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Extended essay

Navigating parental requests: considering the relational potential standard in paediatric end-of-life care in the paediatric intensive care unit

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Ethical navigation of biobanking establishment in Ukraine: learning from the experience of developing countries

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Returning research results to individuals who are incarcerated in the USA

Sahana Raghunathan

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Ethical navigation of biobanking establishment in Ukraine: learning from the experience of developing countries

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ABSTRACT

Building a biobank network in developing countries is essential to foster genomic research and precision medicine for patients' benefit. However, there are serious barriers to establishing biobanks in low-income and middle-income countries (LMICs), including Ukraine. Here, we outline key barriers and essential milestones for the successful expansion of biobanks, genomic research and personalised medicine in Ukraine, drawing from the experience of other LMICs. A lack of legal and ethical governance in conjunction with limited awareness about biobanking and community distrust are the principal threats to establishing biobanks. The experiences of LMICs suggest that Ukraine urgently needs national guidelines covering ethical and legal aspects of biospecimen-related research. National guidelines must be consistent with international ethical recommendations for safeguarding participants' rights, welfare and privacy. Additionally, efforts to educate and engage physicians and patient communities are essential for achieving biobanking goals and benefits for precision medicine and future patients.

INTRODUCTION

Advancements in genetic technologies and genomics have reshaped healthcare, defining the transition from a 'one size fits all' approach to personalised medicine focused on preventing and treating various diseases utilising a patient's clinical and genetic characteristics.[1] Discovering genomic and environmental determinants of health and disease and their interplay is essential for predicting personal susceptibility to various pathologies and individualised risk assessment, early disease detection, personalised treatment for better patient outcomes, and customising disease prevention strategies.[2]

Precision medicine progress relies on using high throughput technologies and integrated data analysis for detecting, measuring and assessing a wide spectrum of biomedical data, including clinical information about patients, and their genetic, genomic, metabolomics, proteomics, histopathological, behavioural and environmental characteristics. The discovery of novel biomarkers depends on the availability of relevant types of biological specimens (blood, fluids, tissue samples, cells or nucleic acids, etc) and associated data from representative groups of patients assembled under specific clinical settings.[3] Thus, biobanking is essential to precision medicine progress.

Historically, systemic genetic studies began in high-income countries (HICs). In 1990, the US National Institutes of Health launched the collaborative international scientific initiative known as the Human Genome Project, which has resulted in the sequencing of about 90% of the human genome. Further implementation of next generation sequencing and other advanced technologies enabling fast and cost-effective massive parallel sequencing of numerous genes determined the identification of multiple new biomarkers and enormous progress in personalised medicine.[4] Population and disease-specific biobanks brought essential knowledge about the role of genetic and environmental factors in various diseases.[5] For instance, the Scandinavian study on 44 788 pairs of twins uncovered the minor role of inherited genetic variants in susceptibility to various neoplasms and highlighted the role of environmental factors in sporadic cancer. Similarly, the UK Biobank established in 2003 provided insights into the role of red and processed meat in colorectal cancer development and discovered the mechanisms of air pollution and genetic factors' contribution to lung cancer pathogenesis.[6]

Biobanking and genomic investigations require significant funding and public investments. Not surprisingly, genetic studies reliant on biobanks are mostly conducted in HICs. This has resulted in a disproportional accumulation of samples and biomedical data from mostly defined social and ethnic groups such as white, middle-class and more highly educated.[7] Therefore, most tissue samples, genetic and genomic data gathered are from individuals of European descent in HICs representing only part of the entire profile of the human population,[8] while the genome of LMICs inhabitance is under-represented. For instance, the biomarkers for breast cancer molecular subtypes were discovered mostly in population-based studies in North America and Western Europe.[9 10] An imbalance in biobanking proliferation has both moral and scientific implications, affecting equitable access and benefits sharing, as well as the interpretation of genomic findings and their clinical application to the global population. This may exacerbate existing health disparities between social, racial and ethnic groups and even between countries.

LMICs have a higher burden of diseases and morbidity-related deaths compared with HICs. For example, about 90% of cancer, infections and maternal death occur in LMICs.[11] Beyond challenging socioeconomic factors, the significant level of ethnic and genetic diversity of LMICs populations could be a root cause of the worse health indicators.[12] Extending the diversity of populations involved in molecular studies can broaden the range of possible genetic alterations driving various illnesses, improve the understanding of diseases' aetiology and facilitate the progress of precision medicine.[13]

Biobanking and genetic research activities in LMICs are limited.[12] To enrich the agency of under-represented populations in genomic databases, multinational consortia have launched several research initiatives in LMICs. Among them, the H3Africa consortium, uniting about 30 African countries, and GenomeAsia 100K project have been building genomic research infrastructure and exploring local genomes with significant diversity.[14 15] Biobanks have also been established in other developing countries including India and Mexico.[16] However, biobank-based genomic studies have been limited in former Soviet republics, including Ukraine, which share similar challenges to establishing biobanks as other developing countries.

Lessons learnt from biobanking development in LMICs illuminate the wide range of ethical problems, gaps and challenges affiliated with power asymmetries, socioeconomic issues and distrust.[17] Alternatively, the Eastern-Central Europe biobanks demonstrated rapid progress in national ethical and legal regulations in the post-soviet era via partnering with the European biobanking infrastructure BBMRI.eu.[18 19] Such strategy facilitated local and international networking and enhanced research activities, stimulating harmonisation of legal and ethical guidelines, standardisation of biospecimen quality and optimisation of capital infrastructure and IT support.[20 21] However, the evolving nature and multidisciplinary context of biobanks, growing international collaboration and variability of national regulations have generated profound ethical, legal and social concerns about many aspects of biobanking.[22] All this complicates the establishment of biobanks in low-resourced and early experienced settings, including Ukraine.

This review addresses the basic ethical framework of biobanking research and discusses obstacles and barriers to implementation in LMICs. We propose a roadmap for biobank and genomic research progress in Ukraine.

CURRENT STATE OF BIOBANKING IN UKRAINE

Currently, in Ukraine, the field of biobanking is under development. The current socioeconomic situation and legal framework in Ukraine share similar features and barriers with other LMICs. Although there are several practicing institution-based and private biobanking-related companies, there is a limited legal framework guiding the collection, storage and use of tissue samples.[23] The existing regulatory documents cover only the field of umbilical cord blood banks and clinical investigations of pharmaceutical products (clinical trials).[24] However, biobanking is not officially recognised as a specific type of research requiring proper ethical and legal regulations. Similarly, there are no national ethical guidelines on biobanking as an object with dual legal nature, as biobanks are supposed to operate with both biosamples and related personal data including health records and genetic information, which complicates the biobanking establishment in Ukraine.

In contrast to many HICs, most operating biobanks in Ukraine are private and differ significantly from academic or governmental repositories in developed countries. Most Ukraine-based biobanks represent various open resources for the international research community, however, few of them collaborate with Ukrainian research networks due to the limited capacities of genomic studies in Ukraine and the low level of awareness about biobanking as a tool for facilitating multi-omics research. Such an international-oriented vector is essential for Ukrainian biobanks' sustainability and drives the implementation of international standards and requirements for samples and data integrity. However, this does not provide benefits for accelerating local research infrastructure and community engagement.

To note, most Ukrainian biobanking organisations possess multiple collection sites model partnering with numerous clinical sites and investigators which determines both benefits and drawbacks.[25] The main proses of the muti-collaborative model are the scale of sample collection and geographic diversity being open for every subject who wills to participate in biobanking projects.[26] To reduce operating costs and optimise sample quality, some Ukrainian biobanks operate as contract research organisations engaging third parties for the provision of such essential services as sample collection, tissue processing and specimen storage, database hosting and storing. However, the described structure increases the risks of samples and data inconsistency under the lack of centralised oversight for quality assurance as there is no official agency responsible for certification on ISO20387 specifications.

Finally, the main challenge for Ukrainian biobanking is a lack of properly trained personnel. As biobanking in Ukraine is legally in 'a grey zone', there are no formal education programmes in Ukrainian high schools. Under the lack of official courses and training, self-learning or learning by doing through the chain of mistakes are the key approaches for getting the competencies. So, hiring professional personnel in biobanks is a challenging task in Ukraine.

The scenario of Ukrainian biobank development is not novel and possesses similarities with other LMICs. So, defining key barriers and learning lessons from other countries are essential for developing the roadmap for further biobanking development in Ukraine.

BARRIERS FOR BIOBANKING IN LMICS

There are several crucial barriers to biobanking research in LMICs that are relevant to the situation in Ukraine, including a lack of national regulations, poor infrastructure for ensuring quality control, limited knowledge among key stakeholders and community mistrust. Each of these will be discussed in detail.

Lack of national legislation and ethical regulations on biobanking and gaps

Although the need for national legislation on biobanking as a driving force of precision medicine development has been actively discussed by Ukrainian lawyers for the last few years, there are still no approved National regulations on biobanking. Many countries in the developing world including Arabian and Latin American countries, Africa and Eastern Europe/Central Asian countries/former Soviet republics lack national policies and governance infrastructure for biobanking[27] even though these activities are ongoing. In some countries, research ethics committees (RECs) use international research ethics guidelines to review research protocols for biobanking.[28] While general governance and quality assurance should be based on international standards, regulating legal and ethical issues by national guidelines aligned with local social and cultural specificities is

recommended.[29] There are specific features of biobanking regulations in Africa compared with the UK, the USA or Australia. Having a long history of exploitation, regulations in some African countries aim to strengthen the protection of participants and their rights. For instance, Uganda's regulations on biobanking outline that the ownership of the sample belongs to its donor while the biobank is a custodian of the specimens and possesses a position of trust. In addition, the national template of the Material Transfer Agreement suggests the possibility of claiming ownership of new products in case of their discovery by third parties outside the country.[30] However, such practice is not widely implemented. Recent studies from Africa have revealed that despite efforts at the international, regional and national levels, 20 (41 %) out of 49 sub-Saharan African countries do not have articulated national ethical principles and regulatory guidance for policymaking, reviewing and monitoring biobanking research. Among 29 African countries where ethical and regulatory guidance exists, only 17 have regulations for research using human samples, with specific recommendations on participants' consent, sample ownership, reuse, storage and sharing.[31]

Gaps in national ethical and legal regulations might result in inconsistent reviews of research protocols by RECs and generate risks to biobank participants. The lack of structured ethical regulations in human research, including genetic and genomic studies in Ukraine, can compromise various ethical issues of biobanking, including the informed consent process, participants protection, samples use and sharing.

Informed consent is a key principle of research ethics in studies involving human subjects.[32] Because of the unique context of biobank research, informed consent should include disclosure of the type of data to be collected, potential sample use in case of secondary research, regulation of data and sample access or sharing, and oversight mechanisms for privacy protection.[33] Donors should have the right to withdraw their consent, and it should be disclosed what will happen to the biosamples and data in case of discontinuation. Finally, informed consent documents must be provided in plain language or translation in case of the international research protocol, and it must be clear that sample collection and donation are separate from healthcare.[33]

Despite the common requirements for informed consent in human research, there are some debates about handling the informed consent procedures governing the enrolment of participants in sample donation and their further use in future studies.[34] Genomic studies approach and personalised medicine evolution have led to the development of innovative formats of the informed consent process.[34] The International Society for Biological and Environmental Biorepositories (ISBER) defines several formats of informed consent,[29] including specific (or traditional), broad and multi-layered (or tiered) consent, which distinguishes layers of information from minimal to more detailed at subsequent steps and offers different choices between categories of diseases or studies associated with distinct ethical, personal or societal issues. As the majority of biobank-based studies are driven by the collaboration between Ukrainian institutions and HICs-based organisations, the format of the informed consent is often dictated by the primary sponsor. This provides both pros and cons for Ukrainian biobanks and research participants. The benefit of such an approach is compliance with international regulations. On the contrary, it needs translation and approval by the local ethical committee and is sometimes taken as a formal procedure.

Besides, the dynamic consent model was suggested for biobanks based on the use of a digital platform for continuous access of donors to their consent for modification.[35] However, its implementation needs modern IT solutions and communication systems.[36] That seems challenging in most LMICs including Ukraine due to strict requirements for IT infrastructure and legislated electronic document flow. Due to the lack of legal regulations on biobank-related studies, most institutions in Ukraine are historically prone to use project-specific informed consent to ensure participants' protection and compliance with institutional requirements for biomedical research. However, for the last few years, there is a trend for incorporating broad consent in biobank-based studies for expanding the range of goals to be achieved and widening opportunities for novel technologies applying to biomarkers discovery.

Anyway, the type of consent must be under applicable national, regional or local regulations and laws, as different jurisdictions may not permit the use of certain types of consent. Developing legal systems for enabling international and local biobanking is essential for regulating the voluntary participation of subjects in research and safeguarding their rights. Sample misuse or secondary use without the participant's informed consent breaks promises, which is a violation of trust and the fundamental ethical principle of respect for autonomy. Lack of compliance with international regulations for data protection could result in inadvertent harm to research participants whose samples are stored in biobanks, which could in turn reduce participation in translational research essential for enhancing healthcare inequities in the future.[37] This addresses the crucial need in arranging participants' protection in biobanking-based studies.

Although biobank-related research is usually considered to pose minimal risks, subjects face some burdens when participating in biobank studies. These risks can be related to the procedures of sample donation (for instance, bleeding during venipuncture, local infections). Additionally, potential breaches of confidentiality are a risk of biobanking.[16]

Biobanks are responsible for protecting donor privacy and confidentiality, especially in the case of samples and data sharing. Advances in molecular studies have transformed the research environment, fostering extensive data sharing nationally and internationally.[22 36] Data sharing and openness provide numerous benefits in healthcare and research. In contrast, improvements in digitalisation and informational technology (IT) solutions elevate the likelihood of external parties' access to databases. Specimens can be identifiable through big data compiled from smartphones, social media, sensors, electronic health records, etc.[36] Basic regulations on access policies already exist and articulate the need for clear criteria for access decisions.[29] For instance, ISBER states 'Specimens and/or data should only be made available for ethical and scientifically appropriate research expected to contribute to scientific discovery'.[29] However, many researchers ask whether current standards of data protection are adequate. In the USA, privacy in biobank-based research is protected by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule as a part of the Federal Policy for Protection of Human Subjects.[38] However, there are no regulations specified in the unique context of biobank research.[39] International Guidelines, including ISBER and Council for International Organisations of Medical Sciences (CIOMS), provide several protective measures. First, biobanks should follow well-documented procedures to protect participants' privacy and confidentiality by anonymisation or de-identifying biospecimens.[29] CIOMS highlights that only anonymised or coded data should be shared with researchers while other parties' access must be limited.[40] Decisions around data access depend on local arrangements for governance and practices and the global policies for biobanking and the sharing of data in biomedical studies.[28] So, biobanks and investigators

managing samples and data are legally and ethically obligated to protect data that are considered confidential information. The development of international consortia is the best strategy for synergy in the cooperative use of biomaterials respecting both effective sample/data use for research and the protection of the rights and interests of donors and communities.[29] So, developing a comprehensive system of samples and data collection and management with proper privacy protection is essential for establishing biobanks in low-resource settings for both fostering precision medicine and participants' rights protection with respect to basic ethical principles.

Developing National policies on the ethics of biobanking and data protection is a primary prerequisite for biobank establishment in LMICs. This is an ethical imperative for biobank legislation and evolution in Ukraine.

Limited infrastructure to ensure quality Sstandards

Progress in genetic studies has resulted in enhanced requirements for standardised collection, handling and storage of samples.[16] By now, quality control has become an ethical imperative for biobank governance and operations, which is essential for reducing preanalytical variability and maintaining specimens' integrity for further molecular studies.[41] This requires the proper use of innovative technologies and state-of-the-science approaches to achieve robust and reproducible research goals.[42] Such a strategy is an ethical prerequisite for building biobanks and dictates high-quality performance adherent to standards.[43] The ISBER and National Cancer Institution (NCI) best practice documents, discovering the essentials of biobank operations and governance, provide detailed recommendations for standardised biobanking management across the network.[44] Unfortunately, numerous research institutions in Ukraine, like in many other LMICs, demonstrate a lack of comprehensive governance structures and limited facilities for proper collection and storage space, trained staff, IT resources and limited financial and administrative support.[45] Such systemic drawbacks can affect the quality of the samples and data provided which have double effects on both research and business. The lack of standardisation for biosample collection and processing is widely recognised as a crucial roadblock to genomic research at the global scale. Thus, biobank enterprises in LMICs should align with the use of state-of-the-science approaches and strict quality control. This defines the urgent need for obligatory and regular quality assurance oversight mechanisms at the national level.[46]

Low level of knowledge and awareness about biobanking among researchers, physicians and communities

The success of biobanking depends on stakeholder understanding and their willingness to adhere to strict legal and ethical regulations.[47] Establishing a biobank requires the active participation of various stakeholders, including REC members, investigators, biobank staff and participants.[45] Their level of awareness and professional competence plays an essential role in biobank establishment in LMICs.[48]

Although public awareness of biospecimens and biobanking has grown significantly in the last decades, studies from LMICs illuminate low literacy and profound misconceptions about biobanking, its goals and regulations.[48] To our knowledge, there were no formal studies assessing the level of stakeholders' awareness and attitude toward biobanking-related issues in Ukraine. For building trust, the experience of the Eastern Europe countries also highlights the need for public discussion of such issues as samples and data sharing, multiple use of biospecimens in future studies, informed consent in case of incompetence and the commercialisation of research.

Notably, even in developed countries, elements of informed consent unique to biobanking are poorly understood by patient participants.[49] This lack of knowledge translates to limited trust in biobanks and related genomic studies, which in turn slows their progress in LMICs.[50] So, disseminating knowledge on biobanking is essential for building research infrastructure and harmonising ethical, legal and quality standards. Training, focus group activities, regular webinars and teleconferences are effective tools for empowering physicians, researchers and REC members in their competence.[51] From the Ukrainian perspective, despite relatively high activities in the field of biobanking, there are no academic courses to be incorporated in the programmes for educating students of medical and biotechnological specialties. Considering the role of biobanking in predictive, preventive and personalised medicine and its continuous progress worldwide, there is a need in preparing the next generations of researchers, healthcare professionals and biobanks for future multidisciplinary studies based on biosamples and data use. To develop the appropriate competencies of biobank staff, there is an urgent need in implementing new study programmes and curricula, incorporating courses, lectures and webinars on biobanking and precision medicine-related issues.[52]

Community distrust in science in LMICs

As the H3Africa project revealed, power asymmetries and historical exploitation have provoked a distrust in science and created barriers to conducting studies that require human tissue samples. Ukraine has a similar socio-historical context, where poor funding of science and long-term brain drain has undermined the research environment, provoking distrust in science, though there were no formal studies discovering stakeholders' attitude to research including biobanking.

Community engagement is essential for building trust.[53] Institutions and researchers worldwide have recognised the value and benefits of community engagement in the establishment of biobanks, especially in LMICs.[28] Various educational activities, increased disclosure, value clarification and community discussions are essential for stakeholders' engagement.[51] The involvement of community representatives in discussions, consultations and policymaking is crucial to improve public awareness about biobanking, its goals and benefits, and to build trust in genetics and genomic medicine in LMICs.[54]

So, there are important differences in medical practice, knowledge and attitudes between HICs and LMICs that impact the practical realities of biobanking, and these differences are reflected in the diverse regulations across countries. Numerous research institutions in LMICs demonstrate a lack of comprehensive governance structures and limited facilities for proper collection and storage of specimens, low resources for quality assurance and IT resources, and limited financial and administrative support.[45] Recognition of the diversity in regulations and acknowledgement of differences in biobanking between developed and developing countries suggests the need to understand the key barriers and articulate the set of key ethical recommendations essential for proper biobanking establishment in Ukraine.

BUILDING A ROADMAP FOR FOSTERING BIOBANKS IN UKRAINE

While in HICs the main challenge for biobanks today is to promote open science and data security, in Ukraine there is a need for the general biobank governance and protection of

research participants against exploitation. Local socioeconomic and cultural settings can compromise the voluntariness of the consent process and undermine the ethical conduct of biobanking research. In Ukraine, a country with a long history of paternalistic and authoritarian culture in medicine, the voluntariness of the informed consent could be neglected. As Hawkins and Emanuel[55] noted. 'In authoritarian cultures, it may also be difficult to get subjects to appreciate that they are free not to participate and that their healthcare will not be jeopardised if they refuse'. Inequalities of knowledge and power in physician–patient relations can affect the consent process. Similarly, there are risks of preanalytical errors, sample misuse, privacy breaches and other issues undermining the values of biobank-driven research. In addition to developing the national guidelines, articulating the governance of biobanking, building ethical communications between biobanks, physicians, research and patients, as well as harnessing the culture of ethical decision-making in the healthcare continuum seem to be crucial prerequisites for fostering biobanks and genomic studies in Ukraine. Many issues of research ethics have already been addressed in Ethics Principles provided by the National Research Foundation of Ukraine. However, further elaboration on ethical issues of research involving human subjects and genetic studies is needed for detailed articulations on specifications for biobanking-based investigations.

To address the needs in the legal and ethical framework for biobanking establishment, the group of scientists, physicians, lawyers, laboratory professionals, managers and other healthcare providers supported by the Ministry of Health of Ukraine joined their efforts to develop national regulations on biobanking. Being part of these efforts, the authors of the paper worked on developing the draft of national regulations to cover all the aspects of biobank-based research with the primary focus on the ethical framework of sample collection and participant protection. Considering the above-mentioned ethical imperatives for biobanking research, the draft of regulation includes the following issues:

- requirements for informed consent processes;
- samples/data access and sharing;
- protection of research participants from risks of social and legal harm;
- adherence to international standards of quality assurance during sample collection, handling and storage, essential for reducing preanalytical variability and specimen integrity for future genomic studies;
- guidance for research ethics committees;
- ensuring the benefits of personalised medicine accrue to all citizens.

The draft of the National regulations was developed and submitted for reviewing and approval before the war started. Despite the challenges of wartime and shifting priorities towards war-related issues, by now the national regulations on biobanking are in progress and have been revised with international experts' involvement for enhancing the harmonisation of Ukrainian biobanks with international best practices.

The next important issue is understanding the level of community awareness about biobanking and readiness to accept the upcoming guidelines. In this context, professional organisations' activities (Ukrainian Association for Research Biobanks and Association of Ukrainian biobanks) in networking, collaborating projects and local training for physicians play essential roles in disseminating knowledge about biobanking goals and benefits, ethical issues, preanalytical standards, etc. The initiative for evaluating stakeholders' (including biobank staff, physicians and patients) perspectives on biobanking through a survey has been launched.

Further development of high-quality samples culture of quality in biobanking in Ukraine also requires the need in for standardisation of the preanalytical phase of biosample-driven research with proper national oversight of quality assurance. Although systemic solutions seem to be a long-term perspective, the first actions have been already implemented through experience and international collaboration.

Implementing professional biobank education is crucial for next-generation biobank formation in Ukraine. Fortunately, various open resources (webinars, lectures, courses) and publications of the ISBER Best Practices, NCI Best Practices for Biospecimen Resources and the Organization for Economic Co-operation and Development guidelines for Human Biobanks and Genetic Research Databases, as well as webinars of BBMRI-ERIC network provide access to regularly updating 'how-to' sources in biobanking.[56] So, in a short-term perspective international collaboration and young biobankers enrollment in courses, training and webinars of ISBER, BBMRI-ERIC, and leading international biobanks seem to be feasible. Besides annual conferences and meetings or webinars of ISBER and other professional organisations are essential source of knowledge on topics relevant to biobank staff and managers.

However, local initiative development is also crucial for creating a strong educational environment in the biobanking field in Ukraine. So, the next step of the roadmap for the next 3 years is focused on engaging Ukrainian and international experts for implementing a set of regular workshops or short courses for local community education and further incorporation into the university curriculum. From the long-term perspective, closer integration between the academic and private sectors of practicing biobanks will enable the implementation of formal certification programmes in biobanking in universities for providing future Ukrainian physicians and laboratory professionals with essential knowledge about biobanking activities and precision medicine.

We believe that implementation of the best practices in biobank management and quality assurance as well as staff education and regular training of biobank stakeholders are essential for reaching the moral imperative of biobanking establishment and getting benefits for Ukrainian society and global health.

CONCLUSIONS

Biobanking in Ukraine faces numerous challenges and barriers. A lack of legal and ethical governance in conjunction with limited awareness about biobanking and community distrust are the principal threats to establishing biobanks. Approval of national guidelines consistent with international ethical recommendations for safeguarding participants' rights and ensuring sample and data integrity are essential for unlocking biobanking progress in Ukraine. Additionally, efforts to educate and engage physicians and patient communities are crucial for fostering biobanking activities and precision medicine.

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