The complex ethical landscape of biobanking

Biobanking activities raise unanswered ethical questions about the collection, storage, and sharing of cells, tissues, bodily fluids, and biodata, including genetic, demographic, and other types of information and images. In addition to human materials, biobanking also involves non-human materials that might be used in human, veterinary, agricultural, ecological, and other types of research and health care.[1,2] Biobanking has become routine in health care, research, and public health emergencies; however, on a global scale, the associated standards of governance are inconsistent and sometimes missing. The complexity and breadth of biobanking practices generate risks, benefits, and responsibilities that have not been adequately identified or resolved.[3]

After searching on the International Compilation of Human Research Standards (US Department for Health and Human Services, Office of Human Research Protections), we found that the existing research on the ethics concerning biobanking of human materials does not provide much guidance. For example, the Declaration of Helsinki invokes only the need for informed consent and research ethics review.[4] The Council for International Organizations of Medical Sciences (CIOMS) published more in-depth guidelines,[5] which included points regarding the "Collection, Storage, and Use of Biological Materials and Related Data" and "Collection, Storage, and Use of Data in Health-related Research". In the guidelines, CIOMS provide general and specific considerations for biobanks, including points relating to governance (such as the mechanisms in place for "keeping participants informed of research outcomes"); the need to formalise procedures for specific and broad consent, withdrawal of consent, and opting out of research on residual tissues; procedures, residual tissues, and "return of results and disclosure of (un)solicited findings", with possibilities for donors to choose to receive subsets of information, and a research ethics committee to assess the need to provide counselling with particular genetic information; "storing and using material and data from low-resource settings" where "community engagement, capacity-building, and equitable distribution of burdens and benefits" are ethically required; and others.[5] The extent to which this guidance is fulfilled in different institutions and countries is unclear.

We have identified some ethical concerns about biobanking in public health, medicine, and health-related research, which include misconceptions about biobanking and distinctions between research, diagnostics, and treatment; unknown consequences of, and harms to, individual and collective donors of materials or information; socioeconomic inequities that impinge on donor understanding and voluntariness and increase their vulnerabilities to harms and wrongs; incommensurate benefits to low-income and middle-income country hosts, research participants, and donors; and complexities of obtaining informed consent in diverse cultural and socioeconomic contexts, particularly during public health emergencies.

During some disease outbreaks and public health emergencies, biobanking materials have been collected from the affected populations and shared between less developed and developed countries, accentuating practical and ethical challenges for all stakeholders. The 2014 Ebola outbreak in Sierra Leone precipitated large-scale biobanking of diagnostic samples, with diagnostics done primarily by external laboratories operating under memoranda of understandings or material transfer agreements. This biobank contributed substantially to the knowledge and control of Ebola disease, but the ethical adequacy of these agreements is questionable, as is the absence of a complete inventory of the samples collected, and their location, ownership, and consent for future use.[6] Similar questions arise about the ethics of biobanking in partnerships between countries examining the Zika and Chikungunya outbreaks.

Several additional ethical concerns exist. Materials collected, stored, shared, transported, or studied in biobanking are often de-identified to protect donors, implying that biobanking is low risk and that de-identifying materials provides adequate protection to donors. Materials added to a biobank, however, are identifiable through analyses of genetics or through big data compiled from smartphones, social media, sensors (such as traffic signals), consumer wearables, electronic health records, and more. These enable sharing and analysis of individual and collective data, and its healthcare and commercial applications.[7] Similar to genetic information, big data material in a biobank might encroach on privacy and confidentiality

and might detrimentally expose information about individuals, families, communities, and populations. If material is collected without disclosure, understanding, and informed consent, biobanking is not as low risk as it initially appears.

Financial limitations in low-income and middle-income countries might limit regulatory oversight, leaving institutions and populations vulnerable to exploitation, regardless of risk level. Balancing risk and benefit is further complicated by commercial interests that aim to profit from biobanking and might be misconstrued as public interests aiming solely or primarily to benefit population health.[8] Greater attention to what constitute adequate benefits of sharing for a given study is needed, including biobank research.[8]

Emerging and re-emerging disease outbreaks and public health emergencies are increasingly frequent. Greater clarity about what biobanking practices are ethically acceptable is needed and will differ depending on the study and context. Empirical and other work on the ethical implications of biobanking in different research contexts and locations is also needed, and its findings should be integrated into policy deliberations in institutions and governments. Guidelines on the ethics of biobanking need to adequately address or resolve the concerns outlined here.

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1 Brankovic I, Malogajski J, Morre A. Biobanking and translation of human genetics and genomics for infectious diseases. *Appl Transl Genom* 2014; **3:** 30–35.
2 Pang T. Genomics for public health improvement: Relevant international ethical and policy issues around genome-wide association studies and biobanks. *Public Health Genom* 2013; **16:** 69–72.
3 Capps B, Lederman Z. One Health and paradigms of public biobanking. *J Med Ethics* 2015; **41:** 258–62.
4 World Medical Association. Declaration of Helsinki. 2013. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (accessed May 10, 2019).
5 Council for International Organizations of Medical Sciences. International Ethical Guidelines for Health-related Research involving Humans. 2016. https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/ (accessed May 10, 2019).
6 Saxena A, Gomes M. Ethical challenges to responding to the Ebola epidemic: the World Health Organization experience. *Clin Trials* 2016; **13:** 96–100.
7 University of Wisconsin Data Science. What is big data? https://datasciencedegree.wisconsin.edu/data-science/what-is-big-data/ (accessed May 10, 2019).
8 Macpherson CC. Research ethics guidelines and moral obligations to developing countries: capacity-building and benefits. *Bioethics* 2019; **33:** 389– 95.