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Review Article

Construction and Application of Biobanks for Infectious Diseases: Focus on SARS-CoV-2

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ABSTRACT

Biobanks are foundational infrastructures that collect and provide standardized, high-quality, and research-ready biological material and associated data. The advent of high-throughput technologies has further supported the creation of biobanks globally. However, the same rate of growth has not occurred in the field of infectious diseases, where biobanks are significantly fewer as compared to other scientific fields such as oncology. This narrative review presents the main aspects that need to be taken into consideration for the construction and application of biological sample infrastructure for infectious diseases, with a number of examples taken from the recent COVID-19 pandemic.

Keywords: infectious diseases, biosafety, biobanking, sample collection, infrastructure creation

INTRODUCTION

Infectious diseases, such as coronavirus disease 2019 (COVID-19), constitute major global health threats with far-reaching consequences. The COVID-19 pandemic swept the world within a short period of time, causing heavy damage to both global public health security and human health.[1–3] Faced with a sudden outbreak, the viral pathogen was isolated in a short time by obtaining and sharing the genetic sequence of the virus,[4,5] carrying out clinical treatments,[6,7] initiating vaccine development and drug screening projects,[8,9] and promoting international cooperation in the global fight against the pandemic.[10] Currently, the outbreak continues to grow in various parts of the world, while there are ongoing scientific and public health debates, particularly on how to prepare for subsequent waves of COVID-19 and a post-pandemic future.[11,12] Thus, the global scientific community requires the provision of high-quality scientific research results to solve the existing clinical and epidemiologic questions and to better combat both the current and potential future pandemics.

The following sample types comprise the important and basic biological materials supporting COVID-19 research: blood, serum, throat swabs, sputum, tracheal suction fluid or bronchial lavage fluid, urine, and feces. They can be collected from patients with confirmed positive test results, asymptomatic infected persons, patients with suspected infection, and their close contacts, as well as from deceased patients' cadaver tissues and organs. All the above are critical in our understanding and research on the disease if accompanied by relevant clinical data; and, because the associations are often weak, samples are needed in large quantities. The implication is clear: if more well-

characterized, high-quality samples are available through biobanks (or repositories), research will advance faster and improve the delivery of healthcare. Thus, biobanking becomes a key element to the success of future treatments and will be relied on to standardize tissue collection for improved scientific quality. The term "biobanking" is widely defined as a process by which biological samples (bodily fluid or tissue) and associated data are collected, annotated, stored, and redistributed for future research for the purpose of improving our understanding of health and disease.[13] Using COVID-19 as an example, this article describes how to maximize and effectively use these limited and precious human biological resources, and how to build a scientific, systematic, and standardized biobank for infectious diseases. Thus, the aspects considered in this review, based on COVID-19 international examples, relate to scientific research for the prevention and control of this infectious disease, as well as the associated biological security.

THE PROGRESS OF BUILDING BIOBANKS

Biobanks are foundational infrastructures supporting scientific and clinical research, and the establishment of biobanks often relies on purposive and/or volunteer-based biological sampling for conducting research around a specific set of questions. The development of health research and its ability to inform policy has convinced governments to generate population biobanks for diagnostic and etiopathogenesis studies over the past 2 decades.[14–17] Additionally, the rapid technological developments and the ability to perform detailed molecular analyses with high throughput support a more robust, detailed annotation of specimens, thus accelerating the need for biobanks to act as high-quality, combined digital and sample facilities.[18] The digital adaptation of biobanks and their subsequent presence online expands communication and networking with end users of samples and data, opening avenues for further collaborations both in the public and private spheres.[19–21] Several recent publications worldwide have described in detail this progress in building and developing biobanks.[22–25]

More specifically, biobanks have been established in response to infectious diseases, often within specific geographic areas that may experience additional healthcare pressures because of prevalent infectious diseases.[26–29] During previous infectious disease outbreaks, several biobanks were created in response to the need for intensified research. These include biobanks for HIV in Spain,[30–32] for viral hepatitis in the UK and Thailand,[29,33] as well as in response to the recent Ebola outbreak in West Africa.[34,35] However, such biobanks tend to focus either on chronic infections or highly endemic ones, being better located to collect the required number of samples. There have been no biobanks specifically built for acute infections or respiratory viruses, owing to the high seasonality and unpredictable variability of such infections. Creating them is a high-risk technical investment in terms of being able to collect the number of specimens as planned. Consequently, the biobanking of acute infectious disease samples often becomes an extended responsibility of existing facilities, taking advantage of staff availability and their expertise, and sometimes of previously collected samples.[36,37] Therefore, the announcement of the creation of COVID-19-specific biobanks—de novo or based on sample collections for other infectious diseases[38,39]—is an unusual occurrence. Nonetheless, it is worth additional consideration because it could become a turning point in the creation of infectious diseases biobanks.

Table 1. Thematic grouping of the fundamental considerations when building a biobank for acute infectious diseases such as coronavirus disease 2019 (COVID-19)

Aspect	Consideration
Operational aspects	Anchor decisions on international standards
	Consider the most common downstream uses
	Set quality assessment protocols
	Allow for the ability to scale up or scale down operations
	Provide staff training
Social and legal aspects	Set data protection policies
	Anchor decisions on national legal frameworks
	Recognize different legal requirements for samples and data
	Adhere to the principle of transparency
	Aim to foster trust
Financial aspects	Differentiate between short- and long-term needs
	Create a clear costing model
	Create a clear business model once costs are known
	Ensure financial models are context dependent
	Balance finances with competing healthcare needs
Biorisk management	Provide biosecurity for both samples and data
	Ensure biosafety for staff and the environment
	Plan for long-term storage
	Set risk assessment policies
	Provide staff training

BASIC PRINCIPLES OF BUILDING A BIOBANK

The elements contributing to the long-term success and sustainability of biorepositories have been described in previous publications through the experiences of well-established institutions.[40–43] It is generally accepted that sustainability of any biobank is dependent on three key aspects: operational, social, and financial.[44] In this review a similar approach is adopted. It presents the fundamental considerations for building an infectious diseases biobank (Table 1), including one for COVID-19-related samples.

Operational Aspects: Driven by the Need

During the first months of the pandemic, hospitals and healthcare providers faced a first wave of COVID-19. It was a novel disease affecting hundreds of thousands of patients, and for which there was no clear physiopathology, clinical pathway, or common protocols to fight against it. Many medically compromised patients had severe disease leading to death, whereas others without any known risk factors needed life support for weeks. Meanwhile, some patients with clinically identical conditions did not experience any symptoms, and others did not become infected by close and prolonged contact with relatives. Finally, survivors of COVID-19 would deal with the uncertainty of chronic lung, heart, liver, or kidney disease, among others. This scenario was repeated in subsequent waves. Thus, long-term follow-up can inform health authorities of the need for specific health programs including for associated disabilities.

As such, the research on COVID-19 is likely to continue apace for many more months if not years. From a biobanking perspective, supporting such research would require large-scale, well-balanced, and representative cohorts of individuals infected with SARS-CoV-2 (from no symptoms to mortality) and nonaffected individuals, with particular attention to high-risk populations. This will allow the accurate stratification of patient samples according to clinical characteristics and experimental needs. At its core, biobanking must include operations with globally accepted standards for collecting and processing high-quality, research-ready samples and data. There will also be a need for biobanks to include the harmonization and standardization of processes to link electronic health records and connect them with similar cohorts elsewhere in the world.

Thankfully over the last few years, technical publications,[45] best practices,[46] and international standards[47] have been published in biobanking that describe the different types of collection, most appropriate methods of preservation for different tissue types depending on their downstream use, and biological and technical requirements involved in long-term storage. Therefore, in addition to prior experience on influenza population cohorts,[48–50] there are good technical operational starting points for creating biobanks that are COVID-19-specific. Such initiatives would still require careful consideration of 1) the availability of large volumes of samples and data; 2) the identification of research activities in which those samples and data would be used, such as the validation of potential new or improved diagnostic tests; 3) the types of collection methods that would render the collected samples fit for purpose for the downstream array of laboratory analyses; and 4) good knowledge of their pathogenicity and contagiousness.

Social and Legal Aspects: Providing Governance and Transparency

Legal and ethical compliance are the foundations for the construction of biobanks. Based on the biosafety characteristics of infectious samples, national and international authorities have clear requirements stipulated in relevant laws and regulations, and they have issued updated guidance in relation to COVID-19.[51–54] In China, for example, highly pathogenic biological samples must be preserved by state-designated organizations, such as the Chinese Center for Disease Control and Prevention. In contrast, commonly used non–highly pathogenic samples can be kept by other organizations; however, the latter must provide regular reports to their allocated district health departments.[55]

Thus, the creation of a COVID-19-specific biobank would have to adhere to a rigorous and highly regulated legal framework, with additional regional or national requirements for reasons of safety and monitoring. Furthermore, there are significant legal and safety requirements for the associated clinical information and. in some cases, for the data derived from the samples (e.g., for genetic data).[56] The information derived from the samples is an important embodiment of their relative value, especially when that information is collected in a harmonized manner per the defined protocols, which render the data immediately comparable to other similar datasets.[57,58]

It is important to note that the handling of data follows different rules and regulations in different parts of the world. For example, in China, the resource management of infectious diseases such as COVID-19 is in the hands of the National Health Commission and the agencies using the sample resources. The latter involve the Chinese Ministry of Education, Chinese Ministry of Science and Technology, the Chinese Academy of Sciences, the National Medical Products Administration, and other relevant commissions within their individual structures. As such, the guidelines and policies are dominated by governmental structures in a rigid top-down approach.

On the other hand, within the European Union (EU) the handling of data—including within biobanks—is delineated by the General Data Protection Regulation (GDPR). This legal framework for the protection of personal data became binding in its entirety and directly applicable in all EU Member States in May 2018.[59] It aims to increase the protection of personal data of European citizens, while reducing legal complexities among the EU Member States. Transparency and accountability are emphasized as its main principles. Additionally, the GDPR includes a new definition for the term *consent*—which must be explicit, clear, and unambiguous—that can be expanded to certain areas of scientific research when in keeping with recognized ethical standards. The GDPR explicitly states that pseudonymized data remain personal data if the key to the data is maintained so that the donors could be reidentified.[60–62] One of the likely effects of this regulation is that EU-based institutions and/or biobanks might be required to appoint a data protection officer to monitor compliance with the regulation. A core chal-

lenge regarding the governance of access to samples and data is that stakeholders in biobanking and research often have different, and sometimes conflicting, interests and responsibilities. The challenges of sample and data ownership, access to samples, and data sharing have been well debated internationally and can inform the creation of COVID-19 biobanks.[63,64]

Therefore, while the principles of transparency and well-regulated governance are central to any biobanking operations, including any involving COVID-19 samples, they are articulated and applied differently among countries. This fragmentation could be further amplified by the differential implementation of the legal protection for samples and data, as well as the protection of the patients' identification. In the latter case, the requirements on data handling are substantial and likely to be strictly enforced in the case of COVID-19-specific biobanks.

Financial Aspects: Ensuring Long-term Sustainability

In terms of financial sustainability, often the short-term aspects are adequately addressed as the outbreak and its potential downstream effects remain in full swing. However, the more challenging aspect remains the long-term sustainability of establishing such a biobank. If it is positioned as a public resource (i.e., hosted by public institutions or agencies and driven by public health needs), then most of these biobanks would likely remain supported by the public sector for the longer term as well; in this way, the operations of this public resource can continue unimpeded.

Achieving long-term financial sustainability will require a multipronged approach, based on the two previous aspects, namely the correct review of existing needs and establishment of a resilient governance framework. Additionally, from an operational perspective it will involve consistent expenditure and revenue tracking reports, careful management of academic collaborations, and potential academic partnerships with commercial enterprises. The development of a costing model would be necessary to determine the actual costs of its services. This tool and other similar ones, based on self-assessment, can be used for longer term budgeting purposes. They could even underpin a fee-for-service scheme, ensuring that pricing does not fall short of covering most of the operational costs. Descriptions of such frameworks have been published previously,[65–67] as have biobank-specific examples; these models can provide guidance for the creation of COVID-19 biobanks.[68,69]

The current COVID-19 experience has clearly demonstrated the discriminant nature of infectious diseases. Specifically, in studies comparing biobanks in high-income countries (HICs) vs low- and middle-income countries (LMICs), the biobanks from LMICs were experiencing financial difficulties, whereas the biobanks from HICs did not experience direct financial impact during the pandemic or did so to a much lesser extent.[70] Such observations reflect similar outcomes from recent reviews on biobanking in LMIC contexts.[71,72] Yet, LMIC populations are likely to bear a disproportionate burden of COVID-19 owing to compromised nutritional status; reduced access to preventive medical care, critical care, and ventilators; slower systemic response; poor sanitation; and lack of personal space.[73] As such, the LMIC-specific review of the COVID-19 response maintained a focus on the need for balancing competing healthcare needs as a constant key consideration during the pandemic.[74]

The Additional Aspect of Biorisk Management

Biorisk management entails both the biosecurity and biosafety aspects. The former refers to the prevention of misuse through loss, theft, diversion, or intentional release of pathogens[75]; and the latter to policies and practices to prevent the unintentional or accidental release of specific biological agents. For COVID-19 biobanks the aspect of biosecurity needs to be considered, and there have been some helpful guidelines already published in this respect. For example, the Organization for Economic Cooperation and Development (OECD) best practices do not address emergency preparedness but do provide some overall guidance on biosecurity.[76] It is anticipated that such guidelines will be revisited and perhaps revised post pandemic to incorporate the lessons learned for both the physical and digital biosecurity aspects.[77,78]

An equal emphasis needs to be placed on the biosafety aspects owing to the potential infectivity of COVID-19 samples, which may threaten the health and safety of people and the environment.[79] A few guidelines have been created and/or revised already by national and international organizations addressing this very aspect.[52–54,80] However, as previously experienced, implementing effective biosecurity and biosafety safeguards can be a complex task requiring well-trained staff.[81–83] The case of COVID-19 biobanks is no exception to this observation.

STRATEGIC BASIS OF THE SAMPLE REPOSITORY

Every outbreak mobilizes different teams of people—depending on the pathogens and locations involved—bringing together communities with different norms. Uncertainties over whether the information belongs to local governments or data collecting agencies can present further barriers to sharing, as does the absence of patient consent, which is often observed for data collected in emergencies.[84] However, in the case of the COVID-19 pandemic, novel approaches have been implemented such as e-signatures and e-consent for clinical trials as well as for the collection and biobanking

of residual human biological material obtained during routine clinical care.[85]

Infectious diseases such as COVID-19 are characterized by sudden spread in the populations, the constant generation of genetic variants, and the eventual possibility of their elimination. Therefore, every sample collected could be irreplaceable and nonreplicable, making each a precious resource for research. Only after these sample resources have been preserved scientifically and systematically according to harmonized protocols, can we better understand the past of the disease and deal with potential future re-emergence. Some of the internationally renowned preservation organizations, such as the Central Bureau of Fungal Cultures in the Netherlands (Centraalbureau voor Schimmelcultures) and the American Type Culture Collection (commonly known as ATCC), have some biological resource samples preserved for many decades and have become global reference points. Therefore, the creation of infectious diseases biobanks can be viewed in the same light as being of great strategic significance; they can provide a resource reserve for COVID-19 and other infectious diseases in the long term.

At present, there are some global sharing mechanisms of pathogenic microorganisms that can be used as a blueprint for COVID-19 biobanks while adhering to ethical, legal, and social implications (ELSI) and data protection aspects and fostering international collaboration. These international sharing mechanisms include the World Health Organization (WHO) Pandemic Influenza Preparedness Framework, the Biodefense and Emerging Infectious Diseases Research Resources Repository (BEI Resources), and Federal Select Agent Program in the United States, and the China National Pathogen Resource Center. Additionally, the United Nations Educational, Scientific and Cultural Organization published "UNESCO Recommendation on Open Science" in 2021. This document recognized the rights of knowledge holders (e.g., biobanks) to receive a fair and equitable share of benefits that may arise from the use of their knowledge; that provision can form the basis for the further development of such biobanks and biobank networks.[86]

Challenges in sample management and effective coordination have been exposed during the COVID-19 pandemic among clinical and scientific research institutions.[87,88] As such, the need remains for developing or upgrading guidelines on the construction and development of biobanks for COVID-19 and other infectious diseases. These guidelines should be based on the technical, scientific, and managerial expertise acquired during the COVID-19 pandemic and from previous recent infectious disease outbreaks. The guidelines should further 1) elucidate interunit resource pathways among sample collection, identification, storage, and use activities; 2) determine the governance, access, and sharing mechanisms among collaborating institutions; 3) conform to international standards and established quality management systems; and 4) form an integrated and coordinated resource support system for the biobanking of infectious disease samples.

At present, major strategic achievements have been made in the fight against the epidemic. For the next steps, countries should 1) strengthen their capability for law-based prevention and control of biobank operations; 2) improve national public health emergency management systems; 3) strengthen the development and management of national infectious disease sample repositories within recognized biosafety strategic systems; 4) determine what is needed to improve the existing systems for infectious disease surveillance, prevention, and control; ; and 5) improve the mechanisms for sharing and using the infectious disease samples to more effectively prevent and control major emergencies and to support improvement in scientific research.

CONCLUSION

The COVID-19 epidemic has been a big shock and test, exposing fundamental challenges in the overall research responses regarding infectious diseases. One of these aspects is the biobanking of infectious diseases samples, which has been taking place on an ad hoc basis, and sometimes using preexisting infrastructure. Perhaps a more effective approach would be to consider the creation of COVID-19 or specialized infectious diseases biobanks as long-term, high-quality, and safe infrastructures. Such biobanks would use the consolidated knowledge of the past decades and lessons from the most recent infectious disease outbreaks to provide well-formulated guidance, collaborate on high-profile research national and international research efforts, and contribute to global security. Where the creation of novel specialized units is not possible (e.g., in resource-restricted settings), then it would be practical to combine such an infrastructure with existing efforts, e.g., TB surveillance, thus using the few specialized pockets of excellence to best advantage.

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