HHS Public Access

Author manuscript

Ann Intern Med. Author manuscript; available in PMC 2024 July 10.

Published in final edited form as:

Ann Intern Med. 2021 December ; 174(12): 1727–1732. doi:10.7326/M21-2857.

Pandemic Response Requires Research Samples: A U.S. Safety-Net Hospital's Experience and Call for National Action

Elizabeth J. Ragan, MPH[*],
Section of Infectious Diseases and Research Operations, Boston Medical Center, Boston, Massachusetts

Caitryn McCallum, MPH[*],
Section of Infectious Diseases, Boston Medical Center, and Center for Emerging Infectious Diseases Policy and Research, Boston University, Boston, Massachusetts

Jai Marathe, MD,
Section of Infectious Diseases, Boston Medical Center, Boston, Massachusetts

Manisha Cole, MS,
Department of Pathology and Laboratory Medicine, Boston Medical Center, Boston, Massachusetts

Melissa Hofman, MSIS,
Clinical Data Warehouse, Boston Medical Center, Boston, Massachusetts

Andrew J. Henderson, PhD,
Section of Infectious Diseases, Boston Medical Center, and Department of Microbiology, Boston University School of Medicine, Boston, Massachusetts

Tyler Flack, MA,
Research Operations, Boston Medical Center, Boston, Massachusetts

Nancy S. Miller, MD,
Department of Pathology and Laboratory Medicine, Boston Medical Center, Boston, Massachusetts

Corresponding Author: Nahid Bhadelia, MD, MALD, 620 Albany Street, Room 401M, Boston, MA 02118; nbhadeli@bu.edu.
[*]Ms. Ragan and Ms. McCallum are co–first authors.
[†]Ms. Duffy and Dr. Bhadelia are co–senior authors.

Disclosures: Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M21-2857.

Author contributions are available at Annals.org.

Author Contributions: Conception and design: E.J. Ragan, C. McCallum, J. Marathe, M. Cole, T. Flack, C.D. Andry, E.R. Duffy, N. Bhadelia.
Analysis and interpretation of the data: E.J. Ragan, C. McCallum, C.D. Andry, E.R. Duffy, N. Bhadelia.
Drafting of the article: E.J. Ragan, C. McCallum, M. Hofman, A.J. Henderson, T. Flack, C.D. Andry, E.R. Duffy, N. Bhadelia.
Critical revision of the article for important intellectual content: C. McCallum, J. Marathe, M. Hofman, A.J. Henderson, N.S. Miller, C.D. Andry, S.I. Pelton, E.R. Duffy, N. Bhadelia.
Final approval of the article: E.J. Ragan, C. McCallum, J. Marathe, M. Cole, M. Hofman, A.J. Henderson, T. Flack, N.S. Miller, E.J. Burks, G.Q. Zhao, R. Denis, N.H. Lin, K.R. Jacobson, C.D. Andry, S.I. Pelton, E.R. Duffy, N. Bhadelia.
Provision of study materials or patients: M. Cole, E.J. Burks, C.D. Andry, E.R. Duffy, N. Bhadelia.
Obtaining of funding: N.H. Lin, K.R. Jacobson, C.D. Andry, N. Bhadelia.
Administrative, technical, or logistic support: E.J. Ragan, C. McCallum, M. Cole, A.J. Henderson, T. Flack, N.S. Miller, E.J. Burks, R. Denis, K.R. Jacobson, C.D. Andry, N. Bhadelia.
Collection and assembly of data: E.J. Ragan, C. McCallum, R. Denis, N.H. Lin, K.R. Jacobson, C.D. Andry, E.R. Duffy, N. Bhadelia.

Eric J. Burks, MD,
Department of Pathology and Laboratory Medicine, Boston Medical Center, Boston, Massachusetts

Grace Qing Zhao, MD, PhD,
Department of Pathology and Laboratory Medicine, Boston Medical Center, Boston, Massachusetts

Ridiane Denis, MD, RN,
General Clinical Research Unit, Boston University, Boston, Massachusetts

Nina H. Lin, MD,
Section of Infectious Diseases, Boston Medical Center, Boston, Massachusetts

Karen R. Jacobson, MD, MPH,
Section of Infectious Diseases, Boston Medical Center, Boston, Massachusetts

Christopher D. Andry, PhD,
Department of Pathology and Laboratory Medicine, Boston Medical Center, and Department of Pathology and Laboratory Medicine, Boston University School of Medicine, Boston, Massachusetts

Stephen I. Pelton, MD,
Section of Pediatric Infectious Diseases, Department of Pediatrics, Boston University Medical Center, Department of Epidemiology, Boston University School of Public Health, and Maxwell Finland Laboratory for Infectious Diseases, Boston, Massachusetts

Elizabeth R. Duffy, MA[†],
Department of Pathology and Laboratory Medicine, Boston Medical Center, and Department of Pathology and Laboratory Medicine, Boston University School of Medicine, Boston, Massachusetts

Nahid Bhadelia, MD, MALD[†]
Section of Infectious Diseases, Boston Medical Center, and Center for Emerging Infectious Diseases Policy and Research and National Emerging Infectious Diseases Laboratories, Boston University, Boston, Massachusetts

Abstract

Biorepositories provide a critical resource for gaining knowledge of emerging infectious diseases and offer a mechanism to rapidly respond to outbreaks; the emergence of the novel coronavirus, SARS-CoV-2, has proved their importance. During the COVID-19 pandemic, the absence of centralized, national biorepository efforts meant that the onus fell on individual institutions to establish sample repositories. As a safety-net hospital, Boston Medical Center (BMC) recognized the importance of creating a COVID-19 biorepository to both support critical science at BMC and ensure representation in research for its urban patient population, most of whom are from underserved communities. This article offers a realistic overview of the authors' experience in establishing this biorepository at the onset of the COVID-19 pandemic during the height of the first surge of cases in Boston, Massachusetts, with the hope that the challenges and solutions described are useful to other institutions. Going forward, funders, policymakers, and infectious

disease and public health communities must support biorepository implementation as an essential element of future pandemic preparedness.

Robust biorepositories are crucial to understanding emerging infectious diseases and offer a mechanism to conduct valuable science while reducing the burden of research during patient care crises. Storage of biological samples across a patient's illness, supplemented with rich clinical data, creates an agnostic resource that can be quickly deployed to answer questions about a new pathogen. For example, biorepositories with positive and negative samples can support diagnostic validation, elucidate histopathology and pathophysiology, and serve as retrospective surveillance tools when new pathogens appear (1, 2). Biorepositories can also support longitudinal studies on disease manifestation or the effect of change in clinical care practices over the course of a pandemic. Researchers can use biorepositories to identify potential links between clinical outcomes, biomarkers, and viral and human genomics (3), as well as answer questions on special populations (such as children and pregnancy dyads).

In the United States, which lacks a centralized national biorepository like those in some European countries (4), collaboration across institutions is often necessary to procure enough samples to produce robust, generalizable data. To support harmonization in procurement, processing, and storage across institutions, the National Cancer Institute established the Biorepositories and Biospecimen Research Branch in 2005 and published the *NCI Best Practices for Biospecimen Resources* (5–7). Although these guides are useful, novel pathogens present challenges not addressed there, and as a result the burden fell to individual institutions to build novel infrastructure in real time in response to COVID-19 (1, 8–11).

Marginalized populations around the world have been disproportionately affected by COVID-19 (12), but also historically and systemically excluded from participating in research that leads to novel therapeutics (13). Boston Medical Center (BMC) is a safety-net hospital serving patient populations that largely are non-White and have insufficient insurance, low income, and no or limited English proficiency; therefore, we recognized the importance of establishing a COVID-19 biorepository to both support critical science at our institution and ensure representation of our patients in research. The resource we developed during the height of the first surge of COVID-19 cases in Boston, Massachusetts, collected samples from the following 3 sources: a newly established cohort of prospectively enrolled adult patients diagnosed with COVID-19 from across the arc of disease course and spectrum of disease severity, clinical remnant samples, and autopsy samples. We share our challenges and solutions to provide insight to other institutions, funders, and infectious disease and public health organizations with the hope that all can support efforts to incorporate biorepositories as a fundamental component of pandemic preparedness.

Responding to the COVID-19 Pandemic

In March 2020, hospitals struggled to balance caring for patients with the need to find immediate solutions to urgent questions (14). Boston Medical Center cares for a patient population disproportionately affected by the COVID-19 pandemic (12). Nearly 76% come from underserved populations, such as low-income or elderly persons (15); more than 50%

identify as African American or Black; more than 20% identify as Hispanic or Latino; and 29% do not speak English as their primary language. By April 2020, BMC had the highest proportion of COVID-19 cases among Boston-area hospitals (16).

From the early days of the pandemic, our hospital's leadership prioritized and supported a centralized research effort. Instead of numerous, independent, investigator-initiated efforts to collect samples, we envisioned the biorepository serving as a central hub, facilitating standardization, optimizing quality of research and health care delivery, and reducing effects on patients and providers. As of August 2021, we have banked 48 000 sample aliquots from 10 500 patients, representing both symptomatic and asymptomatic patients positive for SARS-CoV-2 and patients negative for SARS-CoV-2. Sample types are outlined in Table 1. As of August 2021, these samples have been used in 13 individual research studies addressing such topics as hospital-associated transmission, associations between microbiome and disease outcomes, and persistence of autoimmune antibodies, with publications expected by the end of 2021 (17, 18).

Lessons Learned From Launching a COVID-19 Biorepository

In this section, we outline the challenges of launching a COVID-19 biorepository and the solutions we used to address them (Table 2).

Governance of the Biorepository

Governance is one of the most fundamental aspects of biorepository operation, ensuring both the protection of human subjects and the judicious allocation of resources to projects with real potential for impact. We established a governance committee tasked with reviewing sample requests for scientific validity, potential to advance science, and sample availability. Faculty experts from relevant specialties (such as infectious diseases, microbiology, and biostatistics) appointed by hospital leadership review sample requests monthly. A subcommittee meets biweekly to address ongoing operational issues, such as private–public partnerships, encouraging use among investigators, and building community and patient engagement into the governance structure.

Engaging Our Patient Population

One of the first challenges of launching the prospective cohort was engaging our patient population, among whom there is recognized mistrust resulting from a legacy of mistreatment in clinical research (20). Because clinical staff are often patients' first introduction to research, we prioritized engaging nursing and physician teams. At study onset, our investigators trained clinical staff on the study aims and protocol, and our clinical trials office maintained a continuously available central source for all COVID-19–related study guides for nurses and physicians. Study investigators attended nursing huddles to highlight protocol changes, answer questions, and receive feedback. This support and engagement aided clinical teams in assuaging patient fears and warming patients to research participation, thereby facilitating enrollment and increasing retention.

Another challenge was engaging patients with limited English proficiency. We had team members fluent in Spanish and Haitian Creole, and we also equipped clinical teams

with informational flyers in English, Spanish, and Haitian Creole to share with patients. A moderate amount of philanthropic funds from our hospital supported translation—an element too often circumvented but essential to ensure that research is inclusive and accessible to all. As of August 2021, the demographic profile of our cohort reflected our efforts toward inclusive engagement of underserved populations: 49% of our participants have a primary language other than English, and the racial breakdown includes 42% identifying as Hispanic or Latino; 21% as African American or Black; and 20% as "other" non-White race, declined, or not available.

Research Coordination

Early protocols aimed to minimize the footprint of the research on the wards and reduce its burden on severely ill patients. One of the hospital's first major coordination activities was to consolidate identification, screening, and enrollment of patients positive for SARS-CoV-2 and their triage across studies. Approaches from numerous study members can disrupt care and place undue burden on the patient. Study teams at BMC collaborated closely with clinical trials office leadership, our clinical research unit, and investigators. One person was appointed as a centralized research navigator and worked closely with each individual study team. Each morning, dedicated personnel reviewed all patients to deem eligibility across studies. Patients were approached to determine levels of interest in research as a whole, then assigned to studies on the basis of eligibility.

We also attempted to streamline sample collection. Sponsor policies hindered collaboration by limiting additional collection or retention of samples. Although these policies may make sense in a traditional clinical trial setting, concurrent recruitment of patients for numerous prospective studies—all with the intent of obtaining samples—is not only fiscally inefficient but often logistically infeasible in the context of an emerging outbreak. In the early months of 2020 before study teams were permitted in patient rooms, clinical nurses and phlebotomists aided in research sample collection to ensure alignment with routine clinical care when possible.

Infection Control and Logistic Challenges

Infection control policies presented one of the greatest barriers to enrollment. While patient room access was restricted, a study team member obtained remote verbal consent by calling the patient's room. Interpreter services provided witnessed documentation when patients with limited English proficiency were enrolled. Because visitors were prohibited, study teams called legally authorized representatives to obtain remote consent when necessary. As restrictions lessened and personal protective equipment became more available, study staff entered patient rooms and obtained consent using a disinfected iPad in a plastic bag. Although some institutions allowed informed consent to be waived until a patient's condition stabilized (11), after weighing the ethical implications in our population we chose not to pursue this approach.

Severe supply chain shortages jeopardized sample collection, especially during hospital surges. For several months, viral transport media and COVID-19 testing kits were unavailable. Our institution responded by developing a viral transport media recipe based

on a publicly available protocol (19). Enlisting the support of a group of doctoral students, we manufactured more than 30 000 test kits that were used clinically and in research across BMC.

Sample and Population Selection and Expansion

During the early months of the pandemic, study teams collected samples only from hospitalized patients. Streamlined procedures, a decrease in inpatient admission rates and duration, and an increase in ambulatory COVID-19 care afforded our team the capacity to begin outpatient recruitment. However, the outpatient cohort presented unique and still-unresolved challenges. Because of requirements to self-quarantine (21), we realized the need for visiting nurse services to collect samples during acute infection. Our institution did not have an established vendor, and those approached were not optimized to support clinical research. We considered hiring a traveling research nurse, but human resource recruitment was challenging during the pandemic. Mechanisms for identifying, contracting, and onboarding service vendors, such as visiting nurse services, remain an institution-wide challenge.

We continually reevaluate which samples to collect and at what frequencies. Our governance committee regularly assesses the scientific landscape and forecasts research needs (for example, sample types, time points, and patient characteristics) to allow for dynamic and responsive collection protocols. This has led, for instance, to doubling RNA stabilization tubes collected at baseline visits and shifting to random sampling of SARS-CoV-2–negative samples rather than complete retention.

Obtaining and Linking Clinical Remnant and Tissue Samples

The clinical laboratory traditionally discards samples after 7 days. We developed protocols and procedures to retain these clinical remnants in collaboration with pathology and laboratory medicine departments. After obtaining a waiver of informed consent and HIPAA (Health Insurance Portability and Accountability Act of 1996) authorization, we dedicated personnel and implemented new software to track, match, and retrieve samples at the end of clinical utility. As of August 2021, we review more than 2000 respiratory samples daily for retention from the clinical laboratory. Blood samples are retrieved weekly after being matched to patients who have had a positive test result at any point during the pandemic.

Retrieving blood samples from the clinical chemistry track was not a simple task. The robotic chemistry track receives tens of thousands of blood samples daily for automated testing; however, samples can be retrieved from the storage system only 1 at a time, which halts clinical workflow in the process. To minimize disruptions, we pulled blood overnight when the laboratory was less busy. Integrating the clinical laboratory management system with the biorepository software—effectively linking 2 subsections of the laboratory—required substantial manual hours. Although details may be unique to our hospital, coordination and engagement of laboratory medicine as early stakeholders is essential to identifying and overcoming institution-specific barriers to biorepository sample collection.

We also expanded the capacity of our anatomical pathology team to conduct autopsies on patients with COVID-19. Using remote consent procedures developed for our cohort

study, we obtained informed consent from families restricted from visiting the hospital. Although we initially restricted autopsies to the thoracic cavity, as our understanding of viral transmission improved we expanded to thoracic and full abdominal examination.

Clinical Data

The clinical data warehouse service that already existed at BMC consolidates patient data from the electronic medical record system and other sources to support research. This resource expedited retrieval of demographic and medical history for patients linked to the biorepository. As we learn more about COVID-19, study investigators continually monitor and update pertinent COVID-19–specific variables for collection, including laboratory values, sentinel events, intervention treatment data, and COVID-19 severity. For example, with the introduction of the COVID-19 vaccine, we began collecting information on vaccine type, date, and boosters, along with reinfections, breakthrough infections, and receipt of novel therapeutics. Colleagues who have led long-standing cohorts at BMC consulted on questionnaire development, ensuring appropriateness for our patient population. We leveraged data available in the medical record when possible so as to not overburden ill patients with lengthy surveys. Evolution of patients' symptoms (for example, postacute sequelae of SARS-CoV-2 infection) and the treatment landscape will necessitate continual reassessment of data collection requirements.

Financing

Biorepositories in general are difficult to fund because they have no core scientific aims beyond furnishing scientists with high-quality samples (22). Traditional National Institutes of Health funding is often not nimble enough to respond in the event of an emergency, and the emergency funds in 2020 were not specifically designed to support biorepositories. The startup of our COVID-19 biorepository was ultimately funded by our hospital and grant money from private foundations. Funding a biorepository linked to a diverse patient cohort involves more than the cost of phlebotomists, sample collection tubes, and processing. It also includes the costs of recruitment material and consent form translations, interpreter services, and research staff sensitized to the patient population.

To make our biorepository infrastructure financially sustainable, we established a cost-neutral institutional core with a sample fee structure designed to offset operational and administrative costs. Although charging for samples could inhibit timely research, we determined that our fees per sample would be several times less expensive than those in individual, investigator-initiated studies. Funding support for initial startup and infrastructural costs allowed us to reduce sample fees, especially because we have collected samples broadly and in a volume beyond our own investigators' immediate research capacity in anticipation of future needs.

The Need for Centralized Biorepository Coordination and Resources for the Next Pandemic Response

We share our challenges and successes to inform others' efforts. However, only a truly integrated system will allow for rapid research across large and diverse populations (23).

Had we been able to draw on a baseline infrastructure not only at our institution but across a national network, our overall impact and contributions to the COVID-19 response would inevitably be greater and more rapid. Calls have been made recently for the creation of a "warm base," or research infrastructure, that can provide the scaffolding for activation when future infectious disease emergencies arise (24–27). In particular, such planning should include integration of funding for biorepositories as part of a linked research infrastructure for pandemics and dedicated technical guidance on sample collection and storage for emerging pathogens. A centralized effort that provides technical guidance on how, which, and when research samples should be banked in the setting of novel pathogens—which will inherently vary in incubation period, transmission dynamics, and disease manifestations—will help standardize biorepository efforts across institutions during future pandemics. It will reduce time to adoption and execution for single institutions and increase the speed at which samples are made available for research. Furthermore, connecting existing biorepositories into a national network can enable quick access to many nationally representative samples with linked clinical data to answer generalizable research questions. All of this is possible only if biorepository-specific funding sources exist.

We share our challenges in establishing a biorepository during the global crisis of the COVID-19 pandemic. Although we hope that our lessons help others' efforts, we ultimately envision a nationally supported and coordinated research infrastructure effort to increase capacity and resilience against the threat of future pandemics.

Acknowledgment:

The authors thank the BMC patients whose samples and tissue are contained in the biorepository and have been, and will continue to be, used to support innovative and impactful COVID-19 research. They thank the BMC nurses, physicians, and phlebotomists who have cared for these patients and supported this study and the faculty and staff members of the Biorepository Scientific Review Committee. They also thank the Boston University General Clinical Research Unit for their support in implementing the study, BMC Interpreter Services for supporting the inclusion of patients in research, and the Clinical Trial Office for their support in making COVID-19 research possible at the authors' institution.

Financial Support:

By the BMC Development Office COVID-19 Philanthropy, Massachusetts Consortium for Pathogen Readiness, China Evergrande Group, and Massachusetts Life Sciences Center.

References

1. Lima R, Gootkind EF, De la Flor D, et al. Establishment of a pediatric COVID-19 biorepository: unique considerations and opportunities for studying the impact of the COVID-19 pandemic on children. BMC Med Res Methodol. 2020;20:228. doi:10.1186/s12874-020-01110-y [PubMed: 32917141]
2. Colella JP, Bates J, Burneo SF, et al. Leveraging natural history biorepositories as a global, decentralized, pathogen surveillance network. PLoS Pathog 2021;17:e1009583. doi:10.1371/journal.ppat.1009583 [PubMed: 34081744]
3. Croker JA, Patel R, Campbell KS, et al. Building biorepositories in the midst of a pandemic. J Clin Transl Sci 2021;5:e92. doi:10.1017/cts.2021.6 [PubMed: 34192049]
4. Holub P, Kozera L, Florindi F, et al. ; BBMRI-ERIC community. BBMRI-ERIC's contributions to research and knowledge exchange on COVID-19. Eur J Hum Genet 2020;28:728–731. doi:10.1038/s41431-020-0634-8 [PubMed: 32444797]

5. Greenberg B, Christian J, Henry LM, et al. Biorepositories: addendum to Registries for Evaluating Patient Outcomes: A User's Guide. 3rd ed. Agency for Healthcare Research and Quality; 2018. Accessed at www.ncbi.nlm.nih.gov/books/NBK493631 on 11 September 2021.
6. Vaught J, Rogers J, Myers K, et al. An NCI perspective on creating sustainable biospecimen resources. J Natl Cancer Inst Monogr 2011;2011:1–7. doi:10.1093/jncimonographs/lgr006 [PubMed: 21672889]
7. National Cancer Institute. NCI Best Practices for Biospecimen Resources. March 2016. Accessed at https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf on 1 July 2021.
8. Charney AW, Simons NW, Mouskas K, et al. ; Mount Sinai COVID-19 Biobank Team. Sampling the host response to SARS-CoV-2 in hospitals under siege [Letter]. Nat Med 2020;26:1157–1158. doi:10.1038/s41591-020-1004-3 [PubMed: 32719485]
9. Burke H, Freeman A, Dushianthan A, et al. Research evaluation alongside clinical treatment in COVID-19 (REACT COVID-19): an observational and biobanking study. BMJ Open. 2021;11:e043012. doi:10.1136/bmjopen-2020-043012
10. Shook LL, Shui JE, Boatin AA, et al. Rapid establishment of a COVID-19 perinatal biorepository: early lessons from the first 100 women enrolled. BMC Med Res Methodol 2020;20:215. doi:10.1186/s12874-020-01102-y [PubMed: 32842979]
11. Osman I, Cotzia P, Moran U, et al. The urgency of utilizing COVID-19 biospecimens for research in the heart of the global pandemic [Letter]. J Transl Med 2020;18:219. doi:10.1186/s12967-020-02388-8 [PubMed: 32487093]
12. Seligman B, Ferranna M, Bloom DE. Social determinants of mortality from COVID-19: a simulation study using NHANES. PLoS Med 2021;18:e1003490. doi:10.1371/journal.pmed.1003490 [PubMed: 33428624]
13. Gilmore-Bykovskyi A, Jackson JD, Wilkins CH. The urgency of justice in research: beyond COVID-19. Trends Mol Med 2021;27:97–100. doi:10.1016/j.molmed.2020.11.004 [PubMed: 33277159]
14. Tang Girdwood SC, Murphy ME, Kaplan JM. The need to balance basic and clinical research with the safety of the research environment and personnel in the time of COVID-19 in the United States. Curr Med Res Opin 2020;36:1629–1631. doi:10.1080/03007995.2020.1799773 [PubMed: 32696688]
15. U.S. Department of Health and Human Services. Serving Vulnerable and Underserved Populations. Accessed at www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/006_Serving_Vulnerable_and_Underserved_Populations.pdf on 3 August 2021.
16. Freyer F Inside Boston Medical Center: the heart of the coronavirus storm. Boston Globe. 18 April 2020. Accessed at www.bostonglobe.com/2020/04/18/metro/inside-boston-medical-center-heart-coronavirus-storm on 1 July 2021.
17. Yuen RR, Steiner D, Pihl RMF, et al. Novel ELISA protocol links pre-existing SARS-CoV-2 reactive antibodies with endemic coronavirus immunity and age and reveals improved serologic identification of acute COVID-19 via multi-parameter detection. Front Immunol 2021;12:614676. doi:10.3389/fimmu.2021.614676 [PubMed: 33897682]
18. Bouton TC, Lodi S, Turcinovic J, et al. COVID-19 vaccine impact on rates of SARS-CoV-2 cases and post vaccination strain sequences among healthcare workers at an urban academic medical center: a prospective cohort study. Open Forum Infect Dis 17 September 2021. doi:10.1093/ofid/ofab465
19. U.S. Centers for Disease Control and Prevention. Preparation of viral transport medium. Accessed at www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf on 1 July 2021.
20. George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. Am J Public Health. 2014;104:e16–31. doi:10.2105/AJPH.2013.301706
21. Massachusetts Department of Public Health. Information and guidance for persons in isolation due to COVID-19. 9 August 2020. Accessed at www.mass.gov/doc/information-and-guidance-for-persons-in-isolation-due-to-covid-19-english/download on 20 May 2021.

22. Andry C, Duffy E, Moskaluk CA, et al. Biobanking-budgets and the role of pathology biobanks in precision medicine. Acad Pathol 2017;4:2374289517702924. doi:10.1177/2374289517702924 [PubMed: 28725790]

23. Lurie N, Keusch GT, Dzau VJ. Urgent lessons from COVID 19: why the world needs a standing, coordinated system and sustainable financing for global research and development. Lancet. 2021;397:1229–1236. doi:10.1016/S0140-6736(21)00503-1 [PubMed: 33711296]

24. National Institutes of Health. Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV). Accessed at www.nih.gov/research-training/medical-research-initiatives/activ on 1 August 2021.

25. The White House. Fact Sheet: The American Jobs Plan. 31 March 2021. Accessed at www.whitehouse.gov/briefing-room/statements-releases/2021/03/31/fact-sheet-the-american-jobs-plan on 1 August 2021.

26. Mervis J Biden proposes $250 billion investment in research. Science. 31 March 2021. doi:10.1126/science.abi8002

27. Boston University Center for Emerging Infectious Diseases Policy & Research. HELP Committee pandemic preparedness legislative brief. Accessed at www.bu.edu/ceid/help-committee-pandemic-preparedness-legislative-brief on 1 August 2021.

Table 1.

Sample Types Collected by the Boston Medical Center COVID-19 Biorepository, by Source

Sample Type	Sample Source		
	Prospective Cohort Study	Clinical Remnant	Autopsy
Nasopharyngeal swabs	X	X	
Oropharyngeal swabs	X	X	
Saliva	X		
PBMCs	X		
Serum	X	X	
Plasma	X	X	
PAXgene *	X		
Urine †	X		
Stool †	X		
Lung			X
Liver			X
Kidney			X
Heart			X
Lymph node			X
Bone marrow			X
Spleen			X

PBMC = peripheral blood mononuclear cell.

* RNA stabilization tube produced by BD Biosciences.

† Only inpatient cohort study participants.

Table 2.

Challenges of and Solutions for Launching a COVID-19 Biorepository in Response to the Pandemic

Challenge	Solution
Governance	Establish committee of faculty experts to review sample requests for scientific validity, potential to advance science, and sample availability.
Engage clinical care staff	Train nursing and physician teams on cohort study aims and protocol. Support and engage clinical teams in warming patients to research participation. Attend clinical staff huddles to update on protocol changes and answer questions. Maintain a central source for all COVID-19–related study guides for nurses and physicians to refer to at any time.
Address language barriers	Recruit research staff fluent in most common languages spoken by patient population. Provide translation of study materials, including full consent forms. Provide informational flyers on the study translated into most common languages spoken by patient population.
Balance research and care	Dedicate 1 person to consolidate and manage identification, screening, and enrollment of SARS-CoV-2–positive patients and their triage across multiple studies. Dedicate personnel to deem eligibility across all active COVID-19–related studies on a daily basis.
Reduce patient burden of sample collection	Engage clinical nurses and phlebotomy services to aid in sample collection. Schedule sample collection times concurrent with routine clinical care when possible. Collect samples in outpatient setting when possible.
Adapt to COVID-19 infection control policies	Obtain remote consent over the telephone when in-person consent is not possible. Engage interpreter services to serve as witnesses to the consent process. When infection control policy allows entering patient rooms, use a disinfected iPad in a plastic bag to obtain electronic consent.
Address supply chain shortages	Manufacture test kits using a viral transport media recipe based on publicly available protocol (19).
Ensure samples meet current and future research needs	Empower governance committee and research investigators to regularly reevaluate changes in data elements or sample collection according to new scientific knowledge about emerging pathogen.
Coordinate with clinical laboratory	Engage clinical laboratory teams as early stakeholders to ensure that research's effects on clinical operations are minimized, institution-specific barriers to sample collection are identified, and solutions are established.
Collect relevant data	Partner with investigators with long-standing cohorts at institution to consult on developing questionnaires specific to patient population. Obtain data from electronic medical record when possible to reduce burden on patients. Engage governance committee to advise on updating data collection plans to account for changes in pertinent COVID-19–specific variables (e.g., vaccines, symptoms).
Startup costs and financial sustainability	Establish sample fee structure to offset operational and administrative costs. Engage hospital and private foundations for grant money for startup costs, allowing for reduced sample fees.