Invited Review

Evolution of biobanks and ethical governance for the emerging applications in biomedical research

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Abstract

The establishment of a biobank and effective utilization of the biological resources comes with lot of challenges which require operating processes and effective governance structure with public awareness. As biobank is an evolving field of data driven health-care research, guided strategies in line with the national and international statutory body regulations is important. A trustworthy governance is paramount in developing a sustainable way of establishing, maintaining and successful functioning of a biobank. This paper highlights the structure of biobank governance, challenges and processes of effective integration of governance strategies.

Keywords: Biobank, biomedical research, biorepositories, ethics, governance

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INTRODUCTION

Biobanks are a remarkable and rapidly expanding resource that creates new research platforms while also preserving human dignity, necessitating legal, ethical, and regulatory considerations, as well as the incorporation of biobanks into existing regulations. Despite significant progress in addressing the ethical, legal, and social implications of biobanking, operational sustainability and funding issues persist.[1] The effective utilisation of these biological resources is dependent on an effective governance structure and processes that increase the legitimacy and social licence to operate.[2,3] The fundamental prerequisites for effective governance include transparency, accountability, and the adoption of oversight systems.[3,4]

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Transparency permeating all aspects of a system allows for the storage of samples and data, their use and exchange, and accountability to stakeholders.[3] When the handling of research subjects, personal data, and biological samples increases, oversight systems put in place by the organisation to oversee its activities in the best interests of impacted parties become increasingly important.[5,6]

Expansion of research paradigms such as precision and personalised medicine necessitates large collections of samples and data sharing[6,7] which would propel science and innovation while posing privacy, security, and control of data usage at risk. Furthermore, the quest for extracting relevant patient records from big data has seen

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the emergence of artificial intelligence: a transformative technology with regulatory challenges that must still be addressed.[7,8]

STANDARDIZATION FOR EXCELLENCE

The standardisation of sampling, storage, and quality control protocols is critical to the establishment, reliability, and long-term viability of a biobank.[9] An active quality system must be maintained together with evaluation of quality control in order to adhere to international standards for biobanking. The academic evidence could suffer significantly from a lack of quality control.[9] As pre analytics and processing methods may have an effect on the quality of the samples, some have suggested that the biorepositories should deposit their standard operating procedures (SOPs) in a centralised database to encourage transparency and improve reproducibility of research. This would allow researchers to learn more about sample processing, identify collections that would be a good fit for their investigations, and understand the specifics of the treatment in order to compare results with samples from different biobanks.[10]

In 2018, the first International Organization for Standardization (ISO) document (ISO 20387:2018) was published with the goal of defining the fundamental standards for competency, impartiality, and consistency of biobank operations.[11] An important step toward the global harmonisation of practises is the publication of this document, which is intended for all organisations that conduct biobanking for research and development (apart from clinical and therapeutic diagnostic biobanks).[12] Under ISO 20387:2018, biobanks can receive accreditation for their operations, thereby formally recognising their competency.[13] The ISO further emphasises that biobanks are legal entities that have control over the procedure for acquisition and storage in addition to some or all of the operations related to the collection, preparation, preservation, testing, analysis, and dissemination of designated biological material, as well as associated information and data.[9]

PROCESSES AND MECHANISMS FOR THE SUCCESSFUL OPERATION OF BIOBANKS

In recent years, biobanks have created unique internal procedures that most likely will be crucial in governing access to patient data and biological material.[14,15] SOPs should be used to document the biobanking process, which includes sample and data collection, processing, receiving, and retrieval. Quality checks are essential for each of the processes listed above to ensure that the process and the end product are suitable for purpose. The unique identifier for samples ensures efficient traceability for inventory retrieval. Risks to the effective running of biobank activities, whether internal or external, should be recorded on a risk register. It is necessary to thoroughly document all information related to governance systems, including how these procedures support accountability and the oversight measures put in place, to lower risk related to biobank operations.[2]

The core principles of research oversight are based on consent and the use of samples by the biobank. The primary concerns are privacy, sample utility, and access to information obtained by donors from the samples. When establishing a new biobank, it may be necessary to rely on forward-thinking consent processes to ensure the long-term viability of sample collection. The type of consent can be either general or particular, although in some circumstances a supposed consent may be necessary, and according to a number of ethicists, consent is never truly informed unless a number of requirements are met.[16,17]

Therefore the biobank will require an independent ethics review board, whether it runs under legislation requiring explicit, broad, or any other type of permission. Another challenge in running a biobank would be the reporting of outcomes. The procedures for how and when the results are to be communicated to the donor should be outlined during the consent in order to meet the donor's expectations and define the future connection with their samples. Therefore, it is important to consider the biobank's long-term viability and to establish a perfect balance between the project's commitments to contributors and its scientific requirements.[18]

Another aspect that requires equal attention is the decision on specimen coding versus anonymisation prior to consent, as the efficient use of biospecimens may be hampered by privacy concerns or obligations outlined in the consent form. Harmonising national regulations on data and biological sample protection is a herculean task. The laws governing permission and reciprocity for biobank professionals are subject to change over time, potentially interfering with individual researcher goals and objectives. Aside from concerns about biobank samples being used inappropriately, there have been discussions and debates about the underutilization or inability to return the benefit of research to donors in recent times.[19,20] Therefore, biobank laws should focus on preventing improper use of biological material.[20]

Biobanks are responsible for and liable to adhering to data protection laws in many contexts, including the receipt,

storage, or distribution of biological samples and related data.[21] The premise for running a biobank successfully is to follow best practises that could increase the samples' long-term usefulness and to uphold the fundamental values that have been articulated by the organisation and national regulatory bodies based on international charters like the Declaration of Helsinki. As a result, all relevant local, state, federal, and international laws and regulations must be followed by the biobank.[2]

A critical aspect of biobank management is how the biobank employs strategies to communicate the structure and activities of the same. A majority of biobanks have websites where you can learn about their research interests and organisational structures. This communication could be crucial in understanding how biobanks work. Biobanks could also inform and publish pertinent information about the development of their repositories and data sets, as well as data security measures.[2] By recognizing the information that the stakeholders, including the funders, would want to know, effective communication strategies may offer opportunities to improve accountability.[2]

The use of information technology (IT) infrastructure for data management is vital to biobanks that adhere to a variety of internally defined policies on data storage and security. Information technology, data systems, and record management are also critical components of biobanks. Efforts should be made to ensure that these components are efficient and secure.[5,22] A solid sample traceability system is critical for a successful biobank installation, especially when using a barcoding system and an IT platform that is integrated with all institutional operating systems to automatically integrate data.[5]

With the growing importance of biobanks, there is a continuing debate about sample and data ownership, sample access, and data sharing.[23,24] For the biobank to operate efficiently, data access protocols that govern access to stored data and privacy-preserving mechanisms must be devised.[2,25] The most straightforward way to make this procedure more understandable is to describe the structure and operations of the biobank or to use flowcharts to illustrate pertinent processes. The organisational structure of each biobank typically displays the different working groups and administrative structures that are present there [Figure 1]. The biobank's SOPs should provide a thorough description of both the decision-making and research processes.[2]

Biobanks should ensure not only the traceability of biospecimens and associated data, but also their destruction.[9] In reality, biobanks should be able to control the process of destroying biological samples and/or deleting related data as needed.[9] This necessitates the development of a strategy or plan to guide the process, as well as standard operating procedures for the transfer or destruction of biological material and related data following a specific event.[26] Informed consent frequently omits information concerning sample destruction after giving permission for usage. It is assumed that the material will be used in the future since biobank participants are routinely informed of how their samples will be used to aid scientific research projects. Biobanks may appropriately disclose the risk of specimen destruction in their statements or consent documents, given that they are solely responsible for promoting and defending the interests of those who have provided samples.[27]

To prevent the loss of biological materials following natural or man-made disasters, biobanks should design protocols and regulations for unanticipated events.[28] The document should include the critical elements of the recovery plan and the vital procedures that must be carried out under these conditions. Examples of these include grouping samples into priority categories and creating a list of actions that must be carried out in accordance with standard operating procedures.[28]

ADVISORY AND REGULATORY BODIES

Globally, the biobanks function with advisory committees that provide valuable recommendations on technical, scientific, ethical, and organizational perspectives.[2] The advisory committees function with both national and international experts and professionals.[2] The biobanks can also be associated with international bodies that can provide support and guidance to biobank management on operational and scientific strategies, such as the International Scientific Advisory Board[29] for UK biobanks. Similarly, the Scientific Advisory Board (SAB) for Sweden biobanks, a member of BBMRI-ERIC,[30] provides support to medical universities and health professionals for the the management of national biobanks. SAB assists the biobank board in reviewing the infrastructure, scientific strategies, functioning, and prioritizing the projects. The BioBank India Foundation (BBIF),[31] a non-profit organization, is promoting biobank science in India and has advisory committees to review the ethical, scientific, and training strategies that comprise of national and international experts. In some biobanks, the ethics committee acts as an independent body and governs the research protocols, ethical issues, and issues related to participants or patients.[2] The ethics committee comprises

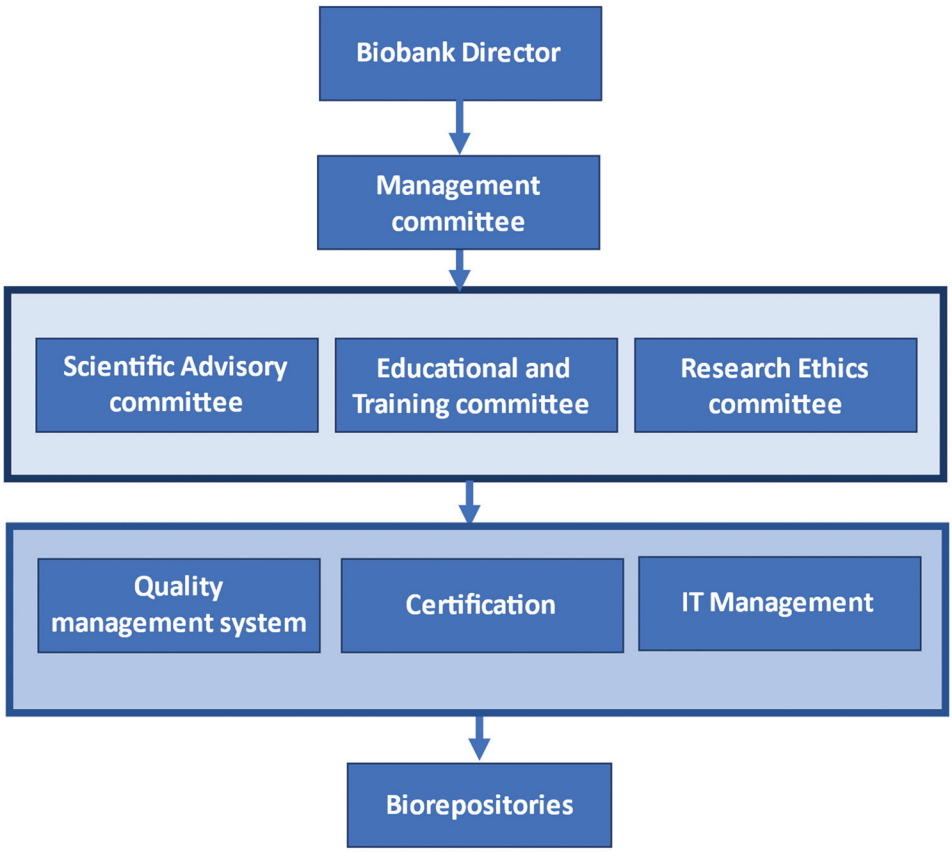

Figure 1: Overview of Biobank governance structure

of researchers, professionals, legal advisers, lay members, and also participant representatives.[2] It deals with issues of informed consent, confidentiality, and personal integrity and acts as a bridge to balance the competing interests between the participants and the biobank.[32] Regulations and ethical practices may vary from country to country, but the general principles of ethics such as informed consent, privacy, confidentiality regarding genetic-, disease-, or risk-related information or "protected health information" (PHI) need be followed. Furthermore, disclosure or non-disclosure of the results of research to the individuals is another issue to be addressed by the ethics committee.[32] In some countries like United States of America, it is not legal for biobanks to provide research results to the patients/participants unless certified by the Clinical Laboratory Improvement Amendments (CLIA).[33]

Another important debate regarding the responsibility of the biobank or the investigators is in reporting the incidental findings to the patient/participant which need to be resolved by the ethics committee based on that particular country's ethical policies.[34] Hence to address such issues related to research involving human subjects, material, or data, legal and ethical, guidelines have been developed by the World Medical Association through the famous Declaration of Helsinki, 1964, with the title "Ethical Principles for Medical Research Involving Human Subjects".[35] The declaration prescribes that all medical research should be conducted in par with ethical principles and states to "protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects".[35] It also proposes to follow ethical, legal, and regulatory norms and standards for medical research as per their country's regulations and international standards.[35] This declaration, along with the "WMA International Code Of Medical Ethics"[36] formed the basis for setting up the ethical standards for research involving human subjects.[37]

In India, the Indian Council of Medical Research (ICMR) is the regulatory body that governs research in biological medicine. It released a handbook titled *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* in 2018,[38] which provides the standard guidelines and principles to be followed for the establishment and management of biorepositories in India. However, there is no regulation or comprehensive privacy law for protection of individual privacy data in India.[39]

BIOBANK CERTIFICATION

Biobanks are required to be audited by external organizations for evaluation of SOPs, quality control and assurance, and best practices adopted by the biobank.[33] Quality management systems (QMSs) have been implemented by biobanks for quality check and have identified ISO 9000 standards for quality management and the recent ISO 20387:2018 standard for biobanking.[2]

ISO 20387:2018[11] defines a biobank as "a legal entity or part of a legal entity that performs Biobanking", and the term biobanking as "the process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analyzing and distributing defined biological material as well as related information and data". Biobanks are facing the challenges of moving forward from the ISO 9001:2015 to ISO 20387:2018 certification scheme.[40]

Biobanks are faced with new challenges of changing its focus from operational aspects such as QMS, SOPs, and technical instructions to the governance and management aspects as per the latest certification scheme.[40] The ISO 20387:2018 certification focuses on the following key objectives: (i) improving the quality of the specimen by implementing QMS; (ii) exchange of biological material and data between the biobank and researchers; (iii) promote public and private sector partnership; (iv) increase stakeholder confidence and assurance; (v) foster research and development (R&D); (vi) lessen the cost by avoiding repeatability; and (vii) reduce research waste by improving the biobank operations.[11,40,41] The ISO 20387:2018 standard of biobanking is currently implemented in several countries such as Austria, Australia, Belgium, Brazil, China, France, Germany, India, Italy, Poland, South Korea, South Africa, UK, and USA.[42]

The guidelines and operational instructions for the biobank was previously released by several international biobanking organizations such as the International Society for Biological and Environmental Repositories (ISBER), European, Middle Eastern & African Society for Biopreservation and Biobanking (ESBB), Organization for Economic Co-operation and Development OECD, International Agency for Research in Cancer (IARC), Canadian Tissue Repository Network (CTRNet), Biobanking and Biomolecular Resources Research Infrastructures (BBMRI-ERIC), all of which have contributed to the harmonization of biobank activities and have also contributed to the drafting of ISO 20387:2018 standards developed specifically for biobanks.[40,42]

AFFILIATION AND MEMBERSHIP

For the operation of the biorepository, biobanks enter into cooperative agreements or affiliate with research institutes. The smaller biobanks tie up with organizations that have specific mandates for regulating its operations, follow effective processes and best practices, manage the cost, and have access to the vast biorepositories of biomaterials.[2] However, stand-alone biobanks have several drawbacks as the sample collections is managed by individuals' efforts.

Inconsistencies in terms of storage conditions with insufficient back-up solutions, shortage of back-up for any technical failures, and failure to maintain controlled storage temperature can have major impact on the quality of samples. The undefined quality of biomaterial can have a consequence of non- reproducible results in research. Privacy of data may be an issue for standalone biobanks because the clinician and researcher may be presented by the same person. Also, sustainability of the sample collection cannot be assured.[43]

Central biobanks operate in the kind of regulated setting needed for biomedical research. Since the samples are not directly related to any research interests at the biobank, the neutral requirement is met. Based on the contract and agreement for the transfer of materials and data between the project partner and the biobank, the centralised biobanks adhere to a defined procedure for processing biospecimens.[43]

The collaboration between biobanks and major organisations or networks of biobanks ensures the biospecimens' consistent quality. One of the first bioresource infrastructures to emerge from the European Strategy Forum on Research Infrastructures (ESFRI) is the Biobanking and Biomolecular Resources Research Infrastructures-European Research Infrastructure Consortium (BBMRI-ERIC), which offers large-scale research infrastructure to all scientific disciplines in Europe. The sustainability and optimization of biospecimens depend on this kind of network infrastructure. It gives researchers access to the biomedical resources and collections of its member biobanks, as well as its knowledge and services.[44] National nodes and BMRI-ERIC members include Austria, Belgium, Bulgaria, Czech Republic, Estonia, France, Finland, Greece, Germany, Hungary, Italy, Malta, the Netherlands, Norway, and Sweden, Turkey, and the United Kingdom. Cyprus, Lithuania, Switzerland, Spain, Turkey, and the International Agency for Research on Cancer (IARC/WHO) are all observers.[30] Similarly, the Canadian Tissue Repository Network is a pan-Canadian

repository for biospecimen storage. It provides access to high-quality research samples and advice on administrative and scientific best practises.[30]

CONCLUSION

Biobanks are a key player in the rapidly evolving field of large-scale, data-driven health care research. Various strategies guide the operation and functioning of biobanks in accordance with international standards while adhering to ethical principles. Biobank governance should include an integrated mechanism that works across multiple fields of science, technology, ethics, and law. Biobank governance is important in increasing the trustworthiness of biobanks among stakeholders and the general public. A biobank's success or failure is determined by the effective integration of governance strategies.

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Conflicts of interest

There are no conflicts of interest.

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