Sustainability of Biobanks and Biobanking in LMICs

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Abstract

Ensuring sustainability is the most important task of a biobank, because biobanks are very resource-intensive infrastructures with a long-term horizon. Only a sustainable biobank can make a significant contribution to research ongoing. However, many different factors must fit and interact to enable sustainability. In this chapter, the particular challenges of biobank sustainability and their biobanking activities with a special focus on LMICs will be discussed.

Keywords

Sustainability · Biobanking · Low-and middle-income countries · Challenges and opportunities · Biobanking stages

Introduction

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Definition of a Biobank

Before sustainability of biobanks can be discussed, especially in LMICs settings, the characteristics of the biobank environment should be explained. A major challenge remains in that there is still no generally accepted definition of what a biobank is. This can be indicative of a rapidly growing field; however, developments in the field of biobanking will be complicated in the longer-term if researchers are unaware that their collection is indeed a biobank and that it needs to follow particular sets of best practices and international standards [1, 2]. A clear definition of the term is therefore an important step towards fostering collaboration amongst researchers, the discoverability and utilization of samples [3]. Additionally, a variation in definitions between different stakeholders and/or geographies—if continued—is likely to generate misunderstandings about the scope of various regulations and guidelines related to sample collections [4]. This is especially important in LMICs settings, where a number of regulatory frameworks have been created in recent years and/or are still in the process of being created [5, 6].

To this end, a biobank can be defined as a systematic collection of samples and data for a defined purpose. The data itself has three dimensions: (1) the data of the donor (e.g., patient and medical history; in the case of the latter, there may be various diseases that are more or less important), (2) the data of the collection process and (3) the data which is generated by using the samples. It can be stated that as soon as the samples are removed from their usual preservation environment, a new “life in data” for these samples begins. One such extreme example is immortal cell lines.

Biobanks service a wide range of stakeholders and research needs, and therefore various models of biobanks exist. From the users’ point of view, there are biobanks that have only one user, few or many (mono-, oligo-, and poly-users) [7]. It is also important whether a biobank is designed for a short period of time, e.g., for the lifetime of a specific project, or for the long term. Lastly, another significant parameter is whether it is a retrospective or prospective collection [8].

Concept of “Biobanking 3.0”

The above definition of biobanks is static and does not allow for the necessary flexibility demanded by rapid technological and experimental needs. On the contrary, the concept “Biobanking 3.0” shows the dynamic components of biobanks and all the activities associated with them, so-called biobanking [9]. This concept takes into account both biobanks that are newly established and activities that are carried out when an established biobank opens up to a new field. As such, this might be a better suited concept for LMIC settings, where the pressure for flexible and interlinking infrastructures is at its greatest. At the beginning of the COVID-19 pandemic, this could be exemplified by those biobanks that had to adapt to the new healthcare context and collect corresponding samples and data from COVID-19 patients within a very short time [10].

In the Biobanking 3.0 concept, five individual activities of biobanks are listed and include (1) the samples that are collected, (2) the personal data that are collected, (3) the sample-related data that are collected, (4) the customer need and (5) sustainability.

At the initial biobanking 1.0 stage, i.e. when a biobank is newly established or a new field is newly established within an existing biobank, the focus is on the quantity or on how many samples can be collected. At this point, it is central that contacts are established with those structures where the corresponding donors can be found and samples are available. Data are also important, but most of them can be collected with a delay. At the biobanking 2.0 stage, the focus is on the quality, and especially the quality of the data collected. Biobanking 1.0 and 2.0 can go hand in hand, and these are usually very short stages. Much more important is the stage of Biobanking 3.0 with the focus on customer needs and sustainability, where biobanks reach operational maturity. This concept gains further momentum when it is used to describe and, if necessary, calculate impact and value.

The Three Dimensions of Sustainability of Biobanks and Biobanking

The basic principles of sustainability are universally valid and applicable across different geographies and fields of activity. This well-established three-pillar concept of sustainable development has already been adapted for biobanks [9]. According to this concept, biobanks can achieve long-term sustainability if the financial, operational and social dimensions are not played off against each other, but are pursued with equal priority [11].

The *financial dimension* involves not only access to finances but also knowing the various sources of finance and how to approach them. These sources of finance can be local, regional, national or international, they can be public/governmental or private, or a mixture of these. But it is equally important to know the real costs of operating a biobank. It can be very difficult to calculate these costs because, as mentioned above, biobanks are very diverse and are integrated into a wide variety of administrative networks [12, 13]. A helpful tool is the Biobanking 3.0 concept mentioned above.

The *operational dimension* of sustainability includes all aspects of how the biobank is managed as a research infrastructure. In this context, a business plan which includes a vision and mission; an analysis of SWOT; risk mitigation; and defined performance metrics including all key business plan elements and monitoring their success against SMART (Specific, Measurable, Achievable, Relevant, Time bound) goals and objectives is a central steering tool. The business plan makes it possible to identify the opportunities that a biobank has and to take the necessary steps to exploit these opportunities [14]. All aspects of the Quality Management System need also to be included in this dimension [15].

The *social dimension* focuses on early and frequent interactions with all stakeholders. These continuous interactions increase or establish social trust and thus ultimately the general value of the biobank [16, 17]. Within LMICs settings, the social dimension has proven particularly important for collections of samples, especially as a number of past experiences were mishandled. This applies in particular in cases where samples were collected within LMICs settings, shipped abroad for the sole academic benefit of external collaborators and without involving the communities and researchers where those samples originated from [18].

Sustainability for Biobanks in LMIC: Challenges and Opportunities

Our analysis does not concern individual biobanks; as mentioned above, the variability within biobanks is enormous. Instead, this chapter focuses on the biggest challenges and opportunities for biobanking in LMICs.

Probably the biggest current challenges are infrastructure and governance [18–21] aspects influencing each other. A biobank is a long-term infrastructural commitment that requires a high level of investment, as well as a structured and continuous environment. Biobanks require buildings that should meet defined requirements, and biobanks need dedicated personnel who ensure continuous operation. The previous experiences of disconnected islands of scientific excellence across LMICs, created for the life cycle of particular research initiatives, would need to be turned into interconnected networks or collaborations [22, 23], where biobanks are the common ground of access to biological resources and data. Such networks increase the resilience of investments, can support research and capacity building and can even mitigate the risk to the overall scientific advance, if one of their participating infrastructures faces financial distress [24, 25].

Ethical, legal, social and regulatory aspects are key challenges for the successful management of biobanks. These are elements that have seen very active research in the last few years, providing evidence for informed governance structures within LMICs [5, 18, 20, 26–30]. It must also be taken into account that biomedical research and, as part of that, biobanking usually does not constitute the first governmental priority, especially as the healthcare system is not primarily oriented towards research [31, 32].

However, there are also many opportunities for biobanks in LMICs, as there are many understudied populations and many diseases with unmet need. In many countries, large cohorts of patients/donors can be accessed [33], and there is general willingness from the wider public to participate in medical research through biobanks [34–36]. Additionally, in LMICs there is a demand for sufficient, educated manpower and a growing young generation of increasingly well-educated, well-connected professionals exists. This will lead to newly established research groups who will generate a considerable demand for samples, data and other biobank services.

Outlook

Many LMICs are developing legal frameworks for research in general and specifically also for biobanking. Biobanks need to be in close contact with these legislative efforts to ensure sustainability is included or protected through such frameworks. A key success factor is good business planning for each individual biobank. While this holds true for all biobanks globally, LMICs cannot afford failing biobanks due to the significant investment needed. LMIC biobankers can learn from the experiences of others and reach for dedicated expertise beyond the timeframes of individual grants/ projects. They should build local, regional or national networks and consortia to become an important stakeholder in all aspects of research and biobanking [5, 19, 33, 37, 38]. There are great opportunities for scientific collaboration by linking to existing infrastructure in LMICs and globally. This includes international organizations and societies like IARC, ISBER, or others for staff educational opportunities, e.g. qualifications and long-distance learning [39, 40].

In summary, there are good reasons to be optimistic about the future prospects of biobanking in LMIC. In addition, biobanks in LMICs can achieve long-term sustainability if the financial, operational and social dimensions are treated with equal priority, and the impact of such biobanks is documented. In this manner, successful biobanks will eventually generate demonstrable value to medical research and general health.

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