6.1 Background

Mirth Connect uses a channel-based architecture to connect HIT systems and allow messages to be filtered, transformed, and routed based on user-defined rules. Channels consist of connectors (both inbound and outbound), filters, and transformers. Multiple filters and a chain of transformers can be associated with a channel.

Endpoints are used to configure connections and their protocol details. Source connectors are used to designate the type of listener to use for incoming messages, such as TCP/IP or a web service. Destination connectors are used to designate the destination of outgoing messages, such as an application server, a JMS queue, or a database. All messages and transactions are optionally logged to an internal database. Mirth Connect can be also configured to auto-generate an HL7 acknowledgement response (ACK).

11.6.2 Connector varieties

Mirth Connect supports sending and receiving healthcare messages over a variety of protocols:

- TCP/MLLP
- Database (MySQL, PostgreSQL, Oracle, Microsoft SQL Server, ODBC)
- File (local file system and network shares)
- PDF and RTF documents
- JMS
- FTP/SFTP
- HTTP
- SMTP
- SOAP (over HTTP)

An open architecture allows for the easy addition of custom and legacy interfaces.

11.6.3 Types of transforms

- Mapping transformer: map data from incoming message to variables
- Script transformer: execute custom script on message (Ex. JavaScript, Python, Tcl)
- HL7 message generator: construct HL7 messages from data source
- XSLT transformer: run XSL Transformations on incoming HL7 v3 or XML encoded messages

11.6.4 Adopters

The Certification Commission for Healthcare Information Technology (CCHIT), in a push to ensure interoperability standards between electronic health records, has adopted Laika, an open source standards software program. At the 2009 Annual HIMSS Conference, Mirth was selected as one of the testing tools for the coming interoperability tests.*[2]

11.6.5 References

[1] "Quality Systems, Inc. Acquires Mirth Corporation". 2013-09-09. Retrieved 2013-09-17.

[2] "Archive for the 'HIMSS' Category". Fred Trotter blog. 2009-04-08. Retrieved 2009-04-16.

11.6.6 External links

- The Mirthcorp website
- Mirth Connect experience in Europe (Belgium/France/Netherlands)
- NIEUW. Mirth support in Nederland
- Mirth Consulting, Support and PlugIn development in Germany
- Mirth Source Code

11.7 Mpro

Mpro may refer to:

- Electronic patient-reported outcome
- SARS coronavirus main proteinase, an enzyme

11.8 Open Dental

Open Dental, previously known as **Free Dental**, is a Practice Management Software licensed under the GNU General Public License.*[3] It is written in the C# programming language compatible with Microsoft .NET Framework and was first released in 2003. Current versions of the software require Microsoft Windows. Earlier versions of the software had supported other operating systems, but Linux support has been dropped.*[4] The full function version is only available under the commercial license because it includes royalty bearing, licensed materials from the American Dental Association (ADA), the Code on Dental Procedures and Nomenclature (CDT).

Open Dental is owned and sponsored by Open Dental Software, Inc., which is incorporated in the State of Oregon in the United States of America.*[5] However, since anyone has the freedom to develop and support Open Dental, in a sense it belongs to the entire dental community. The features and accessibility of Open Dental make it a considerable option for use in dental business. The first Free Dental customer bought the software July 22, 2003.*[6]

11.8.1 Database

The database uses the dual licensed MySQL database program. The structure of the data, or schema, is available for all to see and use (the data is still very secure). It is totally different than the proprietary format that all other dental software uses. Other programs can only export certain fields. In Open Dental, access to and control over every single piece of data is held by the dentist. Both local preferences and those which apply to every computer in the office will be stored in the mySQL database. This also greatly simplifies working with preferences and settings, and adding new workstations without having to spend all day setting them up.

The database schema is published and publicly viewable at http://www.opendental.com/OpenDentalDocumentation67.xml.*[7]

Relational database benefits to dental practice

There are documented benefits to using a relational database when storing and retrieving data: the relational model offers "advantages over the hierarchical and network models through its simpler data representation, superior data independence and easy to use query language".*[8] Open Dental gives the user those benefits over the non-relational platforms used by other dental practice management software programs.

Availability Relational databases like Oracle and MySQL have mechanisms that can be used to keep the availability (of the database) very high. For instance, with MySQL replication, "the active primary database ships transactions to one or more standby databases. These standby databases apply the transactions to their own copies of the data. Should the primary database fail, one of these standby databases can be activated to become the new primary database".*[9] High availability is of clear importance when a customers (patients) have expectations of service at a particular time (an appointment). Open Dental provides replication support for users whose availability, mobility or multiple physical location needs demand it.*[10]

Mobility Mobile dental programs have special needs including offline data collection, central data availability and public health reporting. All of these needs are met with Open Dental. An example of a mobile dental program that has published*[11] their experience using Open Dental is the St. David's Dental Program.*[12]

Retrievability Structured Query Language (SQL) allows the user to pull data from the database for analysis. Open Dental provides over 250 user queries that have been requested by users,*[13] and advanced users may write their own queries to get specialized information from the database.*[14]

Scalability Open Dental can be scaled from a single, one-computer user in a small office to dozens of computers per server over multiple physical locations.*[15]

11.8.2 Goals

The project wants "this software to become the world standard dental software. We want to make it easy to access and share data. We are tired of the restrictive policies of the current dental software companies. We want the user to always have total control, not the software company. And most of all, we want software that just works well".*[16]

There are about 4,000 offices using OD, and an estimated 10,000,000 patient records.

Dr. Jordan Sparks has done most of the initial programming. They have a team of additional programmers employed these days.

11.8.3 Features

Appointment*[17]

- Support unlimited operatories and unlimited providers
- Customizable views, colors, default values
- Easy to set up and modify appointments, recalls
- Show pop-up alerts, financial and medical notes

Family*[18]

- Support complete patient records (HIPAA compliant)
- When possible, fields are filled automatically or checked for potential errors
- Save billing type and insurance information
- Track student status and referrals
- Track credit and contact notes
- Sign Procedure Notes: Digital Signatures. Sign or initial procedure notes using a Topaz signature pad or by using a stylus on a touchscreen.
- Patient Info Terminal: A way for a new patient to enter their own information from the waiting room. The receptionist controls the terminal from another computer. Can also be used to let patient update their info if it has changed. New patients can check off items in list of diseases.

- Medical History Questionnaire: Customized list of questions and answers added to pt info terminal.

Account*[19]

- Customizable and easy recall scheduling
- Send letters and emails to patients
  - Email appointment reminders, recare appointments. Supports SMTP servers that require a user name and password for sending email. Allows saving email to send later.
- Comprehensive billing system with e-claim support
  - E-claims: go through a clearinghouse to submit all e-claims or submit directly to carries that support the X12 files/claims. The X12 EDI Format is the standard defined by ASC (ex-ANSI) and specified by HIPAA. Open dental claims to be the only dental practice management software which natively creates X12 format files without having to go through a clearing house for conversion.
- Track all referrals and lab cases
  - Lab Cases: Each lab can be set up with its own turnaround times on each procedure type. Due dates are calculated automatically, taking into account holidays.
- Create and track payment plans
- Open Dental has built-in accounting that is intended to replace QuickBooks for small offices.
  - Patient's finances are organized on a patient basis, not a family basis.
- Credit Card Processing Integrated credit card processor with swipe terminal.

Treatment Plan*[20]

- Easy to view ' treatment plans
- Support multiple treatment plans
- Print or send electronically insurance preauthorization forms

Chart*[21]

- Easy to enter and organize patients' clinical information
- Full featured 3D tooth charting
- Track progress and treatment notes
- Simple to write and print prescriptions
  - Rx Alerts: Crosslink Diseases to Rx definitions so that an alert is triggered for allergies, etc. when writing an Rx.
- Procedure codes: Currently, the following sets of procedure codes are available as separate databases: blank, usa, canada, uk.
- Perio Charting: voice recognition software to help with charting

Images*[22]

- Add and manage all images
- Integrate with Radiography, scanner, digital camera devices
- Images can be zoomed in and out, rotated.
- Can attach Word, PDF, and Excel files

Manage*[23]

- Create and send e-claims or paper claims
- Billing automation
- Audio and visual office intercom
- Critical data backup
- Flexible user-defined queries and reports
- Track employees' hours and breaks
- Support daily, weekly & monthly task lists
- Built-in accounting module
- Secure remote access
- Language support: The code is all written to automatically adapt to the user's computer settings. The translations are specific to the culture (country), not just the language.
- Time Cards: Customizable pay periods added so that you don't have enter the date range each time. Tracks 40-hour workweek, computes overtime, allows adjustments, and prints.
- New Reporting Framework: The FLOSS RDL Project is included with Open Dental. It will also allow export to PDF.
- Import from XML : This allows other programs to safely pass information to Open Dental without having to worry about accidentally corrupting the database. This will eventually lead to the ability to 'send' a patient 'chart' to another office electronically. The main purpose for now is to allow new patients to fill out their forms online.
- Multiple Server Support

11.8.4 See also

- Comparison of Dental Practice Management Software
- List of FLOSS healthcare programs
- Dentrix
- PracticeWorks
- SoftDent

11.8.5 References

[1] http://www.opendental.com/manual/clinuxmac.html

[2] https://code.google.com/p/gnudental/wiki/GettingStarted

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[4] "Open Dental Software Manual - C#, Linux, and Macintosh". Open Dental Software Inc. Retrieved 2009-06-12.

[5] "Oregon Secretary of State Business Name Search (original url http://egov.sos.state.or.us/br/pkg_web_name_srch_inq.show_detl?p_be_rsn=1173550&p_srce=BR_INQ&p_print=FALSE)". State of Oregon. Retrieved 2009-06-03. External link in |title= (help)

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[17] "Open Dental Software - Appointments Module". Open Dental Software Inc. Retrieved 2009-06-12.

[18] "Open Dental Software - Family Module". Open Dental Software Inc. Retrieved 2009-06-12.

[19] "Open Dental Software - Account Module". Open Dental Software Inc. Retrieved 2009-06-12.

[20] "Open Dental Software - Treatment Plan Module". Open Dental Software Inc. Retrieved 2009-06-12.

[21] "Open Dental Software - Chart Module". Open Dental Software Inc. Retrieved 2009-06-12.

[22] "Open Dental Software - Images Module". Open Dental Software Inc. Retrieved 2009-06-12.

[23] "Open Dental Software - Manage Module". Open Dental Software Inc. Retrieved 2009-06-12.

11.8.6 External links

- Open Dental Website
- MySQL Website
- ADA Vendor Directory of Practice Management Software
- Sourceforge Website
- Dentist Patient Management a plugin for OpenDental
- ConvergedComm CRM plugin for OpenDental

11.9 Personal Health Application

Personal Health Applications (PHA) are tools and services in medical informatics which utilizes information technologies to aid individuals to create their own personal health information.

Personal Health Applications are claimed to be the next generation consumer-centric information system that helps improve health care delivery, self-management and wellness by providing clear and complete information, which increases understanding, competence and awareness. Personal Health Application is now part of the Medicine 2.0 movement.*[1]

11.9.1 Definition

Personal Health Application is an electronic tool of storing, managing and sharing health information in illness and wellness by an individual in a secure and confidential environment.

11.9.2 Benefits

Most people do not carry medical records when they leave home. They do not realize that in an emergency, which no one can predict, these medical records can make a big difference. In fact, they could save a life. Previous medications, history of allergy to medications, and other significant medical or surgical history can help a health professional through PHA tools to optimize treatment.

A Personal Health Application (PHA) tool contains a patient's personal data (name, date of birth and other demographic details). It also includes a patient's diagnosis or health condition and details about the various treatment/assessments delivered by health professionals during an episode of care from a health care provider. It contains an individuals health-related information accumulated during an entire lifetime.

11.9.3 See also

- Personal health record
- eHealth
- mHealth

11.9.4 References

- Clinfowiki (Clinical Informatics Wiki) article on Personal Health Applications

11.9.5 Notes

[1] http://www.medicine20.com/

11.10 Texas Medication Algorithm Project

The **Texas Medication Algorithm Project (TMAP)**[*][1] is a controversial decision-tree medical algorithm, the design of which was based on the expert opinions of mental health specialists. It has provided and rolled out a set of psychiatric management guidelines for doctors treating certain mental disorders within Texas' publicly funded mental health care system, along with manuals relating to each of them. The algorithms commence after diagnosis and cover pharmacological treatment (hence "Medication Algorithm").

11.10.1 History

TMAP was initiated in the fall of 1997 and the initial research covered around 500 patients.

TMAP arose from a collaboration that began in 1995 between the Texas Department of Mental Health and Mental Retardation (TDMHMR), pharmaceutical companies, and the University of Texas Southwestern. The research was supported by the National Institute of Mental Health, the Robert Wood Johnson Foundation, the Meadows Foundation, the Lightner-Sams Foundation, the Nanny Hogan Boyd Charitable Trust, TDMHMR, the Center for Mental Health Services, the Department of Veterans Affairs, the Health Services Research and Development Research Career Scientist Award, the United States Pharmacopoeia Convention Inc. and Mental Health Connections.

Numerous companies that invent and develop antipsychotic medications provided use of their medications and furnished funding for the project. Companies did not participate in the production of the guidelines. [*][2]

In 2004 TMAP was mentioned as an example of a successful project in a paper regarding implementing mental health screening programs throughout the United States, by the President George W. Bush's New Freedom Commission on Mental Health, which looks to expand the program federally. The President had previously been Governor of Texas, in the period when TMAP was implemented. Similar programs have been implemented in about a dozen States, according to a 2004 report in the *British Medical Journal*.

Similar algorithms with similar prescribing advice have been produced elsewhere, for instance at the Maudsley Hospital,[*][3] London.

The development and implementation of TMAP was a result of numerous sponsors such as the National Institute of Mental Health, the Robert Wood Johnson Foundation, the Meadows Foundation, the Lightner-Sams Foundation, the Nanny Hogan Boyd Charitable Trust, TDMHMR, the Center for Mental Health Services, the Department of Veterans Affairs, the Health Services Research and Development Research Career Scientist Award, the United States Pharmacopoeia Convention Inc. and Mental Health Connections, Johnson & Johnson, Abbott Laboratories, Astrazeneca, Novartis, Janssen Pharmaceuticals, GlaxoSmithKline, Wyeth-Ayerst, Forest Laboratories, U.S. Pharmacopeia, Bristol-Myers Squibb Company, Eli Lilly and Company, Janssen Pharmaceutica, Novartis International AG, and Pfizer, Inc. Patented mental health drugs promoted by TMAP include: Risperdal, Zyprexa, Seroquel, Geodon, Depakote, Paxil, Zoloft, Celexa, Wellbutrin, Zyban, Remeron, Serzone, Effexor, Buspar, Adderall,

and Prozac, all manufactured by the above pharmaceutical companies.*[4]

The strategy behind the commission was developed by the pharmaceutical industry, advancing the theory that the primary purpose of the commission was to recommend implementation of TMAP based algorithms on a nationwide basis. TMAP, which advises the use of newer, more expensive medications, has itself has been the subject of controversy in Texas, Pennsylvania and other states where efforts have been made to implement its use.

TMAP origin criticism

Critics also contend that the strategy behind the New Freedom Commission was developed by the pharmaceutical industry, advancing the theory that the primary purpose of the commission was to recommend implementation of TMAP based algorithms on a nationwide basis. TMAP, which advises the use of newer, more expensive medications, has itself has been the subject of controversy in Texas, Pennsylvania and other states where efforts have been made to implement its use.

TMAP, which was created in 1995 while President Bush was governor of Texas, began as an alliance of individuals from the University of Texas, the pharmaceutical industry, and the mental health and corrections systems of Texas. Through the guise of TMAP, critics contend, the drug industry has methodically influenced the decision making of elected and appointed public officials to gain access to citizens in prisons and State psychiatric hospitals. The person primarily responsible for bringing these issues to the public's attention is Allen Jones, a former investigator in the Commonwealth of Pennsylvania Office of Inspector General (OIG), Bureau of Special Investigations.

Jones wrote a lengthy report in which he stated that, behind the recommendations of the New Freedom Commission, was the "political/pharmaceutical alliance." It was this alliance, according to Jones, which developed the Texas project, specifically to promote the use of newer, more expensive antipsychotics and SSRI antidepressants. While investigating for the Commonwealth of Pennsylvania Office of Inspector General, Jones states, "I became increasingly alarmed that all of the drugs recommended by the TMAP program were exclusively the new, patented atypical antipsychotics for schizophrenia, and all of the brand-new, patented SSRI antidepressants. None of it added up. When it became obvious to me that my investigation was not going to be permitted to continue, and it became obvious to the Inspector General's Office that I was not going to stop, I was removed from the investigation on the case. They threatened me with loss of career, with loss of job, with loss of reputation, essentially."*[5] He further claimed this alliance was "poised to consolidate the TMAP effort into a comprehensive national policy to treat mental illness with expensive, patented medications of questionable benefit and deadly side effects, and to force private insurers to pick up more of the tab".*[6]

Allen Jones was forced out of his job at the Pennsylvania Office of Inspector General's Office after he questioned how the state adopted a Medicaid protocol that gave preferential treatment to Janssen Pharmaceutical's drug Risperdal. The protocol, used in many states, was based on the Texas Medication Algorithm Project, which state investigations later revealed to be riddled with kickbacks, conflicts of interest, and bad science. Janssen ultimately settled a lawsuit filed by the Texas Attorney General's Office for $158 million.

A bill, 'The Parental Consent Act of 2005', or HR 181, has been introduced in the US House of Representatives by Ron Paul, a Republican from Texas. The proposal forbids federal funds from being used for any mental health screening of students without the express, written, voluntary, informed consent of parents.

11.10.2 References

[1] DSHS.state.tx.us - Texas Medication Algorithm Project (official site with algorithms etc), Texas Department of State Health Services

[2] http://www.ahrp.org/infomail/05/10/14.php

[3] Lists of Psychopharmacology Algorithms. Compiled by David N. Osser, M.D. and Robert D. Patterson, M.D. (viewed 17 March 2006)

[4] http://www.cchr.org/sites/default/files/Texas_Medication_Algorithm_Project_Allen_Jones.pdf| (page 2)

[5] https://m.youtube.com/watch?v=O2sW2jIf0Ks | (10:12)

[6] http://www.cchr.org/sites/default/files/Texas_Medication_Algorithm_Project_Allen_Jones.pdf

11.10.3 External links

- MentalHealthCommission.gov - President's New Freedom Commission on Mental Health (official US government website)

Chapter 12

Languages and Development Platforms

12.1 MUMPS

This article is about the programming language. For other uses, see Mumps (disambiguation).

MUMPS (***M**assachusetts General Hospital **U**tility **M**ulti-**P**rogramming **S**ystem*) or alternatively **M**, is a general-purpose computer programming language that provides ACID (Atomic, Consistent, Isolated, and Durable) transaction processing. Its differentiating feature is its "built-in" database, enabling high-level access to disk storage using simple symbolic program variables and subscripted arrays, similar to the variables used by most languages to access main memory.

The M database is a key-value database engine optimized for high-throughput transaction processing. As such it is in the class of "schema-less", "schema-free," or NoSQL databases. Internally, M stores data in multidimensional hierarchical sparse arrays (also known as key-value nodes, sub-trees, or associative memory). Each array may have up to 32 subscripts, or dimensions. A scalar can be thought of as an array element with zero subscripts. Nodes with varying numbers of subscripts (including one node with no subscripts) can freely co-exist in the same array.

Perhaps the most unusual aspect of the M language is the notion that the database is accessed through variables, rather than queries or retrievals. This means that accessing volatile memory and non-volatile storage use the same basic syntax, enabling a function to work on either local (volatile) or global (non-volatile) variables. Practically, this provides for extremely high performance data access.*[1]

Originally designed in 1966 for the healthcare industry, M continues to be used today by many large hospitals and banks to provide high-throughput transaction data processing.

12.1.1 History

For context, see Timeline of programming languages.

Genesis

MUMPS was developed by Neil Pappalardo, Robert Greenes, and Curt Marble in Dr. Octo Barnett's animal lab at the Massachusetts General Hospital (MGH) in Boston during 1966 and 1967. The original MUMPS system was, like Unix a few years later, built on a spare DEC PDP-7. Octo Barnett and Neil Pappalardo were also involved with MGH's planning for a Hospital Information System, obtained a backward compatible PDP-9, and began using MUMPS in the admissions cycle and laboratory test reporting. MUMPS was then an interpreted language, yet even then, incorporated a hierarchical database file system to standardize interaction with the data.

Some aspects of MUMPS can be traced from Rand Corporation's JOSS through BBN's TELCOMP and STRINGCOMP. The MUMPS team deliberately chose to include portability between machines as a design goal. Another feature, not widely supported for machines of the era, in operating systems or in computer hardware, was multitasking, which was also built into the language itself.

The portability was soon useful, as MUMPS was shortly adapted to a DEC PDP-15, where it lived for some time. MUMPS was developed with the support of a government research grant, and so MUMPS was released to the public domain (no longer a requirement for grants), and was soon ported to a number of other systems including the popular DEC PDP-8, the Data General Nova and the DEC PDP-11 and the Artronix PC12 minicomputer. Word about MUMPS spread mostly through the medical community, and by the early 1970s was in widespread use, often being locally modified for their own needs.

1970s

By the early 1970s, there were many and varied implementations of MUMPS on a range of hardware platforms. The most widespread was DEC's MUMPS-11 on the PDP-11, and MEDITECH's MIIS. In 1972, many MUMPS users attended a conference which standardized the then-fractured language, and created the **MUMPS Users Group** and **MUMPS Development Committee**

(MDC) to do so. These efforts proved successful; a standard was complete by 1974, and was approved, on September 15, 1977, as ANSI standard, X11.1-1977. At about the same time DEC launched DSM-11 (Digital Standard MUMPS) for the PDP-11. This quickly dominated the market, and became the reference implementation of the time. Also, InterSystems sold ISM-11 for the PDP-11 (which was identical to DSM-11).

1980s

During the early 1980s several vendors brought MUMPS-based platforms that met the ANSI standard to market. The most significant were:

- Digital Equipment Corporation with **DSM** (Digital Standard MUMPS). DSM-11 was superseded by **VAX/DSM** for the VAX/VMS platform, and that was ported to the Alpha in two variants: **DSM for OpenVMS**, and as **DSM for Ultrix**.
- InterSystems with **ISM** (InterSystems M) on VMS (M/VX), M/11+ on the PDP-11 platform, M/PC on MS-DOS, M/DG on Data General, M/VM on IBM VM/CMS, and M/UX on various Unixes.

Other companies developed important MUMPS implementations:

- Greystone Technology Corporation with a compiled version called GT.M.
- DataTree Inc. with an Intel PC based product called **DTM**.
- Micronetics Design Corporation with a product line called **MSM** for UNIX and Intel PC platforms (later ported to IBM's VM operating system, VAX-VMS platforms and Alpha-VMS platforms).
- Computer Consultants (later renamed MGlobal), a Houston-based company originally created **CCSM** on 6800, then 6809, and eventually a port to the 68000, which later became **MacMUMPS**, a Mac OS based product. They also worked on the **MGM** MUMPS implementation. MGlobal also ported their implementation to the DOS platform. MGlobal MUMPS was the first commercial MUMPS for the IBM PC and the only Mac implementation.
- Tandem Computers developed an implementation for their fault-tolerant computers.*[2]

This period also saw considerable MDC activity. The second revision of the ANSI standard for MUMPS (X11.1-1984) was approved on November 15, 1984.

1990s

- On November 11, 1990 the third revision of the ANSI standard (X11.1-1990) was approved.
- In 1992 the same standard was also adopted as ISO standard 11756-1992. Use of **M** as an alternative name for the language was approved around the same time.
- On December 8, 1995 the fourth revision of the standard (X11.1-1995) was approved by ANSI, and by ISO in 1999 as ISO 11756:1999. The MDC finalized a further revision to the standard in 1998 but this has not been presented to ANSI for approval.
- InterSystems' Open M for Windows/NT was released, as well as Open M for Alpha/OSF and Alpha/VMS (their first 64-bit implementations, for the 64-bit Alpha processor).
- In 1997 Unicode support was added in InterSystems' Caché 3.0

2000s

- By 2000, the middleware vendor InterSystems had become the dominant player in the MUMPS market with the purchase of several other vendors. Initially they acquired DataTree Inc. in the early 1990s. And, on December 30, 1995, InterSystems acquired the DSM product line from DEC.*[3] InterSystems consolidated these products into a single product line, branding them, on several hardware platforms, as **OpenM**. In 1997, InterSystems launched a new product named Caché. This was based on their ISM product, but with influences from the other implementations. Micronetics Design Corporation assets were also acquired by InterSystems on June 21, 1998. InterSystems remains the dominant MUMPS vendor, selling Caché to MUMPS developers who write applications for a variety of operating systems.
- Greystone Technology Corporation's GT.M implementation was sold to Sanchez Computer Associates (now part of FIS) in the mid-1990s. On November 7, 2000 Sanchez made GT.M for Linux available under the GPL license*[4] and on October 28, 2005 GT.M for OpenVMS and Tru64 UNIX were also made available under the AGPL license.*[5] GT.M continues to be available on other UNIX platforms under a traditional license.
- During 2000, Ray Newman and others released MUMPS V1, an implementation of MUMPS (initially on FreeBSD) similar to DSM-11. MUMPS V1 has since been ported to Linux, Mac OS X and Windows (using cygwin).*[6] Initially only for the x86 CPU, MUMPS V1 has now been ported to the Raspberry Pi.

- The newest implementation of MUMPS, released in April 2002, is an **MSM** derivative called **M21** from the Real Software Company of Rugby, UK.
- There are also several open source implementations of MUMPS, including some research projects. The most notable of these is Mumps/II, by Dr. Kevin O'Kane (Professor Emeritus, University of Northern Iowa) and students' project. Dr. O'Kane has also ported the interpreter to Mac OS X.*[7]
- One of the original creators of the MUMPS language, Neil Pappalardo, early founded a company called MEDITECH. They extended and built on the MUMPS language, naming the new language MIIS (and later, another language named MAGIC). Unlike InterSystems, MEDITECH no longer sells middleware, so MIIS and MAGIC are now only used internally at MEDITECH.
- On 6 January 2005, and later again on 25 June 2010, ISO re-affirmed its MUMPS-related standards: ISO/IEC 11756:1999, language standard, ISO/IEC 15851:1999, Open MUMPS Interconnect and ISO/IEC 15852:1999, MUMPS Windowing Application Programmers Interface.

12.1.2 Current users of MUMPS applications

The US Department of Veterans Affairs (formerly the Veterans Administration) was one of the earliest major adopters of the MUMPS language. Their development work (and subsequent contributions to the free MUMPS application codebase) was an influence on many medical users worldwide. In 1995, the Veterans Affairs' patient Admission/Tracking/Discharge system, Decentralized Hospital Computer Program (DHCP) was the recipient of the Computerworld Smithsonian Award for best use of Information Technology in Medicine. In July 2006, the Department of Veterans Affairs (VA) / Veterans Health Administration (VHA) was the recipient of the Innovations in American Government Award presented by the Ash Institute of the John F. Kennedy School of Government at Harvard University for its extension of DHCP into the Veterans Health Information Systems and Technology Architecture (VistA). Nearly the entire VA hospital system in the United States, the Indian Health Service, and major parts of the Department of Defense CHCS hospital system use MUMPS databases for clinical data tracking.

Large companies currently using MUMPS include AmeriPath (part of Quest Diagnostics), Care Centric, Allscripts, Epic, Coventry Healthcare, EMIS, Partners HealthCare (including Massachusetts General Hospital), MEDITECH, GE Healthcare (formerly IDX Systems and Centricity), and Sunquest Information Systems (formerly Misys Healthcare*[8]). Many reference laboratories, such as DASA, Quest Diagnostics,*[9] and Dynacare, use MUMPS software written by or based on Antrim Corporation code. Antrim was purchased by Misys Healthcare (now Sunquest Information Systems) in 2001.*[10]

MUMPS is widely used in financial applications. MUMPS gained an early following in the financial sector, and MUMPS applications are in use at many banks and credit unions. It is used by Ameritrade, the largest online trading service in the US with over 12 billion transactions per day, as well as by the Bank of England and Barclays Bank, among others.*[11]*[12]*[13]

Since 2005, the use of MUMPS has been either in the form of GT.M or InterSystems Caché. The latter is being aggressively marketed by InterSystems and has had success in penetrating new markets, such as telecommunications, in addition to existing markets. The European Space Agency announced on May 13, 2010 that it will use the InterSystems Caché database to support the Gaia mission. This mission aims to map the Milky Way with unprecedented precision.*[14]

12.1.3 Overview

MUMPS is a language intended for and designed to build database applications. Secondary language features were included to help programmers make applications using minimal computing resources. The original implementations were interpreted, though modern implementations may be fully or partially compiled. Individual "programs" run in memory "partitions". Early MUMPS memory partitions were limited to 2048 bytes so aggressive abbreviation greatly aided multi-programming on severely resource limited hardware, because more than one MUMPS job could fit into the very small memories extant in hardware at the time. The ability to provide multi-user systems was another language design. The **M**ulti-**P**rogramming in the acronym of language name point to this. Even the earliest machines running MUMPS supported multiple jobs running at the same time. With the change from mini-computers to microcomputers a few years later, even a "single user PC" with a single 8-bit CPU and 16K or 64K of memory could support multiple users, who could connect to it from (non-graphical) video display terminals.

Since memory was tight originally, the language design for MUMPS valued very terse code. Thus, every MUMPS command or function name could be abbreviated from one to three letters in length, e.g. Quit (exit program) as Q, $P = $Piece function, R = Read command, $TR = $Translate function. Spaces and end-of-line markers are significant in MUMPS because line scope promoted the same terse language design. Thus, a single line of program code could express, with few characters, an idea for which other programming languages could require 5 to 10 times as many characters. Abbreviation was a common feature of languages designed in

this period (e.g., FOCAL-69, early BASICs such as Tiny BASIC, etc.). An unfortunate side effect of this, coupled with the early need to write minimalist code, was that MUMPS programmers routinely did not comment code and used extensive abbreviations. This meant that even an expert MUMPS programmer could not just skim through a page of code to see its function but would have to analyze it line by line.

Database interaction is transparently built into the language. The MUMPS language provides a hierarchical database made up of persistent sparse arrays, which is implicitly "opened" for every MUMPS application. All variable names prefixed with the caret character ("^") use permanent (instead of RAM) storage, will maintain their values after the application exits, and will be visible to (and modifiable by) other running applications. Variables using this shared and permanent storage are called *Globals* in MUMPS, because the scoping of these variables is "globally available" to all jobs on the system. The more recent and more common use of the name "global variables" in other languages is a more limited scoping of names, coming from the fact that unscoped variables are "globally" available to any programs running in the same process, but not shared among multiple processes. The MUMPS Storage mode (i.e. Globals stored as persistent sparse arrays), gives the MUMPS database the characteristics of a document-oriented database.*[15]

All variable names which are not prefixed with caret character ("^") are temporary and private. Like global variables, they also have a hierarchical storage model, but are only "locally available" to a single job, thus they are called "locals". Both "globals" and "locals" can have child nodes (called *subscripts* in MUMPS terminology). Subscripts are not limited to numerals—any ASCII character or group of characters can be a subscript identifier. While this is not uncommon for modern languages such as Perl or JavaScript, it was a highly unusual feature in the late 1970s. This capability was not universally implemented in MUMPS systems before the 1984 ANSI standard, as only canonically numeric subscripts were required by the standard to be allowed.*[16] Thus, the variable named 'Car' can have subscripts "Door", "Steering Wheel" and "Engine", each of which can contain a value and have subscripts of their own. The variable ^Car("Door") could have a nested variable subscript of "Color" for example. Thus, you could say

SET ^Car("Door","Color")="BLUE"

to modify a nested child node of ^Car. In MUMPS terms, "Color" is the 2nd subscript of the variable ^Car (both the names of the child-nodes and the child-nodes themselves are likewise called subscripts). Hierarchical variables are similar to objects with properties in many object oriented languages. Additionally, the MUMPS language design requires that all subscripts of variables are automatically kept in sorted order. Numeric subscripts (including floating-point numbers) are stored from lowest to highest. All non-numeric subscripts are stored in alphabetical order following the numbers. In MUMPS terminology, this is *canonical order*. By using only non-negative integer subscripts, the MUMPS programmer can emulate the arrays data type from other languages. Although MUMPS does not natively offer a full set of DBMS features such as mandatory schemas, several DBMS systems have been built on top of it that provide application developers with flat-file, relational and network database features.

Additionally, there are built-in operators which treat a delimited string (e.g., comma-separated values) as an array. Early MUMPS programmers would often store a structure of related information as a delimited string, parsing it after it was read in; this saved disk access time and offered considerable speed advantages on some hardware.

MUMPS has no data types. Numbers can be treated as strings of digits, or strings can be treated as numbers by numeric operators (*coerced*, in MUMPS terminology). Coercion can have some odd side effects, however. For example, when a string is coerced, the parser turns as much of the string (starting from the left) into a number as it can, then discards the rest. Thus the statement IF 20<"30 DUCKS" is evaluated as TRUE in MUMPS.

Other features of the language are intended to help MUMPS applications interact with each other in a multiuser environment. Database locks, process identifiers, and atomicity of database update transactions are all required of standard MUMPS implementations.

In contrast to languages in the C or Wirth traditions, some space characters between MUMPS statements are significant. A single space separates a command from its argument, and a space, or newline, separates each argument from the next MUMPS token. Commands which take no arguments (e.g., ELSE) require two following spaces. The concept is that one space separates the command from the (nonexistent) argument, the next separates the "argument" from the next command. Newlines are also significant; an IF, ELSE or FOR command processes (or skips) everything else till the end-of-line. To make those statements control multiple lines, you must use the DO command to create a code block.

12.1.4 "Hello, World!" example

A simple Hello world program in MUMPS might be:

```
hello() write "Hello, World!",! quit
```

and would be run from the MUMPS command line with the command 'do ^hello'. Since MUMPS allows commands to be strung together on the same line, and since commands can be abbreviated to a single letter, this routine could be made more compact:

hello() w "Hello, World!",! q

The ',!' after the text generates a newline. The 'quit' is not strictly necessary at the end of a function like this, but is good programming practice in case other functions are added below 'hello()' later.

12.1.5 Summary of key language features

Main article: MUMPS syntax

ANSI X11.1-1995 gives a complete, formal description of the language; an annotated version of this standard is available online.*[17]

Data types: There is one universal datatype, which is implicitly coerced to string, integer, or floating-point datatypes as context requires.

Booleans (called *truthvalues* in MUMPS): In IF commands and other syntax that has expressions evaluated as conditions, any string value is evaluated as a numeric value, and if that is a nonzero value, then it is interpreted as True. a<b yields 1 if a is less than b, 0 otherwise.

Declarations: None. All variables are dynamically created at the first time a value is assigned.

Lines: are important syntactic entities, unlike their status in languages patterned on C or Pascal. Multiple statements per line are allowed and are common. The scope of any IF, ELSE, and FOR command is "the remainder of current line."

Case sensitivity: Commands and intrinsic functions are case-insensitive. In contrast, variable names and labels are case-sensitive. There is no special meaning for upper vs. lower-case and few widely followed conventions. The percent sign (%) is legal as first character of variables and labels.

Postconditionals: execution of almost all commands can be controlled by following it with a colon and a truthvalue expression. SET:N<10 A="FOO"sets A to "FOO"if N is less than 10; DO:N>100 PRINTERR, performs PRINTERR if N is greater than 100. This construct provides a conditional whose scope is less than a full line.

Abbreviation: You can abbreviate nearly all commands and native functions to one, two, or three characters.

Reserved words: None. Since MUMPS interprets source code by context, there is no need for reserved words. You may use the names of language commands as variables. There has been no contest such as the International Obfuscated C Code Contest for MUMPS, despite the potential of examples such as the following, perfectly legal, MUMPS code:

GREPTHIS() NEW SET,NEW,THEN,IF,KILL,QUIT SET IF="KILL",SET="11",KILL="ll",QUIT="RETURN",THEN="KILL" IF IF=THEN DO THEN QUIT:$QUIT QUIT QUIT ; (quit) THEN IF IF,SET&KILL SET SET=SET+KILL QUIT

MUMPS can be made more obfuscated by using the contracted operator syntax, as shown in this terse example derived from the example above:

GREPTHIS() N S,N,T,I,K,Q S I="K",S="11",K="ll",Q="R",T="K" I I=T D T Q:$Q Q Q T I I,S&K S S=S+K Q

Arrays: are created dynamically, stored as B-trees, are sparse (i.e. use almost no space for missing nodes), can use any number of subscripts, and subscripts can be strings or numeric (including floating point). Arrays are always automatically stored in sorted order, so there is never any occasion to sort, pack, reorder, or otherwise reorganize the database. Built in functions such as $DATA, $ORDER, $NEXT(deprecated) and $QUERY functions provide efficient examination and traversal of the fundamental array structure, on disk or in memory.

for i=10000:1:12345 set sqtable(i)=i*i set address("Smith","Daniel")="dpbsmith@world.std.com"

Local arrays: variable names not beginning with caret (i.e. "^") are stored in memory by process, are private to the creating process, expire when the creating process terminates. The available storage depends on implementation. For those implementations using partitions, it is limited to the partition size, (A small partition might be 32K). For other implementations, it may be several megabytes.

Global arrays: ^abc, ^def. These are stored on disk, are available to all processes, and are persistent when the creating process terminates. Very large globals (for example, hundreds of gigabytes) are practical and efficient in most implementations. This is MUMPS' main "database" mechanism. It is used instead of calling on the operating system to create, write, and read files.

Indirection: in many contexts, @VBL can be used, and effectively substitutes the contents of VBL into another MUMPS statement. SET XYZ="ABC" SET @XYZ=123 sets the variable ABC to 123. SET SUBROU="REPORT" DO @SUBROU performs the subroutine named REPORT. This substitution allows for lazy evaluation and late binding as well as effectively the operational equivalent of "pointers" in other languages.

Piece function: This breaks variables into segmented pieces guided by a user specified separator string (sometimes called a "delimiter"). Those who know awk will find this familiar. $PIECE(STRINGVAR,"^",3) means the "third caret-separated piece of STRINGVAR." The piece function can also appear as an assignment (SET command) target.

$PIECE("world.std.com",".",2) yields "std".

After

SET X="dpbsmith@world.std.com"

SET $P(X,"@",1)="office" causes X to become "office@world.std.com" (note that $P is equivalent to $PIECE and could be written as such).

Order function: This function treats its input as a structure, and finds the next index that exists which has the same structure except for the last subscript. It returns the sorted value that is ordered after the one given as input. (This treats the array reference as a content-addressable data rather than an address of a value)

Set stuff(6)="xyz" ,stuff(10)=26,stuff(15)=""

$Order(stuff("")) yields 6, $Order(stuff(6)) yields 10, $Order(stuff(8)) yields 10, $Order(stuff(10)) yields 15, $Order(stuff(15)) yields "".

Set i="" For Set i=$O(stuff(i)) Quit:i="" Write !,i,10,stuff(i)

Here, the argument-less *For* repeats until stopped by a terminating *Quit*. This line prints a table of i and stuff(i) where i is successively 6, 10, and 15.

For iterating the database, the Order function returns the next key to use.

GTM>S n="" GTM>S n=$order(^nodex(n)) GTM>zwr n n=" building"GTM>S n=$order(^nodex(n)) GTM>zwr n n=" name:gd" GTM>S n=$order(^nodex(n)) GTM>zwr n n="%kml:guid"

Multi-User/Multi-Tasking/Multi-Processor:
MUMPS supports multiple simultaneous users and processes even when the underlying operating system does not (e.g., MS-DOS). Additionally, there is the ability to specify an environment for a variable, such as by specifying a machine name in a variable (as in SET ^|"DENVER"|A(1000)="Foo"), which can allow you to access data on remote machines.

12.1.6 "MUMPS"vs. "M"naming debate

All of the following positions can be, and have been, supported by knowledgeable people at various times:

- The language's name became M in 1993 when the M Technology Association adopted it.
- The name became M on December 8, 1995 with the approval of ANSI X11.1-1995
- Both M *and* MUMPS are officially accepted names.
- M is only an "alternative name" or "nickname" for the language, and MUMPS is still the official name.

Some of the contention arose in response to strong M advocacy on the part of one commercial interest, InterSystems, whose chief executive disliked the name MUMPS and felt that it represented a serious marketing obstacle. Thus, favoring M to some extent became identified as alignment with InterSystems. The dispute also reflected rivalry between organizations (the M Technology Association, the MUMPS Development Committee, the ANSI and ISO Standards Committees) as to who determines the "official" name of the language. Some writers have attempted to defuse the issue by referring to the language as *M[UMPS]*, square brackets being the customary notation for optional syntax elements. A leading authority, and the author of an open source MUMPS implementation, Professor Kevin O'Kane, uses only 'MUMPS'.

The most recent standard (ISO/IEC 11756:1999, reaffirmed on 25 June 2010), still mentions both M and MUMPS as officially accepted names.

12.1.7 Intellectual Property and Trademark Registration Status

Massachusetts General Hospital registered "MUMPS" as a trademark with the USPTO on November 28, 1971, renewed on November 16, 1992, and expired on August 30, 2003.*[18]

12.1.8 See also

- PSL an extension to MUMPS
- Caché ObjectScript an object oriented extension to MUMPS from a prominent MUMPS vendor
- GT.M an implementation of M
- InterSystems Caché

12.1.9 References

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12.1.11 External links

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- Mumps Programming Language Interpreter (GPL) by Kevin O'Kane, University of Northern Iowa
- MDC - MUMPS Development Committee
- The Annotated M{UMPS} Standards
- MUMPS by Example - out of print book by Ed de Moel. Much of the language syntax is detailed here, with examples of usage.
- MUMPS Systems - Source Forge index
- M Links at Hardhats.org
- M21 - An ANSI M(UMPS) Implementation
- EsiObjects An Object Oriented extension of MUMPS
- M/DB An Open Source MUMPS-based API-compatible alternative to SimpleDB
- MiniM Database Servee A MUMPS Implementation
- Development and Operation of a MUMPS Laboratory Information System: A Decade's Experience at Johns Hopkins Hospital
- IDEA Systems' technology solutions based on Caché and GT.M
- MUMPS documentation, topics, and resources (mixed Czech and English)

Chapter 13

Internet Projects

13.1 Bing Health

Bing Health (previously *Live Search Health*) is a health-related search service as part of Microsoft's Bing search engine. It is a search engine specifically for health-related information through a variety of trusted and credible sources, including Medstory, Mayo Clinic, National Institutes of Health's MedlinePlus, as well as from Wikipedia.*[1]

13.1.1 History

Bing Health comes about as a result of the Microsoft's acquisition of Medstory in February 2007, gaining a foothold in the health search and health information market.*[2]*[3] It was released for beta testing on October 8, 2007 as *Live Search Health* and served as the front-end to Microsoft HealthVault Search. Search results in Live Search Health were presented in a three-column layout with health-related articles from the trusted sources in the left, web search results in the middle, and sponsored results on the right. The topic dashboad on the top also displays relevant topics, and allow users to add the search results to their scrapbook in Microsoft HealthVault Account. One particular feature for Live Search Health is that all health search queries and responses were encrypted to provide a measure of privacy and security when dealing with health issues.*[4]

However, on June 3, 2009, the Live Search Health front-end became fully integrated into Bing search results, accessible only via the "Explorer pane" on the left when the contextual search engine detects a health-related search query entered.*[5]

On January 10, 2010, Bing Health search results got an upgrade. Typing in a specific illness will now highlight important information such as related conditions, and common medications to reduce symptoms. In addition reference materials and documentation about the disease and its history can be shown.*[6]*[7]

Bing Health is only available in the United States

13.1.2 See also

- Bing
- Microsoft HealthVault
- Windows Live

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13.1.4 External links

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13.2 Dossia

Dossia is a Personal health record service offered by some of the largest employers in the United States. Along with Microsoft's HealthVault, Dossia is one of the largest PHR deployments in the world*[1] Unlike Microsoft's PHR effort, Dossia is based on open source software. Dossia released their API in summer of 2009.*[2] Dossia differs from traditional tethered PHR services by providing user access to health information regardless of health plan, employer, or physician. Users also have the ability to download their full record, in electronic form, at any time.

It is an initiative formed from the following companies:

- AT&T
- Applied Materials
- BP America
- Cardinal Health
- Intel
- Pitney Bowes
- Sanofi-aventis
- Walmart
- Abraxis BioScience
- Vanguard Health Systems

Dossia is formed by some of the largest employers in the United States with the intention of offering a PHR to its employees. Given the number of employees of these combined institutions, Dossia could be one of the largest PHR systems in the world.*[3]

13.2.1 Dossia's History

In 2006, a group of Fortune 500 employers, including Applied Materials, BP America, Inc, Intel Corporation, Pitney Bowes Inc., Wal-Mart, Cardinal Health, AT&T, and sanofi-aventis, formed an alliance called the Dossia Consortium. Later, in April 2009, Dossia announced that Abraxis BioScience also joined the Dossia Founders Group. The Consortium's goal was to empower their employees to make smarter, more informed decisions about their healthcare by offering them Personally Controlled Health Records (PCHR). The Consortium funded the development of a web-based framework through which Consortium employees, dependents, and retirees can maintain private, personal, and portable PCHRs.

In 2008, the Dossia Consortium Board of Directors decided to create two additional organizations within the Dossia umbrella. These included the Dossia Foundation and the Dossia Service Corporation. The Dossia Foundation aims at advancing knowledge and progress in the healthcare space through a variety research, strategy, and advocacy initiatives pertaining to Personally Controlled Health Records (PCHRs). The Dossia Service Corporation is responsible for delivering the PCHR infrastructure and service to subscribing employers and customers.

Also during 2008, Dossia established an agreement to work with Children's Hospital Boston to provide strategic and technological expertise and guidance in creating, deploying and operating the electronic health record infrastructure.

In fall of 2008, WalMart was the first Dossia Consortium member to roll out the PCHRs to their 1.4 million employees plus their dependents.*[3] Following WalMart's roll out, Dossia continued to roll out its PCHRs to the other Dossia Consortium members including Vanguard, Intel, Pitney Bowes, AT&T and BP America.*[4]

13.2.2 Dossia's PHP(Personal Health Platform)

The Dossia system enables individuals to gather copies of their own medical data (in digital form) from multiple sources and to create and utilize their own personal, private and portable electronic health records. Initially, the data will come primarily from insurers' databases and the patient's own annotations. As the system develops, additional information will come directly from the patient's medical chart and various other sources. The information the system provides will empower individuals to manage their own healthcare, improve communications with their doctors, and ensure more complete and accurate information for healthcare providers than the current fragmented, paper-based system.

13.2.3 Dossia Board Members

Dossia's board is composed of industry leaders from a variety of Fortune 500 companies.

- Craig Barrett, Chairman, Board Of Directors, Dossia, Executive Chairman, (formerly) Intel
- Jean Paul Gagnon, Secretary, Board of Directors, Dossia Director of Public Policy, sanofi-aventis
- Monica Foster, Vice President of Benefits, Cardinal Health
- Karl Dalal, Director of U.S. Health and Welfare Benefits, BP America
- Adena Handly,Director, Healthcare Marketing, AT&T Business Solutions

- Diana Finucane, Director, Global Benefits Applied Materials
- Andrew Gold, Executive Director, Global Benefit Planning, Pitney Bowes
- Steven Lampkin, Vice President, Benefits Services and Strategic Initiatives, Walmart
- Patrick Soon-Shiong, M.D., Executive Chairman and Chief Executive Officer, Abraxis Health
- Brad Perkins, M.D., Executive VP Strategy and Innovation and Chief Transformation Officer, Vanguard Health Systems
- Tami L. Graham, Intel Global Benefits Design Director, Intel Corporation
- Liz Cirri, Senior Director, Reimbursement, Government Programs, sanofi-aventis

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13.2.5 External links

- Dossia Official Site

13.3 E-Patient

An **e-patient** is a health consumer who participates fully in his/her medical care. Sometimes referred to as an "internet patient," e-patients see themselves as equal partners with their doctors in the healthcare process. E-patients gather information about medical conditions that impact them and their families, using electronic communication tools (including Web 2.0 tools) in coping with medical conditions.*[1] The term encompasses both those who seek guidance for their own ailments and the friends and family members (e-caregivers) who go online on their behalf. e-Patients report two effects of their health research: "better health information and services, and different (but not always better) relationships with their doctors." *[2]

e-Patients are active in their care and are demonstrating the power of the Participatory Medicine or Health 2.0 / Medicine 2.0.*[3] model of care. The "e" can stand for electronic but can also stand for:*[4]

- Equipped with the skills to manage their own condition.
- Enabled to make choices about self-care and those choices are respected.
- Empowered*[5]
- Engaged patients are engaged in their own care
- Equals in their partnership(s) with the physician(s) involved in their care
- Emancipated
- Expert patients can improve their self-rated health status, cope better with fatigue and other generic features of chronic disease such as role limitation, and reduce disability and their dependence on hospital care.*[5]
- Evaluating. This refers not only to the information e-patients find, but also to the source of that information, be it a Web page, a peer, or a health care professional. It also suggests that this evaluation begins, and trust in sources is established, at an early stage.*[6]
- Equal. The e-patient expects to be an equal member of the team. There is evidence from this study that when this situation is not encouraged by professionals, individuals develop mechanisms to manage situations that place them in a location of equal power, but without the open and honest relationship that is also valued.*[6]

Based on the current state of knowledge on the impact of e-patients on the healthcare system and the quality of care received:

- A growing number of people say the internet has played a crucial or important role as they helped another person cope with a major illness.*[7]*[8]
- Since the advent of the Internet, many clinicians have underestimated the benefits and overestimated the risks of online health resources for patients.*[9]*[10]*[11]
- Medical online support groups have become an important healthcare resource.*[12]
- "…the net friendliness of clinicians and provider organizations—as rated by the e-patients they serve—is becoming an important new aspect of healthcare quality." *[13]
- This is one of the most important cultural medical revolutions of the past century, mediated and driven by technology.*[13]

- In order to understand the impact of the e-patient, clinicians will likely need to move beyond "pre-internet medical constructs." *[13] Research must combine expertise from specialties that are not used to working together.

- It is crucial for medical education to take the e-patient into account, and to prepare students for medical practice that includes the e-patient.*[1]

13.3.1 See also

- eHealth
- mHealth
- Doctor–patient relationship
- Patient opinion leader
- Virtual patient

13.3.2 References

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13.3.3 External links

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- E-patients With a Disability or Chronic Disease, from the Pew Internet and American Life Project

- Association of Cancer Online Resources (ACOR), an aggregate of e-patient online communities for knowledge-sharing about cancer.

- Time Magazine article: "When the patient is a Googler"
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13.4 Google Health

Google Health was a personal health information centralization service (sometimes known as personal health record services) by Google introduced in 2008 and cancelled in 2011.*[1] The service allowed Google users to volunteer their health records – either manually or by logging into their accounts at partnered health services providers – into the Google Health system, thereby merging potentially separate health records into one centralized Google Health profile.

Volunteered information could include "health conditions, medications, allergies, and lab results".*[2] Once entered, Google Health used the information to provide the user with a merged health record, information on conditions, and possible interactions between drugs, conditions, and allergies.*[3] Google Health's API was based on a subset of the Continuity of Care Record.*[4]

13.4.1 History

Google Health was under development from mid-2006. In 2008, the service underwent a two-month pilot test with 1,600 patients of The Cleveland Clinic.*[5] Starting on May 20, 2008, Google Health was released to the general public as a service in beta test stage.

On September 15, 2010 Google updated Google Health with a new look and feel.*[6]

On June 24, 2011 Google announced it was retiring Google Health in January 1, 2012; data was available for download through January 1, 2013. The reason Google gave for abandoning the project was the lack of widespread adoption.*[7]

13.4.2 Partners

Google Health, like many other Google products, was free to use for consumers. Unlike other Google services, however, Health contained no advertising.*[8] Google did not reveal how it planned to make money with the service, but a *Wall Street Journal* article said that Google "hasn't ruled [advertising] out for the future."*[9] Google has filed U.S. Patent Application #20070282632, "Method and apparatus for serving advertisements in an electronic medical record system".*[10]

Google Health could import medical and/or drug prescription information from the following partners: Allscripts, Anvita Health, The Beth Israel Deaconess Medical Center, Blue Cross Blue Shield of Massachusetts, The Cleveland Clinic, CVS Caremark, Drugs.com, Healthgrades, Longs Drugs, Medco Health Solutions, Quest Diagnostics, RxAmerica, and Walgreens.*[11]

Users whose health records reside with other providers had to either manually enter their data or pay to have a Google Health partner perform the service. MediConnect Global was one such partner; for a fee, they would retrieve a user's medical records from around the world and add them to his or her profile.

Since January 2010, the Withings WiFi Body scale enables Google Health users to seamlessly update their weight and other data to their online profiles*[12]

Recently, in response to demand for added convenience, Google Health began establishing relationships with telehealth providers that will allow their users to sync the data shared during telehealth consultations with their online health records. To date, partnerships have been formed with the following companies: MDLiveCare and Hello Health.*[13]

13.4.3 Privacy concerns

Google Health was an opt-in service, meaning it could only access medical information *volunteered* by individuals. It did not retrieve any part of a person's medical records without his or her explicit consent and action.*[2] However, it did encourage users to set up profiles for other individuals.*[3]

According to its Terms of Service, Google Health is not considered a "covered entity" under the Health Insurance Portability and Accountability Act of 1996; thus, HIPAA privacy laws do not apply to it.*[14]

In an article covering Google Health's launch, *the New York Times* discussed privacy issues and said that "patients apparently did not shun the Google health records because of qualms that their personal health information might not be secure if held by a large technology company."*[5] Others contend that Google Health may be more private than the current "paper" health record system because of reduced human interaction.*[15]

Post-launch reactions to Google's stance that it was not a covered entity varied. Some were very negative, such as those of Nathan McFeters at ZDNet.*[16] Others, in-

cluding Free/Open Source Software Healthcare activist Fred Trotter, argued that a personal health record service like Google Health would be impossible if it were HIPAA covered.*[17]

13.4.4 Competitors

Google Health is a personal health record (PHR) service whose primary competitors in the United States are Microsoft's HealthVault, Dossia, and the open-source Indivo project. There are numerous other open-source and proprietary PHR systems, including those that compete outside the United States.*[18]

On July 18, 2011, Microsoft released a tool that lets Google Health customers transfer their personal health information to a Microsoft HealthVault account.*[19]

On December 7, 2011, MediConnect Global announced a similar capability that allows displaced Google Health users to transfer their personal health records to a MyMediConnect account.*[20]

13.4.5 Discontinuance

On June 24, 2011, Google announced that Google Health would be discontinued.*[21] Google stated that they were discontinuing Google Health because it did not have as broad impact as had been expected:

Google continued to operate the Google Health site until January 1, 2013, and offered options for users to download data or transfer data to Microsoft's HealthVault.

13.4.6 References

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13.4.7 External links

- Official website
- Google Health Integration

13.5 iMedicor

The **iMedicor** Web portal, which went live on October 10, 2007, is online personal health data exchange and secure messaging portal for physician collaboration, community and referrals. iMedicor reached its 32,000th physician registration on December 12, 2007. It has been discussed in such journals as Healthcare Informatics, Advance for Health Information Professionals,*[1] Virtual Medical Worlds, and Highway Hypodermics among others and received positive review by the Internet journal Medgadget.

The portal's proprietary HIPAA-compliant technology and ability to enable health providers to exchange medical

record data, documentation and images distinguish it from chat-room-style portals for the medical community. The launch of iMedicor's portal coincides with the entrance of Microsoft's Healthvault and Google Health into the personal health record space.

iMedicor has a proprietary HIPAA-compliant interface. HIPAA, which stands for the American Health Insurance Portability and Accountability Act of 1996, is a set of strict rules to be followed by doctors, hospitals and other health care providers concerning the handling and privacy protection of vital patient medical data. Violations can result in serious fines or, in extreme cases, imprisonment.

On November 20, 2007, the iMedicor portal was given a positive review by Medgadget, the influential Internet Journal of Emerging Medical Technologies.*[2] The journal said that iMedicor is "strikingly different" from other medical networks such as iMedExchange and Sermo. Medgadget also stated, "The service behaves more like a typical email provider and a file sharing site, lumped together with a social network for clinicians."

Some of iMedicor's partner associations include the Association of Black Cardiologists (ABC), the American Society for Hypertension (ASH), and the Hypertrophic Cardiomyopathy Association (HCA).

13.5.1 External links

- iMedicor
- Vemics

13.5.2 References

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- January 14, 2008, 09:06 AM Eastern Time - American Society of Hypertension Partners with iMedicor - Online Medical Portal Tapped to Help Expand Hypertension Initiative

13.6 Microsoft Amalga

Microsoft Amalga Unified Intelligence System (formerly known as **Azyxxi**) is a unified health enterprise platform designed to retrieve and display patient information from many sources, including scanned documents, electrocardiograms, X-rays, MRI scans and other medical imaging procedures, lab results, dictated reports of surgery, as well as patient demographics and contact information.

13.6.1 History

Amalga was developed initially as Azyxxi by doctors and researchers at the Washington Hospital Center emergency department in 1996. After heavy adoption, in 2006 it was acquired by the Microsoft Health Solutions Group as part of a plan to enter the fast-growing market for health care information technology. It has since been adopted at a number of leading hospitals and health systems across America including St Joseph Health System, New York Presbyterian Hospital, Georgetown University Hospital, Johns Hopkins, the Mayo Clinic and five hospitals in the MedStar Health group, a nonprofit network in the Baltimore-Washington, D.C. area.*[1]

Amalga can be used to tie together many unrelated medical systems using a wide variety of data types in order to provide an immediate, updated composite portrait of the patient's healthcare history. *[2] All of Amalga's components are integrated using middleware software that allows the creation of standard approaches and tools to interface with the many software and hardware systems found in hospitals.*[2] A physician using Amalga can obtain within seconds a patient's past and present hospital records, medication and allergy lists, lab studies, and views of relevant X-rays, CT Scans, and other clips and images, all organized into one customized format to highlight the most critical information for that user. In clinical use since 1996, Amalga has the ability to manage more than 40 terabytes of data and provide real-time access to more than 12,000 data elements associated with a given patient.

The system was first implemented by the Washington Hospital Center emergency department to reduce average waiting times. Since then it has also been used by the District of Columbia Department of Health for management of such mass-casualty incidents as a bioterrorism attack and in a variety of other settings in Arizona, Maryland, and Virginia.*[3] The Cleveland Clinic recently installed the system in a pilot project as an imaging and data integration system.*[3] Besides clinical data, Amalga is also designed to collect financial and operational data for hospital administrators.

Amalga currently runs on Microsoft Windows Server operating system and uses SQL Server 2008 as the data store.

At the time of acquisition, Microsoft hired Dr. Craig F. Feied, principal designer of the software, and 40 members of the development team at Washington Hospital Center. Dr. Mark Smith, who helped design the system, remained at Washington Hospital Center as director of the emergency department.*[4] Since then the Amalga team has grown to include 115 members.

13.6.2 Amalga HIS

Not to be confused with Amalga UIS above, on July 22, 2010 Microsoft announced that it was shutting down operations and sales for Amalga HIS.*[5] Chillmark Research reported that "Amalga HIS has only six customers today, and those customers will receive support for the next five years. After that, they will be on their own..." *[6]

As for the remnants of Amalga HIS in 2011, Dale Sanders, CIO of the Cayman Island Health Authority stated that "work remains" for Amalga HIS, one drawback of which is its "split personality for data collection at the point of care —orders, problems, medications, and progress notes are orphaned." CIO Sanders found that, after working closely with Microsoft, some of the organizations he consulted "adopted, but the vast majority did not. In the end, we (Northwestern and Microsoft) couldn't agree on a value proposition for Northwestern, which already had Cerner, Epic, and a data warehouse. There wasn't any room or need for a product like Amalga." *[7]

Brian Eastwood of Health IT Exchange concluded, "If nothing else, Amalga HIS outlasted the Kin." *[5]

13.6.3 See also

- Electronic medical record
- Electronic health record
- Health informatics

13.6.4 References

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[2] Pepus, Greg (2007-03-28). "The world of super integration". KMWorld. Retrieved 2006-08-08.

[3] Greene, Jay (2006-10-24). "A deal they just couldn't refuse". Modern Healthcare Online. Retrieved 2006-08-08.

[4] Lohr, Steve (2006-07-27). "Microsoft to Offer Software for Health Care Industry". The New York Times. Retrieved 2006-07-27.

[5] Eastwood, Brian (2010-07-26). "Microsoft Amalga HIS, We Hardly Knew Ye". Health IT Online. Retrieved 2011-12-31.

[6] Moore, John (2010-07-22). "Microsoft Pulls Plug on Amalga HIS". ChillMark Research Online. Retrieved 2011-12-31.

[7] Sanders, Dale (2011-05-05). "Microsoft's Amalga Has Potential, But Work Remains". HealthsystemCIO.com Online. Retrieved 2011-12-31.

13.6.5 External links

- Microsoft Amalga Home Page

13.7 Microsoft HealthVault

Microsoft HealthVault is a web-based personal health record created by Microsoft, in October 2007, to store and maintain health and fitness information.*[1]*[2]*[3]*[4] This website addresses both individuals and healthcare professionals, and in June 2010 expanded its services beyond the United States to include the United Kingdom.*[5]

13.7.1 Components

A HealthVault record stores an individual's health information. Access to a record is through a HealthVault account, which may be authorized to access records for multiple individuals, e.g., so that a parent may manage records for their children, or a child may have access to their parent's records to help the parent deal with medical issues. Authorization of the account can be through Facebook, Windows Live ID, or a limited set of other OpenID providers. Microsoft announced via email to users that Facebook and OpenID sign in will not be available after 31st of May 2016.

13.7.2 Authorization

An individual interacts with their HealthVault record through either the HealthVault website or, more typically, through an app, application, ir device that communicates with the HealthVault platform. When an individual first uses a HealthVault application, they are asked to authorize the application to access a specific set of data types, and those data types are the only ones the application can use. An individual can also share either their entire heath record or selected data with another interested individual, such as a doctor, relative, etc.

13.7.3 Devices

HealthVault Connection Center allows health and fitness data to be exchanged between selected devices (such as blood pressure monitors, heart rate watches, and the Withings wifi bodyscale*[6]) into an individual's HealthVault record. It can also be used to find and download drivers for medical devices.*[7]*[8] Additionally, in 2014, Microsoft introduced the Microsoft Band, a fitness band powered by the *Microsoft Health* service that supports the Microsoft HealthVault for aggregation and integration of various services, such as MyFitnessPal.*[9]*[10]

13.7.4 Medical Imaging

HealthVault supports storage, viewing, uploading, and downloading, by consumers and third parties, of DICOM based medical imaging. Additionally, a plethora of third party HealthVault medical imaging viewers has been released to connect to HealthVault.

13.7.5 Interoperability

HealthVault supports a number of exchange formats, including industry standards such as the Continuity of Care Document and the Continuity of Care Record. Support for industry standards makes it possible to integrate*[11] with many personal health record solutions.

13.7.6 Competitors

HealthVault's primary competitors are Apple's HealthKit, Dossia, World Medical Card, plus a few others. Google announced*[12] in June 2011 that Google Health would be discontinued as of January 1, 2012 and encouraged users to either download their data or to directly transfer it to Microsoft's HealthVault service before January 1, 2013.

13.7.7 See also

- Google Fit
- HealthKit (by Apple)
- Microsoft Band
- MSN Health & Fitness
- Xbox Fitness

13.7.8 References

[1] Hachman, Mark (2007-10-04). "MicrosoftLaunches 'HealthVault' Records-Storage Site". PCMAG.com. Retrieved 2008-02-04.

[2] "Microsoft launches medical records site". Toronto: globeandmail.com. Retrieved 2008-02-04.

[3] "The vault is open". economist.com. 2007-10-04. Retrieved 2008-02-06.

[4] Microsoft Launches Health Records Site

[5] Hoeksma, Jon (2010-06-23). "E-Health Insider :: Microsoft launches HealthVault in UK". *E-Health Insider*. Archived from the original on 2013-03-16. Retrieved 2013-10-16. Microsoft has launched its personal health record platform in the UK

[6] http://cln-online.org/index.php?option=com_content&view=article&id=666:microsoftscales&catid=49:wellness&Itemid=105

[7] "Dr. Microsoft is now ready to see you". Retrieved 2007-10-08.

[8] "HealthVault Connection Center". Retrieved 2007-10-08.

[9] Sullivan, Mark (4 November 2014). "With the launch of the Microsoft Band, HealthVault moves behind the scenes.". *VentureBeat*.

[10] Lein, Adam Z. (3 November 2014). "How many different health platforms does Microsoft need?". *PocketNow*.

[11] "PHR integration". Retrieved 2009-02-09.

[12] Google (2011-06-24). "Official Blog: An update on Google Health and Google PowerMeter". *Google Official Blog*. Google. Archived from the original on 2013-08-17. Retrieved 2013-10-16. can be imported into other personal health tools such as Microsoft® HealthVault™

13.7.9 External links

- Official website
- Microsoft HealthVault Developer Center

13.8 Patient portal

Patient Portals are healthcare-related online applications that allow patients to interact and communicate with their healthcare providers, such as physicians and hospitals. Typically, portal services are available on the Internet at all hours of the day and night. Some patient portal applications exist as stand-alone web sites and sell their services to healthcare providers. Other portal applications are integrated into the existing web site of a healthcare provider. Still others are modules added onto an existing electronic medical record (EMR) system. What all of these services share is the ability of patients to interact with their medical information via the Internet. Currently, the lines between an EMR, a personal health record, and a patient portal are blurring. For example, Intuit Health and Microsoft HealthVault describe themselves as personal health records (PHRs), but they can interface with EMRs and communicate through the Continuity of Care Record standard, displaying patient data on the Internet so it can be viewed through a patient portal.

13.8.1 Features and benefits of patient portals

The central feature that makes any system a patient portal is the ability to expose individual patient health information in a secure manner through the Internet. In

addition, virtually all patient portals allow patients to interact in some way with health care providers. Patient portals benefit both patients and providers by increasing efficiency and productivity. Patient portals are also regarded as a key tool to help physicians meet "meaningful use" requirements in order to receive federal incentive checks, especially for providing health information to patients.*[1] Some patient portal applications enable patients to register and complete forms online, which can streamline visits to clinics and hospitals. Many portal applications also enable patients to request prescription refills online, order eyeglasses and contact lenses, access medical records, pay bills, review lab results, and schedule medical appointments. Patient portals also typically allow patients to communicate directly with healthcare providers by asking questions, leaving comments, or sending e-mail messages.

13.8.2 Disadvantages

The major shortcoming of most patient portals is their linkage to a single health organization. If a patient uses more than one organization for healthcare, the patient normally needs to log on to each organization's portal to access information. This results in a fragmented view of individual patient data.

13.8.3 Practice portals

Portal applications for individual practices typically exist in tandem with patient portals, allowing access to patient information and records, as well as schedules, payments, and messages from patients.*[2] Most patient portals require the practice to have some type of electronic medical record or patient management system, as the patient data needs to be stored in a data repository then retrieved by the patient portal. While lauding its ease-of-use, some physicians note that it is hard to encourage patients to utilize online portals to benefit both themselves and the medical practice staff.*[3]

13.8.4 Security

Health care providers in the US are bound to comply with HIPAA regulations. These regulations specify what patient information must be held in confidence. Something as seemingly trivial as a name is viewed by HIPAA as protected health information. For this reason, security has always been a top concern for the industry when dealing with the adoption of patient portals. While there may be systems that are not HIPAA compliant, certainly most patient and practice portals are secure and compliant with HIPAA regulations. The use of SSL and access control patterns are commonplace in the industry. Patient access is typically validated with a user name and password.*[4]

13.8.5 History

Internet portal technology has been in common use since the 1990s. The financial industry has been particularly adept at using the Internet to grant individual users access to personal information. Possibly because of the strictness of HIPAA regulations, or the lack of financial incentives for the health care providers, the adoption of patient portals has lagged behind other market segments.

The American Recovery and Reinvestment Act of 2009 (ARRA), in particular the HITECH Act within ARRA, sets aside approximately $19 billion for health information technology. This funding will potentially offset the costs of electronic medical record systems for practicing physicians. Because the conversion to electronic medical records is typically complex, systems often transition to patient portals first and then follow with a complete implementation of electronic medical records.

To attest to Meaningful Use Stage 2, eligible professionals must have 5 percent of their patients view, transmit or download their health information. Additionally, providers must implement notifications for follow up appointments and identify clinically relevant health information for more than 10 percent of their patients with two or more appointments in the preceding two years. *[5]

Consequently, personal health record systems are becoming more common and available. In 2012, 57 percent of providers already had a patient portal in place. At present, individual health data are located primarily on paper in physicians' files. Patient portals have been developed to give patients better access to their information. Given the patient mobility and the development of clear interoperable standards, the best documentation of patient medical history may involve data stored outside physician offices.

13.8.6 Future

E-visits (remote use of medical services) may soon become one of the most commonly used options of patient portals. The most likely demographic for uptake of e-visits are patients who live in remote rural areas, far from clinical services. An Internet session would be much cheaper and more convenient than traveling a long distance, especially for simple questions or minor medical complaints.

Providing a route that does not require in-person patient visits to a clinic may potentially benefit both patients and providers. Many organizations find that overall utilization drops when e-visits are implemented, in some places by as much as 25%. This makes e-visits a very interesting proposition for insurance companies, although few actually re-imburse for them currently. E-visits, with the proper functionality, also allow the patient to update their allergies, vital signs, and history information.

Providing e-visits allows the standard healthcare organi-

zation to offer a product that can compete on price with the retail clinics that are popping up in strip malls and Wal-mart.

13.8.7 Vendors

Some vendors, such as athenahealth, Epic Systems, Cerner and Allscripts offer patient portals as one module of a complete Electronic Health Record (EHR) system. Other vendors, such as Medfusion, offer patient portals that can be integrated with any EHR.

Recent market surveys have highlighted best of breed, or applications that excel at one or two functions, are losing ground to portals provided by large vendors. While best of breed portals are better equipped for interoperability, portals supplied by larger vendors may be overall better equipped to handle the patient engagement requirements of Meaningful Use Stage 2.

13.8.8 See also

- Health care
- Health informatics
- Electronic health record
- Personal health record

13.8.9 References

[1] Terry, Ken "Patient Portals: Beyond Meaningful Use". *Physicians Practice*. June 27, 2010.

[2] Practice Portals

[3] Litton, J. Scott "Encouraging Patients to Use Online Communication ". *Physicians Practice*. February 3, 2012.

[4] "Provider HIPAA Checklist" (PDF). CMS. March 2003. Retrieved April 16, 2012.

[5] Centers for Medicare and Medicaid. "http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage_2.html". Accessed 25 May 2014.

13.8.10 Bibliography

13.8.11 External links

- What is a patient portal? at *HealthIT.gov*

13.9 Virtual patient

The term **virtual patient** is used to describe interactive computer simulations used in health care education.*[1] The special focus is targeted on the simulation of clinical processes with virtual patients. Virtual patients combine scientific excellence, modern technologies and the innovative concept of game-based learning. Virtual patients allow the learner to take the role of a health care professional and develop clinical skills such as making diagnoses and therapeutic decisions.*[2] Virtual patients have also been considered computer-based simulations designed to complement clinical training.*[3] The use of virtual patient programmes is increasing in healthcare, partly in response to increasing demands on health care professionals and education of students but also because they allow opportunity for students to practice in a safe environment*[2] There are many different formats a virtual patient may take. However the overarching principle is that of interactivity - a virtual patient will have mechanisms for the learner to interact with the case and material or information is made available to the learner as they complete a range of learning activities. The interactivity is non-sequential.

13.9.1 Forms

Virtual patients may take a number of different forms:

- *Artificial patients*: computer simulations of biochemical processes such as the effect of drugs in organisms, the physiologic processes of a given organ or entire systems (systems biology) in a given organism. These *can be* used in different phases of a compound or drug in development in a given pharmacological research as a *preliminary* to testing on animals and humans for the drug development processes.
- *Real patients*: reflected in data e.g. electronic health records (EHRs). In this case the virtual patient is the reflection of the real patient in terms of data held about them. These are sometimes called e-patients.
- *Physical simulators*: mannequins (sometimes spelled 'manikins'), models or related artefacts.
- *Simulated patients*: where the patient is recreated by humans or computer-generated characters and Virtual Humans acting as such or engaging in other kinds of role-play.
- *Electronic case-studies and scenarios* where users work through problems, situations or similar narrative-based activities.

13.9.2 Types of interaction with simulated or electronic patients

A number of different modes of virtual patient delivery have been defined:

- Predetermined scenario [directed mode]
- The learner may build up the patient or case data from observations and interactions [blank mode]
- The learner may view and appraise or review an existing patient or scenario [critique mode or rehearsal mode]
- The VP may be used as a mechanism to address particular topics [context mode]
- The learner may use a scenario or patient to explore personal/professional dimensions [reflective mode]
- Banks of patients or scenarios may collectively address broad issues of healthcare [pattern mode]

13.9.3 Types of interaction with artificial patients

- To create and run a mathematical quantitative simulation of a healthy person (physiology) and diseased person to test multiple hypothesis against known and unknown processes in a given set or sets of processes to help fill gaps in knowledge of the physiology or system under investigation.

13.9.4 Possible benefits of physical simulators and simulated patients

Simulated patients increase the availability of training opportunities for medical students, making them less dependent on actual cases to learn how to handle different situations. Unlike real patients, simulated patients can be accessed on demand and they can be endlessly replayable to allow the user to explore different options and strategies. They can be structured with narratives that represent real situations while challenging the user with a wide range of tasks. They also allow simulation of rare or unusual events, and reduce risk to actual patients in the process.

Despite their efficacy simulated patients are still a tangent and a prosthesis to reality. They should be viewed as augmenting existing modes and methods of clinical teaching.

13.9.5 Possible benefits of artificial patients

Artificial patients increase the possibility of exploring millions of hypothesis driven experiments on known areas of biological systems to extrapolate the unknown, which enables efficient exploration, informed research and development predictive simulation, which must also be proven by real patient studies clinical trials. If more tests can be done on Artificial patients to filter out possibly unnecessary tests or experiments, fewer subjects pharmacovigilance maybe needed. The Artificial patients insilico modeling are still in the early to middle developmental stages. It will require continual updates and development with the endless availability of new data.

13.9.6 Virtual patient data standards

The MedBiquitous consortium established a working group in 2005 to create a free and open data standard for expressing and exchanging virtual patients between different authoring and delivery systems. This was in part to address the problem of exchanging and reusing virtual patients and in part to encourage and support easier and wider use of virtual patients in general.

This standard has been very successful and is now widely adopted, e.g. in major projects like eViP.

In 2010, this standard attained status as an ANSI standard.

13.9.7 Examples

Case presentations and interactive patient scenarios

Case presentations and interactive patient scenarios are mainly designed to support the training of clinical reasoning skills with virtual patients. The systems are usually web-based and a variety of multimedia elements can be incorporated. Interactivity is often included with questions, specific decision-making tasks, text-composition etc. Most systems provide quantitative and qualitative feedback.[*] [4]

- Virtual Patients from Harvard Medical School
- Medical Exam Tutor
- HCV Virtual Patient program
- (SIMPLE, CLIPP, fmCASES, WISE-MD)
- WebSP from Karolinska Institutet
- Virtual Patient Project from New York University
- Virtual Patients from Centre for Virtual Patients (University of Heidelberg)
- OpenLabyrinth from Canada
- Labyrinth from the University of Edinburgh
- TUSK Case Simulator from Tufts University
- CASUS - Case-based, multimedia learning and authoring system

- (A whole virtual clinic with 25 different faculties and offer 250 virtual patients)
- Shadow Health Digital Standardized Patients™

Virtual worlds

- Virtual Patient from Keele University School of Pharmacy
- Health Assessment with Tina Jones (Shadow Health)

Simulators and manikins

- TheraSim Virtual Patient Simulation
- Limbs and Things simulators
- SimMan simulator
- "Harvey" mannequin
- TraumaMan simulator

Other

- Virtual Patients Group Consortium at the University of Florida, University of Central Florida, Medical College of Georgia, and University of Georgia
- Entelos PhysioLabs / Biologic Systems / Quantitative Mathematical Models

13.9.8 See also

- CAVEman
- InVesalius
- Visible Human Project
- Virtual Physiological Human
- Shadow Health Digital Clinical Experiences™

13.9.9 Notes and references

[1] JiSC (2009) Repurposing existing virtual patients. Available http://www.jisc.ac.uk/whatwedo/programmes/elearningcapital/reproduce/revip.aspx accessed 08.06.09

[2] Imison M, Hughes C(2008) http://www.ascilite.org.au/conferences/melbourne/procs/imison.pdf "The virtual patient project: using low fidelity, student generated online case studies in medical education. in *Hello? Where are you in the landscape of educational technology? Proceedings ascilite Melbourne 2008.*

[3] Huang, Grace (May 2007). "Virtual Patient Simulation at U.S. and Canadian Medical Schools". *Educational Strategies* **82** (5): 446. doi:10.1097/ACM.0b013e31803e8a0a. Retrieved 11 February 2016.

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13.9.10 External links

- The electronic Virtual Patient (eViP) programme
- eLearning since 1996
- TheraSim Virtual Patient Simulation

Chapter 14

Clinical Research Informatics

14.1 Translational research informatics

Translational Research Informatics (TRI) is a sister domain to or a sub-domain of Biomedical informatics or Medical Informatics concerned with the application of informatics theory and methods to translational research. There is some overlap with the related domain of Clinical Research Informatics, but TRI is more concerned with enabling multi-disciplinary research to accelerate clinical outcomes, with clinical trials often being the natural step beyond translational research.

Translational Research as defined by the National Institutes of Health includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational research.

14.1.1 Overview of Translational Research Informatics

Translational Research Informatics can be described as "An integrated software solution to manage the: (i) logistics, (ii) data integration, and (iii) collaboration, required by translational investigators and their supporting institutions." It is the class of informatics systems that sits between and often interoperates with: (i) Health Information Technology/Electronic Medical Record systems, (ii) CTMS/Clinical Research Informatics, and (iii) statistical analysis and data mining.

Translational Research Informatics is relatively new, with most CTSA awardee academic medical centers actively acquiring and integrating systems to enable the end-to-end TRI requirements. One advanced TRI system is being implemented at the Windber Research Institute in collaboration with GenoLogics and InforSense. Translational Research Informatics systems are expected to rapidly develop and evolve over the next couple of years.

14.1.2 Systems in Translational Research Informatics

14.1.3 CTRI Dedicated WIKI

Further discussion of this domain can be found at the Clinical Research Informatics Wiki (CRI Wiki), a wiki dedicated to issues in Clinical and Translational Research Informatics.

14.1.4 See also

- Translational Research
- Biomedical Informatics
- Bioinformatics
- Clinical Research Informatics

14.2 Clinical data management system

A **clinical data management system** or CDMS is a tool used in clinical research to manage the data of a clinical trial. The clinical trial data gathered at the investigator site in the case report form are stored in the CDMS. To reduce the possibility of errors due to human entry, the systems employ various means to verify the data. Systems for clinical data management can be self-contained or part of the functionality of a CTMS. A CTMS with clinical data management functionality can help with the validation of clinical data as well as the help the site employ the data for other important activities like building patient registries and assist in patient recruitment efforts.

14.2.1 Classification

The CDMS can be broadly divided into paper-based and electronic data capturing systems.

Paper-based systems

Case report forms are manually filled at site and mailed to the company for which trial is being performed. The data on forms is transferred to the CDMS tool through data entry.The most popular method being double data entry where two different data entry operators enter the data in the system independently and both the entries are compared by the system. In case the entry of a value conflicts, system alerts and a verification can be done manually. Another method is Single Data Entry.

The data in CDMS are then transferred for the data validation. Also, in these systems during validation the data clarification from sites are done through paper forms, which are printed with the problem description and sent to the investigator site and the site responds by answering on forms and mailing them back.

Electronic data capturing systems

In such CDMS the investigators directly uploads the data on CDMS and the data can then be viewed by the data validation staff. Once the data are uploaded by site, data validation team can send the electronic alerts to sites if there are any problems. Such systems eliminate paper usage in clinical trial validation of data.

14.2.2 Clinical data management

Main article: clinical data management

Once data have been screened for typographical errors, the data can be validated to check for logical errors. An example is a check of the subject's date of birth to ensure that they are within the inclusion criteria for the study. These errors are raised for review to determine if there are errors in the data or if clarifications from the investigator are required.

Another function that the CDMS can perform is the coding of data. Currently, the coding is generally centered around two areas —adverse event terms and medication names. With the variance on the number of references that can be made for adverse event terms or medication names, standard dictionaries of these terms can be loaded into the CDMS. The data items containing the adverse event terms or medication names can be linked to one of these dictionaries. The system can check the data in the CDMS and compare them to the dictionaries. Items that do not match can be flagged for further checking. Some systems allow for the storage of synonyms to allow the system to match common abbreviations and map them to the correct term. As an example, ASA (acetylsalicylic acid) could be mapped to aspirin, a common notation. Popular adverse event dictionaries are MedDRA and WHOART and popular Medication dictionaries are COSTART and WHO Drug Dictionary.

At the end of the clinical trial the data set in the CDMS is extracted and provided to statisticians for further analysis. The analysed data are compiled into clinical study report and sent to the regulatory authorities for approval.

Most of the drug manufacturing companies are using Web-based systems for capturing, managing and reporting clinical data. This not only helps them in faster and more efficient data capture, but also speeds up the process of drug development. Perceptive Informatics, Medidata RAVE and Forte Research Systems' OnCore eClinical, Aetiol EDC [Jade Global Solutions {JGS}] and Merge eClinical's eClinicalOS are examples of Web-based data capture systems. In such systems, studies can be set up for each drug trial. In-built edit checks help in removing erroneous data. The system can also be connected to other external systems. For example, RAVE can be connected to an IVRS (Interactive Voice Response System) facility to capture data through direct telephonic interviews of patients. Although IRT (Interactive Response Technology) systems (IVRS/IWRS) are most commonly associated to the enrollment of a patient in a study thus the system defining the arm of the treament that the patient will take and the treatment kit numbers allocated to this arm (if applicable). Besides rather expensive commercial solutions, there are more and more open source clinical data management systems available on the market.<ref name"Raptis/Mettler">Raptis, D. A.; Mettler, T.; Fischer, M. A.; Patak, M.; Lesurtel, M.; Eshmuminov, D.; De Rougemont, O.; Graf, R.; Clavien, P. A.; Breitenstein, S. (2014). "Managing multicentre clinical trials with open source†". *Informatics for Health and Social Care* **39** (2): 67. doi:10.3109/17538157.2013.812647.</ref>

14.2.3 See also

- Clinical data management
- Clinical Quality Management System
- Clinical trial management system
- Clinical trial
- Electronic data capture
- Electronic Common Technical Document (eCTD)
- Drug development

14.2.4 References

- Stuart Summerhayes, *CDM Regulations Procedures Manual*, Blackwell Publishing, ISBN 1-4051-0740-5
- Tai BC, Seldrup J., A review of software for data management, design and analysis of clinical trials, Ann Acad Med Singap. 2000 Sep;29(5):576-81.

- Greenes RA, Pappalardo AN, Marble CW, Barnett GO., Design and implementation of a clinical data management system, Comput Biomed Res. 1969 Oct;2(5):469-85.

14.2.5 External links

- CDMS at Mayo Clinic
- Association for Clinical Data Management
- Society for Clinical Data Management
- French network of Data Managers in Academic biomedical research
- Data Quality Research Institute

14.3 Case report form

A **case report form** (or CRF) is a paper or electronic questionnaire specifically used in clinical trial research.*[1] The Case Report Form is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events.

The sponsor of the clinical trial develops the CRF to collect the specific data they need in order to test their hypotheses or answer their research questions. The size of a CRF can range from a handwritten one-time 'snapshot' of a patient's physical condition to hundreds of pages of electronically captured data obtained over a period of weeks or months. (It can also include required check-up visits months after the patient's treatment has stopped.)

The sponsor is responsible for designing a CRF that accurately represents the protocol of the clinical trial, as well as managing its production, monitoring the data collection and auditing the content of the filled-in CRFs.

Case report forms contain data obtained during the patient's participation in the clinical trial. Before being sent to the sponsor, this data is usually de-identified (not traceable to the patient) by removing the patient's name, medical record number, etc., and giving the patient a unique study number. The supervising Institutional Review Board (IRB) oversees the release of any personally identifiable data to the sponsor.

From the sponsor's point of view, the main logistic goal of a clinical trial is to obtain accurate CRFs. However, because of human and machine error, the data entered in CRFs is rarely completely accurate or entirely readable. To combat these errors monitors are usually hired by the sponsor to audit the CRF to make sure the CRF contains the correct data.

When the study administrators or automated mechanisms process the CRFs that were sent to the sponsor by local researchers, they make a note of queries. Queries are nonsensible or questionable data that must be explained. Examples of data that would lead to a query: a male patient being on female birth control medication or having had an abortion, or a 15-year-old participant having had hip replacement surgery. Each query has to be resolved by the individual attention of a member of each local research team, as well as an individual in the study administration. To ensure quality control, these queries are usually addressed and resolved before the CRF data is included by the sponsor in the final clinical study report. Depending on variables relating to the nature of the study, (e.g., the health of the study population), the effectiveness of the study administrators in resolving these queries can significantly impact the cost of studies.

14.3.1 eCRF

Originally all case report forms were made on paper. But recently there is a changing trend to perform clinical studies using an electronic case report form (eCRF). This way of working has many advantages:

- Faster and efficient
- High security
- Environmentally friendly

14.3.2 See also

- Clinical trial
- Clinical trial protocol
- Patient-reported outcome
- Patient Diary
- Data clarification form
- Clinical data acquisition
- Electronic Data Capture
- Clinical research associate (CRA)
- Drug development

14.3.3 References

[1] http://www.ct-toolkit.ac.uk/glossary/case-report-form-crf

- Debbie Kennedy, *CRF Designer*, Canary Publications, ISBN 0-9531174-7-2

14.3.4 External links

- International Clinical Sciences Support Center (ICSSC) CRF Development
- Standardized Case Report Form (CRF) Work Group - National Cancer Institute
- Standard Operating Procedure – Develop and Manage a Case Report Form links to CRF information (PDF)

14.4 Clinical coder

A **clinical coder** – also known as **clinical coding officer**, **diagnostic coder**, **medical coder** or **medical records technician** – is a health care professional whose main duties are to analyse clinical statements and assign standard codes using a classification system. The data produced are an integral part of health information management, and are used by local and national governments, private healthcare organizations and international agencies for various purposes, including medical and health services research, epidemiological studies, health resource allocation, case mix management, public health programming, medical billing, and public education.

For example, a clinical coder may use a set of published codes on medical diagnoses and procedures, such as the International Classification of Diseases (ICD) or the Common Coding System for Healthcare Procedures (HCPCS), for reporting to the health insurance provider of the recipient of the care.*[1]*[2] The use of standard codes allows insurance providers to map equivalencies across different service providers who may use different terminologies or abbreviations in their written claims forms, and be used to justify reimbursement of fees and expenses. The codes may cover topics related to diagnoses, procedures, pharmaceuticals or topography. The medical notes may also be divided into specialities for example cardiology, gastroenterology, nephrology, neurology or orthopedic care.

A clinical coder therefore requires a good knowledge of medical terminology, clinical documentation, legal aspects of health information, health data standards, classification conventions, and computer- or paper-based data management, usually as obtained through formal education and/or on-the-job training.*[3]*[4]

14.4.1 Clinical coders in practice

The basic task of a clinical coder is to classify medical and health care concepts using a standardised classification. Most clinical coders are employed in coding inpatient episodes of care. However, mortality events, outpatient episodes, general practitioner visits and population health studies can all be coded.

Clinical coding has three key phases: a) Abstraction; b) Assignment; and c) Review.*[5]

Abstraction

The abstraction phase involves reading the entire record of the health encounter and analysing the information to determine what condition(s) the patient had, what caused it and how it was treated. The information comes from a variety of sources within the medical record, such as clinical notes, laboratory and radiology results, and operation notes.

Assignment

The assignment phase has two parts: finding the appropriate code(s) from the classification for the abstraction; and entering the code into the system being used to collect the coded data.

Review

Reviewing the code set produced from the assignment phase is very important. Clinical coder must ask themselves, "does this code set fairly represent what happened to this patient in this health encounter at this facility." By doing this, clinical coders are checking that they have covered everything that they must, but not used extraneous codes. For health encounters that are funded through a case mix mechanism, the clinical coder will also review the diagnosis-related group (DRG) to ensure that it does fairly represent the health encounter.

14.4.2 Competency levels

Clinical coders may have different competency levels depending on the specific tasks and employment setting.*[6]

Entry-level / trainee coder

An entry level coder has completed (or nearly completed) an introductory training program in using clinical classifications. Depending on the country; this program may be in the form of a certificate, or even a degree; which has to be earned before the trainee is allowed to start coding. All trainee coders will have some form of continuous, on-the-job training; often being overseen by a more senior coder.

Intermediate level coder

An intermediate level coder has acquired the skills necessary to code many cases independently. Coders at this

level are also able to code cases with incomplete information. They have a good understanding of anatomy and physiology along with disease processes. Intermediate level coders have their work audited periodically by an Advanced coder.

Advanced level / senior coder

Advanced level and senior coders are authorized to code all cases including the most complex. Advanced coders will usually be credentialed and will have several years of experience. An advanced coder is also able to train entry-level coders.

Nosologist

Main article: Nosology

A nosologist understands how the classification is underpinned. Nosologists consult nationally and internationally to resolve issues in the classification and are viewed as experts who can not only code, but design and deliver education, assist in the development of the classification and the rules for using it.

Nosologists are usually expert in more than one classification, including morbidity, mortality and casemix. In some countries the term "nosologist" is used as a catch-all term for all levels.*[7]

14.4.3 Education and professional qualification

In some countries, clinical coders may seek voluntary certification or accreditation through assessments conducted by professional associations, health authorities or, in some instances, universities.*[8] The options available to the coder will depend on the country,*[8] and, occasionally, even between states within a country.

United States

As of 2016; the typical qualification for an entry-level medical coder in the United States is completion of a diploma or certificate, or, where they are offered, an associate degree. The diploma, certificate, or degree will usually always include an Internet-based and/or in-person internship, at some form of a medical office or facility, at the conclusion. Some form of on-the-job training, or at least oversight, is also usually provided in the first months on the job, until the coder can earn an intermediate or advanced level of certification and accumulate time on the job. For further academic training, a baccalaureate or master's degree in medical information technology, or a related field, can be earned by those who wish to advance to a supervisory or academic role. That option would be recommended for those wishing to teach medical billing or coding at a college or university, community college, or technical or vocational institute, or who wish to become heads of medical billing and coding departments, especially if the doctor's office or clinic, or other facility (among other working options, a medical school or hospital, a skilled nursing facility or other nursing home, a psychiatric facility, an assisted or independent living facility, a rehabilitation facility, a rest home or domiciliary or boarding house, etc.) is very large and receives complex cases, such as a referral facility or a Level I trauma teaching hospital center. A nosologist (medical coding expert) in the U.S. will usually be certified by either AHIMA or the AAPC (often both) at their highest level of certification and specialty inpatient and/or outpatient certification (pediatrics, obstetrics/gynecology, gerontology, oncology are among those offered by AHIMA and/or the AAPC), have at least 3-5 years of intermediate experience beyond entry-level certification and employment, and often holds an associate, bachelor's, or graduate degree.*[9]*[10]*[11]

The AAPC offers the following entry-level certifications in the U.S.: Certified Professional Coder (CPC); which tests on most areas of medical coding, and also the Certified Inpatient Coder (CIC) and Certified Outpatient Coder (COC). Also in the American Health Information Management Association (AHIMA) offers the entry-level Certified Coding Associate (CCA); which is, like the AAPC's CPC, a wide-ranging introductory test.

Some U.S. states, though decidedly not the majority, as it is a very recent trend, now mandate or at least strongly encourage certification or a degree from a college- or at the minimum, some evidence of competency beyond the record of on the job training- and/or from either the AAPC or AHIMA, to be employed. Some states have registries of medical coders, though these can be voluntary listings- which is, for those few who do, most often the case- and so not mandatory. This trend was accelerated in part by the passage of HIPAA (which enforces among other things, patient privacy and access to and the form of medical records) and the Affordable Care Act (U.S. President Barack Obama's health care reform law); and similar changes in other developed and developing countries, many of which, especially in the Western developed countries, and beyond, use the ICD-10 for diagnostic medical coding, which is a quite complex system of codes. The change to more regulation and training has also been driven by the need to create accurate, detailed, and secure medical records- especially patient charts, bills, and claim form submissions, that can be recorded efficiently in an electronic era of medical records where they need to be carefully shared between different providers or institutions of care, which was encouraged and later required by legislation and institutional policy.*[12]*[13]*[14]*[15]*[16]

14.4.4 Classification types

Clinical coders may use many different classifications, which fall into two main groupings: statistical classifications and nomenclatures.

Statistical classification

Main article: Medical classification

A statistical classification, such as ICD-10 or DSM-5, will bring together similar clinical concepts, and group them into one category. This allows the number of categories to be limited so that the classification does not become too big, but still allows statistical analysis. An example of this is in ICD-10 at code I47.1. The code title (or rubric)* [17] is Supraventricular tachycardia. However, there are several other clinical concepts that are also classified here. Amongst them are paroxysmal atrial tachycardia, paroxysmal junctional tachycardia, auricular tachycardia and nodal tachycardia.

Nomenclature

With a nomenclature, for example SNOMED CT, there is a separate listing and code for every clinical concept. So, in the tachycardia example above, each type and clinical term for tachycardia would have its own code listed. This makes nomenclatures unwieldy for compiling health statistics.

14.4.5 Professional associations

In many countries clinical coders are accommodated for by both professional bodies specific to coding, and organisations who represent the health information management profession as a whole.

Australia

- Clinical Coders' Society of Australia (CCSA)* [18]
- Health Information Management Association of Australia (HIMAA)* [19]

Canada

- Canadian Health Information Management Association (CHIMA)* [20]

United Kingdom

- Institute of Health Records and Information Management (IHRIM)* [21]
- Professional Association of Clinical Coders UK (PACC-UK)* [22]

United States

There are several associations that medical coders in the United States may join, including:

- American Health Information Management Association (AHIMA)* [23]
- AAPC (formerly American Academy of Professional Coders)

The AHIMA and AAPC societies' accredited programs will generally train medical coders at a sufficient level to work in their respective states. Some medical coders elect to be certified by both societies.

AHIMA maintains a list of accredited medical coding certificate (and health information management associate, bachelor's, and graduate programs, through a link on the AHIMA accredited programs page, to CAHIIM) here.* [24]

14.4.6 See also

- Clinical medicine
- Health informatics
- *Diagnostic and Statistical Manual of Mental Disorders* (DSM)
- International Classification of Diseases (ICD) / ICD-11 (in development) / ICD-10 / ICD-9-CM
- WHO Family of International Classifications
- Current Procedural Terminology
- Diagnosis-related group
- Medical diagnosis

14.4.7 References

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[2] Michelle A. Green and JoAnn C. Rowell (2011). *Understanding Health Insurance, A Guide to Billing and Reimbursement, 10e*. Cengage Learning. ISBN 978-1-111-03518-1.

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[9] https://icc.edu/academics/catalog/health-careers/medical-coder/

[10] http://www.midstate.edu/programs/healthinformationtechnology.php

[11] http://www.midwesttech.edu/Program-Description/medical-coder-course-description.html

[12] http://smallbusiness.chron.com/federal-requirements-medical-billing-companies-3069.html

[13] http://www.mb-guide.org/medical-billing-laws.html

[14] http://www.medicalbillingandcoding.net/medical_billing_pros.htm

[15] http://www.medicalbillingandcoding.net/prof_advance.htm

[16] http://www.medicalbillingandcoding.net/medical_billing_schools.htm?pc=&sub=medbilling&qual=associate&ct=either

[17] "3. How to use the ICD". *International statistical classification of diseases and related health problems* (10th revision, 2010 ed.). Geneva: World Health Organization. 2011. p. 19. ISBN 9789241548342. In the context of the ICD, "rubric" denotes either a three-character category or a four-character subcategory.

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[20] "CHIMA: The Canadian Health Information Management Association". Retrieved 16 March 2015.

[21] "IHRIM - Institute of Health Records and Information Management (IHRIM)". Retrieved 16 March 2015.

[22] "PACC-UK - Home". Retrieved 16 March 2015.

[23] "AHIMA Home - American Health Information Management Association". Retrieved 16 March 2015.

[24] http://www.ahima.org/careers/codingprograms

14.4.8 External links

- WHO Family of International Classifications
- American Health Information Management Association
- Canadian Health Information Management Association
- National Library of Medicine (U.S.)

14.5 Clinical data acquisition

Acquisition or collection of clinical trial data can be achieved through various methods that may include, but are not limited to, any of the following: paper or electronic medical records, paper forms completed at a site, interactive voice response systems, local electronic data capture systems, or central web based systems.

There is arguably no more important document than the instrument that is used to acquire the data from the clinical trial with the exception of the protocol, which specifies the conduct of that clinical trial. The quality of the data collected relies first and foremost on the quality of that instrument. No matter how much time and effort go into conducting the clinical trial, if the correct data points were not collected, a meaningful analysis may not be possible. It follows, therefore, that the design, development and quality assurance of such an instrument must be given the utmost attention.

The ICH guidelines on Good clinical practice (GCP) use the term 'Case report form' or 'CRF' to refer to these systems 1 . No matter what CRF is utilized, the quality and integrity of the data is of primary importance. The following recommendations are meant to assist in the design, development and quality assurance of the CRF such that the data collected will meet the highest standards.

For an extensive discussion regarding creation of CRFs and examples of actual data collection forms, see Data Collection Forms for Clinical Trials by Spilker 2 . The following is meant to highlight some of the most important points to consider during the design process.

14.5.1 Minimum standards

- Design the CRF to collect the data specified by the protocol.
- Document the process for CRF design, development, approval and version control.
- Make the CRF available at the clinical site prior to enrollment of a subject.
- Document training of clinical site personnel on the protocol, CRF completion instructions and data submittal procedures prior to enrollment of a subject.

14.5.2 Best practices

- Design the CRF along with protocol to assure collection of only the data that protocol specifies.
- Keep questions, prompts and instructions clear and concise.
- Design the CRF to follow the data flow from the perspective of the person completing it, taking into account the flow of study procedures and typical organization of data in a medical record.
- Avoid referential and redundant data points within the CRF whenever possible. If redundant data collection is used to assess data validity, the measurements should be obtained through independent means.
- Design the CRF with the primary safety and efficacy endpoints in mind as the main goal of data collection.
- Establish and maintain a library of standard forms.
- Make the CRF available for review at the clinical site prior to approval.
- Use NCR (no carbon required) paper or other means to assure exact replicas of paper collection tools.

14.5.3 See also

- Clinical Data Interchange Standards Consortium (CDISC)
- Electronic Data Capture
- Clinical Data Management System (CDMS)
- Clinical Document Architecture (CDA)
- Health Insurance Portability and Accountability Act (HIPAA)
- Directive 95/46/EC on the protection of personal data
- Health Level 7
- SNOMED
- Case Report Form
- Patient-reported outcome
- Data management
- Title 21 CFR Part 11
- SmartPen - technological system for digitally encoding and transmitting Case Report Forms

14.5.4 References

- Debbie Kennedy, *CRF Designer*, Canary Publications, ISBN 0-9531174-7-2
- Rebecca Daniels Kush (2003), *eClinical Trials: Planning and Implementation*, CenterWatch / Thomson Healthcare, ISBN 1-930624-28-X
- Spilker B.L. Schoenfelder J. (1991), Data Collection Forms in Clinical Trials Raven Press, New York.

14.5.5 External links

- FDA Website: Clinical Data Management Regulations
- Association For Clinical Data Management
- Society For Clinical Data Management

14.6 Data clarification form

A **Data Clarification Form** (DCF)*[1] or Data Query Form is a questionnaire specifically used in clinical research. The DCF is the primary data clarification tool from the trial sponsor or Contract Research Organization (CRO) towards the investigator to clarify discrepancies and ask the investigator for clarification. The DCF is part of the data validation process in a clinical trial.

14.6.1 See also

- Clinical trial
- Clinical trial protocol
- Case Report Form
- Patient-reported outcome
- Clinical data acquisition
- Electronic Data Capture
- Clinical research associate (CRA)
- Drug development

14.6.2 References

[1] Krishnankutty, Binny; Naveen Kumar, BR; Moodahadu, Lathas; Bellary, Shantala (2012). "Data management in clinical research: An overview". *Indian Journal of Pharmacology* **44** (2): 168. doi:10.4103/0253-7613.93842. PMID 22529469.

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14.6.3 External links

- DCF entry in Clinical Research Dictionary

14.7 Patient-reported outcome

A **patient-reported outcome** or PRO is a method or questionnaire used in a clinical trial or a clinical setting, where the responses are collected directly from the patient.

14.7.1 Terminology

The term PRO should not be confused with *patient-centered outcomes*. The latter implies that questionnaire covers issues of specific concern to the patient. However, *patient-reported* implies only that the patient provides the information. This information may, or may not, be of concern to the patient. The term PRO should also not be confused with the term "patient reported experience measures" (PREMs), which focuses more on a patient's experience versus outcomes.

The term PROs is synonymous with the increasingly used term 'patient reported outcome measures' (PROMs).

14.7.2 Overview

PRO is an umbrella term that covers a whole range of potential types of measurement but is used specifically to refer to self-reports by the patient. PRO data may be collected via self-administered questionnaires completed by the patient themselves or via interviews. The latter will only qualify as a PRO where the interviewer is gaining the patient's views, not where the interviewer uses patient responses to make a professional assessment or judgment of the impact of the patient's condition. Thus, PROs are a means of gathering patient rather than clinical or other views on outcomes. This patients' perspective can play an important role in drug approval.[*][1][*][2]

14.7.3 Characteristics

A well-designed PRO questionnaire should assess either a single underlying characteristic or, where it addresses multiple characteristics, should be a number of scales that each address a single characteristic. These measurement "characteristics" are termed *constructs* and the questionnaires used to collect them, termed *instruments*, *measures*, *scales* or *tools*.[*][3][*][4] Typically, PRO tools much undergo extensive validation and testing.[*][5][*][6]

A questionnaire that measures a single construct is described as unidimensional. Items (questions) in a unidimensional questionnaire can be added to provide a single scale score. However, it cannot be assumed that a questionnaire is unidimensional simply because the author intended it to be. This must be demonstrated empirically (for example, by confirmatory factor analysis or Rasch analysis). A questionnaire that measures multiple constructs is termed multi-dimensional. A multi-dimensional questionnaire is used to provide a profile of scores; that is, each scale is scored and reported separately. It is possible to create an overall (single summary) score from a multi-dimensional measure using factor analysis or preference-based methods but some may see this as akin to adding apples and oranges together.[*][7]

Questionnaires may be generic (designed to be used in any disease population and cover a broad aspect of the construct measured) or condition-targeted (developed specifically to measure those aspects of outcome that are of importance for a people with a particular medical condition).

The most commonly used PRO questionnaires assess one of the following constructs:

- Symptoms (impairments) and other aspects of well-being
- Functioning (disability)
- Health status
- General health perceptions
- Quality of life (QoL)
- Health related quality of life (HRQoL)
- Reports and Ratings of health care.

Measures of symptoms may focus on a range of impairments or on a specific impairment such as depression or pain. Measures of functioning assess activities such as personal care, activities of daily living and locomotor activities. Health-related quality of life instruments are generally multi-dimensional questionnaires assessing a combination of aspects of impairments and/or disability and reflect a patient's health status. In contrast, QoL goes beyond impairment and disability by asking about the patient's ability to fulfill their needs and also about their emotional response to their restrictions.

A new generation of short and easy-to-use tools to monitor patient outcomes on a regular basis has been recently proposed.[*][8] These tools are quick, effective, and easy to understand, as they allow patients to evaluate their health status and experience in a semi-structured way and accordingly aggregate input data, while automatically tracking their physio-emotional sensitivity. As part of the National Institute of Health's Roadmap Initiative, the Patient-Reported Outcomes Measurement Information System (PROMIS) uses modern advances in psychometrics such as Item Response Theory (IRT) and Computerized Adaptive Testing (CAT) to create highly reliable and validated measurement tools.

14.7.4 Validation and quality assessment

It is essential that a PRO instrument satisfy certain development, psychometric and scaling standards if it is to provide useful information (e.g [*][9]). Specifically, measures should have a sound theoretical basis and should be relevant to the patient group with which they are to be used. They should also be reliable and valid (including responsive to underlying change) and the structure of the scale (whether it possesses a single or multiple domains) should have been thoroughly tested using appropriate methodology in order to justify the use of scale or summary scores. Classic examples of such tools and methods are noted in commonly used oncology tools, such as fact or EORTC tools.[*][10][*][11][*][12][*][13][*][14]

These standards must be maintained throughout every target language population. In order to ensure that developmental standards are consistent in translated versions of a PRO instrument, the translated instrument undergoes a process known as Linguistic validation in which the preliminary translation is adapted to reflect cultural and linguistic differences between diverse target populations.

14.7.5 Preference-based PROs

Preference based PROs can be used for the computation of a Quality-Adjusted Life Year. A preference based PRO has an algorithm attached to the PRO instrument which can 'weigh' the outcomes reported by patients according to the preferences for health outcomes of a group of individuals such as the general public or of patient groups. The purpose of this 'weighing' is to make sure that elements of health that are very important receive larger weight when computing sum scores. For example, individuals may consider problems with their mood to be more important than limitations in usual activities. Examples of generic preference-based PROs are the Health Utilities Index and the EQ-5D. Condition-targeted preference-based PROs also exist, but there are some questions regarding their comparability to generic PROs when used for the computation of Quality Adjusted Life Years.[*][15]

14.7.6 Examples

See also: List of patient-reported quality of life surveys

Many of the common generic PRO tools assess health-related quality of life or patient evaluations of health care. For example, the SF-36 Health Survey, SF-12 Health Survey, Profile, the Nottingham Health Profile, the Health Utilities Index, the Quality of Well-Being Scale, the EuroQol (EQ-5D), and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey instruments are PRO instruments.

Condition-targeted tools may capture any of the constructs listed above, depending on the purpose for which they were designed. Examples include the Adult Asthma Quality of Life Questionnaire (AQLQ), the Kidney Disease Quality of Life Instrument, National Eye Institute Visual Functioning Questionnaire, Epilepsy Surgery Inventory, Migraine Specific Quality of Life (MSQOL), the Ankylosing Spondylitis Quality of Life questionnaire (ASQoL) and the Seattle Angina Questionnaire (SAQ), to name a few.

PROMs in the AJRR

The American Joint Replacement Registry (AJRR) launched their Level III patient-reported outcome (PRO) platform in November 2015.[*][16] AJRR developed the PRO platform within AJRR's Demand Reporting & Electronic Dashboard system. Clinical staff is able to access patient data while having the ability to manage PRO surveys electronically via a secure patient portal. The AJRR Dashboard system can also pull site-specific patient reports and summary results for each PRO measure supported on the AJRR system.[*][16]

AJRR collaborated with several orthopaedic organizations to identify the specific measures that AJRR should recommend and that may be used as national benchmarks. Even though specific measures are recommended, AJRR understands that some institutions may have in place a long-standing PRO data collection process. Participating hospitals are able to submit and retrieve these alternative measures, but there will not be national benchmarks available for them.[*][16]

PROMs in the NHS

Since 1 April 2009 all providers of care funded by the National Health Service (NHS) in England have been required to provide Patient-Reported Outcome Measures (PROMs) in four elective surgical procedures: hip replacement, knee replacement, varicose vein surgery and hernia surgery.[*][17][*][18] Patients are asked to complete a questionnaire before undergoing the surgical procedure; a follow-up questionnaire is then sent to the patient some weeks or months later.[*][19] Patient participation is, however, not compulsory.[*][20]

In December 2013 a team from the London School of Hygiene and Tropical Medicine reviewed the first 3 years of NHS PROMs data which captured responses from more than 50,000 patients who underwent groin hernia repair, varicose vein surgery or hip or knee replacements. They found "no grounds to suggest we should start cutting the amount of surgery we are doing." [*][21]

Patient-reported Outcomes in Drug Licensing and Label Claims

Patient-reported outcomes are important in a regulatory context. The US Food and Drug Administration (FDA) has issued formal Guidance to Industry on PROs in label claims *[22] and the European Medicines Agency (EMA) has produced a reflection paper on HRQoL.*[23] Increasing numbers of regulatory submissions for new drugs provide PRO data to support claims. DeMuro et al. (2013)*[24] have reviewed drug approvals for the years 2006 - 2010. They showed that of 75 drugs approved by both agencies, 35 (47%) had at last one PRO-related claim approved by the EMA compared to 14 (19%) for the FDA. The FDA was more likely to approve claims for symptom reduction, while the EMA approved relatively more claims for improvement in functioning or HrQoL.

14.7.7 See also

- Electronic patient-reported outcome
- Patient diary
- Clinical trial protocol
- Clinical data acquisition
- Case report form
- Data clarification form
- Electronic data capture
- Clinical research associate (CRA)
- Drug development
- Linguistic validation
- Quality of Life in Depression Scale

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14.7.9 External links

- EuroQol Group (EQ-5D)
- Patient Reported Outcomes Measurement Information System
- Medical Outcomes Trust
- Health Surveys
- SF-36.org
- Mapi
- Mapi Research Trust (non-profit organization involved in Patient-Centered Outcomes)
- ProQolid (Patient-Reported Outcome & Quality of Life Instruments Database)
- PROLabels(Database on Patient-Reported Outcome claims in marketing authorizations)
- Vector Psychometric Group, LLC: PRO consulting, development, and delivery systems
- Open Research Exchange: PatientsLikeMe

Chapter 15

Standards, Coding and Nomenclature

15.1 Diagnosis codes

In healthcare, **diagnosis codes** are used as a tool to group and identify diseases, disorders, symptoms, poisonings, adverse effects of drugs & chemicals, injuries and other reasons for patient encounters. Diagnostic coding is the translation of written descriptions of diseases, illnesses and injuries into codes from a particular classification. In medical classification, diagnosis codes are used as part of the clinical coding process alongside intervention codes. Both diagnosis and intervention codes are assigned by a health professional trained in medical classification such as a clinical coder or Health Information Manager.*[1]

Several diagnosis classification systems have been implemented to various degrees of success across the world. The various classifications have a focus towards a particular patient encounter type such as emergency, inpatient, outpatient, mental health as well as surgical care. The International Statistical Classification of Diseases and Related Health Problems (ICD) is one of the most widely used classification systems for diagnosis coding as it allows comparability and use of mortality and morbidity data.*[2]

As the knowledge of health and medical advances arise, the diagnostic codes are generally revised and updated to match the most up to date current body of knowledge in the field of health. The codes may be quite frequently revised as new knowledge is attained. DSM (see below) changes some of its coding to correspond to the codes in ICD. In 2005, for example, DSM changed the diagnostic codes for circadian rhythm sleep disorders from the 307-group to the 327-group; the new codes reflect the moving of these disorders from the Mental Disorders section to the Neurological section in the ICD *[3]

15.1.1 Diagnostic Coding Systems

A number of diagnostic coding systems are currently implemented across the world to code the stay of patients within a typical health setting such as a hospital. The following table provides a basic list of the currently used coding systems:

See also: Medical classification

15.1.2 Financial aspects of Diagnostic Coding

Diagnosis codes are generally used as a representation of admitted episodes in health care settings. The principal diagnosis, additional diagnoses alongside intervention codes essentially depict a patient's admission to a hospital.*[4]

Diagnoses codes are subjected to ethical considerations as they contribute to the total coded medical record in health services areas such as a hospital. Hospitals that are based on Activity Based Funding and Diagnoses Related Group Classification systems are often subjected to high end decision making that could affect the outcome of funding. It's important to look at the scope of diagnoses codes in terms of their application in finance. The diagnoses codes in particular the Principal Diagnoses and Additional Diagnoses can significantly affect the total funding that a hospital may receive for any patient admitted.*[5]

Ethically this highlights the fact that the assignment of the diagnoses code can be influenced by a decision to maximize reimbursement of funding. For example, when looking at the activity based funding model used in the public hospital system in Victoria the total coded medical record is responsible for its reflected funding. These decisions also affect clinical documentation by physicians as recommendations from a Health Information Service can directly affect how a clinician may document a condition that a patient may have. The difference between the codes assigned for confusion and delirium can alter a hospitals DRG assignment as delirium is considered a higher level code than confusion within the ICD-10 coding hierarchy in terms of severity. A clinical coder or Health Information Manager may feel obliged to maximize funding above the ethical requirement to be honest within their diagnostic coding; this highlights the ethical standpoint of diagnoses codes as they should be reflective of a patient's admission.*[6]

15.1.3 Factors affecting accuracy in Diagnostic Coding

Accuracy is a major component in diagnoses codes. The accurate assignment of diagnoses codes in clinical coding is essential in order to effectively depict a patients stay within a typical health service area. A number of factors can contribute to the overall accuracy coding which includes medical record legibility, physician documentation, clinical coder experience, financial decision making, miscoding as well as classification system limitations.

Medical Record Legibility

The legibility of a medical record is a contributing factor in the accuracy of diagnostic coding. The assigned proxy that is extracting information from the medical record is dependent on the quality of the medical record. Factors that contribute to a medical records quality are physician documentation, handwriting legibility, compilation of forms, duplication and inaccurate patient data. For example, if a clinical coder or Health Information Manager was extracting data from a medical record in which the principal diagnoses was unclear due to illegible handwriting, the health professional would have to contact the physician responsible for documenting the diagnoses in order to correctly assign the code. In Australia, the legibility of records has been sufficiently maintained due to the implementation of highly detailed standards and guidelines which aim to improve the legibility of medical records. In particular the paper medical record standard 'AS 2828' created by Standards Australia focuses on a few key areas which are critical to maintaining a legible paper medical record.*[7]

The following criteria should be used as a guideline when creating a medical record specific to the aid of providing clear documentation for diagnostic coding. In particular the legibility of a medical record is dependent on;

1. Durability: If a medical record wasn't durable, overtime if a coder was to revisit the record and it wasn't legible it wouldn't be feasible to code from that record.
2. Ready Identification: A coder must be able to identify the exact record being coded in order to effectively extract diagnoses codes.
3. Reproducible: A coder would need to make sure that the record is reproducible in that copies can be made to aid in effective coding.*[8]

Clinical Coder Experience

The experience of the health professional coding a medical record is an essential variable that must be accounted for when analysing the accuracy of coding. Generally a coder with years of experience is able to extract all the relevant information from a medical record whether it is paper, scanned or semi-electronic. The diagnoses codes selected from the extraction are generally compiled and sequenced in order to represent the admission. An experienced coder may incorrectly assign codes due a lack of application of a classification systems relevant standards. An example to highlight clinical coding experience would be the standard within the Australian Coding Standards *0010 General Abstraction Guidelines*.*[9] These guidelines indicate that a coder must seek further detail within a record in order to correctly assign the correct diagnoses code. An inexperienced coder may simply just use the description from the discharge summary such as *Infarction* and may not use the correct detail which could be further found within the details of the medical record. This directly relates to the accuracy of diagnoses codes as the experience of the health professional coder is significant in its accuracy and contribution to finance.*[10]

15.1.4 Weaknesses in Diagnostic Coding

Generally coding is a concept of modeling reality with reduced effort but with physical copying.

- Hence the result of coding is a reduction to the scope of representation as far as possible to be depicted with the chosen modeling technology. There will be never an escape, but choosing more than one model to serve more than one purpose. That led to various code derivatives, all of them using one basic reference code for ordering as e.g. with ICD-10 coding. However, concurrent depiction of several models in one image remains principally impossible.
- Focusing a code on one purpose lets other purposes unsatisfied. This has to be taken into account when advertising for any coding concept. The operability of coding is generally bound to purpose. Interreferring must be subject of evolutionary development, as code structures are subject of frequent change.*[11]
- Unambiguous coding requires strict restriction to hierarchical tree structures possibly enhanced with multiple links, but no parallel branching for contemporary coding whilst maintaining bijectivity.
- Spatial depictions of n-dimensional code spaces as coding scheme trees on flat screens may enhance imagination, but still leave the dimensionality of image limited to intelligibility of sketching, mostly as a 3D object on a 2D screen. Pivoting such image does not solve the intelligibility problem.
- Projections of code spaces as flattened graphs may ease the depiction of a code, but generally reduce the contained information with the flattening. There is no explanation given with many of the codes for transforming from one code system to another. That leads to specialized usage and to limitations in communication between codes. The escape is with

code reference structures (as e.g. not existing with SNOMED3).

- Hierarchical ordering of more than one code system may be seen as appropriate, as the human body is principally invariant to coding. But the dependency implied with such hierarchies decrease the cross referencing between the code levels down to unintelligibility. The escape is with hyper maps that exceed planar views (as e.g. with SNOMED3) and their referring to other codes (as e.g. yet not existing with SNOMED3).

- Purpose of documenting will be seen as essential just for the validation of a code system in aspects of correctness. However this purpose is timely subordinate to the generating of the respective information. Hence some code system shall support the process of medical diagnosis and of medical treatment of any kind. Escape is with a specialised coding for the processes of working on diagnosis as on working with treatment (as e.g. not intended with SNOMED3).

- Intelligibility of results of coding is achieved by semantic design principles and with ontologies to support navigating in the codes. One major aspect despite the fuzziness of language is the bijectivity of coding. Escape is with explaining the code structure to avoid misinterpreting and various codes for the very same condition (as e.g. yet not served at all with SNOMED3).

15.1.5 See also

- Systematized Nomenclature of Medicine
- Diagnosis-related group
- Medical classification
- Major Diagnostic Category
- MedDRA
- Clinical Audit
- American Health Information Management Association

15.1.6 References

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[11] Towards Semantic Interoperability in Healthcare

15.2 Procedure codes

Procedure codes are a sub-type of medical classification used to identify specific surgical, medical, or diagnostic interventions. The structure of the codes will depend on the classification; for example some use a numerical system, others alphanumeric.

15.2.1 Examples of procedure codes

International

- International Classification of Procedures in Medicine (ICPM) and International Classification of Health Interventions (ICHI)*[1]

- ICPC-2 (International Classification of Primary Care, which contains diagnosis codes, reasons for encounter (RFE), and process of care as well as procedure codes)

North American

- Healthcare Common Procedure Coding System (including Current Procedural Terminology) (used in United States)
- ICD-10 Procedure Coding System (ICD-10-PCS) (used in United States)
- ICD-9-CM Volume 3 (subset of ICD-9-CM) (used in United States)
- Canadian Classification of Health Interventions (CCI) (used in Canada. Replaced CCP.) *[2]
- Nursing Interventions Classification (NIC) (used in United States) *[3]
- Nursing Minimum Data Set (NMDS)
- Nursing Outcomes Classification (NOC)
- SNOMED (P axis)
- Current Dental Terminology (CDT)

European

- OPS-301 (adaptation of ICPM used in Germany)
- OPCS-4 (used by the NHS in England)*[4]
- Classification des Actes Médicaux (CCAM) (used in France)*[5]
- NOMESCO
- Gebührenordnung für ärzte (GOÄ) (Germany)
- Nomenclature des prestations de santé de l'institut national d'assurance maladie invalidité (Belgium)
- TARMED (Switzerland)
- Classificatie van verrichtingen (Dutch)

Other

- Australian Classification of Health Interventions (ACHI)*[6]
- Read codes system, used in United Kingdom General Practice

15.2.2 See also

- diagnosis code
- medical classification

15.2.3 References

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[2] "CCI to Replace ICD-9 in Canada"

[3] "Overview: Nursing Interventions Classification "

[4]

[5] ccam.sante.fr Archived October 16, 2005 at the Wayback Machine

[6] fhs.usyd.edu.au Archived June 20, 2005 at the Wayback Machine

15.3 Bar Code Medication Administration

Bar Code Medication Administration (BCMA) is a barcode system designed to prevent medication errors in healthcare settings and improve the quality and safety of medication administration. The overall goals of BCMA are to improve accuracy, prevent errors, and generate online records of medication administration.

It consists of a barcode reader, a portable or desktop computer with wireless connection, a computer server, and some software. When a nurse gives medicines to a patient in a healthcare setting, the nurse can scan barcode on the wristband on the patient and make sure that the patient is the right patient. The nurse can then scan the barcode on medicine, the nurse and the software can then verify if it is the right medicine at the right dose at the right time by the right route ("Five rights").*[1] Bar Code Medication administration was designed as an additional check to aid the nurse in administering medications; however, it cannot replace the expertise and professional judgment of the nurse.

BCMA was first implemented in 1995 *[2] at the Colmery-O'Neil Veteran Medical Center in Topeka, Kansas, USA. It was conceived by a nurse who was inspired by a car rental service using barcode. From 1999 to 2001, Department of Veterans Affairs promoted the system to 161 facilities.*[3] Cummings and others recommend the BCMA system for its reduction of errors. They suggest healthcare settings to consider the system first while they are waiting for RFID. They also pointed out that adopting the system takes a careful plan and a deep change in work patterns.*[4]

15.3.1 See also

- Barcode technology in healthcare

15.3.2 References

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The Canadian Pharmaceutical Bar Coding Project: The Institute for Safe Medication Practices Canada (ISMP Canada) and Canadian Patient Safety Institute (CPSI) http://www.ismp-canada.org/barcoding/index.htm

15.4 Bidirectional Health Information Exchange

BHIE is an acronym for **Bidirectional Health Information Exchange,** a series of communications protocols developed by the Department of Veterans Affairs. It is used to exchange healthcare information between Department of Veterans Affairs healthcare facilities nationwide and between VA healthcare facilities and Department of Defense healthcare facilities.

It is one of the most widely used healthcare data exchange systems in routine healthcare use, and is used to facilitate healthcare data exchange associated with a patient's medical record.

15.4.1 Types of data managed

Outpatient pharmacy data, allergy data, patient identification correlation, laboratory result data (including surgical pathology reports, cytology and microbiology data, chemistry and hematology data), lab orders data, radiology reports, problem lists, encounters, procedures, and clinical notes are examples of the types of healthcare data that are exchanged using BHIE.

15.4.2 Integration with Electronic Health Record systems

BHIE is currently integrated into the VistA EMR (electronic medical record) system used nationwide in Department of Veterans Affairs hospitals. This integration is able to provide increased efficiency in healthcare for veterans. Veterans Hospitals have regional specialized capabilities, and veterans often travel to receive specialized care. Their VistA medical records are able to be transmitted in their entirety using this protocol.

15.4.3 History

GCPR to BHIE- a brief history

In response to 1998 Presidential Review Directive 5, the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the US Indian Health Service (IHS) collaborated to create the first developmental instances of a secure data-sharing system for electronic patient record data. This was initially called the Government Computer-based Patient Record system, or GCPR.

The development of GCPR used UML modeling tools to define the various expected use cases where medical Care Providers in any Medical Treatment Facility (MTF) would need to have access to patient records or other data from within another participating agency. The UML modeling design was selected for its ability to clearly define the business logic that would be required for the GCPR Framework in an object-oriented way, and for its ability to provide detailed tracking of the iterative development of the Framework software. The UML model for the Framework is still used for the ongoing maintenance and support of the BHIE system.

Early development of the GCPR system proved that it could meet the requirements of a robust interagency data sharing system, but details of implementation, policy, and security management issues caused delays in full implementation of the GCPR system as it was originally designed. As the project progressed, the Indian Health Service withdrew from GCPR participation, and agreements between the DoD and the VA led to the GCPR Near-Term Solution (GCPR-NTS) being managed principally by the VA, with support from the DoD.

The VA installed the preliminary systems for GCPR-NTS in the VA Silver Spring, MD OIFO, where extensive testing took place between the DoD EI/DS and the VA CPRS developers. These teams worked together to finalize the needed infrastructure and security systems for one-way data transport of DoD Separatee data to the VA. The GCPR-NTS was structurally designed to house a static repository of this DoD Separatee data for use by VA Care providers. This one-way transfer of data from DoD to the VA repository continues to be one of the principal functions of the BHIE system.

Upon completion of initial testing, the VA deployed another GCPR-NTS system into the Austin Automation Center, in Austin Texas. This system became the "Production" environment, which came to be known as the GCPR-Mid-Term Solution (GCPR-MTS). As the use of the system grew within the VA, it was later renamed to become the Federal Healthcare Information Exchange, or FHIE. The previously constructed system in the Silver Spring OIFO was re-tasked to become an iterative testing environment for proofing planned changes prior to deployment in the FHIE Production system in Austin.

In 2004, interest in the system for use within the DoD was renewed, and further development was done to add a true bi-directional connection component to the FHIE system. Initially called the Data Sharing Initiative (DSI), adapters were added to the FHIE system using the Web Services XML-based protocol standard. A similar Web Services adapter was developed for the DoD to connect to their CHCS-I legacy patient record systems. In this way, both systems hosted a peer Web Services client that is accessible to the other with proper authentication, allowing bi-directional, query-based data exchanges between the disparate systems. Direct cross-Domain write capability and fully computable data storage and transfers are not supported at this time.

With the addition of the DSI components to the FHIE system, the entire project was renamed the Federal Bi-Directional Healthcare Information Exchange, or BHIE. All references to FHIE (other than historical) are generally being phased out. BHIE represents the previous Framework System as was deployed for the VA, and all additional capabilities added to support near-real-time data exchange between the Framework and participating DoD Medical Treatment Facilities (MTFs). In short: FHIE + DSI = BHIE.

The current BHIE Project participants are exclusively the Department of Defense (DoD) and the Department of Veterans Affairs (VA), though any number of additional Domains will probably be added over time with proper development of adapters and policies. This project has the support of the VA Under-Secretary for Health, and the Acting Assistant Secretary of Defense/Health Affairs of DoD. There is also congressional interest in a successful outcome to this work.

Since 2Q-FY05, the DoD is supporting the development of a separate DoD BHIE Domain, including dedicated hardware and infrastructure to support this new system within the DISA network. The details of the DoD system are still in development, as are the details of the expected interoperability with the existing VA BHIE system.

Additional data types were added to the system during the 2005-2006 operational periods, including the provision of Discharge Summaries from selected DoD MTFs, and the inclusion of Pre-Post deployment form data availability.

In March 2006, the usage of BHIE across the country was outlined before the House Committee on Veterans Affairs.*[1]

In 2007 the DoD's AHLTA interface was connected to BHIE to allow AHLTA clinicians to see VA data and VA clinicians to see DoD data stored within the CDR. Additionally in 2007 the Theater Medical Data Store (TMDS) was connected to BHIE to allow VA and DoD clinicians to access medical records from combat theaters.*[2]

In the 2007-2009 years, a parallel "two-pass" system for exchanging imaging metadata was added to the scope of BHIE. A special-purpose server, the BHIE Imaging Adapter (BIA) was added to the other BHIE systems. This BIA server takes the first pass of an Image Study query, obtains metadata about the images for a specific patient from the BHIE system, then presents a list of available images to the end-user, who can then select the images of interest from the list. The BIA then has variable functions as an intelligent proxy for retrieving and delivering the selected images. As of 2011, other additional functions related to images are being added to both the BIA and BHIE systems.

From 2008 through 2011, the central focus of BHIE was to upgrade the system hardware and migrate all of the Production functions onto the new hardware. The upgrades began in the spring of 2009, when the initial sets of hardware were delivered and development began to create a set of identical-hardware environments on which the BHIE systems' migration could occur. The migration to the new Production BHIE location in Philadelphia, PA was accomplished in January 2011, and enhancements to all of the systems continue as an ongoing process.

The Austin "Legacy" BHIE system remained in Production operation until 2011, when the replacement BHIE hardware installed in Philadelphia, PA assumed all of those functions. The Austin systems went dark and were retired from service in April 2011.

15.4.4 References

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15.4.5 External links

- "BHIE overview". *Department of Veterans Affairs*. Archived from the original on 7 April 2010. Retrieved Apr 1, 2010.

15.5 Classification Commune des Actes Médicaux

Classification Commune des Actes Médicaux is a French medical classification for clinical procedures.* [1] Starting in 2005, the CCAM serves as the reimbursement classification for clinicians. The CCAM was evaluated using OpenGALEN tools and technologies.

This classification is used to establish

- In private practice and hospital fees for acts performed during technical consultations
- In private clinics, the fees for procedures performed
- In public and private hospitals, the DRG and its pricing of hospital stays provided to health insurance as part of T2 A.

The choice of acts of this nomenclature is up to the Evaluation Commission of Acts Professionals (CEAP) of the High Authority of Health

It coexists with the Nomenclature Générale des Actes Professionnels (NGAP).* [2]

15.5.1 Structure

In the version V2, the ACPC 7623 codes included. Each is accompanied by wording to clarify its meaning unambiguously followed by its price in euros and tariff details.

Code Principal

Explicit hierarchical coding. This code and / or its title in the presence of personally identifiable information may impair the protection of people and lift the confidentiality of those who entrust themselves to organizations and managed care organization.

Each code comprises the four letters and three numbers.

- The first letter refers to a large anatomical unit;
- The second letter indicates the body (or function) in the unit corresponding to the first letter;
- The third letter denotes the action performed;
- The fourth letter identifies the surgical approach or technique used.

The next three digits are used to differentiate between acts with four identical letters keys.

e.g. HHFA001: Appendectomy, for the first quadrant

HH. F A. 001 Action Technical topography Counter

Hierarchical ACPC

CCAM codes are structured in a tree whose top-level comprises 19 chapters, organized mainly by large anatomical structure or function:

- 01. central nervous system, device and independent
- 02. eye and notes
- 03. ear
- 04. circulatory
- 05. immune system and hematopoietic
- 06. respiratory
- 07. digestive
- 08. urinary and genital
- 09. acts on the reproductive, pregnancy and the newborn
- 10. endocrine and metabolic
- 11. osteoarticular apparatus and muscle of the head
- 12. osteoarticular apparatus and muscle neck and trunk
- 13. osteoarticular apparatus and muscle of the upper limb
- 14. osteoarticular apparatus and muscle of lower limb
- 15. osteoarticular apparatus and muscle without precision surveying
- 16. integumentary system - mammary glands
- 17. acts without precision surveying
- 18. anesthetic actions and additional statements
- 19. transitional adjustments to the acpc

The second level separates the diagnostic and therapeutic procedures, it is optionally followed by one or more sub-levels.

15.5.2 Modifiers acts and association

Some acts may receive more than their one or more main code details called Modifiers. A modifier is information associated with a label that identifies a particular criterion for the performance of an act or his recovery. It applies to a specific list of acts. Modifiers are explicitly allowed in respect of each of the acts concerned. The application of a modifier leads to a rate increase of the act. Only modifiers can be charged in connection with acts that have

a tariff. The description of these modifiers is found in Article III-2 of Book III of the General Provisions official. Four modifiers than can be priced by deed.

In the context of pricing, the association of acts is the realization of several acts at the same time, for the same patient by the same doctor, since there is no incompatibility between these acts. Codes 1,2,3,4 or 5 and their application rates of these associations are listed in Article III-3 of Paper III.

15.5.3 Versions of CCAM

Version 22 of the'*Technical*ACPC will be applicable on September 30, 2013 for clinics and public hospitals. Version 21 shall be in use until that date.

The construction of the**clinical ACPC** on intellectual activities that is to say without tools or technical movement provided by the medical convention of 2005 was due to start before 2007. A survey of clinicians from FIFG is announced for late 2010.

Revision history

http://www.ameli.fr/fileadmin/user_upload/documents/DATE_CCAM.pdf:

- ACPC's V23 01.25.2011 Official Journal of 26 December 2010 applicable as of January 25, 2011
- V22 ACPC of 30/09/2010 (bariatric surgery, hyperbaric medicine, respiratory support, ...)
- ACPC V21 from 25/05/2010 (recasting of Anatomy Cyto Pathology)
- V20 ACPC 01/05/2010 (recast EBRT)
- ACPC V19 from 01/02/2010
- V18 ACPC 01/01/2010
- V17 ACPC of 19/10/2009
- V16 ACPC 28/05/2009
- ACPC V15 from 21/12/2008 (12001 codes acts)
- ACPC V14, 16/10/2008
- ACPC V13 from 01/05/2008
- V12 ACPC of 14/03/2008
- ACPC 28/12/2007
- V11 (7838 rate changes compared to version 10).
- V10 ACPC of 12/09/2007
- ACPC V9 of 28/06/2007
- V8 ACPC on 16/05/2007
- ACPC V7 of 16/04/2007
- ACPC's V6 16/09/2006
- ACPC V2 from 01/09/2005
- ACPC V1 25/03/2005
- ACPC V0bis, 27/11/2003
- V0 ACPC, 2002

Learn more about the site Health Insurance = 000310000000's ATIH

15.5.4 References

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[2] Bellanger, MM.; Cherilova, V.; Paris, V. (Dec 2005). "The "Health Benefit Basket" in France." . *Eur J Health Econ*. Suppl: 24–9. doi:10.1007/s10198-005-0315-0. PMC 1388081. PMID 16267657.

15.5.5 External links

- The site of the ACPC
- Evaluation Commission Acts Professionals (CEAP) of the Haute Autorité de Santé (HAS)
- [Search http://www.codage.ext.cnamts.fr/codif/ccam/ acts in the ACPC]
- FAQs on the ACPC
- ACPC website of Health Insurance
- the website ATIH
- Rover: free software for viewing and research in the ACPC

15.6 Classification of Pharmaco-Therapeutic Referrals

The ***Classification of Pharmaco-Therapeutic Referrals*** (***CPR***) is a taxonomy focused to define and group together situations requiring a referral from pharmacists to physicians (and vice versa) regarding the pharmacotherapy used by the patients. It has been published in 2008. It is bilingual: English/Spanish (*Clasificación de Derivaciones Fármaco-terapéuticas*).* [1]

It is a simple and efficient classification of pharmaco-therapeutic referrals between physicians and pharmacists

permitting a common inter-professional language.*[2] It is adapted to any type of referrals among health professionals, and to increase its specificity it can be combined with ATC codes, ICD-10, and ICPC-2 PLUS.

It is a part of the *MEDAFAR Project*, whose objective is to improve, through different scientific activities, the coordination processes between physicians and pharmacists working in primary health care.*[3]*[4]*[5]*[6]

15.6.1 Supporting institutions

- Pharmaceutical Care Foundation of Spain (*Fundación Pharmaceutical Care España*)
- Spanish Society of Primary Care Doctors (*Sociedad Española de Médicos de Atención Primaria*) (SEMERGEN)

15.6.2 Authors

- Raimundo Pastor Sánchez (Family practice, "Miguel de Cervantes" Primary Health Centre SERMAS Alcalá de Henares – Madrid – Spain)
- Carmen Alberola Gómez-Escolar (Pharmacist, Vice-President *Fundación Pharmaceutical Care España*)
- Flor Álvarez de Toledo Saavedra (Community pharmacist, Past-President *Fundación Pharmaceutical Care España*)
- Nuria Fernández de Cano Martín (Family practice, "Daroca" Primary Health Centre SERMAS Madrid – Spain)
- Nancy Solá Uthurry (Doctor in Pharmacy, *Fundación Pharmaceutical Care España*)

15.6.3 Structure

It is structured in 4 chapters (E, I, N, S) and 38 rubrics. The terminology used follows the rules of ICPC-2.*[7]

Each rubric consists in an alphanumeric code (the letter corresponds to the chapters and the number to the component) and each title of the rubric (the assigned name) is expressed and explained by:

– A series of terms **related with** the title of the rubric.

– A **definition** expressing the meaning of the rubric

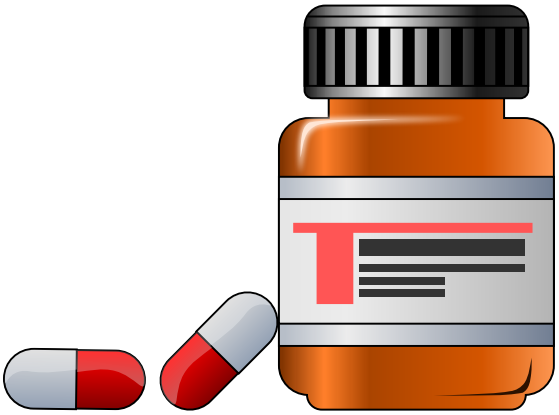
– A list of **inclusion criteria** and another list with **exclusion criteria** to select and qualify the contents corresponding to a rubric.

– Some **example** to illustrate every term.

It also includes a glossary of 51 terms defined by consensus, an alphabetical index with 350 words used in the rubrics; and a standardized model of inter-professional referral form, to facilitate referrals from community pharmacists to primary care physicians.

15.6.4 Classification of Pharmaco-Therapeutic Referrals MEDAFAR

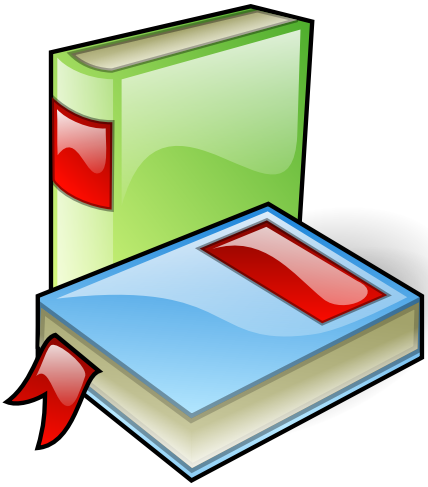
E. Effectiveness / efficiency



- E 0. Effectiveness / Efficiency, unspecified
- E 1. Indication
- E 2. Prescription and dispensing conditions
- E 3. Active substance / excipient
- E 4. Pharmaceutical form / how supplied
- E 5. Dosage
- E 6. Quality
- E 7. Storage
- E 8. Consumption
- E 9. Outcome.

I. Information / health education

- I 0. Information / Health education, unspecified
- I 1. Situation / reason for encounter
- I 2. Health problem
- I 3. Complementary examination
- I 4. Risk
- I 5. Pharmacological treatment
- I 6. No pharmacological treatment
- I 7. Treatment goal
- I 8. Socio-healthcare system.



N. Need

- N 0. Need, unspecified
- N 1. Treatment based on symptoms and/or signs
- N 2. Treatment based on socio–economic-work issues
- N 3. Treatment based on public health issues
- N 4. Prevention
- N 5. Healthcare provision
- N 6. Complementary test for treatment control
- N 7. Administrative activity
- N 8. On patient request (fears, doubts, wants).

S. Safety

- S 0. Safety, unspecified
- S 1. Toxicity
- S 2. Interaction
- S 3. Allergy
- S 4. Addiction (dependence)
- S 5. Other side effects
- S 6. Contraindication
- S 7. Medicalisation
- S 8. Non-regulate substance
- S 9. Data / confidentiality.

15.6.5 See also

- Health care
  - Family medicine / Family practice
  - General practice
  - Pharmaceutical care
  - Primary care
  - Primary health care
- Health care provider
  - Pharmacist
  - Pharmacy technician
- Medical classification
  - ATC codes Anatomical Therapeutic Chemical Classification System
  - ICD-10 International Classification of Diseases

  - International Classification of Primary Care (ICPC) / ICPC-2 PLUS

- Pharmacy
- Pharmacotherapy
- Referral (medicine)

15.6.6 References

[1] Pastor Sánchez R, Alberola Gómez-Escolar C, Álvarez de Toledo Saavedra F, Fernández de Cano Martín N, Solá Uthurry N. Classification of Pharmaco-Terapeutic Referrals (CPR). MEDAFAR. Madrid: IMC; 2008. ISBN 978-84-691-8426-4

[2] Álvarez de Toledo F, Pastor Sánchez R. La Clasificación de Derivaciones Fármaco-Terapéuticas: una herramienta para la coordinación entre médicos y farmacéuticos. Ars Pharm. 2011; 52(Supl 1):20-5.

[3] García Cebrián F. La seguridad del paciente y la colaboración entre médicos y farmacéuticos [editorial]. SEMERGEN. 2006; 32(2):55-7.

[4] Pastor Sánchez R, Barbero González A, del Barrio Sánchez H, García Olmos LM, editores. Comunicación interprofesional en atención primaria de salud. Madrid: REAP; 1996.

[5] Uribe G, Martínez de la Hidalga G. Médicos y farmacéuticos: éxitos y fracasos de colaboración profesional. SEMERGEN. 2002;28(2):86-8.

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[7] International Classification Committee of WONCA. ICPC-2 International Classification of Primary care (2 ed.). Oxford: Oxford University Press; 1998.

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15.6.8 External links

- Classification of Pharmaco-Terapeutic Referrals (CPR)
- Clasificación de Derivaciones Fármaco-terapéuticas (CDF)
- MEDAFAR
- SEMERGEN
- Fundación Pharmaceutical Care España
- ICPC-2e (by the Norwegian Centre for Informatics in Health and Social Care)]
- International Classification of Diseases (ICD)
- ICD-10
- Código ATC (*Anatomical Therapeutic Chemical drug classification)*

15.7 Clinical Context Object Workgroup

In the context of Health informatics, **CCOW** or **Clinical Context Object Workgroup** is an Health Level Seven International standard protocol designed to enable disparate applications to synchronize in real time, and at the user-interface level. It is vendor independent and allows applications to present information at the desktop and/or portal level in a unified way.

CCOW is the primary standard protocol in healthcare to facilitate a process called "Context Management." Context Management is the process of using particular "subjects" of interest (e.g., user, patient, clinical encounter, charge item, etc.) to 'virtually' link disparate applications so that the end-user sees them operate in a unified, cohesive way.

Context Management can be utilized for both CCOW and non-CCOW compliant applications. The CCOW standard exists to facilitate a more robust, and near "plug-and-play" interoperability across disparate applications.

Context Management is often combined with Single Sign On applications in the healthcare environment, but the two are discrete functions. Single Sign On is the process that enables the secure access of disparate applications by a user through use of a single authenticated identifier and password. Context Management augments this by then enabling the user to identify subjects once (e.g., a patient) and have all disparate systems into which the user is granted access to "tune" to this patient simultaneously. As the user further identifies particular "subjects" of interest (e.g., a particular visit), those applications containing information about the selected subject will then automatically and seamlessly to the user "tune" to that information as well. The end result for the user is an aggregated view of all patient information across disparate applications.

Use of Context Management, facilitated by CCOW or non-CCOW compliant applications, is valuable for both client-server, and web-based applications. Furthermore, a fully robust Context Manager will enable use for both client-server and web-based applications on a single desktop / kiosk, allowing the user to utilize both types of applications in a "context aware" session.

CCOW works for both client-server and web-based applications. The acronym CCOW stands for "Clinical Context Object Workgroup", a reference to the standards committee within the HL7 group that developed the standard.

15.7.1 Purpose

The goal of CCOW is seemingly simple, but its implementation is rather complex. CCOW is designed to communicate the name of the active user between various programs on the same machine. The user should only need to log in to one application, and the other applications running on the machine will "know" who is logged in. There are a great deal of exceptions and circumstances that make this scenario far more difficult than it appears.

In order to accomplish this task, every CCOW compliant application on the machine must log in to a central CCOW server called a Vault. The application sends an encrypted application passcode to verify its identity. Once the application is verified, it may change the active

user (also called the "context") on the machine. Each CCOW application also has an application "name" for which there can only be one instance. There is no correct application name (the passcode identifies which application is logging in). There may be multiple instances of the CCOW application connected to the CCOW vault from the same computer. However, they must have different names. One name might be "I like HHAM", while the other might be "I like CCOW". The names are completely arbitrary.

After the application authenticates itself with the CCOW vault, the applications are ready to communicate the context (a.k.a. the active user). Here would be a step-by-step example of a CCOW exchange:

1. The computer boots up and the medical applications load.

2. Each application logs into CCOW using its secret passcode (and unique application name).

3. The compliant application displays a login prompt, and the user logs in as "Mary Jane".

4. Mary Jane has a "CCOW ID". Let us assume that her CCOW ID is "MJane".

5. The compliant application notifies the CCOW vault that "MJane" is now logged in.

6. Once CCOW verifies that "MJane" is a valid CCOW user, the vault notifies all the other applications that "MJane" is logged in.

7. All of the other applications realize that the CCOW ID "MJane" is referring to "Mary Jane" (because they have been configured as such). They log in "Mary Jane" automatically.

8. The transaction is complete. All of the applications running on the machine have been automatically logged in as "Mary Jane".

The purpose of the application passcode is to verify that no unauthorized applications can "hack" into CCOW and change the active user (thereby allowing unauthorized access to medical records).

15.7.2 See also

- Health Level Seven International
- Health Insurance Portability and Accountability Act
- Integrating the Healthcare Enterprise, in particular the Patient Synchronized Applications (PSA) profile

15.7.3 External links

- HL7 Introduction
- HL7 CCOW Standard

15.8 Clinical Data Interchange Standards Consortium

The **Clinical Data Interchange Standards Consortium (CDISC)** is an open, multidisciplinary, neutral, 501(c)(3) non-profit standards developing organization (SDO) that has been working through productive, consensus-based collaborative teams, since its formation in 1997, to develop global standards and innovations to streamline medical research and ensure a link with healthcare. The CDISC mission is "to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare". The CDISC Vision is "informing patient care and safety through higher quality medical research". The CDISC suite of standards supports medical research of any type from protocol through analysis and reporting of results. They have been shown to decrease resources needed by 60% overall and 70-90% in the start-up stages when they are implemented at the beginning of the research process).*[1]

They are harmonized through a model that is now not only a CDISC standard but also an HL7 standard on the path to becoming an ISO/CEN standard, thus giving the CDISC standards (harmonized together through BRIDG) international status and accreditation.

15.8.1 CDISC History

- Late 1997 - Started as a Volunteer group
- Summer 1998 - Invited to form DIA SIAC
- 1999 - SDS v1.0; ODM v0.8
- 2000 - SDS v1.1
- Feb 2000 - formed an Independent, non-profit organization
- Dec 2001 - Global participation
- 2001 - SDS v2.0; ODM v1.0
- 2002 - ODM v1.1; ADaM Models
- 2003 - LAB v1.0; SDTM v1/SDTM-IG v3.0;BRIDG Model Initiated; SEND 1.0
- 2004 - LAB v1.1; ODM v1.2; SDTM v3.1
- 2005 - Define.xml Implementation; Release (v1.0); SEND v.2; ODM v1.2.1; SDTM v1.1/SDTMIG v3.1.1; ODM mapped to HL7 RIM
- 2006 - BRIDG v1.0, v1.1; BRIDG posted as open source model
- 2007 - ODM v1.3; LAB & SDTM Aligned; BRIDG posted as open source model

- 2008 - BRIDG v2.0, v2.1, v2.2; CDASH v1.0; eSDI Document Published
- 2009 - SDTM v1.2/SDTMIG 3.1.2; ADam v2.1; Imaging CRFs; CDISC-IHE RFD and RPE
- 2010 - Protocol Representation Model;(PRM) v1.0; BRIDG v3.0; ODM v1.3.1; HHS-ONC/HITSP Interoperability Specification #158; CDISC-IHE RPE
- 2011 - CDASH v1.1; SEND v3.0; Study Design XML v1.0
- 2013 - SDTM v1.4/SDTMIG v3.2
- 2014 - SHARE R1

15.8.2 Overview of CDISC standards

- Dataset.XML DataSet-XML)
  - Enables communication of study results as well as regulatory submission to FDA (pilot since 2014).*[2]
- Study Data Tabulation Model (SDTM)
  - Recommended for FDA regulatory submissions since 2004.
  - The SDTM Implementation Guide (SDTM-IG) gives a standardized, predefined collection of domains for clinical data submission, each of which is based on the structure and metadata defined by the SDTM.
- Standard for Exchange of Non-clinical Data (SEND)
  - The SEND Implementation Guide (SEND-IG) provides predefined domains and examples of non-clinical (animal) data based on the structure and metadata define by the SDTM.
- Analysis Data Model (ADaM)
  - Defines standards for analysis datasets derived from SDTM domains.
- Operational Data Model (ODM)
  - The highlights of ODM: includes audit trail, utilizes XML technology, machine- and human- readable, all information are independent from databases, storing of ODM is independent from hard- and software.
- Laboratory Data Model (LAB)
  - The Lab standard is used for exchange of laboratory data between labs and CROs
- Case Report Tabulation Data Definition Specification (CRT-DDS)
  - Also referred to as "define.xml", a machine readable version of the regulatory submission "define.pdf" .
- Clinical Data Acquisition Standards Harmonization (CDASH)
  - Defines a minimal data collection set for sixteen safety SDTM Domains, harmonizing element names, definitions and metadata. The objective is to establish a standardized data collection baseline across all submissions.
- CDISC Terminology
  - Defines controlled terminology for SDTM and CDASH, provides extensible lists of controlled terms designed to harmonize data collected across submissions.

15.8.3 Individual CDISC standards

Operational Data Model (ODM)

The CDISC Operational Data Model (ODM) is designed to facilitate the regulatory-compliant acquisition, archive and interchange of metadata and data for clinical research studies. ODM is a vendor neutral, platform independent format for interchange and archive of clinical study data. The model includes the clinical data along with its associated metadata, administrative data, reference data and audit information.*[3] ODM was first introduced in 1999, and the latest version, 1.3.2, was released in 2012.*[4] ODM extensions have been developed to create a number of additional CDISC standards, including Define-XML, Dataset-XML, SDM-XML, and CTR-XML and future planned standard Protocol-XML.

ODM is an XML based standard and it is an XML schema that provides number of constructs for modeling electronic Case Report Forms (CRFs). ODM is often combined with Study Data Model standard to more fully model trial arms or trial activities. ODM is also used in sending forms data from a clinical trial system to an Electronic Health Record (EHR) system.

Define-XML

Define-XML supports the interchange of dataset metadata for clinical research applications in a machine-readable format. An important use case for Define-XML is to support the submission of clinical trials data in CDISC SDTM, SEND or ADaM format to regulatory authorities. The key metadata components to support submissions are:

- Dataset definitions
- Dataset variable definitions

- Controlled Terminology definitions
- Value list definitions
- Links to supporting documents
- Computational method definitions
- Comments definitions

Define-XML can also be used to describe proprietary, non-CDISC dataset structures. The Define-XML model is implemented using extensions to the CDISC Operational Data Model (ODM) XML schema. The current version is 2.0 published in

15.8.4 BRIDG

CDISC BRIDG model is a unifying model of the domain of clinical research and research studies. It defines basic elements such as investigator, subject, study, intervention. It is used to keep all standards consistent. It was first introduced in 2006 with version 2 released in 2008. It can be obtained as UML model as well as .OWL format.

15.8.5 SHARE

CDISC SHARE (Shared Health and Clinical Research Electronic Library) is a metadata repository that supports the development, governance, publishing, and consumption of CDISC standards in human and machine-readable formats. SHARE helps users find, understand, and use rich metadata (i.e., research concepts, data elements and attributes, relationship among data elements, properties in relationship, and controlled terminologies) relevant to clinical studies more efficiently and consistently. With all these information in a single repository, SHARE will improve integration and traceability of clinical data end-to-end, from protocol through analysis. SHARE will provide a collaborative standards development environment that will improve quality, integration, and consistency across CDISC standards.

15.8.6 CDISC registered solutions providers

CDISC maintains a list of solutions providers, subject matter experts and consultants deemed to have sufficient knowledge and experience implementing the various CDISC standards.

15.8.7 ODM and EDC integration

Electronic Data Capture (EDC) systems can be certified as compliant with the Operational Data Model (ODM) by CDISC. There are two main types of integration, ODM Import and ODM Export.

ODM Import

Full import allows importing of ODM-formatted clinical data (MetaData and Data). MetaData only import allows only the importing of MetaData. This is useful for setting up the EDC system to capture data. Basically allows third party software to define the forms, variables etc. used in the EDC system. This provides an EDC vendor-neutral system for defining a study.

ODM Export

The EDC system will generate ODM data files for further processing.

15.8.8 See also

- SDTM
- SEND
- Electronic Common Technical Document (eCTD)
- Electronic Data Capture
- Clinical data acquisition
- Clinical Data Management System (CDMS)
- Data model
- Data warehouse
- Health Level 7
- Health Informatics Service Architecture (HISA)
- LOINC
- SNOMED
- SNOMED CT
- DICOM
- Clinical trial

15.8.9 Further reading

- Vikash Jain and Sandra Minjoe (2014), "A Road Map to Successful CDISC ADaM Submission to FDA: Guidelines, Best Practices & Case Studies", PharmaSUG 2014 - Paper DS15
- Rebecca Daniels Kush (2003), *eClinical Trials: Planning and Implementation*, CenterWatch / Thomson Healthcare, ISBN 1-930624-28-X
- Kevin Lee (2014), "CDISC Electronic Submission", PharmaSUG 2014 – DS14

- A J de Montjoie (2009), 'Introducing the CDISC Standards: New Efficiencies for Medical Research', CDISC Publications
- Henry Winsor (2014), Good versus Better SDTM – Why "Good Enough" May No Longer Be Good Enough When It Comes to SDTM, PharmaSUG 2014 - Paper IB06

15.8.10 References

[1] "Andrea Vadakin: CDISC standards and innovations, 2012" (PDF).

[2] "Dataset".

[3] Huser, V; Sastry, C; Breymaier, M; Idriss, A; Cimino, J. J. (2015). "Standardizing data exchange for clinical research protocols and case report forms: An assessment of the suitability of the Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM)". *Journal of Biomedical Informatics* **57**: 88–99. doi:10.1016/j.jbi.2015.06.023. PMID 26188274.

[4] "ODM".

15.8.11 External links

- Official website

15.9 Clinical Document Architecture

The HL7 **Clinical Document Architecture** (CDA) is an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents for exchange. CDA is an ANSI-certified standard from Health Level Seven International (HL7.org). Release 1.0 was published in November, 2000 and Release 2.0 was published with the HL7 2005 Normative Edition.

CDA specifies the syntax and supplies a framework for specifying the full semantics of a clinical document. It defines a clinical document as having the following six characteristics:

- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

A CDA can contain any type of clinical notes. Typical CDA document types include Discharge Summary, Imaging Report, History & Physical, and Pathology Report. An XML element in a CDA supports unstructured text, as well as links to composite documents encoded in pdf, docx, or rtf, as well as image formats like jpg and png.*[1]

It was developed using the HL7 Development Framework (HDF) and it is based on the HL7 Reference Information Model (RIM) and the HL7 Version 3 Data Types.

The CDA specifies that the content of the document consists of a mandatory textual part (which ensures human interpretation of the document contents) and optional structured parts (for software processing). The structured part relies on coding systems (such as from SNOMED and LOINC) to represent concepts.

CDA Release 2 has been adopted as an ISO standard, ISO/HL7 27932:2009.*[2]

15.9.1 Transport

The CDA standard doesn't specify how the documents should be transported. CDA documents can be transported using HL7 version 2 messages, HL7 version 3 messages, IHE protocols such as XDS, as well as by other mechanisms including: DICOM, MIME attachments to email, http or ftp.

15.9.2 Country specific notes

In the U.S. the CDA standard is probably best known as the basis for the Continuity of Care Document (CCD) specification, based on the data model as specified by ASTMs Continuity of Care Record. The U.S. Healthcare Information Technology Standards Panel has selected the CCD as one of its standards.

In the UK the ITK (Interoperability Toolkit) utilises the 'CDA R2 from HL7 V3 - for CDA profiles' for the Correspondence pack. See 'What standards does ITK utilise?' in the ITK FAQ.

In Australia the Personally Controlled Electronic Health Record(PCEHR) uses 'HL7 CDA format is used to transfer information between different healthcare clinical systems whilst still allowing information to be accessed and viewed'.

15.9.3 See also

- Health Level Seven International
- EHRcom
- Health Informatics Service Architecture (HISA)
- Continuity of Care Record

- Continuity of Care Document
- Gello Expression Language
- Fast Healthcare Interoperability Resources

15.9.4 References

[1] "HL7 Attachment Supplement Specification Release 2 Version 3.5".

[2] "ISO/HL7 27932:2009 - Data Exchange Standards -- HL7 Clinical Document Architecture, Release 2".

15.9.5 External links

- Structured Documents Group of HL7
- CDA Resource Page
- Introduction to the HL7 Standards
- Whitepaper: HL7 version 3: message or document?
- About HL7 CDA at iEHR.eu
- The CDA Book by Keith Boone

15.10 Continuity of Care Document

The **Continuity of Care Document** (CCD) specification is an XML-based markup standard intended to specify the encoding, structure, and semantics of a patient summary clinical document for exchange.*[1]

15.10.1 Structure

The CCD specification is a constraint on the HL7 Clinical Document Architecture (CDA) standard. The CDA specifies that the content of the document consists of a mandatory textual part (which ensures human interpretation of the document contents) and optional structured parts (for software processing). The structured part is based on the HL7 Reference Information Model (RIM) and provides a framework for referring to concepts from coding systems, such as the SNOMED or the LOINC.*[2]

The patient summary contains a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. Its primary use case is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient.*[1]

The CCD specification contains U.S. specific requirements; its use is therefore limited to the U.S. The U.S. Healthcare Information Technology Standards Panel has selected the CCD as one of its standards. CCDs are quickly becoming one of the most ubiquitous and thorough means of transferring health data on patients as each can contain vast amounts of data based on the standard format, in a relatively easy to use and portable file.*[3]

15.10.2 Development history

CCD was developed by Health Level Seven International with consultation and advice from several members of ASTM E31, the technical committee responsible for development and maintenance of the Continuity of Care Record (CCR) standard. In the opinion of HL7 and its members, the CDA CCD combines the benefits of ASTMs Continuity of Care Record (CCR) and the HL7 Clinical Document Architecture (CDA) specifications. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture.*[4]

The public library is relatively limited of reference CCDs available for developers to examine how to encode medical data using the structure and format of the CCD. Not surprisingly, different Electronic Health Record vendors have implemented the CCD standard in different and often incompatible ways.*[5] The National Institute of Standards and Technology (NIST) has produced a sample CCD with valid data that is available for public download.*[6]

15.10.3 CCD and Stage 1 of Meaningful Use

As part of the first stage of U.S. federal incentives for the adoption of electronic health records, known as Meaningful Use, the CCD and Continuity of Care Record (CCR) were both selected as acceptable extract formats for clinical care summaries. To be certified for this federal program, an Electronic Health Record must be able to generate a CCD (or equivalent CCR) that has the sections of allergies, medications, problems, and laboratory results, in addition to patient header information.*[7] Several of these sections also have mandated vocabularies, such as LOINC for laboratory results, according to the federal program.

When ambulatory and inpatient care providers attest that they have achieved the first stage of Meaningful Use, they document that they have tested their capability to "exchange clinical information and patient summary record," which is a core objective of the program.*[8]

Most Electronic Health Record vendors have adopted the CCD rather than the Continuity of Care Record since it is a newer format that harmonizes the Continuity of Care Record and the HL7 Clinical Document Architecture (CDA) specifications.

15.10.4 CCD and Stage 2 of Meaningful Use

In the second stage of Meaningful Use, the CCD, but not the CCR, was included as part of the standard for clinical document exchange.*[9] The selected standard, known as the Consolidated Clinical Document Architecture (C-CDA) was developed by Health Level 7 and includes nine document types, one of which is an updated version of the CCD.*[2] The second stage of Meaningful Use requires that healthcare providers use C-CDA document exchange regularly in care transitions and the CCD has been identified as the most appropriate document for this purpose.*[10] These documents must be capable of including data elements known as the "Common MU Data Set" that include: Patient name, sex, date of birth, race, ethnicity, preferred language, smoking status, problems, medications, medication allergies, laboratory tests, laboratory values/results, vital signs, care plan fields including goals and instructions, procedures and care team members. In addition encounter diagnoses, immunizations, referral reason and discharge instructions may be required base on context. Several tools for the development, testing, validation and implementation have been advanced to support CCD and C-CDA use in the second stage of Meaningful Use which has helped the standard mature in its capability to transmit data between care providers and for other purposes.*[11]*[12]

15.10.5 Competition and Internet Health Industry Standards

CCD and Continuity of Care Record (CCR) are often seen as competing standards.*[13] Google Health supported a subset of CCR until the service was discontinued in January 2012.*[14] while Microsoft HealthVault claims to support a subset of both CCR and CCD.*[15]

15.10.6 See also

- Health Level Seven International
- Clinical Document Architecture
- Healthcare Information Technology Standards Panel
- Continuity of Care Record (CCR)

15.10.7 References

[1] ANSI (2010). "Introduction". *Implementation Guide for CDA R2 HITSP C32, C83, and C80 Summary Documents*. Model-Driven Health Tools (MDHT) for CDA.

[2] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258

[3] D'Amore, JD; Sittig, DF; Ness, RB (May 2012). "How the continuity of care document can advance medical research and public health". *American Journal of Public Health* **102** (5): e1–4. doi:10.2105/AJPH.2011.300640. PMID 22420795.

[4] Ferranti, Jeffrey M.; Musser, R. Clayton; Kawamoto, Kensaku; Hammond, W. Ed (May–Jun 2006). "The Clinical Document Architecture and the Continuity of Care Record: A Critical Analysis". *Journal of the American Medical Informatics Association* **13** (3): 245–252. doi:10.1197/jamia.M1963. PMC 1513652. PMID 16501180.

[5] D'Amore, John D.; Sittig, Dean F.; Wright, Adam; Iyengar, M. Sriram; Ness, Roberta B. (2011). "The Promise of the CCD: Challenges and Opportunity for Quality Improvement and Population Health". *AMIA Annual Symposium Proceedings* **2011**: 285–294. PMC 3243208. PMID 22195080.

[6] http://xreg2.nist.gov/cda-validation/downloads/HITSP_C32_Examples_Jan2010.zip

[7] http://healthcare.nist.gov/docs/170.304.i_ExchangeClinicalinfoPatientSummaryRecordAmb_v1.1.pdf

[8] Blumenthal, David; Tavenner, Marilyn (August 2010). "The "Meaningful Use" Regulation for Electronic Health Records". *New England Journal of Medicine* **363** (6): 501–504. doi:10.1056/NEJMp1006114. PMID 20647183.

[9] http://www.gpo.gov/fdsys/pkg/FR-2012-03-07/html/2012-4430.htm

[10] http://www.healthit.gov/sites/default/files/c-cda_and_meaningfulusecertification.pdf

[11] http://www.sitenv.org

[12] http://healthcare.nist.gov/

[13] Kibbe, David C. (19 June 2008). "Untangling the Electronic Health Data Exchange". *e-CareManagement blog*. Better Health Technologies, LLC.

[14] "Google Health Data API". *Google Code*. Google. 2012. Archived from the original on 21 Feb 2012.

[15] Nolan, Sean (13 July 2008). "Again with the Standards Thing". *Family Health Guy*. MSDN Blogs.

15.10.8 Bibliography

- "Continuity of Care Document (CCD): Changing The Landscape of Healthcare Information Exchange". *Corepoint Health*. Archived from the original on 20 Mar 2012.

15.10.9 External links

- Structured Documents Group of HL7
- CDA Resource Page <- broken link
- Transport Testing Tool for Stage 2 of Meaningful Use
- CCD XML Instance Examples
- Public Library of CCD and C-CDA samples
- Introduction to the HL7 Standards

15.11 Clinical Document Architecture

The HL7 **Clinical Document Architecture** (CDA) is an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents for exchange. CDA is an ANSI-certified standard from Health Level Seven International (HL7.org). Release 1.0 was published in November, 2000 and Release 2.0 was published with the HL7 2005 Normative Edition.

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15.11.1 Transport

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- EHRcom
- Health Informatics Service Architecture (HISA)
- Continuity of Care Record
- Continuity of Care Document
- Gello Expression Language
- Fast Healthcare Interoperability Resources

15.11.4 References

[1] "HL7 Attachment Supplement Specification Release 2 Version 3.5".

[2] "ISO/HL7 27932:2009 - Data Exchange Standards -- HL7 Clinical Document Architecture, Release 2".

15.11.5 External links

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- CDA Resource Page
- Introduction to the HL7 Standards

- Whitepaper: HL7 version 3: message or document?
- About HL7 CDA at iEHR.eu
- The CDA Book by Keith Boone

15.12 Continuity of Care Record

Continuity of Care Record (CCR)*[1] is a health record standard specification developed jointly by ASTM International, the Massachusetts Medical Society (MMS), the Healthcare Information and Management Systems Society (HIMSS), the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), and other health informatics vendors.

15.12.1 CCR Background and Scope

The CCR was generated by health care practitioners based on their views of the data they may want to share in any given situation.*[2] The CCR document is used to allow timely and focused transmission of information to other health professionals involved in the patient's care. *[2] The CCR aims to increase the role of the patient in managing their health and reduce error while improving continuity of patient care.*[3] The CCR standard is a patient health summary standard. It is a way to create flexible documents that contain the most relevant and timely core health information about a patient, and to send these electronically from one caregiver to another. The CCR's intent is also to create a standard of health information transportability when a patient is transferred or referred, or is seen by another healthcare professional. *[4]

15.12.2 Development of the CCR

The CCR is a unique development effort via a syndicate of the following sponsors:

- ASTM International
- Massachusetts Medical Society
- HIMSS
- American Academy of Family Physicians
- American Academy of Pediatrics
- American Medical Association
- Patient Safety Institute
- American Health Care Association
- National Association for the Support of LTC

15.12.3 Content of the CCR

The CCR data set contains a summary of the patient's health status including problems, medications, allergies, and basic information about health insurance, care documentation, and the patient's care plan.*[4] These represent a "snapshot" of a patient's health data that can be useful or possibly lifesaving, if available at the time of clinical encounter. *[2] The ASTM CCR standard's purpose is to permit easy creation by a physician using an electronic health record (EHR) system at the end of an encounter. *[2] More specifically within the CCR, there are mandated core elements in 6 sections. *[4]
These 6 sections are:

1. Header
2. Patient Identifying Information
3. Patient Financial and Insurance Information
4. Health Status of the Patient
5. Care Documentation
6. Care Plan Recommendation

15.12.4 The CCR Standard and Structure

Because it is expressed in the standard data interchange language known as XML, a CCR can potentially be created, read, and interpreted by any EHR or EMR software application. A CCR can also be exported to other formats, such as PDF or Office Open XML (Microsoft Word 2007 format). *[4]

The Continuity of Care Document (CCD) is an HL7 CDA implementation of the Continuity of Care Record (CCR). A CCR document can generally be converted into CCD using Extensible Stylesheet Language Transformations (XSLT), but it is not always possible to perform the inverse transformation, since some CCD features are not supported in CCR.*[5] HITSP provides reference information that demonstrates how CCD and CCR (as HITSP C32) are embedded in CDA.*[6]

Although the CCR and CCD standards could continue to coexist, with CCR providing for basic information requests and CCD servicing more detailed requests, the newer CCD standard might eventually completely supplant CCR.*[7]

15.12.5 Technology and the CCR

As mentioned, the CCR standard uses eXtensible Markup Language (XML) as it is aimed at being technology neutral to allow for maximum applicability.*[4] This specified XML coding provides flexibility that will allow users to formulate, transfer, and view the CCR in a number

of ways, for example, in a browser, in a Health Level 7 (HL7) message, in a secure email, as a PDF file, as an HTML file, or as a word document. This is aimed at producing flexible expression of structured data in avenues such as electronic health record (EHR) systems.*[8] In terms of the CCR's transportability, secure carriage and transmission of the electronic file can occur via physical transport media, for example on a USB thumb drive, tablet or phone, CD ROM, or smart card, and in an electronic sense, secure transmission can occur via a network line, or the Internet.*[8]

15.12.6 See also

- Clinical Document Architecture
- Electronic health record
- Continuity of Care Document

15.12.7 References

[1] ASTM CCR Continuity of Care Record

[2] Ferranti, Jeffrey M.; Musser, R. Clayton; Kawamoto, Kensaku; Hammond, W. Ed (May–Jun 2006). "The Clinical Document Architecture and the Continuity of Care Record: A Critical Analysis". *Journal of the American Medical Informatics Association* **13** (3): 245–252. doi:10.1197/jamia.M1963. PMC 1513652. PMID 16501180.

[3] Kibbe, D. C., Phillips, R. L., & Green, L. A. (2004). The Continuity of Care Record. American Family Physician , 70 (7), 1220-1223.

[4] Americal Society for Testing and Materials.(2013). Continuity of Care Record:The Concept Paper of the CCR.

[5] http://ofps.oreilly.com/titles/9781449305024/meaningful_use_interoperability.html

[6] http://publicaa.ansi.org/sites/apdl/hitspadmin/Matrices/HITSP_09_N_451.pdf

[7] http://e-caremanagement.com/untangling-the-electronic-health-data-exchange/

[8] http://www.nchica.org/Past/06/presentations/Kibbe.pdf

15.12.8 External links

- ASTM CCR Standard E2369-05
- Center for Health Information Technology (CHiT)
- CCR Java library

15.13 COSTART

The **Coding Symbols for a Thesaurus of Adverse Reaction Terms** (**COSTART**) was developed by the United States Food and Drug Administration (FDA) for the coding, filing and retrieving of post-marketing adverse reaction reports.*[1] COSTART provides a method to deal with the variation in vocabulary used by those who submit adverse event reports to the FDA. Use of this dictionary allowed for standardization of adverse reaction reporting towards the FDA in a consistent way.

COSTART was last updated in 1999. It has been replaced by the Medical Dictionary for Regulatory Activities, MedDRA.*[1]

15.13.1 See also

- Pharmacovigilance
- WHOART
- Adverse event

15.13.2 References

[1] "Coding Symbols for Thesaurus of Adverse Reaction Terms (COSTART) Source Information". *Unified Medical Language System® (UMLS®)*. U.S. National Library of Medicine. 23 November 2010. Retrieved 29 June 2015.

15.13.3 External links

- COSTART lookup

15.14 Current Procedural Terminology

The **Current Procedural Terminology** (**CPT**) code set is a medical code set maintained by the American Medical Association through the CPT Editorial Panel.*[1] The CPT code set (copyright protected by the AMA) describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes.

New editions are released each October.*[2] The current version is the CPT 2015. It is available in both a standard edition and a professional edition.*[3]*[4]

CPT coding is similar to ICD-9 and ICD-10 coding, except that it identifies the services rendered rather than the

diagnosis on the claim. ICD code sets also contain procedure codes but these are only used in the inpatient setting.*[5]

CPT is currently identified by the Centers for Medicare and Medicaid Services (CMS)*[6] as Level 1 of the Healthcare Common Procedure Coding System.

The Current Procedural Terminology (CPT) was developed by the American Medical Association (AMA).*[6]

15.14.1 Types of code

There are three types of CPT code: Category I, Category II, and Category III.

Category I

Category I CPT Code(s). There are six main sections:*[7]

Codes for evaluation and management: 99201–99499

- (99201–99216) Office/other outpatient services
- (99217–99220) Hospital observation services
- (99221–99239) Hospital inpatient services
- (99241–99255) Consultations
- (99281–99288) Emergency department services
- (99291–99292) Critical care services
- (99304–99318) Nursing facility services
- (99324–99337) Domiciliary, rest home (boarding home) or custodial care services
- (99339–99340) Domiciliary, rest home (assisted living facility), or home care plan oversight services
- (99341–99350) Home health services
- (99354–99360) Prolonged services
- (99363–99368) Case management services
- (99374–99380) Care plan oversight services
- (99381–99429) Preventive medicine services
- (99441–99444) Non-face-to-face physician services
- (99450–99456) Special evaluation and management services
- (99460–99465) Newborn care services
- (99466–99480) Inpatient neonatal intensive, and pediatric/neonatal critical, care services
- (99487–99489) Complex chronic care coordination services
- (99495–99496) Transitional care management services
- (99499) Other evaluation and management services

Codes for anesthesia: 00100–01999; 99100–99150

- (00100–00222) head
- (00300–00352) neck
- (00400–00474) thorax
- (00500–00580) intrathoracic
- (00600–00670) spine and spinal cord
- (00700–00797) upper abdomen
- (00800–00882) lower abdomen
- (00902–00952) perineum
- (01112–01190) pelvis (except hip)
- (01200–01274) upper leg (except knee)
- (01320–01444) knee and popliteal area
- (01462–01522) lower leg (below knee)
- (01610–01682) shoulder and axillary
- (01710–01782) upper arm and elbow
- (01810–01860) forearm, wrist and hand
- (01916–01936) radiological procedures
- (01951–01953) burn excisions or debridement
- (01958–01969) obstetric
- (01990–01999) other procedures
- (99100–99140) qualifying circumstances for anesthesia
- (99143–99150) moderate (conscious) sedation

Codes for surgery: 10000–69990

- (10000–10022) general
- (10040–19499) integumentary system
- (20000–29999) musculoskeletal system
- (30000–32999) respiratory system
- (33010–37799) cardiovascular system
- (38100–38999) hemic and lymphatic systems
- (39000–39599) mediastinum and diaphragm
- (40490–49999) digestive system

- (50010–53899) urinary system
- (54000–55899) male genital system
- (55920–55980) reproductive system and intersex
- (56405–58999) female genital system
- (59000–59899) maternity care and delivery
- (60000–60699) endocrine system
- (61000–64999) nervous system
- (65091–68899) eye and ocular adnexa
- (69000–69979) auditory system

Codes for Radiology: 70000-79999

- (76506–76999) diagnostic ultrasound
- (77001–77032) radiologic guidance
- (77051–77059) breast mammography
- (77071–77084) bone/joint studies
- (77261–77799) radiation oncology

Codes for pathology and laboratory: 80000–89398

- (80000–80076) organ or disease-oriented panels
- (80100–80103) drug testing
- (80150–80299) therapeutic drug assays
- (80400–80440) evocative/suppression testing
- (80500–80502) consultations (clinical pathology)
- (81000–81099) urinalysis
- (82000–84999) chemistry
- (85002–85999) hematology and coagulation
- (86000–86849) immunology
- (86850–86999) transfusion medicine
- (87001–87999) microbiology
- (88000–88099) anatomic pathology (postmortem)
- (88104–88199) cytopathology
- (88230–88299) cytogenetic studies
- (88300–88399) surgical pathology
- (88720–88741) in vivo (transcutaneous) lab procedures
- (89049–89240) other procedures
- (89250–89398) reproductive medicine procedures

Codes for medicine: 90281–99099; 99151–99199; 99500–99607

- (90281–90399) immune globulins, serum or recombinant prods
- (90465–90474) immunization administration for vaccines/toxoids
- (90476–90749) vaccines, toxoids
- (90801–90899) psychiatry
- (90901–90911) biofeedback
- (90935–90999) dialysis
- (91000–91299) gastroenterology
- (92002–92499) ophthalmology
- (92502–92700) special otorhinolaryngologic services
- (92950–93799) cardiovascular
- (93875–93990) noninvasive vascular diagnostic studies
- (94002–94799) pulmonary
- (95004–95199) allergy and clinical immunology
- (95250–95251) endocrinology
- (95803–96020) neurology and neuromuscular procedures
- (96101–96125) central nervous system assessments/tests (neuro-cognitive, mental status, speech testing)
- (96150–96155) health and behavior assessment/intervention
- (96360–96549) hydration, therapeutic, prophylactic, diagnostic injections and infusions, and chemotherapy and other highly complex drug or highly complex biologic agent administration
- (96567–96571) photodynamic therapy
- (96900–96999) special dermatological procedures
- (97001–97799) physical medicine and rehabilitation
- (97802–97804) medical nutrition therapy
- (97810–97814) acupuncture
- (98925–98929) osteopathic manipulative treatment
- (98940–98943) chiropractic manipulative treatment
- (98960–98962) education and training for patient self-management

- (98966–98969) non-face-to-face nonphysician services
- (99000–99091) special services, procedures and reports
- (99170–99199) other services and procedures
- (99500–99602) home health procedures/services
- (99605–99607) medication therapy management services

Category II

CPT II codes describe clinical components usually included in evaluation and management or clinical services and are not associated with any relative value. Category II codes are reviewed by the Performance Measures Advisory Group (PMAG), an advisory body to the CPT Editorial Panel and the CPT/HCPAC Advisory Committee. The PMAG is composed of performance measurement experts representing the Agency for Healthcare Research and Quality (AHRQ), the American Medical Association (AMA), the Centers for Medicare and Medicaid Services (CMS), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the National Committee for Quality Assurance (NCQA) and the Physician Consortium for Performance Improvement. The PMAG may seek additional expertise and/or input from other national health care organizations, as necessary, for the development of Category II codes. These may include national medical specialty societies, other national health care professional associations, accrediting bodies and federal regulatory agencies.

Category II codes make use of an alphabetical character as the 5th character in the string (i.e., 4 digits followed by the letter F). These digits are not intended to reflect the placement of the code in the regular (Category I) part of the CPT codebook. Appendix H in CPT section contains information about performance measurement exclusion of modifiers, measures, and the measures' source(s). Currently there are 11 Category II codes. They are:

- (0001F-0015F) Composite measures
- (0500F-0575F) Patient management
- (1000F-1220F) Patient history
- (2000F-2050F) Physical examination
- (3006F-3573F) Diagnostic/screening processes or results
- (4000F-4306F) Therapeutic, preventive or other interventions
- (5005F-5100F) Follow-up or other outcomes
- (6005F-6045F) Patient safety
- (7010F-7025F) Structural Measures

CPT II codes are billed in the procedure code field, just as CPT Category I codes are billed. Because CPT II codes are not associated with any relative value, they are billed with a $0.00 billable charge amount.*[8]

Category III

- Category III CPT Code(s) – Emerging technology (Category III codes: 0016T-0207T*[9])

15.14.2 Major psychotherapy revisions

The CPT code revisions that affect counselors are simple and straightforward. Here is a list of psychotherapy CPT codes that will be retired, and their 2013 comparables:

90801 –> \ Family therapy codes (90847 and 90846) will remain unchanged, as will codes for psychological testing.*[10]

15.14.3 Criticism of copyright

CPT is a registered trademark of the American Medical Association. The AMA holds the copyright for the CPT coding system.*[11] This was upheld in Practice Management v. American Medical Association.

Despite the copyrighted nature of the CPT code sets, the use of the code is mandated by almost all health insurance payment and information systems, including the Centers for Medicare and Medicaid Services (CMS) and HIPAA, and the data for the code sets appears in the Federal Register. As a result, it is necessary for most users of the CPT code (principally providers of services) to pay license fees for access to the code.*[12]

Limited CPT search offered by the AMA

The AMA offers a limited search of the CPT manual for personal, non-commercial use on its web site.*[13]

15.14.4 See also

- Medical classification
- Procedure code
- ICD-9
- ICD-10-PCS
- HCPCS
- Specialty Society Relative Value Scale Update Committee

15.14.5 References

[1] AMA (CPT) CPT Process

[2] Laura Southard Durham (1 June 2008). *Lippincott Williams and Wilkins' Administrative Medical Assisting*. Lippincott Williams and Wilkins. pp. 2–. ISBN 978-0-7817-9789-4. Retrieved 26 May 2011.

[3] Michelle Abraham; Jay T. Ahlman; Angela J. Boudreau; Judy L. Connelly; Desiree D. Evans; Rejina L Glenn (30 October 2010). *CPT 2011 Standard Edition*. American Medical Association Press. ISBN 978-1-60359-216-1. Retrieved 26 May 2011.

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[6] Centers for Medicare and Medicaid Services

[7] Marie A. Moisio (8 April 2009). *Medical Terminology for Insurance and Coding*. Cengage Learning. pp. 80–. ISBN 978-1-4283-0426-0. Retrieved 26 May 2011.

[8] AMA coding manual

[9] CPT 2010

[10] Centore, Anthony. "2013 CPT Code Revisions". Thriveworks.com. Retrieved 6 February 2013.

[11] AMA (CPT) CPT Licensing

[12] http://www.ama-assn.org/ama1/pub/upload/mm/37/2009-annual-report.pdf[]

[13] AMA (2012). "cpt® Code/Relative Value Search". Retrieved from https://ocm.ama-assn.org/OCM/CPTRelativeValueSearch.do.

15.14.6 External links

- Official site by the AMA
- CPT® Process – How a Code Becomes a Code from the AMA
- What is CPT® by the AAPC

15.15 Diagnosis-related group

Diagnosis-related group (**DRG**) is a system to classify hospital cases into one of originally 467 groups,*[1] with the last group (coded as 470 through v24, 999 thereafter) being "Ungroupable". This system of classification was developed as a collaborative project by Robert B Fetter, PhD, of the Yale School of Management, and John D. Thompson, MPH, of the Yale School of Public Health.*[2] The system is also referred to as "the DRGs", and its intent was to identify the "products" that a hospital provides. One example of a "product" is an appendectomy. The system was developed in anticipation of convincing Congress to use it for reimbursement, to replace "cost based" reimbursement that had been used up to that point. DRGs are assigned by a "grouper" program based on ICD (International Classification of Diseases) diagnoses, procedures, age, sex, discharge status, and the presence of complications or comorbidities. DRGs have been used in the US since 1982 to determine how much Medicare pays the hospital for each "product", since patients within each category are clinically similar and are expected to use the same level of hospital resources.*[3] DRGs may be further grouped into Major Diagnostic Categories (MDCs). DRGs are also standard practice for establishing reimbursements for other Medicare related reimbursements such as to home healthcare providers.

15.15.1 Purpose

The original objective of diagnosis related groups (DRG) was to develop a classification system that identified the "products" that the patient received. Since the introduction of DRGs in the early 1980s, the healthcare industry has evolved and developed an increased demand for a patient classification system that can serve its original objective at a higher level of sophistication and precision.*[4] To meet those evolving needs, the objective of the DRG system had to expand in scope. Today, there are several different DRG systems that have been developed in the US. They include:*[5]

- Medicare DRG (CMS-DRG & MS-DRG)
- Refined DRGs (R-DRG)
- All Patient DRGs (AP-DRG)
- Severity DRGs (S-DRG)
- All Patient, Severity-Adjusted DRGs (APS-DRG)
- All Patient Refined DRGs (APR-DRG)
- International-Refined DRGs (IR-DRG)

15.15.2 History

The system was created by Robert Barclay Fetter and John D. Thompson at Yale University with the material support of the former Health Care Financing Administration (HCFA), now called the Centers for Medicare & Medicaid Services (CMS).*[2]

DRGs were first implemented in New Jersey, beginning in 1980 with a small number of hospitals partitioned into

three groups according to their budget positions - surplus, breakeven, and deficit - prior to the imposition of DRG payment.*[6]

The New Jersey experiment continued for three years, with additional cadres of hospitals being added to the number of institutions each year until all hospitals in New Jersey were dealing with this prospective payment system.*[7]

DRGs were designed to be homogeneous units of hospital activity to which binding prices could be attached. A central theme in the advocacy of DRGs was that this reimbursement system would, by constraining the hospitals, oblige their administrators to alter the behavior of the physicians and surgeons comprising their medical staffs. Hospitals were forced to leave the "nearly risk-free world of cost reimbursement" *[8] and face the uncertain financial consequences associated with the provision of health care.*[9]

Moreover, DRGs were designed to provide practice pattern information that administrators could use to influence individual physician behavior.*[6]

DRGs were intended to describe all types of patients in an acute hospital setting. The DRGs encompassed elderly patients as well as newborn, pediatric and adult populations.*[10]

The prospective payment system implemented as DRGs had been designed to limit the share of hospital revenues derived from the Medicare program budget,*[6] and in spite of doubtful results in New Jersey, it was decided in 1983 to impose DRGs on hospitals nationwide.

In that year, HCFA assumed responsibility for the maintenance and modifications of these DRG definitions. Since that time, the focus of all Medicare DRG modifications instituted by HCFA/CMS has been on problems relating primarily to the elderly population.

In 1987, New York state passed legislation instituting DRG-based payments for all non-Medicare patients. This legislation required that the New York State Department of Health (NYS DOH) evaluate the applicability of Medicare DRGs to a non-Medicare population. This evaluation concluded that the Medicare DRGs were not adequate for a non-Medicare population. Based on this evaluation, the NYS DOH entered into an agreement with 3M to research and develop all necessary DRG modifications. The modifications resulted in the initial APDRG, which differed from the Medicare DRG in that it provided support for transplants, high-risk obstetric care, nutritional disorders, and pediatrics along with support for other populations. One challenge in working with the APDRG groupers is that there is no set of common data/formulas that is shared across all states as there is with CMS. Each state maintains its own information.

In 1991, the top 10 DRGs overall were: normal newborn, vaginal delivery, heart failure, psychoses, cesarean section, neonate with significant problems, angina pectoris, specific cerebrovascular disorders, pneumonia, and hip/knee replacement. These DRGs comprised nearly 30 percent of all hospital discharges.*[11]

The history, design, and classification rules of the DRG system, as well as its application to patient discharge data and updating procedures, are presented in the CMS *DRG Definitions Manual* (Also known as the *Medicare DRG Definitions Manual* and the *Grouper Manual*). A new version generally appears every October. The 20.0 version appeared in 2002.

In 2007, author Rick Mayes described DRGs as:

15.15.3 DRG changes

This list is incomplete; you can help by expanding it.

15.15.4 See also

- Case mix index
- Diagnosis codes
- Medical classification
- Ambulatory Patient Group, similar to DRG but for outpatient care
- Risk of mortality (ROM)
- Severity of illness (SOI)
- Pay for Performance

15.15.5 References

[1] Mistichelli, Judith Diagnosis Related Groups (DRGs) and the Prospective Payment System: Forecasting Social Implications

[2] Fetter RB, Shin Y, Freeman JL, Averill RF, Thompson JD (1980) Case mix definition by diagnosis related groups. Medical Care 18(2):1–53

[3] Fetter RB, Freeman JL (1986) Diagnosis related groups: product linemanagement within hospitals. Academy of Management Review 11(1):41–54

[4] Baker JJ (2002) Medicare payment system for hospital inpatients: diagnosis related groups. Journal of Health Care Finance 28(3):1–13

[5] https://support.3mhis.com/app/answers/detail/a_id/9907/~{}/definitions-manuals

[6] Lessons of the New Jersey DRG Payment System

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[9] Kuntz L, Scholtes S, Vera A (2008) DRG Cost Weight Volatility and Hospital Performance. OR Spectrum 30(2): 331-354

[10] Nancy Bateman (2012). "The Business of Nurse Management: A Toolkit for Success".

[11] "Most Frequent Diagnoses and Procedures for DRGs, by Insurance Status". Agency for Health Care Policy and Research. Retrieved 2006-04-22.

[12] Mayes, Rick (January 2007). "The Origins, Development, and Passage of Medicare's Revolutionary Prospective Payment System" (abstract). *Journal of the History of Medicine and Allied Sciences* (Oxford University Press) **62** (1): 21–55. doi:10.1093/jhmas/jrj038. ISSN 1468-4373. PMID 16467485. Retrieved 2009-04-06.

[13] Centers for Medicare & Medicaid Services. "ICD-10 MS-DRG Conversion Project".

15.15.6 External links

- Official CMS website
  - DRG codes for FY2005, also referred to as version 23
  - DRG codes for FY2010, also referred to as version 27
- Healthcare Cost and Utilization Project (Search engine can be used to find Definitions Manual)
- Agency for Healthcare Research and Quality (AHRQ).
  - DRG definition.
  - Most Frequent Diagnoses and Procedures for DRGs.
- DRG and ICD (Canada) from the MCHP research unit of the University of Manitoba's Faculty of Medicine.
- Diagnosis Related Groups (DRGs) and the Medicare Program - Implications for Medical Technology (PDF format). A 1983 document found in the "CyberCemetery: OTA Legacy" section of University of North Texas Libraries Government Documents department.
- Mayes, Rick, "The Origins, Development, and Passage of Medicare's Revolutionary Prospective Payment System" *Journal of the History of Medicine and Allied Sciences* Volume 62, Number 1, January 2007, pp. 21–55

15.16 Digital Imaging and Communications in Medicine

Digital Imaging and Communications in Medicine (**DICOM**) is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol. The communication protocol is an application protocol that uses TCP/IP to communicate between systems. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format. The National Electrical Manufacturers Association (NEMA) holds the copyright to this standard.*[1] It was developed by the DICOM Standards Committee, whose members*[2] are also partly members of NEMA.*[3]

DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a picture archiving and communication system (PACS). The different devices come with DICOM conformance statements which clearly state which DICOM classes they support. DICOM has been widely adopted by hospitals and is making inroads in smaller applications like dentists' and doctors' offices.

DICOM is known as NEMA standard PS3, and as ISO standard 12052:2006 "Health informatics -- Digital imaging and communication in medicine (DICOM) including workflow and data management".

15.16.1 Parts of the standard

The DICOM standard is divided into related but independent parts. The links below are to the chunked HTML representation of the current version; as the standard is updated the content at these links remains valid. Alternative formats as well as the DocBook source of the standard text, and additions to the standard (Supplements and Change Proposals), are available through the DICOM Web site and are also indexed on the DICOM status page.

- PS3.1: Introduction and Overview
- PS3.2: Conformance
- PS3.3: Information Object Defintions
- PS3.4: Service Class Specifications
- PS3.5: Data Structure and Encoding
- PS3.6: Data Dictionary
- PS3.7: Message Exchange
- PS3.8: Network Communication Support for Message Exchange
- PS3.9: Retired (formerly Point-to-Point Communication Support for Message Exchange)

- PS3.10: Media Storage and File Format for Media Interchange
- PS3.11: Media Storage Application Profiles
- PS3.12: Media Formats and Physical Media for Media Interchange
- PS3.13: Retired (formerly Print Management Point-to-Point Communication Support)
- PS3.14: Grayscale Standard Display Function
- PS3.15: Security and System Management Profiles
- PS3.16: Content Mapping Resource
- PS3.17: Explanatory Information
- PS3.18: Web Services
- PS3.19: Application Hosting
- PS3.20: Imaging Reports using HL7 Clinical Document Architecture

15.16.2 History

Front page of ACR/NEMA 300, version 1.0, which was released in 1985

DICOM is the a standard developed by American College of Radiology (ACR) and National Electrical Manufacturers Association (NEMA).

In the beginning of the 1980s, it was very difficult for anyone other than manufacturers of computed tomography or magnetic resonance imaging devices to decode the images that the machines generated. Radiologists and medical physicists wanted to use the images for dose-planning for radiation therapy. ACR and NEMA joined forces and formed a standard committee in 1983. Their first standard, ACR/NEMA 300, was released in 1985. Very soon after its release, it became clear that improvements were needed. The text was vague and had internal contradictions.

In 1988 the second version was released. This version gained more acceptance among vendors. The image transmission was specified as over a dedicated 2 pair cable (EIA-485). The first demonstration of ACR/NEMA V2.0 interconnectivity technology was held at Georgetown University, May 21–23, 1990. Six companies participated in this event, DeJarnette Research Systems, General Electric Medical Systems, Merge Technologies, Siemens Medical Systems, Vortech (acquired by Kodak that same year) and 3M. Commercial equipment supporting ACR/NEMA 2.0 was presented at the annual meeting of the Radiological Society of North America (RSNA) in 1990 by these same vendors. Many soon realized that the second version also needed improvement. Several extensions to ACR/NEMA 2.0 were created, like Papyrus (developed by the University Hospital of Geneva, Switzerland) and SPI (Standard Product Interconnect), driven by Siemens Medical Systems and Philips Medical Systems.

The first large-scale deployment of ACR/NEMA technology was made in 1992 by the US Army and Air Force, as part of the MDIS (Medical Diagnostic Imaging Support) program based at f Ft. Detrick, Maryland. Loral Aerospace and Siemens Medical Systems led a consortium of companies in deploying the first US military PACS (Picture Archiving and Communications System) at all major Army and Air Force medical treatment facilities and teleradiology nodes at a large number of US military clinics. DeJarnette Research Systems and Merge Technologies provided the modality gateway interfaces from third party imaging modalities to the Siemens SPI network. The Veterans Administration and the Navy also purchased systems off this contract.

In 1993 the third version of the standard was released. Its name was then changed to "DICOM". New service classes were defined, network support added and the Conformance Statement was introduced. Officially, the latest version of the standard is still 3.0. It has been constantly updated and extended since 1993, but most changes are forward and backward compatible, except in rare cases where the original specification was not interoperable or conflicted with another standard. The standard should be referenced without specification of the date of release of a particular edition, except when specific conformance requirements are invoked that depend on a particular change (e.g., to reference a retired feature).

While the DICOM standard has achieved a near universal

level of acceptance amongst medical imaging equipment vendors and healthcare IT organizations, the standard has its limitations. DICOM is a standard directed at addressing technical interoperability issues in medical imaging. It is not a framework or architecture for achieving a useful clinical workflow. The Integrating the Healthcare Enterprise (IHE) initiative layered on top of DICOM (and HL-7) defines profiles to select features from these standards to implement transactions for specific medical imaging interoperability use cases.

Though always Internet compatible and based on transport over TCP, over time there has been an increasing need to support port 80 http transport to make use easier within the web browser. Most recently, a family of DICOM RESTful web services have been defined to allow mobile device friendly access to DICOM objects and services, which include WADO-RS, STOW-RS and QIDO-RS, which together constitute the DICOMweb initiative,

Derivations

There are some derivations from the DICOM standard into other application areas. These include:

- DICONDE - *Digital Imaging and Communication in Nondestructive Evaluation*, was established in 2004 as a way for nondestructive testing manufacturers and users to share image data.*[4]
- DICOS - *Digital Imaging and Communication in Security* was established in 2009 to be used for image sharing in airport security.*[5]

15.16.3 Data format

DICOM differs from some, but not all, data formats in that it groups information into data sets. That means that a file of a chest x-ray image, for example, actually contains the patient ID within the file, so that the image can never be separated from this information by mistake. This is similar to the way that image formats such as JPEG can also have embedded tags to identify and otherwise describe the image.

A DICOM data object consists of a number of attributes, including items such as name, ID, etc., and also one special attribute containing the image pixel data (i.e. logically, the main object has no "header" as such, being merely a list of attributes, including the pixel data). A single DICOM object can have only one attribute containing pixel data. For many modalities, this corresponds to a single image. However, the attribute may contain multiple "frames", allowing storage of cine loops or other multi-frame data. Another example is NM data, where an NM image, by definition, is a multi-dimensional multi-frame image. In these cases, three- or four-dimensional data can be encapsulated in a single DICOM object. Pixel data can be compressed using a variety of standards, including JPEG, Lossless JPEG, JPEG 2000, and Run-length encoding (RLE). LZW (zip) compression can be used for the whole data set (not just the pixel data), but this has rarely been implemented.

DICOM uses three different Data Element encoding schemes. With Explicit Value Representation (VR) Data Elements, for VRs that are not OB, OW, OF, SQ, UT, or UN, the format for each Data Element is: GROUP (2 bytes) ELEMENT (2 bytes) VR (2 bytes) LengthInByte (2 bytes) Data (variable length). For the other Explicit Data Elements or Implicit Data Elements, see section 7.1 of Part 5 of the DICOM Standard.

The same basic format is used for all applications, including network and file usage, but when written to a file, usually a true "header" (containing copies of a few key attributes and details of the application which wrote it) is added.

15.16.4 Image display

To promote identical grayscale image display on different monitors and consistent hard-copy images from various printers, the DICOM committee developed a lookup table to display digitally assigned pixel values. To use the **DICOM grayscale standard display function (GSDF)**,*[6] images must be viewed (or printed) on devices that have this lookup curve or on devices that have been calibrated to the GSDF curve.*[7]

15.16.5 Value representations

See Table 6.2-1 of PS 3.5.

In addition to a Value Representation, each attribute also has a Value Multiplicity to indicate the number of data elements contained in the attribute. For character string value representations, if more than one data element is being encoded, the successive data elements are separated by the backslash character "\".

15.16.6 Services

DICOM consists of many different services, most of which involve transmission of data over a network, and the file format below is a later and relatively minor addition to the standard.

Store

The DICOM Store service is used to send images or other persistent objects (structured reports, etc.) to a picture archiving and communication system (PACS) or workstation.

Storage commitment

The DICOM storage commitment service is used to confirm that an image has been permanently stored by a device (either on redundant disks or on backup media, e.g. burnt to a CD). The Service Class User (SCU: similar to a client), a modality or workstation, etc., uses the confirmation from the Service Class Provider (SCP: similar to a server), an archive station for instance, to make sure that it is safe to delete the images locally.

Query/Retrieve

This enables a workstation to find lists of images or other such objects and then retrieve them from a picture archiving and communication system.

Modality worklist

A modality is the way or mode in which something exists or is done. You might often see it used with reference to diagnostic modality, which is the way in which a disease or illness is diagnosed by a doctor.

Modality performed procedure step

A complementary service to Modality Worklist, this enables the modality to send a report about a performed examination including data about the images acquired, beginning time, end time, and duration of a study, dose delivered, etc. It helps give the radiology department a more precise handle on resource (acquisition station) use. Also known as MPPS, this service allows a modality to better coordinate with image storage servers by giving the server a list of objects to send before or while actually sending such objects.

Printing

The DICOM Printing service is used to send images to a DICOM Printer, normally to print an "X-Ray" film. There is a standard calibration (defined in DICOM Part 14) to help ensure consistency between various display devices, including hard copy printout.

Off-line media (files)

The off-line media files correspond to Part 10 of the DICOM standard. It describes how to store medical imaging information on removable media. Except for the data set containing, for example, an image and demography, it's also mandatory to include the File Meta Information.

DICOM restricts the filenames on DICOM media to 8 characters (some systems wrongly use 8.3, but this does not conform to the standard). No information must be extracted from these names (PS3.10 Section 6.2.3.2). This is a common source of problems with media created by developers who did not read the specifications carefully. This is a historical requirement to maintain compatibility with older existing systems. It also mandates the presence of a media directory, the DICOMDIR file, which provides index and summary information for all the DICOM files on the media. The DICOMDIR information provides substantially greater information about each file than any filename could, so there is less need for meaningful file names.

DICOM files typically have a .dcm file extension if they are not part of a DICOM media (which requires them to be without extension).

The MIME type for DICOM files is defined by RFC 3240 as application/dicom.

The Uniform Type Identifier type for DICOM files is org.nema.dicom.

There is also an ongoing media exchange test and "connectathon" process for CD media and network operation that is organized by the IHE organization.

15.16.7 Application areas

All of the Defined Terms for Modality are listed in Section C.7.3.1.1.1 of PS 3.3.

15.16.8 Port numbers over IP

DICOM have reserved the following TCP and UDP port numbers by the Internet Assigned Numbers Authority (IANA):

- 104 well-known port for DICOM over Transmission Control Protocol (TCP) or User Datagram Protocol (UDP). Since 104 is in the reserved subset, many operating systems require special privileges to use it.
- 2761 registered port for DICOM using Integrated Secure Communication Layer (ISCL) over TCP or UDP
- 2762 registered port for DICOM using Transport Layer Security (TLS) over TCP or UDP
- 11112 registered port for DICOM using standard, open communication over TCP or UDP

The standard recommends but does not require the use of these port numbers.

15.16.9 Disadvantages

According to a paper presented at an international symposium in 2008, the DICOM standard has problems related to data entry. "A major disadvantage of the DICOM Standard is the possibility for entering probably too many optional fields. This disadvantage is mostly showing in inconsistency of filling all the fields with the data. Some image objects are often incomplete because some fields are left blank and some are filled with incorrect data." *[8]

15.16.10 HL7

DICOM is a standard for handling, storing, printing, and transmitting information in medical imaging. The communication protocol is an application protocol that uses TCP/IP to communicate between systems. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format. The National Electrical Manufacturers Association (NEMA) holds the copyright to this standard. It was developed by the DICOM Standards Committee, whose members are also partly members of NEMA.*[9]

Health Level Seven (HL7), is a non-profit organization involved in the development of international healthcare informatics interoperability standards.[1] "HL7" also refers to some of the specific standards created by the organization (e.g., HL7 v2.x, v3.0, HL7 RIM). The HL7 Strategic Initiatives document is a business plan for our products and services and was designed specifically to meet the business needs of its members and stakeholders. Derived from collaborative efforts with its members, government and non-government agencies and other standards development organizations, the Strategic Initiatives are five high-level organizational strategies that are supported by a detailed tactical plan with clearly defined objectives, milestones, and metrics for success.*[10]

Both of the standards are focused on the data exchange and the data compatibility. Among many standards for the syntax, HL7 and DICOM are most successful. However, everything could not be handled by HL7 solely. DICOM is good for radiology images, but, other clinical images are already handled by other 'lighter' data formats like JPEG, TIFF. So, it is not realistic to use only one standard for every area of clinical information.*[11]

Opening the HL7 and DICOM standards in order to foster the integrated use of persistent health information objects is proposed as a step towards the creation of the health information infrastructure.*[12]

15.16.11 IHE

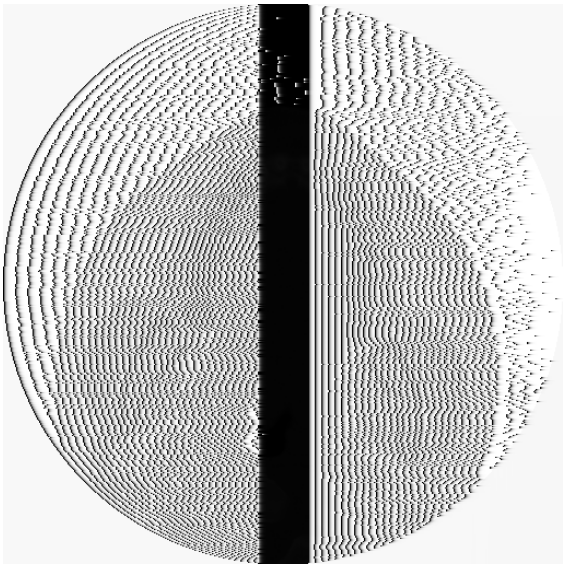
Integrating the Healthcare Enterprise (IHE) was founded in 1997 by members of the Radiological Society of North America (RSNA) and the Healthcare Information and Management Systems Society for the purpose of improving interoperability between information systems. The IHE initiative was charged with the task of using existing standards of health care data communication such as DICOM and HL7 to improve exchange of medical information beyond the radiology department at the hospital level or health systems level. Just as radiologists were confronted in the past with imaging connectivity incompatibilities, entire health systems are continually faced with the task of connecting multiple disparate information systems in which the only reliable communications pathway is the paper printout.

The IHE working group is a panel made up of industry representatives from medical informatics and imaging vendors as well as medical professionals. Their primary focus is to develop a common information model of medical information exchange. The devised IHE technical framework consists of a common lexicon that defines specific medical information transactions using the existing standards of medical information exchange (DICOM and HL7). The specifics of these transactions have been worked out in great detail so that vendors have been free to independently develop solutions to meet the goals of the technical framework. In the year 2001 to 2002, 30 companies took part in the testing and implementation of the IHE demonstrations.*[13]

15.16.12 See also

DICOM Software

- 3DSlicer - a free, open source software package for image analysis and scientific visualization, with the integrated support of components of DICOM standard
- GDCM - Grassroots DICOM library for medical files
- Ginkgo CADx Cross-platform DICOM viewer
- MicroDicom - DICOM viewer for Windows
- Noesis - Free software for processing and converting between hundreds of model, image, and animation formats, including DICOM.*[14]
- OsiriX - Image processing application dedicated to DICOM images
- Orthanc - Lightweight, RESTful DICOM store
- XnView - supports .dic / .dicom for MIME type application/dicom *[15]



GDCM sample as PNG

Medical Records Standards Initiatives, Standards and Organizations

- Health Level 7, a non-profit organization involved in the development of international healthcare informatics interoperability standards
- Integrating the Healthcare Enterprise (IHE), an industry sponsored non-profit organization based in the US state of Illinois

15.16.13 References

[1] DICOM brochure, nema.org.

[2] MEMBERS of the DICOM STANDARDS COMMITTEE

[3] http://www.nema.org/About/Pages/Members.aspx

[4] http://www.astm.org: If a Picture Is Worth 1,000 Words, then Pervasive, Ubiquitous Imaging Is Priceless

[5] http://www.nema.org: Industrial Imaging and Communications Section

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[15] Clunie, D.; Cordonnier, k. (February 2002). *Digital Imaging and Communications in Medicine (DICOM) - Application/dicom MIME Sub-type Registration*. IETF. RFC 3240. https://tools.ietf.org/html/rfc3240. Retrieved 2014-03-02.

15.16.14 External links

- DICOM standard, NEMA.
- Brief introduction to DICOM
- Medical Image FAQ part 2 - Standard formats including DICOM.
- Medical Image FAQ part 8 - Contains a long list DICOM software.
- DICOM Tutorial - DICOM is Easy.

15.17 DOCLE

DOCLE (**Do**ctor **C**ommand **L**anguag**e**), is a non-numeric health coding and medical classification system. The Docle system is used in Health Communication Network's electronic medical record and patient management software package, Medical Director. Medical Director is the most widely used electronic medical record system by Australian primary health care providers.

DOCLE has been modelled on the Linnaean biological classification system since 1995. Docle generates clinical codes from ubiquitous health language using an algorithm, hence it is a human readable clinical coding system.

The design principles of Docle, as enumerated by the author in the www.docle.com website include:

- Docle codes being meaningful and intentional

- Docle codes are derived from ubiquitous health language
- Docle codes grew with evolving order and speciation of large scale structures in a linnean manner.
- Docle codes are designed to strap together and form clinical structures using joiner codes
- The author of Docle, Dr. Y Kuang Oon, has likened clinical codes to "neurons" and joiner codes as the "glia"

15.17.1 See also

- Electronic medical record
- ICD - International Classification of Diseases
- International Classification of Primary Care
- LOINC - Logical Observation Identifiers Names and Codes
- Medical classification
- Medical record
- SNOMED CT - Systematized Nomenclature of Medicine - Clinical Terms

15.17.2 References

- "Docle coding and classification system browser" (HTML). Retrieved 2008-03-29.
- "Medical Director - Product Details" (HTML). *Health Communication Network*. Retrieved 2008-04-04.
- "Docle Systems" (HTML). Retrieved 2008-07-02.

15.17.3 External links

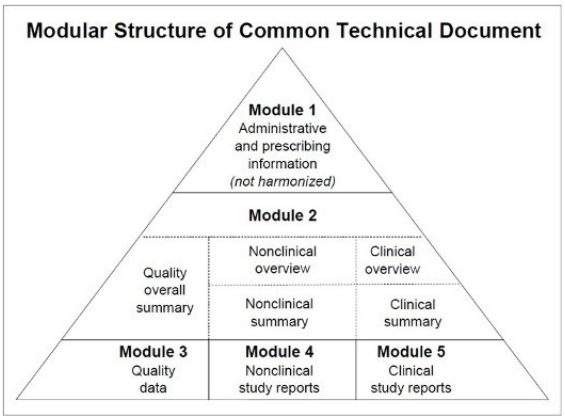
- Docle Systems Web Site

15.18 Electronic Common Technical Document

The **Electronic Common Technical Document (eCTD)** is an interface for the pharmaceutical industry to agency transfer of regulatory information. The content is based on the Common Technical Document (CTD) format.

It was developed by the International Conference on Harmonisation (ICH) Multidisciplinary Group 2 Expert Working Group (ICH M2 EWG). On May 5, 2015, the U.S. Food & Drug Administration published a final, binding guidance document* [1] requiring certain submissions in electronic (eCTD) format within 24 months. The projected date for mandatory electronic submissions is May 5, 2017 for New Drug Applications (NDAs), Biologic License Applications (BLAs), Abbreviated New Drug Applications (ANDAs) and Drug Master Files (DMFs).* [2] To date, more than 600,000 eCTD sequences have been submitted to the FDA.* [3]

15.18.1 Pharmaceutical point of view



The eCTD has five modules:

1. Administrative information and prescribing information
2. Common technical document summaries
3. Quality
4. Nonclinical study reports
5. Clinical study reports

A full table of contents could be quite large.

There are two categories of modules:

- Regional module: 1 (different for each region; i.e., country)
- Common modules: 2–5 (common to all the regions)

The CTD defines the content only of the common modules. The contents of the Regional Module 1 are defined by each of the ICH *regions* (USA, Europe and Japan).

15.18.2 IT point of view

eCTD (data structure)

The eCTD is a message specification for the transfer of files and metadata from a submitter to a receiver. The primary technical components are:

- A high level folder structure (required)
- An XML "backbone" file which provides metadata about content files and lifecycle instructions for the receiving system
- An optional lower level folder structure (recommended folder names are provided in Appendix 4 of the eCTD specification)
- Associated document type definitions (DTDs) and stylesheets.

Each submission message constitutes one "sequence". A cumulative eCTD consists of one or more sequences. While a single sequence may be viewed with web browser and the ICH stylesheet provided, viewing a cumulative eCTD requires specialized eCTD viewers.

The top part of the directory structure is as follows:

ctd-123456/0000/index.xml ctd-123456/0000/index-md5.txt ctd-123456/0000/m1 ctd-123456/0000/m2 ctd-123456/0000/m3 ctd-123456/0000/m4 ctd-123456/0000/m5 ctd-123456/0000/util

The string *ctd-123456/0000* is just an example.

Backbone (header) This is the file index.xml in the *submission sequence number folder*. For example:

ctd-123456/0000/index.xml

The purpose of this file is twofold:

- Manage meta-data for the entire submission
- Constitute a comprehensive table of contents and provide corresponding navigation aid.

Stylesheets Stylesheets that support the presentation and navigation should be included. They must be placed in the directory:

ctd-123456/0000/util/style

See entry 377 in Appendix 4.

DTDs DTDs must be placed in the directory:

ctd-123456/0000/util/dtd

See entries 371–76 in Appendix 4. They must follow a naming convention.

The DTD of the backbone is in Appendix 8. It must be placed in the above directory.

Business process (protocol)

The business process to be supported can be described as follows:

Industry <-----> Message <-----> Agency

The *lifecycle management* is composed at least of:

- *Initial submission*: should be self-contained.
- *Incremental updates*: with its *sequence number*.

15.18.3 See also

- Clinical trial
- Clinical Data Interchange Standards Consortium
- European Medicines Agency (EMA)
- Food and Drug Administration (FDA)
- Ministry of Health, Labour and Welfare (Japan).
- Russian Ministry of Healthcare and Social Development (Russia).

15.18.4 References

[1] "Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (PDF). US FDA. Retrieved 29 October 2015.

[2] Underwood, Brandon. "The End of Paper Submissions". *The eCTD Summit*. GlobalSubmit. Retrieved 29 October 2015.

[3] "Platform Migration Services". *GlobalSubmit*. Retrieved 29 October 2015.

15.18.5 External links

- Electronic Common Technical Document (eCTD) (FDA)

Submissions Management]

15.19 EUDRANET

EUDRANET, the **European Telecommunication Network in Pharmaceuticals** (**E**uropean **U**nion **D**rug **R**egulating **A**uthorities **Net**work), is an IT platform to facilitate the exchange of information between regulatory partners and industry during submission and evaluation of applications. The aim of EUDRANET is to provide appropriate secure services for inter-Administration data interchange and for exchanges between Administrations and industry. EUDRANET is based on the TESTA backbone infrastructure provided by the IDA Programme.

The processes which EUDRANET supports include:

- The submission and evaluation of marketing authorisation applications by pharmaceutical companies;
- The pharmacovigilance of products on the market to ensure the maintenance of high standards of quality as well as adhering to European national and regional regulations;
- The dissemination of relevant information to industry, scientific experts and regulators.

15.19.1 See also

- eHealth
- EudraCT
- EudraGMP
- EudraPharm
- EudraVigilance
- European Medicines Agency
- Qualified Person

15.19.2 External links

- EUDRANET
- Projects of Common Interest for Administrations (European Union)
- e-Health (European Union)

15.20 General Data Format for Biomedical Signals

The **General Data Format for Biomedical Signals** is a scientific and medical data file format. The aim of GDF is to combine and integrate the best features of all biosignal file formats into a single file format.*[1]

The original GDF specification was introduced in 2005 as a new data format to overcome some of the limitations of the European Data Format for Biosignals (EDF). GDF was also designed to unify a number of file formats which had been designed for very specific applications (for example, in ECG research and EEG analysis).*[2] The original specification included a binary header, and used an event table.*[3] An updated specification (GDF v2) was released in 2011 and added fields for additional subject-specific information (gender, age, etc.) and utilized several standard codes for storing physical units and other properties.*[2]

The GDF format is often used in brain–computer interface research.*[4]*[5]*[6] However, since GDF provides a superset of features from many different file formats, it could be also used for many other domains.

The free and open source software BioSig library provides implementations for reading and writing of GDF in GNU Octave/MATLAB and C/C++.*[7] A lightweight C++ library called libGDF is also available and implements version 2 of the GDF format.*[8]

The binary nature of the meta-information might not be suitable for all applications. The Extensible Data Format (XDF) is currently being developed with the aim of providing a flexible and extensible format for all kinds of data streams, but in particular for biosignals.*[9] As of 2015, XDF is in beta release.*[10]

15.20.1 See Also

- List of file formats

15.20.2 External links

- GDF v2.0 specification

15.20.3 References

[1] "Scientific data formats - Filters for Octave and Matlab". Retrieved 3 August 2015.

[2] Schlögl, Alois. "GDF - A general dataformat for biosignals". Retrieved 3 August 2015.

[3] "GDF - A General Dataformat for Biosignals" (PDF). Retrieved 3 August 2015.

[4] "Standards in Brain-Computer Interfaces". Retrieved 3 August 2015.

[5] editors, Brendan Z. Allison...[et al.], (2012). *Towards practical brain-computer interfaces bridging the gap from research to real-world applications*. Berlin: Springer. p. 323. ISBN 9783642297465.

[6] Mellinger, Gerwin Schalk, Jürgen (2010). *A practical guide to brain-computer interfacing with BCI2000 general-purpose software for brain-computer interface research, data acquisition, stimulus presentation, and brain monitoring* (Online-Ausg. ed.). London: Springer. p. 91. ISBN 9781849960922.

[7] "BioSig". *sourceforge.net*. Retrieved 3 August 2015.

[8] "libGDF download - SourceForge.net". *sourceforge.net*. Retrieved 3 August 2015.

[9] "xdf- XDF (Extensible Data Format) - Google Project Hosting". Retrieved 3 August 2015.

[10] "Specifications - xdf - This page contains the format specifications of XDF 1.0 (currently in beta). - XDF (Extensible Data Format) - Google Project Hosting". Retrieved 3 August 2015.

15.21 Health Level 7

Health Level-7 or **HL7** refers to a set of international standards for transfer of clinical and administrative data between software applications used by various healthcare providers. These standards focus on the application layer, which is "layer 7" in the OSI model. The HL7 standards are produced by the Health Level Seven International, an international standards organization, and are adopted by other standards issuing bodies such as American National Standards Institute and International Organization for Standardization.

Hospitals and other healthcare provider organizations typically have many different computer systems used for everything from billing records to patient tracking. All of these systems should communicate with each other (or "interface") when they receive new information, or when they wish to retrieve information, but not all do so.

HL7 International specifies a number of flexible standards, guidelines, and methodologies by which various healthcare systems can communicate with each other. Such guidelines or data standards are a set of rules that allow information to be shared and processed in a uniform and consistent manner. These data standards are meant to allow healthcare organizations to easily share clinical information. Theoretically, this ability to exchange information should help to minimize the tendency for medical care to be geographically isolated and highly variable.*[1]

HL7 International considers the following standards to be its primary standards - those standards that are most commonly used and implemented:*[2]

- Version 2.x Messaging Standard – an interoperability specification for health and medical transactions
- Version 3 Messaging Standard – an interoperability specification for health and medical transactions
- Clinical Document Architecture (CDA) – an exchange model for clinical documents, based on HL7 Version 3
- Continuity of Care Document (CCD) - a US specification for the exchange of medical summaries, based on CDA.
- Structured Product Labeling (SPL) – the published information that accompanies a medicine, based on HL7 Version 3
- Clinical Context Object Workgroup (CCOW) – an interoperability specification for the visual integration of user applications

Other HL7 standards/methodologies include:*[3]

- Fast Healthcare Interoperability Resources (FHIR) - a draft standard for the exchange of resources
- Arden Syntax – a grammar for representing medical conditions and recommendations as a Medical Logic Module (MLM)
- Claims Attachments – a Standard Healthcare Attachment to augment another healthcare transaction
- Functional Specification of Electronic Health Record (EHR) / Personal Health Record (PHR) systems - a standardized description of health and medical functions sought for or available in such software applications
- GELLO – a standard expression language used for clinical decision support

15.21.1 Primary HL7 standards

HL7's primary standards are those standards that Health Level Seven International considers to be most commonly used and implemented.*[2]

HL7 version 2

The HL7 version 2 standard (also known as Pipehat) has the aim to support hospital workflows. It was originally created in 1989.*[4]

HL7 version 2 defines a series of electronic messages to support administrative, logistical, financial as well as clinical processes. Since 1987 the standard has been updated regularly, resulting in versions 2.1, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.5.1 and 2.6. The v2.x standards are backward compatible (e.g., a message based on version 2.3 will be understood by an application that supports version 2.6).

HL7 v2.x messages use a non-XML encoding syntax based on segments (lines) and one-character delimiters.*[5] Segments have composites (fields) separated by the composite delimiter. A composite can have sub-composites (components) separated by the sub-composite delimiter, and sub-composites can have sub-sub-composites (subcomponents) separated by the sub-sub-composite delimiter. The default delimiters are vertical bar or pipe (|) for the field separator, caret (^) for the component separator, and ampersand (&) for the subcomponent separator. The tilde (~) is the default repetition separator. Each segment starts with a 3-character string which identifies the segment type. Each segment of the message contains one specific category of information. Every message has MSH as its first segment, which includes a field that identifies the message type. The message type determines the expected segment types in the message.*[6] The segment types used in a particular message type are specified by the segment grammar notation used in the HL7 standards.

The following is an example of an admission message. MSH is the header segment, PID the Patient Identity,

PV1 is the Patient Visit information, etc. The 5th field in the PID segment is the patient's name, in the order, family name, given name, second names (or their initials), suffix, etc. Depending on the HL7 V2.x standard version, more fields are available in the segment for additional patient information.

MSH|^~\&|MegaReg|XYZHospC|SuperOE|XYZImgCtr|200605290901||
0500||ADT^A01^ADT_A01|01052901|P|2.5
EVN||200605290901||||200605290900
PID|||56782445^^^UAReg^PI||KLEINSAMPLE^BARRY^Q^JR||19620910|M||2028-
9^^HL70005^RA99113^^XYZ|260 GOODWIN
CREST DRIVE^^BIRMINGHAM^AL^35209^^M~NICKELL
S PICKLES^10000 W 100TH
AVE^BIRMINGHAM^AL^35200^^O||||||0105I30001^^^99DEF^AN
PV1||I|W^389^1^UABH^^^^3||||12345^MORGAN^REX^J^^^MD^0010^
OBX|1|NM|^Body Height||1.80|m^Meter^ISO+|||||F
OBX|2|NM|^Body Weight||79|kg^Kilogram^ISO+|||||F
AL1|1||^ASPIRIN DG1|1|I|786.50^CHEST PAIN,
UNSPECIFIED^I9|||A

HL7 v2.x has allowed for the interoperability between electronic Patient Administration Systems (PAS), Electronic Practice Management (EPM) systems, Laboratory Information Systems (LIS), Dietary, Pharmacy and Billing systems as well as Electronic Medical Record (EMR) or Electronic Health Record (EHR) systems. Currently, the HL7 v2.x messaging standard is supported by every major medical information systems vendor in the United States.*[7]

HL7 version 3 Messaging

The HL7 version 3 standard has the aim to support all healthcare workflows. Development of version 3 started around 1995, resulting in an initial standard publication in 2005. The v3 standard, as opposed to version 2, is based on a formal methodology (the HDF) and object-oriented principles.

RIM - ISO/HL7 21731

The Reference Information Model*[8] (RIM) is the cornerstone of the HL7 Version 3 development process and an essential part of the HL7 V3 development methodology. RIM expresses the data content needed in a specific clinical or administrative context and provides an explicit representation of the semantic and lexical connections that exist between the information carried in the fields of HL7 messages.*[9]

HL7 Development Framework - ISO/HL7 27931

The HL7 Version 3 Development Framework (HDF) is a continuously evolving process that seeks to develop specifications that facilitate interoperability between healthcare systems. The HL7 RIM, vocabulary specifications, and model-driven process of analysis and design combine to make HL7 Version 3 one methodology for development of consensus-based standards for healthcare information system interoperability. The HDF is the most current edition of the HL7 V3 development methodology.

The HDF not only documents messaging, but also the processes, tools, actors, rules, and artifacts relevant to development of all HL7 standard specifications. Eventually, the HDF will encompass all of the HL7 standard specifications, including any new standards resulting from analysis of electronic health record architectures and requirements.

HL7 specifications draw upon codes and vocabularies from a variety of sources. The V3 vocabulary work ensures ,that the systems implementing HL7 specifications have an unambiguous understanding of the code sources and code value domains they are using.

V3 Messaging

The HL7 version 3 messaging standard defines a series of Secure Text messages (called *interactions*) to support all healthcare workflows.

HL7 v3 messages are based on an XML encoding syntax, as shown in this example:*[10]*:2.2.1

<POLB_IN224200 ITSVersion="XML_1.0" xmlns="urn:hl7-org:v3" xmlns:xsi=__xunadd_text_character:nN{\textquotedbl}{"}{}http://www.w3.org/2001/XMLSchema-instance"> <id root="2.16.840.1.113883.19.1122.7" extension="CNTRL-3456"/> <creationTime value="200202150930-0400"/> <!-- The version of the datatypes/RIM/vocabulary used is that of May 2006 --> <versionCode code="2006-05"/> <!-- interaction id= Observation Event Complete, w/o Receiver Responsibilities --> <interactionId root="2.16.840.1.113883.1.6" extension="POLB_IN224200"/> <processingCode code="P"/> <processingModeCode nullFlavor="OTH"/> <acceptAckCode code="ER"/> <receiver typeCode="RCV"> <device classCode="DEV" determinerCode="INSTANCE"> <id extension="GHH LAB" root="2.16.840.1.113883.19.1122.1"/> <asLocatedEntity classCode="LOCE"> <location classCode="PLC" determinerCode="INSTANCE"> <id root="2.16.840.1.113883.19.1122.2" extension="ELAB-3"/> </location> </asLocatedEntity> </device> </receiver> <sender typeCode="SND"> <device classCode="DEV" determinerCode="INSTANCE"> <id root="2.16.840.1.113883.19.1122.1" extension="GHH OE"/> <asLocatedEntity classCode="LOCE"> <location classCode="PLC" determinerCode="INSTANCE"> <id root="2.16.840.1.113883.19.1122.2" extension="BLDG24"/> </location> </asLocatedEntity> </device> </sender> <!-- Trigger Event Control Act & Domain Content --> </POLB_IN224200>

Clinical Document Architecture (CDA)

Main article: Clinical Document Architecture

The HL7 Clinical Document Architecture (CDA) is an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents for exchange.*[11] The standard was jointly published with ISO as ISO/HL7 27932.

Continuity of Care Document (CCD)

Main article: Continuity of Care Document

CCD is a US specification for the exchange of medical summaries, based on CDA.

Structured Product Labeling (SPL)

Main article: Structured Product Labeling

SPL describes the published information that accompanies a medicine, based on HL7 Version 3.

CCOW

Main article: CCOW

CCOW, or "Clinical Context Object Workgroup," is a standard protocol designed to enable disparate applications to share user context and patient context in real-time, and at the user-interface level. CCOW implementations typically require a CCOW vault system to manage user security between applications.

15.21.2 Other HL7 Standards/Methods

Fast Healthcare Interoperability Resources (FHIR)

Main article: Fast Healthcare Interoperability Resources

Fast Healthcare Interoperability Resources is a draft standard from HL7 International designed to be easier to implement, more open and more extensible than version 2.x or version 3. It leverages a modern web-based suite of API technology, including a HTTP-based RESTful protocol, HTML and Cascading Style Sheets for user interface integration, a choice of JSON or XML for data representation, OAuth for authorization and ATOM for query results.*[12]

Services Aware Interoperability Framework

Main article: HL7 Services Aware Interoperability Framework

The HL7 Services-Aware Enterprise Architecture Framework (SAIF) provides consistency between all HL7 artifacts, and enables a standardized approach to Enterprise Architecture (EA) development and implementation, and a way to measure the consistency.

SAIF is a way of thinking about producing specifications that explicitly describe the governance, conformance, compliance, and behavioral semantics that are needed to achieve computable semantic working interoperability. The intended information transmission technology might use a messaging, document exchange, or services approach.

SAIF is the framework that is required to rationalize interoperability of other standards. SAIF is an architecture for achieving interoperability, but it is not a whole-solution design for enterprise architecture management.

Arden syntax

Main article: Arden syntax

The Arden syntax is a language for encoding medical knowledge. HL7 International adopted and oversees the standard beginning with Arden syntax 2.0. These Medical Logic Modules (MLMs) are used in the clinical setting as they can contain sufficient knowledge to make single medical decisions. They can produce alerts, diagnoses, and interpretations along with quality assurance function and administrative support. An MLM must run on a computer that meets the minimum system requirements and has the correct program installed. Then, the MLM can give advice for when and where it is needed.

MLLP

A large portion of HL7 messaging is transported by Minimal Lower Layer Protocol (MLLP), also known as Lower Layer Protocol (LLP).*[13] For transmitting via TCP/IP, header and trailer characters are added to the message to identify the beginning and ending of the message because TCP/IP is a continuous stream of bytes. Hybrid Lower Layer Protocol (HLLP) is a variation of MLLP that includes a checksum to help verify message integrity. Amongst other software vendors, MLLP is supported by Microsoft,*[14] Oracle*[15] and Cleo.*[16]

Functional EHR and PHR specifications

Functional specifications for an electronic health record.

15.21.3 See also

- CDISC
- DICOM
- Electronic medical record
- eHealth
- EHRcom
- European Institute for Health Records (European Union)
- Fast Healthcare Interoperability Resources
- Health Informatics
- Health Informatics Service Architecture (HISA)
- Healthcare Services Specification Project (HSSP)
- Integrating the Healthcare Enterprise(IHE)
- ISO TC 215
- LOINC
- Mirth (software)
- openEHR Foundation
- Public Health Information Network
- SNOMED, SNOMED CT
- Nomenclature for Properties and Units terminology

15.21.4 References

This article incorporates text from an open source work, under Creative Commons Attribution-ShareAlike 3.0 license: Spronk 2007.

[1] Joel Rodrigues (2010). *Health Information Systems: Concepts, Methodologies, Tools, and Applications, Volume 1*. IGI Global. ISBN 978-1-60566-988-5.

[2] "HL7 Primary Standards". Health Level Seven International.

[3] "HL7 Standards". Health Level Seven International.

[4] "HL7 FAQs". HL7.

[5] "Understanding HL7 Messages". iNTERFACEWARE.

[6] "HL7 Messages and Descriptions". iNTERFACEWARE.

[7] "Standards Organizations". Assistant Secretary for Planning and Evaluation (ASPE), Health and Human Services (HHS).

[8] "HL7 Reference Information Model". HL7.

[9] "Tools & Resources – V3 Modeling & Methodology Tools". HL7.

[10] Spronk, René, ed. (16 November 2007). "HL7 Message examples: version 2 and version 3". *Ringholm*. Ringholm bv.

[11] *The CDA Book*.

[12] Dan Munro (2014-03-30). "Setting Healthcare Interop On Fire". *Forbes*. Retrieved 2014-11-22.

[13] "LLP - Lower Layer Protocol". iNTERFACEWARE.

[14] "MLLP Receive and Send Components". MSDN.

[15] "Oracle Application Server Integration B2B User's Guide, Supported Protocols". Oracle.

[16] "Which Secure Managed File Transfer Protocol is Right for You?". Cleo.

15.21.5 External links

- HL7.org site
- What does HL7 education mean?
- HL7 International is a member of the Joint Initiative on SDO Global Health Informatics Standardization
- HL7 Tools Page
- Australian Healthcare Messaging Laboratory (AHML) - Online HL7 Message Testing and Certification
- Comprehensive Implementation of HL7 v3 Specifications in Java
- NIST HL7 Conformance Testing Framework
- ICH-HL7 Regulated Product Submissions
- HL7 Tutorial Directory

Critical reviews

- HL7 RIM: An Incoherent Standard
- HL7 RIM Under Scrutiny (attempted rebuttal)(publication date?)
- HL7 WATCH
- Update 2013: Human Action in the Healthcare Domain: A Critical Analysis of HL7's Reference Information Model

15.22 Healthcare Common Procedure Coding System

The **Healthcare Common Procedure Coding System** (**HCPCS**, often pronounced by its acronym as "hick picks") is a set of health care procedure codes based on the American Medical Association's Current Procedural Terminology (CPT).*[1]

15.22.1 History

The acronym *HCPCS* originally stood for *HCFA Common Procedure Coding System*, a medical billing process used by the Centers for Medicare and Medicaid Services (CMS). Prior to 2001, CMS was known as the Health Care Financing Administration (HCFA). HCPCS was established in 1978 to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. Such coding is necessary for Medicare, Medicaid, and other health insurance programs to ensure that insurance claims are processed in an orderly and consistent manner. Initially, use of the codes was voluntary, but with the implementation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) use of the HCPCS for transactions involving health care information became mandatory.*[2]

15.22.2 Levels of codes

HCPCS includes three levels of codes:

- **Level I** consists of the American Medical Association's Current Procedural Terminology (CPT) and is numeric.
- **Level II** codes are alphanumeric and primarily include non-physician services such as ambulance services and prosthetic devices,*[3] and represent items and supplies and non-physician services, not covered by CPT-4 codes (Level I).
- **Level III** codes, also called local codes, were developed by state Medicaid agencies, Medicare contractors, and private insurers for use in specific programs and jurisdictions. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) instructed CMS to adopt a standard coding systems for reporting medical transactions. The use of Level III codes was discontinued on December 31, 2003, in order to adhere to consistent coding standards.

15.22.3 See also

- Centers for Medicare and Medicaid Services
- Current Dental Terminology

15.22.4 References

[1] HCPCS Code range. "HCPCS Codes".

[2] "NEW CMS CODING CHANGES WILL HELP BENEFICIARIES" (PDF). Centers for Medicare and Medicaid Services. October 6, 2004. p. 1. Retrieved January 13, 2016.

[3] HCPCS Level II Codes

15.22.5 External links

- Official site
- HCPCS Complete Reference
- HCPCS Level II alphanumeric procedure and modifier codes
- NDC-HCPCS crosswalk data files
- Free online HCPCS Level 2 Codes Search Engine from drchrono

15.23 Healthcare Information Technology Standards Panel

The American National Standards Institute (ANSI) **Healthcare Information Technology Standards Panel** (HITSP) was created in 2005 as part of efforts by the Office of the National Coordinator for Health Information Technology (ONC, part of the United States Department of Health and Human Services) to promote interoperability in health care by harmonizing health information technology standards. HITSP is chaired by John Halamka, MD, CIO of Harvard Medical School.

15.23.1 Membership

Membership is by organization and there is currently no cost to join. Volunteers commit time to working on standards harmonization efforts as prioritized by the American Health Information Community (AHIC).

15.23.2 Goals

According to their website, HITSP's mission is to "serve as a cooperative partnership between the public and private sectors for the purpose of achieving a widely accepted and useful set of standards specifically to enable and support widespread interoperability among healthcare software applications, as they will interact in a local, regional and national health information network for the United States."

HITSP is generally organized around *Use Cases*, which are profiles of specific interoperability needs that have

been identified by AHIC as being important national priorities. The initial 2006 Use Cases were:

- Consumer Empowerment
  - Registration Summary
  - Medication History
- Electronic Health Records (EHRs)
  - Laboratory Result Reporting
- Biosurveillance
  - Visit
  - Utilization
  - Clinical Data
  - Lab and Radiology

The 2007 Use Cases are:

- Consumer Access to Clinical Information
  - Access to Clinical Data
  - Provider Permissions
  - Personal Health Record (PHR) Transfer
- Emergency Responder EHR
  - On-site Care
  - Emergency Care
  - Definitive Care
  - Provider Authentication and Authorization
- Medication Management
  - Medication Reconciliation
  - Ambulatory Prescriptions
  - Contraindications
- Quality
  - Hospital Measurement and Reporting
  - Clinician Measurement and Reporting
  - Feedback to Clinicians

15.23.3 See also

- Health care in the United States

15.23.4 External links

- Healthcare Information Technology Standards Panel website
- Products & Solutions For Healthcare website

15.24 HISA

The European Committee for Standardization (CEN) **Standard Architecture for Healthcare Information Systems** (ENV 12967), **Health Informatics Service Architecture** or **HISA** is a standard that provides guidance on the development of modular open information technology (IT) systems in the healthcare sector. Broadly, architecture standards outline frameworks which can be used in the development of consistent, coherent applications, databases and workstations. This is done through the definition of hardware and software construction requirements and outlining of protocols for communications.*[1] The HISA standard provides a formal standard for a service-oriented architecture (SOA), specific for the requirements of health services, based on the principles of Open Distributed Processing.*[2] The HISA standard evolved from previous work on healthcare information systems architecture commenced by Reseau d' Information et de Communication Hospitalier Europeen (RICHE) in 1989, and subsequently built upon by a number of organizations across Europe.*[3]

15.24.1 Development of Health Informatics Service Architecture EN/ISO 12967

The HISA standard was developed by CEN Technical Committee (TC) 251, the technical committee for Health Informatics within the federation of European national standards bodies (CEN).*[4] The CEN/TC 251 was made up of four working groups, covering: information models; systems of concepts and terminology; security; and technologies for interoperable communication.*[5] Working Group I were responsible for information models and completed the specifications that became the HISA standard. Working Group I worked with experts from across Europe, plus contributors from Australia and the United States in the development and finalization of ENV 12967.

The CEN HISA standard was adopted by the International Organization for Standardization (ISO) in 2009, with the stated aim of ISO 12967 being to provide guidance on:

- the description, planning and development of new electronic health systems; and
- the integration of existing electronic health systems, both intra- and inter-organizationally, through architecture that integrates common data and business logic into middleware, which is then made available throughout whole information systems.*[6]

15.24.2 The Standard

EN/ISO 12967 is broken down into three parts: Enterprise Viewpoint; Information Viewpoint; and Computational Viewpoint, all of which deal with different aspects of ensuring service architecture supports openness and vendor-independence.*[7]

Part One: Enterprise Viewpoint

The Enterprise Viewpoint component of EN/ISO 12967 provides health services with guidance in describing, planning and developing new IT systems, utilizing an open distributed processing approach. In addition to this it provides direction for the integration of existing information systems, within the one enterprise and across different healthcare organizations. Part one of the standard sets forth the common enterprise-level requirements (e.g. workflows, authorizations) that must be supported through the HISA, which integrates the common data and business logic into a specific architectural layer (i.e. the middleware), accessible throughout the whole information system of the health service.*[8]

Part Two: Information Viewpoint

The Information Viewpoint component of EN/ISO 12967 sets forth the fundamental characteristics of the information model to be implemented by the middleware to provide comprehensive, integrated storage of the common enterprise data and to support the fundamental business processes of the healthcare organisation, as defined in ISO 12967 Part One. The specifications were designed to be universally relevant, whilst being sufficiently specific to allow implementers to derive an efficient design of the system for their organisation. This specification does not aim to provide a fixed, complete specification of all possible data that may be necessary for any given health service. It specifies only a set of characteristics, in terms of overall organisation and individual information objects, identified as fundamental and common to all healthcare organizations.*[9]

Part Three: Computational Viewpoint

The Computational Viewpoint component of EN/ISO 12967 provides details on the fundamental characteristics of the computational model to be implemented by the middleware, to provide a comprehensive and integrated interface to the common, fundamental business processes of the health service. The computational model, like the information model is designed to be universally relevant, whilst still being sufficiently specific to allow implementers to derive an efficient design of the system for their organisation, irrespective of the specifics of the pre-existing information technology environment in which it will be implemented.*[10]

15.24.3 Use of common services

The implementation of a modular, open architecture in healthcare IT systems (as specified by the HISA) relies upon disparate heterogeneous applications interacting and communicating through a middleware layer, made up of common services. In the case of the HISA, these common services are divided into Healthcare-related Common Services and Generic Common Services.*[11]

Healthcare-related Common Services (HCS)

Healthcare-related Common Services are those middleware components responsible for supporting the functionalities and information relevant to the healthcare business domain, including subject of care, activities, resources, authorization, health characteristics and concepts.*[12]

Generic Common Services (GCS)

Generic Common Services are those middleware components are those middleware components responsible for supporting the generic functionality and information requirements that are non-specific to the healthcare domain, and may be broadly relevant to any information system in the business domain.*[13]

15.24.4 See also

- Archetype (information science)
- Clinical Document Architecture (CDA)
- Clinical Data Interchange Standards Consortium (CDISC)
- EN 13606
- Electronic Health Record (EHR)
- Electronic medical record
- European Institute for Health Records
- Health Level 7
- Healthcare Services Specification Project
- OpenEHR
- Public Health Information Network
- National E-Health Transition Authority
- Systems Architecture

15.24.5 References

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15.25 Healthcare Services Specification Project

The **Healthcare Services Specification Project** (HSSP) is a standards development effort to create health industry service-oriented architecture (SOA) standards supportive of the health care market sector. HSSP is a jointly sponsored activity operating within the Health Level Seven (HL7) and the Object Management Group (OMG) standards group. Formally beginning as a collaboration between the HL7 Service-oriented Architecture Special Interest Group and the OMG Healthcare Domain Task Force, HSSP is developing healthcare middleware standards addressing interoperability challenges.

The activity is an effort to create common "service interface specifications" that ultimately can be tractable within a Health IT context. The stated objective of the HSSP project is to create useful, usable healthcare standards that define the functions, semantics, and technology bindings supportive of system-level interoperability. To the extent possible, HSSP specifications complement existing work and standards.

A key tenet to the HSSP approach is to focus on practical needs, capitalizing on open industry participation and maximizing contributions from industry talent interested in engaging.

15.25.1 Context

By design, HSSP specifications are applicable for use in multiple use contexts, including inter-enterprise, intra-enterprise, intra-product, and intra-implementation. In other words, nothing inherent in the standard work deliberately precludes their use in any targeted system setting.

15.25.2 Mission

The following is the stated Mission and Charter of the HSSP project, used with permission.

> Recognizing the need for specifications for services to support healthcare IT as part of national infrastructures (such as US NHII, Australia's HealthConnect and Finland's Terveyshanke), Health Level Seven and the Object Management Group have forged this agreement to collaborate to the advantage of the health domain sector. This charter outlines high-level distribution of responsibilities and separation of concerns specifically related to this services effort. Note that this joint effort between HL7 and OMG is not exclusive. Either organization may engage in independent efforts or similar joint efforts with others. This project is a collaborative effort between HL7 and OMG to identify and document service specifications, functionality, and conformance supportive and relevant to healthcare IT stakeholders and resulting in real-world implementations.
>
> As part of this collaborative effort:
>
> HL7 and OMG shall jointly identify the service candidates for specification and prioritize and select candidate services for specification and implementation, and jointly allocate functions to services. OMG members shall provide expertise in distributed architecture and implementation to HL7 activities to positively impact the selection of services and allocation of functions. HL7 members shall

engage in the OMG RFP process to ensure consistency with the functional requirements.

HL7 shall elaborate the business functional needs, allocate functions to services, and develop conformance criteria for the services specified. HL7 shall also have responsibility for providing the information modeling and content in support of these services. All of the computationally independent work shall occur within HL7, as well as the functional conformance criteria assuring that service implementations meet their specified capability. In general, information models and content will be managed by other HL7 domain committees, and HSSP will work with those committees to define any additions or changes.

OMG shall refine the HL7 developed computationally independent specifications [functional, semantics, information model, terminology, etc.] resulting in computationally dependent standards and user, vendor, and reference implementations. OMG shall provide technical expertise such as Unified Modeling Language (UML) and Model-driven architecture (MDA), as well as leveraging multi-industry solutions. OMG shall leverage the strength of its adoption process to promote rapid standards development and marketplace product support given that submitters are required to produce implementations of the standards they specify.

As a project and through its presence in other organizations, the HSSP will provide an umbrella structure under which various subgroups will be chartered to carry out specific tasks in conjunction and under the auspices of these organizations, such as definition of methodology, architecture and specific services. The HSSP additionally will facilitate between organizations to provide the tools, knowledge, methodologies, or viewpoints deemed necessary for them to fulfill their purpose. The responsibilities of the main HSSP will be to manage the subgroups and verify their charters, as well as provide cohesive vision and any appropriate administrative tasks.

15.25.3 Philosophy

HSSP specification work is divided into two foundational components: functional specifications (manifested as Service Functional Models) and technical specifications (resulting in technology adoptions). The functional specification work is being originated within health industry standards communities, such as HL7 and CEN. The functional models enumerate *what* capabilities are to be supported but not *how* they are supported. The technical specification work details exactly how those functions are manifested and ultimately realized in a technology platform.

The intention behind splitting the standard into two work products is to facilitate and improve involvement from different communities, leveraging each to their strengths. To date, HL7 has been leading in identifying standardization priorities, elaborating the functions desired into Service Functional Models, and in defining conformance criteria that would be used to assess compliance. The OMG has been leading the technical specification process as part of their Technology Adoption Process.

The OMG process requires participants to make commitments to implement standards as working software, ensuring that the technical specifications are used and available. During implementation of these technical specifications, errors and shortcomings of adopted Service Functional Models are captured, logged, and ultimately incorporated into subsequent versions of the Service Functional Models as part of a continuous process improvement approach.

15.25.4 History

Prior to establishing HSSP as a moniker, the activity began informally as an informal group to discuss issues pertaining to SOA and interoperability in a health context. Meeting concurrently with regularly scheduled HL7 Working Group meetings, HSSP operated in this form for several years until June 2005. In June a meeting was hosted in Salt Lake City by the U.S. Veterans Health Administration to establish a formal direction for the group and to initiate steps to formalize its activities.

In January 2006, Health Level Seven accepted the charter of the Service-oriented Architecture Special Interest Group (SOA SIG), which was to become the hosting body for HSSP within the HL7 organization. The OMG Healthcare Domain Task Force had already agreed to sponsor the activity. The HSSP project was formally chartered in January, 2006, operating under a board-level agreement forged between Health Level Seven and the Object Management Group.

15.25.5 See also

- HISA
- Health Level 7 - HL7

15.25.6 References

HSSP Wiki

- Clinical Research Filtered Query Service
- Common Terminology Service II
- Decision Support Service
- Human Services Directory
- Privacy Access Security Services

15.25.7 External links

- Introduction to the HL7 Standards
- Healthcare Services Specification Project (HSSP)

15.26 International Statistical Classification of Diseases and Related Health Problems

"ICD" redirects here. For other uses, see ICD (disambiguation).

The **International Statistical Classification of Diseases and Related Health Problems**, usually called by the short-form name **International Classification of Diseases** (**ICD**), is the international "standard diagnostic tool for epidemiology, health management and clinical purposes".[*][1] The ICD is maintained by the World Health Organization (WHO), the directing and coordinating authority for health within the United Nations System.[*][2] The ICD is designed as a health care classification system, providing a system of diagnostic codes for classifying diseases, including nuanced classifications of a wide variety of signs, symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or disease. This system is designed to map health conditions to corresponding generic categories together with specific variations, assigning for these a designated code, up to six characters long. Thus, major categories are designed to include a set of similar diseases.

The ICD is published by the WHO and used worldwide for morbidity and mortality statistics, reimbursement systems, and automated decision support in health care. This system is designed to promote international comparability in the collection, processing, classification, and presentation of these statistics. As in the case of the analogous (but limited to mental and behavioral disorders) *Diagnostic and Statistical Manual of Mental Disorders* (DSM, currently in version 5), the ICD is a major project to statistically classify health disorders, and provide diagnostic assistance. The ICD is a core statistically based classificatory diagnostic system for health care related issues of the WHO Family of International Classifications (WHO-FIC).[*][3]

The ICD is revised periodically and is currently in its tenth revision. The ICD-10, as it is therefore known, was developed in 1992 to track health statistics. ICD-11 was planned for 2017,[*][4][*][5] but has been pushed back to 2018.[*][6] As of 2007, development plans included using Web 2.0 principles to support detailed revision.[*][7] Annual minor updates and triennial major updates are published by the WHO.[*][8] The ICD is part of a "family" of guides that can be used to complement each other, including also the International Classification of Functioning, Disability and Health which focuses on the domains of functioning (disability) associated with health conditions, from both medical and social perspectives.

15.26.1 Historical synopsis

In 1860, during the international statistical congress held in London, Florence Nightingale made a proposal that was to result in the development of the first model of systemic collection of hospital data. In 1893, a French physician, Jacques Bertillon, introduced the *Bertillon Classification of Causes of Death* at a congress of the International Statistical Institute in Chicago.[*][9] A number of countries and cities adopted Bertillon's system, which was based on the principle of distinguishing between general diseases and those localized to a particular organ or anatomical site, as used by the City of Paris for classifying deaths. Subsequent revisions represented a synthesis of English, German, and Swiss classifications, expanding from the original 44 titles to 161 titles. In 1898, the American Public Health Association (APHA) recommended that the registrars of Canada, Mexico, and the United States also adopt it. The APHA also recommended revising the system every ten years to ensure the system remained current with medical practice advances. As a result, the first international conference to revise the International Classification of Causes of Death took place in 1900, with revisions occurring every ten years thereafter. At that time, the classification system was contained in one book, which included an Alphabetic Index as well as a Tabular List. The book was small compared with current coding texts.

The revisions that followed contained minor changes, until the sixth revision of the classification system. With the sixth revision, the classification system expanded to two volumes. The sixth revision included morbidity and mortality conditions, and its title was modified to reflect the changes: International Statistical Classification of Diseases, Injuries and Causes of Death (ICD). Prior to the sixth revision, responsibility for ICD revisions fell to the Mixed Commission, a group composed of representatives from the International Statistical Institute and the Health

Organization of the League of Nations. In 1948, the WHO assumed responsibility for preparing and publishing the revisions to the ICD every ten years. WHO sponsored the seventh and eighth revisions in 1957 and 1968, respectively. It later become clear that the established ten year interval between revisions was too short.*[9]

The ICD is currently the most widely used statistical classification system for diseases in the world. International health statistics using this system are available at the Global Health Observatory (GHO).*[10]

In addition, some countries —including Australia, Canada, and the United States—have developed their own adaptations of ICD, with more procedure codes for classification of operative or diagnostic procedures.

15.26.2 Versions of ICD

ICD-6

The ICD-6, published in 1949, was the first to be shaped to become suitable for morbidity reporting. Accordingly, the name changed from International List of Causes of Death to International Statistical Classification of Diseases. The combined code section for injuries and their associated accidents was split into two, a chapter for injuries, and a chapter for their external causes. With use for morbidity there was a need for coding mental conditions, and for the first time a section on mental disorders was added.*[11]*[12]

ICD-7

The International Conference for the Seventh Revision of the International Classification of Diseases was held in Paris under the auspices of WHO in February 1955. In accordance with a recommendation of the WHO Expert Committee on Health Statistics, this revision was limited to essential changes and amendments of errors and inconsistencies.*[12]

ICD-8a

See also: List of ICD-8a codes

The Eighth Revision Conference convened by WHO met in Geneva, from 6 to 12 July 1965. This revision was more radical than the Seventh but left unchanged the basic structure of the Classification and the general philosophy of classifying diseases, whenever possible, according to their etiology rather than a particular manifestation. During the years that the Seventh and Eighth Revisions of the ICD were in force, the use of the ICD for indexing hospital medical records increased rapidly and some countries prepared national adaptations which provided the additional detail needed for this application of the ICD. In the USA, a group of consultants was asked to study the 8th revision of ICD (ICD-8a) for its applicability to various users in the United States. This group recommended that further detail be provided for coding hospital and morbidity data. The American Hospital Association's "Advisory Committee to the Central Office on ICDA" developed the needed adaptation proposals, resulting in the publication of the International Classification of Diseases, Adapted (ICDA). In 1968, the United States Public Health Service published the International Classification of Diseases, Adapted, 8th Revision for use in the United States (ICDA-8a). Beginning in 1968, ICDA-8a served as the basis for coding diagnostic data for both official morbidity [and mortality] statistics in the United States.*[12]*[13]

ICD-9

See also: List of ICD-9 codes

The International Conference for the Ninth Revision of the International Classification of Diseases, convened by WHO, met in Geneva from 30 September to 6 October 1975. In the discussions leading up to the conference, it had originally been intended that there should be little change other than updating of the classification. This was mainly because of the expense of adapting data processing systems each time the classification was revised.

There had been an enormous growth of interest in the ICD and ways had to be found of responding to this, partly by modifying the classification itself and partly by introducing special coding provisions. A number of representations were made by specialist bodies which had become interested in using the ICD for their own statistics. Some subject areas in the classification were regarded as inappropriately arranged and there was considerable pressure for more detail and for adaptation of the classification to make it more relevant for the evaluation of medical care, by classifying conditions to the chapters concerned with the part of the body affected rather than to those dealing with the underlying generalized disease.

At the other end of the scale, there were representations from countries and areas where a detailed and sophisticated classification was irrelevant, but which nevertheless needed a classification based on the ICD in order to assess their progress in health care and in the control of disease. A field test with a bi-axial classification approach—one axis (criterion) for anatomy, with another for etiology—showed the impracticability of such approach for routine use.

The final proposals presented to and accepted by the Conference in 1978*[14] retained the basic structure of the ICD, although with much additional detail at the level of the four digit subcategories, and some optional five digit subdivisions. For the benefit of users not requiring such detail, care was taken to ensure that the categories at the

three digit level were appropriate.

For the benefit of users wishing to produce statistics and indexes oriented towards medical care, the Ninth Revision included an optional alternative method of classifying diagnostic statements, including information about both an underlying general disease and a manifestation in a particular organ or site. This system became known as the dagger and asterisk system and is retained in the Tenth Revision. A number of other technical innovations were included in the Ninth Revision, aimed at increasing its flexibility for use in a variety of situations.

It was eventually replaced by ICD-10, the version currently in use by the WHO and most countries. Given the widespread expansion in the tenth revision, it is not possible to convert ICD-9 data sets directly into ICD-10 data sets, although some tools are available to help guide users.*[15] Publication of ICD-9 without IP restrictions in a world with evolving electronic data systems led to a range of products based on ICD-9, such as MeDRA or the Read directory.*[12]*[13]

ICPM When ICD-9 was published by the World Health Organization (WHO), the International Classification of Procedures in Medicine (ICPM) was also developed (1975) and published (1978). The ICPM surgical procedures fascicle was originally created by the United States, based on its adaptations of ICD (called ICDA), which had contained a procedure classification since 1962. ICPM is published separately from the ICD disease classification as a series of supplementary documents called fascicles (bundles or groups of items). Each fascicle contains a classification of modes of laboratory, radiology, surgery, therapy, and other diagnostic procedures. Many countries have adapted and translated the ICPM in parts or as a whole and are using it with amendments since then.*[12]*[13]

ICD-9-CM *International Classification of Diseases, Clinical Modification* (ICD-9-CM) is an adaption created by the U.S. National Center for Health Statistics (NCHS) and used in assigning diagnostic and procedure codes associated with inpatient, outpatient, and physician office utilization in the United States. The ICD-9-CM is based on the ICD-9 but provides for additional morbidity detail. It is updated annually on October 1.*[16]*[17]

It consists of two or three volumes:

- Volumes 1 and 2 contain diagnosis codes. (Volume 1 is a tabular listing, and volume 2 is an index.) Extended for ICD-9-CM
- Volume 3 contains procedure codes for surgical, diagnostic, and therapeutic procedures.*[18] ICD-9-CM only

The NCHS and the Centers for Medicare and Medicaid Services are the U.S. governmental agencies responsible for overseeing all changes and modifications to the ICD-9-CM.

ICD-10

Main article: ICD-10

Work on ICD-10 began in 1983, and the new revision was endorsed by the Forty-third World Health Assembly in May 1990. The latest version came into use in WHO Member States starting in 1994.*[19] The classification system allows more than 155,000 different codes and permits tracking of many new diagnoses and procedures, a significant expansion on the 17,000 codes available in ICD-9.*[20] Adoption was relatively swift in most of the world. Several materials are made available online by WHO to facilitate its use, including a manual, training guidelines, a browser, and files for download.*[3] Some countries have adapted the international standard, such as the "ICD-10-AM" published in Australia in 1998 (also used in New Zealand),*[21] and the "ICD-10-CA" introduced in Canada in 2000.*[22]

ICD-10-CM Main article: ICD-10-CM

Adoption of ICD-10-CM was slow in the United States. Since 1979, the USA had required ICD-9-CM codes*[23] for Medicare and Medicaid claims, and most of the rest of the American medical industry followed suit. On 1 January 1999 the ICD-10 (without clinical extensions) was adopted for reporting mortality, but ICD-9-CM was still used for morbidity. Meanwhile, NCHS received permission from the WHO to create a clinical modification of the ICD-10, and has production of all these systems:

- ICD-10-CM, for diagnosis codes, replaces volumes 1 and 2. Annual updates are provided.
- ICD-10-PCS, for procedure codes, replaces volume 3. Annual updates are provided.

On August 21, 2008, the US Department of Health and Human Services (HHS) proposed new code sets to be used for reporting diagnoses and procedures on health care transactions. Under the proposal, the ICD-9-CM code sets would be replaced with the ICD-10-CM code sets, effective October 1, 2013. On April 17, 2012 the Department of Health and Human Services (HHS) published a proposed rule that would delay, from October 1, 2013 to October 1, 2014,the compliance date for the ICD-10-CM and PCS.*[24] Once again, Congress delayed implementation date to October 1, 2015, after it was inserted into "Doc Fix" Bill without debate over objections of many.

Revisions to ICD-10-CM Include:

- Relevant information for ambulatory and managed care encounter.
- Expanded injury codes.
- New combination codes for diagnosis/symptoms to reduce the number of codes needed to describe a problem fully.
- Addition of sixth and seventh digit classification.
- Classification specific to laterality.
- Classification refinement for increased data granularity.

ICD-10-CA ICD-10-CA is a clinical modification of ICD-10 developed by the Canadian Institute for Health Information for morbidity classification in Canada. ICD-10-CA applies beyond acute hospital care, and includes conditions and situations that are not diseases but represent risk factors to health, such as occupational and environmental factors, lifestyle and psycho-social circumstances.*[22]

ICD-11

The World Health Organization is currently revising the International Classification of Diseases (ICD) towards the ICD-11. The development is taking place on an internet-based workspace, called iCAT (Collaborative Authoring Tool) Platform, somewhat similar to a wiki – yet it requires more structure and peer review process. The WHO collaborates through this platform with all interested parties.

The final draft of the ICD-11 system is expected to be submitted to WHO's World Health Assembly (WHA) for official endorsement by 2017.*[25] The draft review was completed in April 2015*[25] A final version for approval at the WHA is expected in 2018.*[25]

In ICD-11 each disease entity will have definitions that give key descriptions and guidance on what the meaning of the entity/category is in human readable terms - to guide users. This is an advancement over ICD-10, which had only title headings. The Definitions have a standard structure according to a template with standard definition templates and further features exemplified in a "Content Model". The Content Model is a structured framework that captures the knowledge that underpins the definition of an ICD entity. The Content Model therefore allows computerization (with links to ontologies and SNOMED CT). Each ICD entity can be seen from different dimensions or "parameters". For example, there are currently 13 defined main parameters in the Content Model (see below) to describe a category in ICD.

1. ICD Entity Title - *Fully Specified Name*
2. Classification Properties - *disease, disorder, injury, etc.*
3. Textual Definitions - *short standard description*
4. Terms - *synonyms, other inclusion and exclusions*
5. Body System/Structure Description - *anatomy and physiology*
6. Temporal Properties - *acute, chronic or other*
7. Severity of Subtypes Properties - *mild, moderate, severe, or other scales*
8. Manifestation Properties - *signs, symptoms*
9. Causal Properties - *etiology: infectious, external cause, etc.*
10. Functioning Properties - *impact on daily life: activities and participation*
11. Specific Condition Properties - *relates to pregnancy etc.*
12. Treatment Properties - *specific treatment considerations: e.g. resistance*
13. Diagnostic Criteria - *operational definitions for assessment*

ICD exists in 41 Languages in electronic versions and its expression in multiple languages will be systematically pursued in ICD11.

15.26.3 Usage and current topics

History and usage in the United States

In the United States, the U.S. Public Health Service published *The International Classification of Diseases, Adapted for Indexing of Hospital Records and Operation*

Classification (ICDA), completed in 1962 and expanding the ICD-7 in a number of areas to more completely meet the indexing needs of hospitals. The U.S. Public Health Service later published the *Eighth Revision, International Classification of Diseases, Adapted for Use in the United States,* commonly referred to as ICDA-8, for official national morbidity and mortality statistics. This was followed by the *ICD, 9th Revision, Clinical Modification*, known as ICD-9-CM, published by the U.S. Department of Health and Human Services and used by hospitals and other healthcare facilities to better describe the clinical picture of the patient. The diagnosis component of ICD-9-CM is completely consistent with ICD-9 codes, and remains the data standard for reporting morbidity. National adaptations of the ICD-10 progressed to incorporate both clinical code (ICD-10-CM) and procedure code (ICD-10-PCS) with the revisions completed in 2003. In 2009, the U.S. Centers for Medicare and Medicaid Services announced that it would begin using ICD-10 on April 1, 2010, with full compliance by all involved parties by 2013.*[20]

The years for which causes of death in the United States have been classified by each revision as follows:

Cause of death on United States death certificates, statistically compiled by the Centers for Disease Control and Prevention (CDC), are coded in the ICD, which does not include codes for human and system factors commonly called medical errors.*[26]*[27]

Mental and behavioral disorders

The ICD includes a section classifying mental and behavioral disorders (Chapter V). This has developed alongside the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM) and the two manuals seek to use the same codes. There are significant differences, however, such as the ICD including personality disorders in the same way as other mental disorders. The WHO is revising their classifications in these sections as part the development of the ICD-11 (scheduled for 2017), and an "International Advisory Group" has been established to guide this.*[28] An international survey of psychiatrists in 66 countries comparing use of the ICD-10 and DSM-IV found that the former was more often used for clinical diagnosis while the latter was more valued for research.*[29] The ICD is actually the official system for the US, although many mental health professionals do not realize this due to the dominance of the DSM. A psychologist has stated: "Serious problems with the clinical utility of both the ICD and the DSM are widely acknowledged." *[30]

15.26.4 See also

- Clinical coder
- Medical classifications
  - Classification of mental disorders
  - Classification of Pharmaco-Therapeutic Referrals
  - International Classification of Primary Care (ICPC)
  - Research Domain Criteria (RDoC), a framework being developed by the National Institute of Mental Health
- Medical diagnosis
  - Diagnosis-related group
- Medical terminology
  - Current Procedural Terminology
  - MedDRA (Medical Dictionary for Regulatory Activities)
  - Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)

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15.26.6 External links

Note: since adoption of ICD-10 CM in the USA, several online tools have been mushrooming. They all refer to that particular modification and thus are not linked here.

- Official website at World Health Organization (WHO)
- ICD-10 online browser (WHO)
- ICD-10 online training direct access (WHO)
- ICD-10-CM (USA – modification) at Centers for Disease Control and Prevention (CDC)
- ICD-10-CM/PCS codes
- ICD-11 Beta Draft

15.27 ICD-10

ICD-10 is the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD), a medical classification list by the World Health Organization (WHO). It contains codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases.*[1]

The code set allows more than 14,400 different codes and permits the tracking of many new diagnoses. The codes can be expanded to over 16,000 codes by using optional sub-classifications.*[2]

The WHO provides detailed information about ICD online, and makes available a set of materials online, such as an ICD-10 online browser,*[3] ICD-10 Training, ICD-10 online training,*[4] ICD-10 online training support,*[5] and study guide materials for download.

The International version of ICD should not be confused with national modifications of ICD that frequently include much more detail, and sometimes have separate sections for procedures. The US ICD-10 Clinical Modification (ICD-10-CM), for instance, has some 68,000 codes.*[6] The US also has the ICD-10 Procedure Coding System (ICD-10-PCS),*[7] a coding system that contains 76,000 procedure codes that is not used by other countries.

Work on ICD-10 began in 1983 and was completed in 1992.*[1]

15.27.1 List

The following is a list of ICD-10 codes.*[8]

15.27.2 National adoption for clinical use

Some 27*[9]*[10] countries use ICD-10 for reimbursement and resource allocation in their health system. A few of them have made modifications to ICD to better accommodate this use of ICD-10. The article below makes reference to some of these modifications. The unchanged international version of ICD-10 is used in about 110 countries for performing cause of death reporting and statistics.

Canada

Canada introduced ICD-10-CA in 2000.*[11] Canada implemented ICD-10 in a staggered fashion across nine of the 10 provinces between the years of 2001 and 2004. As data was returned, comparison was undertaken of information classified by ICD-9 and ICD-10, beginning with volumes and length of stay within major diagnostic groups.

The large scale realignment of individual diagnostic and procedural codes demanded close analysis of the impacts to existing indicators of healthcare delivery. Using data reported in 2001 and 2002, the Canadian Institute for Health Information, an independent organization that works with the federal government, tabulated the input. Rigorous statistical analysis was conducted to evaluate the comparability of ICD-9 codes to ICD-10 codes as they pertained to the Canadian version of diagnostic groups, Case Mix Groups (CMGs), which are used in the patient classification system to group together patients with similar characteristics.

China

China adopted ICD-10 in 2002.*[12]

Czech Republic

The Czech Republic adopted ICD-10 in 1994, one year after official release from WHO.*[13] The Czech Republic uses the international version without any local modifications. The Czech Republic adopted all updates to the international version (namely in 2004,2010,2011,2012).

France

France introduced a clinical addendum to ICD-10 in 2005. See also website of the ATIH.

Germany

Germany: ICD-10-GM (German Modification)*[14]

Korea

A Korean modification has existed since 2008.*[15]

Netherlands

The Dutch translation of ICD-10 is ICD10-nl, which was created by the WHO-FIC Network in 1994.*[16] There is an online dictionary.

South Africa

ICD-10 was implemented in July 2005 under the auspice of the National ICD-10 Implementation Task Team which is a joint task team between the National Department of Health and the Council for Medical Schemes.*[17]

Sweden

The current Swedish translation of ICD-10 was created in 1997. A clinical modification has added more detail and omits codes of the international version in the context of clinical use of ICD:

The codes F64.1 (Dual-role transvestism), F64.2 (Gender identity disorder of childhood), F65.0 (Fetishism), F65.1 (Fetishistic transvestism), F65.5 (Sadomasochism), F65.6 (Multiple disorders of sexual preference) are not used in Sweden since 1 January 2009 according to a decision by the present Director General of The National Board of Health and Welfare, Sweden. The code O60.0 (Preterm labor without delivery) is not used in Sweden; instead, since 1 January 2009, the Swedish extension codes to O47 (False labor) are recommended for use.

Thailand

A Thai modification has existed since 2007; the Ministry of Public Health has ICD 10 TM. and 1 of 3 first used ICD-10 Code with Czechoslovakia and Denmark in 1994

United Kingdom

ICD-10 was first mandated for use in the UK in 1995.*[18] In 2010 the UK Government made a commitment to update the UK mandated version of ICD-10 every three years.*[19] In line with this, the ICD-10 4th Edition was approved for NHS implementation on 1 April 2012 by the Information Standards Board for Health and Social Care.*[20] Due to the World Health Organization announcing a major update to the 2016 version of ICD-10; the planned release and use of ICD-10 5th Edition was postponed from 2015 until 2016.*[19] As such, ICD-10 5th Edition became the mandated diagnostic classification in the UK from 1 April 2016.*[21]

United States

The US has used ICD-10-CM since October 1, 2015.*[22] This national variant of ICD-10 was provided by the Centers for Medicare and Medicaid Services (CMS) and the National Center for Health Statistics (NCHS), and the use of ICD-10-CM codes are now mandated for all inpatient medical reporting requirements. There are over 70,000 ICD-10-CM codes, which is up from around 14,000 ICD-9-CM codes.*[22]

The use of ICD-10 for coding of death certificates and mortality data was mandated in the United States beginning in 1999.*[23]

The deadline for the United States to begin using Clinical Modification ICD-10-CM for diagnosis coding and Procedure Coding System ICD-10-PCS for inpatient hospital procedure coding was set at October 1, 2015,*[24]*[25] which is a year later than a previous 2014 deadline.*[26] Before that 2014 deadline, the previous deadline has been a year before that on October 1, 2013.*[27]*[28] All HIPAA "covered entities" must make the change; a pre-requisite to ICD-10-CM is the adoption of EDI Version 5010 by January 1, 2012.*[29] Enforcement of 5010 transition by the Centers for Medicare & Medicaid Services (CMS), however, was postponed by CMS until March 31, 2012, with the federal agency citing numerous factors, including slow software upgrades.*[30] The implementation of ICD-10-CM has been subject to previous delays. In January 2009, the date was pushed back by two years, to October 1, 2013 rather than an earlier proposal of October 1, 2011.*[31]

The most recent pushback of the implementation date has inspired a mixed reaction from the healthcare community.*[32] Even though the deadline for ICD-10 was pushed back repeatedly, CMS recommended that medical practices take several years to prepare for implementation of the new code set.*[33] The basic structure of the ICD-10 code is the following: Characters 1-3 (the category of disease); 4 (etiology of disease); 5 (body part affected), 6 (severity of illness) and 7 (placeholder for extension of the code to increase specificity). Not only must new software be installed and tested, but medical practices must provide training for physicians, staff members, and administrators. They will also need to develop new practice policies and guidelines, and update paperwork and forms. For convenience, practices may also create "crosswalks" that will convert their most frequently used ICD-9-CM codes to the ICD-10-CM equivalents.*[34]

15.27.3 References

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[3] ICD-10 online browser

[4] ICD-10 training tool

[5] ICD 10 Online Support

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15.27.4 External links

- Official website at World Health Organization (WHO)
- ICD-10 online browser (WHO)
- ICD-10 online training direct access (WHO)
- ICD-10-CM (USA – modification) at Centers for Disease Control and Prevention (CDC)
- ICD-10-CM/PCS codes

15.28 ICD-10 Procedure Coding System

The **ICD-10 Procedure Coding System** (**ICD-10-PCS**) is an international system of medical classification used for procedural coding. The Centers for Medicare and Medicaid Services, the agency responsible for maintaining the inpatient procedure code set in the U.S., contracted with 3M Health Information Systems in 1993 to design and then develop a procedure classification system to replace Volume 3 of ICD-9-CM. ICD-9-CM contains a procedure classification; ICD-10-CM does not. ICD-10-PCS is the result. ICD-10-PCS was initially released in 1998. It has been updated annually since that time.*[1]

15.28.1 Section structure

Each code consists of seven alphanumeric characters. The second through seventh characters mean the same thing within each section, but may mean different things in other sections. Each character can be any of 34 possible values the ten digits 0-9 and the 24 letters A-H,J-N and P-Z may be used in each character. The letters O and I excluded to avoid confusion with the numbers 0 and 1.*[2] There are no decimals in ICD-10-PCS*[3]

Of the 72,081 codes in ICD-10-PCS, 62,022 are in the first section, "Medical and surgical" .*[4]

Root operations

For medical/surgical, these are the root operation codes:

00 alteration; 01 bypass; 02 change; 03 control; 04 creation; 05 destruction; 06 detachment; 07 dilation; 08 division; 09 drainage; 0B excision; 0C extirpation; 0D extraction; 0F fragmentation; 0G fusion; 0H insertion; 0J inspection; 0K map; 0L occlusion; 0M reattachment; 0N release; 0P removal; 0Q repair; 0R replacement; 0S reposition; 0T resection; 0U supplement ; 0V restriction; 0X transfer; 0Y transplantation

They can be grouped into several categories:*[4]

- take out or eliminate all or a portion of a body part: excision (sigmoid polypectomy), resection (total nephrectomy), extraction (toenail extraction), destruction (rectal polyp fulguration), detachment (below knee amputation). For biopsies, "extraction" is used when force is required (as with endometrial biopsy), and "excision" is used when minimal force is involved (as with liver biopsy). See also ectomy.
- involve putting in or on, putting back, or moving living body part: transplantation (heart transplant), reattachment (finger reattachment), reposition (reposition undescended testicle), transfer (tendon transfer)
- take out or eliminate solid matter, fluids, or gases from a body part: drainage (incision and drainage), extirpation (thrombectomy), fragmentation (lithotripsy of gallstones)
- only involve examination of body parts and regions: inspection (diagnostic arthroscopy), map (cardiac mapping)
- involve putting in or on, putting back, or moving living body part: bypass (gastrojejunal bypass), dilation (coronary artery dilation), occlusion (fallopian tube ligation), restriction (cervical cerclage)
- always involve devices: insertion (pacemaker insertion), replacement (total hip replacement), supplement (herniorrhaphy using mesh), removal

(cardiac pacemaker removal), change (drainage tube change), revision (hip prosthesis adjustment)

- involve cutting and separation only: division (osteotomy), release (peritoneal adhesiolysis)
- involving other repair: control (control of post-prostatectomy bleeding), repair (suture of laceration)
- with other objectives: alteration (face lift), creation (artificial vagina creation), fusion (spinal fusion)

Regions

Regions: 0 Head; 1 Cervical, 2 Thoracic, 3 Lumbar, 4 Sacrum, 5 Pelvis, 6 Lower extremities, 7 Upper extremities, 8 Rib cage, 9 Abdomen

15.28.2 See also

- ICD-10 Clinical Modification

15.28.3 References

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15.28.4 External links

- 2011 ICD-10-PCS and GEMs
- ICD-10 PCS Procedure Code Reference
- ICD-10-PCS Code Browser
- Browser
- Search Engine for ICD-10 PCS and ICD-10 WHO 2010
- ICD-10-PCS Code Search

15.29 International Classification of Diseases for Oncology

The **International Classification of Diseases for Oncology** (**ICD-O**) is a domain-specific extension of the International Statistical Classification of Diseases and Related Health Problems for tumor diseases. This classification is widely used by cancer registries.

It is currently in its third revision (ICD-O-3). ICD-10 includes a list of morphology codes. They stem from ICD-O second edition (ICD-O-2) that was valid at the time of publication.

15.29.1 Axes

The classification has two axes: topography and morphology.

Morphology

The morphology axis is for the shape and structure of the tumor.

This axis has particular importance because the Systematized Nomenclature of Medicine ("SNOMED") has adopted the ICD-O classification of morphology. SNOMED has been changing continuously, and several different versions of SNOMED are in use. Accordingly, mapping of ICD-O codes to SNOMED requires careful assessment of whether entities are indeed true matches.

Topography

The topography axis is for of the tumor's site in the body. It is standardized with the C section of ICD-10.

There were no changes in the topography axis between ICD-O-2 and ICD-O-3.

See List of ICD-10 codes#(C00–C97) Malignant Neoplasms for examples.

15.29.2 International Classification of Diseases for Oncology, Third Edition (ICD-O-3)

5th Digit Behaviour Code for Neoplasms

- **/0** Benign
- **/1** Uncertain whether benign or malignant
  - Borderline malignancy
  - Low malignant potential
  - Uncertain malignant potential

- **/2** Carcinoma in situ
  - Intraepithelial
  - Noninfiltrating
  - Noninvasive
- **/3** Malignant, primary site
- **/6** Malignant, metastatic site
  - Malignant, secondary site
- **/9** Malignant, uncertain whether primary or metastatic site

15.29.3 Morphology Codes (ICD-O-3) *[1]

800 Neoplasms, NOS

M8000/0 Neoplasm, benign

- Tumor, benign
- Unclassified tumor, benign

M8000/1 Neoplasm, uncertain whether benign or malignant

- Neoplasm, NOS
- Tumor, NOS
- Unclassified tumor, uncertain whether benign or malignant
- Unclassified tumor, borderline malignancy

M8000/3 Neoplasm, malignant

- Tumor, malignant, NOS
- Malignancy
- Cancer
- Unclassified tumor, malignant
- Blastoma, NOS

M8000/6 Neoplasm, metastatic

- Neoplasm, metastatic
- Tumor, metastatic
- Tumor, secondary
- Tumor embolus

M8000/9 Neoplasm, malignant, uncertain whether primary or metastatic

- Unclassified tumor, malignant, uncertain whether primary or metastatic

M8001/0 Tumor cells, benign

M8001/1 Tumor cells, uncertain whether benign or malignant

- Tumor cells, NOS

M8001/3 Tumor cells, malignant

M8002/3 Malignant tumor, small cell type

M8003/3 Malignant tumor, giant cell type

M8004/3 Malignant tumor, spindle cell type

- Malignant tumor, fusiform cell type

M8005/0 Clear cell tumor, NOS

M8005/3 Malignant tumor, clear cell type

801–804 Epithelial Neoplasms, NOS

- (M8010/0) Epithelial tumor, benign
- (M8010/2) Carcinoma in situ, NOS
  - Intraepithelial carcinoma, NOS
- (M8010/3) Carcinoma, NOS
  - Epithelial tumor, malignant
- (M8010/6) Carcinoma, metastatic, NOS
  - Secondary carcinoma
- (M8010/9) Carcinomatosis
- (M8011/0) Epithelioma, benign
- (M8011/3) Epithelioma, malignant
  - Epithelioma, NOS
- (M8012/3) Large cell carcinoma, NOS
- (M8013/3) Large cell neuroendocrine carcinoma
- (M8014/3) Large cell carcinoma with rhabdoid phenotype
- (M8015/3) Glassy cell carcinoma
- (M8020/3) Carcinoma, undifferentiated, NOS
- (M8021/3) Carcinoma, anaplastic, NOS
- (M8022/3) Pleomorphic carcinoma
- (M8030/3) Giant cell and spindle cell carcinoma
- (M8031/3) Giant cell carcinoma

- (M8032/3) Spindle cell carcinoma, NOS
- (M8033/3) Pseudosarcomatous carcinoma
  - Sarcomatoid carcinoma
- (M8034/3) Polygonal cell carcinoma
- (M8035/3) Carcinoma with osteoclast-like giant cells
- (M8040/0) Tumorlet, benign
- (M8040/1) Tumorlet, NOS
- (M8041/3) Small cell carcinoma, NOS
  - Reserve cell carcinoma
  - Round cell carcinoma
  - Small cell neuroendocrine carcinoma
- (M8042/3) Oat cell carcinoma (C34._)
- (M8043/3) Small cell carcinoma, fusiform cell
- (M8044/3) Small cell carcinoma, intermediate cell
- (M8045/3) Combined small cell carcinoma
  - Mixed small cell carcinoma
  - Combined small cell-large cell carcinoma
  - Combined small cell-adenocarcinoma
  - Combined small cell-squamous cell carcinoma
- (M8046/3) Non-small cell carcinoma (C34._)

805-808 Squamous Cell Neoplasms

- (M8050/0) Papilloma, NOS *(except papilloma of bladder M8120/1)*
- (M8050/2) Papillary carcinoma in situ
- (M8050/3) Papillary carcinoma, NOS
- (M8051/0) Verrucous papilloma
- (M8051/3) Verrucous carcinoma, NOS
  - Condylomatous carcinoma
  - Verrucous squamous cell carcinoma
  - Verrucous epidermoid carcinoma
  - Warty carcinoma
- (M8052/0) Squamous cell papilloma, NOS
  - Squamous papilloma
  - Keratotic papilloma
- (M8052/2) Papillary squamous cell carcinoma, non-invasive
  - Papillary squamous cell carcinoma in situ
- (M8052/3) Papillary squamous cell carcinoma
  - Papillary epidermoid carcinoma
- (M8053/0) Squamous cell papilloma, inverted
- (M8060/0) Squamous papillomatosis
  - Papillomatosis, NOS
- (M8070/2) Squamous cell carcinoma in situ, NOS
  - Epidermoid carcinoma in situ, NOS
  - Intraepidermal carcinoma, NOS
  - Intraepithelial squamous cell carcinoma
- (M8070/3) Squamous cell carcinoma, NOS
  - Epidermoid carcinoma, NOS
  - Squamous carcinoma
  - Squamous cell epithelioma
- (M8070/6) Squamous cell carcinoma, metastatic, NOS
- (M8071/3) Squamous cell carcinoma, keratinizing, NOS
  - Squamous cell carcinoma, large cell, keratinizing
  - Epidermoid carcinoma, keratinizing
- (M8072/3) Squamous cell carcinoma, large cell, nonkeratinizing, NOS
  - Squamous cell carcinoma, non keratinizing, NOS
  - Epidermoid carcinoma, large cell, nonkeratinizing
- (M8073/3) Squamous cell carcinoma, small cell, nonkeratinizing
  - Epidermoid carcinoma, small cell, nonkeratinizing
- (M8074/3) Squamous cell carcinoma, spindle cell
  - Epidermoid carcinoma, spindle cell
  - Squamous cell carcinoma, sarcomatoid
- (M8075/3) Squamous cell carcinoma, adenoid
  - Squamous cell carcinoma, pseudoglandular
  - Squamous cell carcinoma, acantholytic
- (M8076/2) Squamous cell carcinoma in situ with questionable stromal invasion
  - Epidermoid carcinoma in situ with questionable stromal invasion
- (M8076/3) Squamous cell carcinoma, microinvasive

- (M8077/2) Squamous intraepithelial neoplasia, grade III
  - Cervical intraepithelial neoplasia, grade III (C53._)
    - CIN III, NOS (C53._)
    - CIN III with severe dysplasia (C53._)
  - Vaginal intraepithelial neoplasia, grade III (C52._)
    - VAIN III (C52._)
  - Vulvar intraepithelial neoplasia, grade III (C51._)
    - VIN III (C51._)
  - Anal intraepithelial neoplasia, grade III (C21.1)
    - AIN III (C21.1)
- (M8078/3) Squamous cell carcinoma with horn formation
- (M8080/2) Queyrat erythroplasia (C60._)
- (M8081/2) Bowen disease (C44._)
  - Intraepidermal squamous cell carcinoma, Bowen type (C44._)
- (M8082/3) Lymphoepithelial carcinoma
  - Lymphoepithelioma
  - Lymphoepithelioma-like carcinoma
  - Schmincke tumor (C11._)
- (M8083/3) Basaloid squamous cell carcinoma
- (M8084/3) Squamous cell carcinoma, clear cell type

809-811 Basal cell Neoplasms

- (M8090/1) Basal cell tumor (C44._)
- (M8090/3) Basal cell carcinoma, NOS (C44._)
  - Basal cell epithelioma
  - Rodent ulcer
  - Pigmented basal cell carcinoma
- (M8091/3) Multifocal superficial basal cell carcinoma (C44._)
  - Multicentric basal cell carcinoma
- (M8092/3) Infriltrating basal cell carcinoma, NOS (C44._)
  - Infiltrating basal cell carcinoma, non-sclerosing
  - Infiltrating basal cell carcinoma, sclerosing
  - Basal cell carcinoma, morpheic
  - Basal cell carcinoma, desmoplastic type
- (M8093/3) Basal cell carcinoma, fibroepithelial (C44._)
  - Fibroepithelioma of Pinkus type
  - Fibroepithelial basal cell carcinoma, Pinkus type
  - Pinkus tumor
  - Fibroepithelioma, NOS
- (M8094/3) Basosquamous carcinoma (C44._)
  - Mixed basal-squamous cell carcinoma
- (M8095/3) Metatypical carcinoma
- (M8096/0) Intraepidermal epithelioma of Jadassohn (C44._)
- (M8097/3) Basal cell carcinoma, nodular (C44._)
  - Basal cell carcinoma, micronodular
- (M8098/3) Adenoid basal carcinoma (C53._)
- (M8100/0) Trichoepithelioma (C44._)
  - Brooke tumor
  - Epithelioma adenoides cysticum
- (M8101/0) Trichofolliculoma (C44._)
- (M8102/0) Trichilemmoma (C44._)
- (M8102/3) Trichilemmocarcinoma (C44._)
  - Trichilemmal carcinoma
- (M8103/0) Pilar tumor (C44._)
  - Proliferating trichilemmal cyst
  - Proliferating trichilemmal tumor
- (M8110/0) Pilomatrixoma, NOS (C44._)
  - Calcifying epithelioma of Malherbe
  - Pilomatricoma, NOS
- (M8110/3) Pilomatrix carcinoma (C44._)
  - Pilomatrixoma, malignant
  - Pilomatricoma, malignant
  - Matrical carcinoma

812-813 Transitional cell Papillomas And Carcinomas

- (M8120/0) Transitional cell papilloma, benign
  - Transitional papilloma
- (M8120/1) Urothelial papilloma, NOS
  - Papilloma of baldder (C67._)
  - Transitional cell papilloma, NOS
- (M8120/2) Transitional cell carcinoma in situ
  - Urothelial carcinoma in situ
- (M8120/3) Transitional cell carcinoma, NOS
  - Urothelial carcinoma, NOS
  - Transitional carcinoma
- (M8121/0) Schneiderian papilloma, NOS (C30.0, C31._)
  - Sinonasal papilloma, NOS
  - Sinonasal papilloma, exophytic
  - Sinonasal papilloma, fungiform
  - Transitional cell papilloma, inverted, benign
  - Transitional papilloma, inverted, benign
- (M8121/1) Transitional cell papilloma, inverted, NOS
  - Transitional papilloma, inverted, NOS
  - Schneiderian papilloma, inverted
  - Columnar cell papilloma
  - Cylindrical cell papilloma
  - Oncocytic Schneiderian papilloma
- (M8121/3) Schneiderian carcinoma (C30.0, C31._)
  - Cylindrical cell carcinoma
- (M8122/3) Transitional cell carcinoma, spindle cell
  - Transitional cell carcinoma, sarcomatoid
- (M8123/3) Basaloid carcinoma
- (M8124/3) Cloacogenic carcinoma (C21.2)
- (M8130/1) Papillary transitional cell neoplasm of low malignant potential (C67._)
  - Papillary urothelial neoplasm of low malignant potential
- (M8130/2) Papillary transitional cell carcinoma, non-invasive (C67._)
  - Papillary urothelial carcinoma, non-invasive
- (M8130/3) Papillary transitional cell carcinoma (C67._)
  - Papillary urothelial carcinoma
- (M8131/3) Transitional cell carcinoma, micropapillary (C67._)

814–838 Adenomas And Adenocarcinomas

- (M8140/0) Adenoma, NOS
- (M8140/1) Atypical adenoma
  - Bronchial adenoma, NOS (C34._)
- (M8140/2) Adenocarcinoma in situ, NOS
- (M8140/3) Adenocarcinoma, NOS
- (M8140/6) Adenocarcinoma, metastatic, NOS
- (M8141/3) Scirrhous adenocarcinoma
  - Scirrhous carcinoma
  - Carcinoma with productive fibrosis
- (M8142/3) Linitis plastica (C16._)
- (M8143/3) Superficial spreading adenocarcinoma
- (M8144/3) Adenocarcinoma, intestinal type (C16._)
  - Carcinoma, intestinal type
- (M8145/3) Carcinoma, diffuse type (C16._)
  - Adenocarcinoma, diffuse type
- (M8146/0) Monomorphic adenoma
- (M8147/0) Basal cell adenoma
- (M8147/3) Basal cell adenocarcinoma
- (M8148/2) Glandular intraepithelial neoplasia, grade III
  - Prostatic intraepithelial neoplasia, grade III (C61.9)
    - PIN III
- (M8149/0) Canalicular adenoma
- (M8150/0) Islet cell adenoma (C25._)
  - Islet cell tumor, benign
  - Nesidioblastoma
  - Islet cell adeomatosis
- (M8150/1) Islet cell tumor, NOS (C25._)
- (M8150/3) Islet cell carcinoma (C25._)
  - Islet cell adenocarcinoma
- (M8151/0) Insulinoma, NOS (C25._)
  - Beta cell adenoma
- (M8151/3) Insulinoma, malignant (C25._)
  - Beta cell tumor, malginant

- (M8152/0) Glucagonoma, NOS (C25._)
  - Alpha cell tumor, NOS
- (M8152/3) Glucagonoma, malignant (C25._)
  - Alpha cell tumor, malignant
- (M8153/1) Gastrinoma, NOS
  - G cell tumor, NOS
  - Gastrin cell tumor
- (M8153/3) Gastinoma, malignant
  - G cell tumor, malignant
  - Gastrin cell tumor, malignant
- (M8154/3) Mixed islet cell and exocrine adenocarcinoma (C25._)
  - Mixed acinar-endocrine carcinoma
  - Mixed ductal-endocrine carcinoma
- (M8155/1) Vipoma, NOS
- (M8155/3) Vipoma, malignant
- (M8156/1) Somatostatinoma, NOS
  - Somatostatin cell tumor, NOS
- (M8156/3) Somatostatinoma, malignant
  - somatostatin cell tumor, malignant
- (M8157/1) Enteroglucagonoma, NOS
- (M8157/3) Enteroglucagonoma, malignant
- (M8160/0) Bile duct adenoma (C22.1, C24.0)
  - Cholangioma
- (M8160/3) Cholangiocarcinoma (C22.1, C24.0)
  - Bile duct carcinoma
  - Bile duct adenocarcinoma
- (M8161/0) (C22.1, C24.0)
- (M8161/3) Bile duct cystadenocarcinoma (C22.1, C24.0)
- (M8162/3) Klatskin tumor (C22.1, C24.0)
- (M8170/0) Liver cell adenoma (C22.0)
- (M8170/3) Hepatocellular carcinoma, NOS (C22.0)
  - Liver cell carcinoma
  - Hepatocarcinoma
  - Hepatoma, malignant
  - Hepatoma, NOS
- (M8171/3) Hepatocellular carcinoma, fibrolamellar (C22.0)
- (M8172/3) Hepatocellular carcinoma, scirrhous (C22.0)
  - Sclerosing hepatic carcinoma
- (M8173/3) Hepatocellular carcinoma, spindle cell variant (C22.0)
  - Hepatocellular carcinoma, sarcomatoid
- (M8174/3) Hepatocellular carcinoma, clear cell type (C22.0)
- (M8175/3) Hepatocellular carcinoma, pleomorphic type
- (M8180/3) Combined hepatocellular carcinoma and cholangiocarcinoma (C22.0)
  - Mixed hepatocellular and bilde duct carcinoma
  - Hepatocholangiocarcinoma
- (M8190/0) Trabecular adenoma
- (M8190/3) Trabecular adenocarcinoma
  - Trabecular carcinoma
- (M8191/0) Embryonal adenoma
- (M8200/0) Eccrine dermal cylindroma (C44._)
  - Turban tumor
  - Cylindroma of skin
- (M8200/3) Adenoid cystic carcinoma
  - Adenocystic carcinoma
  - Cylindroma, NOS *(except cylindroma of skin M8200/0)*
  - Adenocarcinoma, cylindroid
  - Bronchial adenoma, cylindroid (C34._)
- (M8201/2) Cribiform carcinoma in situ (C50._)
  - Ductal carcinoma in situ, cribiform type
- (M8201/3) Cribiform carcinoma, NOS
  - Ductal carcinoma, cribiform type
- (M8202/0) Microcystic adenoma (C25._)
- (M8204/0) Lactating adenoma
- (M8210/0) Adenomatous polyp, NOS
  - Polypoid adenoma
- (M8210/2) Adenocarcinoma in situ in adenomatous polyp

    - Adenocarcinoma in situ in tublar adenoma
    - Carcinoma in situ in adeomatous polyp
    - Adenocarcinoma in situ in polypoid adenoma
    - Adenocarcinoma in situ in a polyp, NOS
    - Carcinoma in situ in a polyp, NOS
- (M8210/3) Adenocarcinoma in adeonmatous polyp
    - Adenocarcinoma in tubular adenoma
    - Carcinoma in adeomatous polyp
    - Adenocarcinoma in polypoid adenoma
    - Adenocarcinoma in a polyp, NOS
    - Carcinoma in a polyp, NOS
- (M8211/0) Tubular adenoma, NOS
- (M8211/3) Tubular adenocarcinoma
    - Tubular carcinoma
- (M8212/0) Flat adenoma
- (M8213/0) Serrated adenoma (C18._)
    - Mixed adenomatous and hyperplastic polyp
- (M8214/3) Parietal cell carcinoma (C16._)
    - Parietal cell adenocarcinoma
- (M8215/3) Adenocarcinoma of anal glands (C21.1)
    - Adenocarcinoma of anal ducts
- (M8220/0) Adenomatous polyposis coli (C18._)
    - Familial polyposis coli
    - Adenomatosis, NOS
- (M8220/3) Adenocarcinoma in adenomatous polyposis
- (M8221/0) Multiple adenomatous polyps
- (M8221/3) Adenocarcinoma in multiple adenomatous polyps
- (M8230/2) Ductal carcinoma in situ, solid type (C50._)
    - Intraductal carcinoma, solid type
- (M8230/3) Solid carcinoma, NOS
    - Solid carcinoma with mucin formation
    - Solid adenocarcinoma with mucin formation
- (M8231/3) Carcinoma simplex
- (M8240/1) Carcinoid tumor of uncertain malignant potential
    - Carcinoid tumor, NOS, of appendix (C18.1)
    - Carcinoid, NOS, of appendix
    - Carcinoid tumor, argentaffin, NOS
    - Argentaffinoma, NOS
- (M8240/3) Carcinoid tumor, NOS *(except of appendix M8240/1)*
    - Carcinoid, NOS *(except of appendix)*
    - Typical carcinoid
    - Bronchial adenoma, carcinoid
- (M8241/3) Enterochromaffin cell carcinoid
    - Carcinoid tumor, argentaffin, malignant
    - Argentaffinoma, malignant
    - EC cell carcinoid
    - Serotonin producing carcinoid
- (M8242/1) Enterochromaffin-like cell carcinoid, NOS
    - ECL cell carcinoid, NOS
- (M8242/3) Enterochromaffin-like cell tumor, malignant
    - ECL cell carcinoid, malignant
- (M8243/3) Goblet cell carcinoid
    - Mucocarcinoid tumor
    - Mucinous carcinoid
- (M8244/3) Composite carcinoid
    - Combined carcinoid and adenocarcinoma
    - Mixed carcinoid-adenocarcinoma
- (M8245/1) Tubular carcinoid
- (M8245/3) Adenocarcinoid tumor
- (M8246/3) Neuroendocrine carcinoma, NOS
- (M8247/3) Merkel cell carcinoma (C44._)
    - Merkel cell tumor
    - Primary cutaneous neuroendocrine carcinoma
- (M8248/1) Apudoma
- (M8249/3) Atypical carcinoid tumor
- (M8250/1) Pulmonary adenomatosis (C34._)
- (M8250/3) Bronchiolo-alveolar adenocarcinoma, NOS (C34._)
    - Bronchiolo-alveolar carcinoma, NOS
    - Bronchiolar adenocarcinoma
    - Bronchiolar carcinoma
    - Alveolar cell carcinoma

- (M8251/0) Alveolar adenoma (C34._)
- (M8251/3) Alveolar adenocarcinoma (C34._)
  - Alveolar carcinoma
- (M8252/3) Bronchiolo-alveolar carcinoma, non-mucinous (C34._)
  - Bronchiolo-alveolar carcinoma, Clara cell
  - Bronchiolo-alveolar carcinoma, type II pneumocyte
- (M8253/3) Bronchiolo-alveolar carcinoma, mucinous (C32._)
  - Bronchiolo-alveolar carcinoma, goblet cell type
- (M8254/3) Bronchiolo-alveolar carcinoma, mixed mucinous and non-mucinous (C34._)
  - Bronchiolo-alveolar carcinoma, Clara cell and goblet cell type
  - Bronchiolo-alveolar carcinoma, type II pneumocyte and goblet cell type
  - Bronchiolo-alveolar carcinoma, indeterminate type
- (M8255/3) Adenocarcinoma combined with mixed subtypes
  - Adenomcarcinoma combined with other types of carcinoma
- (M8260/0) Papillary adenoma, NOS
  - Glandular papilloma
- (M8260/3) Papillary adenocarcinoma, NOS
  - Papillary carcinoma of thyroid (C73.9)
  - Papillary renal cell carcinoma (C64.9)
- (M8261/0) Villous adenoma, NOS
  - Villous papilloma
- (M8261/2) Adenocarcinoma in situ in villous adenoma
- (M8261/3) Adenocarcinoma in villous adenoma
- (M8262/3) Villous adenocarcinoma
- (M8263/0) Tubulovillous adenoma, NOS
  - villoglandular adenoma
  - Papillotubular adenoma
- (M8263/2) Adenocarcinoma in situ in tubulovillous adenoma
- (M8263/3) Adenocarcinoma in tubulovillous adenoma
  - Papillotubular adenocarcinoma
  - Tubulopapillary adenocarcinoma
- (M8264/0) Papillomatosis, glandular
  - Biliary papillomatosis (C22.1, C24.0)
- (M8270/0) Chromophobe adenoma (C75.1)
- (M8270/3) Chromophobe carcinoma (C75.1)
  - Chromophobe adenocarcinoma
- (M8271/0) Prolactinoma (C75.1)
- (M8272/0) Pituitary adenoma, NOS (C75.1)
- (M8272/3) Pituitary carcinoma, NOS (C75.1)
- (M8280/0) Acidophil adenoma (C75.1)
  - Eosinophil adenoma
- (M8280/3) Acidophil carcinoma (C75.1)
  - Acidophil adenocarcinoma
  - Eosinophil carcinoma
  - Eosinophil adenocarcinoma
- (M8281/0) Mixed acidophil-basophil adenoma (C75.1)
- (M8290/0) Oxyphilic adenoma
  - Oncocytic adenoma
  - Oncocytoma
  - Hurthle cell adenoma(C73.9)
  - Hurthle cell tumor
  - Follicular adenoma, oxyphilic cell (C73.9)
- (M8290/3) Oxyphilic adenocarcinoma
  - Oncocytic carcinoma
  - Oncocytic adenocarcinoma
  - Hurthlecell carcinoma (C73.9)
  - Hurthle cell adenocarcinoma
  - Follicular carcinoma, oxyphilic cell (C73.9)
- (M8300/0) Basophil adenoma (C75.1)
  - Mucoid cell adenoma
- (M8300/3) Basophil carcinoma (C75.1)
  - Basophil adenocarcinoma
  - Mucoid cell adenocarcinoma
- (M8310/0) Clear cell adenoma
- (M8310/3) Clear cell adenocarcinoma, NOS
  - Clear cell carcinoma
  - Clear cell adenocarcinoma, mesonephroid

- (M8311/1) Hypernephroid tumor
- (M8312/3) Renal cell carcinoma, NOS (C64.9)
  - Renal cell adenocarcinoma
  - Grawitz tumor
  - Hypernephroma
- (M8313/0) Clear cell adenofibroma (C56.9)
  - clear cell cystadenofibroma
- (M8313/1) Clear cell adenofibroma of borderline malignancy
  - Clear cell cystadenofibroma of borderline malignancy
- (M8313/3) Clear cell adenocarcinofibroma (C56.9)
  - Clear cell cystadenocarcinofibroma
- (M8314/3) Lipid-rich carcinoma (C50._)
- (M8315/3) Glycogen-rich carcinoma
- (M8316/3) Cyst-associated renal cell carcinoma (C64.9)
- (M8317/3) Renal cell carcinoma, chromophobe type (C64.9)
  - Chromophobe cell renal carcinoma
- (M8318/3) Renal cell carcinoma, sarcomatoid (C64.9)
  - Renal cell carcinoma, spindle cell
- (M8319/3) collecting duct carcinoma (C64.9)
  - Bellini duct carcinoma
  - Renal carcinoma, collecting duct type
- (M8320/3) Granular cell carcinoma
  - Granular cell adenocarcinoma
- (M8321/0) Chief cell adenoma (C75.0)
- (M8322/0) Water-clear cell adenoma (C75.0)
- (M8322/3) Water-clear cell adenocarcinoma (C75.0)
  - Water-celar cell carcinoma
- (M8323/0) Mixed cell adenoma
- (M8323/3) Mixed cell adenocarcinoma
- (M8324/0) Lipoadenoma
  - Adenolipoma
- (M8325/0) Metanephric adenoma (C64.9)
- (M8330/0) Follicular adenoma (C73.9)
- (M8330/1) Atypical follicular adenoma (C73.9)
- (M8330/3) Follicular adenocarcinoma, NOS (C73.9)
  - Follicular carcinoma, NOS
- (M8331/3) Follicular adenocarcinoma, well differentiated (C73.9)
  - Follicular carcinoma, well differentiated
- (M8332/3) Follicular adenocarcinoma, trabecular (C73.9)
  - Follicular carcinoma, trabecular
  - Follicular adenocarcinoma, moderately differentiated
  - FOlloicular carcinoma, moderatedly differentiated
- (M8333/0) Microfollicular adenoma, NOS (C73.9)
  - Fetal adenoma
- (M8333/3) Fetal adenocarcinoma
- (M8334/0) Macrofollicular adenoma (C73.9)
  - Colloid adenoma
- (M8335/3) Follicular carcinoma, minimally invasive (C73.9)
  - Follicular carcinoma, encapsulated
- (M8336/0) Hyalinizing trabecular adenoma (C73.9)
- (M8337/3)Insular carcinoma (C73.9)
- (M8340/3) Papillary carcinoma, follicular variant (C73.9)
  - Papillary adenocarcinoma, follicular variant
  - Papillary and follicular adenocarcinoma
  - Papillary and follicular carcinoma
- (M8341/3) Papillary microcarcinoma (C73.9)
- (M8342/3) Papillary carcinoma, oxyphilic cell (C73.9)
- (M8343/3) Papillary carcinoma, encapsulated (C73.9)
- (M8344/3) Papillary carcinoma, columnar cell (C73.9)
  - Papillary carcinoma, tall cell
- (M8345/3) Medullary carcinoma with amyloid stroma (C73.9)
  - Parafollicular cell carcinoma
  - C cell carcinoma

- (M8346/3) Mixed medullary-follicular carcinoma (C73.9)
- (M8347/3) Mixed medullary-papillary carcinoma (C73.9)
- (M8350/3) Nonencapsulated sclerosing carcinoma (c73.9)
  - Nonencapsulated sclerosing adenocarcinoma
  - Nonencapsulated sclerosing tumor
  - Papillary carcinoma, diffuse sclerosing
- (M8360/1) Multiple endocrine adenomas
  - Endocrine adenomatosis
- (M8361/0) Juxtaglomerular tumor (C64.9)
  - Reninoma
- (M8370/0) Adrenal cortical adenoma, NOS (C74.0)
  - Adrenal cortical tumor, benign
  - Adrenal cortical tumor, NOS
- (M8370/3) Adrenal cortical carcinoma (C74.0)
  - Adrenal cortical adenocarcinoma
  - Adrenal cortical tumor, malignant
- (M8371/0) Adrenal cortical adenoma, compact cell (C74.0)
- (M8372/0) Adrenal cortical adenoma, pigmented (C74.0)
  - Black adenoma
  - Pigmented adenoma
- (M8373/0) Adrenal cortical adenoma, clear cell (C74.0)
- (M8374/0) Adrenal cortical adenoma, glomerulosa cell (C74.0)
- (M8375/0) Adrenal cortical adenoma, mixed cell (C74.0)
- (M8380/0) Endometrioid adenoma, NOS
  - Endometrioid cystadenoma, NOS
- (M8380/1) Endometrioid adenoma, borderline malignancy
  - Endometrioid cystadenoma, borderline malignancy
  - Endometrioid tumor of low malignant potential
  - Atypical proliferative endometrioid tumor
- (M8380/3) Endometrioid adenocarcinoma, NOS
  - Endometrioid carcinoma, NOS
  - Endometrioid cystadenocarcinoma
- (M8381/0) Endometrioid adenofibroma, NOS
  - Endometrioid cystadenofibroma, NOS
- (M8381/1) Endometrioid adenofibroma, borderline malignancy
  - Endometrioid cystadenofibroma, borderline malignancy
- (M8381/3) Endometriod adenofibroma, malignant
  - Endometrioid cystadenofibroma, malignant
- (M8382/3) Endometrioid adenocarcinoma, secretory variant
- (M8383/3) Endometrioid adenocarcinoma, ciliated cell variant
- (M8384/3) Adenocarcinoma, endocervical type

839–842 Adnexal And Skin appendage Neoplasms

M8390/0 Skin appendage adenoma (C44._)

- Skin appendage tumor, benign
- Adnexal tumor, benign

M8390/3 Skin appendage carcinoma (C44._)

- Adnexal carcinoma

M8391/0 Follicular fibroma (C44._)

- Trichodiscoma
- Fibrofolliculoma
- Perifollicular fibroma

M8392/0 Syringofibroadenoma (C44._)

M8400/0 Sweat gland adenoma (C44._)

- Sweat gland tumor, benign
- Hidradenoma, NOS
- Syringadenoma, NOS

M8400/1 Sweat gland tumor, NOS (C44._)

M8400/3 Sweat gland adenocarcinoma (C44._)

- Sweat gland carcinoma
- Sweat gland tumor, malignant

M8401/0 Apocrine adenoma

- Apocrine cystadenoma

M8401/3 Apocrine adenocarcinoma
M8402/0 Nodular hidradenoma (C44._)

- Eccrine acrospiroma
- Clear cell hidradenoma

M8402/3 Nodular hidradenoma, malignant (C44._)

- Hidradenocarcinoma

M8403/0 Eccrine spiradenoma (C44._)

- Spiradenoma, NOS

M8403/3 Malignant eccrine spiradenoma (C44._)
M8404/0 Hidrocystoma (C44._)

- Eccrine cystadenoma

M8405/0 Papillary hidradenoma

- Hidradenoma papilliferum

M8406/0 Papillary syringadenoma (C44._)

- Papillary syringocystadenoma
- Syringocystadenoma papilliferum

M8407/0 Syringoma, NOS (C44._)
M8407/3 Sclerosing sweat duct carcinoma (C44._)

- Syringomatous carcinoma
- Microcystic adnexal carcinoma

M8408/0 Eccrine papillary adenoma (C44._)
M8408/1 Aggressive digital papillary adenoma (C44._)
M8408/3 Eccrine papillary adenocarcinoma (C44._)

- Digital papillary adenocarcinoma

M8409/0 Eccrine poroma (C44._)
M8410/0 Sebaceous adnoma (C44._)
M8410/3 Sebaceous adenocarcinoma (C44._)

- Sebaceous carcinoma

M8413/3 Eccrine adenocarcinoma (C44._)
M8420/0 Ceruminous adenoma (C44.2)
M8420/3 Ceruminous adenocarcinioma (C44.2)

- Ceruminous carcinoma

843 Mucoepidermoid Neoplasms

M8430/1 Mucoepidermoid tumor
M8430/3 Mucoepidermoid carcinoma

844–849 Cystic, Mucinous And Serous Neoplasms

M8440/0 Cystadenoma, NOS

- Cystoma, NOS

M8440/3 Cystadenocarcinoma, NOS
M8441/0 Serous cystadenoma, NOS

- Serous cystoma
- Serous microcystic adenoma

M8441/3 Serous cystadenocarcinoma, NOS (C56.9)

- Serous adenocarcinoma, NOS
- Serous carcinoma, NOS

M8442/1 Serous cystadenoma, borderline malignancy (C56.9)

- Serous tumor, NOS, of low malignant potential
- Atypical proliferating serous tumor

M8443/0 Clear cell cystadenoma (C56.9)
M8444/1 Clear cell cystic tumor of borderline malignancy (C56.9)

- Atypical proliferating clear cell tumor

M8450/0 Papillary cystadenoma, NOS (C56.9)
M8450/3 Papillary cystadenocarcinoma, NOS (C56.9)

- Papillocystic adenocarcinoma

M8451/1 Papillary cystadenoma, borderline malignancy (C56.9)
M8452/1 Solid pseudo papillary tumor (C25._)

- Papillary cystic tumor
- Solid and papillary epithelial neoplasm
- Solid and cystic tumor

M8452/3 Solid pseudopapillary carcinoma (C25._)

M8453/0 Intraductal papillary-mucinous adenoma (C25._)

M8453/1 Intraductal papillary-mucinous tumor with moderate dysplasia (C25._)

M8453/2 Intraductal papillary-mucinous carcinoma, non-invasive (C25._)

M8453/3 Intraductal papillary-mucinous carcinoma invasive (C25._)

M8454/0 Cystic tumor of atrio-ventricular node (C38.0)

M8460/0 Papillary serous cystadenoma, NOS (C56.9)

M8460/3 Papillary serous cystadenocarcinoma (C56.9)

- Papillary serous adenocarcinoma
- Micropapillary serous carcinoma

M8461/0 Serous surface papilloma (C56.9)

M8461/3 Serous surface papillary carcinoma (C56.9)

- Primary serous papillary carcinoma of peritoneum (C48.1)

M8462/1 Serous papillary cystic tumor of borderline malignancy (C56.9)

- Papillary serous cystadenoma, borderline malignancy
- Papillary serous tumor of low malignant potential
- Atypical proliferative papillary serous tumor

M8463/1 Serous surface papillary tumor of borderline malignancy (C56.9)

M8470/0 Mucinous cystadenoma, NOS (C56.9)

- Mucinous cystoma
- Pseudomucinous cystadenoma, NOS

m8470/1 Mucinous cystic tumor with moderate dysplasia (C25._)

M8470/2 Mucinous cystadenocarcinoma, non-invasive (C25._)

M8470/3 Mucinous cystadenocarcinoma/ NOS (C56.9)

- Pseudomucinous adenocarcinoma
- Pseudomucinous cystadenocarcinoma, NOS

M8471/0 Papillary mucinous cystadenoma, NOS (C56.9)

- Papillary pseudomucinous cystadenoma, NOS

M8471/3 papillary mucinous cystadenocarcinoma (C56.9)

- Papillary pseudomucinous cystadenocarcinoma

M8472/1 Mucinous cystic tumor of borderline malignancy (C56.9)

- Mucinous cystadenoma, borderline malignancy
- Pseudomucinous cystadenoma, borderline malignancy
- Mucinous tumor, NOS, of low malignant potential
- Atypical proliferative mucinous tumor

M8473/1 Papillary mucinous cystadenoma, borderline malignancy (C56.9)

- Papillary pseudomucinous cystadenoma borderline malignancy
- Papillary mucinous tumor of low malignant potential

M8480/0 Mucinous adenoma

M8480/3 Mucinous adenocarcinoma

- Mucinous carcinoma
- Colloid adenocarcinoma
- Colloid carcinoma
- Gelatinous adenocarcinoma
- Gelatinous carcinoma
- Mucoid adenocarcinoma
- Mucoid carcinoma
- Mucous adenocarcinoma
- Mucous carcinoma
- Pseudomyxoma peritonei with unknown primary site (C80.9)

M8480/6 Pseudomyxoma peritonei

M8481/3 Mucin-producing adenocarcinoma

- Mucin-producing carcinoma
- Mucin-secreting adenocarcinoma
- Mucin-secreting carcinoma

M8482/3 Mucinous adenocarcinoma, endocervical type
M8490/3 Signet ring cell carcinoma

- Signet ring cell adenocarcinoma

M8490/6 Metastatic signet ring cell carcinoma

- Krukenberg tumor

850–854 Ductal, Lobular And Medullary Neoplasms

M8500/2 Intraductal carcinoma, noninfiltrating, NOS

- Intraductal adenocarcinoma, noninfiltrating, NOS
- Intraductal carcinoma, NOS
- Ductal carcinoma in situ, NOS (C50._)
- DCIS, NOS
- Ductal intraepithelial neoplasia 3
- DIN 3

M8500/3 Infiltrating duct carcinoma, NOS (C50._)

- Infiltrating duct adenocarcinoma
- Duct adenocarcinoma, NOS
- Duct carcinoma, NOS
- Duct cell carcinoma
- Ductal carcinoma, NOS

M8501/2 Comedocarcinoma, noninfiltrating (C50._)

- Ductal carcinoma in situ, comedo type
- DCIS, comedo type

M8501/3 Comedocarcinoma, NOS (C50._)
M8502/3 Secretory carcinoma of breast (C50._)

- Juvenile carcinoma of breast

M8503/0 Intraductal papilloma

- Duct adenoma, NOS
- Ductal papilloma

M8503/2 Noninfiltrating intraductal papillary adenocarcinoma (C50._)

- Noninfiltrating intraductal papillary carcinoma
- Intraductal papillary adenocarcinoma, NOS
- Intraductal papillary carcinoma, NOS
- Ductal carcinoma in situ, papillary
- DCIS, papillary

M8503/3 Intraductal papillary adenocarcinoma with invasion (C50._)

- Infiltrating papillary adenocarcinoma
- Infiltrating and papillary adenocarcinoma

M8504/0 Intracystic papillary adenoma

- Intracystic papilloma

M8504/2 Noninfiltrating intracystic carcinoma
M8504/3 Intracystic carcinoma, NOS

- Intracystic papillary adenocarcinoma

M8505/0 Intraductal papillomatosis, NOS

- Diffuse intraductal papillomatosis

M8506/0 Adenoma of nipple (C50._)

- Subareolar duct papillomatosis

M8507/2 Intraductal micropapillary carcinoma (C50._)

- Ductal carcinoma in situ, micropapillary
- Intraductal carcinoma, clinging

M8508/3 Cystic hypersecretory carcinoma (C50._)
M8510/3 Medullary carcinoma, NOS

- Medullary adenocarcinoma

M8512/3 Medullary carcinoma with lymphoid stroma
M8513/3 Atypical medullary carcinoma (C50._)
M8514/3 Duct carcinoma, desmoplastic type
M8520/2 Lobular carcinoma in situ, NOS (C50._)

- Lobular carcinoma, noninfiltrating
- LCIS, NOS

M8520/3 Lobular carcinoma, NOS (C50._)

- Lobular adenocarcinoma

- Infiltrating lobular carcinoma, NOS

M8521/3 Infiltrating ductular carcinoma (C50._)

M8522/2 Intraductal carcinoma and lobular carcinoma in situ (C50._)

M8522/3 Infiltrating duct and lobular carcinoma (C50._)

- Lobular and ductal carcinoma
- Infiltrating duct and lobular carcinoma in situ
- Intraductal and lobular carcinoma
- Infiltrating lobular carcinoma and ductal carcinoma in situ

M8523/3 Infiltrating duct mixed with other types of carcinoma (C50._)

- Infiltrating duct and cribiform carcinoma
- Infiltrating duct and mucinous carcinoma
- Infiltrating duct and tubular carcinoma
- Infiltrating duct and colloid carcinoma

M8524/3 Infiltrating lobular mixed with other types of carcinoma (C50._)

M8525/3 Polymorphous low grade adenocarcinoma

- Terminal duct adenocarcinoma

M8530/3 Inflammatory carcinoma (C50._)

- Inflammatory adenocarcinoma

M8540/3 Paget disease, mammary (C50._)

- Paget disease of breast

M8541/3 Paget disease and infiltrating duct carcinoma of breast (C50._)

M8542/3 Paget disease, extramammary *(except paget disease of bone)*

M8543/3 Paget disease and intraductal carcinoma of breast (C50._)

8550 Acinar cell neoplasms

M8550/0 Acinar cell adenoma

- Acinar adenoma
- Acinic cell adenoma

M8550/1 Acinar cell tumor

- Acinic cell tumor

M8550/3 Acinar cell carcinoma

- Acinic cell adenocarcinoma
- Acinar adenocarcinoma
- Acinar carcinoma

M8551/3 Acinar cell cystadenocarcinoma

856–857 Complex epithelial neoplasms

M8560/0 Mixed squamous cell and glandular papilloma

M8560/3 Adenosquamous carcinoma

- Mixed adenocarcinoma and squamous cell carcinoma
- Mixed adenocarcionma and epidermoid carcinoma

M8561/0 Adenolymphoma (C07._, C08._)

- Warthin's tumor
- Papillary cystadenoma lymphomatosum

M8562/3 Epithelial-myoepithelial carcinoma

M8570/3 Adenocarcinoma with squamous metaplasia

- Adenoacanthoma

M8571/3 Adenocarcinoma with cartilaginous and osseus metaplasia

- Adenocarcinoma with cartilaginous metaplasia
- Adenocarcinoma with osseous metaplasia

M8572/3 Adenocarcinoma with spindle cell metaplasia

M8573/3 Adenocarcinoma with apocrine metaplasia

- Carcinoma with apocrine metaplasia

M8574/3 Adenocarcinoma with neuroendocrine differentiation

- Carcinoma with neuroendocrine differentiation

M8575/3 Metaplastic carcinoma, NOS

M8576/3 Hepatoid adenocarcinoma

- Hepatoid carcinoma

858 Thymic Epithelial Neoplasms

- M8580/0 Thymoma, benign (C37.9)
- M8580/1 Thymoma, NOS (C37.9)
- M8580/3 Thymoma, malignant, NOS (C37.9)
- M8581/1 Thymoma, type A, NOS (C37.9)
- Thymoma, spindle cell, NOS
- Thymoma, medullary, NOS

M8581/3 Thymoma, type A, malignant (C37.9)

- Thymoma, spindle cell, malignant
- Thymoma, medullary, malignant

M8582/1 Thymoma, type AB, NOS (C37.9)

- Thymoma, mixed type, NOS

M8582/3 thymoma, type AB, malignant (C37.9)

- Thymoma, mixed type, malignant

M8583/1 Thymoma, type B1, NOS (C37.9)

- Thymoma, lymphocyte-rich, NOS
- Thymoma, lymphocytic, NOS
- Thymoma, predominantly cortical, NOS
- Thymoma, organoid, NOS

M8583/3 Thymoma, type B1, malignant (C37.9)

- Thymoma, lymphocyte-rich, malignant
- Thymoma, lymphocytic, malignant
- Thymoma, predominantly cortical, malignant
- Thymoma, organoid, malignant

M8584/1 Thymoma, type B2, NOS (C37.9)

- Thymoma, cortical, NOS

M8584/3 Thymoma, type B2, malignant (C37.9)

- Thymoma, cortical, malignant

M8585/1 Thymoma, type B3, NOS (C37.9)

- Thymoma, epithelial, NOS
- Thymoma, atypical, NOS

m8585/3 Thymoma, type B3, malignant (C37.9)

- Thymoma, epithelial, malignant
- Thymoma, atypical, malignant
- Well differentiated thymic carcinoma

M8586/3 Thymic carcinoma, NOS (C37.9)

- Thymoma, type C

M8587/0 Ectopic hamartomatous thymoma

M8588/3 Spindle epithelial tumor with thymus-like element

- Spindle epithelial tumor with thymus-like differentiation
- SETTLE

M8589/3 Carcinoma showing thymus-like element

- Carcinoma showing thymus-like differentiation
- CASTLE

859–867 Specialized gonadal neoplasms

M8590/1 Sex cord-stromal tumor, NOS

- Sex cord/gonadal stromal tumor, NOS
- Testicular/ovarian stromal tumor

M8591/1 Sex cord-gonadal stromal tumor, incompletely differentiated

M8592/1 Sex cord-gonadal stromal tumor, mixed forms

M8593/1 Stromal tumor with minor sex cord elements

M8600/0 Thecoma, NOS

- Theca cell tumor

M8600/3 Thecoma, malignant

M8601/0 Thecoma, luteinized

M8602/0 Sclerosing stromal tumor

M8610/0 Luteoma, NOS

- Luteinoma

M8620/1) Granulosa cell tumor, NOS

- , adult type

M8620/3 Granulosa cell tumor, malignant

- Granulosa cell carcinoma
- Granulosa cell tumor, sarcomatoid

M8621/1 Granulosa cell-theca cell tumor

- Theca cell-granulosa cell tumor

M8622/1 Granulosa cell tumor, juvenile

M8623/1 Sex cord tumor with annular tubules

M8630/1 Androblastoma/Arrhenoblastoma, benign

M8630/1 Androblastoma/Arrhenoblastoma, NOS

M8630/3 Androblastoma/Arrhenoblastoma, malignant

M8631/0 Sertoli-Leydig cell tumor, well differentiated

M8631/1 Sertoli-Leydig cell tumor of intermediate differentiation

- Sertoli-Leydig cell tumor, NOS

M8631/3 Sertoli-Leydig cell tumor, poorly differentiated

- Sertoli-Leydig cell tumor, sarcomatoid

M8632/1 Gynandroblastoma

M8633/1 Sertoli-Leydig cell tumor, retiform

M8634/1 Sertoli-Leydig cell tumor, intermediate differentiation, with heterologous elements

- retiform, with heterologous elements

M8634/3 Sertoli-Leydig cell tumor, poorly differentiated, with heterologous elements

M8640/1 Sertoli tumor, NOS

- Pick tubular adenoma
- Sertoli cell adenoma
- Tubular androblastoma, NOS
- Testicular adenoma

M8640/3 Sertoli cell carcinoma (C62._)

M8641/0 Sertoli cell tumor with lipid storage

- Folliculome lipidique (C56.9)
- Tubular androblastoma with lipid storage
- Lipid-rich Sertoli cell tumor

M8642/1 large cell calcifying Sertoli cell tumor

M8650/0 Leydig cell tumor, bening (C62._)

M8650/3 Leydig cell tumor, malignant

- Interstitial cell tumor, malignant

M8660/0 Hilus cell tumor (C56.9)

- Hilar cell tumor

M8670/0 Lipid cell tumor of ovary (C56.9)

- Lipoid cell tumor of ovary
- Steroid cell tumor, NOS
- Masculinovoblastoma

M8670/3 Steroid cell tumor, malignant

M8641/0 Adrenal rest tumor

868–871 Paragangliomas And Glomus tumors

M8680/0 Paraganglioma, benign

M8680/1 Paraganglioma, NOS

M8680/3 paraganglioma, malignant

M8681/1 Sympathetic paraganglioma

M8682/1 Parasympathetic paraganglioma

M8683/0 Gangliocytic paraganglioma (C17.0)

M8690/1 Glomus jugulare tumor, NOS (C75.5)

- Jugular/jugulotympanic paranglioma

M8691/1 Aortic body tumor (C75.5)

- Aortic/aorticopulmonary paraganglioma

M8692/1 Carotid body tumor/paraganglioma (C75.4)

M8693/1 Extra-adrenal paraganglioma, NOS

- Nonchromaffin paraganglioma, NOS
- Chemodectoma

M8693/3 Extra-adrenal paraganglioma, malignant

- Nonchromaffin paraganglioma, malignant

M8700/0 Pheochromocytoma, NOS (C74.1)

- Adrenal medullary/chromaffin paraganglioma

- Chromaffin tumor
- Chromaffinoma

M8700/3 Pheochromocytoma, malignant (C74.1)

- Adrenal medullary paraganglioma, malignant
- Pheochromoblastoma

M8710/3 Glomangiosarcoma

- Glomoid sarcoma

M8711/0 Glomus tumor, NOS
M8711/3 Glomus tumor, Malignant
M8712/0 Glomangioma
M8713/0 Glomangiomyoma

872–879 Nevi And Melanomas

M8720/0 Pigmented nevus, NOS

- Melanocytic nevus
- Nevus, NOS
- Hairy nevus

M8720/2 Melanoma in situ
M8720/3 Malignant melanoma, NOS (except juvenile melanoma M8770/0)

- Melanoma, NOS

M8721/3 Nodular melanoma
M8722/0 Balloon cell nevus
M8722/3 Balloon cell melanoma
M8723/0 Halo nevus

- Regressing nevus

M8723/3 Malignant melanoma, regressing
M8725/0 Neuronevus
M8726/0 Magnocellular nevus (C69.4)

- Melanocytoma, eyeball
- Melanocytoma, NOS

M8727/0 Dysplastic nevus
M8727/0 dysplastic nevus
M8728/0 Diffuse melanocytosis
M8728/1 Meningeal melanocytoma (C70.9)
M8728/3 Meningeal melanomatosis (C70.9)
M8730/0 Nonpigmented nevus

- Achromic nevus

M8740/0 Junctional nevus, NOS

- Intraepidermal nevus

M8740/3 Malignant melanoma in junctional nevus
M8741/2 Precancerous melanosis, NOS
M8741/3 Malignant melanoma in precancerous melanosis
M8742/3 Lentigo maligna melanoma

- Hutchinson melanotic freckle

M8743/3 Superficial spreading melanoma
M8744/3 Acral lentiginous melanoma, malignant
M8745/3 * Desmoplastic melanoma, malignant

- Neurotropic melanoma, malignant
- Melanoma, desmoplastic, amelanotic

M8746/3 Mucosal lentiginous melanoma
M8750/0 Intradermal nevus

- Dermal nevus

M8760/0 compound nevus

- Dermal and epidermal nevus

M8761/0 Small congenital nevus
M8761/1 Giant pigmented nevus, NOS

- Intermediate and giant congenital nevus

M8761/3 Malignant melanoma in giant pigmented nevus/congenital melanocytic nevus
M78762/1 Proliferative dermal lesion in congenital nevus
M8770/0 Epithelioid and spindle cell nevus

- Juvenile nevus

- Juvenile melanoma
- Spitz nevus
- Pigmented spindle cell nevus of Reed

M8770/3 Mixed epithelioid and spindle cell melanoma
M8771/0 Epithelioid cell nevus
M8771/3 Epithelioid cell melanoma
M8772/0 spindle cell nevus, NOS
M8772/3 Spindle cell melanoma, NOS
M8773/3 Spindle cell melanoma, type A
M8774/3 Spindle cell melanoma, type B
M8780/0 Blue nevus, NOS

- Jadassohn blue nevus

M8780/3 blue nevus, malignant
M8790/0 Cellular blue nevus

880 Soft tissue Tumors And Sarcomas, NOS

M8800/0 Soft tissue tumor, benign
M8800/3 Sarcoma, NOS

- Soft tissue sarcoma
- Soft tissue/mesenchymal tumor, malignant

M8800/9 Sarcomatosis, NOS
M8801/3 Spindle cell sarcoma
M8802/3 Giant cell sarcoma (except of bone M9250/3)

- Pleomorphic cell sarcoma

M8803/3 Small cell sarcoma

- Round cell sarcoma

M8804/3 Epithelioid sarcoma

- Epithelioid cell sarcoma

M8805/3 Undifferentiated sarcoma
M8806/3 Desmoplastic small round cell tumor

881–883 Fibromatous neoplasms

M8810/0 Fibroma, NOS
M8810/1 Cellular fibroma (C56.9)
M8810/3 Fibrosarcoma, NOS
M8811/0 Fibromyxoma

- Myxoid fibroma
- Myxofibroma, nos

m8811/3 Fibromyxosarcoma
M8812/0 Periosteal fibroma (C40._, C41._)

- Periosteal sarcoma, NOS

M8813/0 Fascial fibroma
M8813/3 Fascial fibrosarcoma
M8814/3 Infantile fibrosarcoma

- Congenital fibrosarcoma

M8815/0 Solitary fibrous tumor

- Localized fibrous tumor

M8815/3 Solitary fibrous tumor, malignant
M8820/0 Elastofibroma
M8821/1 Aggressive fibromatosis

- Extra-abdominal desmoid
- Desmoid, NOS
- Invasive fibroma

M8822/1 Abdominal fibromatosis

- Abdominal desmoid
- Mesenteric fibromatosis (C48.1)
- Retroperitoneal fibromatosis (C48.0)

M8823/0 Desmoplastic fibroma
M8824/0 Myofibroma
M8824/1 Myofibromatosis

- Congenital generalized fibromatosis
- Infantile myofibromatosis

M8825/0 Myofibroblastoma
M8825/1 Myofibroblastic tumor, nos

- Inflammatory myofibroblastic tumor

M8826/0 Angiomyofibroblastoma
M8827/1 Myobfibroblastic tumor, peribronchial (C34._)

- congenital peribronchial myofibroblastic tumor

M8830/0 Benign fibrous histiocytoma

- Fibrous histiocytoma, NOS
- Fibroxanthoma, NOS
- Xantofibroma

M8830/1 Atypical fibrous histiocytoma

- Atypical fibroxanthoma

M8830/3 Malignant fibrous histiocytoma

- Fibroxanthoma, malignant

M8831/0 Histiocytoma, NOS

- Deep histiocytoma
- Juvenile histiocytoma
- Reticulohistiocytoma

M8832/0 Dermatofibroma, NOS (C44._)

- Sclerosing hemangioma
- Cutaneous histiocytoma
- Subepidermal nodular fibrosis
- Dermatofibroma lenticulare

M8832/3 Dermatofibrosarcoma, NOS (C44._)

- Dermatofibrosarcoma protuberans, NOS

M8833/3 Pigmented dermatofibrosarcoma protuberans

- Bednar tumor

M8834/1 Giant cell fibroblastoma
M8835/1 Plexiform fibrohistiocytic tumor
M8836/1 Angiomatoid fibrous histiocytoma

884 Myxomatous neoplasms

M8840/0 Myxoma, NOS
M8840/3 Myxosarcoma
M8841/1 Angiomyxoma

- Aggressive angiomyxoma

M8842/0 Ossifying fibromyxoid tumor

885–888 Lipomatous neoplasms

M8850/0 Lipoma, NOS
M8850/1 Atypical lipoma

- Superficial well differentiated liposarcoma
- Well differentiated liposarcoma of superficial soft tissue

M8850/3 Liposarcoma, NOS

- Fibroliposarcoma

M8851/0 Fibrolipoma
M8851/3 Liposarcoma, well differentiated

- Liposarcoma, differentiated
- Lipoma-like liposarcoma
- Sclerosing liposarcoma
- Inflammatory liposarcoma

M8852/0 Fibromyxolipoma

- Myxolipoma

M8852/3 Myxoid liposarcoma

- Myxoliposarcoma

M8853/3 Round cell liposarcoma
M8854/0 Pleomorphic lipoma
M8854/3 Pleomorphic liposarcoma
M8855/3 Mixed liposarcoma
M8856/0 Intramuscular lipoma

- Infiltrating lipoma/angiolipoma

M8857/0 Spindle cell lipoma
M8857/3 Fibroblastic liposarcoma
M8858/3 Dedifferentiated liposarcoma
M8860/0 Angiomyolipoma
M8861/0 Angiolipoma, NOS
M8862/0 Chondroid lipoma
M8870/0 Myelolipoma
M8880/0 Hibernoma

- Fetal fat cell lipoma

- Brown fat tumor

M8881/0 Lipoblastomatosis

- Fetal lipoma, NOS
- Fetal lipomatosis
- Lipoblastoma

889–892 Myomatous neoplasms

M8890/0 Leiomyoma, NOS

- Fibroid uterus (C55.9)
- Fibromyoma
- Leiomyofibroma
- Plexiform leiomyoma
- Lipoleiomyoma

M8890/1 Leiomyomatosis, NOS

- Intravascular leiomyomatosis

M8890/3 Leiomyosarcoma, NOS

M8891/0 Epithelioid leiomyoma

- Leiomyoblastoma

M8891/3 Epithelioid leiomyosarcoma

M8892/0 Cellular leiomyoma

M8893/0 Bizarre leiomyoma

- Symplastic/atypical/pleomorphic leiomyoma

M8894/0 Angiomyoma

- Vascular leiomyoma
- Angioleiomyoma

M8894/3 Angiomyosarcoma

M8895/0 Myoma

M8895/3 Myosarcoma

M8896/3 Myxoid leiomyosarcoma

M8897/1 Smooth muscle tumor of uncertain malignant potential

- Smooth muscle tumor, NOS

M8898/1 Metastasizing leiomyoma

M8900/0 Rhabdomyoma, NOS

M8900/3 Rhabdomyosarcoma, NOS

- Rhabdosarcoma

M8901/3 Pleomorphic rhabdomyosarcoma, adult type

- Pleomorphic rhabdomyosarcoma, NOS

M8902/3 Mixed type rhabdomyosarcoma

- Mixed embryonal rhabdomyosarcoma and alveolar rhabdomyosarcoma

M8903/0 Fetal rhabdomyoma

M8904/0 Adult rhabdomyoma

- Glycogenic rhabdomyoma

M8905/0 Genital rhabdomyoma

M8910/3 Embryonal rhabdomyosarcoma, NOS

- Embryonal rhabdomyosarcoma, pleomorphic
- Sarcoma botryoides
- Botryoid sarcoma

M8912/3 Spindle cell rhabdomyosarcoma

M8920/3 Alveolar rhabdomyosarcoma

M8921/3 Rhabdomyosarcoma with ganglionic differentiation

- Ectomesenchymoma

893–899 Complex Mixed And Stromal Neoplasms

M8930/0 Endometrial stromal nodule

M8930/3 Endometrial stromal sarcoma, NOS

- Endometrial sarcoma, NOS
- Endometrial stromal sarcoma, high grade

M8931/3 Endometrial stromal sarcoma, low grade

- Endolymphatic stromal myosis
- Endometrial stromatosis
- Stromal endometriosis
- Stromal myosis, NOS

M8932/0 Adenomyoma

- Atypical polypoid adenomyoma

M8933/3 Adenosarcoma
M8934/3 Carcinofibroma
M8935/0 Stromal tumor, benign
M9835/1 Stromal tumor, NOS
M8935/3 Stromal sarcoma, NOS
M8936/0 Gastrointestinal stromal tumor, benign

- GIST, benign

M8936/1 Gastrointestinal stromal tumor, NOS

- GIST, NOS/uncertain malignant potential
- Gastrointestinal autonomic nerve tumor (GANT)
- Gastrointestinal pacemaker cell tumor

M8936/3 Gastrointestinal stromal sarcoma

- GIST, malignant

M8940/0 Pleomorphic adenoma

- Mixed tumor, NOS
- Mixed tumor, salivary gland type, NOS
- Chondroid syringoma

M8940/3 Mixed tumor, malignant, NOS

- Mixed tumor, malignant, NOS
- Mixed tumor, salivary gland type, malignant
- Malignant chondroid syringoma

M8941/3 Carcinoma in pleomorphic adenoma
M8950/3 Mullerian mixed tumor
M8951/3 Mesodermal mixed tumor
M8959/0 Benign cystic nephroma
M8959/1 Cystic partially differentiated nephroblastoma
M8959/3 Malignant cystic nephroma

- Malignant multilocular cystic nephroma

M8960/1 Mesoblastic nephroma
M8960/3 Nephroblastoma, NOS

- Wilms's tumor
- Nephroma, NOS

M8963/3 malignant rhabdoid tumor

- Rhabdoid sarcoma
- Rhabdoid tumor, NOS

M8964/3 Clear cell sarcoma of kidney
M8965/0 Nephrogenic adenofibroma
M8966/0 Renomedullary interstitial cell tumor

- Renomedullary fibroma

M8967/0 Ossifying renal tumor
M8970/3 Hepatoblastoma

- Embryonal hepatoma

M8971/3 Pancreatoblastoma
M8972/3 Pulmonary blastoma

- Pneumoblastoma

M8973/3 Pleuropulmonary blastoma
M8974/1 Sialoblastoma
M8980/3 Carcinosarcoma, NOS
M8981/3 Carcinosarcoma, embryonal
M8982/0 Myoepithelioma

- Myoepithelial tumor
- Myoepithelial adenoma

M8982/3 Malignant myoepithelioma

- Myoepithelial carcinoma

M8983/0 Adenomyoepithelioma
M8990/0 Mesencymoma, benign
M8990/1 Mesenchymoma, NOS

- Mixed mesenchymal tumor

M8990/3 Mesenchymoma, malignant

- Mixed mesenchymal sarcoma

M8991/3 Embryonal sarcoma

9000–9030) Fibroepithelial Neoplasms

M9000/0 Brenner tumor, NOS

M9000/1 Brenner tumor, borderline malignancy

- Brenner tumor, proliferating

M9000/3 Brenner tumor, malignant

M9010/0 Fibroadenoma, NOS

M9011/0 Intracanalicular fibroadenoma

M9012/0 Pericanalicular fibroadenoma

M9013/0 Adenofibroma, NOS

- Cystadenofibroma, NOS
- Papillary adenofibroma

M9014/0 Serous adenofibroma, NOS

- Serous cystadenofibroma, NOS

M9014/1 Serous adenofibroma of borderline malignancy

- Serous cystadenofibroma of borderline malignancy

M9014/3 Serous adenocarcinofibroma

- Malignant serous adenofibroma
- Serous cystadenocarcinofibroma
- Malignant serous cystadenofibroma

M9015/0 Mucinous adenofibroma, NOS

- Mucinous cystadenofibroma, NOS

M9015/1 Mucinous adenofibroma of borderline malignancy

- Mucinous cystadenofibroma of borderline malignancy

M9015/3 Mucinous adenocarcinofibroma

- Malignant mucinous adenofibroma
- Mucinous cystadenocarcinofibroma
- Malignant mucinous cystadenofibroma

M9016/0 Gian fibroadenoma

M9020/0 Phyllodes tumor, benign

- Cystosarcoma phyllodes, benign

M9020/1 Phyllodes tumor, borderline

- Cystosarcoma phyllodes, NOS
- Phyllodes tumor, NOS

M9020/3 Phyllodes tumor, malignant

- Cystosarcoma phyllodes, malignant

M9030/0 Juvenile fibroadenoma

904 Synovial-Like Neoplasms

M9040/0 Synovioma, benign

M9040/3 Synovial sarcoma, NOS

- Synovioma, NOS
- Synovioma, malignant

M9041/3 Synovial sarcoma, spindle cell

- Synovial sarcoma, monophasic fibrous

M9042/3 Synovial sarcoma, epithelioid cell

M9043/3 Synovial sarcoma, biphasic

M9044/3 Clear cell sarcoma, NOS (except of kiney M9864/3)

- Clear cell sarcoma, of tendons and aponeuroses
- Melanoma, malignant, of soft parts

905 Mesothelial Neoplasms

M9050/0 Mesothelioma, benign

M9050/3 Mesothelioma, malignant or NOS

M9051/0 Fibrous mesothelioma, benign

M9051/3 Fibrous mesothelioma, malignant or NOS

- Spindled mesothelioma
- Sarcomatoid mesothelioma
- Desmoplastic mesothelioma

M9052/0 Epithelioid mesothelioma, benign

- Well differentiated papillary mesothelioma, benign
- mesothelial papilloma

M9052/3 Epithelioid mesothelioma, malignant or NOS
M9053/3 Mesothelioma, biphasic, malignant or NOS
M9054/0 Adenomatoid tumor, NOS
M9055/0 Multicystic mesothelioma, benign

- Cystic mesothelioma, benign

M9055/1 cystic mesothelioma, NOS

906–909 Germ cell Neoplasms

M9060/3 Dysgerminoma
M9061/3 Seminoma, NOS
M9062/3 Seminoma, anaplastic

- Seminoma with high mitotic index

M9063/3 Spermatocytic seminoma

- Spermatocytoma

M9064/2 Intratubular malignant germ cells

- Intratubular germ cell neoplasia

M9064/3 Germinoma

- Germ cell tumor, NOS

M9065/3 Germ cell tumor, nonseminomatous
M9070/3 Embryonal carcinoma, NOS

- Embryonal adenocarcinoma

M9071/3 Yolk sac tumor

- Endodermal sinus tumor
- Polyvesicular vitelline tumor
- Orchioblastoma
- Embryonal carcinoma, infantile
- Hepatoid yolk sac tumor

M9072/3 Polyembryoma

- Embryonal carcinoma, polyembryonal type

M9073/1 Gonadoblastoma

- Gonocytoma

M9080/0 Teratoma, benign

- Adult cystic teratoma
- Adult/cystic teratoma, NOS
- Teratoma, differentiated
- Mature teratoma

M9080/1 Teratoma, NOS

- Solid teratoma

M9080/3 Teratoma, malignant, NOS

- Embryonal teratoma
- Teratoblastoma, malignant
- Immature teratoma, malignant or NOS

M9081/3 Teratocarcinoma

- Mixed embryonal carcinoma and teratoma

M9082/3 malignant teratoma, undifferentiated

- Malignant teratoma, anaplastic

M9083/3 Malignant teratoma, intermediate
M9084/0 Dermoid cyst, NOS

- Dermoid, NOS

M9084/3 Teratoma with malignant transformation

- Dermoid cyst with malignant transformation or with secondary tumor

M9085/3 mixed germ cell tumor

- Mixed teratoma and seminoma

M9090/0 Struma ovarii, NOS
M9090/3 Struma ovarii, malignant
M9091/1 Strumal carcinoid

- Struma ovarii and carcinoid

910 Trophoblastic neoplasms

M9100/0 Hydatidifrom mole, NOS

- Hydatid mole
- Complete hydatidiform mole

M9100/1 Invasive hydatidiform mole

- Chorioadenoma /destruens
- Chorioadenoma
- Invasive mole, NOS
- Malignant hydatidiform mole

M9100/3 Choriocarcinoma, NOS

- Chorionepithelioma
- Chorioepithelioma

M9101/3 Choriocarcinoma combined with other germ cell elements

- combined with teratoma
- combined with embryonal carcinoma

M9102/3 Malignant teratoma, trophoblastic
M9103/0 Partial hydatidiform mole
M9104/1 Placental site trophoblastic tumor
M9105/3 Trophoblastic tumor, epithelioid

911 Mesonephromas

M9110/0 Mesonephroma, benign

- Mesonephric adenoma
- Wolffian duct adenoma

M9110/1 Mesonephric tumor, NOS

- Wolffian duct tumor

M9110/3 Mesonephroma, malignant

- Mesonephric adenocarcinoma
- Mesonephroma, NOS
- Wolffian duct carcinoma

912–916 Blood vessel tumors

M9120/0 Hemangioma, NOS

- Angioma, NOS
- Chorioangioma

M9120/3 Hemangiosarcoma

- Angiosarcoma

M9121/0 Cavernous hemangioma
M9122/0 Venous hemangioma
M9123/0 Racemose hemangioma

- Arteriovenous hemangioma

M9124/3 Kupffer cell sarcoma
M9125/0 Epithelioid hemangioma

- Histiocytoid hemangioma

M9130/0 Hemangioendothelioma, benign
M9130/1 Hemangioendothelioma, NOS

- Angioendothelioma
- Kaposiform hemangioendothelioma

M9130/3 Hemangioendothelioma, malignant

- Hemangioendothelial sarcoma

M9131/0 Capillary hemangioma

- Hemangioma simplex
- Infantile/plexiform/juvenile hemangioma

M9132/0 Intramuscular hemangioma
M9133/1 Epithelioid hemangioendothelioma, NOS
M9133/3 Epithelioid hemangioendothelioma, malignant

- Intravascular bronchial alveolar tumor

M9135/1 Endovascular papillary angioendothelioma

- Dabska tumor

M9136/1 Spindle cell hemangioendothelioma

- Spindle cell angioendothelioma

M9140/3 Kaposi's sarcoma

- Multiple hemorrhagic sarcoma

M9141/0 Angiokeratoma
M9142/0 Verrucous keratotic hemangioma
M9150/0 Hemangiopericytoma, benign
M9150/1 Hemangiopericytoma, NOS

- Hemangiopericytic meningioma

M9150/3 Hemangiopericytoma, malignant
M9160/0 angiofibroma, NOS

- Juvenile angiofibroma
- Fibrous papule of nose
- Involuting nevus
- Giant cell or cellular angiofibroma

M9161/0 Acquired tufted hemangioma
M9161/1 Hemangioblastoma

- Angioblastoma

M9150/0 Hemangiopericytoma, benign
M9150/1 Hemangiopericytoma, NOS

917 Lymphatic vessel tumors

M9170/0 Lymphangioma, NOS

- Lymphangioendothelioma, NOS

M9170/3 Lymphangiosarcoma

- Lymphangioendothelial sarcoma
- Lymphangioendothelioma, malignant

M9171/0 Capillary lymphangioma
M9172/0 Cavernous lymphangioma
M9173/0 Cystic lymphangioma

- Hygroma, NOS
- Cystic Hygroma

M9174/0 Lymphangiomyoma
M9174/1 Lymphangiomyomatosis

- Lymphangioleiomyomatosis

M9175/0 Hemolymphangioma

918–924 Osseous And Chondromatous neoplasms

M9180/0 Osteoma, NOS
M9180/3 Osteosarcoma, NOS

- Osteogenic sarcoma, NOS
- Osteochondrosarcoma
- Osteoblastic sarcoma

M9181/3 Chondroblastic osteosarcoma
M9182/3 Fibroblastic osteosarcoma

- Osteofibrosarcoma

M9183/3 Telangeictatic osteosarcoma
M9184/3 Osteosarcoma in Paget disease of bone
M9185/3 Small cell osteosarcoma

- Round cell osteosarcoma

M9186/3 Central osteosarcoma

- Conventional central osteosarcoma
- Medullary osteo sarcoma

M9187/3 Intraosseous well differentiated osteosarcoma

- Intraosseous low grade osteosarcoma

M9191/0 Osteoid osteoma, NOS
M9192/3 Parosteal osteosarcoma

- Juxtacortical osteosarcoma

M9193/3 Periosteal osteosarcoma
M9194/3 High grade surface osteosarcoma
M9195/3 Intracortical osteosarcoma
M9200/0 Osteoblastmoa, NOS

- Giant osteoid ostemoa

M9200/1 Aggressive osetoblastoma
M9210/0 Osteochondroma

- Cartilagionus exostosis
- Cartilaginous exostosis
- Ecchondroma

M9210/1 Osteochondromatosis, NOS

- Ecchondrosis

M9220/0 Chondroma, NOS

- Enchondroma

M9220/1 Condromatosis, NOS
M9220/3 Chondrosarcoma, NOS

- Fibrochondrosarcoma

M9221/0 Juxtacortical chondroma

- Periosteal chondroma

M9221/3 Juxtacortical chondrosarcoma

- Periosteal chondrosarcoma

M9230/0 Chondroblastoma, NOS

- Chondromatous giant cell tumor
- Codman tumor

M9230/3 Chondroblastoma, malignant
M9231/3 Myxoid chondrosarcoma
M9240/3 Mesenchymal chondrosarcoma
M9241/0 Chondromyxoid fibroma
M9242/3 Clear cell chondrosarcoma
M9243/3 Dedifferentiated chondrosarcoma

925 Giant cell tumors

M9250/1 giant cell tumor of bone, NOS

- Osteoclastoma, NOS

M9250/3 Giant cell tumor of bone, malignant

- Osteoclastoma, malignant
- Giant cell sarcoma of bone

M9251/1 Giant cell tumor of soft parts, NOS
M9251/3 Malignant giant cell tumor of soft parts
M9252/0 Tenosynovial giant cell tumor

- Fibrous histiocytoma of tendon sheath
- Giant cell tumor of tendon sheath

M9252/3 Malignant tenosynovial giant cell tumoe

- Giant cell tumor of tendon sheath, malignant

926 Miscellaneous bone tumors (C40._, C41._)

M9260/3 Ewing's sarcoma/tumor
M9261/3 Adamantinoma of long bones
M9262/0 Ossifying fibroma

- Fibro-osteoma
- Osteofibroma

927–934 Odontogenic tumors C41._)

M9270/0 Odontogenic tumor, benign
M9270/1 Odontogenic tumor, NOS
M9270/3 Odontogenic tumor, malignant

- Odontogenic carcinoma/sarcoma
- Primary intraosseus or ameloblastic carcinoma

M9271/0 Ameloblastic fibrodentinoma

- Dentinoma

M9272/0 Cementoma, NOS

- Periapical cemental dysplasia or cemento-osseus dysplasia

M9273/0 Cementoblastoma, benign
M9274/0 Cementifying fibroma

- Cemento-ossifying fibroma

M9275/0 Gigantiform cementoma

- Florid osseus dysplasia

M9280/0 Odontoma, NOS
M9281/0 Compound odontoma
M9282/0 Complex odontoma
M9290/0 Ameloblastic fibro-odontoma

- Fibroameloblastic odontoma

M9290/3 Ameloblastic odontosarcoma

- Ameloblastic fibrodentinosarcoma or fibro-odontosarcoma

M9300/0 Adenomatoid odontogenic tumor

- Adenomeloblastoma

M9301/0 Calcifying odontogenic cyst

M9302/0 Odontogenic ghost cell tumor

M9310/0 Ameloblastoma, NOS

- Adamantinoma, NOS (except of long bones M9261/3)

M9310/3 Ameloblastoma, malignant

- Adamantinoma, NOS (except of long bones M9261/3)

M9311/0 Odontoameloblastoma

M9312/0 Squamous odontogenic tumor

M9320/0 Odontogenic myxoma

- Odontogenic myxofibroma

M9321/0 Central odontogenic fibroma

- Odontogenic fibroma, NOS

M9322/0 Peripheral odontogenic fibroma

M9330/0 Ameloblastic fibroma

M9330/3 Ameloblastic fibrosarcoma

- Ameloblastic sarcoma
- Odontogenic fibrosarcoma

M9340/0 Calcifying epithelial odontogenic tumor

- Pindbord gumor

M9341/1 clear cell odontogenic tumor

M9342/3 Odontogenic carcinosarcoma

935–937 Miscellaneous tumors

M9350/1 Craniopharyngioma

- Rathke pouch tumor

M9351/1 Craniopharyngioma, adamantinomatous

M9352/1 Craniopharyngioma, papillary

M9360/1 Pinealoma

M9361/1 Pineocytoma

M9362/3 Pineoblastoma

- Mixed pineal tumor
- Mixed pineocytoma-pineoblastoma
- Pineal parenchymal tumor of intermediate differentiation
- Transitional pineal tumor

M9363/0 Melanotic neuroectodermal tumor

- Retinal anlage tumor
- Melanoameloblastoma
- Melanotic progonoma

M9364/3 Peripheral neuroectodermal tumor

- Neuroectodermal tumor, NOS

Peripheral primitive neuroectodermal tumor, NOS (PPNET)

M9365/3 Askin Tumor

M9370/3 Chordoma, NOS

M9371/3 Chondroid chordoma

M9372/3 Dedifferentiated chorcoma

M9373/0 Parachordoma

938–948 Gliomas

M9380/3 Glioma, malignant

- Glioma, NOS (except nasal glioma, not neoplastic)

M9381/3 Gliomatosis cerebri

M9382/3 Mixed glioma

- oligoastrocytoma
- Anaplastic oligoastrocytoma

M9383/1 Subepyndymoma

- Subependymal glioma
- Subependymal astrocytoma, NOS
- Mixed subendymoma-ependymoma

M9384/1 Subependymal giant cell astrocytoma

M9390/0 Choroid plexus papilloma, NOS

M9390/1 Atypical choroid plexus papilloma

M9390/3 Choroid plexus carcinoma

- Choroid plexus papilloma, anaplastic or malignant

M9391/3 Ependymoma, NOS

- Epithelial / cellular / clear cell / tanycytic ependymoma

M9392/3 Ependymoma, anaplastic

- Ependymoblastoma

M9393/3 Papillary ependymoma

M9394/1 Myxopapillary ependymoma

M9400/3 Astrocytoma, NOS

- Astrocytic glioma
- Astroglioma
- Diffuse astrocytoma
- Astrocytoma, low grade
- Diffuse astocytoma, low grade
- Cystic astrocytoma

M9401/3 Astrocytoma, anaplastic

M9410/3 Protoplasmic astrocytoma

M9411/3 Gemistocytic astrocytoma

- Gemistocytoma

M9412/1 Desmoplastic infantile astrocytoma or ganglioglioma

M9413/0 dysembryoplastic neuroepithelial tumor

M9420/3 Fibrillary astrocytoma

- Fibrous astrocytoma

M9421/1 Pilocytic astrocytoma

- Piloid or Juvenile astrocytoma
- Spongioblastoma, NOS

M9423/3 Polar spongioblastoma

- Spongioblastoma polare
- Primitive polar spongioblastoma

M9424/3 Pleomorphic xanthoastrocytoma

M9430/3 Astroblastoma

M9440/3 Glioblastoma, NOS

- Glioblastoma multiforme
- Spongioblastoma multiforme

M9441/3 Giant cell glioblastoma

- Monstrocellular sarcoma

M9442/1 gliofibroma

M9442/3 gliosarcoma

- Glioblastoma with sarcomatous component

M9444/1 Chordoid glioma

- Chordoid glioma of third ventricle

M9450/3 Oligodendroglioma, NOS

M9451/3 Oligodendroglioma, anaplastic

M9460/3 Oligodendroblastoma

M9470/3 Medullablastoma, NOS

- Melanotic medulloblastoma

M9471/3 Desmoplastic nodular medulloblastoma

- Desmoplastic medulloblastoma
- Circumscribed arachnoidal cerebellar sarcoma

M9472/3 Medullomyoblastoma

M9473/3 Primitive neuroectodermal tumor, NOS

- PNET, NOS
- Central primitive neuroectodermal tumor, NOS (CPNET)
- Supratentorial PNET

M9474/3 large cell medulloblastoma

M9480/3 Cerebellar sarcoma, NOS

949–952 Neuroepitheliomatous neoplasms

M9490/0 Ganglioneuroma

M9490/3 Ganglioneuroblastoma

M9491/0 Ganglioneuromatosis

M9492/0 Gangliocytoma

M9493/0 Dysplastic gangliocytoma of cerebellum (Lhermitte-Duclos)

M9500/3 Neuroblastoma, NOS

- Sympathicoblastoma
- Central neuroblastoma

M9501/0 Medulloepithelioma, benign

- Diktyoma, benign

M9501/3 Medulloepithelioma, NOS

- Diktyoma, malignant

M9502/0 Teratoid medulloepithelioma, benign
M9502/3 Teratoid medulloepithelioma
M9503/3 Neuroepithelioma, NOS
M9504/3 Spongioneuroblastoma
M9505/1 Ganglioglioma, NOS
M9505/3 Ganglioglioma, anaplastic
M9506/1 Central neurocytoma

- Neurocytoma
- Cerebellar liponeurocytoma
- Lipomatous medulloblastoma
- Neurolipocytoma
- Medullocytoma

M9507/0 Pacinian tumor
M9508/3 Atypical teratoid/rhabdoid tumor
M9510/0 Retinocytoma
M9510/3 Retinoblastoma, NOS
M9511/3 Retinoblastoma, differentiated
M9512/3 Retinoblastoma, undifferentiated
M9513/3 Retinoblastoma, diffuse
M9514/1 Retinoblastoma, spontaneously regressed
M9520/3 Olfactory neurogenic tumor
M9521/3 Olfactory neurocytoma

- Esthesioneurocytoma

M9522/3 Olfactory neuroblastoma

- Esthesioneuroblastoma

M9523/3 Olfactory neuroepithelioma

- Esthesio neuroepithelioma

953 Meningiomas

M9530/0 Meningioma, NOS

- Microcystic
- Secretory
- Lymphoplasmacyte-rich
- Metaplastic

M9530/1 Meningiomatosis, NOS

- Diffuse
- Multiple meningiomas

M9530/3 Meningioma, malignant

- Anaplastic
- Leptomeningeal sarcoma
- Meningeal sarcoma
- Meningothelial sarcoma

M9531/0 Meningothelial meningioma

- Endotheliomatous meningioma
- Syncytial meningioma

M9532/0 Fibrous meningioma

- Fibroblastic meningioma

M9533/0 Psammomatous meningioma
M9534/0 Angiomatous meningioma
M9537/0 Transitional meningioma
M9538/1 Clear cell meningioma

- Chordoid

M9538/3 Papillary meningioma

- Rhabdoid

M9539/1 Atypical meningioma
M9539/3 Meningeal sarcomatosis

954–957 Nerve sheath tumors

M9540/0 Neurofibroma, NOS

M9540/1 Neurofibromatosis, NOS

- Multiple neurofibromatosis
- Von Recklinghausen disease (except of bone)

M9540/3 Malignant peripheral nerve sheath tumor

- MPNST, NOS
- MPNST with glandular differentiation
- Epithelioid
- with mesenchymal differentiation
- Melanotic
- Melanotic psammomatous

M9541/0 Melanotic neurofibroma

M9550/0 Plexiform neurofibroma

- Plexiform neuroma

M9560/0 Neurilemoma, NOS

- Schwannoma, NOS
- Neurinoma
- Acoustic neuroma
- Pigmented or melanotic schwannoma
- Plexiform / cellular / degenerated / ancient / psammomatous

M9560/1 Neurinomatosis

M9561/3 Malignant peripheral nerve sheath tumor with rhabdomyoblastic differentiation

- MPNST with rhabdomyoblastic differentiation
- Triton tumor, malignant
- Malignant schwannoma with rhabdomyoblastic differentiation

M9562/0 Neurothekeoma

- Nerve sheath myxoma

M9570/0 Neuroma, NOS

M9571/0 Perineurioma, NOS

- Intraneural perineurioma
- Soft tissue perineurioma

M9571/3 Perineurioma, malignant

- Perineural MPNST

M9560/0 Schwannoma, NOS

M9560/0 Neurinoma

M9560/0 Acoustic neuroma

M9570/0 Neuroma, NOS

958 Granular cell tumors and Alveolar soft part sarcoma

M9580/0 Granular cell tumor/myoblastoma, NOS

M9580/3 Granular cell tumor/myoblastoma, malignant

M9581/3 Alveolar soft part sarcoma

M9582/0 Granular cell tumor of the sellar region (C75.1)

(9590–9999) Hematologic (Leukemias, Lymphomas and related disorders)

959 Malignant lymphoma, NOS, Or diffuse

M9590/3 Malignant Lymphoma, NOS

- Lymphoma, NOS
- Microglioma (C71._)

M9591/3 Malignant lymphoma, non-Hodgkin, NOS

- Non-Hodgkin's lymphoma, NOS
- B cell lymphoma, NOS
- Malignant lymphoma, non-cleaved cell, NOS
- Malignant lymphoma, diffuse, NOS
- Malignant lymphoma, lymphocytic, intermediate differentiation, nodular
- Malignant lymphoma, small cell, noncleaved, diffuse
- Malignant lymphoma, undifferentiated cell, non-Burkitt
- Malignant lymphoma, undifferentiated cell type, NOS
- Lymphosarcoma, NOS
- Lymphosarcoma, diffuse

- Reticulum cell sarcoma, NOS
- Reticulum cell sarcoma, diffuse
- Reticulosarcoma, NOS
- Reticulosarcoma, diffuse
- Malignant lymphoma, small cleaved cell, diffuse
- Malignant lymphoma, lymphocytic, poorly differentiated, diffuse
- Malignant lymphoma, small cleaved cell, NOS
- Malignant lymphoma, cleaved cell, NOS

M9596/3 Composite Hodgkin and non-Hodgkin lymphoma

965–966 Hodgkin Lymphoma

M9650/3 Hodgkin lymphoma, NOS

- Hodgkin's disease, NOS
- Malignant lymphoma, Hodgkin

M9651/3 Hodgkin lymphoma, lymphocyte rich

- Lymphocyte-rich classical Hodgkin lymphoma
- Hodgkin disease, lymphocyte predominance, NOS
- Hodgkin disease, lymphocytic-histiocytic predominance
- Hodgkin disease, lymphocyte predominance, diffuse

M9652/3 Mixed cellularity classical Hodgkin lymphoma, NOS

- Hodgkin lymphoma, mixed cellularity, NOS

M9653/3 Lymphocyte-depleted classical Hodgkin lymphoma, NOS

M9654/3 Hodgkin lymphoma, lymphocyte depletion, diffuse fibrosis

M9655/3 Hodgkin lymphoma, lymphocyte depletion, reticular

M9659/3 Nodular lymphocyte predominant Hodgkin lymphoma

- Hodgkin lymphoma, lymphocyte predominance, nodular
- Hodgkin paragranuloma, NOS
- Hodgkin paragranuloma, nodular

M9661/3 Hodgkin granuloma

M9662/3 Hodgkin sarcoma

M9663/3 Nodular sclerosis classical Hodgkin lymphoma

- Hodgkin lymphoma, nodular sclerosis, NOS

M9664/3 Hodgkin lymphoma, nodular sclerosis, cellular phase

- Classical Hodgkin lymphoma, nodular sclerosis, cellular phase

M9665/3 Hodgkin lymphoma, nodular sclerosis, grade 1

- Classical Hodgkin lymphoma, nodular sclerosis grade 1
- Hodgkin disease, nodular sclerosis, lymphocyte predominance
- Hodgkin disease, nodular sclerosis, mixed cellularity

M9667/3 Hodgkin lymphoma, nodular sclerosis, grade 2

- Classical Hodgkin lymphoma, nodular sclerosis, grade 2
- Hodgkin disease, nodular sclerosis, lymphocyte depletion
- Hodgkin disease, nodular sclerosis, syncytial variant

967–972 Non-Hodgkin Lymphomas

967-969 Mature B-cell Lymphomas

M9670/3 Malignant lymphoma, small B lymphocytic, NOS *(see also M9823/3)*

- Small lymphocytic lymphoma
- Malignant lymphoma, small lymphocytic, NOS
- Malignant lymphoma, lymphocytic, well differentiated, diffuse
- Malignant lymphoma, lymphocytic, NOS
- Malignant lymphoma, lymphocytic, diffuse, NOS
- Malignant lymphoma, small cell, NOS
- Malignant lymphoma, small lymphocytic, diffuse
- Malignant lymphoma, small cell diffuse

M9671/3 Malignant lymphoma, lymphoplasmacytic *(see also M9761/3)*

- Lymphoplasmacytic lymphoma
- Malignant lymphoma, lymphoplasmacytoid
- Immunocytoma
- Malignant lymphoma, plasmacytoid
- Plasmacytic lymphoma

M9673/3 Mantle cell lymphoma

- *Includes all variants: blastic, pleomorphic, small cell*
- Mantle zone lymphoma
- Malignant zone lymphoma
- Malignant lymphoma, lymphocytic, intermediate differentiation, diffuse
- Malignant lymphoma, centrocytic
- Malignant lymphomatous polyposis

M9675/3 Malignant lymphoma, mixed small and large cell, diffuse *(see also M9690/3)*

- Malignant lymphoma, mixed lymphocytic-histiocytic, diffuse
- Malignant lymphoma, mixed cell type, diffuse
- Malignant lymphoma, centroblastic-centrocytic,NOS
- Malignant lymphoma, centroblastic-centrocytic, diffuse

M9678/3 Primary effusion lymphoma

M9679/3 Mediastinal large B-cell lymphoma (C38.3)

- Mediastinal (thymic) large cell lymphoma

M9680/3 Malignant lymphoma, large B-cell, diffuse, NOS

- Diffuse large B-cell lymphoma, NOS
- Malignant lymphoma, large cell, NOS
- Malignant lymphoma, large B-cell, NOS
- Malignant lymphoma, histiocytic, NOS
- Malignant lymphoma, histiocytic, diffuse
- Malignant lymphoma, large cell, cleaved and non-cleaved
- Malignant lymphoma, large cell, diffuse, NOS
- Malignant lymphoma, large cleaved cell, NOS
- Malignant lymphoma, large cell, cleaved, NOS
- Malignant lymphoma, large cell, noncleaved, diffuse or NOS
- Malignant lymphoma, large B-cell, diffuse, centroblastic, NOS
- Malignant lymphoma, large B-cell, centroblastic, NOS or diffuse
- Intravascular large B-cell lymphoma
- Angioendotheliomatosis
- Angiotropic lymphoma
- T-cell rich large B-cell lymphoma
- Histiocyte-rich large B-cell lymphoma
- Anaplastic large B-cell lymphoma

M9684/3 Malignant lymphoma, large B-cell, diffuse, immunoblastic, NOS

- Malignant lymphoma, immunoblastic, NOS
- Immunoblastic sarcoma
- Malignant lymphoma, large cell, immunoblastic
- Plasmablastic lymphoma

M9687/3 Burkitt lymphoma, NOS *(see also M9826/3)*

- *Includes all variants*
- Malignant lymphoma, undifferentiated
- Malignant lymphoma, small noncleaved
- Burkitt-like lymphoma

M9689/3 Splenic marginal zone lymphoma

- Splenic marginal zone B-cell lymphoma
- Splenic lymphoma with villous lymphocytes

M9690/3 Follicular lymphoma, NOS *(see also M9675/3)*

- Malignant lymphoma, follicular/follicle center, NOS

M9691/3 Follicular lymphoma, grade 2

- Follicular lymphoma, small cleaved cell

M9698/3 Follicular lymphoma, grade 3

- Malignant lymphoma, large cell/centroblastic, follicular, NOS

M9699/3 Marginal zone B-cell lymphoma, NOS

- Marginal zone lymphoma, NOS
- Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue (MALT-lymphoma)
- BALT lymphoma
- SALT lymphoma
- Monocytoid b-cell lymphoma
- Nodal marginal zone lymphoma
- Nodal marginal zone B-cell lymphoma

970–971 Mature T- and NK-cell Lymphomas

M9700/3 Mycosis fungoides

- Pagetoid reticulosis

M9701/3 Sezary syndrome

- Sezary disease

M9702/3 Mature T-cell lymphoma, NOS

- Peripheral T-cell lymphoma, NOS
- T-cell lymphoma, NOS
- Peripheral T-cell lymphoma, pleomorphic small/medium/large cell/T-zone lymphoma
- Lymphoepithelioid lymphoma
- Lennert lymphoma

M9705/3 Angioimmunoblastic T-cell lymphoma

- Peripheral T-cell lymphoma, AILD (Angioimmunoblastic lymphadenopathy with dysproteinemia)

M9708/3 Subcutaneous panniculitis-like T-cell lymphoma

M9709/3 Cutaneous T-cell lymphoma, NOS (C44._)

- Cutaneous lymphoma, NOS

M9714/3 Anaplastic large cell lymphoma, T cell and Null cell type

- Anaplastic large cell lymphoma, CD30+/NOS

M9716/3 Hepatosplenic (gamma-delta) cell lymphoma

- Hepatosplenic T-cell lymphoma

M9717/3 Intestinal T-cell lymphoma

- Enteropathy type T-cell lymphoma

M9718/3 Primary cutaneous CD 30+ T-cell lymphoproliferative disorder (C44._)

- Lymphomatoid papulosis
- Primary cutaneous anaplastic large cell lymphoma
- Primary cutaneous CD30+ large T-cell lymphoma

M9719/3 NK/T-cell lymphoma, nasal and nasal type

- Extranodal NK/T cell lymphoma, nasal type
- T/NK-cell lymphoma

972 Precursor Cell Lymphoblastic Lymphoma

M9727/3 Precursor cell lymphoblastic lymphoma, NOS (*see also M9835/3)*

- Blastic NK cell lymphoma
- Malignant lymphoma, lymphoblastic, NOS

M9728/3 Precursor B-cell lymphoblastic Lymphoma *(see also M9836/3)*

M9729/3 Precursor T-cell lymphoblastic Lymphoma *(see also M9837/3)*

973 Plasma cell tumors

M9731/3 Plasmacytoma, NOS

- Extramedullary plasmacytoma
- Solitary plasmacytoma of bone (C40._, C41._)
- Solitary myeloma
- Solitary plasmacytoma

M9732/3 Multiple myeloma (C42.1)

- Plasma cell myeloma
- Myeloma, NOS
- Myelomatosis

M9733/3 Plasma cell leukemia (C42.1)

- Plasmacytic leukemia

M9734/3 Plasmacytoma, extramedullary *(not occurring in bone)*

- Extraosseous plasmacytoma

974 Mast cell Tumors

M9740/1 Mastocytoma, NOS or Extracutaneous mastocytoma

- Mast cell tumor, NOS

M9740/3 Mast cell sarcoma

- Malignant mast cell tumor
- Malignant mastocytoma

M9741/3 Malignant mastocytosis

- Systemic tissue mast cell disease
- Aggressive systemic mastocytosis or Systemic mastocytosis with associated clonal, hematological non-mast cell lineage disease

M9742/3 Mast cell leukemia (C42.1)

975 Neoplasms of Histiocytes and Accessory Lymphoid Cells

M9750/3 Malignant histiocytosis

M9751/1 Langerhans cell histiocytosis, NOS

M9752/1 Langerhans cell histiocytosis, unifocal

- Langerhans cell granulomatosis, unifocal
- Langerhans cell histiocytosis, mono-ostotic
- Eosinophilic granuloma

M9753/1 Langerhans cell histiocytosis, multifocal

- Langerhans cell histiocytosis, poly-ostotic

M9754/3 Langerhans cell histiocytosis, disseminated

- Langerhans cell histiocytosis, generalized
- Letterer-Siwe disease
- Acute progressive histiocytosis X

M9755/3 Histiocytic sarcoma

- True histiocytic lymphoma

M9756/3 Langerhans cell sarcoma

M9757/3 Dendritic cell sarcoma, NOS

- Interdigitating dendritic cell sarcoma/tumor

M9758/3 Follicular dendritic cell sarcoma/tumor

976 Immunoproliferative diseases

M9760/3 Immunoproliferative disease, NOS

M9761/3 Waldenstrom macroglobulinemia (C42.0) (see also M9671/3)

M9762/3 Heavy chain disease, NOS

- Alpha heavy chain disease
- Mu heavy chain disease
- Gamma heavy chain disease
- Franklin disease

M9764/3 Immunoproliferative small intestinal disease (C17._)

- Mediterranean lymphoma

M9765/1 Monoclonal gammopathy of undetermined significance

- MGUS
- Monoclonal gammopathy, NOS

(M9766/1) Angiocentric immunoproliferative lesion

- LYmphoid granulomatosis
- Lymphomatoid granulomatosis

M9767/1 Angioimmunoblastic lymphadenopathy

M9768/1 T-gamma lymphoproliferative disease

M9769/1 Immunoglobulin deposition disease

- Systemic light chain disease
- Primary amyloidosis

980-994 Leukemias

980) Leukemias, NOS

M9800/3 Leukemia, NOS

M9801/3 Acute leukemia, NOS

- Blast cell leukemia
- Undifferentiated leukemia
- Stem cell leukemia

M9805/3 Acute biphenotypic leukemia

- Acute leukemia of ambiguous lineage
- Acute mixed lineage leukemia
- Acute bilineal leukemia

(982–983) Lymphoid leukemias (C42.1)

M9820/3 Lymphoid leukemia, NOS

- Lymphocytic leukemia, NOS
- Lymphatic leukemia, NOS

M9823/3 B-cell chronic lymphocytic leukemia/small lymphocytic lymphoma (see also M9670/3)

- Chronic lymphocytic leukemia, B-cell type (includes all variants of BCLL)
- Chronic lymphocytic leukemia
- Chronic lymphoid leukemia
- Chronic lymphatic leukemia

M9826/3 Burkitt cell Leukemia (see also M9687/3)

- Acute lymphoblastic leukemia, mature B-cell type

M9827/3 Adult T-cell leukemia/lymphoma (HTLV-1 positive) includes all variants

- Adult T-cell lymphoma/leukemia

M9831/1 T-cell large granular lymphocytic leukemia

- T-cell large granular lymphocytosis
- NK-cell large granular lymphocytic leukemia
- Large granular lymphocytosis, NOS

M9832/3 Prolymphocytic leukemia, NOS

M9833/3 B-cell prolymphocytic leukemia

M9834/3 T-cell prolymphocytic leukemia

M9835/3 Precursor cell lymphoblastic leukemia, NOS (see also M9727/3)

- Precursor cell lymphoblastic leukemia, not phenotyped
- Acute lymphoblastic leukemia, NOS (see also M9727/3)
- Acute lymphoblastic leukemia, precursor-cell type
- Acute lymphoblastic leukemia-lymphoma, NOS
- Acute lymphocytic leukemia
- Acute lymphoid leukemia
- Acute lymphatic leukemia
- Acute lymphoblastic leukemia, L2 type, NOS
- FAB L2

M9836/3 Precursor B lymphoblastic leukemia (see also M9728/3)

- Pro-B ALL
- Common precursor B ALL
- Pre-B ALL
- Pre-pre-B ALL
- Common ALL
- c-ALL

M9837/3 Precursor T lymphoblastic leukemia (see also M9729/3)

- Pro-T ALL
- Pre-T ALL
- Cortical T ALL
- Mature T ALL

984-993 Myeloid Leukemias (C42.1)

(9840–9849) Erythroleukemias (FAB-M6)

M9840/3 Acute myeloid leukemia, M6 type

- Acute erythroid leukemia
- Erythroleukemia

- FAB M6
- AML M6
- Erythremic myelosis, NOS

(9850–9859) Lymphosarcoma cell leukemia (9860–9869) Myeloid (Granulocytic) Leukemias

M9860/3 Myeloid leukemia, NOS

- Non-lymphocytic leukemia, NOS
- Granulocytic leukemia, NOS
- Myelogenous leukemia, NOS
- Myelomonocytic leukemia, NOS
- Myelocytic leukemia, NOS
- Eosinophilic leukemia
- Monocytic leukemia, NOS

M9861/3 Acute myeloid leukemia, NOS (FAB or WHO type not specified (see also M9930/3)

- Acute myelogenous leukemia
- Acute non-lymphocytic leukemia
- Acute granulocytic leukemia
- Acute myelogenous leukemia
- Acute myelocytic leukemia

M9863/3 Chronic myeloid leukemia, NOS

- Chronic myelogenous leukemia, NOS
- Chronic granulocytic leukemia, NOS
- Chronic myelocytic leukemia, NOS

M9866/3 Acute promyelocytic leukemia t(15;17)(q22;q11-12) * Acute promyelocytic leukemia, PML/RAR-alpha

- Acute myeloid leukemia, t(15:17(q22;q11-12)
- Acute promyelocytic leukemia, NOS

FAB-M3 (includes all variants)

- Acute promyelocytic leukemia (AML with t(15;17)(q22;q12), PML-RARa and variants)

M9867/3) Acute myelomonocytic leukemia

- Acute myelomonocytic leukemia
- FAB-M4

M9870/3 Basophilic leukemia or Acute basophilic leukemia

M9871/3 Acute myeloid leukemia with abnormal marrow eosinophils (includes all variants)

- AML with inv(16)(p13q22) or t(16;16)(p13;q22), CBFb/MYH11 (FAB M4Eo)

M9872/3 Acute myeloid leukemia, minimally differentiated (FAB type M0)

- Acute myeloblastic leukemia]

M9873/3 Acute myeloid leukemia, without maturation (FAB type M1)

M9874/3 Acute myeloid leukemia, with maturation (FAB M2), NOS

M9875/3 Chronic myelogenous leukemia BCR/ABL positive

- Philadelphia chromosome (Ph1 positive)
- t(9;22)(q34;q11)
- Chronic granulocytic leukemia (BCR/ABL positive)/(Ph1 positive)/t(9;22)(q34;q11)

M9876/3 Atypical chronic myelogenous leukemia BCR/ABL negative

- Atypical chronic myeloid leukemia (BCR/ABL negative)/(Ph1 negative)

M9891/3 Acute monoblastic and monocytic leukemia

- Monoblastic leukemia, NOS
- FAB M5 (includes all variants)

M9895/3 Acute myeloid leukemia multilineage dysplasia

- AML with/without prior myelodysplastic syndrome

M9896/3 AML with t(8;21)(q22;q22), AML1/ETO

- FAB M2 with t(8;21)(q22;q22), AML1/ETO

M9897/3 AML with 11q23 (MLL) abnormalities

- AML, MLL

M9910/3 Acute megakaryoblastic leukemia, NOS

- Megakaryocytic leukemia
- (FAB-M7)

M9920/3 Acute myeloid leukemia and myelodysplastic syndrome, therapy related, NOS Therapy-related acute myeloid leukemia, alkylating agent/epipodophyllotoxin related

M9930/3 Chloroma or Myeloid sarcoma (see also M9861/3)

- Granulocytic sarcoma

M9931/3) Acute panmyelosis with myelofibrosis (C42.1)

- Acute panmyelosis, NOS
- Acute myelofibrosis
- Acute myelosclerosis, NOS

994 Other Leukemias (C42.1)

M9940/3 Hairy cell leukemia (C42.1)

- Hairy cell leukemia variant
- Leukemic reticuloendotheliosis

M9945/3 Chronic myelomonocytic, leukemia, NOS

- Type 1
- Type 2

M9946/3 Juvenile myelomonocytic leukemia

M9948/3 Aggressive NK cell leukemia

995-996 Chronic Myeloproliferative Disorders (C42.1)

M9950/3 Polycythemia vera

- Polycythemia rubra vera
- Proliferative polycythemia

M9960/1 Chronic Myeloproliferative disease, NOS

M9961/3 Myelosclerosis with myeloid metaplasia

- Chronic idiopathic myelofibrosis
- Myelofibrosis as a result of myeloproliferative disease
- Agnogenic myeloid metaplasia
- Megakaryocytic myelosclerosis
- Myelofibrosis with myeloid metaplasia

M9962/3 Essential thrombocytemia

- Idiopathic thrombocythemia
- Essential/idiopathic hemorrhagic thrombocythemia

M9963/3 Chronic neutrophilic leukemia

M9964/3 Chronic eosinophilic leukemia / hypereosinophilic syndrome

997 Other Haematologic Disorders

M9970/1 Lymphoproliferative disease/disorder, NOS

- Post-transplant lymphoproliferative disorder, pleomorphic

M9775/1 Myeloproliferative disease, NOS

- Chronic Myeloproliferative disease, unclassifiable
- Myelodysplastic / myeloproliferative diseases, unclassifiable

998 Myelodysplastic syndrome (C42.1)

M9980/3 Chronic myelomonocytic leukemia or Refractory anemia

M9982/3 Refractory anemia with ringed sideroblasts

- with sideroblasts

M9983/3 Refractory anemia with excess blasts

- RAEB
- RAEB I
- RAEB II

M9985/3 Refractory cytopenia with multilineage dysplasia

M9986/3 Myelodysplastic syndrome associated with isolated del(5q) chromosome abnormality

M9989/3 Myelodysplastic syndrome, NOS

15.29.4 See also

- Medical classification

15.29.5 References

[1] International Classification of Diseases for Oncology; Third edition; World Health Organization; Reprinted 2001; Fritz, Percy, Jack, Shanmugaratnam, Sobin, Parkin, Whelan

15.29.6 External links

- Official page at World Health Organization
- Tutorial at National Cancer Institute
- Overview at DIMDI
- Overview of multiple primaries at health-yarkansas.com (PPT)
- History of versions at National Cancer Institute
- ICD-10 Codes for Neoplasms

Morphology

- Cancer.gov – overview, includes link to Excel spreadsheet with codes at National Cancer Institute
- Overview at National Cancer Institute
- Word document – malignancies only at National Cancer Institute
- Overview at University hospital Gießen und Marburg
- Download table German version at DIMDI
- Codes at IARC
- 1st, 2nd, and 3rd editions at wolfbane.com
- List at The National Cancer Registry Ireland
- List at London School of Hygiene & Tropical Medicine

15.30 International Classification of Functioning, Disability and Health

International Classification of Functioning, Disability and Health, also known as **ICF**, is a classification of the health components of functioning and disability.

After nine years of international revision efforts coordinated by the World Health Organization (WHO), the World Health Assembly on May 22, 2001, approved the International Classification of Functioning, Disability and Health and its abbreviation of "ICF." This classification was first created in 1980 and then called the **International Classification of Impairments, Disabilities, and Handicaps**, or **ICIDH**[*][1] by WHO to provide a unifying framework for classifying the health components of functioning and disability.

The ICF classification complements WHO's International Classification of Diseases−10th Revision (ICD), which contains information on diagnosis and health condition, but not on functional status. The ICD and ICF constitute the core classifications in the WHO Family of International Classifications (WHO-FIC).

15.30.1 Overview

The ICF is structured around the following broad components:

- Body functions and structure
- Activities (related to tasks and actions by an individual) and participation (involvement in a life situation)
- Additional information on severity and environmental factors

Functioning and disability are viewed as a complex interaction between the health condition of the individual and the contextual factors of the environment as well as personal factors. The picture produced by this combination of factors and dimensions is of "the person in his or her world". The classification treats these dimensions as interactive and dynamic rather than linear or static. It allows for an assessment of the degree of disability, although it is not a measurement instrument. It is applicable to all people, whatever their health condition. The language of the ICF is neutral as to etiology, placing the emphasis on function rather than condition or disease. It also is carefully designed to be relevant across cultures as well as age groups and genders, making it highly appropriate for heterogeneous populations.

15.30.2 Benefits of ICF

There are benefits of using the ICF for both the patient and the health professional. A major advantage for the patient is the integration of the physical, mental, and social aspects of his or her health condition. All aspects of a person's life (development, participation and environment) are incorporated into the ICF instead of solely focusing on his or her diagnosis. A diagnosis reveals little about one's functional abilities. Diagnoses are important for defining the cause and prognosis, but identifying the limitations of function is often the information used to plan and implement interventions.[*][2] Once a rehabilitation team is aware of the daily activities a client is

required to participate in, the problem solving sequence set up by the ICF can be utilized. An occupational therapist, for example, would observe a patient performing his or her daily activities and note the patient's functional abilities. This information would then be used to determine the extent to which the individual's abilities can be improved through therapy and to what extent the environment can be changed to facilitate the individual's performance.*[3] Intervention at one level (current abilities) has the potential to prevent or modify events at a succeeding level (participation). For example, teaching a deaf child manual signs will foster effective interaction and increase one's participation with his or her family.*[3]

Rehabilitation therapists will be empowered with the ICF not only in their daily work with their patients, but also when working with other medical disciplines; hospitals and other health care administrations; health authorities and policy makers.*[4] All items are operationally defined with clear descriptions that can be applied to real life evaluations with clarity and ease.*[5] The language used in the ICF helps facilitate better communication between these groups of people.

15.30.3 Clinical relevance

Knowing how a disease affects one's functioning enables better planning of services, treatment, and rehabilitation for persons with long-term disabilities or chronic conditions. The current ICF creates a more integrative understanding of health forming a comprehensive profile of an individual instead of focusing on one's disease, illness, or disability.*[6] The implications of using the ICF include an emphasis on the strengths of individuals, assisting individuals in participating more extensively in society by the use of interventions aimed at enhancing their abilities, and taking into consideration the environmental and personal factors that might hamper their participation.*[3] Qualifiers: The ICF qualifiers "may be best translated clinically as the levels of functioning seen in a standardized or clinic setting and in everyday environments".*[7] Qualifiers support standardization and the understanding of functioning in a multidisciplinary assessment. They enable all team members to quantify the extent of problems, even in areas of functioning where one is not a specialist.*[8] Without qualifiers codes have no inherent meaning. An impairment, limitation or restriction, is qualified from 0 (No problem; 0-4%), 1 (Mild problem: 5-24%), 2 (Moderate problem: 25-49%), 3 (Severe problem: 50-95%) to 4 (Complete problem: 96-100%). Environmental factors are quantified with a negative and positive scale denoting the extent to which the environment acts as a barrier or facilitator.*[9] For insurance purposes, the qualifiers can describe the effectiveness of treatment. One can interpret the decreasing of a qualifier score to be an increase in the functional ability of a patient.

15.30.4 ICF Core Sets

An ICF Core Set can serve as a reference framework and a practical tool to classify and describe patient functioning in a more time efficient way. ICF Core Sets can be used along the continuum of care and over the course of a health condition.*[8] The ICF classification includes more than 1,400 categories limiting its use in clinical practice.*[10] It is time consuming for a clinician to utilize the main volume of the ICF with his or her patients. Only a fraction of the categories is needed. As a general rule, 20% of the codes will explain 80% of the variance observed in practice.*[11] ICF Core Sets contain as few as possible, but as many ICF categories as necessary, to describe a patient's level of functioning.*[8] It is hypothesized that using an ICF Core Set will increase the inter-rater reliability when coding clinical cases as only the relevant categories for a particular patient will be utilized. Since all of the relevant categories are listed in an ICF Core Set, its use in multidisciplinary assessments protects health professionals from missing important aspects of functioning.*[8]

15.30.5 Children and Youth Version (ICF-CY)

As clinicians and researchers used the ICF, they became more aware of its limitations. The ICF lacks the ability to classify the functional characteristics of a developing child. Different ICF codes are needed across the first years of a child's life to capture the growth and development of a disability even when the child's diagnosis does not change.*[12] The coding system can provide essential information about the severity of a health condition in terms of its impact on functioning. This can serve a significant role for providers caring for children with spectrum disorders such as autism or cerebral palsy.*[13] Children with these conditions may have the same diagnoses, but their abilities and levels of functioning widely vary across and within individuals over time. The first draft of the ICF-CY was completed in year 2003 and published in 2007. The ICF-CY was developed to be structurally consistent with the ICF for adults. A major difference between the ICF-CY and ICF is that the generic qualifiers from the adult ICF now include developmental aspects for children and youth in the ICF-CY. Descriptions of codes in the ICF-CY were revised and expanded and new content was added to previously unused codes. Codes were added to document characteristics as adaptability, responsivity, predictability, persistence, and approachability. "Sensing" and "exploration of objects" codes were expanded as well as the "importance of learning".*[2] Since a child's main occupation is playing, it is also important to include more codes in this area. Different levels of play have separate codes in the ICF-CY (solitary, onlooker, parallel). This contrasts with the adult ICF as only one code existed in regards to leisure or

recreation.

Changes in ICF-CY codes over time reflect developmental effects attributable to the child's interaction with the environment. Environmental factors influence functioning and development and can be documented as barriers or facilitators using the ICF-CY. The key environments of children and adolescents include their homes, day care centers, schools and recreation settings of playground, parks, and ball fields.*[14] Children will transition between different environments many times as they grow. For example, a child will transition into elementary or high school or from one service setting or agency to another. Attention to these transitions of children with disabilities has been identified as an important role for health care providers.*[14] A transition requires preparation and planning to find an appropriate and accommodating setting for a child's needs. With a coding system such as the ICF-CY, the transition will be smoother and interventions can start where the previous health provider left off.

15.30.6 See also

- Social model of disability

15.30.7 External links

- International Classification of Functioning, Disability and Health (ICF) - WHO
- International Classification of Functioning, Disability and Health (ICF) - CDC
- International Classification of Functioning, Disability and Health (ICF) in the NCBO BioPortal
- ICF case studies: Implementation of ICF in rehabilitation management

Age based "developmental" code sets derived from the ICF CY can be found at *http://www.icf-cydevelopmentalcodesets.com/

- The Italian Portal of Classifications is the ICF and ICF-CY browsing tool of the Italian Collaborating Centre of the World Health Organization for the Family of International Classifications

15.30.8 References

[1] http://www.cdc.gov/nchs/about/otheract/icd9/icfhome.htm

[2] Lollar, D.J., & Simeonsson, R.J. (2005). Diagnosis to function: classification for children and youths. Developmental and Behavioral Pediatrics, 26, 323-330.

[3] Bornman, J. (2004). The World Health Organization's terminology and classification: application to severe disability. Disability and Rehabilitation, 26, 182-188.

[4] Stucki, G., Ewert, T., & Cieza, A. (2002). Value and application of the ICF in rehabilitation medicine. Disability and Rehabilitation, 24, 932-938.

[5] Üstün, T. B., Chatterji, S., Bickenbach, J., Kostanjsek, N., & Schneider, M. (2003). The International Classification of Functioning, Disability and Health: A new tool for understanding disability and health. Disability and Rehabilitation, 25, 565–571.

[6] Hemmingsson, H., & Jonsson, H. (2005). An occupational perspective on the concept of participation in the international classification of functioning, disability and health – some critical remarks. The American Journal of Occupational Therapy, 59, 569-576.

[7] Reed, G., Lux, J., Bufka, L., Peterson, D., Threats, T., Trask, C., Stark, S., Jacobson, J., & Hawley, J. (2005). Operationalizing the International Classification of Functioning, Disability, and Health: A model to guide clinical thinking, practice and research in the field of cerebral palsy. Seminars in Pediatric Neurology, 11, 5-10.

[8] Rauch, A., Cieza, A., & Stucki, G. (2008). How to apply the International Classification of Functioning Disability and Health (ICF) for rehabilitation management in clinical practice. European Journal of Physical and Rehabilitation Medicine, 44, 329-342.

[9] World Health Organization. (2001). International Classification of Functioning, Disability and Health (ICF). Geneva: Author.

[10] Arlinger, M., Stamm, T.A., Pisetsky, D.S., Yarboro, C.H., Cieza, A., Smolen, J.S., & Stucki, G. (2006). ICF core sets: how to specify impairment and function in systemic lupus erythematosus. Lupus, 15, 248-253.

[11] Ustun, B., Chatterji, S., & Kostanjsek, N. (2004). Comments from WHO for the Journal of Rehabilitation Medicine special supplement on ICF core sets. Journal of Rehabiliation Medicine, (Suppl. 44), 7-8.

[12] Simeonsson, R.J., Scarborough, A.A., & Hebbeler, K.M. (2006). ICF and ICD codes provide a standard language of disability in young children. Journal of Clinical Epidemiology, 59, 365-373.

[13] Ogonowski, J., Kronk, R., Rice, C., & Feldman, H. (2004). Inter-rater reliability in assigning ICF codes to children with disabilities. Disability and Rehabilitation, 26, 353-361.

[14] Simeonsson, R.J., Lollar, D., Hollowell, J., & Adams, M. (2000). Revision of the international classification of impairments, disabilities, and handicaps developmental issues. Journal of Clinical Epidemiology, 53, 113-124.

15.31 International Classification of Health Interventions

The **International Classification of Health Interventions** (ICHI) is a system of classifying procedure codes being developed by the World Health Organization. It is currently only available as a beta release for additional coding work, but not yet for operationall application.*[1] The last published version is denoted as alpha version 2.*[2]

ICHI is intentionally designed to replace the "International Classification of Procedures in Medicine" (ICPM), a system that was developed in the 1970s but which never received the same international acceptance as ICD-9. As a result, most nations developed their own standards for coding procedures and interventions incompatible to the ICPM approach.

The initial basis of WHO-ICHI (alpha version) has been largely derived from the "Australian Classification of Health Interventions" (ACHI),*[3] a portion of the Australian standard ICD-10-AM, which in turn was largely derived from ICD-10 and the United States extension ICD-9-CM. Currently (2014) the acceptance of the ICHI in the community of health care professionals might be better, but due to missing formal acceptance the spread of national variations beyond translation widely continues.

For accounting, the Australian health administration generated a code of Diagnosis-related groups which in effect again deviates from the WHO basis. The same phenomenon applies to DRG codes in Germany and other countries. Other codes generated by the UN accredited International Standards Organisation ISO defined a deviating scope.*[4] Cooperation of ISO and WHO is not detected.

15.31.1 See also

- ICD-10-PCS (US-American version for coding)

15.31.2 References

[1] ICHI status of WHO Tokyo meeting 2010

[2] WHO FIC newsletter Volume 11, Number 2, 2013

[3] ICHI alpha version

[4] ISO 9999:2011. Assistive products for persons with disability -- Classification and terminology

15.31.3 External links

- WHO site (International framework for coding, evolution of ICHI paused)
- Australian site (Australian version for coding)

15.32 International Classification of Primary Care

The **International Classification of Primary Care** (**ICPC**) is a classification method for primary care encounters. It allows for the classification of the patient's reason for encounter (RFE), the problems/diagnosis managed, primary or general health care interventions, and the ordering of the data of the primary care session in an episode of care structure. It was developed by the WONCA International Classification Committee (WICC), and was first published in 1987 by Oxford University Press (OUP). A revision and inclusion of criteria and definitions was published in 1998. The second revision was accepted within the World Health Organization's (WHO) Family of International Classifications.*[1]

The classification was developed in a context of increasing demand for quality information on primary care as part of growing worldwide attention to global primary health care objectives, including the WHO's target of "health for all".*[2]

15.32.1 History

The first version of ICPC, which was published in 1987, is referred to as *ICPC-1*. A subsequent revision which was published in the 1993 publication *The International Classification of Primary Care in the European Community: With a Multi-Language Layer* is known as *ICPC-E*.

The 1998 publication, of version 2, is referred to as *ICPC-2*. The acronym *ICPC-2-E*, refers to a revised electronic version, which was released in 2000. Subsequent revisions of ICPC-2 are also labelled with a release date.

15.32.2 Structure

Chapters

The ICPC contains 17 chapters:

- A General and unspecified
- B Blood, blood forming organs, lymphatics, spleen
- D Digestive
- F Eye
- H Ear
- K Circulatory
- L Musculoskeletal
- N Neurological
- P Psychological

- R Respiratory
- S Skin
- T Endocrine, metabolic and nutritional
- U Urology
- W Pregnancy, childbirth, family planning
- X Female genital system and breast
- Y Male genital system
- Z Social problems

Components

The ICPC classification, within each chapter, is based on 3 components coming from 3 different classifications:

- Reason for Encounter Classification (1981)
- International Classification of Process in Primary Care (IC-Process-PC) (1985)
- International Classification of Health Problem in Primary Care (ICHPPC-2-d) (1976, 1983)

15.32.3 See also

- Classifications
  - Medical classification
  - Anatomical Therapeutic Chemical Classification System (ATC classification for drugs)
  - Classification of Pharmaco-Therapeutic Referrals (CPR)
  - International Classification of Functioning, Disability and Health (ICF)
  - International Statistical Classification of Diseases and Related Health Problems (ICD)
  - ICPC-2 PLUS
- Health care
  - Family medicine / Family practice
  - General practice / General practitioner
  - Primary care
  - Primary health care
  - Referral (medicine)
- Health informatics
  - Electronic health record
  - International Organization for Standardization Technical Committee on Health Informatics
- World Organization of Family Doctors (WONCA)
  - WONCA International Classification Committee (WICC)

15.32.4 References

[1] World Health Organization. *International Classification of Primary Care, Second edition (ICPC-2)*. Geneva. Accessed 24 June 2011.

[2] Bentsen BG. "International classification of primary care." *Scand J Prim Health Care.* 1986 Feb;4(1):43-50.

15.32.5 Bibliography

- Bentzen N (ed). WONCA international glossary for general/family practice. Fam Pract. 1995; 12:267.

15.32.6 External links

- WICC at WONCA
- Primary Healthcare Classification Consortium (Classification Committee)
- ICPC-2e (by the Norwegian Centre for Informatics in Health and Social Care)
- University of Sydney Family Medicine Research Centre
- ICPC publication bibliography

15.33 International Healthcare Terminology Standards Development Organisation

The **International Health Terminology Standards Development Organisation** (**IHTSDO**) is an international non-profit organization that owns SNOMED CT, a leading clinical terminology used in electronic health records. IHTSDO was founded in 2007 by 9 charter member countries (Australia, Canada, Denmark, Lithuania, Sweden, the Netherlands, New Zealand, the United Kingdom and the United States) in order to acquire the rights of SNOMED CT from the College of American Pathologists (CAP) and make the development of a global clinical language for healthcare an international, collaborative effort.

15.33.1 Governance

IHTSDO governance is defined in the IHTSDO Articles of Association.*[1] The organization is headquartered in Denmark and is constituted as an association under Danish Law.

Since 2007 the number of Member countries has increased from nine to twenty eight. The Members were (as of March 2016):*[2] Australia, Belgium,

Brunei, Canada, Chile, Czech Republic, Denmark, Estonia, Hong Kong, Iceland, India, Israel, Lithuania, Malaysia, Malta, Netherlands, New Zealand, Poland, Portugal, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, the United Kingdom, the United States and Uruguay. The Member countries provide the bulk of the institutional financing through payment of yearly Member fees, which are based on Gross National Income. Members of IHTSDO can be either an agency of a national government or another body (such as a corporation or regional government agency) which has been endorsed by an appropriate national government authority within the country it represents. Member countries commit themselves to the dissemination of the IHTSDO terminologies within their jurisdiction, including where appropriate the creation of local translations, extensions, and mappings.

The General Assembly (GA) is the organization's highest authority and is composed of representatives from all Member countries with equal representation (although some Member countries have not selected GA representatives and therefore are not represented in the GA). The GA is collectively charged with assuring that the purpose, objects and principles of the Association are pursued and that the interests of IHTSDO are safeguarded. The GA appoints the Management Board (MB), which has overall responsibility for the management and direction of IHTSDO and has a duty to act in the best interests of the organization. The Member countries are also represented by the Member Forum, which provides input on Member priorities and helps develop the IHTSDO plan of work.

The organization is structured into four major areas: customer relations, operations, products & services, and strategy.

Seven Advisory Groups provide advice to the Management Team. In addition there are topic-specific project groups (PGs) and special interest groups (SIGs) which supplement and report to the Standing Committees. These groups are open and are not elected. IHTSDO PGs and SIGs include:

IHTSDO's work is documented on its website. The internal communication is supported by a Collaborative content management system.

15.33.2 Strategic Directions

The broad vision for IHTSDO is set out in their Articles of Association.*[3] In 2015, the General Assembly and the Management Board agreed that the organization's focus for the subsequent 5 years would be (1) demonstrate successful large scale implementations of SNOMED CT (2) remove barriers to adoption for customers and stakeholders, (3) enable continuous development of our product to meet customer requirements, (4) provide scalable products and services that drive SNOMED CT adoption, and (5) set new trends and shape new technologies that increase the overall use of SNOMED CT.*[4]

IHTSDO aims to achieve interoperability and harmonization between its terminology products and those standards produced by other international standards development organisations (SDOs). In support of this IHTSDO has negotiated a number of collaboration agreements with other SDOs, such as the World Health Organization, HL7, ICN, IEEE, Regenstrief Institute & NPU,*[5] openEHR, and WONCA.

15.33.3 Meetings

IHTSDO organizes periodic conferences. Generally within these conferences time is allocated to meetings of advisory groups, project groups and SIGs, to enable them to meet face to face. In addition there are meetings of the Member Forum and the Affiliate Forum. Advisory Groups, PGs and SIGs also communicate throughout the year via conference calls and manage messages and documents in a content management system (CMS).

15.33.4 Documentation

To support implementation of SNOMED CT a number of publications are produced by IHTSDO. These range from user guides to technical implementation guides as well as some educational materials and videos. Documents are available through the public website, but some items such as the videos can be found via YouTube. Member countries also contribute into the public domain and documents, which can often be found on individual Member country websites; a link to these is provided on the IHTSDO webpages.

15.33.5 Office

The IHTSDO head office is located at Gammeltorv 4, 1. sal, 1457 Copenhagen K, Denmark.

15.33.6 References

[1] IHTSDO articles of association

[2] IHTSDO members

[3] IHTSDO Articles of Association

[4]

[5] NPU

15.33.7 External links

- Official website

15.34 ICPC-2 PLUS

ICPC-2 PLUS is an extended terminology classified to ICPC-2 International Classification of Primary Care, which aids data entry, retrieval and analysis. ICPC-2 PLUS takes into account the frequency distribution of problems seen in primary health care. It allows for the classification of the patient's reason for encounter (RFE), the problems/diagnosis managed, primary care interventions, and the ordering of the data of the primary care session in an episode of care structure.

ICPC-2 PLUS provides a list of possible terms matching a keyword (or start of a keyword) entered by the user. The user then selects the most appropriate term. Each term is already classified to ICPC-2 rubrics and a system of additional groupers that may include terms from multiple ICPC-2 rubrics.

Each term has one or more keywords linked to it which may include abbreviations, synonyms, generics or specifics. The keyword searching is thus much broader, faster and better controlled than text mining of free text and labels. Instead of guessing what the physician meant by a term (in free text) prior to classification, the physician is actually prompted with a small list of terms to select from which are already classified.

The product also includes a 'natural language' label for each term which can be used for reports and letters.

Note: The PLUS extension mentioned here is not part of the ICPC-2 standard. The World Organization of Family Doctors (WONCA) and the WONCA International Classification Committee (WICC) have no control over it although they do have control over the ICPC classification which the PLUS extension makes use of. It is similar to the difference between a car and fuel.

15.34.1 History

ICPC-2 PLUS was the successor to 'ICPC PLUS' and were both designed by the Family Medicine Research Centre(FMRC]) for use in Australia. The FMRC continues to update and support ICPC-2 PLUS.

ICPC is being developed by the WONCA International Classification Committee (WICC), and the first version was published as ICPC-1 in 1987 by Oxford University Press (OUP), and a revision and inclusion of criteria and definitions, was published in 1998 as *ICPC-2*.

15.34.2 See also

- Classification of Pharmaco-Therapeutic Referrals
- International Statistical Classification of Diseases and Related Health Problems (ICD)
- International Classification of Primary Care (ICPC-2)
- Medical classification
- Medical record
- Electronic medical record
- WONCA International Classification Committee (WICC)

15.34.3 External links

- ICPC-2 PLUS Introduction (FMRC)
- ICPC story (WICC)
- ICPC-2 Introduction (ULB) (out-of-date, please use other links)

15.35 ISO 27799

The **ISO/IEC 27000-series** (also known as the 'ISMS Family of Standards' or 'ISO27k' for short) comprises information security standards published jointly by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).[*] [1]

The series provides best practice recommendations on information security management, risks and controls within the context of an overall information security management system (ISMS), similar in design to management systems for quality assurance (the ISO 9000 series) and environmental protection (the ISO 14000 series).

The series is deliberately broad in scope, covering more than just privacy, confidentiality and IT or technical security issues. It is applicable to organizations of all shapes and sizes. All organizations are encouraged to assess their information security risks, then implement appropriate information security controls according to their needs, using the guidance and suggestions where relevant. Given the dynamic nature of information security, the ISMS concept incorporates continuous feedback and improvement activities, summarized by Deming's "plan-do-check-act" approach, that seek to address changes in the threats, vulnerabilities or impacts of information security incidents.

The standards are the product of ISO/IEC JTC1 (Joint Technical Committee 1) SC27 (Subcommittee 27), an international body that meets in person twice a year.

The original ISO/IEC standards are sold directly by ISO, while sales outlets associated with various national standards bodies also sell various versions including local translations.

15.35.1 Early History

Many people, and many organisations, have contributed to the development of standards in the ISO27k series. The first standard in this series was ISO/IEC 17799:2000; this was a fast-tracking of the existing British standard BS 7799 part 1:1999*[2] The initial release of BS 7799 was based, in part, on an information security policy manual developed by the Royal Dutch/Shell Group in the late 1980s and early 1990s. In 1993, the Department of Trade and Industry (United Kingdom) convened a team to review existing practice in information security, with the goal of producing a standards document. In 1995, the BSI Group published the first version of BS 7799.*[3] One of the principal authors of BS 7999 recalls that, at the beginning of 1993, "The DTI decided to quickly assemble a group of industry representatives from seven different sectors: Shell ([David Lacey] and Les Riley), BOC Group (Neil Twist), BT (Dennis Willets), Marks & Spencer (Steve Jones), Midland Bank (Richard Hackworth), Nationwide (John Bowles) and Unilever (Rolf Moulton)." .*[4] David Lacey credits Donn B. Parker as having the "original idea of establishing a set of information security controls", and with producing a document containing a "collection of around a hundred baseline controls" by the late 1980s for "the I-4 Information Security circle*[5] which he conceived and founded."

15.35.2 Published standards

The published standards related to "information technology - security techniques" are:

- ISO/IEC 27000 —Information security management systems —Overview and vocabulary*[6]
- ISO/IEC 27001 —Information technology - Security Techniques - Information security management systems —Requirements. The older ISO/IEC 27001:2005 standard relied on the Plan-Do-Check-Act cycle; the newer ISO/IEC 27001:2013 does not, but has been updated in other ways to reflect changes in technologies and in how organizations manage information.
- ISO/IEC 27002 —Code of practice for information security management
- ISO/IEC 27003 —Information security management system implementation guidance
- ISO/IEC 27004 —Information security management —Measurement*[7]
- ISO/IEC 27005 —Information security risk management*[8]
- ISO/IEC 27006 —Requirements for bodies providing audit and certification of information security management systems
- ISO/IEC 27007 —Guidelines for information security management systems auditing (focused on the management system)
- ISO/IEC TR 27008 —Guidance for auditors on ISMS controls (focused on the information security controls)
- ISO/IEC 27010 —Information security management for inter-sector and inter-organizational communications
- ISO/IEC 27011 —Information security management guidelines for telecommunications organizations based on ISO/IEC 27002
- ISO/IEC 27013 —Guideline on the integrated implementation of ISO/IEC 27001 and ISO/IEC 20000-1
- ISO/IEC 27014 —Information security governance.*[9] Mahncke assessed this standard in the context of Australian e-health.*[10]
- ISO/IEC TR 27015 —Information security management guidelines for financial services
- ISO/IEC 27017 —Code of practice for information security controls based on ISO/IEC 27002 for cloud services
- ISO/IEC 27018 —Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors
- ISO/IEC 27031 —Guidelines for information and communication technology readiness for business continuity
- ISO/IEC 27032 —Guideline for cybersecurity
- ISO/IEC 27033-1 —Network security - Part 1: Overview and concepts
- ISO/IEC 27033-2 —Network security - Part 2: Guidelines for the design and implementation of network security
- ISO/IEC 27033-3 —Network security - Part 3: Reference networking scenarios - Threats, design techniques and control issues
- ISO/IEC 27033-5 —Network security - Part 5: Securing communications across networks using Virtual Private Networks (VPNs)
- ISO/IEC 27034-1 —Application security - Part 1: Guideline for application security
- ISO/IEC 27035 —Information security incident management

- ISO/IEC 27036-3 —Information security for supplier relationships - Part 3: Guidelines for information and communication technology supply chain security
- ISO/IEC 27037 —Guidelines for identification, collection, acquisition and preservation of digital evidence
- ISO 27799 —Information security management in health using ISO/IEC 27002. The purpose of ISO 27799 is to provide guidance to health organizations and other holders of personal health information on how to protect such information via implementation of ISO/IEC 27002.

15.35.3 In preparation

- ISO/IEC 27019 —Information security management guidelines based on ISO/IEC 27002 for process control systems specific to the energy utility industry
- ISO/IEC 27033 —IT network security, a multi-part standard based on ISO/IEC 18028:2006 (parts 1-3 are published already)
- ISO/IEC 27036 —Guidelines for security in supplier relationships
- ISO/IEC 27038 —Specification for redaction of digital documents
- ISO/IEC 27039 —Intrusion detection and protection systems
- ISO/IEC 27040 —Guideline on storage security* [11]
- ISO/IEC 27041 —Assurance for digital evidence investigation methods
- ISO/IEC 27042 —Analysis and interpretation of digital evidence
- ISO/IEC 27043 —Digital evidence investigation principles and processes

15.35.4 See also

- ISO/IEC JTC 1/SC 27 - IT Security techniques
- BS 7799, the original British Standard from which ISO/IEC 17799, ISO/IEC 27002 and ISO/IEC 27001 were derived
- Document management system
- Sarbanes–Oxley Act
- Standard of Good Practice published by the Information Security Forum

15.35.5 References

[1] ISO Freely Available Standards - see ISO/IEC 27000:2014

[2] "ISO27k timeline". *ISO27001security.com*. IsecT Ltd. Retrieved 1 April 2016.

[3] Jake Kouns, Daniel Minoli (2011). *Information Technology Risk Management in Enterprise Environments : a Review of Industry Practices and a Practical Guide to Risk Management Teams*. Somerset: Wiley.

[4] "David Lacey on the Origins of ISO27k". Tripwire.com. 18 October 2013.

[5] https://i4online.com/

[6] http://standards.iso.org/ittf/PubliclyAvailableStandards/c041933_ISO_IEC_27000_2009.zip

[7] http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=42106

[8] http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?csnumber=56742

[9] ISO/IEC 27014

[10] Mahncke, R. J. (2013). The Applicability of ISO/IEC27014:2013 For Use Within General Medical Practice.

[11] "ISO/IEC 27040". *ISO Standards Catalogue*. ISO. Retrieved 2014-06-15.

15.35.6 External links

- The ISO 17799 Newsletter
- Opensource software to support ISO 27000 processes

15.36 ISO/IEEE 11073

CEN ISO/IEEE 11073 Health informatics - Medical / health device communication standards enable communication between medical, health care and wellness devices and with external computer systems. They provide automatic and detailed electronic data capture of client-related and vital signs information, and of device operational data.

15.36.1 Background

Goals

1. Real-time plug-and-play interoperability for citizen-related medical, healthcare and wellness devices;
2. Efficient exchange of care device data, acquired at the point-of-care, in all care environments.

- "Real-time" means that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second.
- "Plug-and-play" means that all a user has to do is make the connection – the systems automatically detect, configure, and communicate without any other human interaction
- "Efficient exchange of care device data" means that information that is captured at the point-of-care (e.g., personal vital signs data) can be archived, retrieved, and processed by many different types of applications without extensive software and equipment support, and without needless loss of information.

The standards are targeted at personal health and fitness devices (such as glucose monitors, pulse oximeters, weighing scales, medication dispensers and activity monitors) and at continuing and acute care devices (such as pulse oximeters, ventilators and infusion pumps). They comprise a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced. There are four main partitions to the standards:

- Device data, including a nomenclature, or terminology, optimized for vital signs information representation based on an object-oriented data model, and device specialisations;
- General application services (e.g., polled vs. "event driven" services);
- Internetworking and gateway standards (e.g., an observation reporting interface from CEN ISO/IEEE 11073-based messaging and data representation to HL7 or DICOM);
- Transports (e.g., cable connected or wireless).

Problems

- In the absence of standards for these devices, (a) data is captured either manually or at considerable expense (using specialized equipment), or (b) it is not captured at all, which is most often the case.
- Manually captured data is labour-intensive, recorded infrequently (e.g., written down hourly by a nurse clinician), and prone to human error.
- Use of expensive custom connectivity equipment (a) drives up the cost of care delivery; (b) is only used for patients with the highest acuity; and (c) tends to lock care providers into single companies or partnerships that provide "complete" information system solutions, making it difficult to choose best-of-breed technologies to meet client needs, or the most cost effective systems.
- Development and deployment of advanced care delivery systems are hindered. For example, systems that collect real-time data from multiple devices and use the information to detect safety problems (e.g., adverse drug events), or to quickly determine a client's condition and automatically, or with minimal carer involvement, optimally adjust a device's operation (e.g., for insulin delivery based on glucose level information) cannot operate without these standards.
- With no standardisation in this area, even when similar devices do provide communications, there is no consistency in the information and services that are provided, thus inhibiting the development of advanced care delivery systems or even consistent health records.

In short: appropriate use of 11073 device communication standards can help deliver better health, fitness and care, more quickly, safely, and at a lower cost.

Motivation

- These are the only standards addressing this area of connectivity.
- They provide a complete solution for medical device connectivity, starting at the physical cable or wireless connection up through the abstract representation of information and the services used for its management and exchange.
- They can enable full disclosure of device-mediated information. So measurement modalities be declared in detail and the associated metrics & alerts communicated, together with any user-made changes to settings. In addition, the device can communicate its manufacturer, model, serial number, configuration, operating status and network location – all in real time if required.
- The IEEE 11073 standards have been developed with a high level of international participation. They have been, and continue to be, adopted as International Organisation for Standardisation(ISO) standards through ISO TC215 Health Informatics and

as European standards through the Committee for European Normalisation (CEN) TC251 Health Informatics, specifically as the CEN ISO/IEEE 11073 series. The end result is a single set of internationally harmonized standards that have been developed and adopted by ISO and CEN member countries.

- These CEN ISO/IEEE 11073 standards have been developed in close coordination with other standards development organisations, including IEEE 802, IHTSDO, IrDA, HL7, DICOM, and CLSI.
- Memoranda of Understanding with IHE, IHTSDO, and HL7; and (through ISO) close liaison with Continua Health Alliance assist still wider integration.
- The CEN ISO/IEEE 11073 nomenclature is now being used to populate, and to establish equivalence, within SNOMED CT - the most widely used clinical terminology.
- A liaison between the IEEE 11073 standards group and the USA Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) in the USA helps ensure that patient safety and efficacy concerns are fully addressed in the standards.
- The Continua Health Alliance and the English NHS National Programme for Information Technology (NPfIT) both specify use of the standards for device communication.
- The standards have been included in the USA National Committee on Vital and Health Statistics recommendations to the Department of Health and Human Services related to patient medical record information message formats supporting Health Insurance Portability and Accountability Act (HIPAA) compliant implementations.
- The cost of integrating innovative technologies into established product lines is reduced —and a barrier to new companies is lowered.

Availability

11073 standards are available freely to those actively involved in their development, others may purchase them. For published and draft standards **search for '11073' at**: IEEE,*[1] ISO *[2] or CEN.*[3] Standards may be purchased from the national standards organisation or bookstore (e.g. AFNOR, BSI, DIN, JIS, UNI, etc.).

15.36.2 Overview

The ISO/IEEE 11073 Medical / Health Device Communication Standards are a family of ISO, IEEE, and CEN joint standards addressing the interoperability of medical devices. The ISO/IEEE 11073 standard family defines parts of a system, with which it is possible, to exchange and evaluate vital signs data between different medical devices, as well as remote control these devices.

Point-of-care medical device

The 'core' standards are: 11073-10101, 11073-10201, 11073-20101 and 11073-30200

Personal health device

ISO/IEEE 11073 personal health device (PHD) standards are a group of standards addressing the interoperability of personal health devices (PHDs) such as weighing scales, blood pressure monitors, blood glucose monitors and the like. The standards draw upon earlier IEEE11073 standards work, but differ from this earlier work due to an emphasis on devices for personal use (rather than hospital use) and a simpler communications model.

These are described in more detail at ISO/IEEE 11073 Personal Health Data (PHD) Standards

15.36.3 Core standard

Nomenclature

Within this standard nomenclature codes are defined, these give the possibility to clearly identify objects and attributes in relation to the so-called OID-Code (). The nomenclature is divided in partitions, to demarcate codes with regards to content and functions. Programmatically these codes are defined as constants, those can be used by a pseudonym.
example in C++:

#define MDC_PART_OBJ 1 /* Definition for the Partition Object Infrastructure */ #define MDC_MOC_VMS_MDS_SIMP 37 /* Define the Object Simple Medical Device System */

Domain information model

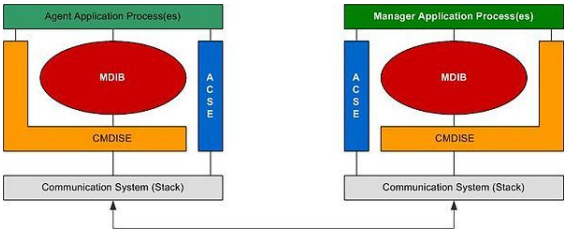
This standard is the "heart" of VITAL. Within this, objects and their arrangement in a Domain Information Model for vital signs data transmission are defined. Beyond this the standard defines a service model for the standardized communication.

Base standard

The common background for assembly and transmission of objects and their attributes are defined in this standard. It's subdivided in a communication model and an information model. The communication model describes the

layers 5 to 7 of the OSI 7-layer model. The information model defines the modeling, formatting and the syntax for transmission coding of the objects.

15.36.4 Agent/manager principle



Agents and managers in ISO/IEEE 11073

All defined parts of this standard family are designed to allow communication according to this principle. The arrangement of two or more medical devices as a system, so that the components are possible to understand and to interact, are the basic idea of this principle.

The agent is the part of the principle that is connected to the medical devices. It provides the data. The manager keeps a copy of the agent data, reacts on update events from them, and triggers events on the agent. In most use cases the manager is only used to remotely monitor and display agent data, but in some cases it may also remotely control the agents. Agents and manager are built in the same structure. This enables an agent to act as a manager and reverse. Besides the plain agent-manager application, hybrid systems over multiple stages are possible.

Agent application process(es)

This module is the interface between a proprietary (eventually native) protocol and the ISO/IEEE (VITAL) object world. It is not defined within the standard and as a result it can be implemented free.

Medical data information base

MMOs (Managed Medical Objects) are stored hierarchically within a tree structure in a form named Domain Information Model (DIM). This MMOs and their arrangement in the DIM are defined within this standard. The implementation of the MDIB (Medical Device Information Base) and their functionallity is out of the scope of the standard.

Association service control element

This module is subject to the standards ISO/IEC 15953 and ISO/IEC 15954. It has services available, that controlling the association assembly and disassembly. A possible association and their condition is negotiated here, no MMOs are transmitted over this module.

Common medical device information service element

Services for the data exchange of MMOs (Managed Medical Objects) between Agent-Manager systems, are defined in this module. This data exchange is highly dynamic. Objects are created, changed or deleted by services named CREATE, UPDATE, DELETE. Through reports, which can be defined detailed down to the single object attribute, it is possible to trigger complex operations in Agent or Manager, through this services.

Presentation layer

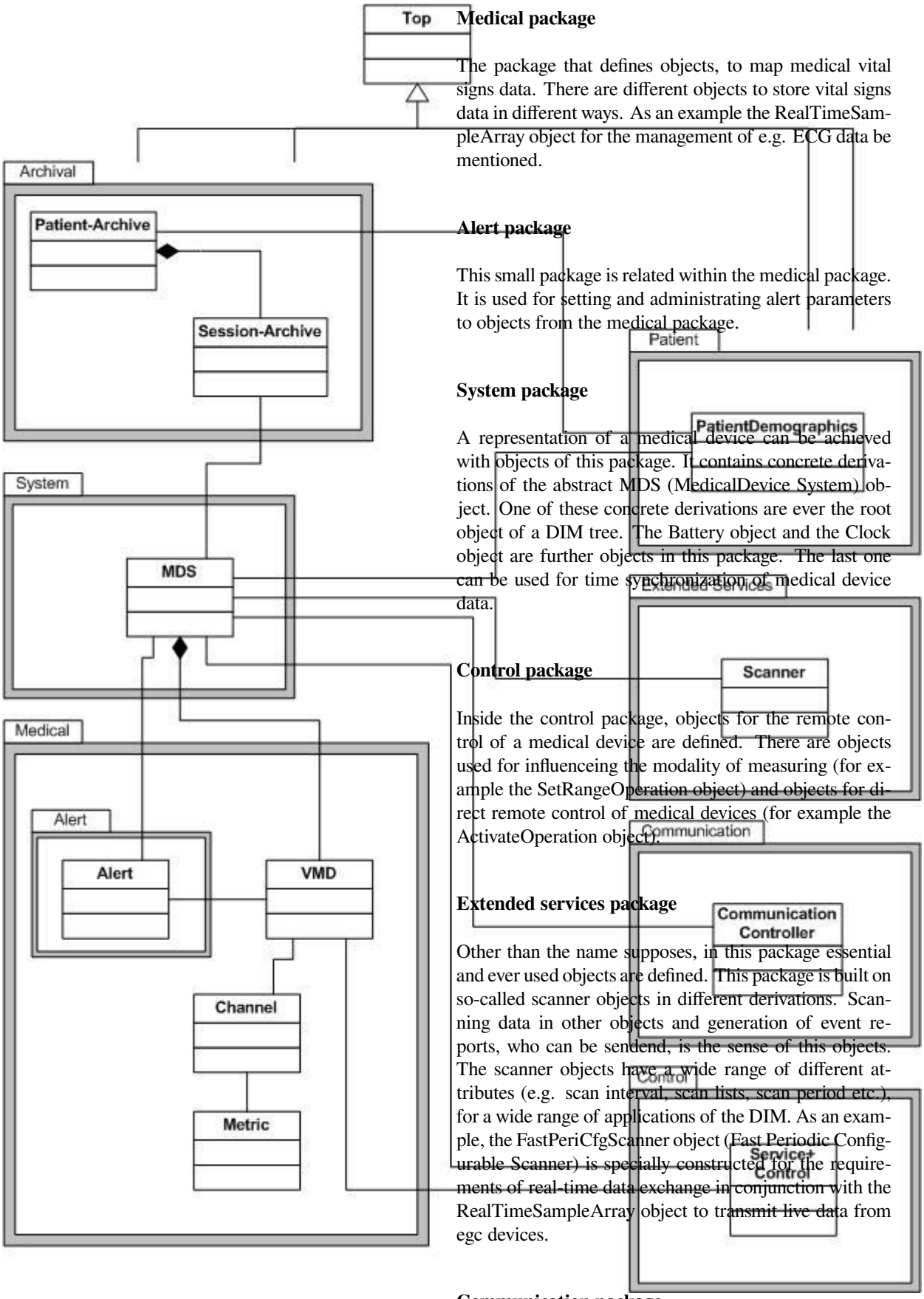
This layer contains the encoding of object data. Objects, groups of objects attributes or single attributes are encoded by ASN.1 representations, respectively the spezialization MDER (Medical Device encoding Rules).

Session layer

That layer controls connection at the session level.

15.36.5 Domain information model

The central core of the standard is the so-called Domain Information Model. Objects containing vital-sign data representations and their relationships are defined in this model. Objects for additional services around vital signs data objects, are defined also here.



For content sensitive classification of the objects, they are divided into packages.

Medical package

The package that defines objects, to map medical vital signs data. There are different objects to store vital signs data in different ways. As an example the RealTimeSampleArray object for the management of e.g. ECG data be mentioned.

Alert package

This small package is related within the medical package. It is used for setting and administrating alert parameters to objects from the medical package.

System package

A representation of a medical device can be achieved with objects of this package. It contains concrete derivations of the abstract MDS (MedicalDevice System) object. One of these concrete derivations are ever the root object of a DIM tree. The Battery object and the Clock object are further objects in this package. The last one can be used for time synchronization of medical device data.

Control package

Inside the control package, objects for the remote control of a medical device are defined. There are objects used for influenceing the modality of measuring (for example the SetRangeOperation object) and objects for direct remote control of medical devices (for example the ActivateOperation object).

Extended services package

Other than the name supposes, in this package essential and ever used objects are defined. This package is built on so-called scanner objects in different derivations. Scanning data in other objects and generation of event reports, who can be sendend, is the sense of this objects. The scanner objects have a wide range of different attributes (e.g. scan interval, scan lists, scan period etc.), for a wide range of applications of the DIM. As an example, the FastPeriCfgScanner object (Fast Periodic Configurable Scanner) is specially constructed for the requirements of real-time data exchange in conjunction with the RealTimeSampleArray object to transmit live data from egc devices.

Communication package

The objects in these package contain information, which are responsible for basic communication profiles. These

packages are developed very open, so that different communication profiles and interfaces to proprietary device interfaces can be built. Annotation by the author: From a historic view, the standard was developed for the first time in the early 90s, this package has to be reconstructed.

Archival package

Storing Patient related data in online or offline archives is the idea for objects in the archival package. For Example, the Patient Archive object can store vital signs data, demographic data and treatment data in one object.

Patient package

The patient package contains only one object, the Patient Demographics object. This object contains patient related data and can be set in relationship to an MDS object or one of the objects from the archive package, to give anonymous data the reference to patient data.

15.36.6 Communication model

The complete communication sequence can be very complex. This article should provide basic information, that can be described in more detail at a later time in a separate article.

Finite state machine

The finite state machine regulates the synchronization of an Agent Manager system over different conditions. A complete session roundtrip starts up with the disconnected state, is transferred by multiple stages to the initialized state, in what the actual data transfer shall be done, and ends with the disconnected state.

Initializing MDIB

During the association phase, the configuring state will be reached. In this condition Agent and Manager are to exchange object data for the first time. In the process a MDSCreateEvent in the form of a report would be triggered. This report creates a copy of the MDS root object from the Agent MDIB in the Manager MDIB. Afterward a Contextscanner object is created in the Agent MDIB. This scanner object scans the complete MDIB and generates a report containing the complete Agent MDIB representation, except the MDS root object. The Manager evaluates this report and creates the objects defined here in his own MDIB copy. At this point the manager has an exact copy of the Agent MDIB. Both are now at configured state.

Data exchange through services

The Common Medical Device Information Service Element (CMDISE) provides a GET service, to deliver data requested by the Manager. The Agent GET service retrieves a list of attribute ids. These ids identify explicit values within Agents MDIB. Now the Agent creates a report, containing the requested values. This report is sent back to the Manager.

Data exchange through scanner objects

In an MDIB, additional objects shall be created through the CREATE service of CMDISE. The Manager requests the Agent through this service to create a scanner object itself, and to fix the scanner object on one or more values. Optional for example the scan interval for the data delivery can be set. The Agent creates the scanner object in his own MDIB and sends the Manager a response message. Now the Manager creates a copy of the scanner object in his MDIB. The data updates from Agent to Manager now occur automatically through the scanner object. Through CMDISE's DELETE service, the scanner object can be deleted, like all other MDIB objects.

15.36.7 References

[1] http://shop.ieee.org/ieeestore

[2] http://www.iso.org/iso/search.htm?qt=11073&searchSubmit=Search&sort=rel&type=simple&published=true

[3] http://www.cen.eu/esearch/extendedsearch.aspx

Android 4.0 implements support for IEEE 11073 via the BluetoothHealth class

NIST Standard Conformance Tools

15.37 ISO/TC 215

The **ISO/TC 215** is the International Organization for Standardization's (ISO) Technical Committee (TC) on health informatics. TC 215 works on the standardization of Health Information and Communications Technology (ICT), to allow for compatibility and interoperability between independent systems.

15.37.1 Working Groups

ISO TC 215 consists of several Working Groups (WG), each dealing with an aspect of Electronic Health Records (EHR).

- CAG 1: Executive council, harmonization and operations

- WG 1: Data structure
- WG 2: Messaging and communications
- WG 3: Health Concept Representation
- WG 4: Privacy and Security
- WG 5: Health Cards >>Transitioned to a Task Force on Health Cards.
- WG 6: Pharmacy and medicines business
- WG 7: Devices
- WG 8: Business requirements for Electronic Health Records
- WG 9: SDO Harmonization

Task Forces: --e-Business for Healthcare Transactions —Multidisciplinary for Healthcare Clinicians —Harmonized Joint Work Group for Devices —Traditional Medicine (Currently restricted to Far Eastern Traditional Medicine) --Health Cards—Patient Safety and Quality

15.37.2 Standards

July 2009 Current list of completed standards and other deliverables from TC 215:

ISO/HL7 27931 2009

Data Exchange Standards—Health Level Seven Version 2.5 -- An application protocol for electronic data exchange in healthcare environments Health Level 7

ISO/TR 27809 2007

Health informatics —Measures for ensuring patient safety of health software

ISO 27799 2008

Health informatics—Information security management in health using ISO/IEC 27002

ISO/TS 25238 2007

Health informatics—Classification of safety risks from health software

ISO/TS 25237 2008

Health informatics—Pseudonymization

ISO 22857 2004

Health informatics—Guidelines on data protection to facilitate trans-border flows of personal health information

ISO/TR 22790 2007

Health informatics—Functional characteristics of prescriber support systems

ISO/TS 22600-2 2006

Health informatics—Privilege management and access control—Part 2: Formal models

ISO/TS 22600-1 2006

Health informatics—Privilege management and access control—Part 1: Overview and policy management

ISO/TR 22221 2006

Health informatics - Good principles and practices for a clinical data warehouse

ISO/TS 22220 2009

Health Informatics—Identification of subjects of health care

ISO/HL7 21731 2006

Health informatics—HL7 version 3 -- Reference information model—Release 1

ISO/TR 21730 2007

Health informatics—Use of mobile wireless communication and computing technology in healthcare facilities —Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices

ISO/TS 21667 2004

Health informatics —Health indicators conceptual framework

ISO 21549-7 2007

Health informatics—Patient healthcard data—Part 7: Medication data

ISO 21549-6 2008

Health informatics—Patient healthcard data—Part 6: Administrative data

ISO 21549-5 2008

Health informatics—Patient healthcard data—Part 5: Identification data

ISO 21549-4 2006

Health informatics—Patient healthcard data—Part 4: Extended clinical data

ISO 21549-3 2004

Health informatics—Patient healthcard data—Part 3: Limited clinical data

ISO 21549-2 2004

Health informatics—Patient healthcard data—Part 2: Common objects

ISO 21549-1 2004

Health informatics—Patient healthcard data—Part 1: General structure

ISO/TS 21298 2008

Health informatics—Functional and structural roles

ISO/TS 21091 2005

Health informatics—Directory services for security, communications and identification of professionals and patients

ISO/TR 21089 2004

Health informatics—Trusted end-to-end information flows

ISO/TR 20514 2005

Health informatics—Electronic health record—Definition, scope and context

ISO 20302 2006

Health informatics—Health cards—Numbering system and registration procedure for issuer identifiers

ISO 20301 2006

Health informatics—Health cards—General characteristics

ISO 18812 2003

Health informatics—Clinical analyser interfaces to laboratory information systems—Use profiles

ISO/TS 18308 2004

Health informatics—Requirements for an electronic health record architecture

ISO/TR 18307 2001

Health informatics—Interoperability and compatibility in messaging and communication standards—Key characteristics

ISO 18232 2006

Health Informatics—Messages and communication—Format of length limited globally unique string identifiers

ISO 18104 2003

Health informatics—Integration of a reference terminology model for nursing

ISO 17432 2004

Health informatics—Messages and communication—Web access to DICOM persistent objects

ISO/TS 17120:2004 Health informatics—Country identifier standards (Withdrawn 2009-09-22)

ISO/TR 17119 2005

Health informatics - Health informatics profiling framework

ISO/TS 17117 2002

Health informatics—Controlled health terminology—Structure and high-level indicators

ISO 17115 2007

Health informatics—Vocabulary for terminological systems

ISO 17090-3 2008

Health informatics—Public key infrastructure—Part 3: Policy management of certification

and authority

ISO 17090-2 2008

Health informatics—Public key infrastructure—Part 2: Certificate profile

ISO 17090-1 2008

Health informatics—Public key infrastructure—Part 1: Overview of digital certificate services

ISO/TS 16058 2004

Health informatics—Interoperability of telelearning systems

ISO/TR 16056-2 2004

Health informatics—Interoperability of telehealth systems and networks—Part 2: Real-time systems

ISO/TR 16056-1 2004

Health informatics—Interoperability of telehealth systems and networks—Part 1: Introduction and definitions

EN 14463 2007

Health informatics-A syntax to represent the content of medical classification systems - ClaML

ISO 13606-3 2009

Health informatics—Electronic health record communication—Part 3: Reference archetypes and term lists

ISO 13606-2 2008

Health informatics—Electronic health record communication—Part 2: Archetype interchange specification

ISO 13606-1 2008

Health informatics—Electronic health record communication—Part 1: Reference model

ISO/TR 12773-2 2009

Business requirements for health summary records—Part 2: Environmental scan

ISO/TR 12773-1 2009

Business requirements for health summary records—Part 1: Requirements

ISO 12052 2006 (DICOM)

Health informatics—Digital imaging and communication in medicine (DICOM) including workflow and data management

ISO/TR 11487 2008

Health informatics—Clinical stakeholder participation in the work of ISO TC 215

ISO/IEEE 11073

ISO/TS 11073-92001 2007

Health informatics—Medical waveform format—Part 92001: Encoding rules

ISO 11073-91064 2009

Health informatics—Standard communication protocol—Part 91064: Computer-assisted electrocardiography

ISO 11073-90101 2008

Health informatics—Point-of-care medical device communication—Part 90101: Analytical instruments—Point-of-care test

ISO/IEEE 11073-30300 2004

Health informatics—Point-of-care medical device communication—Part 30300: Transport profile—Infrared wireless

ISO/IEEE 11073-30200 2004

Health informatics—Point-of-care medical device communication—Part 30200: Transport profile—Cable connected

ISO/IEEE 11073-20101 2004

Health informatics—Point-of-care medical device communication—Part 20101: Application profiles—Base standard

ISO/IEEE 11073-10201 2004

Health informatics—Point-of-care medical device communication—Part 10201: Domain information model

ISO/IEEE 11073-10101 2004

Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature

15.37.3 See also

- Medical record
- Electronic medical record
- International Medical Informatics Association
- Canada Health Infoway
- European Institute for Health Records
- National Resource Center for Health Information Technology
- CEN/TC 251 (European Union)
- Data governance

15.37.4 External links

- http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=54960
- ISO/TC 215 is a member of the Joint Initiative on SDO Global Health Informatics Standardization
- http://www.himss.org/ASP/topics_ISO.asp

15.38 LOINC

Logical Observation Identifiers Names and Codes (LOINC) is a database and universal standard for identifying medical laboratory observations. First developed in 1994, it was created and is maintained by the Regenstrief Institute, a US nonprofit medical research organization. LOINC was created in response to the demand for an electronic database for clinical care and management and is publicly available at no cost.

It is endorsed by the American Clinical Laboratory Association and the College of American Pathologists. Since its inception, the database has expanded to include not just medical laboratory code names but also nursing diagnosis, nursing interventions, outcomes classification, and patient care data sets.

15.38.1 Function

LOINC applies universal code names and identifiers to medical terminology related to electronic health records. The purpose is to assist in the electronic exchange and gathering of clinical results (such as laboratory tests, clinical observations, outcomes management and research). LOINC has two main parts: laboratory LOINC and clinical LOINC. Clinical LOINC contains a subdomain of Document Ontology which captures types of clinical reports and documents.*[1]*[2]

Several standards, such as **IHE** or **HL7**, use LOINC to electronically transfer results from different reporting systems to the appropriate healthcare networks. However, the health information enclosed is identified by a multiplicity of code values that may vary according to the entity producing those results. This has obvious disadvantages to the healthcare network that may need to adopt different codes to access and manage information coming from multiple sources. Managed care providers, for example, often have negotiated contracts that reimburse episodes of care and unique coding to trigger automated claim payment. Mapping each entity-specific code to its corresponding universal code can represent a significant investment of both human and financial capital.

A universal code system will enable facilities and departments across the world to receive and send results from their areas for comparison and consultation and may contribute toward a larger public health initiative of improving clinical outcomes and quality of care.

LOINC is one of the standards for use in U.S. Federal Government systems for the electronic exchange of clinical health information. In 1999, it was identified by the HL7 Standards Development Organization as a preferred code set for laboratory test names in transactions between health care facilities, laboratories, laboratory testing devices, and public health authorities.*[3]

15.38.2 Format

A formal, distinct, and unique 6-part name is given to each term for test or observation identity.*[4] The database currently has over 71,000 observation terms that can be accessed and understood universally. Each database record includes six fields for the unique specification of each identified single test, observation, or measurement:

1. Component- what is measured, evaluated, or observed (example: urea,...)
2. Kind of property- characteristics of what is measured, such as length, mass, volume, time stamp and so on
3. Time aspect- interval of time over which the observation or measurement was made
4. System- context or specimen type within which the observation was made (example: blood, urine,...)
5. Type of scale- the scale of measure. The scale may be quantitative, ordinal, nominal or narrative
6. Type of method- procedure used to make the measurement or observation

A unique code (format: nnnnn-n) is assigned to each entry upon registration. Other database fields include status and mapping information for database change management, synonyms, related terms, substance information (e.g. molar mass, CAS registry number), choices of answers for nominal scales, translations.

15.38.3 Uses

Some of the advantages resulting from adopting LOINC may include improved communication in integrated healthcare delivery networks, improved community wide electronic health records, the automatic transfer to public health authorities of case reports for reportable diseases (e.g. for disease control or detection of epidemics), improved transfer of payment information for services rendered and a significant improvement in the overall quality of health care by reducing errors in the system.

The fact that universal standards are being promoted (if not adopted by national organizations and agencies) is an indication that the dialogue will continue regarding the development, structure, financing, monitoring, enforcement, and integration of standards within the broader health care system.

International interest in LOINC continues to grow. A number of efforts have been undertaken to translate the LOINC documents and terms into various languages, such as Simplified Chinese, German, Spanish. For more information on LOINC International, see LOINC International. As of January, 2009, the software RELMA (**Re**genstrief **L**OINC **M**apping **A**ssistant) is available in separate downloads that contain an additional word index in Spanish, Simplified Chinese, or Korean, which allows searching in these languages in addition to English.*[5] Harmonization efforts between LOINC and SNOMED CT were initiated in 2012.

15.38.4 See also

- CDA
- CDISC
- Clinical Care Classification System
- DICOM
- DOCLE

- HL7
- Public Health Information Network
- SNOMED, SNOMED CT
- UMLS
- Controlled vocabulary
- Template:LOINC

15.38.5 References

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[2] "Suitability of LOINC Document Ontology as a reference terminology for clinical document types: A case report of a research-oriented EHR". Retrieved 2 Oct 2012.

[3] "LOINC and other standards". Retrieved 7 November 2011.

[4] Alex A. T. Bui; Ricky K. Taira (August 2009). *Medical Imaging Informatics*. Springer. pp. 107–. ISBN 978-1-4419-0384-6. Retrieved 31 May 2011.

[5] "RELMA Version 4.00 Available". Retrieved 7 November 2011.

15.38.6 External links

- LOINC pages of Regenstrief Institute, Inc.
  - LOINC International
  - Web site of the Regenstrief LOINC Mapping Assistant (RELMA)
- Introduction to the HL7 Standards
- U.S. National Library of Medicine
- Chinese LOINC Interface System - a pilot project that aims to show a simplified Chinese version of LOINC terms.
- LOINC JSON API - an open API for searching and retrieving LOINC code metadata in JSON
- ITServer-LOINC Browser - A free online LOINC browser that shows all the attributes and the official mapping with SNOMED CT

15.39 MEDCIN

MEDCIN, a system of standardized medical terminology, is a proprietary medical vocabulary and was developed by Medicomp Systems, Inc. MEDCIN is a point-of-care terminology, intended for use in Electronic Health Record (EHR) systems,[*][1] and it includes over 280,000 clinical data elements encompassing symptoms, history, physical examination, tests, diagnoses and therapy.[*][2] This clinical vocabulary contains over 26 years of research and development as well as the capability to cross map to leading codification systems such as SNOMED CT, CPT, ICD-9-CM/ICD-10-CM, DSM, LOINC, CDT and the Clinical Care Classification (CCC) System for nursing and allied health.[*][3]

The MEDCIN coding system is touted especially for point-of-care documentation and architecture. Several Electronic Health Record (EHR) systems embed MEDCIN, which allows them to produce structured and numerically codified patient charts. Such structuring enables the aggregation, analysis, and mining of clinical and practice management data related to a disease, a patient or a population.

15.39.1 History

MEDCIN was initially developed by Peter S. Goltra, founder of Medicomp Systems "as an intelligent clinical database for documentation at the time of care."[*][4] The first few years of the development were spent in designing the structure of a knowledge engine that would enable the population of relationships between clinical events. Since 1978, the MEDCIN database engine has been continuously refined and expanded to include concepts from clinical histories, test, physical examination, therapies and diagnoses to enable coding of complete patient encounters with the collaboration of physicians and teaching institutions such as Cornell, Harvard, and Johns Hopkins.[*][5][*][6]

15.39.2 Features

Multiple Hierarchical Structure

MEDCIN data elements are organized in multiple clinical hierarchies, where users can easily navigate to a medical term by following down the tree of clinical propositions. The clinical propositions define unique intellectual clinical content. An example of such similar propositions include "wheezing which is worse during cold weather" and "wheezing which is worse with a cold" differ in meaning significantly to clinicians and therefore it enables the software to present relevant items to clinical users.[*][7]

This hierarchy provides an inheritance of clinical properties between data elements, which greatly enhances the

capabilities of EHR systems and as well providing logical presentation structures for the clinical users.*[8] The linkage of MEDCIN data elements through the use of describing many diagnoses in the diagnostic index creates multiple hierarchies.*[8] The MEDCIN engine uses Intelligent Prompting and navigation tools to enable clinicians to select specific clinical terms that they need rather than having to create new terms for rapid documentation. *[9]*[10]

Enhances EHRs usability

MEDCIN has been designed to work as an interface terminology*[11] to include components to make EHRs more usable when it is used in conjunction with proprietary physician and nursing documentation tools.*[12] According to Rosenbloom et al. (2006), investigators such as Chute et al., McDonald et al., Rose et al. and Campbell et al. have defined clinical interface terminologies as "a systematic collection of health care-related phrases (term)" (p. 277) that supports the capturing of patient-related clinical information entered by clinicians into software programs such as clinical note capture and decision support tools.*[13]

For an interface terminology to be clinical usable, it has to be able to describe any clinical presentation with speed, ease of use, and accuracy for clinicians to accomplish the intended tasks (e.g. documenting patient care) when using the medical terminology.*[13] In addition, the terms in medical terminology must have medical relationships.*[10] The MEDCIN's presentation engine, accomplish this usability criteria by using the Intelligent Prompting capabilities to present a relevant list of MEDCIN clinical terms for rapid clinical documentations. Another usability feature that the MEDCIN's presentation engine provides is the medical relationships of clinical terms through multiple clinical hierarchies for each MEDCIN term.*[10]

Support ICD-10-CM coding

In August 2012, Medicomp Systems released the new updated version of the MEDCIN ® Engine embedded with ICD-10-CM (International Classification of Diseases, 10th Revision, Clinical Modification) mappings and functionality to comply with the transition from ICD-9-CM to ICD-10-CM as mandated by the US Department of Health and Human Services.*[14]*[15] This new version is specially designed to make the ICD-10 more usable in the EHR systems by providing clinicians easier access to bi-directional mappings, accurate data and codes through their EHR products.*[16] The ICD-10 is published by the World Health Organization (WHO) to enable the systematic collection of morbidity and mortality data from different countries for statistical analysis.*[17]

Integration to most EHRs and Legacy systems

MEDCIN terminology engine can be easily integrated into existing EHRs and legacy systems to enable mapping of existing terminologies and other coding systems such as ICD, DSM, CPT, LOINC, SNOMED CT and the Clinical Care Classification (CCC) System to generate seamless codified data at point of care.*[8]*[15] MEDCIN's interoperability features enable easy access and sharing of patient data between health care facilities.

15.39.3 Interface with Electronic Health Record (EHR) systems

MEDCIN has been implemented into several commercial EHR systems as an interface terminology to support integrated care, clinical documentation, health maintenance monitoring and disease management, and the care planning functions of physicians, nurses and allied health professionals.*[6]*[18] Such commercial EHR systems include MedcomSoft Record (developed by MedcomSoft Inc) and the United States Department of Defence's (DoD) EHR system, the Armed Forces Health Longitudinal Technology Application (AHLTA).

MedcomSoft Record

In 2006, MedcomSoft introduced an interoperable EHR system, MedcomSoft Record, that integrates with MEDCIN engine to produce structure data that is automatically codified and provides cross mapping to other industry standard reference terminologies such as SNOMED, LOINC and ICD-9.*[19] This integration also enables laboratory test results and drug prescriptions to be automatically codified with MEDCIN numeric codes in the same way as clinical notes.

AHLTA

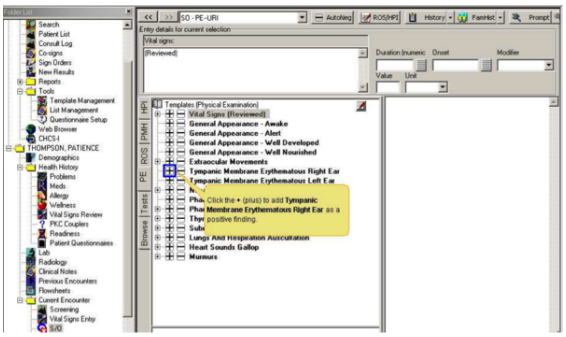

Figure 1: AHLTA and MEDCIN terminology systems

AHLTA is an EHR system developed for the US Department of Defense. This application uses the Medicomp's MEDCIN terminology engine for clinical documentation

purposes. Figure 1, shows an example of the MEDCIN terminology where the physician can search for the correct terms for input into the patient note.*[20]

15.39.4 MEDCIN Nursing Plan of Care

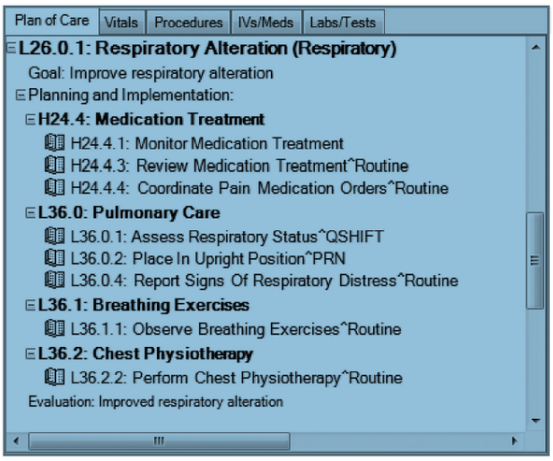

Figure 2: MEDCIN plan of care with nursing diagnoses

The Nursing Plan of Care (POC) was developed by Medicomp Systems, for the Clinical Care Classification (CCC) System.*[18] The CCC System is a standardized, coded nursing terminology that provides a unique framework and coding structure for accessing, classifying and documenting patient care by nurses and other allied health professionals.*[21] The CCC is directly linked in the MEDCIN nursing POC to medical terminology with the purpose of creating patient plan of care by extracting a pool of documentation from the EHR history.*[18] The CCC nursing terminology is integrated into the MEDCIN clinical database through a contextual hierarchical tree, providing an array of terminology standards and concepts with Intelligent Prompting capabilities of the MEDCIN engine.*[18] "MEDCIN® used a diagnostic index to provide a method to link signs and symptoms and as well clinical diagnoses to CCC nursing diagnoses, interventions, goals, actions and outcome." *[22] This method enables the MEDCIN clinical database to be populated with CCC nursing terminology as illustrated in Figure 2.

15.39.5 Sample Computer Applications Using MEDCIN

- Electronic Medical Records
- Greenway Health Intergy EHR
- Origin Healthcare Solutions, EMRge
- Computerized Physician Order Entry (e.g. E-Prescribing or Laboratory Order Entry)
- Emergency Room Charting
- MedcomSoft Record
- Pulse EMR

15.39.6 See also

- Clinical Care Classification System
- Current Procedural Terminology (CPT)
- International Classification of Diseases Revision 9 (ICD-9)
- LOINC
- National Drug Code (NDC)
- SNOMED
- Health Level 7 (HL7)
- Health informatics

15.39.7 Further reading

- Goltra, Peter S. *MEDCIN: A New Nomenclature for Clinical Medicine*. Ann Arbour, MI 1997:Springer-Verlag ISBN 0-387-94953-4.

15.39.8 References

[1] "Medicom Systems" . Retrieved 14 April 2013.

[2] "2012AB MEDCIN Source Information" . Retrieved 26 May 2013.

[3] Whittenburg, L. (2012) The CCC system in medicomp's point of care knowledge engine (MEDCIN) (pp.52) In Saba, V. (2012) Clinical Care Classification (CCC) System Version 2.5, 2nd Edition: User's Guide, New York,NY: Springer Publishing.

[4] Brown, S.H.; Rosenbloom, S.T.; Bauer, B.A.; Wahner-Roedler, D.; Froehling, D.A.; Bailey, K.R.; Lincoln, M.J.; Montella, D.; Fielstein, E.M.; Elkin, P.L. (2007). "Direct Comparison of MEDCIN® and SNOMED CT® for Representation of a General Medical Evaluation Template" . *AMA Symposium Proceedings*: 75–79. PMC 2655894. PMID 18693801.

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[8] Zanstra, P.E, van der Haring, E.J, Cornet, R, (2003). Introduction of a Clinical Terminology in the Netherlands: Needs, Constraints, Opportunities. Depts. Medical Informatics, UMC St Radboud Nijmegen, AMC Amsterdam. pg 62

[9] "SNOMED and MEDCIN: Hand in Hand and Toe to Toe". 2012. Retrieved 1 May 2013.

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[11] Gasch, A.; Gasch, B. (2010). *Successfully choosing your EMR 15 crucial decisions*. Oxford: John Wiley & Sons. p. 117. ISBN 9781444320336.

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[13] Rosenbloom, S.T.; Miller,R.A.; Johnson, K.B.; Elkin, P.L.; Brown, S.H. (2006). "Interface Terminologies: Facilitating Direct Entry of Clinical Data into Electronic Health Record Systems". *Journal of the American Medical Informatics Association* **13** (3): 277–288. doi:10.1197/jamia.m1957. PMC 1513664. PMID 16501181.

[14] "ICD-10 Code Set to Replace ICD-9". American Medical Association. Retrieved 3 June 2013.

[15] "Why Medicomp?". Retrieved 14 April 2013.

[16] "Medicomp Releases ICD-10-CM with New Version of the Powerful MEDCIN Engine® (2011)". Retrieved 14 April 2013.

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15.39.9 External links

- Medicomp home page

15.40 MedDRA

MedDRA or **Medical Dictionary for Regulatory Activities** is a clinically validated international medical terminology dictionary (and thesaurus) used by regulatory authorities in the pharmaceutical industry during the regulatory process, from pre-marketing to post-marketing activities, and for data entry, retrieval, evaluation, and presentation. In addition, it is the adverse event classification dictionary endorsed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Originally available in English and Japanese, MedDRA is now also translated into Chinese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese and Spanish. *[1] MedDRA is widely used internationally, including in the United States, European Union, and Japan. Its use is currently mandated in Europe and Japan for safety reporting.

15.40.1 Organization of the dictionary

The MedDRA dictionary is organized by System Organ Class (SOC), divided into High-Level Group Terms (HLGT), High-Level Terms (HLT), Preferred Terms (PT) and finally into Lowest Level Terms (LLT).*[2] In addition, the MedDRA dictionary includes Standardized MedDRA Queries (SMQs). SMQs are groupings of terms that relate to a defined medical condition or area of interest.

Individual cases are usually coded for data entry at the most specific (LLT) level, and outputs of counts or cases are usually provided at the PT level. The higher levels (HLT, HLGT and SOC) as well as SMQ are used for searching and for organisation and subtotalling of outputs.

15.40.2 Maintenance of MedDRA

MedDRA is managed by the MSSO (Maintenance and Support Services Organization). The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) is the Trustee of the International Conference on Harmonisation (ICH) Steering Committee and holds the intellectual property rights (ownership) of MedDRA. The ICH has contracted Northrop Grumman to act as the MSSO. MedDRA is free for regulators and priced according to company revenue for industry. The Japanese counterpart for MSSO is called JMO. *[3]

The MSSO updates MedDRA according to subscriber change requests, for example to add a new medical concept that is yet to be in MedDRA or to change an existing concept. The decisions are made by international medical officers on how to map the terminology within the grouping categories according to a general consensus based on language considerations internationally.

The MSSO releases updated MedDRA versions twice a year - in March and September. The March release is the main annual release and contains changes at the HLT level and above along with LLT and PT changes. The September release typically contains changes only at the LLT and PT level. The September 2015 Version 18.1 release is the current version.

15.40.3 See also

- COSTART
- Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)
- WHOART

15.40.4 References

[1] "Welcome to MedDRA".

[2] "What are the structural elements of the terminology in MedDRA?". *MedDRA FAQ*. Retrieved 25 January 2012.

[3] "About MSSO".

15.40.5 External links

- MedDRA and the MSSO

15.41 Medical Subject Headings

"MeSH" redirects here. For the organic chemical, see Methanethiol.

Medical Subject Headings (**MeSH**) is a comprehensive controlled vocabulary for the purpose of indexing journal articles and books in the life sciences; it serves as a thesaurus that facilitates searching. Created and updated by the United States National Library of Medicine (NLM), it is used by the MEDLINE/PubMed article database and by NLM's catalog of book holdings. MeSH is also used by ClinicalTrials.gov registry to classify which diseases are studied by trials registered in ClinicalTrials.gov.

MeSH was introduced in 1960, with the NLM's own index catalogue and the subject headings of the Quarterly Cumulative Index Medicus (1940 edition) as precursors. The yearly printed version of MeSH was discontinued in 2007 and MeSH is now available online only.*[2] It can be browsed and downloaded free of charge through PubMed. Originally in English, MeSH has been translated into numerous other languages and allows retrieval of documents from different languages.

15.41.1 Structure of MeSH

The 2009 version of MeSH contains a total of 25,186 *subject headings*, also known as *descriptors*.*[2] Most of these are accompanied by a short description or definition, links to related descriptors, and a list of synonyms or very similar terms (known as *entry terms*). These additional information and the hierarchical structure (see below) make the MeSH essentially a thesaurus, rather than a plain subject headings list.*[3]

Descriptor hierarchy

The *descriptors* or *subject headings* are arranged in a hierarchy. A given descriptor may appear at several locations in the hierarchical tree. The tree locations carry systematic labels known as *tree numbers*, and consequently one descriptor can carry several tree numbers. For example, the descriptor "Digestive System Neoplasms" has the tree numbers C06.301 and C04.588.274; C stands for Diseases, C06 for Digestive System Diseases and C06.301 for Digestive System Neoplasms; C04 for Neoplasms, C04.588 for Neoplasms By Site, and C04.588.274 also for Digestive System Neoplasms. The tree numbers of a given descriptor are subject to change as MeSH is updated. Every descriptor also carries a unique alphanumerical ID that will not change.

Descriptions

Most subject headings come with a short description or definition. See the MeSH description for diabetes type 2 as an example. The explanatory text is written by the MeSH team based on their standard sources if not otherwise stated. References are mostly encyclopaedias and standard textbooks of the subject areas. References for specific statements in the descriptions are not given, instead readers are referred to the bibliography.

Qualifiers

In addition to the descriptor hierarchy, MeSH contains a small number of standard *qualifiers* (also known as *subheadings*), which can be added to descriptors to narrow down the topic.*[4] For example, "Measles" is a descriptor and "epidemiology" is a qualifier; "Measles/epidemiology" describes the subheading of epidemiological articles about Measles. The "epidemiology" qualifier can be added to all other disease descrip-

tors. Not all descriptor/qualifier combinations are allowed since some of them may be meaningless. In all there are 83 different qualifiers.

Supplements

In addition to the descriptors, MeSH also contains some 139,000 *Supplementary Concept Records*. These do not belong to the controlled vocabulary as such; instead they enlarge the thesaurus and contain links to the closest fitting descriptor to be used in a MEDLINE search. Many of these records describe chemical substances..

15.41.2 Use in Medline/PubMed

In MEDLINE/PubMed, every journal article is indexed with about 10–15 subject headings, subheadings and supplementary concept records, with some of them designated as *major* and marked with an asterisk, indicating the article's major topics. When performing a MEDLINE search via PubMed, entry terms are automatically translated into (i.e. mapped to) the corresponding descriptors with a good degree of reliability; it is recommended to check the 'Details tab' in PubMed to see how a search formulation was translated. By default, a search for a descriptor will include all the descriptors in the hierarchy below the given one.

15.41.3 Use in ClinicalTrials.gov

In ClinicalTrials.gov, each trial has keywords that describe the trial. The ClinicalTrials.gov team assigns each trial two sets of MeSH terms. One set for conditions studied by the trial and another set of interventions used in the trial. The XML file that can be downloaded for each trial contains these MeSH keywords.

15.41.4 Categories

For the full hierarchy, see List of MeSH codes

The top-level categories in the MeSH descriptor hierarchy are:

- Anatomy [A]
- Organisms [B]
- Diseases [C]
- Chemicals and Drugs [D]
- Analytical, Diagnostic and Therapeutic Techniques and Equipment [E]
- Psychiatry and Psychology [F]
- Biological Sciences [G]
- Physical Sciences [H]
- Anthropology, Education, Sociology and Social Phenomena [I]
- Technology and Food and Beverages [J]
- Humanities [K]
- Information Science [L]
- Persons [M]
- Health Care [N]
- Publication Characteristics [V]
- Geographic Locations [Z]

15.41.5 See also

- GoPubMed, searching Medline with MeSH as "table of content"
- Medical classification
- Medical literature retrieval

15.41.6 References

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[3] Introduction to MeSH – 2010

[4] List of qualifiers – MeSH 2009

15.41.7 External links

- Medical Subject Heading Home provided by National Library of Medicine, National Institutes of Health (U.S.)
- MeSH database tutorials
- Automatic Term Mapping
- Browsing MeSH:
  - Entrez
  - MeSH Browser
  - Visual MeSH Browser mapping drug-disease relationships in research
  - Reference.MD
- List of qualifiers – 2009

15.42 Minimum Data Set

The **Minimum Data Set** (**MDS**) is part of the U.S. federally mandated process for clinical assessment of all residents in Medicare or Medicaid certified nursing homes. This process provides a comprehensive assessment of each resident's functional capabilities and helps nursing home staff identify health problems.

Resource Utilization Groups (RUG) are part of this process, and provide the foundation upon which a resident's individual care plan is formulated. MDS assessment forms are completed for all residents in certified nursing homes, regardless of source of payment for the individual resident. MDS assessments are required for residents on admission to the nursing facility and then periodically, within specific guidelines and time frames. In most cases, participants in the assessment process are licensed health care professionals, usually Registered Nurses, employed by the nursing home. MDS information is transmitted electronically by nursing homes to the MDS database in their respective states. MDS information from the state databases is captured into the national MDS database at Centers for Medicare and Medicaid Services (CMS).

Categories of MDS (Minimum Data Set)

1) Cognitive patterns

2) Communication and hearing patterns

3) Vision patterns

4) Physical functioning and structural problems

5) Continence

6) Psychosocial well-being

7) Mood and behavior patterns

8) Activity pursuit patterns

9) Disease diagnoses

10) Other health conditions

11) Oral/nutritional status

12) Oral/dental status

13) Skin condition

14) Medication use

15) Treatments and procedures

15.42.1 References

- CMS - MDS Quality Indicator and Resident Reports

15.43 Multiscale Electrophysiology Format

Multiscale Electrophysiology Format (MEF) was developed to handle the large amounts of data produced by large-scale electrophysiology in human and animal subjects. MEF can store any time series data up to 24 bits in length, and employs lossless range encoded difference compression. Subject identifying information in the file header can be encrypted using 128-bit AES encryption in order to comply with HIPAA requirements for patient privacy when transmitting data across an open network.

Compressed data is stored in independent blocks to allow direct access to the data, facilitate parallel processing and limit the effects of potential damage to files. Data fidelity is ensured by a 32-bit cyclic redundancy check in each compressed data block using the Koopman polynomial (0xEB31D82E), which has a Hamming distance of from 4 to 114 kbits.

A formal specification *[1] and source code *[2] are available online.

15.43.1 See also

- Range encoding
- AES encryption
- CRC-32

15.43.2 References

[1] MEF Format Specification

[2] Source code

15.43.3 Sources

- Martin, GNN. Range encoding: an algorithm for removing redundancy from a digitised message. Video & Data Recoding Conference, Southampton, 1979.
- Koopman, P. 32-Bit Cyclic Redundancy Codes for Internet Applications. The International Conference on Dependable Systems and Networks (June 2002). 459.
- Brinkmann, BH et al. Large-scale electrophysiology: acquisition, compression, encryption, and storage of big data. Journal of Neuroscience Methods 180 (2009) 185–192. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2720128/)

15.44 NANDA

NANDA International (formerly the North American Nursing Diagnosis Association) is a professional organization of nurses standardized nursing terminology that was officially founded in 1982 and develops, researches, disseminates and refines the nomenclature, criteria, and taxonomy of nursing diagnoses. In 2002, NANDA relaunched as **NANDA International** in response to the broadening scope of its membership. NANDA International published *Nursing Diagnosis* quarterly, which became the *International Journal of Nursing Knowledge* in 2002. Other related international associations are *ACENDIO* (Europe), *AENTDE* (Spanish language), *AFEDI* (French language) and *JSND* (Japan). The Membership Network Groups foster collaboration among NANDA-I members in countries (Brazil, Colombia, Ecuador, Mexico and Nigeria-Ghana) and for languages: the German Language Group (Germany, Austria, Switzerland) and the Dutch Language Group (Netherlands and Belgium).

15.44.1 History

In 1973, Kristine Gebbie and Mary Ann Lavin called the First National Conference on the Classification of Nursing Diagnoses. It was held in St. Louis, Missouri. Attendees produced a beginning classification, an alphabetized list of nursing diagnoses. The conference also created three structures: A National Clearinghouse for Nursing Diagnoses, located at Saint Louis University and led by Ann Becker; a Nursing Diagnosis Newsletter, edited by Anne Perry; and a National Conference Group to standardize nursing terminology and led by Marjory Gordon. In 1982 NANDA was formed. It included members from the United States and Canada.

NANDA developed a nursing classification to organize nursing diagnoses into different categories. Although the taxonomy was revised to accommodate new diagnoses, in 1994 it became apparent that an overhaul was needed. In 2002 Taxonomy II, which was a revised version of Gordon's functional health patterns, was released.

In 2002, NANDA became NANDA International in response to requests from its growing base of membership from outside North America. The acronym of NANDA was retained in the name because of the name recognition, but it is no longer merely "North American", and in fact boasts members from 32 countries as of 2010.

15.44.2 Presidents

- 1982-1988 Dr. Marjory Gordon
- 1988-1993 Jane Lancour
- 1993-1997 Dr. Lois Hoskins
- 1997-2001 Dr. Judith Warren
- 2001-2005 Dr. Dorothy A. Jones
- 2005-2006 Kay Avant
- 2006-2007 Mary Ann Lavin
- 2007-2008 Martha Craft-Rosenberg
- 2008-2009 Dr. Heather Herdman
- 2009-2012 Prof. Dickon Weir-Hughes
- 2012-2016 Dr. Jane Brokel

15.44.3 Taxonomy II

The current structure of NANDA's nursing diagnoses is referred to as Taxonomy II and has three levels: 13 domains, 47 classes, and 216 diagnoses.

15.44.4 See also

- Nursing diagnoses (category)
- Nursing diagnosis
- Nursing process

15.44.5 References

- Herdman, TH (Ed.) Nursing Diagnoses: Definitions and classification 2009-2011. Wiley-Blackwell: Singapore.
- Gebbie, KM & Lavin, MA (1975). Proceedings of the First National Conference on the Classification of Nursing Diagnoses. St. Louis: Mosby.

15.44.6 External links

- NANDA International's official website

15.45 Nursing Interventions Classification

The **Nursing Interventions Classification** (NIC) is a care classification system which describes the activities that nurses perform as a part of the planning phase of the nursing process associated with the creation of a nursing care plan.

The NIC provides a four level hierarchy whose first two levels consists of a list of 433 different interventions, each with a definition in general terms, and then the ground-level list of a variable number of specific activities a nurse

could perform to complete the intervention. The second two levels form a taxonomy in which each intervention is grouped into 27 classes, and each class is grouped into 6 domains.

An intent of this structure is to make it easier for a nurse to select an intervention for the situation, and to use a computer to describe the intervention in terms of standardized labels for classes and domains. Another intent is in each case to make it easy to use a Nursing Minimum Data Set (NMDS).

The terminology is an American Nurses' Association-recognized terminology, which is included in the UMLS, and is HL7 registered.[*][1][*][2][*][3][*][4]

15.45.1 See also

- Clinical Care Classification System
- Nursing Outcomes Classification
- NANDA
- Nursing care plan
- Nursing diagnosis
- Nursing process
- Nursing care
- Omaha System

15.45.2 References

[1] Iowa Intervention Project (1996). Nursing Interventions Classification (NIC) (2nd ed.), St. Louis: Mosby-Year Book

[2] Henry SB, Warren JJ, Lange L, Button P., *A review of major nursing vocabularies and the extent to which they have the characteristics required for implementation in computer-based systems*, J Am Med Inform Assoc. 1998 Jul-Aug;5(4):321-8

[3] Henry SB, Mead CN., *Nursing classification systems: necessary but not sufficient for representing "what nurses do" for inclusion in computer-based patient record systems*, J Am Med Inform Assoc. 1997 May-Jun;4(3):222-32

[4] Nursing Interventions Classification

15.46 Nursing Minimum Data Set

The **Nursing Minimum Data Set** (NMDS) is a classification system which allows for the standardized collection of essential nursing data. The collected data are meant to provide an accurate description of the nursing process used when providing nursing care. The NMDS allow for the analysis and comparison of nursing data across populations, settings, geographic areas, and time.[*][1][*][2]

15.46.1 See also

- Effective therapeutic regimen management
- Nursing diagnosis
- NANDA
- Nursing care plan
- Nursing Outcomes Classification (NOC)
- Nursing Interventions Classification (NIC)
- Omaha System
- Minimum Data Set

15.46.2 References

[1] Werley, HH; Devine, EC; Zorn, CR; Ryan, P; Westra, BL (April 1991). "The Nursing Minimum Data Set: abstraction tool for standardized, comparable, essential data". *American Journal of Public Health* **81** (4): 421–426. doi:10.2105/ajph.81.4.421. PMC 1405031. PMID 2003618.

[2] Williams, CA (April 1991). "The Nursing Minimum Data Set: a major priority for public health nursing but not a panacea". *American Journal of Public Health* **81** (4): 413–414. doi:10.2105/ajph.81.4.413. PMC 1405046. PMID 2003616.

15.46.3 External links

- Denehy, Janice (January 2012). "Nursing Minimum Data Set for School Nursing Practice: Position Statement". *National Association of School Nurses*. Retrieved 25 August 2014.

15.47 Nursing Outcomes Classification

The **Nursing Outcomes Classification** (NOC) is a classification system which describes patient outcomes sensitive to nursing intervention. The NOC is a system to evaluate the effects of nursing care as a part of the nursing process. The NOC contains 330 outcomes, and each with a label, a definition, and a set of indicators and measures to determine achievement of the nursing outcome and are included The terminology is an American Nurses' Association-recognized terminology, is included in the UMLS, and is HL7 registered.[*][1][*][2]

15.47.1 See also

- Clinical Care Classification System
- Nursing care plan
- Nursing diagnosis
- Nursing process
- NANDA
- Nursing Interventions Classification
- Diagnosis-related group
- Omaha System

15.47.2 References

[1] Donahue, M.P. & Brighton, V., *Nursing outcome classification: Development and implementation*, Journal of Nursing Care Quality, 1998, 12(5)

[2] S. Moorhead, M. Johnson, M. Maas, E. Swanson, *Nursing Outcomes Classification (NOC)*, Elsevier, Fourth Edition, 936 pages, 2007, ISBN 0-323-05408-0

15.47.3 External links

- Nursing Outcomes Classification (U. Iowa)

15.48 OpenGALEN

OpenGALEN is a not-for-profit organisation that provides an open source medical terminology. This terminology is written in a formal language called GRAIL (GALEN Representation And Integration Language)* [1] and also distributed in OWL.

15.48.1 Background

The GALEN technologies were developed with research funding provided by the European Community Framework III (GALEN Project) and Framework IV (GALEN-In-Use Project) programmes.

Early phases of the GALEN Programme developed the GRAIL concept modelling language, experimented with different structures for the GALEN Common Reference Model, and, in parallel, tested the usefulness of the approach with a series of clinical demonstrator projects.

Later phases of the GALEN Programme, during the late 1990s, have concentrated on robust implementations of GRAIL and the Terminology Server, development of the GALEN Common Reference Model in both scope and detail, and development of tools and techniques to enable the further development, scaling-up and maintenance of the model. An important additional focus has been in developing tools and techniques with which we can map the information found in existing coding and Medical classification schemes to the GALEN Common Reference Model.

OpenGALEN has been set up as a not-for-profit Dutch Foundation by the universities of Manchester and Nijmegen to make the results of the GALEN projects available to the world.

15.48.2 GALEN Common Reference Model

The **GALEN Common Reference Model** is the model of medical concepts (or clinical terminology) being built in GRAIL. This model forms the underlying structural foundation for the services provided by a GALEN Terminology Server.

The GALEN Common Reference Model is written in the formal language GRAIL (see below). The GRAIL statements in the model are equivalent with sentences like these:

- Ulcer is a kind of inflammatory lesion
- The process whose outcome is an ulcer is called ulceration
- The stomach is a part of the GI tract
- It is sensible to talk about ulcers located in the stomach
- Ulcers located in the stomach are called Gastric Ulcers
- Ulcers located in the stomach are actually located on the mucosa of the wall of the stomach

The GALEN Common Reference Model is available from the OpenGALEN Foundation as open source.

15.48.3 Projects

The GALEN tools and technologies were used in France for the development of the French classification of procedures Classification Commune des Actes Médicaux (CCAM).

15.48.4 References

[1] http://www.opengalen.org/faq/faq1.html#1.2

- Rector, A.; Rogers, J.; Zanstra, P.; Van Der Haring, E. (2003). "OpenGALEN: Open source medical terminology and tools" . *AMIA Annual Symposium Proceedings*: 982. PMC 1480228. PMID 14728486.

- Rector, A.; Solomon, W.; Nowlan, W.; Rush, T.; Zanstra, P.; Claassen, W. (1995). "A Terminology Server for medical language and medical information systems". *Methods of information in medicine* **34** (1–2): 147–157. PMID 9082124.

- Rector, A.; Zanstra, P.; Solomon, W.; Rogers, J.; Baud, R.; Ceusters, W.; Claassen, W.; Kirby, J.; Rodrigues, J.; Rossi Mori, A. R.; Van Der Haring, E. J.; Wagner, J. (1998). "Reconciling users' needs and formal requirements: Issues in developing a reusable ontology for medicine". *IEEE transactions on information technology in biomedicine : a publication of the IEEE Engineering in Medicine and Biology Society* **2** (4): 229–242. doi:10.1109/4233.737578. PMID 10719533.

- Rogers, J.; Roberts, A.; Solomon, D.; Van Der Haring, E.; Wroe, C.; Zanstra, P.; Rector, A. (2001). "GALEN ten years on: Tasks and supporting tools". *Studies in health technology and informatics* **84** (Pt 1): 256–260. PMID 11604744.

- Ten Napel, H.; Rogers, J. (2001). "Assessment of the GALEN methodology on holistic classifications for professions allied to medicine". *Studies in health technology and informatics* **84** (Pt 2): 1369–1373. PMID 11604951.

- Rogers, J.; Rector, A. (2000). "GALEN's model of parts and wholes: Experience and comparisons". *AMIA Annual Symposium Proceedings*: 714–718. PMC 2243933. PMID 11079977.

- Solomon, W.; Roberts, A.; Rogers, J.; Wroe, C.; Rector, A. (2000). "Having our cake and eating it too: How the GALEN Intermediate Representation reconciles internal complexity with users' requirements for appropriateness and simplicity". *AMIA Annual Symposium Proceedings*: 819–823. PMC 2244105. PMID 11079998.

- Rogers, J. (2006). "Quality assurance of medical ontologies". *Methods of information in medicine* **45** (3): 267–274. PMID 16685334.

15.48.5 External links

- OpenGALEN Web site
- CCAM, Classification Commune des Actes Médicaux
- University of Manchester, Bio-Health Informatics Group
- University of Nijmegen, Medical Informatics

15.49 SNOMED

For the collection of information officially organized with the SNOMED system, see SNOMED CT.

The **Systematized Nomenclature of Medicine** (**SNOMED**) is a systematic, computer-processable collection of medical terms, in human and veterinary medicine, to provide codes, terms, synonyms and definitions which cover anatomy, diseases, findings, procedures, microorganisms, substances, etc. It allows a consistent way to index, store, retrieve, and aggregate medical data across specialties and sites of care. Although now international, SNOMED was started in the U.S. by the College of American Pathologists (CAP)*[1] in 1973 and revised into the 1990s. In 2002 CAP's SNOMED Reference Terminology (SNOMED RT) was merged with, and expanded by, the National Health Service's Clinical Terms Version 3 (previously known as the Read codes) to produce SNOMED CT.*[2]*[3]

Versions of SNOMED released prior to 2001 were based on a multiaxial, hierarchical classification system.*[1] As in any such system, a disease may be located in a body organ (anatomy), which results in a code in a topography axis and may lead to morphological alterations represented by a morphology code.

In 2002 the first release of SNOMED CT adopted a completely different structure. A sub-type hierarchy, supported by defining relationships based on description logic, replaced the axes described in this article. Versions of SNOMED prior to SNOMED CT are planned to be formally deprecated from 2017.*[4] Therefore readers interested in current information about SNOMED are directed to the article on SNOMED CT.

15.49.1 Purpose

SNOMED was designed as a comprehensive nomenclature of clinical medicine for the purpose of accurately storing and/or retrieving records of clinical care in human and veterinary medicine. The metaphor used by Roger A. Côté, the first editorial chair, was that SNOMED would become the periodical table of elements of medicine because of its definitional organization beyond the hierarchical design. Indeed, diseases and procedures were ordered hierarchically and are further referenced back to more elementary terms (see Reference Ontology and Multi-Axial Design, below).

15.49.2 History

SNOMED was originally conceived by Dr. Roger A. Côté as an extension of the design of the Systematized Nomenclature of Pathology (SNOP) applicable for all

medicine. SNOP was originally designed by Dr. Arnold Pratt to describe pathological specimen according to their morphology and anatomy (topography). The ambitious development of SNOMED required many more axes (see multi-axial design, below). SNOMED was jointly proposed for development to the College of American Pathologists by Drs. Côté and Dr. Arnold Pratt and the former was appointed as Editorial Chair of the Committee on Nomenclature and Classification of Diseases of the College of American Pathologists and developed the Systematized Nomenclature of Medicine (SNOMED) from 1973 to 1997. In 1998, Dr. Kent Spackman was appointed Chair of this Committee and spearheaded the transformation of the multi-axis systems into a highly computable form (See SNOMED CT): a directed acyclic graph anchored in formal representation logic. In 2007, the newly formed International Health Terminology Standards Development Organisation (IHTSDO) acquired all the Intellectual Property of SNOMED CT and all antecedent SNOMED versions.

Brief timeline:

- 1965 SNOP
- 1974 SNOMED
- 1979 SNOMED II
- 1993 SNOMED International 3.0
- 1995 SNOMED Microglossary of Signs and Symptoms
- 1993-98 SNOMED International versions 3.1-3.5
- 2002 First release of SNOMED CT
- 2007 All versions of SNOMED acquired by IHTSDO
- 2017 All SNOMED versions except SNOMED CT will be formally deprecated by IHTSDO

15.49.3 Reference ontology

SNOMED was designed from its inception with complex concepts defined in terms of simpler ones. For example, a disease can be defined in terms of its abnormal anatomy, abnormal functions and morphology. In some cases, the etiology of the disease is known and can be attributed to an infectious agent, a physical trauma or a chemical or pharmaceutical agent.

15.49.4 Multi-axial design

The current concept uses eleven (11) axes that comprise terms organised in hierarchical trees. The axes and some examples are provided below:

T (Topography) – Anatomic terms

- (T-28000) Lung
- (T-32000) Heart
- (T-51000) Mouth
- (T-D2500) Hip
- (T-D9600) Heel

M (Morphology) – Changes found in cells, tissues and organs

- (M-40000) Inflammation
- (M-44000) Granuloma
- (M-54700) Infarcted
- (M-54701) Microscopic infarct

For the Morphology axis, SNOMED has agreed to collaborate and use the same harmonized codes shared with International Classification of Diseases for Oncology. Additional examples on topology are provided on that page.

L (Living organisms) – Bacteria and viruses

- (L-21801) Mycobacterium tuberculosis
- (L-25116) Streptococcus pneumoniae

C (Chemical) – Drugs

- (C-C137A) Bufferin Analgesic Tablets
- (C-C137B) Bufferin Analgesic Caplets

F (Function) – Signs and symptoms

- (F-03003) Fever

J (Occupation) – Terms that describe the occupation

- Kindergarten teacher (13420)
- Computer programmer (08420)
- Doctor (06105)
- Professional Nurse (General) (07110)
- Beautician (57040)

D (Diagnosis) – Diagnostic terms

- (D-13510) Pneumococcal pneumonia
- (D-14800) Tuberculosis
- (D3-15000) Myocardial infarction

P (Procedure) – Administrative, diagnostic and therapeutic procedures

A (Physical agents, forces, activities) – Devices and activities associated with the disease

S (Social context) – Social conditions and important relationships in medicine

- (S-10120) Mother

G (General) – Syntactic linkages and qualifiers

15.49.5 See also

- Diagnosis code
- Drug class
- DOCLE
- Medical classification
- SNOMED CT
- Medical Dictionary for Regulatory Activities (MedDRA)

15.49.6 References

[1] Roger A. Côté (1986). "Architecture of SNOMED". *Proceedings of the Annual Symposium on Computer Application in Medical Care*: 74–80. PMC: 2245000.

[2] "SNOMED Clinical Terms To Be Added To UMLS Metathesaurus". United States National Library of Medicine. 24 May 2006. Retrieved 8 October 2015.

[3] "FAQs: SNOMED CT in the UMLS". United States National Library of Medicine. 22 May 2012. Retrieved 8 October 2015.

[4] Deprecation of Antecedent Versions of SNOMED by IHTSDO General Assembly

15.49.7 External links

- Official page at snomed.org (now redirects to www.ihtsdo.org)
- Studies of the formal structure of SNOMED CT at buffalo.edu
- Browser at vetmed.vt.edu
- Dataline SNOMED Browser: Looks up clinical terms online for free.
- SNOCat: the SNOMED Categorizer/Browser to automatically encode medical narratives - provided by the BiTeM group (http://bitem.hesge.ch) !

15.50 SNOMED CT

SNOMED CT [*][lower-alpha 1] or **SNOMED Clinical Terms** is a systematically organized computer processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting. SNOMED CT is considered to be the most comprehensive, multilingual clinical healthcare terminology in the world.[*][1] The primary purpose of SNOMED CT is to encode the meanings that are used in health information and to support the effective clinical recording of data with the aim of improving patient care. SNOMED CT provides the core general terminology for electronic health records. SNOMED CT comprehensive coverage includes: clinical findings, symptoms, diagnoses, procedures, body structures, organisms and other etiologies, substances, pharmaceuticals, devices and specimens.

SNOMED CT is maintained and distributed by the IHTSDO, an international non-profit standards development organization, located in Copenhagen, Denmark.

SNOMED CT provides for consistent information interchange and is fundamental to an interoperable electronic health record. It provides a consistent means to index, store, retrieve, and aggregate clinical data across specialties and sites of care. It also helps in organizing the content of electronic health records systems by reducing the variability in the way data are captured, encoded and used for clinical care of patients and research.[*][2] SNOMED CT can be used to directly record clinical details of individuals in electronic patient records. It also provides the user with a number of linkages to clinical care pathways, shared care plans and other knowledge resources, in order to facilitate informed decision-making, and to support long-term patient care. The availability of free automatic coding tools and services, which can return a ranked list of SNOMED CT descriptors to encode any clinical report, could help healthcare professionals to navigate the terminology.

SNOMED CT is a terminology that can cross-map to other international standards and classifications.[*][3] Specific language editions are available which augment the international edition and can contain language translations, as well as additional national terms. For example, SNOMED CT-AU, released in December 2009 in Australia, is based on the international version of SNOMED CT, but encompasses words and ideas that are clinically and technically unique to Australia.[*][4]

15.50.1 History

SNOMED was started in 1965 as a Systematized Nomenclature of Pathology (SNOP) and was further developed into a logic-based health care terminology.*[5]*[6]

SNOMED CT was created in 1999 by the merger, expansion and restructuring of two large-scale terminologies: SNOMED Reference Terminology (SNOMED RT), developed by the College of American Pathologists (CAP); and the Clinical Terms Version 3 (CTV3) (formerly known as the Read codes), developed by the National Health Service of the United Kingdom (NHS).*[7]*[8] The final product was released in January 2002.

The historical strength of SNOMED was its coverage of medical specialties. SNOMED RT, with over 120,000 concepts, was designed to serve as a common reference terminology for the aggregation and retrieval of pathology health care data recorded by multiple organizations and individuals. The strength of CTV3 was its terminologies for general practice. CTV3, with 200,000 interrelated concepts, was used for storing structured information about primary care encounters in individual, patient-based records.*[9] Currently, SNOMED CT contains more than 311,000 active concepts and provides the core general terminology for the electronic health record (EHR).*[10]

In July 2003, the National Library of Medicine (NLM), on behalf of the United States Department of Health and Human Services, entered into an agreement with the College of American Pathologists to make SNOMED CT available to U.S. users at no cost through the National Library of Medicine's Unified Medical Language System UMLS Metathesaurus. The contract provided NLM with a perpetual license for the core SNOMED CT (in Spanish and English) and its ongoing updates.*[7]*[11]*[12]

In April 2007, SNOMED CT intellectual property rights were transferred from the CAP to the International Health Terminology Standards Development Organisation IHTSDO in order to promote international adoption and use of SNOMED CT. IHTSDO is responsible for "ongoing maintenance, development, quality assurance, and distribution of SNOMED CT" internationally *[4]*[6]*[8] and consists of a number of the world's leading e-health countries, including: Australia, Canada, Czech Republic, Denmark, Estonia, Hong Kong, Iceland, Israel, Lithuania, Malaysia, Malta, Netherlands, New Zealand, Poland, Singapore, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom, United States and Uruguay.*[13]

SNOMED CT is a multinational and multilingual terminology, which can manage different languages and dialects. SNOMED CT is currently available in American English, British English, Spanish, Danish and Swedish, with other translations under way or nearly completed in French and Dutch. SNOMED CT cross maps to other terminologies, such as: ICD-9-CM, ICD-10, ICD-O-3, ICD-10-AM, Laboratory LOINC and OPCS-4. It supports ANSI, DICOM, HL7, and ISO standards. SNOMED CT is currently used in a joint project with the World Health Organization (WHO) as the ontological basis of the upcoming ICD-11.

15.50.2 Structure

SNOMED CT consists of four primary core components:

1. **Concept Codes** - numerical codes that identify clinical terms, primitive or defined, organized in hierarchies
2. **Descriptions** - textual descriptions of Concept Codes
3. **Relationships** - relationships between Concept Codes that have a related meaning
4. **Reference Sets** - used to group Concepts or Descriptions into sets, including reference sets and cross-maps to other classifications and standards.*[14]

SNOMED CT "Concepts" are representational units that categorize all the things that characterize health care processes and need to be recorded therein. In 2011, SNOMED CT included more than 311,000 concepts, which are uniquely identified by a concept ID, i.e. the concept 22298006 refers to *Myocardial infarction*. All SNOMED CT concepts are organized into acyclic taxonomic (is-a) hierarchies; for example, *Viral pneumonia* IS-A *Infectious pneumonia* IS-A *Pneumonia* IS-A *Lung disease*. Concepts may have multiple parents, for example *Infectious pneumonia* is also a child of *Infectious disease*. The taxonomic structure allows data to be recorded and later accessed at different levels of aggregation. SNOMED CT concepts are linked by approximately 1,360,000 links, called *relationships*.*[15]

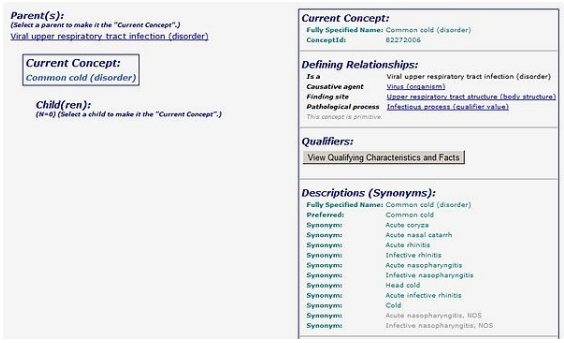
Concepts are further described by various clinical terms or phrases, called Descriptions, which are divided into *Fully Specified Names* (FSNs), *Preferred Terms* (PTs), and *Synonyms*. Each Concept has exactly one FSN, which is unique across all of SNOMED CT. It has, in addition, exactly one PT, which has been decided by a group of clinicians to be the most common way of expressing the meaning of the concept. It may have zero to many Synonyms. Synonyms are additional terms and phrases used to refer to this concept. They do not have to be unique or unambiguous.

The formal model underlying SNOMED CT

SNOMED CT can be characterized as a multilingual thesaurus with an ontological foundation. Thesaurus-like

features are concept–term relations such as the synonymous descriptions "Acute coryza", "Acute nasal catarrh", "Acute rhinitis", "Common cold" (as well as Spanish "resfrío común" and "rinitis infecciosa") for the concept 82272006.

Under ontological scrutiny, SNOMED-CT is a class hierarchy (with extensive overlap of classes in contrast to typical statistical classifications like ICD). This means that the SNOMED CT concept 82272006 defines the class of all the individual disease instances that match the criteria for "common cold" (e.g., one patient may have "head cold" noted in their record, and another may have "Acute coryza"; both can be found as instances of "common cold"). The superclass (Is-A) Relation relates classes in terms of inclusion of their members. That is, all individual "cold-processes" are also included in all superclasses of the class Common Cold, such as Viral upper respiratory tract infection (Figure).



Common cold *as a primitive concept in SNOMED CT*

SNOMED CT's relational statements are basically triplets of the form Concept_1 - Relation_x - Concept_2, with Relation_x being from a small number of relation types (called linkage concepts), e.g. *finding site*, *due to*, etc. The interpretation of these triplets is (implicitly) based on the semantics of a simple Description logic (DL). E.g., the triplet *Common Cold* - **causative agent** – *Virus*, corresponds to the first-order expression

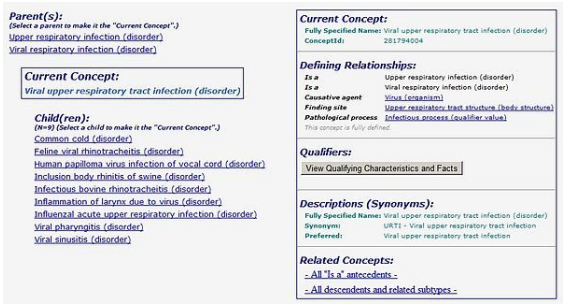
forall x: instance-of (x, *Common cold*) -> exists y: instance-of (y, *Virus*) and **causative-agent** (y, x)

or the more intuitive DL expression

Common cold subClassOf **causative-agent** some *Virus*

In the *Common cold* example the concept description is "primitive", which means that necessary criteria are given that must be met for each instance, without being sufficient for classifying a disorder as an instance of *Common Cold* . In contrast, the example *Viral upper respiratory tract infection* depicts a fully described concept, which is represented in description logic as follows:

Viral upper respiratory tract infection equivalentTo *Upper respiratory infection* and *Viral respiratory infection* and **Causative-agent** some *Virus* and **Finding-site** some *Upper respiratory tract structure* and **Pathological-process**



Viral upper respiratory tract infection *as a defined concept in SNOMED CT*

some *Infectious process*

This means that each and every individual disorder for which all definitional criteria are met can be classified as an instance of Viral upper respiratory tract infection.

Description logics

As of 2011, SNOMED CT content limits itself to a subset of the EL++ formalism, restricting itself to the following operators:

- Top, bottom
- Primitive roles and concepts with asserted parent(s) for each
- Concept definition and conjunction but NOT disjunction or negation
- Role hierarchy but not role composition
- Domain and range constraints
- Existential but not universal restriction
- A restricted form of role inclusion axiom (xRy ^ ySz => xRz)
- The logic will be extended in the near future to include General Concept Inclusion Axioms.

Precoordination and postcoordination

SNOMED CT provides a compositional syntax* [16] that can be used to create expressions that represent clinical ideas which are not explicitly represented by SNOMED CT concepts.

For example, there is no explicit concept for a "third degree burn of left index finger caused by hot water". However, using the compositional syntax it can be represented as

284196006 | burn of skin | : 116676008 | associated morphology | = 80247002 | third degree burn injury | , 272741003 | laterality | = 7771000 | left | , 246075003 |

causative agent | = 47448006 | hot water | , 363698007 | finding site | = 83738005 | index finger structure

Such expressions are said to have been 'postcoordinated'. Post-coordination avoids the need to create large numbers of defined Concepts within SNOMED CT. However, many systems only allow for precoordinated representations. Reliable analysis and comparison of post-coordinated expressions is possible using appropriate algorithms machinery to efficiently process the expression taking account of the underlying description logic.

For example, the postcoordinated expression above can be transformed using a set of standard rules to the following "normal form expression" which enables comparison with similar concepts.

64572001 | disease | : 246075003 | causative agent | = 47448006 | hot water | , 363698007 | finding site | = (83738005 | index finger structure | : 272741003 | laterality | = 7771000 | left |) , { 116676008 | associated morphology | = 80247002 | third degree burn injury | , 363698007 | finding site | = 39937001 | skin structure | }

Known deficiencies and mitigation strategies

Earlier SNOMED versions had faceted structure ordered by semantic axes, requiring that more complex situations required to be coded by a coordination of different codes. This had two major shortcomings. On the one hand, the necessity of post-coordination was perceived as a user-unfriendly obstacle, which has certainly contributed to the rather low adoption of early SNOMED versions. On the other hand, uniform coding was difficult to obtain. E.g.,*Acute appendicitis* could be post-coordinated in three different ways*[17] with no means to compute semantic equivalences. SNOMED RT had addressed this problem by introducing description logic formula. With the addition of CTV3 a large number of concepts were redefined using formal expressions. However, the fusion with CTV3, as a historically grown terminology with many close-to user descriptions, introduced some problems which still affect SNOMED CT. In addition to a confusing taxonomic web of many hierarchical levels with massive multiple inheritance (e.g. there are 36 taxonomic ancestors for *Acute appendicitis*), many ambiguous, context-dependent concepts have found their way into SNOMED CT. Pre-coordination was sometimes pushed to extremes, so there are, for example, 350 different concepts for burns found on the head.

A further phenomenon which characterizes parts of SNOMED CT is the so called *epistemic intrusion*.*[18] In principle, the task of terminology (and even an ontology) should be limited to providing context-free term or class meanings. The contextualization of these representational units should be ideally the task of an information model.*[19] Human language is misleading here, as we use syntactically similar expression to represent categorically distinct entities, e.g. *Ectopic pregnancy* vs. *Suspected pregnancy*. The first one refers to a real pregnancy, the second one to a piece of (uncertain) *information*. In SNOMED CT most (but not all) of these context-dependent concepts are concentrated in the subhierachy *Situation with explicit context*. A major reason for why such concepts cannot be dispensed with is that SNOMED CT takes on, in many cases, the functionality of information models, as the latter do not exist in a given implementation.

With the establishment of IHTSDO SNOMED CT became more accessible to a wider audience. Criticism of the state of the terminology was sparked by numerous substantive weaknesses as well as on the lack of quality assurance measures.*[20] From the beginning IHTSDO was open regarding such (also academic) criticism. In the last few years considerable progress has been made regarding quality assurance and tooling.

The need for a more principled ontological foundation was gradually accepted, as well as a better understanding of description logic semantics. Redesign priorities were formulated regarding observables,*[21] disorders, findings,*[22] substances, organisms etc. Translation guidelines*[23] were elaborated as well as guidelines for content submission requests and a strategy for the inclusion of pre-coordinated content. There are still known deficiencies regarding the "ontological commitment" of SNOMED CT,*[24] e.g., the clarification of which kind of entity is an instance of a given SNOMED CT concept. The same term can be interpreted as a disorder or a patient with a disorder, for example *Tumour* might denote a process or a piece of tissue; *Allergy* may denote an allergic reaction or just an allergic disposition. A more recent strategy is the use of rigorously typed upper-level ontologies to disambiguate SNOMED CT content.

The increased take-up of SNOMED CT into applications in daily use across the world to support patient care is leading to a larger engaged community. This has led to an increase in the resource allocated to authoring SNOMED CT terms as well as to an increase in collaboration to take SNOMED CT into a robust industry used standard. This is leading to an increase in the number of software tools and development of materials that contribute to knowledge base to support implementation. A number of on-line communities that focus on particular aspects of SNOMED CT and its implementation are also developing.

In theory, description logic reasoning can be applied to any new candidate post-coordinated expressions in order to assess whether it is a parent or ancestor of, a child or other descendent of, or semantically equivalent to any existing concept from the existing pre-coordinated concepts. However, partly as the continuing fall-out from the merger with CTV3, SNOMED still contains undiscovered semantically duplicate primitive and defined concepts. Additionally, many concepts remain primitive whilst their semantics can also be legitimately defined in

terms of other primitives and roles concurrently in the system. Because of these omissions and actual or possible redundancies of semantic content, real-world performance of algorithms to infer subsumption or semantic equivalence will be unpredictably imperfect.

SNOMED CT and ICD

SNOMED CT is a clinical terminology designed to capture and represent patient data for clinical purposes.*[25] The International Statistical Classification of Diseases and Related Health Problems (ICD) is an internationally used medical classification system; which is used to assign diagnostic and, in some national modifications, procedural codes in order to produce coded data for statistical analysis, epidemiology, reimbursement and resource allocation.*[26] Both systems use standardized definitions and form a common medical language used within electronic health record (EHR) systems.*[27] SNOMED CT enables information input into an EHR system during the course of patient care, while ICD facilitates information retrieval, or output, for secondary data purposes.*[27]*[28]

15.50.3 Use

SNOMED CT is used in a number of different ways, some of which are:

- It captures clinical information at the level of detail needed for the provision of healthcare
- Through sharing data it can reduce the need to repeat health history at each new encounter with a healthcare professional
- Information can be recorded by different people in different locations and combined into simple information views within the patient record
- Use of a common terminology decreases the potential for differing interpretation of information
- Electronic recording in a common way reduces errors and can help to ensure completeness in recording all relevant data
- Standardised information makes analysis easier, supporting quality, cost effective practice, research and future clinical guideline development
- A clinical terminology allows a health care provider to identify patients based on specified coded information, and more effectively manage screening, treatment and follow up

Use cases

More specifically, the following sample computer applications use SNOMED CT:

- Electronic Health Record Systems
- Computerized Provider Order Entry CPOE such as E-Prescribing or Laboratory Order Entry
- Catalogues of clinical services; *e.g.*, for Diagnostic Imaging procedures
- Knowledge databases used in clinical decision support systems (CDSS)
- Remote Intensive Care Unit Monitoring
- Laboratory Reporting
- Emergency Room Charting
- Cancer Reporting
- Genetic Databases

Access

SNOMED CT is maintained and distributed by the IHTSDO, an international non-profit standards development organization, located in Copenhagen, Denmark. The use of SNOMED CT in production systems requires a license. There are two models. On the one hand SNOMED CT can be achieved by national membership in the IHTSDO (charged according to the GNP). On the other hand it can be used via a corporate business license (dependent on the number of end users). LDCs (least developed countries) can use SNOMED CT without charges. For scientific research in medical informatics, for demonstrations or evaluation purposes SNOMED CT sources can be freely downloaded and used. The original SNOMED CT sources in tabular form are accessible by registered users of the Unified Medical Language System (UMLS) who have signed an agreement. Numerous online and offline browsers are available. Those wishing to obtain a license for its use and to download SNOMED CT should contact their National Release Centre, links to which are provided on the IHTSDO web site .

License free subsets To facilitate adoption of SNOMED CT and use of SNOMED CT in other standards, there are license free subsets. For example a set of 7,314 codes and descriptions is free for use by users of DICOM-compliant software (without restriction to IHTSDO member countries).*[29]

15.50.4 See also

- CDISC
- Clinical Care Classification System
- DOCLE
- EN 13606
- HL7
- IHTSDO - International Health Terminology Standards Development Organization
- MEDCIN
- MedDRA
- Omaha System

15.50.5 Notes

[1] From **S**ystematized **No**menclature Of **Med**icine **C**linical **T**erms

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[12] Unified Medical Language System

[13]

[14]

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15.50.7 External links

- IHTSDO Web Site - Home of the owners of SNOMED
- SNOMED CT Value Proposition
- SNOMED CT Online Documentation Directory
- CAP SNOMED Terminology Solutions - the original creators of SNOMED CT
- Online SNOMED CT Browser English and German
- CliniClue SNOMED CT Browser (Windows) - freeware download
- UMLS-SNOMED FAQs
- NHS Connecting for Health UK
- SNOB - Desktop SNOMED Browser (Windows/WINE) - freeware download
- SNOMED CT Browser with SNOFLAKE view at dataline.co.uk
- VMIL terminology browser
- SNOCat: the SNOMED Categorizer/Browser
- Minnow SNOMED CT Browser (Windows/Mac OS X/Linux) - freeware download
- Problems with SNOMED (Papers by Barry Smith)
- Snow Owl - Freeware multiplatform SNOMED CT browser and authoring tool integrating Protégé.
- "What Is SNOMED Clinical Terms"
- *Health Data Management*, February 14, 2002: "New Clinical Terminology Available from SNOMED,"
- SNOMED CT-AU® Information
- ITServer - Online SNOMED CT Browser English and Spanish
- SNQuery - SNOMED CT Expression Constraint Language Execution Engine

15.51 Standard for Exchange of Non-clinical Data

The **Standard for Exchange of Nonclinical Data** (**SEND**) is an implementation of the CDISC Standard Data Tabulation Model (SDTM) for nonclinical studies, which specifies a way to present nonclinical data in a consistent format. These types of studies are related to animal testing conducted during drug development. Raw data of toxicology animal studies started after December 18th 2016 to support submission of new drugs to the US Food and Drug Administration will be submitted to the agency using SEND.

Having a common model to which the industry can conform enables benefits such as the ability for vendors to develop tools, for inter-organizational data exchange that is consistent in format regardless of the parties involved, and so on.

A SEND package consists of a few parts, but the main focus is on individual endpoint data. Endpoints typically map to domains (essentially, datasets), with a number of variables (a.k.a., columns or fields).

15.51.1 SEND Implementation

The SEND Implementation Guide (SENDIG) is a document that provides implementers with specifications for implementing SEND, including how to model various nonclinical endpoints, rules to doing so, and examples with sample data. This document is available on the CDISC SEND website.

Supplementing the guide is the SEND Implementation Wiki is a wiki hosted by PhUSE designed to assist with the implementation process and filling in some of the gaps, most notably containing:

- SEND, CT, and Define.xml Fundamentals pages - providing entry-level descriptions of fundamental concepts in SEND, such as SEND itself, Controlled Terminology (CT), and Define.xml
- Getting SEND-ready - to help new implementers get started
- FAQ - providing a large, evolving list of commonly asked questions

Companion to the wiki is the SEND Implementation Forum, which allows implementers to ask questions and get responses from SEND experts. New implementers are encouraged to ask questions here.

15.51.2 History

The work on this standard began in July 2002 —subsequently, a U.S. Food and Drug Administration pilot

project was initiated in July 2003 through a Cooperative Research and Development Agreement (CRADA). Feedback from this pilot and continuous efforts to more closely align this implementation with the SDTM for human clinical trials led to development of SEND 2.3, but without widespread adoption.

In 2006, with renewed FDA interest, the industry met to revive SEND and work on a version that, with FDA backing, would cover regulatory submission as well as operational data transfer needs. By 2007, an FDA pilot was announced, during which time the SEND team worked on the SENDIG (implementation guide).

SENDIG 3.0 was released to production in July 2011. This was soon followed by the FDA's statement of preference for SEND datasets.

In December 2014, the FDA CDER and CBER divisions released guidance for industry enforcing the usage of SEND as part of Investigational New Drug (IND) and Biologic License Application (BLA) submission to the US Food and Drug Administration. All studies started after December 15th 2016 supporting IND and BLA submissions will need to be compliant with SEND. The Pharmaceuticals and Medical Devices Agency in Japan will enforce its use in the future, most probably in 2020. The European Medicines Agency also expressed interest and is recommending the use of SEND.

SENDIG 3.1 is expected to be delivered in 2016, extending the format with new data domains. Consider the SENDIG and the PhUSE SEND Implementation Wiki pages for additional related information.

15.51.3 See also

- CDISC
- SDTM
- PhUSE

15.51.4 External links

- CDISC SEND - for the SEND Implementation Guide, Controlled Terminology, and more
- FDA Data Standards - for the FDA's list of supported standards and associated resources
- SEND Implementation Wiki - for frequently asked questions and implementation assistance
- SEND Implementation Forum - for asking questions about implementing SEND

15.52 TC 251

CEN/TC 251 (CEN Technical Committee 251) is a technical decision making body within the CEN system working on standardization in the field of Health Information and Communications Technology (ICT) in the European Union. The goal is to achieve compatibility and interoperability between independent systems and to enable modularity in Electronic Health Record systems.

Workgroups establish requirements for health information structure in order to support clinical and administrative procedures, technical methods to support interoperable systems. In addition they establish requirements regarding safety, security and quality.

15.52.1 Workgroups

The two Working Groups (WGs) in CEN/TC 251 are :

- WG 1: Enterprise and Information
- WG 2: Technology and Applications

15.52.2 See also

- ContSys
- EHRcom
- European Institute for Health Records
- Health Informatics Service Architecture (HISA)
- HIPAA (USA)
- Health Level 7 International
- International Classification of Primary Care (ICPC)
- ISO TC 215
- openEHR Foundation
- ProRec

15.52.3 External links

- CEN/TC 251 - Published standards
- CEN/TC 251 is a member of the Global Health Informatics Standardization
- Joint Initiative Council

15.53 WHOART

The **WHO Adverse Reactions Terminology** (WHOART) is a dictionary meant to serve as a basis for rational coding of adverse reaction terms. The system is maintained by the Uppsala Monitoring Centre (UMC), the World Health Organization Collaborating Centre for International Drug Monitoring.

15.53.1 Structure

- 32 System-organ classesbody organ groups
- 180 High level terms for grouping Preferred terms
- 2085 Preferred terms principal terms for describing adverse reactions
- 3445 Included terms synonyms to Preferred terms

15.53.2 See also

- Pharmacovigilance
- COSTART
- MedDRA
- Adverse event

15.53.3 References

- WHO Adverse Reactions Terminology

Chapter 16

Healthcare Ontologies

16.1 Nosology

Nosology (from Ancient Greek νόσος *(nosos)*, meaning "disease", and -λογία *(-logia)*, meaning "study of-") is a branch of medicine that deals with classification of diseases.

16.1.1 Types of classification

Diseases may be classified by etiology (cause), pathogenesis (mechanism by which the disease is caused), or by symptom(s).

Alternatively, diseases may be classified according to the organ system involved, though this is often complicated since many diseases affect more than one organ.

A chief difficulty in nosology is that diseases often cannot be defined and classified clearly, especially when etiology or pathogenesis are unknown. Thus diagnostic terms often only reflect a symptom or set of symptoms (syndrome).

Traditionally diseases were defined as syndromes by their symptoms. When more information is available, they are also defined by the damage they produce. When etiology is known, they are better defined by their etiology, though still important are their characteristics.

Probably the last described kind of diseases are molecular diseases, defined by their molecular characteristics. This was introduced in November 1949, with the seminal paper, "Sickle Cell Anemia, a Molecular Disease",*[1] in *Science* magazine, Linus Pauling, Harvey Itano and their collaborators laid the groundwork for establishing the field of molecular medicine.

16.1.2 Coding systems

Several classifications of diseases have been historically proposed, and normally all of them assign a code to every supported disease. Some of them codify diseases following the path of the classification tree, and others like SNOMED use a multifactor classification system.

The most known coding system is the World Health Organization ICD-Series, but there are other accepted classifications like DOCLE, NANDA or SNOMED*[2] Historically there were others like Berkson Coding System that are not maintained anymore.

There are also coding systems for symptoms presents in the diseases and biological findings. They are normally included in medical dictionaries, also with a codification system. Some of them are MeSH (Medical Subject Headings), COSTART (Coding Symbols for Thesaurus of Adverse Reaction Terms) or MedDRA (Medical Dictionary for Regulatory Activities)*[3] Other systems like Current Procedural Terminology do not deal directly with diseases but with the related procedures.

16.1.3 Extended nosology and general medical conditions

In a wide sense, nosology deals not only with diseases, but with any kind of medical condition, like injuries, lesions or disorders.*[4]*[5]

Medical conditions, like diseases, can be defined by etiology (cause), pathogenesis (mechanism by which the disease is caused), or by a collection of symptoms and medical signs, specially when the other two definitions are not available (idiopathic diseases).

From a nosological point of view, medical conditions could be divided in syndromes, diseases, disorders, lesions and injuries, each one with some specific meaning:

Disorder In medicine, a **disorder** is a functional abnormality or disturbance. Medical disorders can be categorized into mental disorders, physical disorders, genetic disorders, emotional and behavioral disorders, and functional disorders. The term *disorder* is often considered more value-neutral and less stigmatizing than the terms *disease* or *illness*, and therefore is a preferred terminology in some circumstances. In mental health, the term *mental disorder* is used as a way of acknowledging the complex interaction of biological, social, and psychological factors in psychiatric conditions. However, the term *disorder* is also used in many other areas of medicine, primarily to identify physical disorders that are not

caused by infectious organisms, such as metabolic disorders.

Disease The term *disease* broadly refers to any condition that impairs the normal functioning of the body. For this reason, diseases are associated with dysfunctioning of the body's normal homeostatic process.*[6] Commonly, the term *disease* is used to refer specifically to infectious diseases, which are clinically evident diseases that result from the presence of pathogenic microbial agents, including viruses, bacteria, fungi, protozoa, multicellular organisms, and aberrant proteins known as prions. An infection that does not and will not produce clinically evident impairment of normal functioning, such as the presence of the normal bacteria and yeasts in the gut, or of a passenger virus, is not considered a disease. By contrast, an infection that is asymptomatic during its incubation period, but expected to produce symptoms later, is usually considered a disease. Non-infectious diseases are all other diseases, including most forms of cancer, heart disease, and genetic disease.

Illness and *sickness* are generally used as synonyms for *disease*. However, these terms are occasionally used to refer specifically to the patient's personal experience of his or her disease. In this model, it is possible for a person to have a disease without being ill (to have an objectively definable, but asymptomatic, medical condition), and to be *ill* without being *diseased* (such as when a person perceives a normal experience as a medical condition, or medicalizes a non-disease situation in his or her life).

Normally four main types of diseases are considered: pathogenic diseases, deficiency diseases, hereditary diseases, and physiological diseases.

Syndrome A syndrome is the association of several medical signs, symptoms, and or other characteristics that often occur together. Some syndromes, such as Down syndrome, have only one cause; others, such as Parkinsonian syndrome, have multiple possible causes. In other cases, the cause of the syndrome is unknown. A familiar syndrome name often remains in use even after an underlying cause has been found, or when there are a number of different possible primary causes.

In cases of viral infections, like HIV, it is important to make a difference between the infection (considered as a disease, even while it is silent) and the associated symptoms (a syndrome). In the case of HIV the syndrome is named AIDS

Injury and lesions Injury is damage to the body. This maybe caused by accidents, falls, hits, weapons, and other causes. Major trauma is injury that has the potential to cause prolonged disability or death. Lesion is any abnormality in the tissue of an organism (in layman's terms, "damage"), usually caused by disease or trauma. Lesion is derived from the Latin word laesio meaning injury. Similar to the ICD-10 the World Health Organization produces the International Classification of External Causes of Injury (ICECI). Sequelae of resolved diseases sometimes are considered inside lesions and other times inside diseases.

Some medical conditions cannot be classified in any of these groups, but they can still be important enough to be considered as medical conditions. For example, to be a carrier of a genetical disease, or a viral infection unable to progress to disease, normally is not considered inside any of the previous groups. Cases of infections able to progress, but with low possibilities, like latent tuberculosis, are also considered outside the category of diseases.

The term "medical condition" can also be applied to physiological states outside the context of disease, as for example when referring to "symptoms of pregnancy". It can also refer to the normal residual scars of a disease after it has resolved, for example lungs fibrosis after a tuberculosis.

16.1.4 History

The Ayurveda is a collection of early Indian works about medicine. In China the Huangdi Neijing is another ancient text. In the West, Hippocrates was one of the earliest writers on the subject of disease. The Metzora (parsha) also includes an early discussion of the treatment of skin diseases.

In the 10th century the Arabian psychologist Najab uddin Unhammad classified a nosology of nine major categories of mental disorders, which included 30 different mental illnesses in total. Some of the categories he described included obsessive-compulsive disorders, delusional disorders, degenerative diseases, involutional melancholia, and states of abnormal excitement.*[7]

In the 17th century, the English physician Thomas Sydenham was the first to propose a syndrome based classification of diseases. For Sydenham a disease and a syndrome were equivalent concepts.*[8]

In the 18th century, the taxonomist Carl Linnaeus, Francois Boissier de Sauvages, and psychiatrist Philippe Pinel developed an early classification of physical illnesses. Thomas Sydenham's work in the late 17th century might also be considered a nosology. In the 19th century, Emil Kraepelin and then Jacques Bertillon developed their own nosologies. Bertillon's work, classifying causes of death, was a precursor of the modern code

system, the International Classification of Diseases.

The early nosological efforts grouped diseases by their symptoms, whereas modern systems (e.g. SNOMED) focus on grouping diseases by the anatomy and etiology involved.

16.1.5 Applications

- Nosology is used extensively in public health, to allow epidemiological studies of public health issues. Analysis of death certificates requires nosological coding of causes of death.
- Nosological classifications are used in medical administration, such as filing of health insurance claims, and patient records, among others

16.1.6 See also

- Clinical coder
- Diagnosis code
- Differential diagnosis
- International Statistical Classification of Diseases and Related Health Problems (ICD)
  - ICD-10 (ICD 10th Revision)
- Medical classification
- Pathology (study of disease)
- Category:Diseases and disorders (Wikipedia's categorization of diseases)

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16.1.8 External links

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- International Classification of Diseases by the World Health Organization.

16.2 Archetype

In the field of informatics, an **archetype** is a formal reusable model of a domain concept. Traditionally, the term *archetype* is used in psychology to mean an idealized model of a person, personality or behaviour (see *Archetype*). The usage of the term in informatics is derived from this traditional meaning, but applied to domain modelling instead.

An archetype is defined by the OpenEHR Foundation (for health informatics) as follows:*[1]

> *An archetype is a computable expression of a domain content model in the form of structured constraint statements, based on some reference model. openEHR archetypes are based on the openEHR reference model. Archetypes are all expressed in the same formalism. In general, they are defined for wide re-use, however, they can be specialized to include local particularities. They can accommodate any number of natural languages and terminologies.*

The use of archetypes in health informatics was first documented by Thomas Beale, who stated the concept was coined by Derek Renouf. According to Beale, Renouf applied archetypes to configuring Smalltalk systems.*[2]

16.2.1 See also

- EHRcom
- European Institute for Health Records
- Good European Health Record

- HISA
- Information science
- OpenEHR

16.2.2 References

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16.3 OBO Foundry

The Open Biomedical Ontologies (OBO) Foundry (now **The Open Biological and Biomedical Ontologies (OBO) Foundry**) is a collaborative experiment involving developers of science-based ontologies. (Smith et al., 2007) The Foundry is concerned with establishing a set of principles for ontology development with the goal of creating a suite of orthogonal interoperable reference ontologies in the biomedical domain. The Foundry approach has been adopted by the Neuroscience Information Framework (NIF) Standard and by the cROP (Common Reference Ontologies for Plants) initiatives.

16.3.1 Introduction

The Foundry initiative rests on the belief that the value of data is greatly enhanced when it exists in a form that allows it to be integrated with other data. One approach to integration is through the annotation of multiple bodies of data using common controlled vocabularies. Ideally, such controlled vocabularies take the form of 'ontologies', which means that they are constructed in such a way as to support logical reasoning over the data annotated in their terms.

The success of this general approach in helping to tame the explosive proliferation of data in the biomedical domain—most conspicuously through the work of the Gene Ontology Consortium—has led to the development of certain proposed principles of good practice in ontology development, which are now being put into practice within the framework of the Open Biomedical Ontologies consortium through its OBO Foundry initiative. Existing OBO ontologies, including the Gene Ontology, are undergoing coordinated reform and new ontologies are being created in a coordinated effort to create a family of ontologies designed to be interoperable and logically well formed and to incorporate accurate representations of biological reality.

The Open Biological and Biomedical Ontologies (formerly The Open Biomedical Ontologies as well as The Open Biological Ontologies) is an effort to create controlled vocabularies for shared use across different biological and medical domains. As of 2006, OBO ontologies form part of the resources of the National Center for Biomedical Ontology, where they form a central component of the NCBO's BioPortal.

The OBO Foundry is a collaborative experiment, involving a group of OBO ontology developers who have agreed in advance to the adoption of a growing set of principles specifying best practices in ontology development. The goal is to develop a set of interoperable humanly validated reference ontologies for all major domains of biomedical research. The project is summarized in this article published in Nature Biotechnology.

16.3.2 Custodians

The custodians of the OBO Foundry are:

- Michael Ashburner (Cambridge, UK)
- Suzanna Lewis (Berkeley)
- Chris Mungall (Berkeley)
- Alan Ruttenberg (Cambridge, MA)
- Richard Scheuermann (JCVI)
- Barry Smith (Buffalo/Saarbrücken)

16.3.3 Principles

(Version as of 24 April 2006.)

1. The ontology is open in the sense that it is available to be used by all under the following two constraints (1) its origin must be acknowledged and (2) it is not to be altered and subsequently redistributed under the original name or with the same identifiers.

2. The ontology is in, or can be expressed in, a common formal language. (A provisional list of languages supported by OBO is provided at http://obo.sf.net/.)

3. The ontology possesses a unique identifier space within OBO.

4. The ontology provider has procedures for identifying distinct successive versions.

5. The ontology has a clearly specified and clearly delineated content.

6. The ontology includes textual definitions for all terms.

7. The ontology uses relations which are unambiguously defined following the pattern of definitions laid down in the OBO Relation Ontology.

8. The ontology is well documented.

9. The ontology has a plurality of independent users.

10. The ontologies in the OBO Foundry will be developed in a collaborative effort.

16.3.4 Members of the OBO Foundry (March 2010)

The goal of the OBO Foundry initiative is to create an evolving group of biological and biomedical ontologies which will have the potential to cover a wide range of life science phenomena in a modular fashion. To realize this goal, we have subjected a number of candidate ontologies to a process of review, the first phase of which has now been completed, and the results are reported here. The following six ontologies have satisfied the OBO Foundry principles and are recommended as preferred targets for community convergence.

- CHEBI: Chemical Entities of Biological Interest
- GO: Gene Ontology
- PATO: Phenotypic Quality Ontology
- PRO: Protein Ontology
- XAO: Xenopus Anatomy Ontology
- ZFA: Zebrafish Anatomy Ontology

16.3.5 Candidate Members of the OBO Foundry

The following groups of ontologies can be informally distinguished among current OBO Foundry candidate members:

Mature Ontologies undergoing reform

- Cell Ontology (CL)
- Foundational Model of Anatomy (FMA) Ontology
- Plant growth and developmental stage
- Plant structure
- Sequence Ontology (SO)

Ontologies being built ab initio within the Foundry framework

- Common Anatomy Reference Ontology (CARO)
- Environment Ontology (EnvO)
- Fish Multi-Species Anatomy Ontology (NSF funding received)
- Infectious Disease Ontology (IDO)
- Malaria Ontology (IDO-MAL)
- Influenza Ontology
- Ixodidae and Argasidae (Tick) Anatomy Ontology
- Mosquito Anatomy Ontology (MAO)
- Ontology for Biomedical Investigations (OBI)
- Ontology for General Medical Science
- RNA Ontology (RnaO)
- Spider Anatomy Ontology (SPD)
- Subcellular Anatomy Ontology (SAO)
- Vaccine Ontology

Other candidate ontologies

- Disease Ontology
- Drosophila Development
- Drosophila Gross Anatomy
- Human Phenotype Ontology
- Mammalian Phenotype
- Mouse Adult Gross Anatomy
- Mouse Gross Anatomy and Development
- Mouse Pathology
- Systems Biology Ontology
- Teleost Anatomy and Development
- Teleost Taxonomy
- Tick Gross Anatomy

16.3.6 References

Brush MH, Vasilevsky N, Torniai C, Johnson T, Shaffer C, Haendel MA. "Developing a Reagent Application Ontology within the OBO Foundry Framework", *Proceedings of the International Conference on Biomedical Ontology*, Buffalo, NY, 2011.

M Courtot, C Mungall, RR Brinkman, A Ruttenberg, '[ceur-ws.org/Vol-833/paper72.pdf Building the OBO Foundry-One Policy at a Time]", *Proceedings of the International Conference on Biomedical Ontology*, (CEUR 993), 2011.

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A Ghazvinian, NF Noy, MA Musen" ,"How orthogonal are the OBO Foundry ontologies" , *J Biomed Semantics* 2011; 2(Suppl 2): S2. doi: 10.1186/2041-1480-2-S2-S22011

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P Seyed, SC Shapiro, "[ceur-ws.org/Vol-833/paper23.pdf Applying Rigidity to Standardizing OBO Foundry Candidate Ontologies]", *Proceedings of the International Conference on Biomedical Ontology* (CEUR 993), 2011.

Smith, B.; Ashburner, M.; Rosse, C.; Bard, J.; Bug, W.; Ceusters, W.; et al. (2007). "The OBO Foundry: Coordinated evolution of ontologies to support biomedical data integration" . Nature Biotechnology 25 (11): 1251–1255. doi:10.1038/nbt1346. PMC 2814061. PMID 17989687.

CF Taylor, D Field, S-A Sansone, R Apweiler, M Ashburner, et al. "Promoting Coherent Minimum Reporting Requirements for Biological and Biomedical Investigations: The MIBBI Project" , *Nature Biotechnology*, 26 (2008), 889-896. PMC2771753

16.4 Ontology for Biomedical Investigations

The OBI Consortium logo.

The **Ontology for Biomedical Investigations (OBI)** is an open access, integrated ontology for the description of biological and clinical investigations. OBI provides a model for the design of an investigation, the protocols and instrumentation used, the materials used, the data generated and the type of analysis performed on it. The project is being developed as part of the OBO Foundry and as such adheres to all the principles therein such as orthogonal coverage (i.e. clear delineation from other foundry member ontologies) and the use of a common formal language. In OBI the common formal language used is the Web Ontology Language (OWL). As of March 2008, a pre-release version of the ontology was made available at the project's SVN repository*[1]

16.4.1 Scope of the Ontology

The Ontology for Biomedical Investigations (OBI) addresses the need for controlled vocabularies to support integration and joint ("cross-omics") analysis of experimental data, a need originally identified in the transcriptomics domain by the FGED Society, which developed the MGED Ontology as an annotation resource for microarray data.*[2] OBI uses the Basic Formal Ontology*[3] upper level ontology as a means of describing general entities that do not belong to a specific problem domain. As such, all OBI classes are a subclass of some BFO class.

The ontology has the scope of modeling all biomedical investigations and as such contains ontology terms for aspects such as:

- biological material - for example blood plasma
- instrument (and parts of an instrument therein) - for example DNA microarray, centrifuge
- information content - such as an image or a digital information entity such as an electronic medical record
- design and execution of an investigation (and individual experiments therein) - for example study design, electrophoresis material separaition
- data transformation (incorporating aspects such as data normalization and data analysis) - for example principal components analysis dimensionality reduction, mean calculation

Less 'concrete' aspects such as the role a given entity may play in a particular scenario (for example the role of a chemical compound in an experiment) and the function of an entity (for example the digestive function of the stomach to nutriate the body) are also covered in the ontology.

16.4.2 OBI Consortium

The MGED Ontology was originally identified in the transcriptomics domain by the FGED Society and was developed to address the needs of data integration. Following a mutual decision to collaborate, this effort later became a wider collaboration between groups such as FGED, PSI and MSI in response to the needs of areas such as transcriptomics, proteomics and metabolomics and the FuGO (Functional Genomics Investigation Ontology)* [4] was created. This later became the OBI covering the wider scope of all biomedical investigations.

As an international, cross-domain initiative, the OBI consortium draws upon a pool of experts from a variety of fields, not limited to biology. The current list of OBI consortium members is available at the OBI consortium website. The consortium is made up of a coordinating committee which is a combination of two subgroups, the Community Representative (those representing a particular biomedical community) and the Core Developers (ontology developers who may or may not be members of any single community). Separate to the coordinating committee is the Developers Working Group which consists of developers within the communities collaborating in the development of OBI at the discretion of current OBI Consortium members.

16.4.3 References

[1] Ontology for Biomedical Investigations (OBI) | Home

[2] Smith *et al.* (2007) Nature Biotechnology 25, 1251 - 1255 (2007)

[3] Basic Formal Ontology (BFO) | Home

[4] Whetzel, PL et al. Development of FuGO: an ontology for functional genomics investigations. OMICS 10, 199–204

16.4.4 External links

- The OBI Consortium project homepage http://obi-ontology.org/
- The OBI Consortium SVN Repository homepage http://obi.svn.sourceforge.net/viewvc/obi/
- The OBI Consortium mailing list homepage http://obi-ontology.org/page/Mailing_lists

16.4.5 Papers on OBI

- J Biomed Semantics. 2010. Modeling biomedical experimental processes with OBI, Ryan R Brinkman, Mélanie Courtot, Dirk Derom, Jennifer M Fostel, Yongqun He, Phillip Lord, James Malone, Helen Parkinson, Bjoern Peters, Philippe Rocca-Serra, Alan Ruttenberg, Susanna-Assunta Sansone, Larisa N Soldatova, Christian J Stoeckert, Jr., Jessica A Turner, Jie Zheng, and the OBI consortium
- OWLED 2008. The OWL of Biomedical Investigations, Mélanie Courtot, William Bug, Frank Gibson, Allyson L. Lister, James Malone, Daniel Schober, Ryan Brinkman and Alan Ruttenberg.
- Development of an Application Ontology for Beta Cell Genomics Based On the Ontology for Biomedical Investigations

J Zheng, E Manduchi, CJ Stoeckert J. 2013

- The Semanticscience Integrated Ontology (SIO) for Biomedical Research and Knowledge Discovery

M Dumontier, CJO Baker, J Baran, A Callahan ···2013

- Workshop on laboratory protocol standards for the molecular methods database

MK Müller, P Lambrix, MJ Taussig, JE Litton···2013

- The representation of biomedical protocols

Larisa N. Soldatova, Ross D. King, Piyali S. Basu, Emma Haddi, Nigel Saunders 2013

- Modeling biomedical experimental processes with OBI RR Brinkman, M Courtot, D Derom, JM Fostel, Y He···- 2010

16.5 Open Biomedical Ontologies

Open Biomedical Ontologies (abbreviated **OBO**; formerly Open Biological Ontologies) is an effort to create controlled vocabularies for shared use across different biological and medical domains. As of 2006, OBO forms part of the resources of the U.S. National Center for Biomedical Ontology where it will form a central element of the NCBO's BioPortal.

16.5.1 OBO Foundry

The OBO Ontology library forms the basis of the OBO Foundry,* [1] a collaborative experiment involving a group of ontology developers who have agreed in advance to the adoption of a growing set of principles specifying best practices in ontology development. These principles are designed to foster interoperability of ontologies within the broader OBO framework and also to ensure a gradual improvement of quality and formal rigor in ontologies. The library operates to design ways to meet the increasing needs of data and information integration in the biomedical domain.

16.5.2 Related Projects

Ontology Lookup Service

The Ontology Lookup Service is a spin-off of the PRIDE project, which required a centralized query interface for ontology and controlled vocabulary lookup. While many of the ontologies queriable by the OLS are available online, each has its own query interface and output format. The OLS provides a web service interface to query multiple ontologies from a single location with a unified output format.

Gene Ontology Consortium

The goal of the Gene ontology (GO) consortium is to produce a controlled vocabulary that can be applied to all organisms even as knowledge of gene and protein roles in cells is accumulating and changing. GO provides three structured networks of defined terms to describe gene product attributes.

Sequence Ontology

The Sequence Ontology (SO) is a part of the Gene Ontology project and the aim is to develop an ontology suitable for describing biological sequences. It is a joint effort by genome annotation centres, including WormBase, the Berkeley Drosophila Genome Project, FlyBase, the Mouse Genome Informatics group, and the Sanger Institute.

Generic Model Organism Databases

The Generic Model Organism Project (GMOD) is a joint effort by the model organism system databases WormBase, FlyBase, MGI, SGD, Gramene, Rat Genome Database, EcoCyc, and TAIR to develop reusable components suitable for creating new community databases of biology.

Standards and Ontologies for Functional Genomics

SOFG is both a meeting and a website; it aims to bring together biologists, bioinformaticians, and computer scientists who are developing and using standards and ontologies with an emphasis on describing high-throughput functional genomics experiments.

FGED

The Functional Genomics Data (FGED) Society is an international organisation of biologists, computer scientists, and data analysts that aims to facilitate the sharing of microarray data generated by functional genomics experiments.

Ontology for Biomedical Investigations

The Ontology for Biomedical Investigations (OBI) is an open access, integrated ontology for the description of biological and clinical investigations. OBI provides a model for the design of an investigation, the protocols and instrumentation used, the materials used, the data generated and the type of analysis performed on it. The project is being developed as part of the OBO Foundry and as such adheres to all the principles therein such as orthogonal coverage (i.e. clear delineation from other foundry member ontologies) and the use of a common formal language. In OBI the common formal language used is the Web Ontology Language (OWL).

Plant ontology

The Plant Ontology Consortium (POC) aims to develop, curate and share structured controlled vocabularies (ontologies) that describe plant structures and growth/developmental stages. Through this effort, the project aims to facilitate cross database querying by fostering consistent use of these vocabularies in the annotation of tissue and/or growth stage specific expression of genes, proteins and phenotypes.

Phenoscape

Phenoscape is a project to develop a database of phenotype data for species across the Osteriophysi, a large group of Teleost fish. The data is captured using annotations that combine terms from an Anatomy Ontology, an accompanying Taxonomic Ontology, and quality terms from the PATO ontology of phenotype qualities. Several other OBO ontologies are also used. The anatomy ontology was developed from the zebrafish anatomy ontology developed by the Zebrafish Information Network.

16.5.3 OBO and Semantic Web

OBO & OWL Roundtrip Transformations

As a community effort, a standard common mapping has been created for lossless roundtrip transformations between Open Biomedical Ontologies (OBO) format and OWL. The research contains methodical examination of each of the constructs of OBO and a layer cake for OBO, similar to the Semantic Web stack.*[2]

16.5.4 References

[1] Smith, B.; Ashburner, M.; Rosse, C.; Bard, J.; Bug, W.; Ceusters, W.; Goldberg, L. J.; Eilbeck, K.; Ireland, A.; Mungall, C. J.; Leontis, N.; Rocca-Serra, P.; Ruttenberg, A.; Sansone, S. A.; Scheuermann, R. H.; Shah, N.; Whetzel, P. L.; Lewis, S. (2007). "The OBO Foundry: Coordinated evolution of ontologies to support biomedical data integration". *Nature Biotechnology* **25** (11): 1251–1255. doi:10.1038/nbt1346. PMC 2814061. PMID 17989687.

[2] Antezana, E.; Egana, M.; De Baets, B.; Kuiper, M.; Mironov, V. (2008). "ONTO-PERL: An API for supporting the development and analysis of bio-ontologies". *Bioinformatics* **24** (6): 885–887. doi:10.1093/bioinformatics/btn042. PMID 18245124.

16.5.5 External links

- Open Biomedical Ontologies (OBO)

- Ontology browser for most of the Open Biological Ontologies at BRENDA website
- PubOnto: OBO-based literature search tool
- Project Page
- Morphster Project
- ONTO-PERL
- SimCT Web-based tool to display relationships between biological objects annotated to an ontology in the form of a tree, based on their annotation similarity.

16.6 TIME-ITEM

TIME-ITEM is an ontology of *Topics* that describes the content of undergraduate medical education. TIME is an acronym for "Topics for Indexing Medical Education"; ITEM is an acronym for "Index de thèmes pour l'éducation médicale." Version 1.0 of the taxonomy has been released and the web application that allows users to work with it is still under development. Its developers are seeking more collaborators to expand and validate the taxonomy and to guide future development of the web application.

16.6.1 History

The development of TIME-ITEM began at the University of Ottawa in 2006. It was initially developed to act as a content index for a curriculum map being constructed there. After its initial presentation at the 2006 conference of the Canadian Association for Medical Education,[*][1] early collaborators included the University of British Columbia, McMaster University and Queen's University.

16.6.2 Features

The TIME-ITEM ontology is unique in that it is designed specifically for undergraduate medical education. As such, it includes fewer strictly biomedical entries than other common medical vocabularies (such as MeSH or SNOMED CT) but more entries relating to the medico-social concepts of communication, collaboration, professionalism, etc.[*][2]

Topics within TIME-ITEM are arranged poly-hierarchically, meaning any Topic can have more than one parent. Relationships are established based on the logic that learning about a Topic contributes to the learning of all its parent Topics.

In addition to housing the ontology of Topics, the TIME-ITEM web application can house multiple Outcome frameworks. All Outcomes, whether private Outcomes entered by single institutions or publicly available medical education Outcomes (such as CanMeds 2005) are hierarchically linked to one or more Topics in the ontology. In this way, the contribution of each Topic to multiple Outcomes is made explicit.[*][3]

The structure of the XML documents exported from TIME-ITEM (which contain the hierarchy of Outcomes and TIME-ITEM Topics) is being developed alongside the MedBiquitous Competency standards.

The taxonomy currently exists in English only but translation to Canadian French is in progress.

16.6.3 Applications

TIME-ITEM is intended to be a general-use ontology for medical education informatics. It has two primary potential applications:

1. Inclusion in curriculum maps. By mapping learning objects or sessions to TIME-ITEM Topics in a curriculum map, the map becomes searchable for both granular and broad concepts. If one or more Outcome frameworks are included with the Topic ontology, then the contribution of each curricular element to one or more Outcomes is made explicit. This also facilitates curriculum evaluation in terms of one or more outcome frameworks.

2. Indexing learning, assessment and portfolio objects. Metatagging learning objects or assessment objects with a controlled vocabulary enhances the organization and retrieval of objects from a repository. Metatagging electronic portfolio entries allows one to show how multiple entries "add up" to a demonstration of competence with respect to certain educational outcomes.

The possibility of expanding or modifying TIME-ITEM for use in postgraduate/continuing medical education and in nursing education is currently being explored.

16.6.4 See also

- Curriculum mapping
- Outcome-based education
- Category:Medical classification
- Ontology (computer science)
- Controlled vocabulary
- Education informatics

16.6.5 References

[1] Willett T & Clarke M. A Map of Medical Concepts: A General-use Database for Applications in Medical Education. AFMC Resource Group on Medical Informatics Reception. At the Canadian Association for Medical Education Conference (May 2006) London, Canada

[2] Willett, TG.; Marshall, KC.; Broudo, M.; Clarke, M. (Apr 2008). "It's about TIME: a general-purpose taxonomy of subjects in medical education". *Med Educ* **42** (4): 432–8. doi:10.1111/j.1365-2923.2008.03012.x. PMID 18298447.

[3] Willett TG, Marshall KC, Broudo M & Clarke M. TIME as a generic index for outcome-based medical education. *Medical Teacher* 2008; 29(7):655-9.

16.6.6 External links

- http://www.time-item.org (Registration required, by application only)

Chapter 17

Associations, Committees and Conferences

17.1 American Association for Medical Systems and Informatics

The **American Association for Medical Systems and Informatics** (**AAMSI**) was an organization created to encourage improvements in the state of medical care by encouraging the development of computer systems for that field.

On August 19, 1981, the American Association for Medical Systems and Informatics was incorporated. This organization came into existence as a result of the efforts of two predecessor organizations, the Society for Computer Medicine (SCM), incorporated in November, 1972, and the Society for Advanced Medical Systems (SAMS), incorporated in November, 1975, to merge into one. Formal dissolution of SCM and SAMS occurred on April 30, 1982. AAMSI's main purpose was to support patient care, teaching, research, and health administration through the development and implementation of computer systems. To meet this goal, the association served as a clearinghouse for information on medical systems and informatics, supported committees which contributed to the advance of medical informatics and sponsored annual conferences on advances in medical information systems.*[1]

In 1989, AAMSI merged with the Symposium on Computer Applications in Medical Care (SCAMC) and the American College of Medical Informatics (ACMI) to form the American Medical Informatics Association (AMIA).*[2]

A collection of AAMSI's papers were donated to the National Library of Medicine in 1987.*[3]

17.1.1 See also

- American Medical Informatics Association

17.1.2 Notes

[1] This article uses content from the United States National Library of Medicine (NLM), located at http://www.nlm.nih.gov/. For copyright information, see http://www.nlm.nih.gov/copyright.html

[2] http://www.amia.org/college/ Retrieved on 2009-03-03.

[3] "American Association for Medical Systems Informatics Records 1972-1984". National Library of Medicine.

17.1.3 External links

- American Association for Medical Systems Informatics Records (1972-1984)—National Library of Medicine finding aid

17.2 American College of Medical Informatics

The **American College of Medical Informatics***[1] (**ACMI**) is a college of elected fellows from the United States and abroad who have made significant and sustained contributions to the field of medical informatics. Initially incorporated in 1984, the organization later dissolved its separate corporate status to merge with the American Association for Medical Systems and Informatics (AAMSI) and the Symposium on Computer Applications in Medical Care (SCAMC) when the American Medical Informatics Association (AMIA) was formed in 1989. The College now exists as an elected body of fellows within AMIA, with its own bylaws and regulations that guide the organization, its activities, and its relationship with the parent organization. The College is fiscally self-sufficient, and its officers prepare and submit its financial plan annually for approval by the AMIA Board of Directors.

17.2.1 History

The College was initially created using an election process that assured that the founding fellows would be

elected by their peers. Five individuals, Marsden S. Blois, Morris F. Collen, Donald A. B. Lindberg, Thomas E. Piemme, and Edward H. Shortliffe, prepared a ballot of over 100 names of leaders in the field and sent the ballot to all listed individuals. Nominees were asked to vote for 50 colleagues to become the founding fellows, and in this way the initial set of 52 fellows was selected (three individuals were tied for the fiftieth place). The founding fellows then incorporated, elected officers, and initiated a process through which the existing fellows nominate and elect new fellows. The number of people and international associates elected through the years has now reached close the 300 inducted Fellows of the ACMI, with approximately fifteen to twenty new fellows and international associates elected each year. Photographs of people elected through 1993 were published in the inaugural issue of JAMIA, the Journal of the American Medical Informatics Association, in January 1994, and each year's class of newly elected fellows is published in JAMIA.

17.2.2 See also

- List of members of the American College of Medical Informatics with biographies on Wikipedia
- American Medical Informatics Association

17.2.3 References

[1] ACMI Web Portal

17.2.4 External links

- ACMI homepage

17.3 American Health Information Management Association

The **American Health Information Management Association** (AHIMA) is a professional organization for the field of effective management of health data and medical record needed to deliver quality healthcare to the public management. Traditionally practicing in hospitals and to referring paper files and records, the field presently refers to all healthcare systems and types of media.

As of 2013, the association has more than 71,000 members in four membership classifications. Each member subsequently belongs to a relevant state chapter. The *Journal of AHIMA* has a circulation of 61,000 and publishes both peer-reviewed and non-peer-reviewed articles. The association's membership is majority female.

AHIMA describes its foundation as a sister organization to Association for Healthcare Documentation Integrity (AHDI) and states the foundation has a charitable and educational nature. The foundation's stated mission is to be the pre-eminent foundation recognized for excellence in health information leadership, policy and research for the healthcare industry and the public. The foundation formulates and issues opinions, supports education, conducts research and compiles its contributions into the AHIMA BoK (body of knowledge).

17.3.1 History

The organization traces its history back to 1928 when the American College of Surgeons established the Association of Record Librarians of North America (ARLNA) to "elevate the standards of clinical records in hospitals and other medical institutions." The organization has had three name changes in its history, all were justified with an explanation that reflected the progression of contemporary medical record use, practices and perceptions. In 1938 the association became the American Association of Medical Record Librarians (AAMRL).

In 1970, the association became the American Medical Record Association (AMRA) and in 1991, the title American Health Information Management Association (AHIMA) was adopted. Incorporation occurred in 1943 and became effective the next year. Its current name captures the expanded scope of clinical data beyond the single hospital medical record to health information comprising the entire continuum of care.

AHIMA's stated mission is to be the professional community that improves healthcare by advancing best practices and standards for health information management and the trusted source for education, research, and professional credentialing. AHIMA leads the health informatics and information management community to advance professional practice and standards.

AHIMA is working to promote this mission through:

- **Informatics**: Transforming data into Health Intelligence
- **Leadership**: Developing HIM leaders across all healthcare sectors
- **Information Governance**: Being recognized as the health industry experts in information governance
- **Innovation**: Increasing thought leadership and evidence-based HIM research
- **Public Good**: Empowering consumers to optimize their health through management of their personal health information

17.3.2 Credentials

The association offers seven credentials pertaining to four areas of practice:

- Health Information Management (HIM)
- Coding
- Data Analysis
- Privacy

Two credentials require formal education, the others are acquired by a combination of testing and work experience. AHIMA requires members obtain regular continuing education to maintain their credentials.

17.3.3 See also

- Commission on Accreditation for Health Informatics and Information Management Education
- Health information management

17.3.4 References

- AHIMA entry - TheFreeDictionary

17.3.5 External links

- AHIMA.org is the American Health Information Management Association's official site
- ArHIMA.org is the Arkansas Health Information Management Association's official site
- WHIMA.org is the Wisconsin Health Information Management Association's official site
- TXHIMA.org is the Texas Health Information Management Association's official site
- WSHIMA.org is the Washington State Health Information Management Association's official site
- MNHIMA.org is the Minnesota Health Information Management Association's official site
- WVHIMA.org is the West Virginia Health Information Management Association's official site
- NJHIMA.org is the New Jersey Health Information Management Association's official site

17.4 American Telemedicine Association

The **American Telemedicine Association** (**ATA**), established in 1993 as a non-profit organization, ATA goal is to promote access to medical care for consumers and health professionals via telecommunications technology (alternatively referred to as telemedicine, telehealth or eHealth). Membership in ATA is open to individuals, companies and other healthcare and technology organizations.

The American Telemedicine Association is the leading resource and advocate promoting access to medical care for consumers and health professionals via telecommunications technology. ATA seeks to bring together diverse groups from traditional medicine, academic medical centers, technology and telecommunications companies, e-health, medical societies, government and others to overcome barriers to the advancement of telemedicine through the professional, ethical and equitable improvement in health care delivery. ATA is governed by a Board of Directors elected by the Association's membership.

The Association implements these objectives by:

- Educating government about telemedicine as an essential component in the delivery of modern medical care.
- Serving as a clearinghouse for telemedical information and services.
- Fostering networking and collaboration among interests in medicine and technology.
- Promoting research and education including the sponsorship of scientific educational meetings and theTelemedicine and e-Health Journal.
- Spearheading the development of appropriate clinical and industry policies and standards.

In accordance with the mission of the organization, ATA provides a broad range of services for its members and the industry as a whole.

- ATA Annual Meeting - the world's largest scientific meeting and exposition focusing exclusively on telemedicine, with hundreds of presentations, posters and workshops.
- On-line Member News Updates - direct, exclusive news briefs via email about the latest event and activities affecting telemedicine professionals.
- ATA Website - a widely used resource for telemedicine news and information.
- ATA Online Membership Directory - the single source of who's who in telemedicine.
- *Telemedicine and e-Health* - a peer-reviewed publication encompassing all aspects of clinical telemedicine practice; technical advances and enabling technologies; continuing medical education; and the impact of telemedicine on the quality, cost-effectiveness, and access to health care.

- Special Interest Groups (SIGs), Regional Chapters and Discussion Groups - allow members to address issues related to the advancement and application of telemedicine regarding specific areas including home telehealth, ocular telehealth, technology, teledermatology, telemental health, telenursing, telepathology, and telerehabilitation.

17.4.1 See also

- General Maxwell R. Thurman Award
- Telemedicine
- Telehealth
- Telerehabilitation
- EHealth
- MHealth
- List of video telecommunication services and product brands

17.4.2 References

- Choi, Candice (March 13, 2006). "Doctors, Patients Back Telemedicine". *Bangor Daily News*. Retrieved September 7, 2010.
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- "Tribal Healthcare 2000: Telecommunications and Telemedicine". *The Ojibwe News*. June 13, 1997. Retrieved September 7, 2010.

17.4.3 External links

- ATA homepage
- Wiki for telemedicine (ATAwiki)

17.5 Belgian Health Telematics Commission

The **Belgian Health Telematics Commission** (BHTC) is a Belgian government committee working on standards for exchanging and sharing of health information, between health care participants. The committee provides advice on eHealth to the Belgian government.*[1]*[2] Professor Georges De Moor is head of the committee.

The BHTC consists of several working groups:

- Data
- Hospitals
- Telemedicine
- Label: homologation of (para)medical software

Georges De Moor, together with Jos Devlies and Geert Thienpont, authored the 2006 *eHealth strategy and implementation activities in Belgium* report.*[3]

17.5.1 See also

- Belgian Medical Informatics Association
- BeHealth
- FLOW
- KMEHR
- SumEHR
- HL7
- European Institute for Health Records
- ProRec
- EUDRANET

17.5.2 References

[1] Belgian Telematics Commission, *Recommendations regarding national development of standardized electronic health care messages*, Stud Health Technol Inform. 2004;110:112-7

[2] Belgian Telematics Commission, *Digital signature and electronic certificates in health care*, Stud Health Technol Inform. 2004;110:87-9

[3] eHealth strategy and implementation activities in Belgium

17.5.3 Source

- Telematics Commission
- Rcommendations
- Telematics Standards in relation to the Health Sector (PDF, advice)

17.6 Brazilian Congress on Health Informatics

The **Sociedade Brasileira de Informática em Saúde** (Brazilian Society of Health Informatics), abbreviated as **SBIS**, is a professional society created in November 1986 in Campinas, during the First Brazilian Congress

on Health Informatics.*[1] It has the mission of promoting the development and the interchange of ideas and results in the fields devoted to the information technologies applied to the health sciences (Medical informatics, Telemedicine, Bioinformatics, etc.).

17.6.1 Mission and areas of interest

SBIS is a nonprofit membership organization of individuals and institutions interested in developing and using information technologies to improve health care in Brazil. To accomplish its goal, SBIS may develop the following activities:

- Stimulate educational activities related to health informatics;
- Stimulate scientific research and technical development in Health Informatics;
- Organize conferences, symposiums, courses, seminars, and other activities that lead to experience and knowledge exchange;
- Cooperate with sister societies;
- Contribute to the definition of healthcare policies;
- Promote Health Informatics as a means to reduce costs and improve the quality of healthcare services.

Some of SBIS areas of interest are:

- Health information systems
- Health information management
- Electronic patient record
- Telemedicine and telehealth
- Medical decision support systems
- Biological signal processing
- Medical image processing
- Internet applications in health
- Health information standards
- Health informatics education
- Distance education in health

Currently it has around 780 associates, thus being the third largest in the Americas, after the American Medical Informatics Association and the Canada's Health Informatics Association, and the largest in Latin America, according to the International Medical Informatics Association.*[2] The Society is affiliated to the International Medical Informatics Association since 1988.

17.6.2 Governance

The current Executive Board (2008–2010) is led by Dr. Cláudio Giulliano Alves da Costa (President). Former presidents were: Roberto J. Rodrigues, Renato M.E. Sabbatini, Mariza Machado Klück, Beatriz de Faria Leão, Daniel Sigulem, Umberto Tachinardi, Lincoln de Assis Moura Jr. and Heimar de Fátima Marin. Short histories of Health Informatics in Brazil have been published elsewhere*[3]*[4] by former presidents of the Society.

17.6.3 Conferences and Meetings

SBIS organizes since 1986 a biannual national conference, the Brazilian Congress of Health Informatics and a biannual specialized conference on Electronic Health Records (PEP); besides other, smaller and less periodical meetings.

The **Brazilian Congress on Health Informatics** takes place in different cities every two years and has as its main subjects the applications of information technology and telematics to medicine, nursing, dentistry and allied health care sciences, from the point of view of the expert scientific and technical worker in these areas. The first conference was organized in November 1986, in the city of Campinas by Dr. Renato M.E. Sabbatini. The vice-president was Dr. Hugo Sabatino, and the editor-in-chief of the Conference's proceedings was Dr. Renato G.G. Terzi, all with the Medical School at the same university. During this conference, the Brazilian Society of Health Informatics was launched, as well as the *Brazilian Journal of Health Informatics*. The conference was then repeated in 1988 (São Paulo), 1990, 1992, 1994, 1996 (Campos do Jordão), 1998, 2000, 2002, 2004 (Natal), 2006 (Florianópolis) and 2008 (Campos do Jordão). The next conference will be held in November 2010, in Porto de Galinhas, Pernambuco.

17.6.4 Publications

SBIS' flagship periodical is the on-line scientific journal, *Journal of Health Informatics* (Heimar Marin, Editor-in-Chief). It also publishes *SBIS News*, an electronic bulletin hosted by Yahoo! Groups (Renato M.E. Sabbatini, editor-in-chief), and coordinates the SBIS-L e-mail discussion list.

17.6.5 Electronic Health Record Certification Project

In collaboration with the Brazilian Federal Council of Medicine since 2007, SBIS has developed one of few programs in the developing world geared towards the software certification in the area of electronic health records. The standards for access, information security, digital certification, patient confidentiality, storage of records, etc., have been discussed together and officially approved by a number of decrees enforced by CFM and are part now of a Manual, a course for buildup of a task force of specialized consultants. The certification standards cover ambulatory healthcare, clinical laboratory and other areas, and in the future will be expanded for inpatient health records and Picture archiving and communication system.

17.6.6 Professional Education

In 2008 the Society approved the creation of a new initiative and a directorship to boost educational activities in health informatics.*[5]*[6] A website and a Learning Management System based on Moodle server were created in 2009 (address). The site is used to support presential courses as well as to offer purely distance courses, seminars, lectures, and other educational activities. The site has also a digital library*[7] with on-line references to papers, reviews, e-books, multimedia files, etc., which are deemed useful for education and learning purposes. In addition, webconferencing facilities using DimDim have been added and can be used by associated individuals and institutions.

17.6.7 Professional Certificate in Health Informatics

In October 2009 the Society launched a program for certificating health care professionals as specialists, in a manner similar to medical specialties coordinated by the Brazilian Medical Association and the Federal Council of Medicine in Brazil. The program entails a minimum list of technical proficiency, a written and oral annual examination, and the issue of a certificate which is valid for five years. The revalidation of the certificate will be mandatory by means of continuing education credits. The Society installed also an educational accreditation program in place, for recognizing courses and curricula in health informatics, for this purpose, with a point-based system of credits. The entire program is under the responsibility of a new Directorship of Professional Education, coordinated by Prof. Renato M.E. Sabbatini.

17.6.8 References

[1] Sabbatini, RME: Associações de Informática em Saúde. Revista Informédica, 2 (10): 13-14, 1994 (In Portuguese)

[2] International Medical Informatics Association

[3] Marin, H.F. Informática em Saúde no Brasil. 2008 Conference of IMIA-LAC, International Medical Informatics Association Federation for Latin America and the Caribbeam. Published by the Argentinian Association of Medical Informatics, Buenos Aires, Argentina, 2008 (in PDF, in Portuguese)

[4] Sabbatini, R.M.E. História da Informática em Saúde no Brasil. Revista Informática Médica, 1(5), Set/Out 1998. (In Portuguese)

[5] Costa, CGA: Retrospectiva 2009 e Planos para 2010 da SBIS, Published December 29, 2009

[6] Sociedade Brasileira de Informática em Saúde. Diretoria de Educação e Capacitação Profissional. São Paulo, 2009.

[7] Biblioteca Virtual em Informática em Saúde, São Paulo, 2009.

17.6.9 External links

- SBIS Home Page
- Journal of Health Informatics Home Page
- Distance Education Site
- Email Discussion Group
- Electronic news bulletin

17.7 Brazilian Congress on Health Informatics

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[1] Sabbatini, RME: Associações de Informática em Saúde. Revista Informédica, 2 (10): 13-14, 1994 (In Portuguese)

[2] International Medical Informatics Association

[3] Marin, H.F. Informática em Saúde no Brasil. 2008 Conference of IMIA-LAC, International Medical Informatics Association Federation for Latin America and the Caribbeam. Published by the Argentinian Association of Medical Informatics, Buenos Aires, Argentina, 2008 (in PDF, in Portuguese)

[4] Sabbatini, R.M.E. História da Informática em Saúde no Brasil. Revista Informática Médica, 1(5), Set/Out 1998. (In Portuguese)

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[7] Biblioteca Virtual em Informática em Saúde, São Paulo, 2009.

17.7.9 External links

- SBIS Home Page
- Journal of Health Informatics Home Page
- Distance Education Site
- Email Discussion Group
- Electronic news bulletin

17.8 Center for Telehealth and E-Health Law

The Center for Telehealth & E-Health Law (CTeL), established in 1995 by a consortium including the Mayo Foundation, Cleveland Clinic Foundation, Texas Children's Hospital, and the Mid-West Rural Telemedicine Consortium, is a non-profit organization committed to overcoming legal and regulatory barriers to the utilization of telehealth and related e-health services.*[1] CTeL, based in Washington, D.C., specializes in compiling, analyzing and disseminating information on legal and regulatory issues information associated with telemedicine. It also handles underlying issues such as licensure and reimbursement.

CTeL briefs public policymakers, writes reports, and provides testimony in support of telehealth. In its materials, CTeL argues that expanding the use of telehealth can improve patient safety, reduce medical errors, and increase patient access to primary and specialty care in both rural and urban settings. CTeL offers a variety of services,

including involvement in public policy. CTeL activities include:

- "Telehealth Leadership Conference" - annual conference dedicated solely to telehealth issues and telehealth advocacy.
- Telehealth Policy Clerkship Program - offered for second and third year law students interested in public policy and legal issues as they apply to advancing communication technologies in the practice of medicine.
- Washington Live! Brown Bag Lunches in Washington, D.C. – monthly seminars on various topics of interest in telehealth and e-health.
- *The National Telehealth Resource Center (NTRC), one of several telehealth resource centers funded through a grant from the Office for the Advancement of Telehealth at the Health Resources and Services Administration (HRSA) in the Department of Health and Human Services.*[2]
- In 2004, CTeL worked with HRSA's Office for the Advancement of Telehealth (OAT) and the University of Colorado Health Sciences Center to perform an analysis of the use of telehealth in skilled nursing facilities for a report to Congress. This report is titled "Multi-State Telehealth Practice" and summarizes the current state of physician and nurse licensure issues.
- Also in 2004, CTeL was recognized by the United States Department of Commerce: "[The] progress there has been in resolving such issues can be attributed to a very recent and concentrated effort by such stakeholders as···Center for Telemedicine Law, and the Office for the Advancement of Telehealth (OAT), within the Department of Health and Human Services (HHS)." – Innovation, Demand, & Investment in Telehealth, US Commerce Department, Feb. 2004.

17.8.1 References

[1] Center for Telehealth and e-Health Law Archived December 18, 2008, at the Wayback Machine.

[2] HRSA - Telehealth Grantee Directory Archived January 4, 2008, at the Wayback Machine.

17.8.2 External links

- CTeL
- Office for the Advancement of Telehealth

17.9 European Federation for Medical Informatics

The **European Federation for Medical Informatics** (EFMI) is a non-profit organization, which was conceived at a meeting, assisted by the Regional Office for Europe of the World Health Organisation (WHO), in Copenhagen, (Denmark, Europe), in September 1976.

17.9.1 Objectives

The EFMI wants to:

- advance international co-operation and dissemination of information in Medical Informatics in Europe
- promote high standards in the application of medical informatics
- promote research and development in medical informatics
- encourage high standards in education in medical informatics
- function as the autonomous European Regional Council of the International Medical Informatics Association (IMIA)

17.9.2 Organizations

- Working Group Medical Informatics (AKMI) of the Austrian Society for Biomedical Engineering ÖGBMT) and of the Austrian Computer Society (OCG) (Austria)
- Belgian Medical Informatics Association (Belgium)
- Society for Medical Informatics of Bosnia & Herzegovina (Bosnia-Herzegovina)
- Croatian Society for Medical Informatics (Croatia)
- The Cyprus Society of Medical Informatics (Cyprus)
- Czech Society for Biomedical Engineering and Medical Informatics (Czech Republic)
- The Danish Society for Medical Informatics (Denmark)
- Finnish Social and Health Informatics Association (FinnSHIA) (Finland)
- French Medical Informatics Association (AIM) (France)
- German Association for Medical Informatics, Biometry and Epidemiology (Germany)

- Greek Health Informatics Association (Greece)
- National Institute for Strategic Health Research (Hungary)
- Icelandic Society of Information Processing (Iceland)
- Healthcare Informatics Society of Ireland (Ireland)
- The Israeli Association for Medical Informatics (Israel)
- Italian Medical Informatics Society (AIIM) (Italy)
- State Medical and Pharmaceutical University "N. Testemitanu" (Moldova, Republic of)
- VMBI, Society for Healthcare Informatics (Netherlands)
- Norwegian Society for Medical Informatics (Norway)
- The Technical University of Lodz (Politechnika Łódzka) (Poland)
- Faculty of Medicine of Oporto University (Portugal)
- Romanian Society of Medical Informatics (Romania)
- N. N. Burdenko Neurosurgical Institute (Russian Federation)
- Association for Medical Informatics of Serbia (Serbia)
- Slovenian Medical Informatics Association (SIMIA) (Slovenia)
- Spanish Society of Health Informatics (Spain)
- Swedish Federation for Medical Informatics (SFMI) (Sweden)
- Swiss Society for Medical Informatics (Switzerland)
- Turkish Medical Informatics Association (TurkMIA) (Turkey)
- The Ukraine Association for "Computer Medicine" (UACM) (Ukraine)
- British Computer Society Health Informatics Forum (BCSHIF) (United Kingdom)

17.9.3 See also

- European Institute for Health Records
- Health informatics
- Electronic Health Record (EHR)
- Electronic Medical Record (EMR)

17.9.4 External links

- European Federation for Medical Informatics

17.10 European Health Telematics Observatory

The **European Health Telematics Observatory** (EHTO) is a non-profit organization which collects, analyses and makes available in a user-friendly form information on developments in the field of health telematics. The organization contributes to the deployment of health telematics applications and standards in Europe. EHTO works on the dissemination of results of the European Telematics Applications Programme (TAP) of the Fourth Framework Programme to the European health care sector.

17.10.1 Participants

- Portugal: Portugal Telecom
- Belgium: RAMIT (Research in Advanced Medical Informatics and Telematics)
- France: CNEH (Centre National de l'Equipement Hospitalier)
- Ireland: IHC Centre for Health Informatics
- Spain: IETT Ingenieria y Prevencion de Riesgos
- Greece: BIOTRAST
- Finland: VTT Information Technology

17.10.2 See also

- Health informatics
- European Institute for Health Records
- European Health Telematics Association (EHTEL)
- ProRec

17.10.3 Source

- EHTO (Doc)
- European Telematics

17.10.4 External links

- European Health Telematics Observatory

17.11 European Institute for Health Records

EuroRec logo

The **European Institute for Health Records** or **EuroRec Institute** is a non-profit organization founded in 2002 as part of the ProRec initiative. On 13 May 2003, the institute was established as a non-profit organization under French law. Current President of EuroRec is Prof. Dipak Kalra. The institute is involved in the promotion of high quality Electronic Health Record systems in the European Union. One of the main missions of the institute is to support, as the European authorised certification body, EHRs certification development, testing and assessment by defining functional and other criteria.

The objectives of the institute are:

1. To federate the established ProRec centres that comply with a set of explicit criteria.
2. To develop specifically those activities that cannot be handled at the level of ProRec centres and/or within their scope, according to the principle of subsidiarity and in view of both synergy and economy of scale.

17.11.1 European Projects

ARGOS

The main goal of the ARGOS project was to contribute to creating "Transatlantic Observatory for Meeting Global Health Policy Challenges through ICT-Enabled Solutions" to allow promotion of "Common Methods for Responding to Global eHealth Challenges in the EU and the US".* [1] The results are used to provide various users recommendations in sustaining co-ordinated actions. It is important to both Europe and America of United States because:* [2]

- There is a barrier in fostering healthcare globally as citizens travel and migrate
- It will help improve their products to better promote themselves in global markets
- The global experiences will become important information for both Europe and America

Through the challenges of enhancing ehealth strategy development, promoting benefits of consistent strategies and supporting large scale ehealth infrastructure implementations will allow Europe and United States researchers and policy makers gain mutual understanding and learning.* [3]

The main topics that were address within this project was; ehealth interoperability an EHR certifications, establishing an approach and identification of indicators of the usage and benefits of ehealth, and aiding clinicians in diagnosis and treatment of rare diseases through human physiology and disease modelling and simulation. However the project has highlighted challenges in establishing competent ehealth informatics staff.* [4] There are variations of understanding, qualification and definition of workforce requirements through Europe and The United States.* [5]

HITCH: Healthcare Interoperability Testing and Conformance Harmonisation

HITCH project begun 01/01/10 and ended on the 30/06/11. The objective of this project was to involve major stakeholders in defining and agreeing a roadmap that is essential to the foundation for the Interoperability Conformance Testing of information systems in the field of healthcare.* [6] HITCH project aims to propose plans on achieving interoperability conformance testing foundation starting 2011 through evaluating existing approaches and identifying potential gaps in initiatives.* [7] The roadmap will identify specific needs in improving processes and tools development that will support research. The roadmap will be tested in real-world settings with healthcare IT applications to determine the next logicals steps in establishing a credibility amongst major stakeholders (vendors, users, patients and authorities).* [8]

Q-REC: European Quality Labelling and Certification of Electronic Health Record systems (EHRs)

The Q-REC project started 01/01/06 and finished on 30/06/08. It is a project that is a Specific Support Action and its objective is to supplement the existing e-Health ERA Co-ordination Project "Towards the establishment of a European e Health Research Area". It aims is to create an credible, sustainable and efficient means in certifying EHR system in Europe by concentrating EHR Systems Quality Labeling and Certification Development, Resources for EHR interoperatability, and Benchmarking Services.* [9]

Some of the goals stated by Q-REC and EuroREC webpage *[10] includes:

EHR Systems Quality Labelling and Certification Development

- Developing a modern report on EHR-Certification Schemas that has been implemented in at least three European countries;
- Completing a Pan-European Requirements Assay;
- Proposing a Labelling Terminology and Functional Profiles for EHRs to be certified;
- Comparing and harmonising the EHR-Certification Procedures at a European level;
- Drafting Model Certification Guidelines and Procedures;
- Planning the Validation of the Guidelines.

Resources for EHR Interoperability

- Producing a register for Conformance Criteria and Guidance Documents for obtaining EHR Certification;
- Establishing EHR Archetypes guidelines and inventory;
- Establishing a registration process for Coding Schemes in Europe (as mandated by CEN/TC 251);
- Providing relevant EHR related standards inventory;

Benchmarking Services

- Defining services that uses benchmarking for Manual for Quality Labelling and Certification;
- Preparing the Business Plan for new EHR-Certification related Services

This project was done with EuroRec institute whose mission was to promote high quality EHRs throughout Europe. Through its networks and its centres acting as platforms along with the collaboration with eHealth ERA consortium and European Health Care Authorities (HCA)/ Ministries groups, EuroRec has provided various methods in assessing the needs and optimal choice methods for quality labelling and certification of EHRs.*[11]

RIDE: A Roadmap for Interoperability of eHealth Systems in Support of COM 356 with Special Emphasis on Semantic Interoperability

RIDE is a project that aims to provide a solid foundation for the action plans of eHealth Communication COM 356. It begun on 01/01/06 and ended on 31/12/07. Through research and development into the interoperability of eHealth systems, meaningful recommendations can be made for actions at a European level. The lack of complete harmonisation between clinical practice, terminology and EHR systems have highlighted that there is an unrealistic expectation in developing a single universally clinical data model. Hence the RIDE project objective is to provide a roadmap through focusing on current limitations of policies and strategies in solutions for ehealth interoperability and assessing health's European best practices in regards to providing semantic interoperability.*[12]

EHR-IMPLEMENT: National policies for EHR Implementation in the European area: social and organizational issues

The objective of EHR-IMPLEMENT is to provide best practice, policy and strategic recommendations in the implementation of EHR in Europe. This is done though the collection and analysis of EHR implementations in various countries. Previous EHR projects have always addressed the technological area in EHR. Other commonly overlooked in projects, the EHR-IMPLEMENT will focus the social and organisational on a broad national initiative, as these factor may potentially hinder, if not ruin the EHR implementation.*[13]

This project comprised a case study approach and a foused survey at a European level. It aims to analyse and collect information on best practices and eloborate recommendations for policy makers to facilitate EHR into member states.*[14]

According to EuroREC,*[15] these are the main objectives of the projects:

- Analysis of national policies and strategies for the implementation of EHR
- Conducting a survey regarding policy and action plans for National Implementation of EHR into Member States.
- Investigating EHR users in the implementation process.
- Raising issues of EHR implementation
- Identifying best practices towards EHR implementation in Europe
- Promoting information sharing and mutual learning through supporting the development of a community of scientific experts, technical personnel and National Health System representatives
- Providing results and recommendations of the project amongst stakeholders across Europe

17.11.2 See also

- CEN/TC 251
- Canada Health Infoway
- Centers for Medicare and Medicaid Services (USA)
- Clinical Document Architecture (CDA)
- Directorate-General for Information Society and Media (European Commission)
- EHRcom
- European Federation for Medical Informatics (EFMI)
- European Health Telematics Association (EHTEL)
- European Health Telematics Observatory (EHTO)
- Health Informatics Service Architecture (HISA)
- Health Insurance Portability and Accountability Act (HIPAA, USA)
- Health Level 7
- International Classification of Primary Care (ICPC)
- Kind Messages for Electronic Healthcare Record (KMEHR)
- National Resource Center for Health Information Technology
- openEHR Foundation

17.11.3 Sources

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17.11.4 External links

- European Institute for Health Records
- CEN/TC 125 (European Standardization of Health Informatics)
- COM (2004) 356 final
- Directorate H - ICT For Citizens and Businesses (Unit H1 - ICT for Health)

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[2] "ARGOS" (webpage). 2013. Retrieved 2013-01-06.

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[4] "ARGOS" (webpage). 2013. Retrieved 2013-01-06.

[5] "ARGOS" (webpage). 2013. Retrieved 2013-01-06.

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[13] "National policies for EHR Implementation in the European area: social and organizational issues" (webpage). 2013. Retrieved 2013-12-05.

[14] "National policies for EHR Implementation in the European area: social and organizational issues" (webpage). 2013. Retrieved 2013-12-05.

[15] "National policies for EHR Implementation in the European area: social and organizational issues" (webpage). 2013. Retrieved 2013-12-05.

17.12 Health On the Net Foundation

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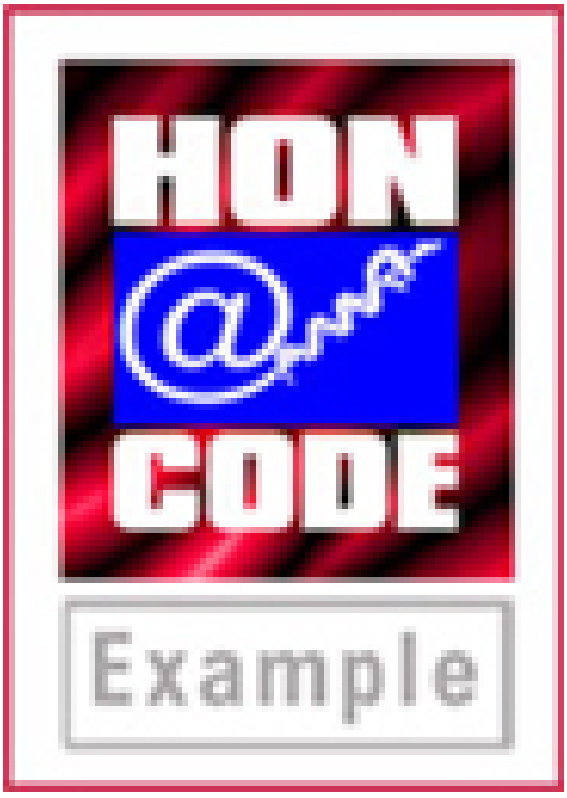
Health On the Net Foundation (HON) is a not-for-profit organization founded in 1995 under the auspices of the Geneva Ministry of Health and based in Geneva, Switzerland. This came about following the gathering of 60 of the world's foremost experts on telemedicine to discuss the growing concerns over the unequal quality of online health information. The unanimous conclusion of this gathering was to create a permanent body that would, in the words of the program, "promote the effective and

reliable use of the new technologies for telemedicine in healthcare around the world" . The HON Foundation became one of the first organizations to guide both lay users and medical professionals to reliable sources of health information in cyberspace.

17.12.1 Mission

The mission of the foundation is to guide the growing community of healthcare consumers and providers on the World Wide Web to sound, reliable medical information and expertise. In this way, HON seeks to contribute to improved health care through patient empowerment and better informed health professionals.

17.12.2 Certification



The HONcode Logo

HON Foundation issued a code of conduct (HONcode) for medical and health websites to address reliability and usefulness of medical information on the Internet. HONCode is not designed to rate the veracity of the information provided by a Web site. Rather, the code only states that the site holds to the standards, so that readers can know the source and purpose of the medical information presented. The HONcode is voluntary,[*][1] which means that webmasters and information providers can apply for HONcode certification. Following this, the website is reviewed by a specialized team of health and legal professionals. The HONcode certification is a dynamic state and is extended every year according to site compliance. It is the oldest and the most used ethical and trustworthy code for medical and health-related information on the Internet.

The principles of the HONcode are:

1. Authority – information and advice given only by medical professionals with credentials of author/s, or a clear statement if this is not the case
2. Complementarity – information and help are to support, not replace, patient-healthcare professional relationships which is the desired means of contact
3. Confidentiality – how the site treats personal and non-personal information of readers
4. Attribution – references to source of information (URL if available) and when it was last updated
5. Justifiability – any treatment, product or service must be supported by balanced, well-referenced scientific information
6. Transparency of authorship – contact information, preferably including email addresses, of authors should be available
7. Transparency of sponsorship – sources of funding for the site
8. Honesty in advertising and editorial policy – details about advertising on the site and clear distinction between advertised and editorial material

Currently HONcode certifies more than 5,000 websites, covering 72 countries and has been translated into 34 languages. It is used to sensitize web publishers to the need for quality information and create awareness in health professionals and so, help guide their patients to trustworthy health information.

HON offers all users the trustworthy websites and support groups, medical images and terminology, journal articles, and news through its search engines MedHunt, HONcodeHunt and HONselect. HON also provides two databases of trustworthy health information, one on eye diseases and the other on general medical conditions. Provisu.ch is a database of reliable health information on all eye diseases and is accessible by those with poor or no vision through its variability of letter size and audio version. Santeromande.ch is an extensive database, mainly directed towards the French-speaking public of Switzerland and neighbouring France and provides reliable health information, directory of registered health professionals, medical centers or hospitals, medical associations and federal organizations.

Health On the Net Foundation was granted on 23 July 2002 NGO status by the Economic and Social Council of the United Nations. HON also has a partnership at

the French governmental level, when it was accredited in 2007 by the French National Authority (HAS) to be the official certifying body for all French health websites.

17.12.3 Limits and Criticism

Despite its name, the HONcode only applies to editorial processes and details, but not to the actual published contents. The term of "certification" is thus misleading to the general public, as it gives to guarantee that the contents of the website are trustworthy, reliable or otherwise independent.*[2] Besides, the certification process is mostly based on self-declaration and not peer-reviewed, thus easy to get without even meeting the HONcode principles.

Some experts believe that the HONcode principles themselves are subject to criticism, unadapted to modern Internet usages*[3] and not following their very own rules.*[4] In response to those limitations, some previously certified website decided not to display the Health On the Net logo anymore,*[5] where others went so far as warning visitors to mistrust certified websites.*[6]

In 2014, the foundation introduced a mandatory membership fee starting at the first certification renewal (initial registration stays free).*[7] The exact amount of the fee, ranging from 50 to 325 euros, is not publicly disclosed and depends on the website's Alexa ranking, introducing a further bias favoriting disguised commercial websites instead of benevolent and scientific communities.

17.12.4 Misuse of HONcode

In 2000 a journal article raised a number of problems with the HONcode logo, indicating that consumers may mistake it as an award or interpret it as an indicator for assessed information. Other issues with the HONcode logo were discussed in the *Journal of Medical Internet Research*, a peer-reviewed eHealth journal.*[8] Websites that are not in compliance with HONcode can continue to display the logo, as Health On the Net Foundation (HON) has no means of obligating the offending webmaster to remove the logo. Clicking on that logo (for verification) will not indicate that the site is out of compliance, as HONcode only indicates that sites are "undergoing annual review". Hence, websites that are not in compliance with HONcode may still be displaying the HONcode logo, calling into question the entire principle of HONcode. Other problems with the application of the HONcode principles are that HON does not have a means of verifying many of the principles, such as credentials (medical or otherwise) as stated on websites displaying the logo, or that copyright or confidentiality is not violated by webmasters. HONcode relies on the webmaster for honest representations about compliance with the principles.

In recent times however, HON has developed ways to counteract the misuse of the HONcode. One of these is the use of an active and dynamic logo which shows its validity and reflects the site compliance in real time. In addition, all medical credentials are verified through national databases of registered medical professionals. HON has always encouraged the internet community to demand for quality health information and the general public plays a large role in the policing of the HONcode by HON.

As of 2004, consumer protection advocate Stephen Barrett was a strong supporter of HONcode and made efforts to improve compliance with its rules and to expose those who misuse it. In a "Special to *The Washington Post*" published in 2004, coverage of his views on the subject were provided, including suggested improvements and his criticisms of many named misusers.*[9]

In cases of suspected fraudulent websites, or of misuse of the HONcode, HON advises internet users to alert Quackwatch or HON itself: "If you come across a healthcare Web site that you believe is either possibly or blatantly fraudulent and does NOT display the HONcode, please alert Quackwatch. Of course, if such a site DOES display the HONcode, alert us immediately." *[10]

17.12.5 References

[1] Greenberg L, D'Andrea G, Lorence D (June 2004). "Setting the public agenda for online health search: a white paper and action agenda". *Journal of Medical Internet Research* **6** (2): e18. doi:10.2196/jmir.6.2.e18. PMC 1550592. PMID 15249267.

[2]

[3] In January 2016, the principles were last updated in March 2010.

[4]

[5]

[6]

[7]

[8] JMIR article

[9] Christopher Wanjek. Attacking Their HONor: Some Dispute Value of Logo Used to Verify Accuracy, Integrity Of Health Web Site Contents. Special to *The Washington Post*, April 20, 2004; Page HE01

[10] "How to be a vigilant user" Health On the Net Foundation, accessed 8 April 2009.

17.12.6 External links

- Health On the Net website
- JMIR article

- Provisu website
- Santeromande website
- Presentation of HONcode on French National Authority website
- Policing the HONcode

17.13 HISA

The European Committee for Standardization (CEN) **Standard Architecture for Healthcare Information Systems** (ENV 12967), **Health Informatics Service Architecture** or **HISA** is a standard that provides guidance on the development of modular open information technology (IT) systems in the healthcare sector. Broadly, architecture standards outline frameworks which can be used in the development of consistent, coherent applications, databases and workstations. This is done through the definition of hardware and software construction requirements and outlining of protocols for communications.*[1] The HISA standard provides a formal standard for a service-oriented architecture (SOA), specific for the requirements of health services, based on the principles of Open Distributed Processing.*[2] The HISA standard evolved from previous work on healthcare information systems architecture commenced by Reseau d' Information et de Communication Hospitalier Europeen (RICHE) in 1989, and subsequently built upon by a number of organizations across Europe.*[3]

17.13.1 Development of Health Informatics Service Architecture EN/ISO 12967

The HISA standard was developed by CEN Technical Committee (TC) 251, the technical committee for Health Informatics within the federation of European national standards bodies (CEN).*[4] The CEN/TC 251 was made up of four working groups, covering: information models; systems of concepts and terminology; security; and technologies for interoperable communication.*[5] Working Group I were responsible for information models and completed the specifications that became the HISA standard. Working Group I worked with experts from across Europe, plus contributors from Australia and the United States in the development and finalization of ENV 12967.

The CEN HISA standard was adopted by the International Organization for Standardization (ISO) in 2009, with the stated aim of ISO 12967 being to provide guidance on:

- the description, planning and development of new electronic health systems; and
- the integration of existing electronic health systems, both intra- and inter-organizationally, through architecture that integrates common data and business logic into middleware, which is then made available throughout whole information systems.*[6]

17.13.2 The Standard

EN/ISO 12967 is broken down into three parts: Enterprise Viewpoint; Information Viewpoint; and Computational Viewpoint, all of which deal with different aspects of ensuring service architecture supports openness and vendor-independence.*[7]

Part One: Enterprise Viewpoint

The Enterprise Viewpoint component of EN/ISO 12967 provides health services with guidance in describing, planning and developing new IT systems, utilizing an open distributed processing approach. In addition to this it provides direction for the integration of existing information systems, within the one enterprise and across different healthcare organizations. Part one of the standard sets forth the common enterprise-level requirements (e.g. workflows, authorizations) that must be supported through the HISA, which integrates the common data and business logic into a specific architectural layer (i.e. the middleware), accessible throughout the whole information system of the health service.*[8]

Part Two: Information Viewpoint

The Information Viewpoint component of EN/ISO 12967 sets forth the fundamental characteristics of the information model to be implemented by the middleware to provide comprehensive, integrated storage of the common enterprise data and to support the fundamental business processes of the healthcare organisation, as defined in ISO 12967 Part One. The specifications were designed to be universally relevant, whilst being sufficiently specific to allow implementers to derive an efficient design of the system for their organisation. This specification does not aim to provide a fixed, complete specification of all possible data that may be necessary for any given health service. It specifies only a set of characteristics, in terms of overall organisation and individual information objects, identified as fundamental and common to all healthcare organizations.*[9]

Part Three: Computational Viewpoint

The Computational Viewpoint component of EN/ISO 12967 provides details on the fundamental characteristics of the computational model to be implemented by the middleware, to provide a comprehensive and integrated interface to the common, fundamental business processes of the health service. The computational model, like the information model is designed to be universally relevant, whilst still being sufficiently specific to allow implementers to derive an efficient design of the system for their organisation, irrespective of the specifics of the pre-

existing information technology environment in which it will be implemented.*[10]

17.13.3 Use of common services

The implementation of a modular, open architecture in healthcare IT systems (as specified by the HISA) relies upon disparate heterogeneous applications interacting and communicating through a middleware layer, made up of common services. In the case of the HISA, these common services are divided into Healthcare-related Common Services and Generic Common Services.*[11]

Healthcare-related Common Services (HCS)

Healthcare-related Common Services are those middleware components responsible for supporting the functionalities and information relevant to the healthcare business domain, including subject of care, activities, resources, authorization, health characteristics and concepts.*[12]

Generic Common Services (GCS)

Generic Common Services are those middleware components are those middleware components responsible for supporting the generic functionality and information requirements that are non-specific to the healthcare domain, and may be broadly relevant to any information system in the business domain.*[13]

17.13.4 See also

- Archetype (information science)
- Clinical Document Architecture (CDA)
- Clinical Data Interchange Standards Consortium (CDISC)
- EN 13606
- Electronic Health Record (EHR)
- Electronic medical record
- European Institute for Health Records
- Health Level 7
- Healthcare Services Specification Project
- OpenEHR
- Public Health Information Network
- National E-Health Transition Authority
- Systems Architecture

17.13.5 References

[1] Engel, Kjeld. Blobel, Bernd. Pharow, Peter. (2006) Standards for Enabling Health Informatics Interoperability, *Ubiquity: Technologies for Better Health in Aging Societies* IOS Press

[2] Klein, Gunnar. Sottile, Pier Angelo. Endsleff, Frederik. (2007) Another HISA - The new standard: Health Informatics - Service Architecture,Studies in Health Technology and Informatics,129(Pt 1):478-82

[3] Kalra,Dipak. (2002) Clinical Foundations and Information Architecture for the Implementation of a Federated Health Record Service, University College, London

[4] Klein, Gunnar. Sottile, Pier Angelo. Endsleff, Frederik. (2007) Another HISA - The new standard: Health Informatics - Service Architecture,Studies in Health Technology and Informatics,129(Pt 1):478-82

[5] Kalra,Dipak. (2002) Clinical Foundations and Information Architecture for the Implementation of a Federated Health Record Service, University College, London

[6] "ISO 12967 - Health Informatics Service Architecture" . ISO. Retrieved 14 April 2013.

[7] Klein, Gunnar. Sottile, Pier Angelo. Endsleff, Frederik. (2007) Another HISA - The new standard: Health Informatics - Service Architecture,Studies in Health Technology and Informatics,129(Pt 1):478-82

[8] European Committee for Standardization: http://www.cen.eu/cen/Pages/default.aspx

[9] European Committee for Standardization: http://www.cen.eu/cen/Pages/default.aspx

[10] European Committee for Standardization: http://www.cen.eu/cen/Pages/default.aspx

[11] Kalra,Dipak. (2002) Clinical Foundations and Information Architecture for the Implementation of a Federated Health Record Service, University College, London

[12] Kalra,Dipak. (2002) Clinical Foundations and Information Architecture for the Implementation of a Federated Health Record Service, University College, London

[13] Kalra,Dipak. (2002) Clinical Foundations and Information Architecture for the Implementation of a Federated Health Record Service, University College, London

17.14 Indian Association for Medical Informatics

The **Indian Association for Medical Informatics** (**IAMI**) is a professional society that plays a role in promoting and furthering the application of informatics in the fields of healthcare, bioscience and medicine in India. It was established in 1993.

IAMI logo

17.14.1 Goals and objectives

The objectives of the IAMI are to sensitize the Indian medical community to the benefits of Information Technology (IT), bring about awareness and ensure greater utilization of IT in healthcare facilities across the length and breadth of India. The IAMI also aims to provide necessary assistance and guidance to other organizations to implement and reap the benefits of IT for health care. It supports introduction of computer literacy along with medical education, development of computerized as well as medical digital libraries, access to information and creation of databases. IAMI emphasizes on research and development of medical informatics as an independent discipline. It provides various communication and interaction channels among its members by means of e-groups and through publication of a scholarly journal mentioned below.

17.14.2 Affiliation

It is the Indian National Member at IMIA

17.14.3 History

IAMI was registered in September 1993 with its Registered Office being the Department of Clinical Pharmacology, Nizam's Institute of Medical Sciences , in Hyderabad, India.

It has been organising a conference every two years on roles and applications of informatics in medicine, health and allied fields in various states of India.

The first biennial conference was held in 1995 at Hyderabad.

Second conference was held in 1997 at Indian Institute of Science, Bangalore.

Third conference of 1999 in Hyderabad was postponed due to natural calamities. A workshop was also held at NIMS in lieu later.

The third conference was held in 2001 in New Delhi

The fourth conference was held in 2003 at PGIMER, Chandigarh.

A mid-conference was held in 2004 at the South-Eastern Railways Hospital, Kolkata.

Fifth conference was held in 2005 at Sri Guru Ram Das Institute of Medical Sciences in Amritsar.

IAMI has conducted many beginners' courses for doctors, nurses, paramedical personnel and computer professional class. This enabled the association in enrolling many hospitals, institutes and organizations as Institutional Life Members. It is aiming at making Medical Informatics as one of the elective subjects in the UG curriculum for all medical colleges in India and to get academic credits from the Medical Council of India and other autonomous bodies under the Ministry of Health and Family Welfare (India), Government of India for all the delegates participating in the conferences, seminars and workshops organized by the association.

In 2001, it started a discussion group for Medical Informatics. Which has now grown as the de facto information source for medical informatics related activities in India both for its members as well as non-members. Its active members include almost the entire Who's Who of medical informatics scene of India. IAMI got its own web site in 2002. Its Journal "Indian Journal of Medical Informatics" (IJMI, ISSN 0973-0397) was started in May 2004 .

17.14.4 Membership

IAMI membership consists of Personal, Institutional and Honorary Members .

Many of its key office bearers are part of several Government of India (GOI) initiatives in the areas of telemedicine, especially in the area of development of standards and guidelines for the practice of telemedicine, online medical education and electronic medical records or electronic health records.

17.14.5 Journal

It brings out the scientific journal called *Indian Journal of Medical Informatics* .

17.14.6 Discussion group

Members of the association have an active discussion group where healthcare IT enthusiasts discuss topics of

their interest.Several discussion threads run in parallel. There is also a "Topic of the month" which is the main focus of the discussion.

17.14.7 External links

- IAMI
- List of Mentors in Healthcare Informatics
- Indian Journal of Medical Informatics (IJMI)

17.15 International Medical Informatics Association

This article is about the medical organization. For the Aegean islets, see Imia/Kardak.

The **International Medical Informatics Association**

IMIA Logo

(**IMIA**) is an independent organization that plays a role in promoting and furthering the application of information science in modern society, particularly in the fields of healthcare, bioscience and medicine. It was established in 1967 as a technical committee of the International Federation for Information Processing (IFIP). It became an independent organization in 1987 and was established under Swiss law in 1989.

17.15.1 Goals and objectives

- the promotion of informatics in health care and biomedical research
- the advancement of international cooperation
- the stimulation of research, development and education
- the dissemination and exchange of information

Inherent in this mission is to bring together, from a global perspective, scientists, researchers, vendors, consultants and suppliers in an environment of cooperation and sharing. The international membership network of national member societies, IMIA regions, corporate and academic institutional members, and working and special interest groups, constitute the "IMIA family".

IMIA organizes various conferences and events around the world and is currently focusing on "bridging the knowledge gap" by facilitating and providing support to developing nations. Specific goals include supporting the ongoing development of the African Region.

17.15.2 Code of Ethics for Health Information Professionals

The International Medical Informatics Association approved the endorsement of the IMIA Code of Ethics for Health Information Professionals at its General Assembly meeting on October 4, 2002 in Taipei. The code is the culmination of several years of a global collaborative effort led by IMIA's working Group on Data Protection in Health Information, Chaired by Professor Ab Baker.

17.15.3 Membership

IMIA membership consists of National, Institutional and Affiliate Members and Honorary Fellows.

National Members represent individual countries. A member is a society, a group of societies, or an appropriate body, which is representative of the medical, and health informatics activities within that country. Where no representative societies exist, IMIA accommodates involvement through "Corresponding" members within developing countries.

17.15.4 National member societies

- Argentine Association of Medical Informatics
- Health Informatics Society of Australia Ltd. (HISA)
- Working Group Medical Informatics (AKMI) of the Austrian Society for Biomedical Engineering ÖGBMT) and of the Austrian Computer Society (OCG)
- Belgian Medical Informatics Association
- Society for Medical Informatics of Bosnia and Herzegovina
- Brazilian Society of Health Informatics
- British Computer Society Health Informatics Forum
- COACH: Canada's Health Informatics Association

- China Medical Informatics Association
- Croatian Society for Medical Informatics
- Cuban Society of Medical Informatics
- Czech Society for Biomedical Engineering and Medical Informatics
- The Danish Society for Medical Informatics
- Ethiopian Health Informatics Association
- Finnish Social and Health Informatics Association (FinnSHIA)
- French Medical Informatics Association (AIM)
- German Association for Medical Informatics, Biometry and Epidemiology
- Greek Health Informatics Association
- Hong Kong Society of Medical Informatics
- John von Neumann Computer Society (Hungary)
- Indian Association for Medical Informatics
- Iranian Medical Informatics Association
- Healthcare Informatics Society of Ireland
- The Israeli Association for Medical informatics
- Italian Medical Informatics Society (AIIM)
- Ivorian Society of Biosciences and Health Informatics (ISBHI)
- Japan Association for Medical Informatics
- Medical Pharmaceutical Information Association (MedPharmInfo)(Kazakhstan)
- Korea Society of Medical Informatics (KOSMI)
- Medical Informatics Association of Malawi (MIAM)
- Malaysian Health Informatics Association (MHIA)
- The Mali Society of Biomedical and Health Information (SOMBIS)
- Health Informatics New Zealand
- Association for Health Informatics of Nigeria (AHIN)
- Norwegian Society for Medical Informatics
- Philippine Medical Informatics Society, Inc.
- Polish Society of Medical Informatics
- Romanian Society of Medical Informatics
- The Saudi Association for Health Informatics (SAHI)
- Association for Medical and Bio-Informatics, Singapore (AMBIS)
- Slovak Society of Biomedical Engineering and Medical Informatics
- Slovenian Medical Informatics Association (SIMIA)
- South African Health Informatics Association
- Spanish Society of Health Informatics
- Swedish Federation for Medical Informatics
- Swiss Society for Medical Informatics
- Taiwan Association for Medical Informatics (TAMI)
- VMBI, Society for Healthcare Informatics (Netherlands)
- Turkish Medical Informatics Association (TURKMIA)
- The Ukrainian Association for Computer Medicine (UACM)
- American Medical Informatics Association
- Uruguayan Society of Health Informatics
- Venezuelan Association of Computer Science in Health (AVIS)

17.15.5 Working and special interest groups

The IMIA family includes a growing number of Working and Special Interest Groups, which consist of individuals who share common interests in a particular focal field. The groups hold Working Conferences on leading edge and timely health and medical informatics issues.

IMIA Working Groups and Special Interest Groups include:

- Biomedical Pattern Recognition (WG 07)
- Biomedical Statistics and Information Processing (WG 12)
- Consumer Health Informatics (WG2)
- Dental Informatics (WG 11)
- Health and Medical Informatics Education (WG1)
- Health Informatics for Development (WG 09)
- Health Information Systems (WG 10)

- Informatics in Genomic Medicine (IGM)
- Intelligent Data Analysis and Data Mining (WG 03)
- Medical Concept Representation (WG 06)
- Mental Health Informatics (WG 08)
- Open Source Health Informatics
- Organizational and Social Issues (WG 13)
- Primary Health Care Informatics (WG 05)
- Security in Health Information Systems (WG 04)
- SIG NI Nursing Informatics
- Social Media Working Group
- Standards in Health Care Informatics (WG 16)
- Technology Assessment & Quality Development in Health Informatics (WG 15)
- Telematics in Health Care (WG 18)
- Wearable Sensors in Healthcare

17.15.6 See also

- European Federation for Medical Informatics (EFMI)
- ISO TC 215
- MedInfo

17.15.7 External links

- International Medical Informatics Association
- IMIA Yearbook
- ACI - Applied Clinical Informatics

17.16 Medinfo

MedInfo is the name of the international medical informatics conference organized every 3 years by the International Medical Informatics Association. It is the most important international conference in the field with 3000+ health and medical informatics professions attending from all over the world. MedInfo also serves to bring together all officers of the International Medical Informatics Association (IMIA) Board together with national representatives in the General Assembly of IMIA.

The General Assembly elects the officers of IMIA. The IMIA Board consists of the President (the Past or the Elect President), Treasurer and Secretary as its officers. In addition it has other Vice Presidents for targeted areas: Membership, MedInfo, Services, Special Affairs, Strategic Plan Implementation, and Working Groups. With the exception of the President and the Vice President of MedInfo all officers serve a three-year term that can be extended for a second three-year term. The President is on a 5-year cycle and the Vice President of MedInfo has one 3-year cycle and elected the year before the next Medinfo meeting so that he/she can be mentored through one MedInfo cycle.

17.16.1 MedInfo conferences

MedInfo has been held every 3 years since its inception in 1974. The table below gives an overview of these conferences.

17.16.2 Other definitions

Medinfo is also an acronym for Medical Information, often a pharmaceutical information service provided by pharmacovigilance or medical affairs departments.

17.16.3 See also

- International Medical Informatics Association

17.16.4 References

- Peterson, H. and Hutter, M. (2007). "IMIA's publication history". *IMIA Yearbook of Medical Informatics Methods Inf. Med. v46 iSuppl. 1. 192-196*. ISBN 978-3-7945-2608-6.
- Anderson, J., Forsythe, J.M. (Eds.). *MEDINFO 74*. Amsterdam: North-Holland. ISBN 0-444-10771-1.
- Shires, D.B., Wolf, H. (Eds.). *MEDINFO 77*. Amsterdam: North-Holland. ISBN 978-0-7204-0754-9.
- Lindberg, D.A.B., Kaihara, S. (Eds.). *MEDINFO 80*. Amsterdam: North-Holland. ISBN 0-444-86029-0.
- van Bemmel, J.H., Ball, M.J., Wigertz, O. (Eds.). *MEDINFO 83*. Amsterdam: North-Holland. ISBN 0-444-86525-X.
- Salamon, R., Blum, B.I., Jørgensen, M. (Eds.). *MEDINFO 86*. Amsterdam: North-Holland. ISBN 0-444-70110-9.
- Barber, B., Cao, D., Qin, D., Wagner, G. (Eds.). *MEDINFO 89*. Amsterdam: North-Holland. ISBN 0-444-88138-7.
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- Patel, V., Rogers, R., Haux, R. (Eds.). *MEDINFO 01*. Amsterdam: IOS Press. ISBN 978-1-58603-194-7.
- Fieschi, M., Coiera, E., Li, Y.-C. (Eds.). *MEDIFNO 04*. Amsterdam: IOS Press. ISBN 978-1-58603-444-3.
- Kuhn, K.A., Warren, J.R., Leong, T.-Y. (Eds.). *MEDINFO 2007*. Amsterdam: IOS Press. ISBN 978-1-58603-774-1.

17.16.5 External links

- http://www.imia-medinfo.org/medinfo2010/ (Cape Town, South Africa)
- http://www.imia-medinfo.org/new2/node/9

17.17 National Resource Center for Health Information Technology

In 2004, the Agency for Healthcare Research and Quality of the United States Department of Health and Human Services created the AHRQ National Resource Center for Health Information Technology (the National Resource Center or NRC) to support over 125 federal grants and contracts that are demonstrating the value and implementation of information technology in health care (health information technology).

With leadership from the National Opinion Research Center (NORC), the Regenstrief Institute, the Vanderbilt Center for Better Health, the Center for IT Leadership (CITL) and the eHealth Initiative, the NRC monitors and provides technical assistance to federal grants that are implementing technologies such as Electronic health records, Computerized Physician Order Entry, Health information exchange (HIE) and Telemedicine. The NRC directs almost half of its efforts and funding towards monitoring health IT development in rural communities.

In addition to its support of federal grants and agencies, the National Resource Center disseminates knowledge and best practices observed by the projects it supports. By way of the NRC's web site, health providers, administrators and researchers share lessons learned for how best to improve health care quality, safety, and efficiency in the United States through successful health IT adoption and usage.

The NRC does not provide grant money to individuals or organizations to do research in the fields of health care or health informatics. The NRC does provide, however, free educational resources and events where theory and case examples are presented by researchers active in these fields.

17.17.1 See also

- Canada Health Infoway
- European Institute for Health Records
- ISO TC 215

17.17.2 External links

- National Resource Center for Health Information Technology
- Agency for Healthcare Research and Quality (AHRQ)
- Glossary of Health Care Informatics Terms

17.18 Open Source Health Care Alliance

The **Open Source Health Care Alliance** is an international collaboration promoting the development and use of open source software and open access publications in the health care domain.

Membership is open to persons worldwide who are interested in furthering the objects of OSHCA and shall consist of anyone who has accepted the premise of OSHCA's Vision, Mission Statements and Principles by indicating such acceptance via OSHCA's Internet Registration process.

OSHCA was first formed in 1999 as an informal organization of interested parties. The organization achieved formal non-profit status in Malaysia on 31 October 2006 under the leadership of Dr. Molly Cheah and a pro tem committee of industry leaders. The first AGM will be held in 2007 following the OSHCA2007 conference (May 8–11) at the Federal Hotel in Kuala Lumpur, Malaysia.

17.18.1 Mission

OSHCA defines its mission as

- Promote to policy makers the concept of Free/Open Source Software in Health Care so as to adopt or give equal opportunity to Free/Open Source Solutions.
- Provide leadership role in refining the Free/Open Source Software Concepts as applied to health care to ensure best practices and patient safety are not compromised.
- Make recommendations on the development and use of Health information Standards for data interchange and representation formalisms.
- Provide Guidelines for Quality Control on Free/Open Source Health Care Software development.
- Participate in and support Human Capacity Building, including contributing/participating in project proposals and project management to achieve developing country priorities.
- Enable collaboration of members including, sharing technical knowledge in Free/Open Source Health Care Projects and providing information Resources to Free/Open Source Health Care software developers.
- Promote and help the formation of development consortia for health care related projects, including assisting in finding funding for projects to reach critical mass for a visible and lasting impact on health related Millennium Development Goals (MDGs).
- Use collaboration with strategic organisations with compatible goals as a means of achieving the mission.

17.18.2 External links

- official website

17.19 The Continua Health Alliance

Continua Health Alliance is an international non-profit, open industry group of nearly 240 healthcare providers, communications, medical, and fitness device companies. Continua Health Alliance members aim to develop a system to deliver personal and individual healthcare. Continua was a founding member of Personal Connected Health Alliance which was launched in February 2014 with other founding members mHealth SUMMIT and HIMSS.

17.19.1 Overview

Continua Health Alliance is an international not-for-profit industry organization enabling end-to-end, plug-and-play connectivity of devices and services for personal health management and healthcare delivery. Its mission is to empower information-driven health management and facilitate the incorporation of health and wellness into the day-to-day lives of consumers. Continua is a pioneer in establishing industry standards and security for connected health technologies such as smart phones, gateways and remote monitoring devices. Its activities include a certification and brand support program, events and collaborations to support technology and clinical innovation, as well as outreach to employers, payers, governments and care providers. With nearly 220 member companies reaching across the globe, Continua comprises technology, medical device and healthcare industry leaders and service providers dedicated to making personal connected health a reality.

Continua Health Alliance is working toward establishing systems of interoperable telehealth devices and services in three major categories: chronic disease management, aging independently, and health and physical fitness.

17.19.2 Devices and services

Continua Health Alliance version 1 design guidelines are based on proven connectivity technical standards and include Bluetooth for wireless and USB for wired device connection. The group released the guidelines to the public in June 2009.*[1]

The group is establishing a product certification program using its recognizable logo, the Continua Certified Logo program, signifying that the product is interoperable with other Continua-certified products. Products made under Continua Health Alliance guidelines will provide consumers with increased assurance of interoperability between devices, enabling them to more easily share information with caregivers and service providers.

Through collaborations with government agencies and other regulatory bodies, Continua works to provide guidelines for the effective management of diverse products and services from a global network of vendors. Continua Health Alliance products make use of the ISO/IEEE 11073 Personal Health Data (PHD) Standards.

Continua design guidelines are not available to the public without signing a Non-disclosure agreement. Continua's guidelines help technology developers build end-to-end, plug-and-play systems more efficiently and cost effectively.

17.19.3 Milestones

Continua Health Alliance was founded on June 6, 2006*[2]

Continua Health alliance performed its first public demonstration of interoperability on October 27, 2008 at the Partners Center for Connected Health 5th Annual Connected Health Symposium in Boston.*[3]

Continua Health Alliance certified its first product, the Nonin 2500 PalmSAT handheld pulse oximeter with USB, on January 26, 2009.*[4]

By the end of December 2014 there are more than 100 certified products.*[5]

Continua selected Bluetooth Low Energy and ZigBee wireless protocols as the wireless standards for its Version 2 Design Guidelines which have been released. Bluetooth Low Energy is to be used for low-power mobile devices. ZigBee will be used for networked low-power sensors such as those enabling independent living.*[6]

Beginning in 2012, Continua invites non-members to request a copy of its Design Guidelines after signing a non-disclosure agreement.*[7]

Continua has working groups and operations in the U.S., EU, Japan, India and China.

17.19.4 Members

Continua Health Alliance currently has nearly 220 member companies.*[8]

Continua's Board of Directors is currently composed of the following companies:*[9]

- Fujitsu
- Intel Corporation
- Oracle Corporation
- Orange
- Philips
- Qualcomm
- Roche Diagnostics
- Sharp
- UnitedHealth Group

Organisational Structure

The Organisation is primarily staffed by volunteers from the member organisations that are organised in to working groups that address the goals of the alliance. Below the board of directors sit the following main working groups:*[10]

- Emerging Markets Working Group
- EU Working Group
- Global Development and Outreach Working Group
- Marketing Council
- Market Adoption Working Group
- Regulatory Working Group
- Technical Working Group
- Test & Certification Work Group
- Use Case Working Group
- U.S. Policy Working Group

Relevant standards

- ISO/IEEE 11073
- ISO/IEEE 11073 Personal Health Data (PHD) Standards
- Bluetooth
- USB
- HL7
- Integrating the Healthcare Enterprise
- Zigbee

Website

The Continua Alliance website contains a full listing of member organisations, a directory of qualified products, and a clear statement of their mission.

17.19.5 See also

- Connected Health
- eHealth
- Telehealth
- Telemedicine
- Health 2.0

17.19.6 References

[1] http://www.continuaalliance.org/static/cms_workspace/Continua_Version_One_Design_Guidelines_Now_Available_final.pdf

[2] http://continuaalliance.org/news-and-media/press-releases/founding-continua.html

[3] http://continuaalliance.org/static/binary/cms_workspace/Continua_Update_release_v_FINAL_2_.pdf

[4] http://www.nonin.com/News.aspx?NewsID=86

[5] http://www.continuaalliance.org/products/certified-products.html

[6] http://www.continuaalliance.org/static/cms_workspace/Continua_06082009_vFINAL.pdf

[7] http://www.continuaalliance.org/products/design-guidelines.html

[8] Member Companies (English)

[9] Board of Directors (English)

[10] http://www.continuaalliance.org/static/cms_workspace/Continua_Overview_Presentation_7.16.12_web.pdf

17.19.7 External links

- Continua Health Alliance website

17.20 UNESCO Chair in Telemedicine

UNESCO Chair of Telemedicine (UNES_CT) is a portion of UNESCO that was founded in 1999. It undertakes international activities related to the promotion of the information society and fights against technology transfer problems having the role of an "intermediate body". The Chair is the first UNESCO Telemedicine Chair, and his activity is related with development and diffusion of Telemedicine and Information Society in Health Care in developing areas and undeveloped countries particularly South-America and Africa.

17.20.1 Activities

The expertise of the UNESCO chair of Telemedicine as a University Institution is based in the previous CATAI's expertise founded in 1994 in the field of Information Society/Telemedicine with which is collaborating closely and from which received part of the sponsorship.

Activities include: training and teaching aspects, to gain a minimal structured knowledge in Medical Informatics, have established the "Telemedicine Body of Knowledge" covering sociology, economics, technology transfer, technology and organizational issues, standardization, security and liability aspects in cooperation with the Universities of Queens-UK, Aveiro-PT, Belfast-IRL, Genova-IT, Innsbruck-AU, Udine-IT, Berlin-D, Athens-GR. CATAI published the first textbook of Telemedicine in English, complemented with a CD multimedia material particularly designed for developing countries, worldwide known by Winter and Summer Courses of Telemedicine training following the "Telemedicine Body of Knowledge". At the present moment the book is translated into 6 languages (SP,E,IT,GR,FR,D) and is published in Spanish (PanAmerican Editorial) with title : "Telemedicine" 2001. Is participating in all editions of the European Telemedicine Glossary edited by the EC-DG Information Society. In the 4th Ed-2002 is the author of the Electronic Clinical Record.

17.20.2 History

CATAI developed the Videophone network in the Canary Islands in 1991 for distant support. At the present it includes the best practice implementation pilots in phone medicine (oncology -particularly home-care- and psychiatry -particularly childhood psychiatry), Tele-ECG and Tele-ultrasounds -particularly obstetrics & gynaecology.

Fist in the world (1991) to carry out distant DNA quantitation, it was applied to image analysis prognostic factors in breast cancer. Objective image analysis and prognostic factors have been incorporated into the regional breast cancer registry of 3000 patients (see above);

CATAI was the promoter of the Centre of Excellence in Telemedicine, sponsored by Science Park DG-XIII, with enrolment of 3 continents: Europe, Africa and America to concentrate best practice examples as well as top experts to implement real world applications and development of hardware-software systems ready to be used. These activities link mainly technological firms of the UK and Germany.

The UNESCO chair was leader of two EU projects (Leonardo-DG XXII ; Science Park-DGXIII) and participating in other two (DGXIII- Teleultrasound for developing countries; Leonardo-DGXXII Teaching Medical informatics). Leader in Canary Islands and in the main land - Barcelona- of a project on Telephonic Medicine. Partner in 5 EU projects (Smart-USB; KOD or knowledge on demand, ASKLEPIOS, CHS or Citizen Home Services, CATAI-CTC)

UNESCO Chair of Telemedicine was involved in developing countries health support through the Midjan group-ITU-D working group of Telemedicine, TeleInViVo ultrasound devices with pilots in Katastan, Mali and Uganda. Additionally, the UNESCO chair was promoted the network of Telemedicine together with Argentina, Venezuela, Peru, and participated in ITU-Developing

Word Congress in Malta 1997, and Georgia Telemedicine meeting in 1999. Is currently actively working with South-America (Venezuela, Argentina, Cuba, Chile, Peru) and Africa (Uganda, Kenya)

17.20.3 Awards

- Economical initiatives, Canary islands 1995;
- Ordesa award in paediatrics 1989;
- Award Portugal-Spanish cooperation 1994;
- Award Royal Academy Medicine 1993 and 1999.
- Included in "Who is Who in the World" since 1996 scheduled up to 2000. Included in the 3rd Ed. of "Who is Who in Science and Engineering" .
- the Lattice Price 99 of ESF (European Science Foundation) in Innovation & Research in teaching, nominated by the STOA European Parliament Office.

17.20.4 References

- UNESCO Chair in Telemedicine - CATAI - University of La Laguna (Spain)
- UNESCO Education Portal
- University of La Laguna

17.21 World Health Imaging, Telemedicine, and Informatics Alliance

The **World Health Imaging, Telemedicine and Informatics Alliance** (WHITIA) is a non-profit global health technology and social venture established in 2006 by affiliates of Northwestern University near Chicago, Illinois.*[1]*[4] WHITIA cultivates high-level strategic relationships with non-governmental organizations, imaging industry innovators and academic institutions in order to integrate and deliver meaningful, sustainable, diagnostic technology to underserved communities worldwide. WHITIA's vision is to facilitate the deployment of thousands of digital medical imaging systems worldwide, providing one billion people with access to diagnostic imaging.*[5] WHITIA was formerly known as the World Health Imaging Alliance (WHIA) until it formally expanded its scope in June 2009.

WHITIA's first formal public launch was in April 2009 at the Healthcare Information and Management Systems Society (HIMSS) Annual Conference & Exhibition in Chicago, Illinois. WHITIA announced strategic partners including SEDECAL, Carestream Health and Merge Healthcare, receiving extensive coverage in Health IT magazines and publications.*[6]*[7] At the 2009 Annual Conference of the Society for Imaging Informatics in Medicine (SIIM) in Charlotte, North Carolina, WHITIA announced its partnership with SIIM, which will allow both organizations to collaborate on specific initiatives.*[8]*[9] WHITIA was recently ranked #15 of the top 25 most influential people, institutions, and organizations in the radiology industry.*[10]

At the 2009 RSNA Annual Meeting, WHITIA launched, **Remi-d**, a remote-operated screening X-ray system for use in the developing world. Its strengths in these areas stem from the higher burden of Human Immunodeficiency Virus (HIV) and Tuberculosis (TB) co-infection, high incidences of Black Lung disease, or outbreaks of other infectious respiratory diseases. The teleradiology and remote-controlled features of Remi-d allow resource-limited areas such as sub-Saharan Africa, South and Central America and Southeast Asia, where radiologists and radiographers are in short supply to have a functioning X-ray service.*[11]

WHITIA currently has pilot integrated digital X-ray sites in South Africa and Guatemala at established clinics in need and is expanding to new qualified sites in partnership with NGOs such as Rotary International while cooperating with the local and national governments.*[12]

17.21.1 Guatemala clinics

The Guatemala pilot sites in urban Guatemala City and rural Río Hondo provide essential healthcare technology to thousands of people in the communities served. They are designed to be models for the wider expansion of the WHITIA network throughout the clinics in need in urban and rural Guatemala. The system's specific design for Guatemala City is an integration of some of WHITIA's partners' strengths and generosity:

- SEDECAL provides the X-ray generator and controls
- Carestream Health donates the computed radiography (CR) digital scanner and plates
- Kane X-ray donates personnel to perform installation and set up of the CR and PACS

This project was largely funded by several US and Guatemalan Rotary clubs along with the key resource support of the Guatemalan municipal and national governments.*[13]

17.21.2 References

[1] "McCormick students and faculty tackle health care challenge in the developing world" . Robert R. McCormick

School of Engineering and Applied Science, Northwestern University. Retrieved 2009-07-02.

[2] "Board of Directors". Retrieved 2009-07-02.

[3] "Personnel". Retrieved 2009-07-02.

[4] "World Health Imaging Alliance Partners For X-Rays in Developing World". McCormick School of Engineering. Retrieved 2009-07-04.

[5] "Welcome to WHITIA | Homepage". Worldhealthimaging.org. Retrieved 2012-04-15.

[6] "Not-for-Profit Has a Vision to Help a Billion People". Reuters. 2009-04-06. Retrieved 2009-07-02.

[7] "World Health Imaging Alliance Poised to Bring Imaging Diagnostics and Data to the Developing World". Yahoo Finance. Retrieved 2009-07-02.

[8] "World Health Imaging Alliance (WHIA) Announces Support From The Society for Imaging Informatics in Medicine (SIIM)". Business Wire. Retrieved 2009-07-02.

[9] "World Health Imaging Alliance poised to bring imaging diagnostics and data to the developing world". Imaging Economics. Retrieved 2009-07-02.

[10] "25 Most Influential in Radiology". rt Image. Retrieved 2009-10-22.

[11] "WHITIA launches digital medical X-ray device for screening infectious diseases in developing countries". THE MEDICAL NEWS. Retrieved 2009-12-01.

[12] "SIIM to Support World Health Imaging Alliance". HealthTech Wire. Retrieved 2009-07-02.

[13] "WHITIA Announces the Completion of Digital X-ray Pilot Sites in Urban and Rural Guatemala". Business Wire. Retrieved 2011-01-09.

17.21.3 External links

- Official webpage
- Video interview with WHITIA staff and overview of mission. Shown at Rotary International Convention 2008

Chapter 18

Publications

18.1 List of medical and health informatics journals

This is a list of journals related to medical and health informatics.

- *BMC Medical Informatics and Decision Making*
- *Computers in Biology and Medicine*
- *Health Informatics Journal*
- *Journal of the American Medical Informatics Association*
- *Journal of Biomedical Informatics*
- *Journal of Information Professionals in Health*
- *Journal of Medical Internet Research*
- *Medical & Biological Engineering & Computing*
- *Methods of Information in Medicine*
- *Statistics in Medicine*

18.1.1 See also

- List of medical journals
- Lists of academic journals

18.2 ACIMED

ACIMED (*Journal of Information Professionals in Health*) is a Spanish language journal of medical informatics published by the National Center of Information on Medical Sciences in Cuba. It was first published in 1993 and is the first Spanish language journal to be published on the subject of medical informatics.

18.3 Journal of Medical Internet Research

The ***Journal of Medical Internet Research*** is a peer-reviewed open-access medical journal established in 1999 covering eHealth and "healthcare in the Internet age". The editor-in-chief is Gunther Eysenbach. According to the *Journal Citation Reports* the journal has a 2014 impact factor of 3.428, ranking it third out of 24 journals in the category "Medical Informatics"[*][1] and ninth among 88 journals in the category "Health Care Sciences & Services".[*][2] The journal was incorporated as JMIR Publications in 2011 and was a cofounder of the Open Access Scholarly Publishers Association.

Shortly after incorporation, several spin-off journals were launched, focusing on specific subtopics within eHealth, such as mHealth, serious games, mental health, and cancer.

JMIR has faced criticism for using the editorial board of its main journal for its spin-off journals and for offering a fast-track review pathway for a surcharge.[*][3] Eysenbach, the editor-in-chief, has commented that the spin-off journals will eventually have their own boards and that the fast-track option does not affect the quality or integrity of its peer-review processes.[*][4][*][5]

18.3.1 References

[1] "Journals Ranked by Impact: Medical Informatics". *2014 Journal Citation Reports*. Web of Science (Science ed.). Thomson Reuters. 2015.

[2] "Journals Ranked by Impact: Health Care Sciences & Services". *2014 Journal Citation Reports*. Web of Science (Science ed.). Thomson Reuters. 2015.

[3] Beall, Jeffrey. "JMIR Publications: A Model for Open-Access Health Sciences Publishers?". *Scholarly Open Access*. Retrieved 2015-12-22.

[4] Eysenbach, Gunther. "Response by JMIR Publications to Jeffrey Beall's Blog Post". Retrieved 2015-12-23.

[5] Eysenbach, Gunther. "Gunther Eysenbach's random research rants: JMIR's Fast-Track Experiment (Innovations in Scholarly Publishing: Part 1)". Gunther Eysenbach.

18.3.2 External links

- Official website

Chapter 19

National Projects

19.1 BeHealth

BeHealth is a Belgian eHealth digital platform which provides digital access to all health information and applications through one portal site, on behalf of both healthcare providers and patients. BeHealth has been created on 23 December 2004. It first aim is to interconnect multiple applications from a number of social security actors, but with the goal to provide broader services over time.

19.1.1 See also

- Telematics
- Belgian Health Telematics Commission (BHTC)
- FLOW
- Summarized Electronic Health Record (SumEHR)
- KMEHR

19.1.2 External links

- e-Health

19.2 Canada Health Infoway

Canada Health Infoway is an independent, federally funded, not-for-profit organization tasked with accelerating the adoption of digital health solutions, such as electronic health records, across Canada. As a strategic investor, Infoway works with the Canadian provinces and territories to co-fund the implementation of electronic medical records and other digital health projects. Infoway's members are Canada's 14 federal, provincial and territorial Deputy Ministers of Health.

The use of digital health solutions is intended to improve access to care for Canadians, improve the efficiency of individual health care providers and make the health care system as a whole more efficient.

An estimation indicated that by 2014, 74 per cent of physicians in Canada have electronic medical records.*[1]

As of 2016, the Government of Canada has allocated $2.15 billion to Canada Health Infoway.*[2]

19.2.1 Projects

Since 2001, Infoway has approved projects in the following targeted program areas:

- Diagnostic Imaging Systems
- Drug Information Systems
- Innovation and Adoption
- Interoperable EHR
- Laboratory Information Systems
- Patient Access to Quality Care
- Public Health Surveillance
- Registries
- Telehealth

19.2.2 Goals

The goal of Canada Health Infoway is to improve health care and the health of Canadians by working with partners to accelerate the development, adoption and effective use of digital health solutions across Canada. Infoway has helped fund several types of digital health solutions, such as laboratory information systems, diagnostic imaging systems, drug information systems, registries and interoperable electronic health records.

It has been reported that electronic medical records saved $1.3 billion over six years, improved chronic disease management and improved communications amongst care providers.*[3]

In 2015, Canada's clinical interoperability action plan was launched and Canada Health Infoway is working in

collaboration with the health care community to drive clinical interoperability in three priority areas: medication management, communicable disease management and the co-ordination of care. Another goal of Canada Health Infoway is to help drive the development of consumer health solutions such as e-visits and e-booking through demonstration projects and innovation challenges.

In January 2016, Infoway set out three goals for the 2016-2017 fiscal year:*[4]

- Facilitate better, safer and more appropriate prescription drug use by Canadians by establishing a multi-jurisdiction e-prescribing solution.
- Scale proven, patient-centred digital health solutions to empower patients and deliver access, quality and efficiency benefits.
- Continue to leverage foundational investments to support more seamless health services and better informed care.

[1] https://www.infoway-inforoute.ca/en/component/edocman/resources/i-infoway-i-corporate/business-plans/2858-summary-corporate-plan-2016-2017

19.2.3 Auditor General report

A 2009 report by the Auditor General of Canada found that Canada Health Infoway showed "due regard" for taxpayers' money in its financial management. Canada Health Infoway accepted all recommendations listed in the report.

Auditor-General Sheila Fraser's 2010 report states "Infoway has accomplished much in the eight years since its creation. Using the funding agreements with Health Canada as a starting point, Infoway developed an approach to providing for compatible electronic health records by identifying the key requirements and components of an EHR and developing a blueprint for the design of health information systems. It consulted widely with partners and stakeholders to obtain their input and support. In addition, it established appropriate governance mechanisms and developed a risk management strategy. It has implemented appropriate management controls for operational spending, although controls for contracting for goods and services need to be strengthened." *[5]

19.2.4 See also

- Royal Commission on the Future of Health Care in Canada
- European Institute for Health Records
- National Resource Center for Health Information Technology (USA)
- ISO TC 215
- RTSS
- Canadian EMR

19.2.5 Notes

[1] Collier, Roger (2015-01-06). "National Physician Survey: EMR use at 75%". *Canadian Medical Association Journal* **187** (1): E17–E18. doi:10.1503/cmaj.109-4957. ISSN 0820-3946. PMC 4284187. PMID 25487665.

[2] Finance, Government of Canada, Department of. "Budget 2016: Chapter 5 - An Inclusive and Fair Canada". *www.budget.gc.ca*. Retrieved 2016-05-02.

[3] "E-health records saved medical system $1.3B in 6 years". Retrieved 2015-09-17.

[4] "Canada Health Infoway, Summary Corporate Plan 2016-2017". *Canada Health Infoway*. January 29, 2016.

[5] Canada., Government of Canada, Office of the Auditor General of. "Chapter 4—Electronic Health Records". *www.oag-bvg.gc.ca*. Retrieved 2016-05-02.

19.2.6 External links

- Canada Health Infoway
- 2009 Auditor General Report
- 2010 Auditor General Report
- ImagineNation Challenges
- Better Health Together

19.3 Distance Learning and Telemedicine Grant and Loan Program

The **Distance Learning and Telemedicine Grant and Loan Program** (**DLT**) is a program authorized by the 1990 farm bill (P.L. 101-624) to provide grants to rural schools and health care providers to help them invest in telecommunications facilities and equipment to bring educational and medical resources to rural areas where the services otherwise might be unavailable. The 1996 farm bill (P.L. 104-127) reauthorized and streamlined the program.

The program was also reauthorized in the 2002 farm bill (P.L. 107-171, Sec. 6203).

DLT is administered by the Rural Utilities Service.

19.3.1 References

- This article incorporates public domain material from the Congressional Research Service document "Report for Congress: Agriculture: A Glossary of Terms, Programs, and Laws, 2005 Edition" by Jasper Womach.

19.3.2 External links

- Distance Learning and Telemedicine Grant and Loan Program official website

19.4 eHealth Ontario

eHealth Ontario is the agency tasked with facilitating the development of Ontario's proposed public Electronic Health Record system. Health Informatics in Canada is run provincially, with different provinces creating different systems, albeit sometimes under voluntary Pan-Canadian guidelines published by the federal body Canada Health Infoway. eHealth Ontario was created in September 2008 out of a merger between the Ontario Ministry of Health's electronic health program and the Smart Systems for Health Agency (SSHA), with a mandate to create electronic health records for all patients in the province by 2015. It has been plagued by delays and its CEO was fired over a multimillion-dollar contracts scandal in 2009.*[1] Today eHealth employs approximately 700 people.*[2]

19.4.1 Drug Profile Viewer System

The Drug Profile Viewer System tracks the prescription drug claims information of 2.5 million Ontario Drug Benefit Program and Trillium Drug Program recipients. This system is in use in hospitals throughout Ontario and access is being expanded to health care providers outside of the hospital setting.*[3]

19.4.2 ePrescribing

eHealth Ontario created a pilot project through which some doctors are now able to electronically send prescriptions to participating local pharmacies instead of having to manually write down the prescriptions on paper. That pilot project is ongoing.*[4]

19.4.3 Media Attention over Consultant Use and Contracting Practices

In May 2009, there were opposition calls for Ontario Health Minister David Caplan's resignation after it was revealed that eHealth Ontario CEO Sarah Kramer had approved about $4.8 million in no-bid contracts during the first four months of the agency's operation, while also spending $50,000 to refurnish her office, and paying consultants up to $300 an hour.*[5] One consultant earned about $192,000 in five months.*[6] Additionally, nine senior eHealth employees had been fired in a four-month period, some reportedly for challenging the agency's tendering practices.*[7]

Kramer was later forced to resign in June 2009, amid questions surrounding a $114,000 bonus paid to her. She received a $317,000 severance package with benefits for 10 months.*[8]

eHealth Ontario argued that the no-bid contracts were necessary due to the rapid transition process to eHealth from its predecessor Smart Systems for Health Agency, while Caplan defended Kramer's bonus as part of her move from another agency. The opposition argued that the government of Premier Dalton McGuinty spent five years and $647 million on the forerunner of eHealth Ontario: the Smart Systems for Health Agency, which used 15 per cent of its $225-million annual budget on consultants despite employing 166 people with annual salaries exceeding $100,000, before the project was shut down and restarted as eHealth Ontario.

In a public statement, Kramer argued that when she took over as CEO of eHealth Ontario, she "was charged with turning around a failing behemoth - SSHA - which had already run through more than $600 million dollars with hardly anything to show for it in terms of moving Ontario closer to the goal of eHealth, and modernizing and improving the quality and safety of health care for Ontarians." *[9]

Journalists have argued that Sarah Kramer received a "trial by media" and that the province of Ontario will be at a loss with her departure, as delivery of eHealth initiatives will be slowed. Marcus Gee from the Globe and Mail writes, "what happened at eHealth may or may not qualify as scandalous. What happened to Ms. Kramer certainly does. This was media lynching. A good woman and a first-rate civil servant has been hounded from public life, and all of us will suffer for it." *[10]

Journalists and former health policy advisors have noted that this media attention detracted from the organization's mandate and ability to deliver on much needed eHealth initiatives and healthcare reform in the province of Ontario. One past policy director for a former Ontario Minister of Health, argued that the public's focus should be on holding the government accountable for mitigating the problems that have resulted and demanding progress on eHealth.*[11]

Andre Picard, a Canadian public health reporter, argued that the public's focus should be on the delivery of electronic health records and not "disingenuous tsk-tsking about the hiring of consultants."He writes, "the true scandal in Ontario is the utter failure of the Ministry of Health to create electronic health records, which will ultimately

lead to better and more efficient patient care." [12] Picard argued that Ministry of Health bureaucrats are powerless when it comes to making real change in healthcare, as their political boss's only vision for healthcare is not irritating the public so they can be re-elected. The result is change and innovation can, seemingly, only come from independent agencies or outside consultants.[12]

Two inquiries were launched, but in August 2009, the independent review of eHealth Ontario had been dropped, with Caplan saying it would duplicate the work of Ontario's auditor general.[13]

On October 6, 2009, David Caplan resigned, one day before the release of the report into spending scandals.[14]

19.4.4 References

[1] "Head of eHealth Ontario is fired amid contracts scandal, gets big package". *CBC News*. 2009-06-07. Retrieved 2009-08-26.

[2] "eHealthStrategy" (PDF). Retrieved 2009-08-26.

[3] eHealth Ontario (2011). "Drug Profile Viewer". Retrieved 11 February 2012.

[4] eHealth Ontario (2011). "ePrescribing". Retrieved 11 February 2012.

[5] "ehealth-mcguinty-review". *CBC News*. 2009-05-28. Retrieved 2009-08-26.

[6] "Another untendered contract surfaces at embattled eHealth Ontario". *CBC News*. 2009-06-04. Retrieved 2009-08-26.

[7] "Opposition wants minister's resignation over eHealth spending". *CBC News*. 2009-05-28. Retrieved 2010-09-06.

[8] Talaga, Tanya (2009-06-11). "eHealth scandal reaches Premier's inner circle". *The Star* (Toronto). Retrieved 2009-08-26.

[9] "Statement by Sarah Kramer (CNW)". Retrieved 2009-08-27.

[10] "Scandal or not, there's no justice in Sarah Kramer's trial by media". *The Globe and Mail* (Toronto). Archived from the original on October 11, 2009. Retrieved 2009-08-27.

[11] "Critics' scrutiny of eHealth needs new focus". Retrieved 2009-08-27.

[12] Picard, Andre (2009-06-24). "The real eHealth Ontario scandal isn't over Choco Bites". *The Globe and Mail* (Toronto). Retrieved 2009-08-27.

[13] Leslie, Keith (2009-07-22). "McGuinty quietly drops eHealth review". *The Globe and Mail* (Toronto). Retrieved 2009-08-26.

[14] "Ontario health minister resigns". *CBC News*. 2009-10-07. Retrieved 2009-10-06.

19.4.5 External links

- Official website
- Electronic Health Record App

19.5 HealthConnect

See also: HealthConnect brand

HealthConnect has been Australia's change management strategy to transition from paper-based and legacy digital health records towards electronic health records planned system of electronic health records.[1]

The long-term goal of the HealthConnect strategy is to deliver better health outcomes through standardised, sharable clinical information.[1] The "better health outcomes" would translate to improved quality and safety in health care and disease prevention. These would be achieved by ensuring important clinical information is available and of high quality, when and where it is needed.[2]

Trials were carried out as part of the HealthConnect strategy in various parts of Australia during 2004. These included an EHR pilot in Brisbane South and a surgical patient information sharing trial at Townsville Hospital. In 2005 trials were conducted in Tasmania at the Launceston General Hospital and across the Northern Territory.[3] Defunct research consortium Distributed Systems Technology Centre (DSTC) was awarded a A$2.9 million contract to develop technology for HealthConnect. After the first round of trials the vision for HeathConnect was greatly altered. In 2007 a second phase of testing began.

The NT Health Connect Trial was largely successful and is "the most advanced eHealth implementations of their kind in Australia in terms of range of services, service coverage and consumer and health professional participation", according to their website. The project was upgraded and rename "Shared Electronic Health Record". A 2008 review of SEHR found it to be rated very highly among end users, accelerated rollouts and upgrades continued through 2009 and 2010. Of particular note was the ability for SEHR to achieve an estimated 90% uptake of residents from participating remote indigenous communities. (In such communities, it is difficult to maintain accurate records. The 2011 Census, for example, had focused action towards remote communities in an attempt to identify the extent of this problem [4])

19.5.1 See also

- Electronic health record

19.5.2 References

[1] "Health Connect". Department of Health and Aging, Government of Australia. 20 June 2008. Retrieved 22 June 2010.

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19.5.3 External links

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19.6 Health Information Systems Programme

See also: Holistic Information Security Practitioner

The **Health Information Systems Programme (HISP)**, aims to support the improvement of health care systems in the southern hemisphere by increasing the capacity of health care workers to make decisions based on accurate information. HISP provides training and support for users of the open source District Health Information System (DHIS 2) software, which is under continuous development. The global network of HISP is managed and coordinated by the Department of Informatics at the University of Oslo.

The project started in post-apartheid South Africa, and has been introduced in a number of countries in Africa and Asia.

19.6.1 External links

- The HISP Network
- Department of Informatics, University of Oslo
- The DHIS 2 software
- HISP South Africa
- HISP India

19.7 District Health Information System

The **District Health Information Software** (**DHIS**) is used in more than 40 countries around the world. DHIS is an open source software platform for reporting, analysis and dissemination of data for all health programs, developed by the Health Information Systems Programme (HISP). The core development activities of the DHIS 2 platform (see note on releases and versions further down) are coordinated by the Department of Informatics at the University of Oslo, and supported by NORAD, PEPFAR, The Global Fund to Fight AIDS, Tuberculosis and Malaria, UNICEF and the University of Oslo.

The solution covers aggregated data (e.g. routine health facility data, staffing, equipment, infrastructure, population estimates), and event data (disease outbreaks, survey/audit data, patient satisfaction surveys, longitudinal patient records etc.). The system supports the capture of data linked to any level in an organisational hierarchy, any data collection frequency, a high degree of customisation at both the input and output side. DHIS 2 comes with easy to use analytics through tailored Dashboards, charts, pivot tables and maps, and can be extended with Apps or used by third-party software through the open Web-API. It has been translated into a number of languages.

The DHIS was originally developed for three health districts in Cape Town in 1998-99, but has since spread via the HISP network to more than 40 countries in Africa, Asia and Latin-America. The initial scope - routine monthly Primary Health Center data – has systematically been expanded to cover nearly all aspects of health data and information, and recently been used by other sectors such as Education, Water and Sanitation, Forestry, and Food Security.

19.7.1 Versions and releases

DHIS (by HISP community) is available in several versions:

- DHIS 1.3
- DHIS 1.4
- DHIS 2

DHIS 1.3 and 1.4

The DHIS version 1 series goes back to 1996 and was developed on the Microsoft Access platform consisting of VBA for the interface or program logic (front-end), Access as a database (back-end), Excel for reporting and Windows as the OS. DHIS 1.4 (from 2005) is a significant overhaul of the version 1.3 database structure, using

various output formats for reporting. It bridges the gap between DHIS 1.3 and 2.

DHIS 2

DHIS 2 (from 2008) is a continuation of DHIS version 1 developed on open source Java technologies and available as an online web application. The first release, version 2.0, came in February 2008 after three years of development releases, and the most recent (as of January 2016) version is 2.22. DHIS 2 is developed using open-source Java frameworks and tools, such as the Spring Framework, Hibernate, Struts2, Maven, and JUnit. Follow the latest DHIS 2 development on the DHIS 2 Launchpad site and read more on the Official DHIS 2 site. *[1]

19.7.2 References

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19.7.3 External links to DHIS

- DHIS 2 site
- DHIS 2 on Launchpad (development platform)
- DHIS 2 and HISP background - the research network
- DHIS2 translations site
- Video on DHIS 2 in Ghana by Norad
- DHIS 1.4 site

19.7.4 DHIS by Eycon for Pakistan

Another software with the same name "DHIS" is developed by Eycon. This software is being used by Ministry of Health Government of Pakistan. Its Development history goes back to early 90's when an MS Access based system named **Hospital Management Information System - HMIS** was developed and was used in Health department. In its Next version the DHIS was developed using opensource technologies by AZM, funded by JICA . While in the upcoming and present version it was developed for the online system as a web based application by **Eycon Pvt Ltd***[1] and funded by TRF . Which is now being used in Pakistani Health Department for the maintenance of Data of Health Facilities and is managed , supported by Eycon Pvt.

19.7.5 External links to DHIS (by Eycon)

- DHIS Punjab site
- DHIS KPK site¨

[1] Eycon Pvt Ltd www.eycon.co

19.8 FLOW

FLOW is a Belgian national health care network, meant for health care providers and patients. It is an acronym which stands for *Facilities* (services and related infrastructure), *Legal implementation* (the telex files), *Organisations* (locoregional teams) and *Wisdom* (coordination and supervision center). The system is built around the principle of a shared health patient record.

19.8.1 Regions

- FLOW Alfa: Wallonia
- FLOW Beta: Brussels
- FLOW Gamma: Flanders

19.8.2 See also

- Belgian Health Telematics Commission (BHTC)
- BeHealth
- KMEHR
- SumEHR

19.8.3 Source

- FLOW
- Note de Politique Generale (3 Dec. 2004)

19.9 Health informatics in China

Health informatics in China (Chinese: 医学信息学) is about the Health informatics or Medical informatics or Healthcare information system/technology in China.

The main review and assessment of health informatics in China*[1] for the WHO-Health Metrics Network was conducted in 2006 which details Provincial assessments, developing strategic plan outline, improving community health monitoring system, household surveys, routine health statistics system.

Due to the Health Informatization Development Plan, all hospitals are required to increase investment in building

digitized hospitals. This requirement is expected to accelerate the growth of China's HIT market by about 25 to 30% a year during 2006-2010.*[2]

By the end of 2006, China's investment in its healthcare information systems (HIS) had increased by nearly 16 percent to RMB 5.8 billion, year-on-year. This amount accounts for approximately 0.5% of the country's total healthcare expenditures of RMB 866 billion during the same period.

The market size is expected to expand to approximately RMB 15 billion in 2010. The development of China's HIT industry is generally considered to be at a preliminary stage, resembling that of western countries 20 years ago. However, as China learns more about available and emerging technologies, it now has the opportunity to leapfrog ahead.

19.9.1 Healthcare overview

Expenditure

China spent $97 billion, or 5.5% of its GDP, on healthcare in 2004. As previously stated, public spending on healthcare remains low; public spending in 2004 accounted for only 17% of total healthcare expenditure while out-of-pocket expenses reached 53.6%.

Coverage

About 130 million people are covered under the National Social Insurance Program for Urban Employees, a program established in 2005. Another 50 million people are covered through government insurance. Yet less than 30% of the China's population has medical insurance. Indeed, over 35% of the urban population and 50% of people in rural areas have no coverage at all.

Infrastructure

China's current healthcare system is primarily composed of large public hospitals, supplemented by a small number of private, for-profit hospitals. As of 2005, there were 18,703 hospitals in China. Among them, 2,027 were private hospitals (10.83%). Chinese hospitals can be divided into three categories: general hospitals (70%), traditional Chinese medicine (TCM) hospitals (14%), and specialty hospitals (16%).

In addition, China has 5,895 outpatient facilities: 1,266 outpatient facilities and 541 traditional medicine facilities. As of 2005 China had 1,938,272 registered doctors who are primarily employed by hospitals.

19.9.2 History

Economic reforms in the early 1980s resulted in major changes in China's healthcare system, especially as a result of the dismantling of the rural cooperative medical system. After being given considerable financial independence, hospitals began to generate the majority of their income through user fees, a practice that continues today. Healthcare is now provided on a fee-for-service basis. The pricing structure attempts to facilitate equity by providing basic care below cost, with profits reaped through the (often excessive) sale of drugs and high-technology services; this structure leads to inefficiency and inappropriate patient care. Healthcare insurance coverage in China is low, with less than 30% of the population receiving any medical insurance.

China's health information technology HIT development has a brief history. Development commenced in the mid-1990s with financial management systems; only in the last five years or so have clinical systems been implemented. China has made progress in a relatively short time period, but weak application software and a scarcity of implementation skills delay further progress. Most Chinese hospitals are attempting to dramatically improve and extensively digitize their work processes in the near future.

Project on Construction of National Public Health Information System

The work group of the Ministry of Health for information construction has drafted the Project on Construction of National Public Health Information System. The "Project" confirmed the guideline, objectives and principles of public health information system construction, proposed framework for further actions. On September 17, 2003, information construction workgroup of the Ministry of Health held a Meeting via television and telephone on construction of public health information system in China. The agenda included a work report in the field of information construction of the Ministry of Health, the introduction of Construction Project of the National Public Health Information System (Draft) and a report from the National Center of Disease Control on relevant requirements of SARS report system via network.*[3]

Mortality statistics

As part of a major revamp of its health information system, China is merging two systems for collecting mortality data to gain a more accurate picture of how many people die and why. Cause-of-death data are playing an increasingly important role in the public health policy of China. Recently, Chinese Center for Disease Control and Prevention took part in a research project led by the Center for Statistics of the Ministry of Health on the

disease burden and long-term health problems in China; the results were dramatic.*[4]

19.9.3 HIT Adoption

Health information technology is now entering its second software generation in China, and IT usage in hospitals resembles that of the late 1970s in the United States. Most hospitals in China incorporate IT software into their payment and billing systems, and many have also begun integrating IT into clinical systems in the past five years.

The use of IT in clinical systems has emerged on a departmental basis. As a result of inexperience with IT infrastructure, however, hospitals have encountered several obstacles. Fragmentation, duplicative systems, and poor integration between diverse software systems have created "information islands" that impede data sharing.

Three valuable lessons are evident from China's HIT development over the past ten years:

- Medical information should be integrated across all departments in the hospital. Poor integration of diverse software systems within hospitals impedes inter-hospital information exchanges and creates problems as IT use expands.
- In order for IT systems to benefit clinical services and hospital management, effective overall IT planning is necessary. Oversimplification of IT planning and a lack of clinician engagement have in the recent past led to poor return on investment (ROI) in HIT.
- Implementation requires not only strong project-management skills but also attention to end-user requirements and needs as well as to work processes re-engineering. Poor implementation has resulted in a large amount of work-process redundancy.

Government policy

The Chinese government adopted an "informatization" approach in the 1990s, promoting IT development in all major industries, including the health sector, with one goal being to bridge the information divide. HIT policy began in 1995 with the "Golden Health Project," which sought to create the foundation for electronically linking health administration departments and hospitals as well as medical education and research institutes. Government efforts in the 21st century increasingly focus on health IT. For example, the 2003–2010 Ministry of Health Guidelines for HIT Development in China call for the introduction of EHRs and regional health information networks to be implemented throughout the country. Many hospitals are considering system-wide upgrades, and larger budgets are more readily available for these kinds of investments.

Organizations

The Ministry of Health within the government and independent hospital administrators are the primary drivers of HIT adoption in China. Following the SARS epidemic, the Chinese government realized the importance of integrating an effective IT infrastructure into the country's health system. Additionally, after a decade of small investments in IT systems hospital leaders have become aware that IT can improve work processes and increase management efficiency.

Many other associations involved in HIT exist in China, including the

- National Medical Information Education (NMIE),
- Association of Chinese Health Informatics,
- Chinese Health Information Association, and
- Chinese Hospital Information Management Association (CHIMA). CHIMA is a branch of the Chinese Hospital Association, a nonprofit national industry and academic association focused on Health IT (similar to the AMIA in the United States).

Funding

Provincial and local governments in China are the primary funders for regional health information networks and HIT in public hospitals. The national government facilitates investigation of standards and IT infrastructure development. Hospitals invest their own funds into clinical and institutional HIT systems. As of 2006, China spends a little over 0.7% ($700 million) of its national health budget on HIT. Of these funds: 70% goes toward hardware, 20% toward software, and 10% toward services.

Planning

Spending on healthcare in China will grow dramatically over the next five years, potentially rising to 7% of GDP. HIT spending in China will likely grow even faster, with China's national goal to create EHR and regional health information networks throughout China. Major IT upgrades are now being considered in many hospitals. The focus of future HIT development in China includes the following:

- electronic health records
- regional health information networks to share electronic health data
- better integration of diverse systems within individual hospitals, including agreement upon standards to support IT progress, and better management of

change so that the new IT systems will make Chinese hospitals operate more efficiently. In order to accomplish these objectives over the next several years, hospitals will involve experts for IT planning and implementation of the new systems.

Challenges

19.9.4 Hospital information system

Progress of **hospital information system** (HIS) in China has made significant progress in recent years. HIS has played a very important role in hospital, and the construction and employment of HIS can improve the efficiency and quality of healthcare work. But the development of HIS in China is unbalanced and there are many problems such as nonstandard hospital management, poor standardization, and lack of consolidation of software development. As a consequence, the current HIS is not able to meet the needs of reform in China's healthcare system. In the future, for the sake of medical information sharing, telemedicine, hospital efficiency enhancement, integration needs to be realized.

In recent years, Hospital Information System (HIS) has been developed in several areas. Many hospitals have constructed HIS. According to the Ministry of Health in 2004, there were 6,063 hospitals out of 15,924 that had established hospital information systems.*[5] It is estimated that about 70% of county-level hospitals and above have constructed HIS by mid-2007.

In 2004, the total cost for information technology (IT) in health sector was estimated at approximately RMB 3.5 billions (US$423.5 million), which increased 25% compared with 2003. Most of the resources were committed to HIS. Construction of HIS has taken good effect, which changed the style of hospital management, offered tremendous opportunities to reduce clinical errors (e.g. medication errors, diagnostic errors), to support health care professionals (e.g. availability of timely, up-to-date patient information), to increase the efficiency of care (e.g. less waiting times for patients), or even to improve the quality of patient care.*[6] Today, HIS is not only a symbol of modern management, but also one of core competence of a hospital.

Nowadays, with reform in healthcare system and the entry into WTO, HISs is confronting many challenges in China. Medical domain will develop into standardization and internationalization, which stimulate different grade hospitals and many related organizations (e.g. insurance agents, finance organizations, community station), into a big integer. But the forepart HIS didn't consider medical information standards, and can't share medical information.

Current status

Computers began to be used in hospitals in China in the 1970s, but used as hospital information management since 1984. According to the contents, styles and scopes, HIS in China experienced four phases.*[7] They are as follows:

1. Stand-alone. Mostly used in out-patients charge, in-patient charge and drug warehouse management during the late 1970s and early 1980s.
2. Department local area network. Representative applications are inpatient management; outpatient charge and drug deliver system, and drug management system.
3. Integrity of hospital information system. Many big hospital constructed integrity hospital information system on ethernet over 100m since the early 1990s.
4. Telemedicine. With the development of IT and network, many big hospitals commenced to study implement telemedicine, through which the diagnostic digital images such as CT scans, MRIs and ultrasound CT can be transmitted.

The first three phases focus on hospital information management and the fourth phase patient-centered.

In general, construction of HIS in China has made significant progress since the 1990s. According to some sample investigation about HIS, there are many characters as follows: the development of HIS are imbalanced, the differences among different regions are very significant. In more developed regions, the proportion of hospitals with HIS is high, and the level of HIS is also high, most of them are in the third phase, and a few hospitals are in fourth phase.

In fact, the HIS in many hospitals is no worse than that in advanced foreign hospitals. On the other hand, the level of HIS in developing regions is low, the proportion of hospitals with HIS is also low, and most of them are in the second phase. But the potential market of HIS is very good. By 2004, the proportion of hospitals with HIS in East China was above 80%, whereas, it was less than 20% in Northwest China.

"No. 1 Military Project"

"No. 1 Military Project" was important in China's HIS development.*[7] This project is a hospital information system consisting of over 30 basic subsystems. It was developed by General Logistics Department of PLA collaborating with Hewlett-Packard in 1997. The project has achieved success and improved the development of health informatics in China. So far, over 200 hospitals have adopted this system. This kind of HIS has become

a succeeded and advanced representative one in China. The HIS of "No. 1 Military Project" was applied in Xiaotangshan hospital during the outbreak of SARS in 2003. The patients suffered SARS were treated and the system played an important role and was praised highly by specialists.

Although construction of HIS has achieved greatly, yet most HIS concentrates more on the fiscal operations of a hospital and the administrative aspects. Only 10% of hospitals with HIS have developed patient-centered Clinical Information System, while 5% are constructing Picture Archiving and Communication System.

Main problems

Although there has been good progress during last two decades, especially during last 10 years, there have been many problems which limit further progress. The main problems are as follows.

Lack of Standardization/Interoperability Hospital information relate to medical treatment, education, medical research, personnel, money, and substance, et al. Unification of the titles, the concept, the classification and the codes are the basic precondition for information interchange. But the most difficulty is that the standards are not unified. For example, the titles and codes of the case reports, drugs, personnel, equipment, inspection and examination differ in different hospitals. The definition, description and practice operation for the same thing are different. Owing to without unified and authoritative hospital standardization data dictionaries, as well as different HIS developed by different companies with different codes and standards, two bad results come into being. The first one is that every hospital has to develop consumer dictionary, which result in tremendous waste of personnel, money, substance and time. The second one is that standards and user dictionaries are established differently, which affect the unit into the internet and can't share information. As discussed in the previous section, the HIS of "Np. 1 Military Project" was excellent. Even though, there are many problems in standardization. Results from some researchers' investigation revealed that 99 code tables should be consistent, but there are only 31 are consistent. Even worse, 27 codes in 27 military hospitals have 27 formats.*[8] Using message standards, including the Health Level 7 (**HL7**), is the precondition to ensure interoperability between different hospitals systems. However most hospitals haven't considered this problem and few HIS apply HL7. Only in some developed regions, such as Guangdong province, the governments require that developers of HIS must adopt or refer to HL7 standard to transmit patient clinical information. The reform in Chinese healthcare system requires different grade hospitals and many related organizations, such as insurance agents, finance organizations, community station, can share and interoperate in-patients' information. But the poor information standardization in HIS can't meet the need.

Unified Layout of Software Systems HIS developments began to accelerate since the early 1990s. All level of health administrations, hospitals and some information development companies invested huge personnel and money into HIS developing. Especially in developed regions such as Beijing, Shanghai, Guangdong, Shandong, Jiangsu, the HIS achieved success and have larger scale. Yet the reasons those without plans as a whole and control for HIS by the related health administrations, without standards to comply with and without surveillance by some related administrations lead to non-normative HIS developing processes. These are two poor results. The first one is that HIS were developed free, the software had no standards, the developed platform therefore varied. The second problem is that the HIS develop companies were in different levels, and many of them didn't specialize in HIS develop, they were not familiar with the style of hospital management and workflows, or they only knew some specific hospitals. Furthermore, some companies have the idea of eager for quick success and instant benefit, and only considered the current benefits without long term investment. Some companies even thought that HIS market had potential, so they made some simple system packages together, and took some measures to deceive the users. All above brought severe negative influence to HIS development.*[9]

Models of Hospital Management The models of hospitals management have major influences on HIS construction. HIS implementation requires both technical structural and behavioral sense, and development of HIS should be carried out within the context of the development itself.*[10] Application with HIS but without studying and absorbing has become one bottle neck for HIS development. Compared with hospitals' directors with MBA diploma in developed countries, who manage the hospitals, most of hospitals directors in China are good medicine experts, however, they aren't familiar with modernization management. They have experience in management methods, but didn't know normative and science management. When constructing HIS in their hospitals, they usually requested the HIS accommodate with their existing management modes in spite of their management modes were nonscientific and unreasonable. Besides the complexity of hospital's management, workflows and circumstances in different hospitals differ very much. To meet the need of the hospitals management, the developers had to act according to actual circumstance, which lead to the HISs can't meet the need of information communication and share because of low currency and commercialization. Good HIS should optimize hospital process, but in many Chinese hospitals, this was not the case, poor hospital process flow compromises the good HIS.

National standardization priorities

See also: Guobiao

There are many problems in HIS construction in China, among which interoperability is one of the most important. The absence of universal and consistent standards for managing and exchanging clinical and administrative information has been identified as bottleneck to utilize and improve the HIS. Therefore, one of priorities in national standardization actions is to accelerate the development of essential standards for HIS. In fact, after several years of running information systems, health providers recognized that standards were the basis for the information sharing and interoperability. The government of China also realized this problem and has taken efforts to construct the health information platform and network. One hypothesis is that because standardization for health informatics is an authoritative field, in which market mechanism does not work. Also, due to misalignment of incentives, often providers who invest in standardization cannot gain benefit directly, therefore they might prefer to invest in network than in standardization. The government may play a role to stimulate adoption by setting standards. In fact, the government had indeed taken measures to enforce the construction of standardization. In 2003, Ministry of Health released the Development Layout of National Health Informatics (2003–2010).*[11]

The layout indicates one of principles of standardization for health informatics: combining adoption of international standards and development of national standards. In the late 2003, the *Leading Group for Health Informatics* in the Ministry of Health started three projects to solve the problem of lacking health informatics standards, including Chinese National Health Information Framework and Standardization, Basic Data Set Standards of Public Health and Basic Data Set Standardization of Hospital System (CBDSS). CBDSS is one important project of the medical information standardization programs, which would improve information progress of hospital and the whole health system. Chinese Hospital Information Management Association (CHIMA) undertook the task of CBDSS project .The goal of this project is to produce a set of data set standards, which is necessary for HIS. By now, most of this project is completed, 11 subgroups and 1 shared group CBDSS came into being.*[12] Since 2003, the government had launched over ten projects related health standardization in succession, and substantial progress was made in standardization of medical information.

Dependency theory

At present, the majority HISs running in China are Hospital Management Information Systems (HIMIS), and they are not able to share medical images diagnostic information due to the various standards and formats adopted by different manufactures. Now there are HIS, Radiology Information System (RIS), Laboratory Information System (LIS) and Picture Archiving and Communication System (PACS) in many bigger hospitals, each system run independently in most hospitals. With the development of health researches and health standardization, this problem can be solved with HIS.*[13] In the future, for the sake of medical information sharing, telemedicine, hospital efficiency enhancement, medical service extension, optimizing the working procedure,*[14] HIMIS will develop into patient-centered HIS, all the independent systems including the electronic patient record will realize integration. Furthermore, HIS will shift from supporting health care professionals to patients and consumers, from institution-centered to regional and global health information system with new and strongly extended functionalities and tasks.*[15]

19.9.5 International cooperation

SGER: Transnational Public Health Informatics Research: US-China Collaboration

This public health informatics Small Grant for Exploratory Research is a small-scale, exploratory, high-risk proposal that is potentially transformative in its research collaborations between the US and China. The proposal team is building on the momentum gained from two US-China public health informatics workshops held in Beijing in March 2008. New partnerships are expected to emerge. The outcomes have the potential to transform approaches to public health informatics, not only in US and China, but potentially across the globe, in particular in exploring transnational social networks and taking advantage of the kinds of data collection and integration methodologies and technologies employed by the two countries' public health agencies. It affords the opportunity to provide new and longer-term research and educational programs between US and Chinese institutions and practitioners.*[16]

19.9.6 See also

- Clinical Document Architecture
- eHealth
- Electronic health record (EHR)
- Electronic medical record (EMR)
- HL7
- Health information management (HIM)
- ISO TC 215
- International Medical Informatics Association

- LOINC
- mHealth
- Public health informatics
- Telemedicine

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Journals

- Journal of Medical Informatics 医学信息学杂志
- Chinese Journal of Health Informatics and Management
- International Journal of Software and Informatics
- Journal of Health Informatics in Developing Countries

19.9.8 External links

- China Hospital Information Management Association
- CMIA —China Medical Informatics Association
- China HIS
- China National Institute of Standardization
- Chinese Health Information Standardization Society CHISS
- Chinese LOINC Interface System - a pilot project that aims to show a simplified Chinese version of LOINC terms.
- National Medical Information Education
- Department of Medical Informatics - Peking University
- Chinese Medical & Biological Information
- EVIPNet Beijing

Courses

- "Medical informatics"

HL7

- Health Level Seven (HL7)

PACS

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19.10 NHS Direct

For the service in Wales, see NHS Direct Wales

NHS Direct was the health advice and information service provided by the National Health Service (NHS), established in Mar 1998. The nurse-led telephone information service provided residents and visitors in England with healthcare advice 24 hours a day, every day of the year through telephone contact on the national non-geographic 0845 46 47 number.*[1] The programme also provided a web based symptom checkers on the NHS Direct website and via mobile, both as apps for iPhone and Android smart phones and a mobile website.

It was discontinued on 31 March 2014.*[2] As a part of the National Health Service, NHS Direct services were free, although the 0845 number was usually chargeable as a non-geographic number. Some landline providers allowed 0845 calls within "inclusive" minutes.

Users of the service, through whichever channel, were asked questions about their symptoms or problem. Common problems were often given simple self care advice, which they could follow thereby avoiding an expensive visit to a health care professional. More complex problems were assessed by a nurse and could then be given treatment advice or referred on to another service within the NHS.

As well as these core services, NHS Direct provided a number of commissioned services throughout the NHS, such as specialised support for patients with long term conditions, access to GP and dental healthcare out of hours, and a professional response system for times of public health anxiety.

NHS Direct only provided its service for residents and visitors in England, and there are corresponding public services covering Scotland (NHS 24) and Wales (NHS Direct Wales). Northern Ireland does not have such a service.

19.10.1 Health and symptomatic advice

NHS Direct's core service was the provision of health advice to the public through the national telephone service or through digital channels including the website.

Telephone service

In England and Wales, the NHS Direct telephone service was available on **0845 46 47** and was run by a specially trained team of information handlers and healthcare professionals, including nurses and dental nurses. The service was equipped to deal with a huge range of health enquiries, from symptomatic queries that require assessment and treatment, to requests for local healthcare services and healthy living advice.

Every person that called NHS Direct feeling unwell was assessed to establish the severity of their symptoms, so as to re-route any urgent or life-threatening situations to the emergency services as quickly as possible.

Other symptomatic callers were able to speak to a nurse, who asked about their condition in order to recommend the best course of action. This could be giving advice about treating the problem at home, suggesting a visit to a pharmacist, or advising an appointment with their GP, which, if in the out of hours period (when the GP surgeries are closed), could possibly be arranged over the phone.*[3]

As many callers were advised to look after their symptoms at home without seeing their GP, the NHS Direct telephone service reduced the demand on NHS resources and helped to avoid unnecessary trips to the doctor, dentist and accident and emergency department.

The NHS Direct telephone service also provided a confidential interpreter service in many different languages, which could be accessed by stating the language required when the call was answered. For those who are deaf or hard of hearing, there was a textphone service available on **0845 606 4647**.

Website

The NHS Direct website had a variety of symptom checkers, based on the same system used on the telephone service and could either give self care advice or direct a user to another NHS service. For more complex queries, the symptom checkers allowed the user to receive a call back from a nurse or to take part in a webchat for further information and help.

All NHS Direct health advice and information on the website passed through a rigorous clinical check by medical professionals before it was published.*[4]

Non-urgent health queries could be submitted to the NHS Direct online enquiry service and the website also offered a confidential webchat service for those needing advice about unprotected sex or emergency contraception.

Mobile services

NHS Direct offered its full range of symptom checkers optimised for mobile devices on its mobile website and also launched stand alone 'apps' for iPhone and Android smart phones, both available in the normal app stores.*[5]*[6]

19.10.2 Other services

Digital television channel

NHS Direct provided an interactive TV service via Sky Interactive until 31 March 2009, when the service was closed.*[7]

The Freeview service, on channel 100 is now hosted by NHS Choices.*[8]

The digital television service contained condensed versions of many of the most common and popular health encyclopaedia topics and common health questions.

Commissioned services

Although it is not well known, NHS Direct supplies a multitude of additional commissioned services within the NHS.

NHS Direct supported many local health authorities in England, including Primary Care Trusts (PCTs), helping them to deliver high quality healthcare to people in each region.

These services ranged from dedicated projects in particular areas, such as the local telephone helpline set up for Sandwell PCT after a dental health scare, to schemes that were developed nationwide. These include a telephone-based pre and post operative assessment for patients having surgery, and allocating care managers to give regular coaching and advice to those with long term conditions, such as diabetes and cardiovascular disease.

19.10.3 History and background

NHS Direct was launched in 1998 after the government identified a need for a telephone health advice line staffed by nurses as part of its plans to modernise the NHS.*[9]

The aim of NHS Direct, as stated by the government in the NHS White Paper, *The New NHS*, was "to provide people at home with easier and faster advice and information about health, illness, and the NHS, so that they are better able to care for themselves and their families" .*[10]

The NHS Direct telephone service began taking calls in three contact centres in Lancashire, Northumbria and Milton Keynes in March 1998.*[11] These original sites were set up as pilots but soon proved successful, reaching over 1 million people and earning highly positive feedback. Additional waves of pilots were established in contact centres around England until the whole country was covered by the NHS Direct telephone service in 2000.*[10]

NHS Direct added a website to its services at the end of 1999, allowing users to find clinically accurate health advice and information anonymously. Since its creation, the NHS Direct website was steadily improved and developed, attracting more users. By 2008, there were over 1.5 million visitors to the website every month.*[10] NHS Direct's services continued to expand and improve. It had been said that this has made the organisation "the largest and most successful healthcare provider of its kind, anywhere in the world" .*[12]

It was reported that each call made to NHS Direct cost £25 to answer - an earlier official report had put the total at £16.*[13]

In April 2007, NHS Direct became an NHS Trust, giving it the opportunity to apply for foundation trust status.*[1]

In August 2010, the BBC reported that David Cameron's coalition government was planning to scrap the NHS Direct 0845 46 47 helpline telephone service in favour of the cheaper NHS 111 number. This intention was set out in the white paper, but was portrayed in the media as a 'leak' by the Conservative Health Secretary Andrew Lansley.*[14] The service was shut down on 26 March 2014.*[15]*[16] A copy of the website was archived a few weeks before the official closedown.*[17]

19.10.4 Abolition of NHS Direct helpline (England)

The Department of Health has confirmed that NHS Direct's telephone number is to be phased out in favour of the new non-emergency NHS 111 number, following three pilots in the North East, East Midlands and East of England. NHS 111 is intended to work in an integrated way with local GPs, out-of-hours services, ambulance services and hospitals, for the benefit of patients and to help the NHS become more efficient. NHS Direct was intended to have an ongoing role, along with other providers, in helping to deliver the NHS 111 Service and, in the interim, continued providing local and national telephone and web-based services on behalf of its commissioners. The Labour party, which founded NHS Direct, voiced its opposition to the proposal, although it had promised to introduce the new 111 hotline nationally in its election manifesto.*[18]*[19]

19.10.5 Closure

It was announced in October 2013 that NHS Direct would be closed down in 2014.*[20] after the organisation became entangled in and failed to deliver correctly a number of contracts to deliver NHS 111.

19.10.6 References

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[16] "NHS Direct: closed for business" . *Good to Know*. IPC Media Women's Network. 2014-03-28. Archived from the original on 2014-04-26.

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[19] "A new national 111 telephone number will make non-emergency services far easier for people to access and book". *Labour Party*. 2010. Archived from the original on 2010-04-14.

[20] "NHS Direct to close down next year". *BBC News*. 2013-10-24. Archived from the original on 2013-10-24.

19.10.7 External links

- NHS Direct
- NHS Direct on Facebook
- NHS Direct on Twitter
- NHS Direct's channel on YouTube

19.11 NHS National Programme for IT

NHS Connecting for Health (CFH) Agency was part of the UK Department of Health and was formed on 1 April 2005, having replaced the former NHS Information Authority. It was part of the Department of Health Informatics Directorate, with the role to maintain and develop the NHS national IT infrastructure. It adopted the responsibility of delivering the **NHS National Programme for IT** (NPfIT), an initiative by the Department of Health in England to move the National Health Service (NHS) in England towards a single, centrally-mandated electronic care record for patients and to connect 30,000 general practitioners to 300 hospitals, providing secure and audited access to these records by authorised health professionals.

NHS Connecting for Health ceased to exist on 31 March 2013, and some projects and responsibilities were taken over by Health and Social Care Information Centre.

19.11.1 History

Contracts for the NPfIT Spine and five Clusters were awarded in December 2003 and January 2004.[*][1][*][2][*][3][*][4]

It was planned that patients would also have access to their records online through a service called HealthSpace. NPfIT is said by NHS CFH to be "the world's biggest civil information technology programme".[*][5]

The cost of the programme, together with its ongoing problems of management and the withdrawal or sacking of two of the four IT providers, have placed it at the centre of ongoing controversy, and the Commons Public Accounts Committee has repeatedly expressed serious concerns over its scope, planning, budgeting, and practical value to patients.[*][6][*][7][*][8] As of January 2009, while some systems were being deployed across the NHS, other key components of the system were estimated to be four years behind schedule, and others had yet to be deployed outside individual primary care trusts (PCTs).[*][8]

While the *Daily Mail* announced on 22 September 2011 that "£12bn NHS computer system is scrapped..." ,[*][9] *The Guardian* noted that the announcement from the Department of Health on 9 September,[*][10] had been "part of a process towards localising NHS IT that has been under way for several years".[*][11] Whilst remaining aspects of the National Programme for IT were cancelled, most of the spending would proceed with the Department of Health seeking for local software solutions rather than a single nationally imposed system.[*][12]

19.11.2 Structure and scope of the programme

The programme was established in October 2002 following several Department of Health reports on IT Strategies for the NHS, and on 1 April 2005 a new agency called NHS Connecting for Health (CfH) was formed to deliver the programme.[*][13] CfH absorbed both staff and workstreams from the abolished NHS Information Authority, the organisation it replaced. CfH was based in Leeds, West Yorkshire. By 2009, it was still managed nationally by CfH, with responsibility for delivery shared with the chief executives of the ten NHS strategic health authorities.[*][8]

19.11.3 Reviews

The refusal of the Department of Health to make "concrete, objective information about NPfIT's progress [...] available to external observers", nor even to MPs, attracted significant criticism, and was one of the issues which in April 2006 prompted 23 academics[*][14] in computer-related fields to raise concerns about the programme in an open letter to the Health Select Committee.[*][15][*][16] 2006-10-06 the same signatories wrote a second open letter[*][17]

A report by the King's Fund in 2007 also criticised the government's "apparent reluctance to audit and evaluate the programme", questioning their failure to develop an ICT strategy whose benefits are likely to outweigh costs and the poor evidence base for key technologies.[*][18]

A report by the Public Accounts Committee in 2009 called the risks to the successful deployment of the system "as serious as ever", adding that key deliverables at the heart of the project were "way off the pace", noting

that "even the revised completion date of 2014–2015 for these systems now looks doubtful in the light of the termination last year of Fujitsu's contract covering the South", and concluding "essential systems are late, or, when deployed, do not meet expectations of clinical staff".*[19]

The initial reports into the feasibility of the scheme, known to have been conducted by McKinsey, and subsequent reports by IT industry analyst Ovum among others*[20] have never been published nor made available to MPs.*[21]

19.11.4 Costs

Originally expected to cost £2.3 billion (bn) over three years, in June 2006 the total cost was estimated by the National Audit Office to be £12.4bn over 10 years, and the NAO also noted that "...it was not demonstrated that the financial value of the benefits exceeds the cost of the Programme".*[22] Similarly, the British Computer Society (2006) concluded that "...the central costs incurred by NHS are such that, so far, the value for money from services deployed is poor".*[23] Officials involved in the programme have been quoted in the media estimating the final cost to be as high as £20bn, indicating a cost overrun of 440% to 770%.*[24]

In April 2007, the Public Accounts Committee of the House of Commons issued a damning 175-page report on the programme. The Committee chairman, Edward Leigh, claimed "This is the biggest IT project in the world and it is turning into the biggest disaster." The report concluded that, despite a probable expenditure of 20 billion pounds "at the present rate of progress it is unlikely that significant clinical benefits will be delivered by the end of the contract period." *[6]

In September 2013, the Public Accounts Committee said that although the National Programme for IT had been effectively disbanded in 2011, some large regional contracts and other costs remained outstanding and were still costing the public dearly. It described the former National Programme for IT as one of the "worst and most expensive contracting fiascos" ever.*[25]

The costs of the venture should have been lessened by the contracts signed by the IT providers making them liable for huge sums of money if they withdrew from the project; however, when Accenture withdrew in September 2006, then Director-General for NPfIT Richard Granger charged them not £1bn, as the contract permitted, but just £63m.*[26] Granger's first job was with Andersen Consulting,*[27] which later became Accenture.

19.11.5 Deliverables

The programme was divided into a number of key deliverables.

*NHSmail was renamed to *Contact* in late 2004,*[28] before being reverted to NHSmail in April 2006.*[29]

The Spine (including PDS and PSIS)

The Spine is a set of national services used by the NHS Care Record Service. These include:

- **The Personal Demographics Service (PDS)**, which stores demographic information about each patient and their NHS Number. Patients cannot opt-out from this component of the spine, although they can mark their record as 'sensitive' to prevent their contact details being viewed by 831,000 staff.
- **The Summary Care Record (SCR)**. The Summary Care Record is a summary of patient's clinical information, such as allergies and adverse reactions to medicine.
- **The Secondary Uses Service (SUS)**, which uses data from patient records to provide anonymised and pseudonymised business reports and statistics for research, planning and public health delivery.

The Spine also provides a set of security services, to ensure access to information stored on the Spine is appropriately controlled. These security measures were queried during the early stages of Spine development, with leaked internal memos seen by the *Sunday Times* mentioning "fundamental" design flaws.*[30] In addition, government spokeswoman Caroline Flint failed to dispel concerns regarding access to patients' data by persons not involved in their care when she commented in March 2007 that "*in general* only those staff who are working as part of a team that is providing a patient with care, that is, those having a legitimate relationship with the patient, will be able to see a patient's health record." *[21]

The Spine was migrated to a new Open Source system in August 2014.*[31]

Exceptions

The NHS in Wales is also running a national programme for service improvement and development via the use of Information Technology – this project is called Informing Healthcare. A challenge facing both NHS CFH and Informing Healthcare is that the use of national systems previously developed by the NHS Information Authority are shared by both of these organisations and the Isle of Man. Separate provision needs to be made for devolution, while maintaining links for patients travelling across national borders.

NPfIT is currently focussed on delivering the NHS Care Record Service to GPs, Acute and Primary Hospitals, medical clinics and local hospitals and surgeries. Whilst

there are no immediate plans to include opticians or dentists in the electronic care record, services are delivered to these areas of the NHS.

Clusters and Local Service Providers

The programme originally divided England into five areas known as "clusters": Southern, London, East & East Midlands, North West & West Midlands, and North East. For each cluster, a different *Local Service Provider* (LSP) was contracted to be responsible for delivering services at a local level. This structure was intended to avoid the risk of committing to one supplier which might not then deliver; by having a number of different suppliers implementing similar systems in parallel, a degree of competition would be present which would not be if a single national contract had been tendered. Four clusters were awarded in two tranches on 8 and 23 December 2003,[*][1][*][3] with the fifth on 26 January 2004.[*][4] However, in July 2007 Accenture withdrew from their 2 clusters, and in May 2008 Fujitsu had their contract terminated, meaning that half the original contractors had dropped out of the project. As of May 2008, two IT providers were LSPs for the main body of the programme:

- Computer Sciences Corporation (CSC) – North, Midlands & Eastern (NME) cluster
- BT Health London (formerly BT Capital Care Alliance) – London cluster
- Accenture had full responsibility for the North East and East/East Midlands clusters until January 2007, when it handed over the bulk of its responsibilities to the CSC, retaining responsibility for Picture archiving and communication system (PACS) rollout only.
- Fujitsu – had responsibility for the Southern cluster until May 2008 when their contract was terminated.[*][32] Most of their responsibilities were subsequently transferred to BT Health except for PACS which was transferred to the CSC Alliance.

Local ownership

In the first half of 2007, David Nicholson announced the "National Programme, Local Ownership programme" (known as "NLOP") which dissolved the 5 clusters and devolved responsibility for the delivery of the programme to the ten English NHS strategic health authorities (SHAs).[*][33] Connecting for Health retains responsibility for the contracts with the LSPs.[*][34]

Under NLOP, staff employed by CfH in the Clusters had their employment transferred to the SHAs, with some being recruited to revised national CfH posts.

National Application Service Providers

In addition to these LSPs the programme has appointed *National Application Service Providers* (NASPs) who are responsible for services that are common to all users e.g. Choose and Book and the national elements of the NHS Care Records Service that support the summary patient record and ensure patient confidentiality and information security. As of October 2005, the NASPs are:

- BT – NHS Care Records Service and N3
- Atos Origin and Cerner – Choose & Book
- Cable and Wireless – NHSmail

Changes to service providers

In March 2004, EDS had their 10-year contract to supply the NHSMail service terminated.[*][35][*][36] On 1 July 2004, Cable and Wireless were contracted to provide this service, which was initially renamed *Contact*.[*][37]

IDX Systems Corporation was removed from the Southern Cluster Fujitsu Alliance in August 2005 following repeated failure to meet deadlines.[*][32] They were replaced in September 2005 by Cerner Corporation.

In early 2006, ComMedica's contract for supply of PACS to the North-West/West-Midlands cluster was terminated, and they were replaced by GE Healthcare.

In July 2006, the London region started the contractual replacement of IDX (which had been bought out by GE Healthcare in January 2006) as its supplier. Systems for secondary care, primary care and community and mental health services are proposed by BT to be provided by Cerner, INPS (formerly in Practice Systems) and CSE Healthcare Systems, part of the CSE-Global group of companies, respectively.[*][38] This is subject to contractual negotiation known as 'CCN2'.

In September 2006, the CSC Alliance, Accenture and Connecting for Health signed a tripartite agreement that as of January 2007, the CSC Alliance would take over the responsibility for the majority of care systems the North East and Eastern clusters from Accenture, with the exception of PACS. As part of the handover process, around 300 Accenture personnel transferred under a TUPE process to CSC, and CSC took over the leases for some of Accenture's premises in Leeds. Accenture now retains only a small presence in the city for the delivery of its PACS responsibilities.

In May 2008 it was announced that following the failure to conclude renegotiation of the contract for the Southern Cluster, CfH terminated the contract with Fujitsu.[*][39] The majority of the Southern Cluster care systems were subsequently transferred to BT Health except for PACS which was transferred to the CSC Alliance, aligning with the technology deployed by each company.

19.11.6 Criticisms of the programme

Failure to deliver clinical benefits

The 2009 Public Accounts Committee report noted that the NPfIT had provided "little clinical functionality...to-date"

The latest PAC report here 18 July 2011

The National Programme for IT in the NHS: an update on the delivery of detailed care records systems

Data security risks

NPfIT has been criticised for inadequate attention to security and patient privacy, with the Public Accounts Committee noting "patients and doctors have understandable concerns about data security", and that the Department of Health did not have a full picture of data security across the NHS.*[8] In 2000, the NHS Executive won the "Most Heinous Government Organisation" Big Brother Award from Privacy International for its plans to implement what would become the NPfIT.*[40] In 2004 the NPfIT won the "Most Appalling Project" Big Brother Award *because of its plans to computerise patient records without putting in place adequate privacy safeguards.*[41]

The balance between the right to privacy and the right to the best quality care is a sensitive one. Also there are sanctions against those who access data inappropriately, specifically instant dismissal and loss of professional registration.

More worryingly, a January 2005 survey among doctors indicates that support for the initiative as an 'important NHS priority' has dropped to 41%, from 70% the previous year.*[42] There have been concerns raised by clinicians that clinician engagement has not been addressed as much as might be expected for such a large project.

Concerns over confidentiality, and the security of medical data uploaded to the Spine have also led to opposition from civil liberties campaigners such as NO2ID the anti-database state pressure group and The Big Opt Out who provide patients with a letter to send to their doctor so that their records are withheld from the database.

Reservations of medical staff

As of 5 August 2005, research carried out across the NHS in England suggested that clinical staff felt that the programme was failing to engage the clinicians fully, and was at risk of becoming a white elephant. The Public Accounts Committee observed in 2009 that "the current levels of support reflect the fact that for many staff the benefits of the Programme are still theoretical".*[8]

Surveys in 2008 suggested that two-thirds of doctors would refuse to have their own medical records on the system.*[43]

Impact on IT providers

According to the Daily Telegraph, the head of NPfIT, Richard Granger, 'shifted a vast amount of the risk associated with the project to service providers, which have to demonstrate that their systems work before being paid.' The contracts meant that withdrawing from the project would leave the providers liable for 50% of the value of the contract; however, as previously mentioned, when Accenture withdrew in September 2006, Granger chose not to use these clauses, saving Accenture more than £930m.*[26]

The programme's largest software provider iSOFT has been seriously affected by this process and is under investigation by the UK Financial Services Authority for irregular accounting.*[44] On 28 September 2006, the consultancy Accenture announced its intention to withdraw from £2bn of 10-year contracts with NPfIT, which were taken over in January 2007 by the CSC Alliance – both Accenture and CSC laid blame with iSOFT, although CSC has said it will be retaining iSOFT as its software provider for all its clusters.*[45] Earlier in the year Accenture had written off $450m from its accounts because of 'significant delays' in the programme. iSOFT announced in March 2011 that trading in its shares would be suspended pending a corporate announcement. Subsequently in April 2011, the company announced that it was recommending a cash offer from CSC. CSC acquired iSOFT in August 2011

19.11.7 Implementation

The first trusts in the London & Southern Clusters to implement the new Cerner system found it problematic, with NHS hospital trust board minutes revealing a catalogue of errors. Difficulties with the system meant that:*[46]

- 2007: Enfield PCT were unable to obtain vital data on patients awaiting operations and were obliged to delay 63 patients of the Barnet and Chase Farm Hospitals. Further, 20 patients were not readmitted for treatment within 28 days towards the end of the year because the surveillance system for tracking them "was not operational in the new ... system". Buckinghamshire Hospitals NHS Trust found that problems with the system had meant potentially infectious patients with MRSA were not isolated for up to 17 days, requiring six weeks work by staff to update them manually.
- April 2008: Enfield PCT found that the system had failed to flag up possible child-abuse victims entering hospital to key staff, "leaving the responsibility to the receptionist"
- May 2008: Enfield PCT found that 272 elective operations were cancelled at the last minute for "non-clinical reasons"

- May 2008: Barts and The London NHS Trust blamed their failure over the preceding six months to meet targets for treating emergency patients within four hours on staff not being familiar with the new computer system. The same report cited "breaches of the two-week urgent cancer access guarantee" and delays in assessing 11 patients with possible cancer as being due to the computer system.
- July 2008: the Royal Free Hampstead NHS Trust said 12,000 patient records had to be manually amended over a three-week period due to the system, and noted that "The outpatient appointment centre has experienced a significant increase in the time taken to process individual patient appointment bookings. This has had a consequent and negative effect on call-answer performance."

19.11.8 Management team

The NHS appointed a management team, responsible for the delivery of the system:[*][47]

- **Richard Granger** the former Director General of IT for the NHS, took up his post in October 2002, before which he was a partner at Deloitte Consulting, responsible for procurement and delivery of a number of large scale IT programmes, including the Congestion Charging Scheme for London. In October 2006, he was suggested by *The Sunday Times* to be the highest paid civil servant, on a basic of £280,000 per year, £100,000 per year more than then-Prime Minister Tony Blair.[*][48] Granger announced on 16 June 2007 that he would leave the agency "during the latter part" of 2007.[*][49] Granger finally left the programme in February 2008.[*][50] Granger's credentials were questioned by his own mother, a campaigner for the preservation of local health services in her area, who expressed her amazement at his appointment, criticising the whole scheme as "a gross waste of money".[*][27]
- **Gordon Hextall** – Chief operating officer for NHS Connecting for Health. A career civil servant. On Richard Granger's departure, Hextall assumed overall responsibility for the programme.
- **Richard Jeavons** – Senior responsible owner for service implementation. Previous posts included being CEO of the West Yorkshire NHS strategic health authority.
- **Harry Cayton** – Chair of the Care Record Development Board.

In 2009, overall leadership of CfH was described by the Public Accounts Committee as having been "uncertain" since the announcement that Richard Granger would be leaving the project.[*][8]

19.11.9 See also

- Megaproject
- National Identity Register
- Citizen Information Project
- Cost overrun
- Universal Child Database
- Medical privacy
- Health Informatics
- N3 (NHS)
- NHS Care Records Service
- Choose and Book
- OPCS-4
- Picture archiving and communication system (PACS)
- NHS Electronic Prescription Service
- Quality Management and Analysis System
- NHSmail

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- June 2006: NHS risks £20bn white elephant, say auditors
- Times Online: Patient records go on database
- Computer loophole hits hi-tech NHS trial
- NHS IT upgrade success 'at risk'
- The Big Opt Out, Advice to patients – How to opt out
- Opting out of the NHS Database Detailed information from Dr Neil Bhatia, a GP in Hampshire
- NHS Information Standards Board for Health and Social Care

19.12 Ontario Telemedicine Network

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Warning: Page using Template:Infobox company with unknown parameter "Company_name" (this message is shown only in preview).

The **Ontario Telemedicine Network** (OTN) is one of the largest telemedicine networks in the world. It uses two-way videoconferencing to provide access to care for patients in every hospital and hundreds of other health care locations across the province. In addition to clinical care, OTN facilitates the delivery of distance education and meetings for health care professionals and patients.

19.12.1 OTN Members and Network Partners

The Network has nearly 600 Members, including all public hospitals, Family Health Teams, clinics, physician offices, nursing stations, medical and nursing schools, professional organizations, Community Care Access Centres, LHIN offices, First Nations Communities, long-term care homes, educational facilities and public health.*[1]

19.12.2 OTN Utilization

The Network consists of more than 1200 sites and 2200 endpoints and more than 3200 health care referrers and consultants use the Network to provide care to patients. In fiscal 2010-11, more than 134,000 patients received care via OTN, a 30% increase over the same period the previous year.*[1]

OTN supports access to care across a wide variety of clinical therapeutic areas of care. The top five clinical categories supporting patient care are mental health and addictions; internal medicine; oncology; surgery and rehabilitation services.*[1]

In addition to facilitating the delivery of patient care, OTN enables teaching and learning at a distance via videoconferencing and webcasting. More than 390,000 health care professionals participate in OTN-facilitated education each year.*[2] In fiscal 2010-11, OTN hosted 11,595 educational events, and 13,146 administrative events. In fiscal 2010-11, OTN hosted more than 1,500 webcasts, a 67% increase over the previous year. There was also a 19% increase in viewership of archived webcasts over 2009-2010, for a total of 28,264 views.*[1]

Use of Telemedicine in the Province resulted in an avoidance of 121 million kilometres of patient travel and an elimination of nearly 65 million kilograms of pollutants.*[1]

19.12.3 References

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19.12.4 External links

- Ontario Telemedicine Network website

19.13 Public Health Information Network

The **Public Health Information Network (PHIN)** is a national initiative, developed by the Centers for Disease Control and Prevention (CDC), for advancing fully capable and interoperable information systems in public health organizations. The initiative involves establishing and implementing a framework for public health information systems.

19.13.1 PHIN Design

PHIN is designed to do the following:

- Enable the consistent exchange of health data
- Protect the security of the health data exchanged
- Ensure that the network will be available at all times

PHIN Structure

The 5 Functional Areas of PHIN:

1. Detection and Monitoring
2. Data Analysis
3. Knowledge Management
4. Alerting
5. Response

The PHIN Framework

"PHIN will elevate and integrate the capabilities of public health information systems across the wide variety of organizations that participate in public health and across the wide variety of interrelated public health functional needs. PHIN is both a response to the needs for better integration among public health systems and a plan for developing systems and infrastructure to better support public health activities and improve public health outcomes. PHIN targets the support and integration of systems for disease surveillance, national health status indicators, data analysis, public health decision support, information resources and knowledge management, alerting and communications and the management of public health response. PHIN includes a portfolio of software solutions and artifacts necessary in building and maintaining interconnected information systems throughout public health at the local, state and federal levels. PHIN advances the National Health Information Infrastructure and federal E-Gov agendas by working with the Federal

Health Architecture (FHA) and implementing the Consolidated Health Informatics (CHI) standards for reducing the burden of private sector reporting through the automated use of electronic clinical data for public health purposes as an alternative to manual reporting. It is consistent with other private sector initiatives such as Connecting for Health and e-Health as well as the industry standards for clinical data messaging such as HL7. PHIN also aligns with the federal e-Gov technical architecture standards such as ebXML and public key infrastructure (PKI). See Standards Development Organizations for more information on national standards."

19.13.2 PHIN's Impact on Public Health

PHIN attempts to provide the public health sector with continuous access to necessary health care information. Access to near real-time data attempts to improve community based interventions that are implemented as a result of terrorism or disease outbreaks.

PHIN provides supports and helps improve the outcomes of various public health programs including the following:

- The U.S. Department of Health and Human Services
  - Desired outcome: improving public health information systems.
- The Secretary of the U.S. Department of Health and Human Services
  - Supports: Terrorism Defense, Healthcare Delivery Improvement, and IT Enhancements.
- Healthy People 2010
  - Supports: Focus area 23 - ensure that public health agencies have the adequate infrastructure to effectively provide essential public health services.
- Partners in public health
  - Desired outcome: "Roadmap" for establishing national capacity for public health systems.

19.13.3 Budget and funding

PHIN first received funding in 2004 through the Department of Health and Human Services and the Centers for Disease Control and Prevention. Between 25% and 30% of the $849 million of funding received through the Public Health Response and Preparedness Cooperative Agreement was to be used to focus on improving public health preparedness in all 50 states, 4 metropolitan areas and 8 US territories. In 2004 the initiative of the program was to "ensure that all public health partners have, or at least will have, access to a system or systems to accomplish established preparedness functions." For year 2005, additional finances will be available to states through the terrorism cooperative agreement. This agreement will support the development of current and new systems, in state health and public health departments, which will meet the PHIN standards and specifications.

19.13.4 Partnerships

In order to collect and assess information system requirements for PHIN, the CDC works with public health partners, some of which include:

- NACCHO - National Association of County and City Health Officials
- ASTHO - Association of State and Territorial Health Officials

With the assistance of these partners, PHIN can target the following functional areas regarding preparedness:

1. Early Event Detection
2. Outbreak Management
3. Connecting Laboratory Services
4. Partner Communications and Alerting
5. Countermeasure/Response Administration

19.13.5 Governance

The approval of technical and data standards for PHIN is completed by two working groups in the CDC Information Council (CIC). The following organizations are represented on each working group by 2 members of its staff: Association of State and Territorial Health Officials (ASTHO), National Association of County and City Health Officials (NACCHO), and Centers for Disease Control and Prevention (CDC). By regulation the standards conform to Department of Health and Human Services (HHS) requirements and the Federal Health architecture.

CIC also ensures that the following standards are met:

- E-Gov activities, which includes all regulations contained in the Government Paperwork Elimination Act (GPEA) goals
- Consolidated Health Informatics (CHI) initiative
- Federal Geographic Data Committee standards required by Office of Management and Budget (OMB) Circular A-16

- Public Health line of business and Public Health Monitoring Sub-function of the Federal Enterprise Architecture Business Reference Model

For more information on these standards, refer to the PHIN Conceptual Diagram provided by PHIN and the CDC.

19.13.6 Preparedness

Early Event Detection

In the realm of preparedness, the PHIN has developed systems to promote early event detection. Information systems that connect health care providers to the PHIN allow for rapid reporting of cases that may lead to public health emergencies. These information systems include call reporting systems, web-based systems, and other electronic case reporting systems. The PHIN has set up technical requirements so that facilities can be equipped to participate in these rapid reporting systems. These requirements also ensure that facilities can protect patient privacy in their reports and ensure integration with outbreak management.

Outbreak Management

Another component in preparedness, the PHIN has a division of outbreak management which allows public health agencies to be adequately prepared for true outbreaks. The outbreak management system is integrated with the early event detection systems to ensure rapid, smooth awareness of outbreaks. The CDC and PHIN currently employ an Outbreak Management System software application to effectively manage data related to outbreaks. OMS demonstration

19.13.7 Connecting Laboratories

Another component of PHIN is connecting laboratories through a set of computer communication standards called HL7. This allows specimen receipts and laboratory results to be exchanged between health organizations and agencies. This is especially useful in times of a health outbreak or other disaster.

19.13.8 Countermeasure and Response Administration

The PHIN also works to track and support the supply of vaccinations and as well as the administration of these tasks. As part of this functionality, the PHIN allows limited supplies of vaccines and other needed drugs to be allocated properly when they are in short supply. Some vaccines and drugs will be traceable to clinics and drug administrators. PHIN also supports response administration by allowing adverse events to be monitored and quarantined populations to be monitored if necessary.

19.13.9 Standards and Specifications

PHIN has a set of Vocabulary Standards and Specifications that:

1. Supports the development and deployment of standards-based public health information systems.
2. Seeks to promote the use of standards-based vocabulary
3. Fosters the use and exchange of consistent information among public health collaborators.
4. Ensures that the vocabularies are aligned with PHIN and CHI standards.

19.13.10 Training

If you are interested in training, CDC offers online trainings on different topics such as: Outbreak Management, Countermeasure and Response Administration, Certification and it also offers PHIN Roadshow Webinairs. Please check calendar of available trainings at:

http://www.cdc.gov/phin/webinars-and-training.html

19.13.11 See also

- HL7
- LOINC
- Health Insurance Portability and Accountability Act
- AtHoc, Inc. Mass Notification and Emergency Communication Systems

19.13.12 External links

- Official website

19.14 SAPPHIRE

The **Situational Awareness and Preparedness for Public Health Incidences and Reasoning Engines (SAPPHIRE)** is a semantics-based health information system capable of tracking and evaluating situations and occurrences that may affect public health. It was developed in 2004 by Dr. Parsa Mirhaji at the University of Texas Health Science Center at Houston using the Semantic Web technologies.

19.14.1 Technology

SAPPHIRE is based upon developing Semantic Web technologies —a set of formats and programming languages (such as the Resource Description Framework language and the Web Ontology Language (OWL)) that find and analyze data on the World Wide Web to enable users to understand and utilize organized information online. *[1] The system is used to gather, organize and impart information on important happenings and events, assisting public health-care professionals to prepare and act. It permits data to be interpreted distinctly, meeting the specific needs of diverse industries, users and disciplines rather than a generalized, universal format. The SAPPHIRE system was developed by the Health Science Center using the RDF technologies developed by Oracle, Inc. and TopQuadrant, Inc.*[2]

19.14.2 Function

SAPPHIRE helps track specific incidences such as the spread and treatment of influenza, AIDS and related information. The system frequently gathers information from select public hospitals, emergency services and care providers and their electronic health records and information provided by medical professionals. *[1] The information is integrated and categorized - flu-related symptoms are analyzed for trends that may indicate probabilities of flu epidemics. Such data is transmitted to institutions such as the Centers for Disease Control and Prevention. SAPPHIRE's processes have also reduced the administrative burdens and inefficiencies at hospitals and clinics. *[1]

19.14.3 Usage after Hurricane Katrina

The University of Houston conducted a pilot test of SAPPHIRE in the aftermath of Hurricane Katrina in the fall of 2005, which devastated the populations and infrastructures of southern Mississippi, Louisiana, Alabama and Texas. Implemented swiftly within hours of mass evacuations, the SAPPHIRE system successfully monitored and analyzed public health information for the usage of government officials and services, who feared outbreaks of epidemics. Officials used hand-held computers to gather data from the evacuees and transmit directly to the SAPPHIRE database. *[3] SAPPHIRE was specifically used to analyze the health of the evacuees at the Astrodome, Reliant Park and the George R. Brown Convention Center.*[2] A PDA extension of SAPPHIRE enabled more than 300 volunteers, led by the UT School of Public Health, to collect and analyze critical health data. SAPPHIRE gathered information from nearly 9,000 confidential patient cases of the past to help services respond to the specific needs of the evacuees, helping to identify environment-specific vulnerabilities, prevalence and conditions for diseases and epidemics.*[2] SAPPHIRE was recorded to have assisted in identifying outbreaks of gastrointestinal, respiratory diseases and conjunctivitis much sooner than previously possible.*[3]

19.14.4 See also

- Ontology (computer science)
- FOAF (software)

19.14.5 References

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19.14.6 External links

- Press Release
- The KnowMED Incorporation
- Parsa Mirhaji

19.15 SmartCare

The **SmartCare** electronic health record system (EHR) has been developed and deployed by the Zambia Ministry of Health (MoH) in collaboration with the Centers for Disease Control and Prevention (CDC) and many other implementing partners.

SmartCare is:

- A fully integrated electronic health record system to provide continuity of care
- A clinical management information system at the facility and district (management/admin) level
- A key component in 'one National M&E system'

SmartCare is also the name of a child care management software solution available in the United States.

19.15.1 Programme vision

- Every Zambian receives cost-effective, confidential, quality health care whenever and wherever they need it.

- Every man, woman and child has an electronic health record;
- Every point of clinical service can access and update this record;
- Every clinician understands the value of this record and is committed to maintaining it;
- Each clinical facility, District, Provincial and the national Ministry of Health HQ routinely monitors & evaluates reports from this data, and uses this information to optimally allocate human and other resources, and to assure continuous systematic improvement in health services.

19.15.2 Programme mission

- To enable the delivery of cost-effective, confidential, quality health care for everyone, everywhere, every time, by improving health records and related health information systems.

19.15.3 System innovations

- **Distributed database system:** Given resource constraints in developing countries such as Zambia where electricity is still not available in some parts of the nation, having Internet access throughout the nation will take many more year. SmartCare data is held at each facility in a distributed design; unlike centralized designs of most systems. Internet is not essential, merely an added benefit.
- **Care Card:** SmartCare uses client carried care cards or staff carried flash drives for a lower-tech connectivity solution that works today. An individual's health information is stored on a very compressed, secure care card to maintain continuity of care between visits, health services and health facilities. The individual's health record is also stored on the health facility installation database for backup and generation of facility level and health management information system reports.
- **Touchscreen:** Making the data capture task bearable can be the most challenging part of EHR design. SmartCare extends a successful Malawi idea, where touchscreen data entry by existing staff lowers this barrier. The software works well with a touch screen monitor enabling the clinician to view and record patient data. This tool, in combination with client specific data, can provide decision support for over-extended clinicians, and clinician assistants. Clinicians can 'read and touch' to enter data; no typing is required. See the image at top for example screen with touch screen technology enabled.
- **GIS data visualization:** Aggregate health data stored at health facilities can be visualized in GIS maps. This includes live patient data as well as static data from health surveys.

19.15.4 Deployment status in Zambia

- Ministry of Health, Zambia has deployed SmartCare in > 800 facilities (clinical and district/provincial/national levels), in 94 districts (mid-2014); patient enrollment >200,000
- Partners are supporting deployment in government and private facilities (for instance: ZPCT >44, CIDRZ >56, AIDSRelief >12), but government deployment & enrollment rates are increasing most rapidly

19.15.5 Future plans in Zambia

- Capacity building and systems strengthening by developing SmartCare
- Completion of ambulatory service modules e.g. OPD, family planning, and children's clinic
- Systems integrations with other health record systems in Zambia ex: ZEPRS
- Integration of drug stock management system

19.15.6 Customizations

- Ethiopia - Electronic Health Record System called SmartCare-Ethiopia. The system is currently being piloted in one of the hospitals (as of December 2007)
- Zambian National Blood Transfusion Service - Blood donor data collection and reporting system called the SmartDonor module. The system is being piloted at the national blood transfusion centre headquarters (as of January 2009) and plans to deploy to the 9 provincial transfusion centres are underway

19.15.7 Related systems

- OpenMRS
- OpenEMR
- WorldVistA
- ZEPRS

19.15.8 External links

- http://www.smartcare.org.zm Official SmartCare Website

19.15.9 References

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Chapter 20

International Projects

20.1 Building Europe-Africa Collaborative Network for Applying IST in Health Care Sector

This article is about health-information initiative. For the Tales of the BeanWorld character, see Tales of the Beanworld. For the constructed language used in *xkcd*, see Time (xkcd) § Language.

The **BEANISH** initiative (**Building Europe Africa collaborative Network for applying IST in Health care sector**) seeks to support the application and sharing of IST application development in the African health-care sector. In order to do so, the initiative will involve various institutional actors (government, universities, private sector and NGOs) to strengthen and extend an existing Europe-Africa collaborative R&D network, namely HISP (Health Information Systems Programme). This is intended to strengthen cooperation, learning and innovation on both continents.

The initiative is formally a WITFOR (World Information Technology Forum) project, proposed by EU-African partners and IFIP (International Federation for Information Processing).

20.1.1 External links

- BEANISH Home Page

20.2 Global Infectious Disease Epidemiology Network

Global Infectious Diseases and Epidemiology Online Network (GIDEON) is a web-based program for decision support and informatics in the fields of Infectious Diseases and Geographic Medicine. As of 2005, more than 300 generic infectious diseases occur haphazardly in time and space and are challenged by over 250 drugs and vaccines. 1,500 species of pathogenic bacteria, viruses, parasites and fungi have been described. Printed media can no longer follow the dynamics of diseases, outbreaks and epidemics in "real time."

20.2.1 Organization

GIDEON consists of four modules. The first Diagnosis module generates a Bayesian ranked differential diagnosis based on signs, symptoms, laboratory tests, country of origin and incubation period - and can be used for diagnosis support and simulation of all infectious diseases in all countries. Since the program is web-based, this module can also be adapted to disease and bioterror surveillance.

The second module follows the epidemiology of individual diseases, including their global background and status in each of 205 countries and regions. All past and current outbreaks of all diseases, in all countries, are described in detail. The user may also access a list of diseases compatible with any combination of agent, vector, vehicle, reservoir and country (for example, one could list all the mosquito-borne flaviviruses of Brazil which have an avian reservoir). Over 30,000 graphs display all the data, and are updated in "real time." These graphs can be used for preparation of PowerPoint displays, pamphlets, lecture notes, etc. Several thousand high-quality images are also available, including clinical lesions, roentgenograms, Photomicrographs and disease life cycles.

The third module is an interactive encyclopedia which incorporates the pharmacology, usage, testing standards and global trade names of all antiinfective drugs and vaccines.

The fourth module is designed to identify or characterize all species of bacteria, mycobacteria and yeasts. The database includes 50 to 100 taxa which may not appear in standard texts and laboratory databases for several months.

Additional options allow users to add data (in their own font / language) relevant to their own institution, electronic patient charts, material from the internet, important telephone numbers, drug prices, antimicrobial resistance patterns, etc. This form of custom data is particularly useful when running GIDEON on institutional networks. The data in GIDEON are derived from:

- all peer-reviewed journals in the fields of Infectious Diseases, Pediatrics, Internal Medicine, Tropical Medicine, Travel Medicine, Antimicrobial Pharmacology and Clinical Microbiology
- a monthly electronic literature search based on all relevant keywords
- all available health ministry reports (both printed and electronic)
- standard texts
- abstracts of major meetings

20.2.2 Related products

- VIPatients created by the author of GIDEON

20.2.3 External links

- GIDEON description at EBSCO
- GIDEON

20.3 Integrating the Healthcare Enterprise

Integrating the Healthcare Enterprise (**IHE**) is a nonprofit organization based in the US state of Illinois.*[1] It sponsors an initiative by the healthcare industry to improve the way computer systems share information. IHE was established in 1998 by a consortium of radiologists and information technology (IT) experts.

20.3.1 Operations

IHE created and operates a process through which interoperability of health care IT systems can be improved. The group gathers case requirements, identifies available standards, and develops technical guidelines which manufacturers can implement. IHE also stages "connectathons" and "interoperability showcases" in which vendors assemble to demonstrate the interoperability of their products.*[2]

20.3.2 Sponsorship

IHE is sponsored by the Healthcare Information and Management Systems Society (HIMSS), the Radiological Society of North America (RSNA), and the American College of Cardiology (ACC). The eye care domain is sponsored by the American Academy of Ophthalmology.

20.3.3 Projects

IHE integration profiles describe a clinical information need or workflow scenario and document how to use established standards to accomplish it. A group of systems that implement the same integration profile address the need/scenario in a mutually compatible way.

For example, the Digital Imaging and Communications in Medicine (DICOM) standards specify many different formats for image data. A given set of images that might comply with some optional parts of the standards might still not be accepted by an application in use by a particular radiologist. Profiles reduce the chances of these incompatibilities.*[3]

The Logical Observation Identifiers Names and Codes (LOINC) standard codes for use in databases are often used in IHE profiles.*[4]

A model for cross-enterprise document sharing called XDS allows hospitals to share electronic records that use the Health Level 7 (HL7) standards and LOINC codes.*[5]*[6] The United States Department of Veterans Affairs revised its plans in 1999 to adopt IHE recommendations.*[7]

IHE integration statements are prepared and published by a vendor to list the IHE profiles supported by a specific release of a specific product.

IHE technical frameworks are detailed documents which specify the integration profiles and associated actors (systems) and transactions.*[8] For example, one specification is for a common way of binding identification numbers to patients.*[9]

IHE connectathons are annual events where equipment vendors bring products with IHE profiles and test them with other vendors.*[10] The events are held in Europe, USA, Korea, Japan and Australia.*[11]*[12]*[13]*[14]The term "connectathon" was coined in the 1980s by Sun Microsystems for similar vendor-neutral interoperability testing of the Network File System protocols and related technologies.*[15] The first NFS Connectathon was held in 1985.*[16]

In 2008, an agreement was announced for cooperation with the Continua Health Alliance.*[17]

In 2012, a guide was published on access to health data from mobile devices.*[18]

Although in 2004 an estimate was that complete interoperability could be completed in ten years, by 2013 results were still mixed.*[19]

In 2013, co-chairs were David Mendelson, director of clinical informatics at Mount Sinai Medical Center*[20] and Elliot B. Sloane of the Center for Healthcare Information Research and Policy and research professor at Drexel University.*[21]*[22]

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20.3.5 External links

- Official website

Chapter 21

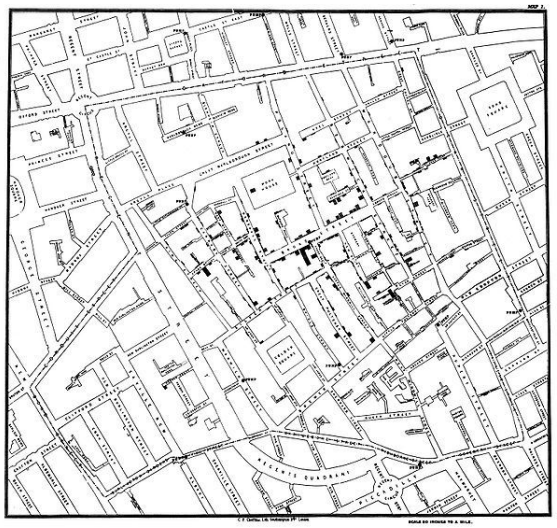
Miscellanea

21.1 GIS and Public Health

Geographic information systems (GISs) and geographic information science (GIScience) combine computer-mapping capabilities with additional database management and data analysis tools. Commercial GIS systems are very powerful and have touched many applications and industries, including environmental science, urban planning, agricultural applications, and others.

Public health is another focus area that has made increasing use of GIS techniques. A strict definition of public health is difficult to pin down, as it is used in different ways by different groups. In general, public health differs from personal health in that it is (1) focused on the health of populations rather than of individuals, (2) focused more on prevention than on treatment, and (3) operates in a mainly governmental (rather than private) context.*[1] These efforts fall naturally within the domain of problems requiring use of spatial analysis as part of the solution, and GIS and other spatial analysis tools are therefore recognized as providing potentially transformational capabilities for public health efforts.

This article presents some history of use of geographic information and geographic information systems in public health application areas, provides some examples showing the utilization of GIS techniques in solving specific public health problems, and finally addresses several potential issues arising from increased use of these GIS techniques in the public health arena.



Dr. Snow's map showing cholera cases in London during the epidemic of 1854.

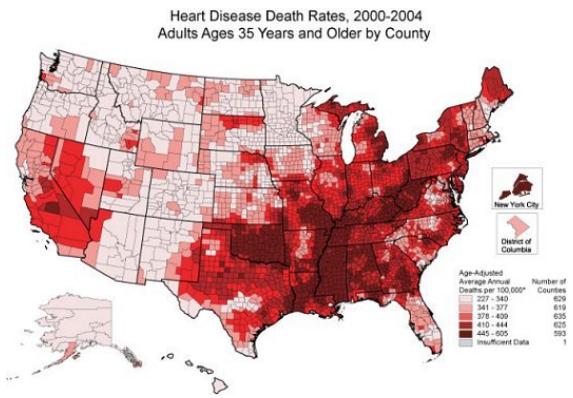
21.1.1 History

Public health efforts have been based on analysis and use of spatial data for many years. Dr. John Snow (physician), often credited as the father of epidemiology, is arguably the most famous of those examples.*[2] Dr. Snow used a hand-drawn map to analyze the geographic locations of deaths related to cholera in London in the mid-1850s. His map, which superimposed the locations of cholera deaths with those of public water supplies, pinpointed the Broad Street pump as the most likely source of the cholera outbreak. Removal of the pump handle led to a rapid decline in the incidence of cholera, helping the medical community to eventually conclude that cholera was a water-borne disease.

Dr. Snow's work provides an indication of how a GIS could benefit public health investigations and other research. He continued to analyze his data, eventually showing that the incidence rate of cholera was also related to local elevation as well as soil type and alkalinity. Low-lying areas, particularly those with poorly draining soil, were found to have higher incidence rates for cholera, which Dr. Snow attributed to the pools of water that tended to collect there, again showing evidence that cholera was in fact a water-borne disease (rather than one borne by 'miasma' as was commonly believed at the time.*[3]

This is an early example of what has come to be known as disease diffusion mapping, an area of study based on the idea that a disease starts from some source or central point and then spreads throughout the local area according to patterns and conditions there. This is another area of research where the capabilities of a GIS have been shown to be of help to practitioners.

21.1.2 GIS for public health



More modern disease map showing deaths from heart disease among white males in the US from 2000–2004.

Today's public health problems are much larger in scope than those Dr. Snow faced, and researchers today depend on modern GIS and other computer mapping applications to assist in their analyses. For example, see the map to the right depicting death rates from heart disease among white males above age 35 in the US between 2000 and 2004.*[4]

Public health informatics (PHI) is an emerging specialty which focuses on the application of information science and technology to public health practice and research.*[5] As part of that effort, a GIS – or more generally a spatial decision support system (SDSS) – offers improved geographic visualization techniques, leading to faster, better, and more robust understanding and decision-making capabilities in the public health arena.*[6]

For example, GIS displays have been used to show a clear relationship between clusters of emergent Hepatitis C cases and those of known intravenous drug users in Connecticut.*[7] Causality is difficult to prove conclusively – collocation does not establish causation – but confirmation of previously established causal relationships (like intravenous drug use and Hepatitis C) can strengthen acceptance of those relationships, as well as help to demonstrate the utility and reliability of GIS-related solution techniques. Conversely, showing the coincidence of potential causal factors with the ultimate effect can help suggest a potential causal relationship, thereby driving further investigation and analysis (source needed?).

Alternately, GIS techniques have been used to show a lack of correlation between causes and effects or between different effects. For example, the distributions of both birth defects and infant mortality in Iowa were studied, and the researchers found no relationship in those data.*[8] This led to the conclusion that birth defects and infant mortality are likely unrelated, and are likely due to different causes and risk factors.

GIS can support public health in different ways as well. First and foremost, GIS displays can help inform proper understanding and drive better decisions. For example, elimination of health disparities is one of two primary goals of Healthy People 2010, one of the preeminent public health programs in existence today in the US. GIS can play a significant role in that effort, helping public health practitioners identify areas of disparities or inequities, and ideally helping them identify and develop solutions to address those shortcomings. GIS can also help researchers integrate disparate data from a wide variety of sources, and can even be used to enforce quality control measures on those data. Much public health data is still manually generated, and is therefore subject to human-generated mistakes and miscoding. For example, geographic analysis of health care data from North Carolina showed that just over 40% of the records contained errors of some sort in the geographic information (city, county, or zip code), errors that would have gone undetected without the visual displays provided by GIS.*[9] Correction of these errors led not only to more correct GIS displays, but also improved ALL analyses using those data.

21.1.3 Issues with GIS for public health

There are also concerns or issues with use of GIS tools for public health efforts. Chief among those is a concern for privacy and confidentiality of individuals.*[10] Public health is concerned about the health of the population as a whole, but must use data on the health of individuals to make many of those assessments, and protecting the privacy and confidentiality of those individuals is of paramount importance. Use of GIS displays and related databases raises the potential of compromising those privacy standards, so some precautions are necessary to avoid pinpointing individuals based on spatial data. For example, data may need to be aggregated to cover larger areas such as a zip code or county, helping to mask individual identities. Maps can also be constructed at smaller scales so that less detail is revealed. Alternately, key identifying features (such as the road and street network) can be left off the maps to mask exact location, or it may even be advisable to intentionally offset the location markers by some random amount if deemed necessary.*[11]

It is well established in the literature that statistical inference based on aggregated data can lead researchers to erroneous conclusions, suggesting relationships that in fact do not exist or obscuring relationships that do in fact exist. This issue is known as the modifiable areal unit problem. For example, New York public health officials worried that cancer clusters and causes would be misidentified after they were forced to post maps showing cancer cases by ZIP code on the internet. Their assertion was that ZIP codes were designed for a purpose unrelated to public health issues, and so use of these arbitrary boundaries might lead to inappropriate groupings and then to incorrect conclusions.*[12]

21.1.4 Summary

Use of GIS in public health is an application area still in its infancy. Like most new applications, there is a lot of promise, but also a lot of pitfalls that must be avoided along the way. Many researchers and practitioners are concentrating of this effort, hoping that the benefits outweigh the risks and the costs associated with this emerging application area for modern GIS techniques.

21.1.5 See also

- Geospatial predictive modeling
- Public health
- Time geography

21.1.6 Footnotes

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21.1.7 External links

- National Center for Health Statistics
- GIS and Public Health at Esri
- Consortium for Public Health Informatics
- International Journal of Health Geographics

21.2 Neuroinformatics

For the scientific journal, see Neuroinformatics (journal).

Neuroinformatics is a research field concerned with the organization of neuroscience data by the application of computational models and analytical tools. These areas of research are important for the integration and analysis of increasingly large-volume, high-dimensional, and fine-grain experimental data. Neuroinformaticians provide computational tools, mathematical models, and create interoperable databases for clinicians and research scientists. Neuroscience is a heterogeneous field, consisting of many and various sub-disciplines (e.g., Cognitive Psychology, Behavioral Neuroscience, and Behavioral Genetics). In order for our understanding of the brain to continue to deepen, it is necessary that these sub-disciplines are able to share data and findings in a meaningful way; Neuroinformaticians facilitate this.*[1]

Neuroinformatics stands at the intersection of neuroscience and information science. Other fields, like genomics, have demonstrated the effectiveness of freely-distributed databases and the application of theoretical and computational models for solving complex problems. In Neuroinformatics, such facilities allow researchers to more easily quantitatively confirm their working theories by computational modeling. Additionally, neuroinformatics fosters collaborative research —an important fact that facilitates the field's

interest in studying the multi-level complexity of the brain.

There are three main directions where neuroinformatics has to be applied:* [2]

1. the development of tools and databases for management and sharing of neuroscience data at all levels of analysis,

2. the development of tools for analyzing and modeling neuroscience data,

3. the development of computational models of the nervous system and neural processes.

In the recent decade, as vast amounts of diverse data about the brain were gathered by many research groups, the problem was raised of how to integrate the data from thousands of publications in order to enable efficient tools for further research. The biological and neuroscience data are highly interconnected and complex, and by itself, integration represents a great challenge for scientists.

Combining informatics research and brain research provides benefits for both fields of science. On one hand, informatics facilitates brain data processing and data handling, by providing new electronic and software technologies for arranging databases, modeling and communication in brain research. On the other hand, enhanced discoveries in the field of neuroscience will invoke the development of new methods in information technologies (IT).

21.2.1 History

Starting in 1989, the United States National Institute of Mental Health (NIMH), the National Institute of Drug Abuse (NIDA) and the National Science Foundation (NSF) provided the National Academy of Sciences Institute of Medicine with funds to undertake a careful analysis and study of the need to create databases, share neuroscientific data and to examine how the field of information technology could create the tools needed for the increasing volume and modalities of neuroscientific data. The positive recommendations were reported in 1991 ("Mapping The Brain And Its Functions. Integrating Enabling Technologies Into Neuroscience Research." National Academy Press, Washington, D.C. ed. Pechura, C.M., and Martin, J.B.) This positive report enabled NIMH, now directed by Allan Leshner, to create the "Human Brain Project" (HBP), with the first grants awarded in 1993. The HBP was led by Koslow along with cooperative efforts of other NIH Institutes, the NSF, the National Aeronautics and Space Administration and the Department of Energy. The HPG and grant-funding initiative in this area slightly preceded the explosive expansion of the World Wide Web. From 1993 through 2004 this program grew to over 100 million dollars in funded grants.

Next, Koslow pursued the globalization of the HPG and neuroinformatics through the European Union and the Office for Economic Co-operation and Development (OECD), Paris, France. Two particular opportunities occurred in 1996.

- The first was the existence of the US/European Commission Biotechnology Task force co-chaired by Mary Clutter from NSF. Within the mandate of this committee, of which Koslow was a member the United States European Commission Committee on Neuroinformatics was established and co-chaired by Koslow from the United States. This committee resulted in the European Commission initiating support for neuroinformatics in Framework 5 and it has continued to support activities in neuroinformatics research and training.

- A second opportunity for globalization of neuroinformatics occurred when the participating governments of the Mega Science Forum (MSF) of the OECD were asked if they had any new scientific initiatives to bring forward for scientific cooperation around the globe. The White House Office of Science and Technology Policy requested that agencies in the federal government meet at NIH to decide if cooperation were needed that would be of global benefit. The NIH held a series of meetings in which proposals from different agencies were discussed. The proposal recommendation from the U.S. for the MSF was a combination of the NSF and NIH proposals. Jim Edwards of NSF supported databases and data-sharing in the area of biodiversity; Koslow proposed the HPG ? as a model for sharing neuroscientific data, with the new moniker of *neuroinformatics*.

The two related initiates were combined to form the United States proposal on "Biological Informatics". This initiative was supported by the White House Office of Science and Technology Policy and presented at the OECD MSF by Edwards and Koslow. An MSF committee was established on Biological Informatics with two subcommittees: 1. Biodiversity (Chair, James Edwards, NSF), and 2. Neuroinformatics (Chair, Stephen Koslow, NIH). At the end of two years the Neuroinformatics subcommittee of the Biological Working Group issued a report supporting a global neuroinformatics effort. Koslow, working with the NIH and the White House Office of Science and Technology Policy to establishing a new Neuroinformatics working group to develop specific recommendation to support the more general recommendations of the first report. The Global Science Forum (GSF; renamed from MSF) of the OECD supported this recommendation.

The International Neuroinformatics Coordinating Facility

This committee presented 3 recommendations to the member governments of GSF. These recommendations were:

1. National neuroinformatics programs should be continued or initiated in each country should have a national node to both provide research resources nationally and to serve as the contact for national and international coordination.

2. An International Neuroinformatics Coordinating Facility (INCF) should be established. The INCF will coordinate the implementation of a global neuroinformatics network through integration of national neuroinformatics nodes.

3. A new international funding scheme should be established. This scheme should eliminate national and disciplinary barriers and provide a most efficient approach to global collaborative research and data sharing. In this new scheme, each country will be expected to fund the participating researchers from their country.

The GSF neuroinformatics committee then developed a business plan for the operation, support and establishment of the INCF which was supported and approved by the GSF Science Ministers at its 2004 meeting. In 2006 the INCF was created and its central office established and set into operation at the Karolinska Institute, Stockholm, Sweden under the leadership of Sten Grillner. Sixteen countries (Australia, Canada, China, the Czech Republic, Denmark, Finland, France, Germany, India, Italy, Japan, the Netherlands, Norway, Sweden, Switzerland, the United Kingdom and the United States), and the EU Commission established the legal basis for the INCF and Programme in International Neuroinformatics (PIN). To date, fourteen countries (Czech Republic, Finland, France, Germany, Italy, Japan, Norway, Sweden, Switzerland, and the United States) are members of the INCF. Membership is pending for several other countries.

The goal of the INCF is to coordinate and promote international activities in neuroinformatics. The INCF contributes to the development and maintenance of database and computational infrastructure and support mechanisms for neuroscience applications. The system is expected to provide access to all freely accessible human brain data and resources to the international research community. The more general task of INCF is to provide conditions for developing convenient and flexible applications for neuroscience laboratories in order to improve our knowledge about the human brain and its disorders.

Society for Neuroscience Brain Information Group

On the foundation of all of these activities, Huda Akil, the 2003 President of the Society for Neuroscience (SfN) established the Brain Information Group (BIG) to evaluate the importance of neuroinformatics to neuroscience and specifically to the SfN. Following the report from BIG, SfN also established a neuroinformatics committee.

In 2004, SfN announced the Neuroscience Database Gateway (NDG) as a universal resource for neuroscientists through which almost any neuroscience databases and tools may be reached. The NDG was established with funding from NIDA, NINDS and NIMH. The Neuroscience Database Gateway has transitioned to a new enhanced platform, the Neuroscience Information Framework <http://www.neuinfo.org>. Funded by the NIH Neuroscience BLueprint, the NIF is a dynamic portal providing access to neuroscience-relevant resources (data, tools, materials) from a single search interface. The NIF builds upon the foundation of the NDG, but provides a unique set of tools tailored especially for neuroscientists: a more expansive catalog, the ability to search multiple databases directly from the NIF home page, a custom web index of neuroscience resources, and a neuroscience-focused literature search function.

21.2.2 Collaboration with other disciplines

Neuroinformatics is formed at the intersections of the following fields:

- neuroscience
- computer science
- biology
- experimental psychology
- medicine
- engineering
- physical sciences
- mathematics
- chemistry

Biology is concerned with molecular data (from genes to cell specific expression); medicine and anatomy with the structure of synapses and systems level anatomy; engineering – electrophysiology (from single channels to scalp surface EEG), brain imaging; computer science – databases, software tools, mathematical sciences – models, chemistry – neurotransmitters, etc. Neuroscience uses all aforementioned experimental and theoretical studies to learn about the brain through its various levels. Medical and biological specialists help to identify

the unique cell types, and their elements and anatomical connections. Functions of complex organic molecules and structures, including a myriad of biochemical, molecular, and genetic mechanisms which regulate and control brain function, are determined by specialists in chemistry and cell biology. Brain imaging determines structural and functional information during mental and behavioral activity. Specialists in biophysics and physiology study physical processes within neural cells neuronal networks. The data from these fields of research is analyzed and arranged in databases and neural models in order to integrate various elements into a sophisticated system; this is the point where neuroinformatics meets other disciplines.

Neuroscience provides the following types of data and information on which neuroinformatics operates:

- Molecular and cellular data (ion channel, action potential, genetics, cytology of neurons, protein pathways),
- Data from organs and systems (visual cortex, perception, audition, sensory system, pain, taste, motor system, spinal cord),
- Cognitive data (language, emotion, motor learning, sexual behavior, decision making, social neuroscience),
- Developmental information (neuronal differentiation, cell survival, synaptic formation, motor differentiation, injury and regeneration, axon guidance, growth factors),
- Information about diseases and aging (autonomic nervous system, depression, anxiety, Parkinson's disease, addiction, memory loss),
- Neural engineering data (brain-computer interface), and
- Computational neuroscience data (computational models of various neuronal systems, from membrane currents, proteins to learning and memory).

Neuroinformatics uses databases, the Internet, and visualization in the storage and analysis of the mentioned neuroscience data.

21.2.3 Research programs and groups

Neuroscience Information Framework

Main article: Neuroscience Information Framework

The Neuroscience Information Framework (NIF) is an initiative of the NIH Blueprint for Neuroscience Research, which was established in 2004 by the National Institutes of Health. Unlike general search engines, NIF provides deeper access to a more focused set of resources that are relevant to neuroscience, search strategies tailored to neuroscience, and access to content that is traditionally "hidden" from web search engines. The NIF is a dynamic inventory of neuroscience databases, annotated and integrated with a unified system of biomedical terminology (i.e. NeuroLex). NIF supports concept-based queries across multiple scales of biological structure and multiple levels of biological function, making it easier to search for and understand the results. NIF will also provide a registry through which resources providers can disclose availability of resources relevant to neuroscience research. NIF is not intended to be a warehouse or repository itself, but a means for disclosing and locating resources elsewhere available via the web.

Genes to Cognition Project

Main article: Genes to Cognition Project

A neuroscience research programme that studies genes, the brain and behaviour in an integrated manner. It is engaged in a large-scale investigation of the function of molecules found at the synapse. This is mainly focused on proteins that interact with the NMDA receptor, a receptor for the neurotransmitter, glutamate, which is required for processes of synaptic plasticity such as long-term potentiation (LTP). Many of the techniques used are high-throughput in nature, and integrating the various data sources, along with guiding the experiments has raised numerous informatics questions. The program is primarily run by Professor Seth Grant at the Wellcome Trust Sanger Institute, but there are many other teams of collaborators across the world.

Neurogenetics: GeneNetwork

Genenetwork started as component of the NIH Human Brain Project in 1999 with a focus on the genetic analysis of brain structure and function. This international program consists of tightly integrated genome and phenome data sets for human, mouse, and rat that are designed specifically for large-scale systems and network studies relating gene variants to differences in mRNA and protein expression and to differences in CNS structure and behavior. The great majority of data are open access. GeneNetwork has a companion neuroimaging web site —the Mouse Brain Library—that contains high resolution images for thousands of genetically defined strains of mice.

The Blue Brain Project

Main article: Blue Brain

The Blue Brain Project was founded in May 2005, and uses an 8000 processor Blue Gene/L supercomputer developed by IBM. At the time, this was one of the fastest supercomputers in the world. The project involves:

- **Databases**: 3D reconstructed model neurons, synapses, synaptic pathways, microcircuit statistics, computer model neurons, virtual neurons.
- **Visualization**: microcircuit builder and simulation results visualizator, 2D, 3D and immersive visualization systems are being developed.
- **Simulation**: a simulation environment for large scale simulations of morphologically complex neurons on 8000 processors of IBM's Blue Gene supercomputer.
- **Simulations and experiments**: iterations between large scale simulations of neocortical microcircuits and experiments in order to verify the computational model and explore predictions.

The mission of the Blue Brain Project is to understand mammalian brain function and dysfunction through detailed simulations. The Blue Brain Project will invite researchers to build their own models of different brain regions in different species and at different levels of detail using Blue Brain Software for simulation on Blue Gene. These models will be deposited in an internet database from which Blue Brain software can extract and connect models together to build brain regions and begin the first whole brain simulations.

The Neuroinformatics Portal Pilot

The project is part of a larger effort to enhance the exchange of neuroscience data, data-analysis tools, and modeling software. The portal is supported from many members of the OECD Working Group on Neuroinformatics. The Portal Pilot is promoted by the German Ministry for Science and Education.

The Neuronal Time Series Analysis (NTSA)

NTSA Workbench is a set of tools, techniques and standards designed to meet the needs of neuroscientists who work with neuronal time series data. The goal of this project is to develop information system that will make the storage, organization, retrieval, analysis and sharing of experimental and simulated neuronal data easier. The ultimate aim is to develop a set of tools, techniques and standards in order to satisfy the needs of neuroscientists who work with neuronal data.

Japan national neuroinformatics resource

The Visiome Platform is the Neuroinformatics Search Service that provides access to mathematical models, experimental data, analysis libraries and related resources.

An online portal for neurophysiological data sharing is also available at BrainLiner.jp as part of the MEXT Strategic Research Program for Brain Sciences (SRPBS).

The CARMEN project

The CARMEN project is a multi-site (11 universities in the United Kingdom) research project aimed at using GRID computing to enable experimental neuroscientists to archive their datasets in a structured database, making them widely accessible for further research, and for modellers and algorithm developers to exploit.

The Cognitive Atlas

The Cognitive Atlas is a project developing a shared knowledge base in cognitive science and neuroscience. This comprises two basic kinds of knowledge: tasks and concepts, providing definitions and properties thereof, and also relationships between them. An important feature of the site is ability to cite literature for assertions (e.g. "The Stroop task measures executive control") and to discuss their validity. It contributes to NeuroLex and the Neuroscience Information Framework, allows programmatic access to the database, and is built around semantic web technologies.

21.2.4 Research groups

- *The Institute of Neuroinformatics* (INI) was established at the University of Zurich at the end of 1995. The mission of the Institute is to discover the key principles by which brains work and to implement these in artificial systems that interact intelligently with the real world.
- *The THOR Center for Neuroinformatics* was established April 1998 at the Department of Mathematical Modelling, Technical University of Denmark. Besides pursuing independent research goals, the THOR Center hosts a number of related projects concerning neural networks, functional neuroimaging, multimedia signal processing, and biomedical signal processing.
- *Netherlands state program* in neuroinformatics started in the light of the international OECD Global Science Forum which aim is to create a worldwide program in Neuroinformatics.
- Shun-ichi Amari, Laboratory for Mathematical Neuroscience, RIKEN Brain Science Institute

Wako, Saitama, Japan. The target of Laboratory for Mathematical Neuroscience is to establish mathematical foundations of brain-style computations toward construction of a new type of information science.

- Gary Egan, Neuroimaging & Neuroinformatics, Howard Florey Institute, University of Melbourne, Melbourne, Australia. Institute scientists utilize brain imaging techniques, such as magnetic resonance imaging, to reveal the organization of brain networks involved in human thought.
- Andreas VM Herz Computational Neuroscience, ITB, Humboldt-University Berlin, Berlin Germany. This group focuses on computational neurobiology, in particular on the dynamics and signal processing capabilities of systems with spiking neurons.
- Nicolas Le Novère, EBI Computational Neurobiology, EMBL-EBI Hinxton, United Kingdom. The main goal of the group is to build realistic models of neuronal function at various levels, from the synapse to the micro-circuit, based on the precise knowledge of molecule functions and interactions (Systems Biology)
- *The Neuroinformatics Group in Bielefeld* has been active in the field of Artificial Neural Networks since 1989. Current research programmes within the group are focused on the improvement of man-machine-interfaces, robot-force-control, eye-tracking experiments, machine vision, virtual reality and distributed systems.
- Hanchuan Peng, Allen Institute for Brain Science, Seattle, USA. This group has focused on using large scale imaging computing and data analysis techniques to reconstruct single neuron models and mapping them in brains of different animals.
- Laboratory of Computational Embodied Neuroscience (LOCEN), Institute of Cognitive Sciences and Technologies, Italian National Research Council (ISTC-CNR), Rome, Italy. This group, founded in 2006 and currently led by Gianluca Baldassarre, has two objectives: (a) understanding the brain mechanisms underlying learning and expression of sensorimotor behaviour, and related motivations and higher-level cognition grounded on it, on the basis of embodied computational models; (b) transferring the acquired knowledge to building innovative controllers for autonomous humanoid robots capable of learning in an open-ended fashion on the basis of intrinsic and extrinsic motivations.

21.2.5 Books in the field

- Computing the Brain: A Guide to Neuroinformatics by Michael A. Arbib and Jeffrey S. Grethe (2001), ISBN 978-0123885432
- Electronic Collaboration in Science (Progress in Neuroinformatics Research Series) by Stephen H. Koslow and Michael F. Huerta (2000), ISBN 978-1138003187
- Databasing the Brain: From Data to Knowledge (Neuroinformatics) by Steven H. Koslow and Shankar Subramaniam, (2005), ISBN 978-0471309215
- Neuroinformatics: An Overview of the Human Brain Project (Progress in Neuroinformatics Research Series) by Stephen H. Koslow and Michael F. Huerta (1997),
- Neuroscience Databases: A Practical Guide by Rolf Kötter (2002),
- Biomedical Informatics: Computer Applications in Health Care and Biomedicine (Health Informatics) by James J. Cimino and Edward H. Shortliffe. (2006),
- Computational Neuroanatomy: Principles and Methods edited by Giorgio Ascoli (2002),
- Observed Brain Dynamics by Partha P. Mitra and Hemant Bokil (2007), ISBN 978-0195178081
- Neuroinformatics In: Methods in Molecular Biology. Ed. Chiquito J. Crasto, (2007),
- Principles of Computational Modelling in Neuroscience by David Steratt et al. (2011)

21.2.6 Journals in the field

- *Frontiers in Neuroinformatics*. Open-access journal receiving submissions from all areas of neuroinformatics
- *Neuroinformatics*. The aim of this journal is to encourage, facilitate, and disseminate the use of software tools and databases in the neuroscience community to discover the key principles by which brains work
- *Journal of Computational Neuroscience*
- *PLoS Computational Biology*
- *Brain Informatics*
- *Biological Cybernetics*
- *Neural Computation*
- *Journal on Web Semantics*. Theory and Applications, Artificial Intelligence
- *Journal of Integrative Neuroscience*. Journal of Neuroscience

- *Neural Information Processing*. Letters and Review Neuroscience, Computational, Neuroinformatics, Theory and Applications
- *Interdisciplinary Description of Complex Systems*. General science
- *Neuron*. General Neuroscience, Cellular Neuroscience
- *Science*. General Science

21.2.7 Technologies and developments

The main technological tendencies in neuroinformatics are:

1. Application of computer science for building databases, tools, and networks in neuroscience;
2. Analysis and modeling of neuronal systems.

In order to organize and operate with neural data scientists need to use the standard terminology and atlases that precisely describe the brain structures and their relationships.

- Neuron Tracing and Reconstruction is an essential technique to establish digital models of the morphology of neurons. Such morphology is useful for neuron classification and simulation.
- **BrainML**[*] [3] is a system that provides a standard XML metaformat for exchanging neuroscience data.
- The **Biomedical Informatics Research Network** (BIRN)[*] [4] is an example of a grid system for neuroscience. BIRN is a geographically distributed virtual community of shared resources offering vast scope of services to advance the diagnosis and treatment of disease. BIRN allows combining databases, interfaces and tools into a single environment.
- **Budapest Reference Connectome** is a web based 3D visualization tool to browse connections in the human brain. Nodes, and connections are calculated from the MRI datasets of the Human Connectome Project.
- **GeneWays**[*] [5] is concerned with cellular morphology and circuits. GeneWays is a system for automatically extracting, analyzing, visualizing and integrating molecular pathway data from the research literature. The system focuses on interactions between molecular substances and actions, providing a graphical view on the collected information and allows researchers to review and correct the integrated information.
- **Neocortical Microcircuit Database** (NMDB).[*] [6] A database of versatile brain's data from cells to complex structures. Researchers are able not only to add data to the database but also to acquire and edit one.
- **SenseLab**.[*] [7] SenseLab is a long-term effort to build integrated, multidisciplinary models of neurons and neural systems. It was founded in 1993 as part of the original Human Brain Project. A collection of multilevel neuronal databases and tools. SenseLab contains six related databases that support experimental and theoretical research on the membrane properties that mediate information processing in nerve cells, using the olfactory pathway as a model system.
- **BrainMaps.org**[*] [8] is an interactive high-resolution digital brain atlas using a high-speed database and virtual microscope that is based on over 12 million megapixels of scanned images of several species, including human.

Another approach in the area of the brain mappings is the probabilistic atlases obtained from the real data from different group of people, formed by specific factors, like age, gender, diseased etc. Provides more flexible tools for brain research and allow obtaining more reliable and precise results, which cannot be achieved with the help of traditional brain atlases.

21.2.8 See also

- Outline of the human brain
- Outline of brain mapping
- List of neuroscience databases
- Brain simulation
- Computational neuroscience
- Computational anatomy
- Systems neuroscience
- Vision science
- Brain-reading
- Human Brain Project
- Connectogram
- Neuroethology

21.2.9 Notes and references

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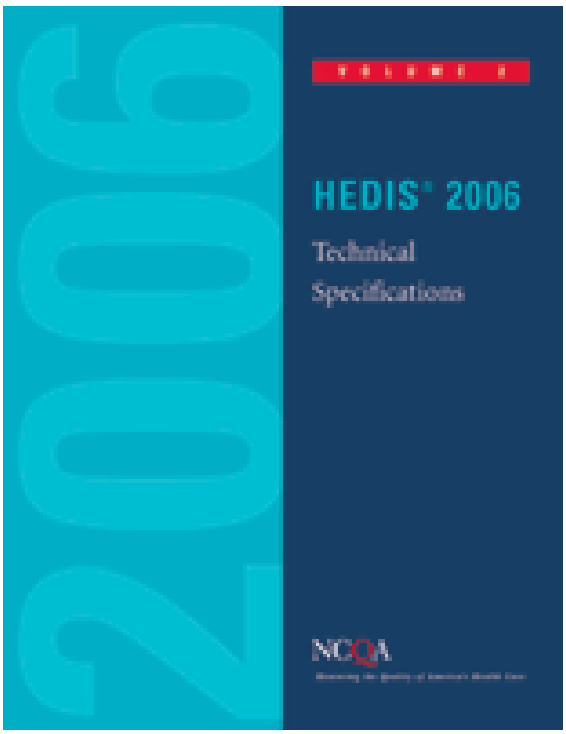
21.3 Healthcare Effectiveness Data and Information Set



HEDIS 2006 Volume 2: Technical Specifications

The **Healthcare Effectiveness Data and Information Set** (**HEDIS**) is a widely used set of performance measures in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA).

HEDIS was designed to allow consumers to compare health plan performance to other plans and to national or regional benchmarks. Although not originally intended for trending, HEDIS results are increasingly used to track year-to-year performance. HEDIS is one component of NCQA's accreditation process, although some plans submit HEDIS data without seeking accreditation. An incentive for many health plans to collect HEDIS data is a Centers for Medicare and Medicaid Services (CMS) requirement that health maintenance organizations (HMOs) submit Medicare HEDIS data in order to provide HMO services for Medicare enrollees under a program called Medicare Advantage.

HEDIS was originally titled the "HMO Employer Data and Information Set" as of version 1.0 of 1991.*[1] In 1993, Version 2.0 of HEDIS was known as the "Health Plan Employer Data and Information Set".*[2] Version 3.0 of HEDIS was released in 1997.*[1] In July 2007, NCQA announced that the meaning of "HEDIS" would be changed to "Healthcare Effectiveness Data and Information Set." *[3]

In current usage, the "reporting year" after the term

"HEDIS" is one year following the year reflected in the data; for example, the "HEDIS 2009" reports, available in June 2009, contain analyses of data collected from "measurement year" January–December 2008.[*][4]

21.3.1 Structure

The 81 HEDIS measures are divided into five "domains of care":[*][5][*][6]

- Effectiveness of Care
- Access/Availability of Care
- Experience of Care
- Utilization and Relative Resource Use
- Health Plan Descriptive Information

The 2016 specification is available here.

Measures are added, deleted, and revised annually. For example, a measure for the length of stay after giving birth was deleted after legislation mandating minimum length of stay rendered this measure nearly useless. Increased attention to medical care for seniors prompted the addition of measures related to glaucoma screening and osteoporosis treatment for older adults. Other health care concerns covered by HEDIS are immunizations, cancer screenings, treatment after heart attacks, diabetes, asthma, flu shots, access to services, dental care, alcohol and drug dependence treatment, timeliness of handling phone calls, prenatal and postpartum care, mental health care, well-care or preventive visits, inpatient utilization, drug utilization, and distribution of members by age, sex, and product lines.

New measures in HEDIS 2013 are "Asthma Medication Ratio," "Diabetes Screening for People With Schizophrenia and Bipolar Disorder Who Are Using Antipsychotic Medications," "Diabetes Monitoring for People With Diabetes and Schizophrenia," "Cardiovascular Monitoring for People With Cardiovascular Disease and Schizophrenia," and "Adherence to Antipsychotic Medications for Individuals With Schizophrenia."

21.3.2 Data collection

HEDIS data are collected through surveys, medical charts and insurance claims for hospitalizations, medical office visits and procedures. Survey measures must be conducted by an NCQA-approved external survey organization. Clinical measures use the **administrative** or **hybrid** data collection methodology, as specified by NCQA. **Administrative** data are electronic records of services, including insurance claims and registration systems from hospitals, clinics, medical offices, pharmacies and labs. For example, a measure titled Childhood Immunization Status requires health plans to identify 2 year old children who have been enrolled for at least a year. The plans report the percentage of children who received specified immunizations. Plans may collect data for this measure by reviewing insurance claims or automated immunization records, but this method will not include immunizations received at community clinics that do not submit insurance claims. For this measure, plans are allowed to select a random sample of the population and supplement claims data with data from medical records. By doing so, plans may identify additional immunizations and report more favorable and accurate rates. However, the hybrid method is more costly, time-consuming and requires nurses or medical record reviewers who are authorized to review confidential medical records.

21.3.3 Reporting

HEDIS results must be audited by an NCQA-approved auditing firm for public reporting. NCQA has an on-line reporting tool called Quality Compass that is available for a fee of several thousand dollars. It provides detailed data on all measures and is intended for employers, consultants and insurance brokers who purchase health insurance for groups. NCQA's web site includes a summary of HEDIS results by health plan. NCQA also collaborates annually with U.S. News & World Report to rank HMOs using an index that combines many HEDIS measures and accreditation status. The "Best Health Plans" list is published in the magazine in October and is available on the magazine's web site. Other local business organizations, governmental agencies and media report HEDIS results, usually when they are released in the fall.

21.3.4 Advantages and disadvantages

Advantages

Proponents cite the following advantages of HEDIS measures:

- HEDIS measures undergo a selection process that has been described as "rigorous" [*][7][*](p. 205). Steps in the process include assessment of a measure's "importance, scientific soundness and feasibility"; field testing; public comment; a one-year trial period in which results are not reported publicly; and evaluation of publicly reported measures by "statistical analysis, review of audit results and user comments".[*][8]
- HEDIS data are useful for "evaluating current performance and setting goals".[*][9]
- In some studies, attainment of HEDIS measures is associated with cost-effective practices or with better health outcomes.

  - In a 2002 study, HEDIS measures "generally reflect[ed] cost-effective practices".[10]
  - A 2003 study of Medicare managed care plans determined that plan-level health outcomes were associated with HEDIS measures.[11]
  - An "Acute Outpatient Depression Indicator" score based on a HEDIS measure predicted improvement in depression severity in one 2005 study.[12]
- As stated in a 2006 Institute of Medicine (IOM) report, "HEDIS measures focus largely on processes of care";[13] the strengths of process measures include the facts that they "reflect care that patients actually receive," thereby leading to "buy-in from providers," and that they are "directly actionable for quality improvement activities"[13] (p. 179).
- HEDIS measures are "widely known and accepted"[7] (p. 205). The NCQA claims that over 90% of U.S. health plans use HEDIS measures.[14]

Disadvantages

HEDIS was described in 1995 as "very controversial".[15] Criticisms of HEDIS measures have included:

- HEDIS measures do not account for many important aspects of health care quality.
  - In 1998, HEDIS measures were said to "offer little insight into... [a health] plan's ability to treat serious illnesses".[16]
  - A 2002 study found "there are numerous non-HEDIS interventions with some evidence of cost effectiveness, particularly interventions to promote healthy behaviors".[10]
  - According to a 2005 study, HEDIS-Medicaid 3.0 measures covered only 22% of the services recommended by the second U.S. Preventive Services Task Force (USPSTF).[17]
- Attempts by health care providers to improve their HEDIS measures may cause harm to patients.
  - As of 2001, there was concern that the asthma HEDIS measure may "encourag[e] more casual prescribing of controller medications" and may place emphasis "on the prescribing of a controller medication rather than on its actual use".[18]
  - There is a risk of hypoglycemia if a provider strives to meet the HEDIS measure concerning a hemoglobin A1c (HbA1c) level of <7% that was adopted in 2006 for HEDIS 2007.[19] NCQA later decided to not report results of the HbA1c<7% measure publicly in 2008, to modify the HbA1c<7% measure for HEDIS 2009 "by adding exclusions for members within a specific age cohort and with certain comorbid conditions," and to add a new HbA1c<8% measure.[20]
- The process to develop HEDIS measures may be flawed.
  - There is a possible conflict of interest because NCQA "works closely with the managed-care industry".[15] Furthermore, approximately half of NCQA's budget is derived from accreditation fees, "which may create an incentive against setting [HEDIS] standards too high".[21]
  - The process to develop the measures is not completely "transparent," that is, "information about existing conditions, decisions and actions" is not completely "accessible, visible and understandable".[19]
- In some cases, attainment of HEDIS measures is not proven to be associated with better health outcomes.
  - In 2004, a multi-site study determined that persons with persistent asthma per the HEDIS definition at the time had more "asthma-related adverse events" if they were classified by HEDIS as having appropriate asthma therapy than if they did not have appropriate therapy.[22] This cause of this "unexpected" finding was thought to be that some people with intermittent asthma were miscategorized by HEDIS as having persistent asthma.[22]
  - A 2008 study of 1056 adults with asthma found that "compliance with the HEDIS asthma measure is not favorably associated with relevant patient-oriented outcomes" such as scores on an Asthma Control Test.[23]
  - Although "glaucoma screening in older adults" is a current HEDIS measure,[6] the USPSTF found "insufficient evidence to recommend for or against screening adults for glaucoma" in 2005;[24] as of 2008, the American Academy of Ophthalmology was attempting to convince the USPSTF to review its statement.[25] Furthermore, a 2006 Cochrane review ("last assessed as up-to-date" in 2009) concluded that there was "insufficient evidence to recommend population based screening" for glaucoma because no pertinent randomized controlled trials exist.[26] One summary of the Cochrane review was "population-based screening for glaucoma... is not clinically or cost-effective".[27]
- A 2001 IOM report noted that "there is incomplete reporting of [HEDIS] measures and health plans resulting in lack of representativeness at the national level"[7] (p. 205).

- As stated in the 2006 IOM report, the limitations of HEDIS process measures include "sample size constraints for condition-specific measures," "may be confounded by patient compliance and other factors," and "variable extent to which process measures link to important patient outcomes" *[13]*(p. 179).

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21.3.6 External links

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21.4 E-epidemiology

E-epidemiology is the science underlying the acquisition, maintenance and application of epidemiological knowledge and information using digital media such as the internet, mobile phones, digital paper, digital TV. E-epidemiology also refers to the large-scale epidemiological studies that are increasingly conducted through distributed global collaborations enabled by the Internet.

The traditional approach in performing epidemiological trials by using paper questionnaires is both costly and time-consuming. The questionnaires have to be transformed to analyzable data and a large number of personnel are needed throughout the procedure. Modern communication tools, such as the web, cell phones and other current and future communication devices, allow rapidly and cost-efficient assembly of data on determinants for lifestyle and health for broad segments of the population. Modern IT technology provides means for storage, organization and retrieval of large amounts of biological and lifestyle data, which will ensure more data and more reliable statistical results. Efficient number crunching computing, using modern analytical tools and simulation based inference procedures allow knowledge to be extracted from the resulting large and complex data-structures. Web portals directly connected to the studies enables instant feedback and information to the participants. It also allows animations and other web based tools linked to the questionnaires, which can increase the interactivity and facilitates flow of information between the study participant and the study centre. The web portal will also generate a possibility for the Universities to carry out the third assignment, which is to spread the knowledge generated at the University to the public.

Important aspects of e-epidemiology include the development of security and confidentiality preserving solutions to protect individual integrity and research data ownership.[*][1][*][2] But entering an epidemiological trial via the Internet is probably safer then traditional manners. Accurate security programmes and firewalls are a critical condition for handling personal records over the Internet.

21.4.1 See also

- Epidemiology
- Mathematical Modelling in Epidemiology
- World Community Grid

21.4.2 References

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[2] Miquel Porta (2014) *A dictionary of epidemiology*, 6th edn, New York: Oxford University Press. ISBN 9780199976737.

21.4.3 External links

- MEB.ki.se - Professor Jan-Eric Litton (faculty homepage), Karolinska Institutet (Swedish website)
- http://www.phi.man.ac.uk/Presentations/e-epidemiology.pdf

21.5 Epi Info

Epi Info is public domain statistical software for epidemiology developed by Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia (USA).

Epi Info has been in existence for over 20 years and is currently available for Microsoft Windows. The program allows for electronic survey creation, data entry, and analysis. Within the analysis module, analytic routines include t-tests, ANOVA, nonparametric statistics, cross

tabulations and stratification with estimates of odds ratios, risk ratios, and risk differences, logistic regression (conditional and unconditional), survival analysis (Kaplan Meier and Cox proportional hazard), and analysis of complex survey data. The software is in the public domain, free, and can be downloaded from http://www.cdc.gov/epiinfo. Limited support is available.

An analysis conducted in 2003 documented over 1,000,000 downloads of Epi Info from 180 countries.*[1]

21.5.1 History

Epi Info has been in development for over 20 years. The first version, Epi Info 1, was originally implemented by Jeff Dean (computer scientist) as an unpaid intern in high school. It was an MS-DOS batch file on 5.25" floppy disks and released in 1985.*[2] MS-DOS continued to be the only supported operating system until the release of Epi Info 2000, which was written in Microsoft's Visual Basic and became the first Windows-compatible version. The last MS-DOS version was Epi Info 6.04d released in January 2001.

Epi Info 2000 changed the way data was stored by adopting the Microsoft Access database format, rather than continuing to use the plain-text file format from the MS-DOS versions. Following the release of Epi Info 2000 was Epi Info 2002, then Epi Info version 3.0, and finally the open-source Epi Info 7. Epi Info 7 was made open source on November 13, 2008 when its source code was uploaded to Codeplex for the first time. The 7 series is the presently maintained Epi Info product line. Note that Epi Info 3 for Windows is different from Epi Info 3 for MS-DOS even though they share the same version number.

21.5.2 Features

From a user's perspective, the most important functions of Epi Info are the ability to rapidly develop a questionnaire, customize the data entry process, quickly enter data into that questionnaire, and then analyze the data. For epidemiological uses, such as outbreak investigations, being able to rapidly create an electronic data entry screen and then do immediate analysis on the collected data can save considerable amounts of time versus using paper surveys.

Epi Info uses three distinct modules to accomplish these tasks: Form Designer, Enter, and Analysis. Other modules include the Dashboard module, a mapping module, and various utilities such as StatCalc.

Electronic questionnaires are created in the Form Designer module. Individual questions can be placed anywhere on a page and each form may contain multiple pages. The user is given a high degree of control over the form's appearance and function. The user defines both the question's prompt and the format of the data that is to be collected. Data types include numbers, text strings, dates, times, and Boolean. Users can also create drop-down lists, code tables, and comment legal fields. One of the more powerful features of Form Designer is the ability to program intelligence into a form through a feature called "check code". Check code allows for certain events to occur depending on what action a data entry person has taken. For example, if the data entry person types "Male" into a question on gender, any questions relating to pregnancy might then be hidden or disabled. Skip patterns, message boxes, and math operations are also available. Relational database modeling is supported, as users may link their form to any number of other forms in their database.

The "Classic Analysis" module is where users analyze their data. Import and export functions exist that allow for data to be converted between plain-text, CSV, Microsoft Excel, Microsoft Access, MySQL, Microsoft SQL Server, and other formats. Many advanced statistical routines are provided, such as t-tests, ANOVA, nonparametric statistics, cross tabulations and stratification with estimates of odds ratios, risk ratios, and risk differences, logistic regression (conditional and unconditional), survival analysis (Kaplan Meier and Cox proportional hazard), and analysis of complex survey data.

The "Visual Dashboard" module is a lighter-weight Analysis component that is designed to be easy to use, but does not contain the full set of data management features that the "Classic Analysis" module does.

Using the Map module, data can be displayed either by geographic reference or by GPS coordinates.

Older versions of Epi Info contained a Report module and a Menu module. The Report module allowed the user to edit and format the raw output from other Epi Info modules into presentable documents. The menu module allowed for the editing and re-arranging of the basic Epi Info menu structure. This module was powerful enough that several applications have been built off of it (in versions of Epi Info prior to version 7), including the National Electronic Telecommunications System for Surveillance (NETSS) for Epi Info 6. Unlike the other modules, the menu module does not have a design-mode user interface, but instead resides in a .mnu file whose scripts must be edited manually. In Epi Info 7, the Visual Dashboard assumes some of the basic functions of the report module.

Epi Info 7 includes a number of nutritional anthropometric functions that can assist in recording and evaluating measurements of length, stature, weight, head circumference, and arm circumference for children and adolescents. They can be used to calculate percentiles and number of standard deviations from the mean (Z-scores) using the CDC/WHO 1978 growth reference, CDC 2000 growth reference, the WHO Child Growth Reference, or the WHO Reference 2007. It replaces the NutStat and

EpiNut modules found in prior versions of Epi Info.

21.5.3 Open Epi

OPenEpi is an online version of the software and has in-built statistical calculators. For more information, see the article OpenEpi.

21.5.4 Future developments

Version 7 is in continuing development as an open source project. Source code is available at Epi Info's Codeplex website. Web-based data entry, web-based analysis, and mobile data collection tools are currently available and will see continued improvement in 2014 and beyond.

21.5.5 Release history

21.5.6 See also

- Quantitative parasitology (free software)
- CSPro
- OpenEpi
- X-12-ARIMA
- AnSWR
- Epi Map
- Free statistical software

21.5.7 References

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[3] "CDC Epi Info - Museam Version 5". CDC. Retrieved 2009-02-02.

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21.5.8 External links

- Epi Info
- Epi Info Community of Users
- Epi Info Community Portal
- Epi Info Community Edition (open source version)
- Open Epi
- Epi Info - YouTube page. Official instructional videos

21.6 OpenEpi

OpenEpi is a free, web-based, open source, operating system-independent series of programs for use in epidemiology, biostatistics, public health, and medicine, providing a number of epidemiologic and statistical tools for summary data.[*][1][*][2][*][3][*][4][*][5][*][6][*][7][*][8][*][9][*][10][*][11] OpenEpi was developed in JavaScript and HTML, and can be run in modern web browsers. The program can be run from the OpenEpi website or downloaded and run without a web connection. The source code and documentation is downloadable and freely available for use by other investigators. OpenEpi has been reviewed, both by media organizations and in research journals.[*][12][*][13][*][14][*][15][*][16]

The OpenEpi developers have had extensive experience in the development and testing of Epi Info, a program developed by the Centers for Disease Control and Prevention (CDC) and widely used around the world for data entry and analysis. OpenEpi was developed to perform analyses found in the DOS version of Epi Info modules StatCalc and EpiTable, to improve upon the types of analyses provided by these modules, and to provide a number of tools and calculations not currently available in Epi Info. It is the first step toward an entirely web-based set of epidemiologic software tools. OpenEpi can be thought of as an important companion to Epi Info and to other programs such as SAS, PSPP, SPSS, Stata, SYSTAT, Minitab, Epidata, and R (see the R programming language). Another functionally similar Windows-based program is Winpepi. See also list of statistical packages and comparison of statistical packages. Both OpenEpi and Epi Info were developed with the goal of providing tools for low and moderate resource areas of the world. The initial development of OpenEpi was supported by a grant from the Bill and Melinda Gates Foundation to Emory University.[*][17]

The types of calculations currently performed by OpenEpi include:

- Various confidence intervals for proportions, rates, standardized mortality ratio, mean, median, percentiles
- 2x2 crude and stratified tables for count and rate data
- Matched case-control analysis
- Test for trend with count data
- Independent t-test and one-way ANOVA
- Diagnostic and screening test analyses with receiver operating characteristic (ROC) curves
- Sample size for proportions, cross-sectional surveys, unmatched case-control, cohort, randomized controlled trials, and comparison of two means

- Power calculations for proportions (unmatched case-control, cross-sectional, cohort, randomized controlled trials) and for the comparison of two means
- Random number generator

For epidemiologists and other health researchers, OpenEpi performs a number of calculations based on tables not found in most epidemiologic and statistical packages. For example, for a single 2x2 table, in addition to the results presented in other programs, OpenEpi provides estimates for:

- Etiologic or prevented fraction in the population and in exposed with confidence intervals, based on risk, odds, or rate data
- The cross-product and MLE odds ratio estimate
- Mid-p exact p-values and confidence limits for the odds ratio
- Calculations of rate ratios and rate differences with confidence intervals and statistical tests.

For stratified 2x2 tables with count data, OpenEpi provides:

- Mantel-Haenszel (MH) and precision-based estimates of the risk ratio and odds ratio
- Precision-based adjusted risk difference
- Tests for interaction for the risk ratio, odds ratio, and risk difference
- Four different confidence limit methods for the odds ratio.

Similar to Epi Info, in a stratified analysis, both crude and adjusted estimates are provided so that the assessment of confounding can be made. With rate data, OpenEpi provides adjusted rate ratio's and rate differences, and tests for interaction. Finally, with count data, OpenEpi also performs a test for trend, for both crude data and stratified data.

In addition to being used to analyze data by health researchers, OpenEpi has been used as a training tool for teaching epidemiology to students at: Emory University, University of Massachusetts, University of Michigan, University of Minnesota, Morehouse College, Columbia University, University of Wisconsin, San Jose State University, University of Medicine and Dentistry of New Jersey, University of Washington, and elsewhere. This includes campus-based and distance learning courses. Because OpenEpi is easy to use, requires no programming experience, and can be run on the internet, students can use the program and focus on the interpretation of results. Users can run the program in English, French, Spanish, Portuguese or Italian.

Comments and suggestions for improvements are welcomed and the developers respond to user queries. The developers encourage others to develop modules that could be added to OpenEpi and provide a developer's tool at the website. Planned future development include improvements to existing modules, development of new modules, translation into other languages, and add the ability to cut and paste data and/or read data files.

21.6.1 See also

- Quantitative parasitology (free software)
- Web based simulation
- Free statistical software

21.6.2 References

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21.6.3 External links

- Official website

21.7 Living Human Project

The **Living Human Project** (**LHP**) is developing a worldwide, distributed repository of anatomo-functional data and of simulation algorithms relative to the human musculoskeletal apparatus, fully integrated into a seamless simulation environment and directly accessible by any researcher in the world. This infrastructure will be used to create the physiome of the **human musculoskeletal system**.

21.7.1 The Story so far

This initiative started in 2002 as a result of the BioNet coordination action, aimed to establish the grand challenges for European biomechanics. The BioNet consensus document clearly pointed out the need for an Internet-based virtual community as a mean to share biomechanics data.

In 2003 a group of partners who were also involved with the BioNet action wrote a public document drafting a possible strategy to have the LHP started.

In the meanwhile Marco Viceconti, a researcher at the Rizzoli Institute in Bologna (Italy) started a voluntary effort called Biomechanics European Lab (BEL). The idea was to create a community of interested colleagues, who would develop the LHP without any centralised funding.

In 2006 The BEL was merged with to Biomed Town, a new Internet community reserved to all those who have professional interest in biomedical research. The BEL data repository remains available on Biomed Town for historical reasons.

It was evident that the most important limiting factor for LHP was the lack of an adequate information technology infrastructure. This need is now being matched by two separate provisions.

21.7.2 Living Human Digital Library

A consortium of European institutions is developing the Living Human Digital Library, as part of the LHDL STRP project supported by the European Commission. This wiki page contains constantly updated information on the LHDL project.

The LHDL project will end in January 2009; soon after, the LHDL consortium will release a biomedical data management and sharing service, called **Physiome Space**. Physiome Space will make possible for single researchers as well as for large consortia to share with their peers very large collections of biomedical data, including medical imaging, computer simulations, etc. It is possible to sign up for the beta users group, which should start in the last quarter of 2008.

21.7.3 Biomed Town

The users of LHP, e.g. all those research, industry, or clinical professionals that are interested in the musculoskeletal system in every possible way and at every dimensional scale, from the whole body down to the cell and the proteins, created a collaborative community within Biomed Town. The activities of the LHDL Consortium are hosted in the LHDL Building. The community consensus process takes place in the Living Human Square.

21.7.4 See also

- List of omics topics in biology
- Virtual Physiological Human
- Physiomics
- Physiome
- Physiology
- EuroPhysiome
- Human anatomy

21.7.5 References

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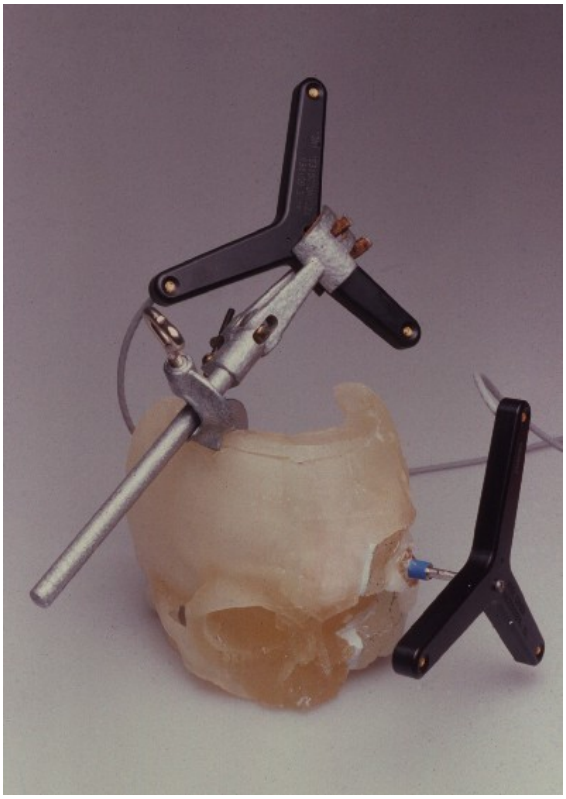
21.8 Stereolithography

Stereolithographic models have been used in medicine since the 1990s,*[1] for creating 3D corporeal models of various anatomical regions of a patient, based on datasets from CT-scans.

21.8.1 Usage

- Stereolithography is a Rapid prototyping process that creates solid physical models directly from computer data. In industry this data comes from 3D computer-aided design (CAD) data. The process can also be used to build highly accurate replicas of human (or animal) anatomy by using computer images from medical scanners.*[2] Typically Computed tomography (CT) is used but Magnetic Resonance Imaging (MRI) can also be used. Models have also been made from Ultra Sound and more recently from lower cost Cone Beam CT scanners. Medical models can also be made using a range of other Rapid Prototyping processes although stereolithography remains popular.

- Medical models are used in medicine and surgery to provide surgeons with a better appreciation of the anatomical situation of a patient, before surgery. Although the advent of improved 3D computer reconstruction and virtual surgical planning means that in some cases models are not needed they remain popular for complex surgeries particularly in cranial surgery, maxillofacial surgery, oral surgery and neurosurgery.



Stereolithographic model of a skull, using an infrared system

- Stereolithographic models are used as an aid to diagnosis, preoperative planning and implant design and manufacture. This might involve for example planning and rehearsing osteotomies. Surgeons use models to help plan surgeries but prosthetists and technologists also use models as an aid to the design and manufacture of custom-fitting implants. Medical models are frequently used to help in the construction of Cranioplasty plates for example.

21.8.2 Medical Modelling Process

The process of medical modelling involves several stages including image acquisition, image segmentation, data translation, model building and post-processing.*[3] Medical modelling involves first acquiring a 3D CT scan (or other form of scan data). The CT data should be in a suitable format and acquired using suitable parameters to obtain a high quality model.*[4] This data consists of a series of cross sectional images of the human anatomy. In these images different tissues show up as different levels

of grey. Selecting a range of grey values enables specific tissues to be isolated. A region of interest is then selected and all the pixels connected to the target point within that grey value range are selected. This enables a specific organ to be selected. Most frequently this will be bone but it could be any tissue that can be identified in the scan image. This process is referred to as segmentation. The segmented data may then be interpolated and have other processes performed on it to translate it into a format suitable for the stereolithography process.

Whilst the stereolithography process is inherently accurate the accuracy of a medical model depends on many factors, especially the operator performing the segmentation correctly. There are potential errors possible when making medical models using stereolithography but these are easy to avoid with practice and well trained operators.*[5]

21.8.3 Commercial Services

There are several specialist companies that provide medical modelling services such as for example PDR in the United Kingdom, Medical Modeling Inc. in the USA and Materialise in Belgium. As Rapid Prototyping machines become more affordable many hospitals are investing in their own medical modelling facilities.

21.8.4 References

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21.9 Virtual Physiological Human

The **Virtual Physiological Human** (**VPH**) is a methodological and technological framework that, once established, will enable collaborative investigation of the human body as a single complex system.*[1]*[2] The collective framework will make it possible to share resources and observations formed by institutions and organizations creating disparate, but integrated computer models of the mechanical, physical and biochemical functions of a living human body.

The Virtual Physiological Human (VPH) is a framework which aims to be descriptive, integrative and predictive:*[3]*[4]*[5]*[6]

- Descriptive. The framework should allow observations made in laboratories, hospitals and the field, at a variety of locations situated anywhere in the world, to be collected, catalogued, organized, shared and combined in any possible way.

- Integrative. The framework should enable experts to analyse these observations collaboratively and develop systemic hypotheses that involve the knowledge of multiple scientific disciplines.

- Predictive. The framework should make it possible to interconnect predictive models defined at different scales, with multiple methods and varying levels of detail, into systemic networks that solidify those systemic hypotheses; it should also make it possible to verify their validity by comparison with other clinical or laboratory observations.

The framework is formed by large collections of anatomical, physiological, and pathological data stored in digital format, by predictive simulations developed from these collections, and by services intended to support researchers in the creation and maintenance of these models, as well as in the creation of end-user technologies to be used in the clinical practice. Virtual Physiological Human (VPH) models aim to integrate physiological processes across different length and time scales (multi-scale modelling).*[3] These models make possible the combination of patient-specific data with population-based representations. The objective is to develop a systemic approach which avoids a reductionist approach and seeks not to subdivide biological systems in any particular way by dimensional scale (body, organ, tissue, cells, molecules), by scientific discipline (biology, physiology, biophysics, biochemistry, molecular biology, bioengineering) or anatomical subsystem (cardiovascular, musculoskeletal, gastrointestinal, etc.).*[5]

21.9.1 History of Virtual Physiological Human (VPH)

The initial concepts that brought to the Virtual Physiological Human came from the IUPS physiome project. The IUPS physiome project was formed in 1997, and was the first worldwide effort to define the physiome through the development of databases and models which facilitated the understanding of the integrative function of cells, organs, and organisms.*[7] The project focused on compiling and providing a central repository of databases, linking experimental information and computational models from many laboratories into a single, self-consistent framework.

The Physiome is the quantitative and integrated description of the functional behaviour of the physiological state of an individual or species.*[8]*

Following the launch of the Physiome Project, there were many other worldwide initiatives of loosely coupled actions all focusing on the development of methods for modelling and simulation of human pathophysiology. In 2005, an expert workshop of the Physiome was held as part of the Functional Imaging and Modelling of the Heart Conference in Barcelona where a White Paper*[9] was created. The paper was entitled 'Towards Virtual Physiological Human: Multilevel modelling and simulation of the human anatomy and physiology'. The goal of this paper was to shape a clear overview of on-going relevant VPH activities, to build a consensus on how they can be complemented by new initiatives for researchers in the EU and to identify possible mid-term and long term research challenges.

In 2006, the European Commission funded a coordination and support action entitled *STEP: Structuring The EuroPhysiome*. The STEP consortium promoted a very large consensus process that involved more than 300 stakeholders including researchers, industry experts, policy makers, clinicians, etc. The prime result of this process was a booklet entitled *Seeding the EuroPhysiome: A Roadmap to the Virtual Physiological Human*.*[6] The STEP action and the resulting research roadmap were instrumental in the development of the concept of Virtual Physiological Human here provided, and in the initiation of much larger process that involves significant research funding, large collaborative projects, and a number of connected initiatives, not only in Europe but also in the United States, Japan, and China.

The Virtual Physiological Human now forms a core target of the 7th Framework Programme*[10] of the European Commission, and aims to support the development of patient-specific computer models and their application in personalised and predictive healthcare.*[11] The Virtual Physiological Human Network of Excellence VPH NoE aims to connect the various VPH projects within the 7th Framework Programme.

21.9.2 Aim of the Virtual Physiological Human

VPH related projects have received substantial funding from the European Commission in order to further scientific progress in this area. The European Commission is insistent that VPH-related projects demonstrate strong industrial participation and clearly indicate a route from basic science into clinical practice.*[5] In the future, it is hoped that the VPH will eventually lead to a better healthcare system which aims to have the following benefits:*[6]

- personalized care solutions
- reduced need for experiments on animals
- more holistic approach to medicine
- preventative approach to treatment of disease

Personalized care solutions are a key aim of the VPH, with new modelling environments for predictive, individualized healthcare to result in better patient safety and drug efficacy. It is anticipated that the VPH could also result in healthcare improvement through greater understanding of pathophysiological processes.*[3] The use of biomedical data from a patient to simulate potential treatments and outcomes could prevent the patient from experiencing unnecessary or ineffective treatments.*[12] The use of in silico (by computer simulation) modelling and testing of drugs could also reduce the need for experiments on animals.

A future goal is that there will be also be a more holistic approach to medicine with the body treated as a single multi organ system rather than as a collection of individual organs. Advanced integrative tools should further help to improve the European healthcare system on a number of different levels that include diagnosis, treatment and care of patients and in particular quality of life.*[6]

The Virtual Physiological Human is in conclusion a framework of methods and technologies that once fully established will make possible **Personalised, Predictive, and Integrative medicine**.

21.9.3 See also

- Physiome
- Physiology
- EuroPhysiome
- Cytome
- Human anatomy
- Living Human Project

- VPHOP (Osteoporotic Virtual Physiological Human)
- EuResist (Integrated system for the clinical management of antiretroviral drug resistance)
- Virtual Physiological Rat
- *In silico* clinical trials

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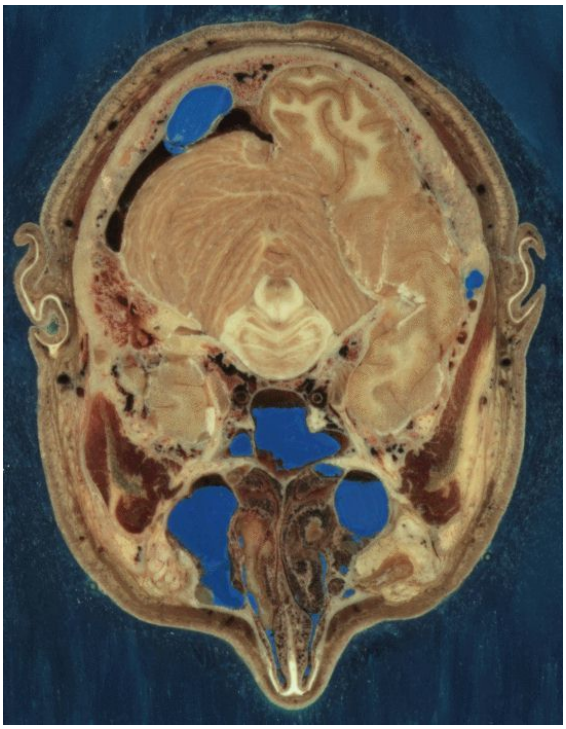
21.9.6 External links

- Operating on the Virtual Human BBC news feature on Heart Surgery as part of the VPH Initiative (January 2009)

21.10 Visible Human Project

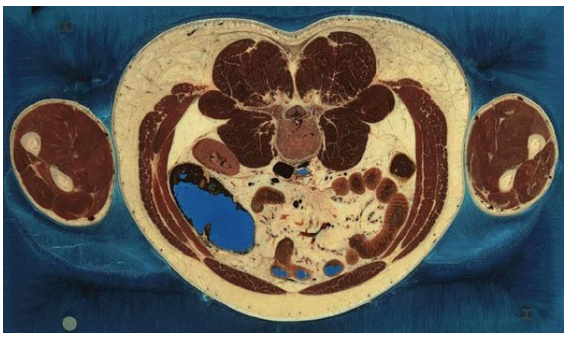


Cryosection through the head of a human male.

The **Visible Human Project** is an effort to create a detailed data set of cross-sectional photographs of the human body, in order to facilitate anatomy visualization

applications. A male and a female cadaver were cut into thin slices which were then photographed and digitized. The project is run by the U.S. National Library of Medicine (NLM) under the direction of Michael J. Ackerman. Planning began in 1986;*[1] the data set of the male was completed in November 1994 and the one of the female in November 1995. The project can be viewed today at the National Museum of Health and Medicine near Washington, DC. There are currently efforts to repeat this project with higher resolution images but only with parts of the body instead of a cadaver.

21.10.1 Data



Cryosection through the abdomen of a human male, including the upper extremities.

The male cadaver was encased and frozen in a gelatin and water mixture in order to stabilize the specimen for cutting. The specimen was then "cut" in the axial plane at 1 millimeter intervals. Each of the resulting 1,871 "slices" was photographed in both analog and digital, yielding 15 gigabytes of data. In 2000, the photos were rescanned at a higher resolution, yielding more than 65 gigabytes. The female cadaver was cut into slices at .33 millimeter intervals, resulting in some 40 gigabytes of data.

The term "cut" is a bit of a misnomer, yet it is used to describe the process of grinding away the top surface of a specimen at regular intervals. The term "slice," also a misnomer, refers to the revealed surface of the specimen to be photographed; the process of grinding the surface away is entirely destructive to the specimen and leaves no usable or preservable "slice" of the cadaver.

The data is supplemented by axial sections of the whole body obtained by computed tomography, axial sections of the head and neck obtained by magnetic resonance imaging, and coronal sections of the rest of the body also obtained by magnetic resonance imaging.

The scanning, slicing and photographing took place at the University of Colorado Anschutz Medical Campus, where additional cutting of anatomical specimens continues to take place.

21.10.2 Donors

The male cadaver is from Joseph Paul Jernigan, a 38-year-old Texas murderer who was executed by lethal injection on August 5, 1993. At the prompting of a prison chaplain he had agreed to donate his body for scientific research or medical use, without knowing about the Visible Human Project. Some people have voiced ethical concerns over this. One of the most notable statements came from the University of Vienna which demanded that the images be withdrawn with reference to the point that the medical profession should have no association with executions, and that the donor's informed consent could be scrutinised.*[2]

The 59-year-old female donor remains anonymous. In the press she has been described as a Maryland housewife who died from a heart attack and whose husband requested that she be part of the project.

21.10.3 Problems with the data sets

Freezing caused the brain of the man to be slightly swollen, and his inner ear ossicles were lost during preparation of the slices. Nerves are hard to make out since they have almost the same color as fat, but many have nevertheless been identified. Small blood vessels were collapsed by the freezing process. Tendons are difficult to cut cleanly, and they occasionally smear across the slice surfaces.

The male has only one testicle, is missing his appendix, and has tissue deterioration at the site of lethal injection. Also visible are tissue damage to the dorsum of each forearm by formalin injection and damage to the right sartorius from opening the right femoral vein for drainage. The male was also not "cut" while in standard anatomical position, so the cuts through his arms are oblique.

The reproductive organs of the woman are not representative of those of a young woman. The specimen contains several pathologies, including cardiovascular disease and diverticulitis.

21.10.4 Discoveries

By studying the data set, researchers at Columbia University found several errors in anatomy textbooks, related to the shape of a muscle in the pelvic region and the location of the urinary bladder and prostate.*[3]

21.10.5 License

The data may be bought on tape or downloaded free of charge; one has to specify the intended use and sign a license agreement that allows NLM to use and modify the resulting application. NLM can cancel the agreement

at any time, at which point the user has to erase the data files.

21.10.6 Applications using the data

Various projects to make the raw data more useful for educational purposes are under way. It is necessary to build a three-dimensional virtual model of the body where the organs are labeled, may be removed selectively and viewed from all sides, and ideally are even animated. Two commercial software products accomplish the majority of these goals, the VH Dissector from Touch of Life Technologies and "Voxel-Man 3D-Navigator" from the University of Hamburg *[4] NLM itself has started an open source project, the Insight Toolkit, whose aim is to automatically deduce organ boundaries from the data.

The data were used for Alexander Tsiaras's book and CD-ROM "Body Voyage" which features a three-dimensional tour through the body.*[5]

A "Virtual Radiography" application creates Digitally Reconstructed Radiographs and "virtual surgery", where endoscopic procedures or balloon angioplasty are simulated: the surgeon can view the progress of the instrument on a screen and receives realistic tactile feedback according to what kind of tissue the instrument would currently be touching.

The male data set was used in "Project 12:31", a series of photographic light paintings by Croix Gagnon and Frank Schott.

21.10.7 See also

- 3D Indiana
- Anatomography
- ImageVis3D
- Insight Segmentation and Registration Toolkit
- Primal Pictures
- Zygote Body

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21.10.9 External links

- Home page of the project, including links to the various other projects that use the data
- The Visible Human Male: A Technical Report, Detailed history of methods used to prepare the male cadaver and gather image data as published in the free article in the Journal of the American Medical Informatics Association 1996
- Visible Human Server by the EPFL (Ecole Polytechnique Fédérale de Lausanne). Extensive Java applets to view, extract and animate slices. Also applets for 3D feature extraction.
- Touch of Life Technologies A commercial website which produces the VH Dissector, a virtual dissection program that uses the Visible Human datasets.
- University of Michigan Visible Human Project page

Chapter 22

People

22.1 Edward H. Shortliffe

Edward ("Ted") Hance Shortliffe (born 1947) is a Canadian-born American biomedical informatician, physician, and computer scientist. Shortliffe is a pioneer in the use of artificial intelligence in medicine. He was the principal developer of the clinical expert system MYCIN, one of the first rule-based artificial intelligence expert systems, which obtained clinical data interactively from a physician user and was used to diagnose and recommend treatment for severe infections. While never used in practice (because it preceded the era of local-area networking and could not be integrated with patient records and physician workflow), its performance was shown to be comparable to and sometimes more accurate than that of Stanford infectious disease faculty.*[1] This spurred the development of a wide range of activity in the development of rule-based expert systems, knowledge representation, belief nets and other areas, and its design greatly influenced the subsequent development of computing in medicine.

He is also regarded as a founder of the field of biomedical informatics, and in 2006 received one of its highest honors, the Morris F. Collen Award given by the American College of Medical Informatics.*[2]

He has held administrative positions in academic medicine, research and national bodies including the Institute of Medicine, American College of Physicians, the National Science Foundation, National Institutes of Health, and National Library of Medicine (NLM), and been influential in the development of medicine, computing and biomedical informatics nationally and internationally. His interests include the broad range of issues related to integrated medical decision-support systems and their implementation, biomedical informatics and medical education and training, and the Internet in medicine.

In March 2007, he became founding dean of the University of Arizona's College of Medicine - Phoenix campus. He stepped down from this position in May 2008 and in January 2009 transferred his primary academic appointment to Arizona State University where he became professor of biomedical informatics. He maintained a secondary appointment as professor of basic medical sciences and of medicine at the University of Arizona College of Medicine (Phoenix Campus). In November 2009 he transferred his academic home to a part-time appointment as professor at the School of Biomedical Informatics, University of Texas Health Science Center at the Texas Medical Center in Houston, where he lived until November 2011. Since that time he has returned to New York City where he continues as an adjunct professor of biomedical informatics at Columbia University.

In July 2009, Shortliffe assumed a position as president and chief executive officer of the American Medical Informatics Association, an organization that he helped to form between 1988 and 1990 when he was President of the Symposium on Computer Applications in Medical Care. In late 2011 he announced his intention to step down from this position in 2012.

22.1.1 Biography and career

Shortliffe grew up in Edmonton, Alberta, until his family moved to Connecticut when he was 6. He attended the Loomis School in Connecticut (now Loommis-Chaeffee School) and later Gresham's School in the United Kingdom. His father was a physician and hospital administrator; his mother, an English teacher. He has one brother and one sister.

As an undergraduate at Harvard, he started working in the computer laboratory of G. Octo Barnett at Massachusetts General Hospital and realized that he could have a career spanning both medicine and computing.

After receiving an AB in applied mathematics *magna cum laude* from Harvard College in 1970, he received an M.D. (1976) and Ph.D. in Medical Information Systems (1975) from Stanford University, with a dissertation on the MYCIN system, for which he also won the 1976 Grace Murray Hopper Award for outstanding computer scientists under the age of 30. He completed internal medicine house-staff training from 1976-1979 at Massachusetts General Hospital and Stanford Hospital. In 1979 he joined the Stanford faculty in internal medicine and computer science, where he directed the Stanford University Medical EXpertimental computer resource (SUMEX) and subsequently the Center for Ad-

vanced Medical Informatics at Stanford (CAMIS), continuing his work on expert systems, including ONCOCIN (an oncology decision support program), T-HELPER, and other projects in the Stanford Heuristic Programming Project.*[3] He also simultaneously served as chief of general internal medicine and associate chair of medicine for primary care, and was principal investigator of the InterMed Collaboratory, which developed the science of computable guidelines for medical decision support.

In 1980 he founded one of the earliest formal degree programs in biomedical informatics at Stanford University, emphasizing a rigorous and experimentalist approach. From 2003-2007 he served on the Board of Directors of Medco Health Solutions, a large pharmacy benefits manager headquartered in Franklin Lakes, New Jersey.

In 2000 he moved to Columbia University as chair of the department of biomedical informatics, deputy vice president (Columbia University Medical Center), senior associate dean for strategic information resources (College of Physicians and Surgeons), professor of medicine, professor of computer science, and director of medical informatics services for the New York-Presbyterian Hospital. He continued work on decision support guidelines including the development of the Guideline Interchange Format (GLIF3).*[4]

From March 2007 until May 2008 he served as the founding dean of the Phoenix campus of the University of Arizona's College of Medicine and from November 2009 to October 2011 he served as professor in the School of Biomedical Informatics at the University of Texas Health Sciences Center in Houston, Texas. He has served as president and chief executive officer of the American Medical Informatics Association from 2009-2012 and continues to hold adjunct faculty appointments in biomedical informatics at Columbia University and Arizona State University.

22.1.2 Advisory activities

At age 39, Shortliffe was elected to the Institute of Medicine of the United States National Academy of Sciences (where he has served on the IOM executive council). He is also an elected member or fellow of the American Association for Artificial Intelligence, American Society for Clinical Investigation, the Association of American Physicians, and the American Clinical and Climatological Association.

He is a founding member of the American Medical Informatics Association and was one of five founding fellows of the American College of Medical Informatics. He is a master of the American College of Physicians and was a member of that organization's Board of Regents from 1996-2002. He is editor-in-chief of the *Journal of Biomedical Informatics* and serves on the editorial boards for several other biomedical informatics publications.

He has served on the oversight committee for the Division of Engineering and Physical Sciences (National Academy of Sciences) and the Biomedical Informatics Expert Panel (National Center for Research Resources at the National Institutes of Health). He also served on the National Committee for Vital and Health Statistics (NCVHS) and on the President's Information Technology Advisory Committee. Earlier he served on the Computer Science and Telecommunications Board (National Research Council), the Biomedical Library Review Committee (National Library of Medicine), and was recipient of a research career development award from the latter agency.

He is the author of more than 300 publications including seven books.

22.1.3 Honors

- Morris F. Collen Award for Distinguished Contributions to Medical Informatics, American Medical Informatics Association, November 2006*[5]
- Appointed Rolf H. Scholdager Professor of Biomedical Informatics, Columbia University, June 2005
- National Associate, National Academies, Washington, DC, December 2004.
- Mastership, American College of Physicians, November 2002
- Young Investigator Award, Western Society for Clinical Investigation, February 1987.
- Henry J. Kaiser Family Foundation Faculty Scholar in General Internal Medicine, July 1983 —June 1988.
- Research Career Development Award, National Library of Medicine, July 1979—June 1984.
- Grace Murray Hopper Award (Distinguished computer scientist under age 30), Association for Computing Machinery, October 1976.

22.1.4 Books and Representative Papers

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6. Boxwala AA, Peleg M, Tu S, Ogunyemi O, Zeng QT, Wang D, Patel VL, Greenes RA, Shortliffe EH. `GLIF3: a representation format for sharable computer-interpretable clinical practice guidelines.' Journal of Biomedical Informatics 2004;37(3):147-161.

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9. Greenes, R.A. and Shortliffe, E.H. Medical informatics: an emerging academic discipline and institutional priority. JAMA 1990;263:1114-1120. See http://jama.jamanetwork.com/pdfaccess.ashx?ResourceID=517040&PDFSource=13

10. Detmer, W.M. and Shortliffe, E.H. Using the Internet to improve knowledge diffusion in medicine. Commun ACM, 1997;40(8):101-108.

11. Shortliffe EH. Strategic Action in Health Information Technology: Why the Obvious Has Taken So Long. Health Affairs 2005;24:1222-1233.

12. Shortliffe EH. Biomedical informatics in the education of physicians. J Am Med Assoc 2010:304(11):1227-1228.

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[1] 1. Rule-Based Expert Systems: The MYCIN Experiments of the Stanford Heuristic Programming Project - (edited by Bruce G. Buchanan and Edward H. Shortliffe; ebook version http://www.aaaipress.org/Classic/Buchanan/buchanan.html)

[2] Greenes, R. A.; Buchanan, B. G.; Ellison, D. (2007). "Presentation of the 2006 Morris F. Collen Award to Edward H. (Ted) Shortliffe". *Journal of the American Medical Informatics Association* **14** (3): 376–85. doi:10.1197/jamia.M2374. PMC 2244891. PMID 17557382.

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[5] Archived October 6, 2008, at the Wayback Machine.

[6] Masys, D. (2006). "Biomedical Informatics: Computer Applications in Health Care and Biomedicine". *JAMA: the Journal of the American Medical Association* **296** (21): 2624. doi:10.1001/jama.296.21.2624.

22.1.6 External links

- Official website
- Video of Morris Collen award ceremony
- Tree of Shortliffe's students

22.2 Don E. Detmer

Don E. Detmer, MD, MA, FACMI, FACS is Professor Emeritus and Professor of Medical Education at the University of Virginia and Visiting Professor at CHIME, University College of London.

22.2.1 Biography and career

Don Detmer chaired the 1991 study, "The Computer-based Patient Record". He was a member of the committee that developed the IOM Reports, "To Err is Human" and "Crossing the Quality Chasm." From 1999-2003 he was the Dennis Gillings Professor of Health Management at Cambridge University and is a lifetime member of Clare Hall College, Cambridge.

Considered to be a mover of the US National Health Information Infrastructure, Dr. Detmer has also been a consultant to the government of England and the Hospital Authority of Hong Kong. Prior to the years in England, he was Vice President for Health Sciences at the Universities of Virginia and Utah. While at Virginia he led implementation of a physician order entry system and was principal investigator of its IAIMS grant. While at the University of Wisconsin–Madison, he developed the nation's first Administrative Medicine Program, a Master's degree program for clinician-executives. As a surgeon, he was instrumental in the adoption and development of ambulatory surgery in the early 1970s and was team physician for the Wisconsin Badgers for ten years

while also serving as President of the Medical Staff. He won a UW–Madison Chancellor's Distinguished Teaching Award.

Detmer was appointed as President and CEO of the American Medical Informatics Association in 2004 until 2009 when he became Senior Advisor to AMIA until 2011.

Detmer's education includes a medical degree from the University of Kansas with subsequent training at the National Institutes of Health, the Johns Hopkins Hospital, Duke University Medical Center, the Institute of Medicine, and Harvard Business School. His MA is from the University of Cambridge.

Don's research interests include national health information policy, quality improvement, administrative medicine, vascular surgery, sports medicine, and management of academic health centers. He has written and edited a number of research articles, books, book chapters, and monographs on these topics. He enjoys grandchildren, horse riding, fly-fishing, reading biographies, and various crafts.

22.2.2 Advisory Activities

Don Detmer is a former trustee of the Nuffield Trust, a member of the Institute of Medicine as well as a lifetime Associate of the US National Academies, a fellow of AAAS, and the American Colleges of Medical Informatics, Sports Medicine, and Surgeons. He founded the Blue Ridge Academic Health Group and co-chaired it through 2011. He chairs the board of Medbiquitous. He was on the steering committee of a policy report for the Office of the National Coordinator on Health Information Technology to create a national framework for clinical decision support.

Dr. Detmer is past chairman of the Board on Health Care Services of the IOM, the National Committee on Vital and Health Statistics, and the Board of Regents of the National Library of Medicine. He was a Commissioner on the Commission on Systemic Interoperability. In 2013 he stepped down from his position as the inaugural Medical Director for Advocacy and Health Policy of the American College of Surgeons.

22.2.3 Awards and honors

- Fellow, American Academy of Nursing (Hon), 2012
- Walsh McDermott Medal, Institute of Medicine, Washington, DC, 2009
- Inaugural recipient, Don Eugene Detmer Signature Award in Health Policy Contributions in Informatics, AMIA, 2008
- National Associate, National Academies, Washington, DC, 2002
- Medal of Respect from Mongolian State University, Ulan Bator, 2001
- Fellow, American Association for the Advancement of Science, 1998
- President's Award, American Medical Informatics Association, 1996, 1998
- Distinguished Alumnus, Duke University Medical Alumni Association

22.2.4 Publications

Books

- Dick, Richard; Detmer, Don E.; Steen, Elaine B. (eds.) (1997). *The Computer-Based Patient Record*. Washington: National Academy Press. ISBN 0-309-05532-6. Cite uses deprecated parameter |coauthors= (help)
- Lohr, Kathleen; Vanselow, Neal A.; Detmer, Don E. (eds.) (1996). *The Nation's Physician Workforce: Options for Balancing Supply and Requirements*. Washington: National Academy Press. ISBN 0-309-05431-1. Cite uses deprecated parameter |coauthors= (help)
- Detmer, Don E.; Steen, Elaine B. (eds.) (2005). *The Academic Health Center: Leadership and Performance*. Cambridge: Cambridge University Press. ISBN 0-521-82718-3. Cite uses deprecated parameter |coauthors= (help)

Reports

- Detmer D, Steen E. *Learning from abroad: lessons and questions on personal health records for national policy*. AARP. Mar 2006.

Journal Articles

- Google Scholar publications
- Medline (Pubmed) publications

22.2.5 References

- http://aspe.hhs.gov/sp/nhii/Conference03/DetmerBio.htm
- http://www.amia.org/inside/leadership/boardbios.asp#Detmer

22.2.6 External links

- American Medical Informatics Association
- Medbiquitous

22.3 Homer R. Warner

Homer Richards Warner (April 18, 1922 - November 30, 2012) was an American cardiologist who was an early proponent of medical informatics.*[1]*[2] He has pioneered many aspects of computer applications to medicine. Author of the book, *Computer-Assisted Medical Decision-Making*, published in 1979, he served as CIO for the University's Health Sciences Center, as president of the American College of Medical Informatics (where an award has been created in his honor), and was actively involved with the National Institutes of Health.*[3] He was first chair of the Department of Medical Informatics. University of Utah was the first medical school in the U.S. to formally organize a degree in medical informatics.*[3]

Dr. Homer was emeritus chair of the University of Utah's Department of Medical Informatics. He was also a senior member of the Institute of Medicine of the National Academy of Sciences and president of the American College of Medical Informatics. For over 25 years, Dr. Warner served almost continuously on research review groups for the National Institutes of Health, the National Center for Health Services Research and the National Library of Medicine.

22.3.1 Biography

He was born in Salt Lake City on April 18, 1922 to Homer Warner.*[1] He joined the United States Navy during World War II and was trained as a pilot but never saw combat.*[1]

Warner received his B.S. in 1946 from the University of Utah. He received his M.D., also from the University of Utah, in 1949. By 1953 he had worked at Parkland Hospital in Dallas, Texas and at the Mayo Clinic in Rochester, Minnesota and had earned a Ph.D. in physiology from the University of Minnesota.*[1]

Medical Informatics

Beginning in the mid-1950s, Dr. Warner began his work using computers for decision support in cardiology at Intermountain Healthcare LDS Hospital in Salt Lake City. His ground-breaking work set the stage for the growth of the new field of academic study called medical informatics. In the 1970s, Dr. Warner and his Intermountain colleagues created one of the nation's first versions of an electronic medical record. Designed to assist clinicians in decision-making, Intermountain's now famous HELP system has been operational for nearly 40 years.

University of Utah

In 1964, Warner and his associates formally taught computer applications to medicine at the University of Utah in the Department of Biophysics and Bioengineering within the School of Engineering. In 1972, the department was split in two and Warner directed one of the splits: the Department of Medical Biophysics and Computing in the School of Medicine.*[4]

The department is internationally recognized for its contributions to computer applications in clinical care, medical education and research. The mission of the department is to improve health care outcomes through information systems in both the private and public sectors of the health care industry.*[4]

Much of the department's success is directly attributable to Warner's accomplishments. The department has produced the largest group of medical informatics professionals educated at any institution in the United States.*[4]

Warner served as director of the cardiovascular laboratory at LDS Hospital from 1954 to 1970 and was honored as Physician of the Year in 1985.

In 1988, he was elected to senior membership in the Institute of Medicine of the National Academy of Sciences. New members are chosen for major contributions to health and medicine as well as from related fields.

Personal life

Warner was a member of The Church of Jesus Christ of Latter-day Saints.

Death

He died on November 30, 2012 in Salt Lake City from complications of pancreatitis.*[1]

22.3.2 Awards

Morris F. Collen Award.*[3]*[5]

- Homer Warner wing of the IHC Medical Center in Utah

22.3.3 Intermountain Homer Warner Center for Informatics Research

Intermountain Healthcare officially opened a new center to support its clinical information systems on February 16, 2011 on the campus of Intermountain Medical Center in Salt Lake City. Named after Dr. Warner, the Homer Warner Center for Informatics Research honors one of

the industry's recognized fathers of clinical computer systems.

Advanced information systems help caregivers improve medical delivery and outcomes. For example, these systems automate routine functions, facilitate communication among caregivers, support decision-making processes, and allow statistical analysis to help improve care processes and implement best medical practices.

Intermountain has been an industry leader in using computers in the practice of medicine for several decades. Thanks to the hard work and vision of Dr. Homer Warner and his colleagues, Intermountain has an outstanding legacy on which to build all of its future information systems. Beginning in the mid-1950s, Dr. Warner began his work using computers for decision support in cardiology at Intermountain's LDS Hospital in Salt Lake City. In the 1970s, Dr. Warner and his Intermountain colleagues created one of the nation's first versions of an electronic medical record. Designed to assist clinicians in decision-making, Intermountain's now famous HELP system has been operational for nearly 40 years.

22.3.4 Homer R. Warner award

The award was created by the Object Management Group (OMG), self described as "an international, open membership, not-for-profit computer industry consortium". *[6]*[7]

It includes a $1000 prize, and is presented each year at the American Medical Informatics Association (AMIA). It is named for Warner. It is awarded for the paper that best describes approaches to improving computerized information acquisition, knowledge data acquisition and management, and experimental results documenting the value of these approaches.*[8]

Recipients

- Dr. Kensaku Kawamoto in 2012.*[9]
- Dr. Per H. Gesteland in 2011.
- Dr. Milos Hauskrecht in 2010.
- Dr. Hua Xu in 2009.
- Dr. Joshua C. Denny in 2008.
- Dr. Charlene R. Weir in 2007.
- Dr. Hamish S. F. Fraser, Director of Informatics and Telemedicine for Partners in Health, in 2006.*[10]
- Dr. Paul D. Clayton of Intermountain Health Care in 2005.*[11]
- Drs. Paul Biondich and David Taylor jointly in 2003.*[12]
- Dr. Randolph A. Miller, professor and chair of Biomedical Informatics, and David Sanders, research fellow in Biomedical Informatics, on November 2001.*[8]
- Dr. Peter Elkin for outstanding contribution to the field of Medical Informatics.*[13]

22.3.5 Bibliography

Some relevant books listed at Oregon Health & Science University (OSHU) library:

- Knowledge engineering in health informatics Homer R. Warner, Dean K. Sorenson, Omar Bouhaddou. New York : Springer, c1997.
- Computer-assisted medical decision-making Homer R. Warner. Imprint New York : Academic Press, 1979.

Papers published at *Journal of the American Medical Informatics Association*

- "Medical informatics: a real discipline?" HR Warner. *J Am Med Inform Assoc* 1995;2(4):207-214.
- "An event model of medical information representation", SM Huff, RA Rocha, BE Bray, HR Warner, and PJ Haug. *J Am Med Inform Assoc* 1995;2(2):116-134.

To illustrate his contribution to informatics applied to medicine, on the patent called "Rules-based patient care system for use in healthcare locations" issued on January 1, 2008, the references list includes seven works where he has collaborated.*[14]

22.3.6 References

[1] Bruce Weber (December 10, 2012). "Homer R. Warner, a Pioneer of Using Computers in Patient Care, Dies at 90". *New York Times*. Retrieved 2012-12-11. Homer R. Warner, a physiologist whose research fusing engineering and medicine helped introduce computer analysis to diagnosing illnesses, died on Nov. 30 in Salt Lake City. He was 90. The cause was complications of pancreatitis, his son Homer Jr. said. ... Homer Richards Warner was born in Salt Lake City on April 18, 1922. His father, also named Homer, was an auto dealer and a sports official.

[2] Father of medical informatics, Utah's Homer Warner dies, retrieved December 4, 2012

[3] Hall of Fame of Utah Technology Council, retrieved March 17, 2008 Archived February 8, 2008, at the Wayback Machine.

[4] department of medical informatics at University of Utah

[5] Presentation of the Morris F. Collen Award to Homer R. Warner, MD, PhD: "why not? Let's do it!", retrieved March 17, 2008

[6] Object Management Group website, retrieved March 17, 2008

[7] The Homer R. Warner Healthcare Interoperability Award;Call for Nominees.

[8] The Reporter: Miller, Sanders receive award, retrieved March 17, 2008

[9] http://www.amia.org/news-and-publications/amia-enews/amia-e-news-111512-amia-2012-winnerscollendistinguished-papersvideo

[10] http://deimos3.apple.com/WebObjects/Core.woa/FeedEnclosure/utah.edu.1356509518.01392594598.1390525251/enclosure.pdf

[11] http://www.amia.org/files/as05_paper_warner_0.pdf

[12] http://www2.amia.org/meetings/f03/post/awards.html

[13] Human Factors Engineering in HEALTH INFORMATICS Presentation of the members of the Scientific Program Committee and the presenters at the second conference on Human Factors Engineering and Usability for Healthcare Information Technology Applications

[14] United States Patent 7315825 Rules-based patient care system for use in healthcare locations, retrieved March 17, 2008

22.4 Robert Ledley

Robert Steven Ledley (June 28, 1926 – July 24, 2012), Professor of Physiology and Biophysics and Professor of Radiology at Georgetown University School of Medicine, pioneered the use of electronic digital computers in biology and medicine. In 1959, he wrote two influential articles in *Science*: "Reasoning Foundations of Medical Diagnosis" (with Lee B. Lusted) and "Digital Electronic Computers in Biomedical Science". Both articles encouraged biomedical researchers and physicians to adopt computer technology. In 1960 he established the National Biomedical Research Foundation (NBRF), a non-profit research organization dedicated to promoting the use of computers and electronic equipment in biomedical research. At the NBRF Ledley pursued several major projects: the early 1960s development of the Film Input to Digital Automatic Computer (FIDAC), which automated the analysis of chromosomes; the invention of the Automatic Computerized Transverse Axial (ACTA) whole-body CT scanner in the mid-1970s; managing the *Atlas of Protein Sequence and Structure* (created in 1965 by Margaret O. Dayhoff); and the establishment of the Protein Information Resource in 1984. Ledley also served as editor of several major peer-reviewed biomedical journals. In 1990, Ledley was inducted into the National Inventors Hall of Fame. He was awarded the National Medal of Technology in 1997. He retired as president and research director of the NBRF in 2010.

22.4.1 Family and Education

Robert Ledley was born on June 28, 1926 in Flushing Meadows, Queens, New York City, USA.*[1] His father, Joseph Levy, was an accountant and his mother, Kate Levy, was a schoolteacher before becoming a homemaker. Robert had a sister, Marion, and a half-brother, Ralph. All three siblings were surnamed Ledley.*[2]

Among Ledley's childhood friends in Flushing was Margaret Oakley Dayhoff, who would later spend most of her career working at the National Biomedical Research Foundation and who would become a founder of the field of bioinformatics.*[3] Ledley attended the Horace Mann School, from which he graduated in 1943.*[4]

As an undergraduate student at Columbia University Ledley excelled in physics, taking undergraduate and graduate courses within his first two years as a student. When, however, he informed his parents of his desire to become a physicist, they objected on the grounds that a career in physics would not be feasible for him given the scarcity of steady jobs in that field. Instead, they urged him to make his living as a dentist. Ledley attempted to follow both paths at once; he enrolled in the New York University College of Dentistry while continuing to pursue his education in physics at Columbia.*[5] During the day, Ledley would take dentistry training courses at NYU, then he would take the subway to Columbia to take evening courses in physics. After receiving his DDS from NYU in 1948, Ledley became a full-time physics graduate student at Columbia, where he took courses from many noted physicists including I.I. Rabi (who joked that Ledley was the only physicist who could pull a man's tooth), Enrico Fermi, Hans Bethe, and J.A. Wheeler. Ledley received a MS in physics from Columbia in 1950.*[6]

In 1949, Ledley married Terry Wachtell (born 1926), a mathematics teacher at Queens College, and sister of Herbert Wachtell.*[7] The couple had two sons, Fred (born 1954) and Gary (born 1957). When the couple moved to the DC area in the early 1950s, Terry was employed as a computer programmer until leaving work to raise their sons. Both sons graduated from Georgetown University School of Medicine.*[8] Fred Ledley is Professor of Natural and Applied Sciences at Bentley University and is the author of numerous scientific papers as well as the novel, *Sputnik's Child* (2011).*[9] Gary Ledley is a practicing cardiologist associated with Drexel University.*[10]

Robert Ledley died of Alzheimer's disease in Kensington, Maryland, USA on July 24, 2012.*[11]

22.4.2 Early Research Career

U.S. Army Dental Research

In 1950, shortly after the outbreak of the Korean War, Ledley was contacted by a U.S. Army recruitment officer, who offered him a choice: he could volunteer to join the U.S. Army Dental Corps as a First Lieutenant or be conscripted into the infantry as a private. Ledley promptly volunteered, and was sent to the U.S. Army Medical Field Service School for training.*[6] Because Ledley was also trained in physics, he was assigned to a dental research unit at Walter Reed General Hospital, in Washington, D.C..

During his time in the Army Ledley was responsible for improving prosthetic dental devices (such as dentures) then widely used by Army personnel. Notably, Ledley drew on his training in dentistry and physics to develop a system that optimized the process of fitting dentures by allowing dentists to determine the "angle of chew," or the mean slope of each tooth relative to the surface of an object (e.g. a piece of food) being bitten. Ledley presented this work to the American Physical Society in 1952, and it generated nationwide attention via an Associated Press newspaper story titled "Mathematics Used to Keep False Teeth in Place." *[12]

Work with Standards Eastern Automatic Computer

Terry Ledley operating the Standards Eastern Automatic Computer (SEAC) at the National Bureau of Standards in the early 1950s. Robert Ledley learned to program on this computer, first via paper tapes Terry brought to him and then by using the machine extensively himself.

Ledley's work on dental prosthetics brought him into collaboration with researchers based at the National Bureau of Standards Dental Materials Research Section, where he was offered a research job in 1952 following his discharge from the Army. There he encountered the Standards Eastern Automatic Computer, one of the earliest stored-program electronic digital computers. Ledley's first interaction with SEAC came via his wife, Terry, who worked as one of the machine's programmers – Robert taught himself to program by examining programs (on perforated paper tape) and manuals Terry brought home. Ledley started to use SEAC himself for his dental research, but after proving an adept programmer and troubleshooter, he found himself working with SEAC (and later DYSEAC) full-time on a wide variety of projects, including a remote-controlled aircraft guidance system.*[13]

For Ledley, working with SEAC produced an epiphany, concerning both his career and the potential importance of computers to biomedical research. He recalled: "I had previously realized that although, conceptually, physics equations could be written to describe any biomedical phenomenon, such equations would be so complex that they could not feasibly be solved in closed form. Thus SEAC would be my panacea, because the equations would become tractable to numerical methods of solutions. Or so I truly believed at the time. That was to be my field, application of computers to biomedical problems." *[13]

Operations Research and the RNA Tie Club

Though Ledley had envisioned a career of employing computers to solve biomedical problems as early as the early 1950s, it would be several years before he would pursue that career full-time. At the National Bureau of Standards, Ledley's work was primarily related to solving military problems using the techniques of operations research. For instance, he published an article in the journal *Operations Research* showing how one could use Boolean algebra to reduce complex military decision-making problems to the point where they could be resolved using a collection of truth tables and yes-or-no questions.*[14]

When Ledley lost his job at the NBS in 1954 due to budget cuts, he turned down an offer to work for IBM (which hired Ledley's colleagues en masse).*[14] Instead, he found employment as an "Operations Research Analyst" at the Operations Research Office at Johns Hopkins University. There, his work remained mostly focused on military problems, but his expertise in biology, physics, mathematics, and computing caught the attention of one of his new ORO colleagues, George Gamow.*[14] Gamow, who was renowned for his contributions to the Big Bang cosmological model, had taken an interest in molecular biology immediately after James D. Watson and Francis Crick elucidated the double helix structure of DNA in 1953. Gamow believed Ledley's skills could be instrumental in helping to crack the genetic code, that is, by solving the problem of how a DNA sequence translates into proteins. In 1954, Gamow invited Ledley to join the elite RNA Tie Club; some other members of the club were Watson, Crick, Richard Feynman, Max Delbrück, Edward Teller, and Sydney Brenner.*[15]

Ledley's main work for the RNA Tie Club was an effort to generate a set of contingency tables for the purpose of writing a computer program that would deter-

mine the correspondence between any three-letter sequence (triplet) of nucleotide bases and any amino acid (the building blocks of proteins). Sponsored by Gamow, Ledley published his work in 1955 in the Proceedings of the National Academy of Sciences.*[16] Though Ledley had produced a combinatorial table that could theoretically be used to determine which three-letter sequence of DNA bases corresponded to which amino acid, the problem required several thousand years of computation time on the world's fastest computers (circa 1955) to produce a solution.*[13]

Having established that computers could not be used reasonably quickly to decode DNA, Ledley drifted away from the RNA Tie Club. Ultimately the code was broken in the 1961 Nirenberg and Matthaei experiment, which did not use computers and which was not carried out by RNA Tie Club members.*[17]

Electrical Engineering

In 1956, Ledley was hired as an assistant professor of electrical engineering at the George Washington University School of Engineering and Applied Science.*[1] There, he taught some of the earliest courses on computer programming and wrote his first book, *Digital Computer and Control Engineering* (1960). At GWU, Ledley acquired the Florida Automatic Computer I and II, two descendants of SEAC that had been discarded by the US Air Force as surplus, for the purpose of establishing a "computation center" that would use the computers to automate Frederick Sanger's process of determining the amino acid sequence of proteins.*[13] The center was never built, however, because the National Institutes of Health rejected Ledley's request for a grant to fund it, and because the university balked at the prospect of installing and supporting the two enormous computers.*[13]

Collaboration with Lee B. Lusted

Lee B. Lusted (1922-1994), a radiologist with a background in electrical engineering, became aware of Ledley's work in 1956 after Ledley gave a presentation titled "An Operations-Research View of Medicine and Health" to the annual meeting of the Operations Research Society of America.*[18] After the meeting, Lusted telephoned Ledley, and the two found that they shared a strong interest in using electronics and mathematics to improve medicine. The two men immediately began to collaborate on developing ways to teach physicians and biomedical researchers, who rarely had much training in electronics or mathematics, to use electronic digital computers in their work.*[19]

In 1959, Ledley and Lusted published "Reasoning Foundations of Medical Diagnosis," a widely read article in *Science*, which introduced operations research techniques to medical workers. Areas covered included: symbolic logic, Bayes' theorem (probability), and value theory.*[20] In the article, physicians were instructed how to create diagnostic databases using edge-notched cards to prepare for a time when they would have the opportunity to enter their data into electronic computers for analysis.*[20] Ledley and Lusted expressed hope that by harnessing computers, much of physicians' work would become automated and that many human errors could therefore be avoided.*[21]

Within medicine, Ledley and Lusted's article has remained influential for decades, especially within the field of medical decision making.*[22] Among its most enthusiastic readers was cardiologist Homer R. Warner, who emulated Ledley and Lusted's methods at his research clinic at LDS Hospital in Utah. Warner's work, in turn, shaped many of the practices and priorities of the heavily computerized Intermountain Healthcare, Inc., which was in 2009 portrayed by the Obama administration as an exemplary model of a healthcare system that provided high-quality and low-cost care.*[18]*[23]

The article also brought national media attention to Ledley and Lusted's work. Articles about the work of the two men ran in several major US newspapers. A small demonstration device Ledley built to show how electronic diagnosis would work was described in the New York World Telegram as a "A Metal Brain for Diagnosis," while the New York Post ran a headline: "Dr. Univac Wanted in Surgery." *[24] On several occasions, Ledley and Lusted explained to journalists that they believed that computers would aid physicians rather than replace them, and that the process of introducing computers to medicine would be very challenging due to the non-quantitative nature of much medical information.*[24] They also envisioned, years before the development of ARPANET, a national network of medical computers that would allow healthcare providers to create a nationally-accessible medical record for each American and would allow rapid mass data analysis as information was gathered by individual clinics and sent to regional and national computer centers.*[24]*[25]

NAS-NRC Survey and Computer Advocacy

In early 1957, Ledley was hired on a part-time basis by the National Academy of Sciences - National Research Council (NAS-NRC) to conduct a national survey of current and potential computer use in biology and medicine in the United States.*[15] Supported by Senator Hubert Humphrey and NIH Director James A. Shannon, the NAS-NRC commissioned the survey in an effort to help physicians and life scientists overcome their reluctance to use computers.*[26]

Ledley published his survey findings in a November 6, 1959 *Science* article, "Digital Electronic Computers in Biomedical Science," in which he called on biologists to

train in mathematics and engineering in order to effectively use electronic digital computers.*[27] He predicted that in the long run, "perhaps the greatest utilization of computers will be in biomedical applications."*[27] Like the earlier *Science* article co-authored with Lusted, Ledley's new piece was widely read – among its most influential and enthusiastic readers was Joshua Lederberg, who spent much of the later part of his career using computers to solve problems in biology research.*[28]

Ledley's survey and article also shaped the National Institutes of Health's first major effort to encourage biomedical researchers to use computers.*[29] This effort began shortly after the Soviet launch of Sputnik in October 1957—in reaction to Sputnik, the U.S. Congress sought means boost U.S. scientific and technological productivity. Beginning in 1960, Congress allocated roughly $40 million to the NIH for the purpose of stimulating computer use in biomedical research.*[29] Ledley's survey recommendations, particularly his call for biomedical workers to train extensively in mathematics and engineering, served as a guide for the NIH effort, which was carried out by the NIH's Advisory Committee on Computers in Research (ACCR).*[29] The ACCR was led from 1960 to 1964 by Ledley's collaborator, Lee Lusted. During those years, the committee established several major biomedical computing centers around the USA and sponsored the development of the LINC.*[29] The ACCR's successor, the Computers in Research Study Section, was headed by Homer Warner, one of the first research physicians to employ Ledley and Lusted's techniques in a clinical setting.*[30]

NBRF "Christmas Tree" showing projects and journals initiated by the organization up to 1991. At the base is the establishment of the foundation in 1960. The ornaments represent (moving from bottom to top and from left to right): the Atlas of Protein Sequence and Structure (initiated in 1965), Computers in Biology and Medicine *(journal founded in 1969),* Pattern Recognition *(journal founded in 1967), first protein datatape (1972), ACTA (prototype built 1974),* Computer Languages *(journal founded in 1972), first nucleic acid datatape (1979),* Computerized Medical Imaging and Graphics *(journal founded in 1981 -- this grew out of the 1976 journal* Computerized Tomography *and the 1977 journal* Computerized Radiology*), CENOG (prototype built 1978), Protein Information Resource (launched in 1984), 1990 was the NBRF's 30th year.*

22.4.3 National Biomedical Research Foundation

Establishment and Goals of the NBRF

Following his survey work for the NAS-NRC and the publication of his and Lusted's articles in *Science*, Ledley sought federal government and university support his efforts to development computers and computer programs for use by biomedical researchers. With the support of the NAS-NRC, Ledley chartered in 1960 the National Biomedical Research Foundation (NBRF), a nonprofit organization, initially based in an NAS-NRC-owned building near Dupont Circle, Washington, D.C.*[31]

Believing that his career as a university faculty member would ultimately constrain his research, Ledley left his position at GWU in order to dedicate his full-time to running the NBRF. Ledley would lead the NBRF until his retirement in 2010. Early employees included: Louis S. Rotolo (Ledley's assistant in the NAS-NRC survey), James B. Wilson (Ledley's former graduate student at GWU), and Margaret O. Dayhoff (a quantum chemist with a Ph.D. from Columbia and Ledley's childhood friend from Flushing).*[31]

Grounded in Ledley's belief that computer use would substantially improve biology and medicine by helping to mathematize those areas, the NBRF's mission was to "stimulate biomedical research scientists to utilize computers by setting an example through its own pioneering research and development in new areas of computer applications."*[32] Starting with an annual budget of under $100,000 and a half-dozen employees, the NBRF grew into a multimillion-dollar operation with more than 20 employees by the early 1980s.*[31] Initially the vast majority of NBRF's support came from the NIH, but by 1980 it drew support from a variety of federal, university, and corporate sources, in addition to generating revenue through the publication of journals and the sale of electronic instruments, software, and patents.*[31]

In 1970, the NBRF began its affiliation with the

Georgetown University Medical Center. The university, which had allocated space for a biomedical computing facility that had never been built, provided office and laboratory space for the NBRF, while the NBRF would serve as a computing resource for the university as well as bring funding and prestige to the university through its research and development activities.*[31]

As part of the move, Ledley was appointed to Georgetown University's faculty as a professor of radiology, physiology, and biophysics.*[8] The NBRF was physically located at Georgetown from 1970 to 2006.*[31] Between 2006 and 2010 it was based in offices in Washington, D.C. and Bethesda, MD.

In 2011, the NBRF was reincorporated in Massachusetts and has adopted a new mission statement.

FIDAC and Pattern Recognition

Robert Ledley pictured with FIDAC in 2007.

Robert Ledley posing with an IBM 360 that was used in conjunction with FIDAC. The sheets of paper on the left side of the photograph are printouts of digitized chromosome micrographs. Stacks of IBM punched cards are present near Ledley's right arm.

The NBRF's earliest area of emphasis was developing optical pattern recognition technology. Working with Wilson in 1960 and 1961, Ledley built the Automatic Device for Antibiotic Determination (ADAD), a computerized light-measuring device that tested for efficacy of antibiotic drugs by measuring transparency in petri dish cultures.*[32] Areas that were transparent were likely areas where the antibiotics had killed the bacterial populations; areas that were opaque likely areas where the bacteria were still alive.*[32] The NBRF sold several ADAD units to the Food and Drug Administration, and to large pharmaceutical companies.*[31]

Building on the success of ADAD, Ledley, Wilson, and a newcomer to the NBRF, electrical engineer Thomas Golab, developed the Film Input to Digital Automatic Computer (FIDAC) in the mid-1960s.*[33] FIDAC was designed to scan a photograph into its memory and then send that information to a larger computer (e.g. IBM 360) in order to recognize patterns in the scanned image.*[33] To digitize a photograph, FIDAC would impose a 700 x 500 point grid (of arbitrary size) onto it and then measure the light level at each point. Depending on the light level detected at it, each point was assigned an integer ranging from 0 to 9. FIDAC could generate a 350,000-point scan in under 0.5 seconds.*[33]

Ledley designed FIDAC to scan photomicrographs of chromosomes in order to automate the labor-intensive task of karyotype analysis, which is used to detect conditions such as Turner syndrome and Down Syndrome.*[33] Once programmed to distinguish chromosomes from the background and then to recognize abnormalities in a given sample (e.g. the presence of extra chromosome(s), abnormally-shaped chromosome(s)), FIDAC could perform in 40 seconds a chromosome analysis that took a skilled technician 15 minutes to complete by hand.*[33]

Beyond chromosome analysis, FIDAC was adapted to digitize and analyze photographs of neurons and Pap smears as well as schlieren photographs.*[33] About a dozen FIDAC units were sold during the 1960s, and by the early 1970s there was considerable demand for a smaller version of the machine.*[33] Ultimately the Jet Propulsion Laboratory was awarded an NIH grant to develop a small, FIDAC-like instrument for use in laboratories and clinics.*[33]

To facilitate discussion among users and developers of FIDAC, Ledley founded in 1969 the peer-reviewed journal '**Pattern Recognition**', the official journal of the Pattern Recognition Society. Ledley remained the editor of *Pattern Recognition* until 2010.*[33]

ACTA and Computerized Tomography (CT/CAT scanning)

Ledley is most widely known for his 1970s efforts to develop computerized tomography (CT) or CAT scanners. This work began in 1973, when the NBRF lost most of its NIH funding due to federal budget cuts. During this time, the NBRF had also become increasingly involved in on-campus computing projects.*[34] Quickly trying to

Robert Ledley at the exhibit of the ACTA whole-body CT scanner at the Smithsonian's National Museum of American History.

raise enough funds to cover the NBRF employee salaries, Ledley looked for projects the organization could undertake for Georgetown University.*[34] After learning that Georgetown research physicians were frustrated by the $500,000 cost of a CT scanner they wished to buy from EMI (EMI-Scanner), Ledley promised them that the NBRF could build a similar machine for only half the price. The university agreed to give Ledley a chance, and for the next several months a team led by Ledley, Golab, Wilson, and Frank Rabbitt, worked to develop a prototype.*[34]*[35]

Aside from reducing cost, the NBRF team aimed to overcome the major constraint of the EMI-Scanner, namely that it required X-rays to be shone through a water tank enclosing the object being scanned—this constraint limited the use of the scanner to only patients' heads and required physicians to place patients' heads into a rubber bladder extending into a water tank.*[35] Building on their experience in medical imaging, and working with Godfrey Hounsfield's early designs for the EMI machine as well as the theoretical papers of Allan McLeod Cormack and William H. Oldendorf, the NBRF team concluded that the necessity of using a water tank could be eliminated by changing the algorithm used to assemble X-rays into a 3-D image. Unlike the EMI's head-only scanner, which used a relaxation algorithm, the NBRF machine used a convolution algorithm.*[35]

In 1974, after several months of working with Georgetown's machinists and auto body specialists at a nearby Cadillac dealer, Ledley's team completed construction of the Automatic Computerized Transverse Axial (ACTA) scanner.*[34] The machine had 30 photomultiplier tubes as detectors and completed a scan in 9 translate/rotate cycles, much faster than the EMI-scanner. It used a DEC PDP-11/34 minicomputer both to operate the servomechanisms and to acquire and process the images. Most importantly, ACTA could scan the entire body, whereas the EMI-scanner could only scan the head.*[34]

ACTA was immediately successful at Georgetown. Late in the prototype's development, David C. McCullough, a pediatric neurosurgeon at Georgetown University Hospital used ACTA—without Ledley's knowledge—to examine a child who hit his head in a bicycle accident.*[34] McCullough used the machine to detect brain bleeding in the boy and the precise information about the location of the bleeding to quickly plan and perform life-saving surgery.*[34] News of this and other similar cases spread quickly and Ledley soon faced worldwide demand for machines like ACTA.*[35]

Ledley established Digital Information Science Corporation (DISCO) in 1974, which sold the ACTA scanners for $300,000 each.*[35] On November 25, 1975, Ledley was issued the patent for the design of ACTA.*[36]*[37] Later in 1975, DISCO sold the ACTA rights to Pfizer for $1.5 million in cash and $10 million in guaranteed research funding (paid out over 10 years) for the NBRF.*[35] Pfizer's ACTA 0100 and its successor, the 200FS, were sold to hospitals worldwide between 1975 and 1977, but Pfizer lost the medical imaging market to G.E. and Technicare, which both sold next-generation CT scanners.*[35]

As the use of CT scanners became widespread, Ledley rose to considerable prominence. The ACTA prototype was displayed at the Smithsonian's National Museum of American History, in Washington, D.C.. The Smithsonian also established an archive for materials related to the development of ACTA.*[1] For his role in developing ACTA, Ledley was inducted into the National Inventors Hall of Fame in 1990 and was awarded the National Medal of Technology and Innovation in 1997.

Bioinformatics

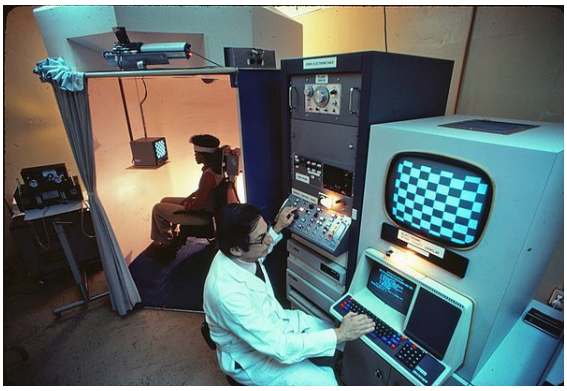
Alongside Ledley's work on imaging technology, his NBRF colleague Margaret Oakley Dayhoff was developing resources for the study of life on the molecular level. Her 1965 *Atlas of Protein Sequence and Structure* sought to provide a comprehensive collection of the scientific community's data on protein sequencing.*[38] Published annually by the NBRF, first on paper then (as the volume of information grew much larger) on magnetic tape and finally on CD-ROM, the *Atlas* served as an information clearinghouse for the growing community of protein sequencers.*[35] By the mid-1970s the *Atlas* had become the primary repository of protein sequence data, and ultimately served as a model for the Protein Data Bank and the nucleic acid sequence database GenBank, both now major resources for biologists.*[35]*[39]

After Dayhoff died suddenly in 1983, Ledley and Winona Barker (who joined the NBRF in the late 1960s) took charge of the project.*[35] During the mid-1980s Ledley and Barker led a team that developed the Protein Identification Resource (later called the Protein Information Resource or PIR), an online version of the *Atlas*. Researchers using modems or Tymnet could access the PIR to look up sequence information or add to the collection.*[35] As of 2012, the PIR remains an important re-

source for biologists; it is managed jointly by the University of Delaware and Georgetown University, and is a major component of UniProt.

Other NBRF Computing Projects

The NBRF "Bat," a 3-D mouse (left) used for interacting with stereo images (right).



Robert Ledley operating CENOG at the NBRF circa 1980.

From 1979 to 1980, Ledley and Golab developed the Computerized Electro Neuro Ophthalmograph (CENOG). This machine enabled healthcare providers to automatically analyze ocular motility, an important factor in the diagnosis of neurological and ophthalmic disorders.*[8] CENOG generated considerable media attention in the early 1980s, largely because it served as a demonstration of the feasibility of automated medical diagnosis.*[40]*[41]

While at the NBRF, Ledley also carried out work related to computer design. In 1970, when Moore's Law was still a relatively new idea, and when the most powerful computers had 1,000 to 2,000 logic gates, Ledley wrote a paper titled "Realization of a Billion-Gate Computer" in which he speculated on the capabilities of a transistorized computer that had 1,000,000,000 logic gates. He proposed that such a machine would: 1) have no fixed logic design; 2) be capable of redesign some of its own components; 3) be able to "self-heal." *[42] Billion-transistor microprocessors have been commonplace in personal computers since 2010, though these machines are not as dynamic (in terms of logic structure) as Ledley had predicted.

In the late 1980s, Ledley lead the team that developed the Bat, a three-dimensional mouse that allowed users to interact with objects in three-dimensional space (generated using stereo images).*[8]

22.4.4 Scientific Journals

During his long career at the NBRF, Ledley served as editor of four major peer-reviewed journals. In 1969, he launched *Pattern Recognition*[*][43] and *Computers in Biology and Medicine*.*[44] The former focuses on computerized approaches to pattern recognition, while the latter publishes articles, algorithms, and technical descriptions related to the use of computers in biomedicine. In 1972, Ledley started *Computer Languages, Systems and Structures*, the mission of which is to publish "papers on all aspects of the design, implementation and use of programming languages, from theory to practice." *[45] In 1976, following the success of ACTA, Ledley initiated *Computerized Tomography*, which was renamed *Computerized Radiology* in 1977, and subsequently renamed *Computerized Medical Imaging and Graphics* in 1981. It serves as "a source for the exchange of information concerning the medical use of new developments in imaging diagnosis, intervention, and follow up." *[46] Ledley served as editor of all four journals until his retirement in 2010. The journals are currently published by Elsevier.

22.4.5 Honors, memberships, and affiliations

- Morris F. Collen Award, American College of Medical Informatics (AMIA) (1998)
- National Inventors Hall of Fame (inducted 1990)
- National Medal of Technology (1997)
- Vicennial Gold Medal for Distinguished Service, Georgetown University (1990)
- Member, Institute of Medicine, National Academy of Sciences (1999)
- Distinguished Alumnus, New York University (1999)

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22.4.9 External links

- Protein Information Resource (Georgetown University)
- Presentation of Morris F. Collen Award to Robert S. Ledley on YouTube American College of Medical Informatics (AMIA), 1998
- "A Lifetime of Biomedical Computing: A Conversation with Robert Ledley" at the Wayback Machine (archived July 4, 2009) public lecture, National Institutes of Health, February 21, 2008.

22.5 Vimla L. Patel

Vimla Lodhia Patel, is a Fijian-born Canadian cognitive psychologist and biomedical informaticist.

In the past decade, Dr. Patel has worked in the area of biomedical informatics, in particular studying the mediating roles of technology on performance. Her work includes studies of medical errors and error reduction in emergency care and other critical medical environments, (including telephone triage). Her past work in health cognition includes studies of risk-taking behavior and sexual decision making as it pertains to HIV in youth and adolescents. Her current work focuses mostly on identifying underlying cognition in medical error and learning.

22.5.1 Biography and career

Dr. Patel was born in Fiji and obtained a degree in biochemistry and microbiology from University of Otago in New Zealand, and MA and PhD in Educational Psychology (Medical Cognition,1980,1981) from McGill University in Montreal, where she also served as professor of Medicine and Psychology and director of the Centre for Medical Education. She was a founding member of HEALnet (Health Evidence Application and Linkage Network), which made seminal contributions furthering informatics research and application in Canada. She was also a member of the InterMed Collaboratory, which developed guidelines for medical decision support, and has done extensive work in India, Africa, and Colombia in cross-cultural cognition research.

In 2000 she became director of the Laboratory of Cognition and Decision Making in the department of Biomedical Informatics at Columbia University, where she was also faculty in the department of Psychiatry and Teacher's College. From 2007-09, she served as interim chair and vice chair of Department of BMI at Arizona State University. Dr. Patel was a Professor of Biomedical Informatics and Co-Director of the Center for Cognitive Informatics and Decision Making at the University of Texas at Houston from 2009-11.As of November 2011, Dr.Patel joined the New York Academy of Medicine as a Senior Research Scientist and is the head of the Center for Cognitive Studies in Medicine and Public Health and is an adjunct professor of Biomedical informatics at Columbia University in NY.

22.5.2 Research

In 1978 Elstein, Shulman and Sprafka*[1] applied cognitive science methods to investigate physicians' clinical competence, developing a model of hypothetico-deductive reasoning which proposed that physicians reason by generating and testing a set of hypotheses to explain clinical data. This is an example of backward (hypothesis-to-data) reasoning. In 1986, Patel and Groen*[2] demonstrated that experts who accurately diagnosed complex clinical problems used forward reasoning (data to hypothesis), in contrast to novice subjects who used backward reasoning and misdiagnosed or partially diagnosed the same problems.

Patel also applied text comprehension methods to understanding the use of clinical practice guidelines with the goal of increasing adoption of best practices.*[3] Patel and colleagues have recently argued for new paradigm for error studies, where instead of zero error tolerance, detection and correction of potential error is viewed as an integral part of cognitive work in a complex workplace.*[4]

She is the author of more than 300 publications in cognitive psychology, biomedical informatics, medical education and related fields.

22.5.3 Honors

- Member, Committee on Patient Safety and Health Information Technology, Institute of Medicine (IOM). 2010-2011.
- Science and Technology Research Award (STAR) with Edward Shortliffe, UTH System, Houston,Texas. 2009
- Vice Chair, AMIA Program Committee. 2009

- Service Faculty of the Year Award, School of Computing and Informatics, Arizona State University. 2008
- Member, Clinical Research Review Committee, The National Center for Research Resources (NCRR). 2007-2009
- Selected for *Marquis Who's Who in the World*. 2007
- Member, Committee on Opportunities in Basic Research in the Behavioral and the Social Sciences for the Military, National Research Council, U.S.A. 2006
- Elected Fellow, New York Academy of Medicine. 2004
- Vice President (Member Service), International Medical Informatics Association Governing Board. 2003-2006
- Outstanding Manuscript Award in Educational Methodology, Journal of Dental Education. 2002
- Member, Bio-engineering Training and Education Program, National Science Foundation, USA. 1999-2007
- Chair, Editorial Committee, Medinfo2001, International Medical Informatics Association, London, UK. 1999
- D.Sc. (honorary), University of Victoria, BC, Canada. 1998
- Member, Roundtable on Work, Learning and Assessment, National Research Council, U.S.A. 1997
- Elected Member, Board of Governors, Cognitive Science Society. 1997
- Elected Fellow, American College of Medical Informatics. 1996
- Fellow, The Royal Society of Canada (elected by the Academy of Humanities and Social Sciences). 1996
- Elected "Woman of Science" for the year (Sweden). 1994

22.5.4 External links

- Vimla Patel's Homepage

22.5.5 Publications

- Journal Articles
- Book Chapters
- Medline Publications
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Chapter 23

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23.1 Text

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- **Health informatics** *Source:* https://en.wikipedia.org/wiki/Health_informatics?oldid=719489053 *Contributors:* Christopher Mahan, William Avery, Rsabbatini, Edward, Nealmcb, Kku, Karada, Paul A, Ronz, Angela, Topbanana, Francs2000, Hadal, Mystyc, Cobaltbluetony, Jfdwolff, Devans, Khalid hassani, Erich gasboy, SarekOfVulcan, Inversetime, Mako098765, APH, KVeil, Latorilla, Pak21, SeaLion, Dmeranda, Bender235, Hayabusa future, Enric Naval, Sakaton, Nsaa, Udo Altmann, Wonglkd, Arthena, Rodw, Peterjm, Versageek, Mindmatrix, D3dtn01, Ruud Koot, Tabletop, Timtom27, Graham87, BD2412, Ryan Norton, Rjwilmsi, Hiberniantears, MapsMan, Ian Pitchford, Winhunter, Spencerk, Chobot, Bgwhite, YurikBot, Wavelength, Midgley, Deanforrest, Chris Capoccia, Gaius Cornelius, NawlinWiki, Cquan, Manuelhp42, THB, Supten, Finizio, Vojtech huser, Phaedrus86, HexiToFor~enwiki, Egbert J. van der Haring, Bondegezou, Mikeyww, ArielGold, SmackBot, CCRadvocate, InverseHypercube, Frana003, InvictaHOG, Kilo-Lima, Gilliam, Donama, Hmains, Chris the speller, Jethero, Jprg1966, Oli Filth, Eloraby, Radagast83, Codish, Magnit, Infomd, Euchiasmus, Severoon, Mrteabiscuit, Aftereight, Beetstra, Novangelis, ChrisCork, Ryanjo, Drkhalifa, Argon233, Yaris678, Cydebot, Rmccready, I.M.S., Dancter, Chrislk02, John L Hardy, Thijs!bot, Epbr123, Hazmat2, Herrfous, Dirkstanley, Dawnseeker2000, Obiwankenobi, Seaphoto, Dylan Lake, Kauczuk, Cpwonghkg, Alexav8, JAnDbot, MER-C, Ph.eyes, Vinaitheerthan, Godcast, Jwojt, Dpugrad01, Dulciana, Theroadislong, Asangansi, Mysteryquest, RufusScholasticus, Pvosta, ChristofG, Tgeairn, Bertrow, Mike.lifeguard, McSly, Cankersore, Krishnachandranvn, Jovember, Flatterworld, Atama, Wingnam, Ross Fraser, Bonadea, GregWoodhouse, Lalvers, Davecrosby uk, Funandtrvl, Sirrtoby, MilkTheImp, White, Jim, Optigan13, Hankhuck, Michaeldsuarez, Bcheng23, Synthebot, Stuart.turner.ucdavis, Ya5irha55an, Sue Rangell, Moonriddengirl, Perspectoff, Heatherkhill, Keilana, Jsfouche, Cbond~enwiki, Falemi, Lightmouse, Cwh377, StaticGull, Ward20, Dmasys, Sabathecat, Stevecalloway, Stillwaterising, ShelleyAdams, ImageRemovalBot, Beeblebrox, ClueBot, Katiem222, The Thing That Should Not Be, Ostmoe, Jan1nad, Patrickbarmore, Ignorance is strength, WDavis1911, Niceguyedc, Rahilrizvi, Edknol, Jeanhcjean, Pojoman, JBart98, Atharhaq, Loop 9, Bio guru 2000, Aleksd, Podkayneofmars, Attaboy, DumZiBoT, XLinkBot, Muzaffarmalik, SwirlBoy39, Medinfodocs, Mithumukherjee, Wegely, Addbot, Basilicofresco, Maralpa, Gdavidzon, Megata Sanshiro, Mootros, Megan marie2008, Terrillja, Tide rolls, Lightbot, Pietrow, Zorrobot, Bainca, Abduallah mohammed, Luckas-bot, True54, Yobot, Andresswift, TestEditBot, AnomieBOT, VanishedUser sdu9aya9fasdsopa, Rjanag, Jim1138, Bluerasberry, Materialscientist, Citation bot, LilHelpa, Eastwest112, Capricorn42, Csstsrg, HInformatics, Dtparry, Jdegreef, Eghdam~enwiki, MerlLinkBot, FrescoBot, Epsos, Xavier Canals-Riera, Bainchri, Yves.lussier, Cnwilliams, Publicoption, Richarddav, Professor m f smith, Michaelmdx, CanaDanjl, R.alrajhi, Difu Wu, RjwilmsiBot, Monica murero, EmausBot, John of Reading, Daskalak, Ahvankampen, Dewritech, MartinThoma, Mons0122, Lingmac, Louise sch, AManWithNoPlan, Kilopi, Scsdirectories, Jesanj, Cforrester101, MainFrame, Dmckay84, ClueBot NG, Nicholsn, Tammy b530, Anindya87, BarryRobson, Snipun, Jeanhcjean999, Widr, Guptan99, Gracetupelo, Helpful Pixie Bot, BG19bot, Neøn, Who.was.phone, Rds1970, Vendomedpt, Vbhise, Nishkarsh k, Shabbirgchy, Jennifer Teplits, MrBill3, Glacialfox, Lellis.easc, BattyBot, Ummuldrg, Hälsoinformatik, Justincheng12345-bot, Jjhert1, TheJJJunk, Khazar2, Health Informatics Chris, Leprechaun0226, SPHer, Giso6150, JYBot, Dexbot, Hmainsbot1, Briancrouch, Teleenfermeria, UseTheCommandLine, Captivatedbelle, Dvwoodcock, Jamesmcmahon0, Beasarah, Davis.devries, Drscarlat, Toni Lee (Tong Li), Ggspamm, Angievil8x, Djcorfield, Drchriswilliams, AntilopeP, Sîc S. Drêwalla, Davidbrownz, Tmdwiki, Monkbot, Patient Zero, Wuser6, JoeHebda, Soshifiedsone, Jan8818, Poiuytrewqvtaatv123321, DemetriusGiannopoulos, Robert Stan Day, CMTrunick, IvanZuev, MedTechStudent, Lise-lyse, KasparBot, Argio Ypt, Maboitiz, Ajinen and Anonymous: 310
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- **Health 2.0** *Source:* https://en.wikipedia.org/wiki/Health_2.0?oldid=715364738 *Contributors:* Rsabbatini, Fschoenm, Mandarax, Rjwilmsi, Jeffrey Henning, PaulWicks, Varano, Bondegezou, Rathfelder, NeilN, SmackBot, NCurse, Ehheh, CmdrObot, Vzach, Wikid77, David from Downunder, Shekharsahu, Obiwankenobi, Froid, WhatamIdoing, Niceguyedc, Alexbot, Patriciajane, Apparition11, XLinkBot, BAPHughes, Dodoïste, Addbot, MrOllie, Yobot, AnomieBOT, Bluerasberry, Drilnoth, Skariface, FrescoBot, EugeneBorukhovich, PaoloRomano, SBehrs, John of Reading, ISkanderIT, Midas02, Kasirbot, Sweet tea van, Socialf5, 1002a5, Proorlovwiki, ChrisGualtieri, Petardugz, Mogism, SFK2, SmileBlueJay97, Michelon-CNGOF, Jpgs33, Prpennin and Anonymous: 32
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- **Medical integration environment** *Source:* https://en.wikipedia.org/wiki/Medical_integration_environment?oldid=699147380 *Contributors:* Rich Farmbrough, Forderud, Malcolma, Nadamarketing, SmackBot, Bluebot, GoodDay, Cydebot, MarshBot, DGG, Curious brain, Yobot, Medical Studies and Anonymous: 1

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- **ICU quality and management tools** *Source:* https://en.wikipedia.org/wiki/ICU_quality_and_management_tools?oldid=685261470 *Contributors:* Edward, Orangemike, Versageek, Ron Ritzman, RHaworth, Uncle G, Rjwilmsi, SmackBot, Darth Panda, Kuru, Cereis, Addbot, MuZemike, Materialscientist, Citation bot, LilHelpa, Citation bot 1, Jonesey95, Josve05a, Drscarlat, Mxdlvn and Anonymous: 4
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- **COmputer STored Ambulatory Record (COSTAR)** *Source:* https://en.wikipedia.org/wiki/Computer_Stored_Ambulatory_Record?oldid=644130828 *Contributors:* Petersam, Ketiltrout, Cydebot, Obiwankenobi, Postcard Cathy, Johnpacklambert, CMBJ, Jsfouche, JLBot, Dawynn and Delusion23
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- **Telemedicine** *Source:* https://en.wikipedia.org/wiki/Telemedicine?oldid=718603841 *Contributors:* Heron, Rsabbatini, Ubiquity, Infrogmation, Kku, Sbbhattacharyya, Hadal, Cobaltbluetony, Wmahan, Onco p53, Piotrus, Kate, Chris Howard, Rich Farmbrough, Pak21, Slipstream, Arcadian, Shanafme, Mpulier, Alib, Slugmaster, Velella, Wtshymanski, HenryLi, Ceyockey, Stuartyeates, Scjessey, Mandarax, Rjwilmsi, JHMM13, Thenthorn, FlaBot, Ground Zero, Nihiltres, Wavelength, NTBot~enwiki, Robert A West, Bjerrk, Supten, SGogia, Phaedrus86, Kawika, Light current, Deville, StuRat, Closedmouth, Badgettrg, KnowledgeOfSelf, Eskimbot, DOC DS, Ohnoitsjamie, Carl.bunderson, Chris the speller, EBMdoc, Deli nk, PureRED, A. B., Davidcohen, Nixeagle, JonHarder, Mebrooks1969, Mini-Geek, Anriz, Spsood, Allenplanet, Mochachocca, Novangelis, Iridescent, JoeBot, Az1568, Audiosmurf, AbsolutDan, CmdrObot, Danapsimer, Harej bot, Drkhalifa, Argon233, Cydebot, Carlitosau~enwiki, Gogo Dodo, Hebrides, GRBerry, Paddles, Alaibot, Omicronpersei8, Kubanczyk, Mereda, Headbomb, Aiko, Dawnseeker2000, Obiwankenobi, Kauczuk, Lboehner-ejohnson, Harryzilber, Barek, Fetchcomms, Albany NY, Magioladitis, GRIFFEY366, DerHexer, Pvosta, MartinBot, Gogia7, R'n'B, CommonsDelinker, Tmulak, NatureBoyMD, Sunidesus, Mukherjiarnab, Stanqo, Tiggerjay, Treisijs, Llorenzi, VolkovBot, Ianalis, Mamurphy88, Spotharaju, Journalist1983, CMBJ, EditingFrenzy, SieBot, Celtic fairies, OKBot, Mrnicksmith, Ken123BOT, Escape Orbit, YSSYguy, Martarius, ClueBot, ImperfectlyInformed, Eilily, Dtolj, PixelBot, Jleder, Apparition11, Disasterlogistics, Scatter22, Wanscher, XLinkBot, Jytdog, WikHead, Mco44, Basmah79, Addbot, Satbuff, Riteview, MAgrell, Mootros, MagnusA.Bot, MrOllie, Shltn, Aditya.m4, Lightbot, Legobot, Middayexpress, Yobot, Ptbotgourou, Dgilperez, Torbinsky, Bbb23, AnomieBOT, Piano non troppo, WurmE, Paf25, Materialscientist, Citation bot, GB fan, Broadband118, GenOrl, Chillin69x, Jwcknet, Lenapi, FrescoBot, Kunalkhurana1, Interoperable, Ngtm, Jonesey95, Yazmínmx3, Ryansean, Australian-Melodrama, Дмитрий Кошелев, Orenburg1, Trappist the monk, Thielst, Diannaa, Vgprak, Umashankar08, John of Reading, Pch123, Sumsum2010, Julie345, Lenapi2009, We hope, JivaGroup, Mtavella, Ebrambot, Nan KT, SporkBot, Tolly4bolly, Gauri Batra, KAErps, Zeeshanchattha, Zubinthakore, ClueBot NG, Dibnisha, Neon369, Snotbot, Frietjes, Carv123456, Helpful Pixie Bot, Imedpub, BG19bot, Paperclip777, Sterling.M.Archer, Balsamfir, Badon, MrBill3, Etayvas, Pkloeb, BattyBot, Pratyya Ghosh, Ggalonso, ChrisGualtieri, Arcandam, Jihadcola, Terinavy, Jaeztheangel, FaradayLupin, Me, Myself, and I are Here, Wikilove222, Leitoxx, Ashleyleia, Lenapi 1980, FieldsTom, Ewdevlin, Bryanrutherford0, Drchriswilliams, Annelillxy, Albahja00, Monkbot, Filedelinkerbot, Shjn14, Luleaa, Scoopny16, Cullum007, Themanzack, Toniov88, KasparBot, Mmorris999, KK-CIMT, Pyellowlees, DonnatarCastle and Anonymous: 204

- **Telecare** *Source:* https://en.wikipedia.org/wiki/Telecare?oldid=718998947 *Contributors:* Rsabbatini, Darrelljon, Tawker, Sgkay, Paul foord, Srleffler, Number 57, Rathfelder, Gilliam, Bluebot, Pgillman, -fin, Geologyguy, Iridescent, Argon233, Cydebot, Stillplaygbc, Calltech, DGG, Uncle Dick, Alinja, Technopat, Mild Bill Hiccup, Trivialist, David111180, Presnser, Addbot, Karstenandjason, OlEnglish, Yobot, TaBOT-zerem, Jim1138, MindNoGap, FrescoBot, Qingostarr, Fayedizard, Mean as custard, EmausBot, Speechpathology, Klbrain, AvicAWB, Tleckie, TelecareTechnology, G2003, CliftonRugby, DBigXray, BG19bot, Naivepanda, WikiHannibal, Fraulein451, SFK2, AnotherSkierDude, Aquajones, Psychicgravel, Nano Hernandez, OliviaMarketing94, Matthewhenfrey and Anonymous: 15

- **Telephone triage** *Source:* https://en.wikipedia.org/wiki/Telenursing?oldid=704818268 *Contributors:* Rsabbatini, Edward, RJFJR, The Rambling Man, THB, Ezeu, SmackBot, Steve carlson, Commander Keane bot, TenPoundHammer, Harryzilber, Sarahj2107, Alejotheo~enwiki, Wheeler4040, CMBJ, Jsfouche, Trivialist, Jytdog, Addbot, Bunnyhop11, AnomieBOT, Bluerasberry, Flobach, Earlypsychosis, Kiwi128, Tolly4bolly, ClueBot NG, Amy D. Schubert, MrBill3, Me, Myself, and I are Here, Sheila Wheeler, Mmorris999 and Anonymous: 14
- **Remote guidance** *Source:* https://en.wikipedia.org/wiki/Remote_guidance?oldid=712400290 *Contributors:* Rsabbatini, Panthouse, Rathfelder, Paddles, Alaibot, Nono64, Oh Snap, Nubiatech, Irubinfeld, MrOllie, Fartherred, FreedomFireCom, KLBot2, BG19bot, Hamish59, Hamoudafg and Anonymous: 3
- **Tele-epidemiology** *Source:* https://en.wikipedia.org/wiki/Tele-epidemiology?oldid=603797457 *Contributors:* Rsabbatini, Woohookitty, Hbdragon88, SmackBot, Bazonka, Mojo Hand, Tirkfl, DGG, Emeraude, JPDMichel, Apteva, Bluerasberry, Dr P Michel, John of Reading, GoingBatty, BG19bot, Mhi1002 and Anonymous: 3
- **Telenursing** *Source:* https://en.wikipedia.org/wiki/Telenursing?oldid=704818268 *Contributors:* Rsabbatini, Edward, RJFJR, The Rambling Man, THB, Ezeu, SmackBot, Steve carlson, Commander Keane bot, TenPoundHammer, Harryzilber, Sarahj2107, Alejotheo~enwiki, Wheeler4040, CMBJ, Jsfouche, Trivialist, Jytdog, Addbot, Bunnyhop11, AnomieBOT, Bluerasberry, Flobach, Earlypsychosis, Kiwi128, Tolly4bolly, ClueBot NG, Amy D. Schubert, MrBill3, Me, Myself, and I are Here, Sheila Wheeler, Mmorris999 and Anonymous: 14
- **Teledermatology** *Source:* https://en.wikipedia.org/wiki/Teledermatology?oldid=703997076 *Contributors:* Rsabbatini, Edward, Smalljim, Rjwilmsi, Ferozkal, Cydebot, Paddles, MER-C, Magioladitis, TheAllSeeingEye, WhatamIdoing, LaMona, R'n'B, My Core Competency is Competency, SimonPucher, Alexbot, Apparition11, XLinkBot, Jytdog, Addbot, Luckas-bot, Mission Fleg, AnomieBOT, WurmE, Bluerasberry, T-scope, Omnipaedista, Klughammer, John of Reading, Skattili, BG19bot, Ahelsinger, Phan Ni Mai, Shjn14, Ayben~enwiki, FourViolas, Narnaulvijay, Mmorris999 and Anonymous: 9
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- **Telepsychiatry** *Source:* https://en.wikipedia.org/wiki/Telepsychiatry?oldid=673834698 *Contributors:* Rsabbatini, Topbanana, Alansohn, BD2412, Rjwilmsi, Chris Capoccia, Welsh, Supten, Perry Middlemiss, SmackBot, Khazar, Gobonobo, Cydebot, Bddmagic, Thijs!bot, Obiwankenobi, Harryzilber, MER-C, Magioladitis, I JethroBT, WhatamIdoing, Belovedfreak, Philip Trueman, Anna Lincoln, Doc James, AlleborgoBot, Snevetsm, Escape Orbit, Jytdog, Addbot, Homepsychiatry, Wpwatchdog, Bluerasberry, Citation bot, Afishkind, Rougue scholar, RjwilmsiBot, H3llBot, Carv123456, BG19bot, Doc.amiba, Oliviaboy, Fraulein451, Smaddaloni, Thereandnot, Cristiejx, Bryanrutherford0, Monkbot, Factchecker1880, Acosens, Mmorris999, Telepsychiatry and Anonymous: 11
- **Teleradiology** *Source:* https://en.wikipedia.org/wiki/Teleradiology?oldid=718963482 *Contributors:* Rsabbatini, Ronz, Arcadian, Alansohn, Wouterstomp, Woohookitty, FreplySpang, Hibana, Wavelength, WAvegetarian, Pegship, NeilN, SmackBot, Kukini, Mwarf, Robofish, Ourhistory153, Cydebot, Magioladitis, WhatamIdoing, Blabberhand, Mijanul, McSly, Davecrosby uk, Aesopos, TXiKiBoT, Lamro, Jkeirn, CMBJ, Greasybackflop, Jmoock, Trivialist, Dekisugi, Usteleradiology, Hercule, Apparition11, WikHead, Rickwjenn, Radiologygenius, Wyatt915, Addbot, Riteview, FauxClaud, MrOllie, Yobot, Shanetapper, Mitesh harlalka, Paf25, Bluerasberry, FrescoBot, Asharafshahi, Michaelmdx, AidenRyan, Alph Bot, Ciscoperin, John of Reading, Jeepersjoseph, Josve05a, AvicAWB, Ithilias, Sueotis, DEE115, Khazar2, Ebenezerpc, Jlstenger, Bryanrutherford0, Noyster, Kunika38, Sogutucu, Robert Svendsen and Anonymous: 72
- **Telerehabilitation** *Source:* https://en.wikipedia.org/wiki/Telerehabilitation?oldid=681560348 *Contributors:* Rsabbatini, Skysmith, Piotrus, Rich Farmbrough, STHayden, RyanGerbil10, Woohookitty, Jeff3000, Josh Parris, Koavf, Jlittlet, RussBot, Joel7687, PGPirate, SmackBot, Bluebot, Oli Filth, Zvar, Dbrienza, Acebrock, Hargle, Briancua, Ecohn, Cydebot, Colinlee, SummerPhD, Harryzilber, Suepalsbo, Gwern, Sunidesus, Obracy, Sam Blacketer, B Pete, CMBJ, Barkeep, Jytdog, Mysoberlife, Yobot, Bluerasberry, J04n, Janezp, Jonkerz, Uanfala, Fæ, Braincricket, Jn.mdel, Helpful Pixie Bot, Mmorris999, LuisADJr and Anonymous: 15
- **Virtual reality in telerehabilitation** *Source:* https://en.wikipedia.org/wiki/Virtual_reality_in_telerehabilitation?oldid=698742892 *Contributors:* Rsabbatini, Piotrus, Lovelac7, VishalB, Circeus, Jeff3000, Rjwilmsi, SmackBot, Salamurai, Tesseran, TeflonII, Cydebot, Alphachimpbot, Jbkim486, Sunidesus, Barkeep, DOI bot, Citation bot, Citation bot 1, Trappist the monk, Klbrain, Helpful Pixie Bot, Wbm1058, Monkbot and Anonymous: 2
- **Wireless Medical Telemetry Service** *Source:* https://en.wikipedia.org/wiki/Wireless_Medical_Telemetry_Service?oldid=660193833 *Contributors:* Rsabbatini, Trlovejoy, Ground Zero, Magioladitis, Fabrictramp, War wizard90, DGG, Katharineamy, Bobwhitten, Malcolmxl5, RTG, Wireless friend, Yobot, Le Deluge and Pschon
- **Computer assisted surgery** *Source:* https://en.wikipedia.org/wiki/Computer-assisted_surgery?oldid=718131473 *Contributors:* Zundark, Rsabbatini, Edward, Ronz, Rich Farmbrough, Arcadian, Sjschen, Woohookitty, Jeff3000, GregorB, Graham87, Ground Zero, Kkmurray, Chris the speller, Alexwagner, Fmalan, Frap, Kvng, Hu12, Cydebot, Darklilac, Magioladitis, Theroadislong, Inventis, Billinghurst, CMBJ, Harry-, Denisarona, Chaosdruid, Jytdog, Rüdiger Marmulla, Horia Ionescu, Addbot, Cst17, SMEAC, Quercus solaris, Manoj.adonis, Ben Ben, Yobot, AnomieBOT, Materialscientist, Eumolpo, DexDor, EmausBot, Dcirovic, Wingman4l7, Leggwork, Hazard-Bot, EdoBot, ClueBot NG, Danim, Dlugose, BG19bot, Khazar2, Rbhavanirao, Iztwoz, MedicusMagnificus, Uhehpshvuhehpshv, Zypcu, Markbiggs, Bahadurali93, SimulaModel, Chfchchf and Anonymous: 34
- **Remote surgery** *Source:* https://en.wikipedia.org/wiki/Remote_surgery?oldid=709419032 *Contributors:* Rsabbatini, Edward, SWAdair, WhiteDragon, Kate, Arcadian, Kierano, Pearle, Wouterstomp, Ddlamb, Hu, Wtshymanski, Suruena, Recury, Bgwhite, Wavelength, Piet Delport, Rayc, Kkmurray, Crumley, Vicarious, SmackBot, Thumperward, WikiPedant, Courcelles, Cydebot, Networkvideo, Tahirferoz, Harryzilber, CosineKitty, Magioladitis, Jonpro, Michaeldsuarez, Sun Creator, Chaosdruid, DumZiBoT, Dthomsen8, Rüdiger Marmulla, Mmaurn, Fraggle81, Alusayman, THEN WHO WAS PHONE?, AnomieBOT, Bluerasberry, Info IST, Materialscientist, Venice85, LittleWink, Wingman4l7, Danim, Helpful Pixie Bot, Eleventh1, Crocodilesareforwimps, Badon, BattyBot, Cyberbot II, Khkopp, Ekips39, Tentinator, ImSorryThatThisUsernameIsNowTaken, Wisi eu and Anonymous: 27
- **Robotic surgery** *Source:* https://en.wikipedia.org/wiki/Robot-assisted_surgery?oldid=718948042 *Contributors:* William Avery, Rsabbatini, Booyabazooka, Mac, Topbanana, Mushroom, SWAdair, Rich Farmbrough, Bender235, Mwanner, Alansohn, Snowolf, TaintedMustard, TenOfAllTrades, Oleg Alexandrov, Woohookitty, Ekem, Essjay, Mandarax, Rjwilmsi, Jake Wartenberg, Lonestarnot, Stevenfruitsmaak, Wavelength, Chris Capoccia, Eleassar, Alynna Kasmira, BrainyBroad, Abedhammoud, Joel7687, Anetode, Sharik, Tony1, Dbfirs, DeadEyeArrow, Closedmouth, Arthur Rubin, Wsiegmund, UponThisRock, SmackBot, Incnis Mrsi, McGeddon, Garchy, Verne Equinox,

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- **Surgical Segment Navigator** *Source:* https://en.wikipedia.org/wiki/Surgical_segment_navigator?oldid=550644407 *Contributors:* Zundark, Rsabbatini, Drbreznjev, Tony1, Iridescent, Cydebot, Obiwankenobi, Rüdiger Marmulla, Horia Ionescu, Addbot, J04n and Anonymous: 1
- **Bone segment navigation** *Source:* https://en.wikipedia.org/wiki/Bone_segment_navigation?oldid=647559532 *Contributors:* Rsabbatini, Rich Farmbrough, Jeff3000, Tabletop, Rjwilmsi, Muhammad Hamza, Cydebot, CommonsDelinker, Nono64, Rüdiger Marmulla, Horia Ionescu, Addbot, J04n, EmausBot, Wingman4l7, Mohamed-Ahmed-FG, Filedelinkerbot and Anonymous: 2
- **Robotic prostatectomy** *Source:* https://en.wikipedia.org/wiki/Robot-assisted_surgery?oldid=718948042 *Contributors:* William Avery, Rsabbatini, Booyabazooka, Mac, Topbanana, Mushroom, SWAdair, Rich Farmbrough, Bender235, Mwanner, Alansohn, Snowolf, TaintedMustard, TenOfAllTrades, Oleg Alexandrov, Woohookitty, Ekem, Essjay, Mandarax, Rjwilmsi, Jake Wartenberg, Lonestarnot, Stevenfruitsmaak, Wavelength, Chris Capoccia, Eleassar, Alynna Kasmira, BrainyBroad, Abedhammoud, Joel7687, Anetode, Sharik, Tony1, Dbfirs, DeadEyeArrow, Closedmouth, Arthur Rubin, Wsiegmund, UponThisRock, SmackBot, Incnis Mrsi, McGeddon, Garchy, Verne Equinox, DOC DS, Gilliam, KD5TVI, Chris the speller, Keegan, Thumperward, Kcordina, Decltype, DMacks, Wizardman, Ohconfucius, Disavian, Inoesomestuff, Pedantic of Purley, Muadd, Kvng, Dl2000, Phuzion, Hu12, Iridescent, JoeBot, Shoeofdeath, JForget, CmdrObot, Basawala, Requestion, Old Guard, Cydebot, LouisBB, Khatru2, Networkvideo, Studerby, Thijs!bot, Headbomb, Nick Number, SusanLesch, KrakatoaKatie, AntiVandalBot, Autocracy, Mtreat, Lfstevens, JAnDbot, Leuko, MER-C, Albany NY, Z22, Yurei-eggtart, Bongwarrior, WODUP, Pencilla, Theroadislong, ArchStanton69, Afein, K ideas, Flowanda, MartinBot, Nono64, Tgeairn, J.delanoy, Ahzahraee, Hans Dunkelberg, Jiuguang Wang, BenTels, Extransit, Mikael Häggström, NewEnglandYankee, Kraftlos, Jamesontai, V8Wiki, Isabelogden, Sushil Dawka, Tlspiegel, Vandido, Hqb, Timekeeper77, Raymondwinn, Djiboun, Dfiinter, Alievrenkut, Almazan, Fltnsplr, Doc James, Journalist1983, Bakerstmd, Ronsword, Gbawden, Dtom, Tri57angle, Hertz1888, Holme215, Flyer22 Reborn, Kahmed198, Faradayplank, Animagi1981, Acidburnben, ClueBot, Docmarcg, DragonBot, Fixitright, Ottawa4ever, Chaosdruid, HardJeans, Versus22, Blinman, TheRedClay, DumZiBoT, Jytdog, Little Mountain 5, Padfoot79, Nmishra9, Rüdiger Marmulla, Addbot, Meddevicefan, Fyrael, Toyokuni3, Mootros, GeneralAtrocity, Ronhjones, Sciencefirst, West.andrew.g, Steeler73, Tide rolls, Lightbot, Ben Ben, Math Champion, Vincent323, Yobot, Fraggle81, Nojudi, GiggsHammouri, Tempodivalse, DiverDave, AnomieBOT, Ciphers, Danielanb, Jim1138, Everton61, AdjustShift, Sheara33, Emeransid, Citation bot, Quebec99, Xqbot, Texas141, Drsaurabhk, FrescoBot, □□□□, Roltel, Alephnyc, Harrypuns, Pinethicket, Tom.Reding, Skyerise, Prometheus57, Culicidae, Jaquesk, Inlandmamba, Soumzzzz, Trappist the monk, 122589423KM, Rtclawson, Vrenator, Lord of the Pit, DARTH SIDIOUS 2, Helloher, RjwilmsiBot, AuroraIT~enwiki, John of Reading, Dewritech, Backroadrider, GoingBatty, MMC.Einstein, Brobdignagian, ZéroBot, Cheeze1010101, H3llBot, Wingman4l7, Thine Antique Pen, PRPLwiki, Brandmeister, Donner60, ClueBot NG, Gynonc, AlbertBickford, Pete LaRose, Jeff Song, Biggleswiki, Everton47, Harborrat99, Danim, Sloaneguy, Crazymonkey1123, Helpful Pixie Bot, BG19bot, Virtualerian, NedShaurer, Frze, Anupriya.khare, DimetroBot, Bulletinchocolate, Marczulajtis, MAKOjosh, Shaun, BattyBot, Tmoney1975, Cyberbot II, RocketRobotEngineer, Webclient101, Jamesx12345, Rbhavanirao, Eccejamin, Horatiot burns, Robotikcerrahi, Iztwoz, GregdeGland, Everymorning, RRPK2000, Uhehpshvuhehpshv, Znajmi, Allme2013, Lagoset, Monkbot, DrivenByNumbers, Marlaric, Celesteroyce, HelenEBunch, BriFranklin13, Hennk, KH-1, Narky Blert, Sskopos, Sravyakalva, SRgmu and Anonymous: 303
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