The Promise and Plight of BioBanking Initiatives During the COVID-19 Pandemic: The Urgent Need to Change Existing Practices

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More than ever human biospecimens are needed to help in the fight against Covid-19. This is why biobanks collecting biospecimens are pivotal research resources [1] to understand pathogen characteristics associated with virulence, replication and transmission dynamics, factors underlying individual susceptibility, in order to develop biomarkers of disease progression, severity and seroconversion, and to evaluate and validate new treatments or vaccines. Rapid development of COVID-19 biorepositories is therefore a priority in the public's interest across the globe but two main questions come to light:

1. While millions of dollars are being urgently invested worldwide in COVID-19 biobank initiatives [2] either directly to build a collection, or indirectly as a pre-requisite step towards a scientific purpose, a serious question on how these funds are being applied arises. Can we be sure that these initiatives are well-coordinated and in synergy at the international level? Most importantly, are all these invaluable samples being collected in a fit-for-purpose manner where they can make a significant difference for society?
2. While it is a reality that the development of new drugs, vaccines and biomarkers to solve unmet medical needs such as the current COVID-19 pandemic, relies heavily on the biopharma industry to translate research from bench to bedside, it seems that many of these biobank initiatives, most of them funded with public money, are not necessarily intended to be shared with industry scientists in an effective and rapid way.

A better, fit for purpose design of COVID-19 biospecimen collections is needed

As typically has been the case for several past large biobanking initiatives in other diseases, one can predict that most of the current COVID-19 biospecimen collections will not meet the needs of the broader scientific community, as they are usually collected in the context of answering a single scientific question raised by one vocal academic scientist with the noble intent of furthering scientific knowledge, and with the ultimate purpose of publishing a scientific article [3, 4].

Individual biobank utilization suffers as a result of "biohoarding" [5], as well as poorly addressing factors such as the clear definition of scientific needs, fit-for-purpose design, informed consent considerations, as well as access policies and operating procedures [6].

Beyond the pitfalls of individual biobanks, it is a fact that many continue to build sample collections in silos without any coordination between the types of samples and clinical data that are being collected, or harmonization of how (and for what purpose) the patients are being asked to provide informed consent, and with the sole objective of answering similar, or even the same, scientific questions [7]. Yet their sample

collections, while overlapping with those of other biobanks, may not be compatible so as to be combined and pooled, thus significantly limiting the potential of achieving a greater goal beyond that of a scientific publication. Sample collection protocols, at conception, are not designed to fit a purpose.

Much has been written about selecting appropriate biobanking models for the purposes of the initiatives [8], aligning the naming of repositories so as to reflect the purpose of the initiatives, and ultimately that many initiatives end up as "biovaults" and "biohoards" that do not share their collections and that do not yield the expected benefits to individual donors, the broader health community and society in general [9].

Within the COVID-19 context, a critically important opportunity for building crucial biobanking initiatives may again be wasted if collections are not appropriately designed for global cooperation, and not open to coordination, harmonization and sharing at the international level, rendering them incompatible with international efforts involving multiple stakeholders including academia and industry.

A better mutual understanding and cooperation with Industry is needed

The biopharma industry is vital for the health benefits of patients [10] and definitely needs these precious COVID-19 samples in order to rapidly develop and validate reliable products necessary to fight COVID-19. Unfortunately, this access is not always possible or is exceedingly cumbersome, which is especially acute now, while the world is embroiled in a struggle with a pandemic. Despite the fact that there is an obvious potential fit between academic biobanks and industry, cooperation between academia and industry never comes easily or naturally [11]. The different cultures, objectives, and working practices exacerbate the lack of mutual understanding and acceptance between these stakeholders [12]. However more than ever, academia and industry must cooperate efficiently to fight COVID-19 in unity. It is time for mutual understanding, greater trust, and changing age-old traditional working practices, to benefit both academic biobanks and the biomedical industry, and above all the patients. At least during this current critical period, biobanks must become more open and more flexible, as this is the only way to unlock the potential of the tremendous investments that are made in biobanks, and to boost the translational research from bench to bedside that is urgently needed for patients and the public benefit.

In that respect, funding bodies also have a responsibility to make sure that their disbursed funds will be used in an efficient and effective manner by all stakeholders to bring true treatment and diagnostic solutions to the current and perhaps future COVID-19 crises. Perhaps the international funding organizations such as the World Health Organization, Bill and Melinda Gates Foundation, and programs like the EU's Horizon 2020, could consider imposing sharing and utilization requirements for grant applicants, since it is unlikely that applicants will do so of their own free will once the money is disbursed.

Towards a better model

The forces driving and sustaining research in Industry and Academia are different. Even if the ultimate goal of the scientist from academia and their industry counterpart is to discover, validate, and make available new drugs or diagnostics, their respective incentives and constraints are at odds. Academia strives for immediate publications (before patentability), while industry strives to preserve and protect their intellectual property (before publications) [12].

Based on these conflicting objectives, it is clear that cooperation between the parties is tenuous at best and new models must be developed [13]. Such models would (1) allow the academic scientist to publish, (2) enable efficient translational research by industry, and (3) give the biobanks a chance to become self-sustaining. What is needed is a big dose of consideration and mutual education, leading to a heightened level

of respect and understanding between biobanks, industry, as well as the patient. Only then can we get beyond the current mistrust and siloed fiefdoms, improving our efficiency and effectiveness, towards the ultimate goal of improving the health of patients.

For their part, academic biobanks must accept that a biobank is a research infrastructure with the single most important task of serving the whole research community, including both industry and academia. Conversely, industry must acknowledge that biobanking is a scientific activity dealing with human beings which depends on scientific recognition and publications. However, we must keep in mind that publication policy must not be a bottleneck for revealing information of crucial importance, as lessons from the Ebola public health emergency clearly show that significant delays in sharing information occurred as a result of the "publishing imperative" as an incentive for tenure, promotion, pay, and status, comprising of the time taken by authors to prepare, write and submit their papers as well as overall peer review time and completion of the publication [3].

A better use of existing networks of specialized biobanks is needed

Perhaps it is high time that, as individuals, scientists, academics, researchers, and industry representatives with a common mission, we come together as a group with national and international funding agencies, NGOs, industry representatives, scientific experts, as well as of course the main biobank associations, to rapidly share resources and data [14] in order to collectively improve our performance for the sake of the public and patients around the world. If we don't get our act together on COVID-19 soon, it will be too late for thousands of people who depend on us during this pandemic, and we will again repeat the failure when the virus inevitably comes back.

We should move away from the concept of a biobank, a concept most commonly understood as a vault for biological samples [15]. It should be stressed that donors' biomaterials are in fact entrusted to biobanks for the purpose of being stored and used in the interest of the donor and society. To encourage this paradigm shift, the concept of international networks must be introduced and will definitely better serve the urgent needs not only during the current COVID-19 pandemic and beyond, but also leading to more efficient research models for other diseases.

Irrespective of their specialization, biobanks are often grouped per country, with recommendations or standards established by Biobanking societies as the key drivers of alignment. However, considering that the COVID-19 is a global pandemic which requires global coordination, we believe it might be better for biobanks to realign and regroup to prevent duplication in the development of collections, thereby also increasing their utility to the scientific community.

A network of biobanks, focusing on COVID-19 and the same scientific questions, collecting samples in a harmonized way will result in an international resource built and managed with the same proper ethical care and technical acumen, but most importantly with a judicious balance between academic (primary research) and industry (applied research) needs. This will assure that long-term biobank sustainability is built-in from the beginning.

This shift would be consistent with the moral and ethical obligations biobankers have to their donors – to make proper use of the samples and associated data that have been entrusted to their biobank.

Achieving a greater good together, beyond the sum of the parts

Properly structured, an International Network of COVID-19 Biobanks will have multiple benefits:

- It would allow representatives of different biobanks to engage with other members of the scientific community in more active scientific collaboration to more rapidly and effectively:
    - understand pathogen characteristics associated with virulence, replication and transmission dynamics and factors underlying individual susceptibility and protection;
    - develop and validate treatments, vaccines, and new laboratory testing assays;
    - understand how Sars-CoV-2 infection will impact other biobanking activities such as sample collection to non-COVID-related diseases and the impact of asymptomatic/non-diagnosed infections in biobank sample collection procedures to ensure the safety of biobank personnel scientists manipulating samples [16, 17].
- It will generate publications for all participating biobanks in the process;
- It would enable the development of a large, high-quality, standardized, fit-for-purpose human biospecimen collection for current and future research and development;
- It may open the door to sustainability if the network shares with industry.

Conclusion

As we all grapple with the COVID-19 pandemic, we are again reminded of the challenges, inefficiencies and pitfalls in translating research from bench to bedside. Many COVID-19 collections are being publicly funded and have started to collect patient samples, while industry (who is in a position to most rapidly deliver practical solutions to the patient) is effectively at risk of being shut out from access to these samples.

Unfortunately, despite repeated calls for greater collaboration between academia and industry over the years, it appears that little has changed, even during the current global turmoil. Perhaps, at the very least during states of health emergency, academic biobanks and industry could simplify their policies and accelerate their processes required to work together.

Renewing our call for communication, cooperation, understanding, and trust, we propose the concept of International Networks of disease-oriented biobanks as way to align our efforts for the greater good of current and future patients. This will also enable quicker development of new tests, vaccines, and treatments, while still allowing primary basic research to take place as well as ensuring an important social return on the initial funding provided.

While it is clear that the current state of health emergency will have an impact on biobanking [16, 17] and biospecimen sharing practices, what remains to be seen is how the academia-industry cooperation will evolve and what, if anything, each of the stakeholders will contribute to sculpting the new reality.

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