Modeling consent in the time of COVID-19

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ABSTRACT

Effective responses to the COVID-19 pandemic require novel solutions for research and responsible data sharing. Biobanking presents itself as a key priority in furthering our understanding of COVID-19. In this article, we propose a tripartite approach to consent to create resources for research relating to COVID-19. The approach aims to link three levels of participation: COVID-19 patients, respiratory/infectious disease patients, and longitudinal study participants. We explore the potential approaches that can be taken to consent processes with these three participant groups. We furthermore describe an access model for both single-site and multi-site data and sample storage. Through dealing with these topics at a high level, the model may be adapted to local legal and ethical requirements while still pursuing its ultimate goal: the creation of a research infrastructure that supports transparent, strong, and open science.

KEYWORDS: biobanking, consent, data sharing, pandemic

INTRODUCTION

Societies are choosing to adopt strict public health measures to contain the spread of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Such measures, which frequently target restrictions on individual movement, “should not impair
international collaboration in the fight against the pandemic”.¹ It is useful to remember that the term ‘pandemic’ derives from the ancient Greek πάνδημος (pándēmos), ‘of or belonging to the whole people’.²

What about creating the research resources needed to confront the virus and its associated disease, COVID-19? If this situation does indeed belong to all of us, and so brings us all into its web of responsibilities, what are its implications in the time of consent? Consent is, at its core, the ultimate expression of individual autonomy and self-determination. Now, for the first time, many individuals are asked to think beyond their own health or of that of their family members and to consider their fellow citizens around the world by contributing to common resources such as biobanks. The rapid, devastating, progression of the pandemic also means that timely, concerted action by all involved is a scientific and ethical imperative.

In this article, we propose a generic model for participant consent in order to create public resources for understanding COVID-19. Ideally, there will be three groups: COVID-19 patients, other respiratory and infectious disease patients, and longitudinal study participants. Combining the data and samples of these three groups provides an invaluable resource with which we can elucidate the trajectory of COVID within the population and understand the disease's interaction with individual genetic variability. The model can be adapted according to the particular ethico-legal landscape and research infrastructure of a given locale. Our model aims to build an understanding of COVID-19 with reference to other diseases and across countries.

INTERNATIONAL INITIATIVES

Statements, policies, frameworks and other normative documents from international organizations have highlighted the need to collaborate and to share data as evidenced by the 2017 Organisation for Economic Co-operation and Development (OECD)’s Recommendation on Health Data Governance.³ COVID-19 has only increased this need. The Wellcome statement, Sharing research data and findings relevant to the novel coronavirus (COVID-19) outbreak, whose signatories include the Fonds de recherche du Québec, Genome Canada and the National Institutes of Health, called on researchers, journals and funders to ensure that research and data are shared openly and rapidly.⁴ Organizations such as the WHO also recognized that pre-existing policies on the sharing of pathogen genomes, clinical trial data and other data types need to be updated.⁵ The March 26, 2020 joint statement on COVID-19 from UNESCO’s International Bioethics Committee (IBC) and the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) furthermore called for world action to “adopt uniform criteria of data collection” regarding the pandemic, so as to ensure data inter-

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¹ International Bioethics Committee & World Commission on the Ethics of Scientific Knowledge and Technology, Statement on COVID-19: ethical considerations from a global perspective 10 (2020), https://unesdoc.unesco.org/ark:/48223/pf0000373115.
² pandemic, adj. and n., OED Online, http://www.oed.com/view/Entry/136746 (last visited Apr 1, 2020).
³ OECD, Recommendation on Health Data Governance (2017).
⁴ Wellcome, Sharing research data and findings relevant to the novel coronavirus (COVID-19) outbreak | Wellcome, https://wellcome.ac.uk/coronavirus-covid-19/open-data (last visited Apr 3, 2020).
⁵ Vasee Moorthy et al., Data sharing for novel coronavirus (COVID-19), 98 Bull. World Health Organ., 150–150 (2020), http://www.who.int/entity/bulletin/volumes/98/3/20-251561.pdf (last visited Apr 1, 2020).
operaibility in international collaboration. Alongside the international vision of these initiatives lays the privacy and data protection law, which poses complications for data intensive science. Recent guidance from the European Data Protection Board on COVID-related research, for example, takes an arguably conservative approach to interpreting European data protection law by emphasizing how little the pandemic changes data protection norms.

It has been recognized that biobanks have an essential role to play in filling research gaps to adequately respond to COVID-19. The pan-European biobanking consortium, BBMRI-ERIC (Biobanking and BioMolecular resources Research Infrastructure—European Research Infrastructure Consortium), thus far has nodes in 13 countries that are offering a combination of technical expertise, samples and data relating to patients with COVID-19, as well as population cohorts. Other initiatives are also underway. Quebec, for example, has launched the Quebec COVID-19 Biobank, which is a unique, decentralized and federated initiative to enable the collection, storage and sharing of samples and data for research on COVID-19. It builds on the expertise of leading health research networks, as well as that of the clinical research centers of Quebec’s major hospitals. While its overall framework is still in development, it is foreseen that samples will be stored locally, but a virtual database with a central access portal will ensure the possibility of meaningful, collaborative analysis by Quebec, Canadian, and international researchers.

CONSENT

In the absence of public resources and governance infrastructures that favor transparency as well as strong and open science, it scantly matters whether consent is broad or not. Without these elements, the full potential of a broad consent, which is expressive of a research participant’s desire to contribute to the common good, will not be realized. Research into COVID-19 will, amongst other goals, eventually serve...
to understand inter-individual genetic variability in response to COVID-19 infection, determine the prevalence of risk variants in the population, with the ambition to better protect high-risk individuals and communities. In the context of a pandemic, however, the speed and yet, long-term, international quality and reproducibility of such research are of the essence. Yet, the complexities of managing clinical care for COVID patients from admission through intensive care means that tackling responsibilities relating to sample collection and management must be carefully integrated with clinical care. Indeed, providing high-quality clinical care to COVID patients and reducing the risks of contamination of research staff remain primordial.

Classical consent conundrums based on an ethos ill-suited for public health research could be considered a major hurdle for a biobank research approach. Furthermore, clinical realities on the ground will need to be considered during the recruitment process. Do current, traditional consent processes present sufficient flexibility to build a comprehensive COVID research biobank? We consider that building an infrastructure responsive to the pandemic needs of actual and future COVID requires a tripartite strategy for the collection of samples and data from: COVID patients (A); participants (already enrolled or to be enrolled) in respiratory diseases research generally (B), and finally, study participants who are representative of a given population (C).

A. COVID-19 Patients

In the context of research during a pandemic (including preparing for the next one), we first posit the need for the more systematic and streamlined biobanking of samples and data from patients themselves. Owing to the infectious nature of COVID, obtaining samples and informed consent highlights the need for creative solutions. If contact is to be kept to a minimum, the research team is unlikely to be able to seek consent themselves. Instead, clinicians and nursing staff may be the ones to implement the requisite consent processes in a way that is safe and continues to prioritize the patient's clinical care. In this vein, it is essential that research participation be distinguished from clinical care when seeking consent. Moreover, innovative sample management practices are required. For example, samples could be taken only at the time when samples of the same type are taken for clinical care.

For COVID patients, their written consent may not be possible, as they are highly contagious and often too ill to comply with such formalities. Collection of samples and data (e.g., respiratory secretions, blood and other tissue samples, etc.), however, are part of the standard of care in their use for the patient’s medical diagnosis and treatment. In such situations, written consent can be deferred and verbal or digital consent could be obtained using informational videos to facilitate an understanding of the research, for those who are able to watch and understand them. It is moreover possible to implement a second step of obtaining written consent upon the patient’s discharge. For those unable, a consent by their legal representative/next of kin, if present, would be the approach to take. If not present, a simple notification could be provided to the legal representative/next of kin. In cases where the patient suddenly loses their capacity due to COVID-related complications, their legal representative/next of kin may consent on their behalf. If not available, another family member of the patient could consent. Once the patient regains their ability to consent, they will be consented. If they unfortunately die before regaining their ability, the consent of the legal representative would remain
valid, depending on the jurisdiction (e.g., in the USA, the Common Rule does not apply to deceased individuals\(^{13}\)), or could be sought. The consent should explain the coded privacy protections and mention ongoing linkage with health administrative data as well as deposit in the COVID biobank. Broad national and international sharing and the possibility of recontact should also be mentioned.

B. Respiratory/Infectious Disease Patients
For samples and data already collected (legacy) for coded research from respiratory and/or infectious disease patients under a broad consent, researchers will already have the ability to recontact by virtue of the broad consent. As such, participants should be notified of the new COVID research use through the habitual communication channels. The need for access to the medical record should also be explained.

As for new patients recruited prospectively for research today, we suggest the use of a simple consent form for the collection, storage and use of samples and data for COVID research biobanking, including biomedical and genetic research. Furthermore, researchers should seek explicit consent for access to medical records and ongoing linkage to health administrative data as well as recontact for future research.

Both of these groups can be used as controls and, since the biobank serves as a basic research resource, no results or secondary findings will be returned.

C. Population Participants
As already mentioned, population biobanks also have a key role to play in research related to COVID-19. Large population studies such as the Canadian Longitudinal Study on Aging (CLSA), All of Us (US), UK Biobank, CARTaGENE (Quebec), the Estonian Biobank and others already have data and samples of participants representative of contemporary, heterogeneous populations. Researchers can obtain access to these research infrastructures, thus allowing the use of highly phenotyped samples and data with the potential for ongoing linkage to health and administrative data. Additionally, some studies may collect data about COVID-19 through the sending of questionnaires to participants (e.g., CLSA).\(^{14}\) These data may be used for epidemiological studies, stratification, etc., as provided for in the broad research consents. Crucially, data sharing is already foreseen by these studies. Population biobanks will communicate as usual with their participants concerning such participation by publishing their lists of approved COVID access request in their newsletters, etc.

D. Access
The recent Wellcome statement makes the case that data sharing obligations are heightened in times of pandemics. This requires, for example, that, ‘researchers share interim and final research data relating to the outbreak, together with protocols and standards used to collect the data, as rapidly and widely as possible - including with public health and research communities and the WHO.’\(^{15}\) Indeed, simply building this useful resource for research is not enough. In this regard, access frameworks and policies have

\(^{13}\) The Common Rule, 45 C.F.R. §46.102(e)(1)(i).

\(^{14}\) CLSA response to COVID-19 | Canadian Longitudinal Study on Aging, https://www.clsa-elcv.ca/coronavirus (last visited Apr 26, 2020).

\(^{15}\) Wellcome, supra note 4.
a key role to play in a biobank’s future contributions to research. While protecting the identity of participants, access must be provided to local researchers and those from the broader international community. To facilitate this, we propose an independent access committee to process and approve access requests (i.e., controlled access). Depending on the approach to storage, access to samples could be provided by a centralized committee, as with data. The public health emergency created by COVID-19 and expanded sharing requirements will likely require an important time commitment and flexibility of individual members of the access committee to efficiently authorize multiple requests from numerous users worldwide. For an approach that foresees multi-site storage, a cooperative, federated model could be established, with access determined by local sites but coordinated by a central body. Finally, enriched data should be returned to the databases, allowing the biobank to evolve with further use.

CONCLUSION
We propose this three-tiered approach for COVID research biobanking. At all three levels, national and international data sharing is possible. Both medical and research needs as well as current legal and ethical constraints are met by our three levels of notification and consent processes. One foundation is crucial, however, for patients, research participants, physicians, researchers and citizens contributing to a COVID research biobank—trust. Such trust can only come through robust and transparent governance structures and clear, ongoing communication with the public.16 We foresee a time in the near future, where biobanking samples for public health research involving broad data sharing between countries will become the standard of care and, hopefully, prior to facing any new pandemics. In the meantime, we hope that our proposed approach can contribute to demonstrating the vast potential of research to help address emerging pandemic more efficiently, ethically and rationally.

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16 Khaled El Emam et al., Physician privacy concerns when disclosing patient data for public health purposes during a pandemic influenza outbreak, 11 BMC Public Health 454 (2011), https://doi.org/10.1186/1471-2458-11-454 (last visited Apr 1, 2020).