Optimizing The George Washington University COVID-19 Biorepository for Data and Specimen Collection for Research

Lauren Joyce, BS, MPH(c)[1], Alfateh Sidahmed, MD[2], Leyn Shakhtour, BS(c)[1], Nandan Srinivasa, BA, MD(c)[3], Bitana Saintilma, RN, BSN[2], John Dobbs, BA,MD(c)[3], Gavin Truong, MD,[3] Sanjana Rao, BS, MD(c)[3], Ruben Singh[3], Aileen Y. Chang, MD[4], MSPH, FACP, Hana Akselrod, MD, MPH,[4] Adrienne N. Poon, MD, MPH, FACP[4]

1.Milken Institute School of Public Health; 2. GW Medical Faculty Associates; 3. School of Medicine and Health Sciences; The George Washington University; 4. Department of

THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

Learning Objectives

- Describe the development of the GWU COVID-19 biorepository
- Create a profile of patients enrolled during the acute phase
- Explore the value of a COVID-19 biorepository in helping answer important epidemiological/scientific research questions
- Discuss lessons learned in establishing the GWU COVID-19 Biorepository

Background and Purpose

- First reported in December 2019, the novel coronavirus named (SARS-CoV-2), which causes the severe acute respiratory syndrome known as COVID-19, has spread rapidly across the world.
- SARS-CoV-2 RNA has been detected not only in the respiratory tract but also in blood, urine, and stool specimens.
- In the greater Washington, DC region (DMV), which includes parts of Maryland and Virginia and houses the nation's capital, there have been 1,057,944 cases and 19,417 deaths reported since March 5 and continues to grow.
- We have established a prospective longitudinal cohort study of patients diagnosed with COVID-19 at the George Washington University, in Washington, DC with plans for follow-up over the course of one year.

Goal of the biorepository:
- Collect both biospecimens and clinical data to promote scientific inquiry into the basic science, pathogenesis, and mechanisms of the virus causing COVID-19

Project Description

Participant Recruitment: Confirmed SARS-CoV-2 positive patients identified from chart review or physician referral are invited to participate through informed signed consent under an IRB approved protocol.

Figure 1: COVID-19 Specimen Collection Time Points

Acute Phase → 10 Weeks Post Acute → 6 Months Post Acute → 12 Months Post Acute

Specimen Collections:
- Nasopharyngeal or oropharyngeal swabs for RT-PCR
- Serological tests from adult patients: 30mL in acute phase and 50mL in post-acute phase including those with post-acute sequelae
- Urine studies
- Rectal, vaginal, and penile swabs are collected to detect mucosal shedding at follow-up time points

Clinical Data:
- Clinical interviews conducted by the research team
- Chart abstractions performed
- De-identified clinical data entered into a secure RedCap database

Results

92 COVID-19 PCR positive participants have been enrolled since April 2020 and enrollment and data collection are ongoing. Healthy controls are also being enrolled as a comparison group and 13 have been enrolled so far. An overview of patient enrollment according to follow-up time period is shown in Table 1. The enrollment, follow-up, and data entry process is shown in Figure 2.

Table 1. Number of COVID-19 Patients Enrolled at Various Timepoints

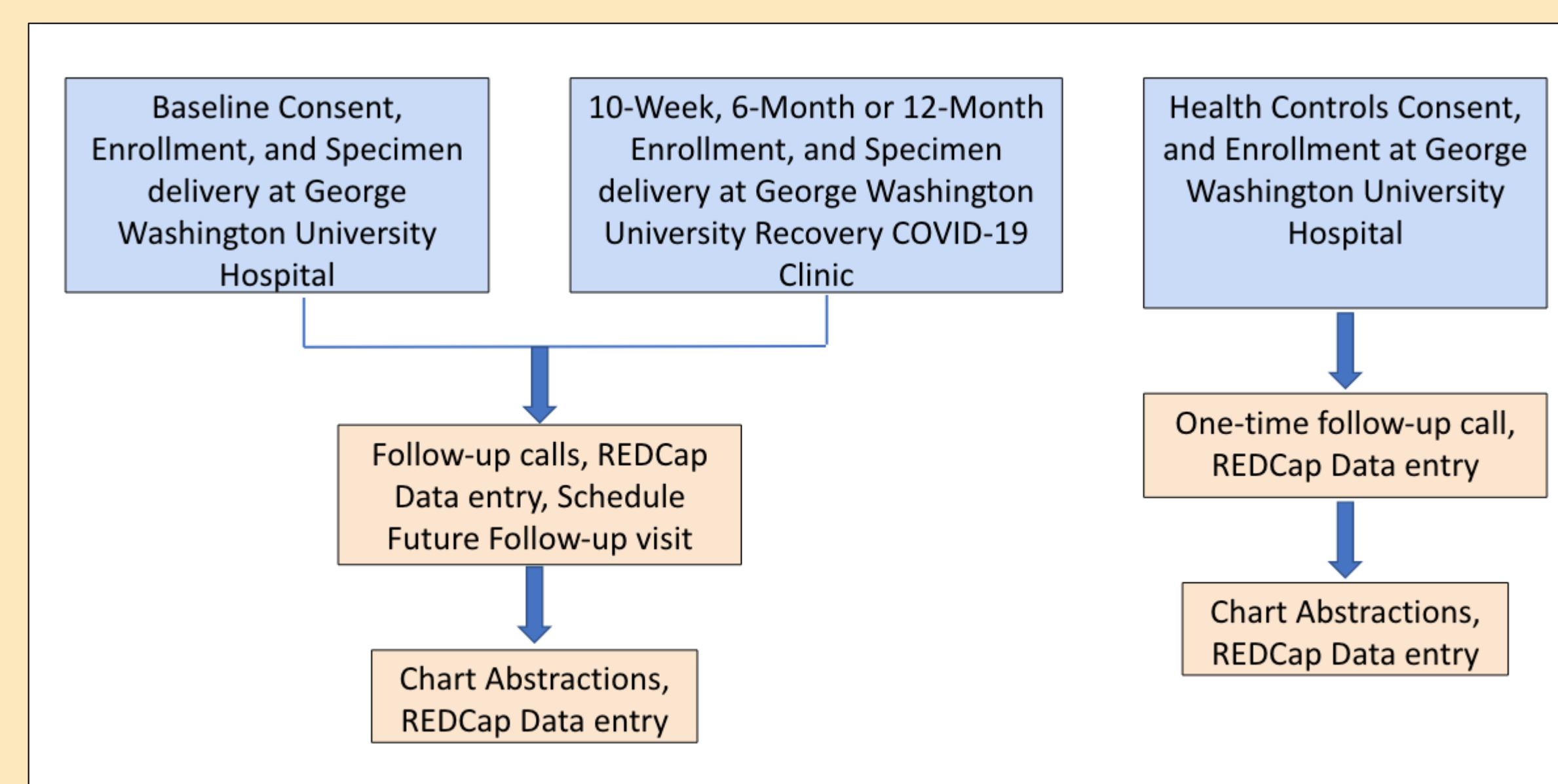|	Enrolled at Baseline (1-11 Days)	Enrolled at 10-weeks	Enrolled at 6-months	Enrolled at 12-months
Number of COVID-19 patients (N=92)	49 (53.3%)	19 (20.7%)	21 (22.8%)	3 (3.3%)

Figure 2. Process overview of Biobank enrollment and data entry

Given patient retention and data collection challenges exist, various approaches have been implemented to optimize data and specimen collection.

Retention strategies have included:
- Verification of multiple sources of contact information at baseline
- Utilization of Cisco Jabber app technology to contact enrolled patients
- The implementation of a COVID-19 biorepository email account to send scheduled reminder notifications to patients
- Reimbursement by providing patients gift cards at follow-up visits
- Scheduling future visits during baseline
- Bolstering data collection through data extraction from electronic medical records

Lessons Learned

- The creation and establishment of a COVID-19 biorepository will be a valuable resource for scientific investigators to study the pathogenesis and mechanisms of the SARS-CoV-2 virus in the acute phase and longitudinally in follow-up as well as in patients with post acute sequelae of COVID-19.
- Willingness of communities of color to participate in this study and support better understanding of COVID-19 is invaluable towards the study of health disparities facing this community.
- A strong participant education effort is important to coincide with this project, in particular, for how this contribution would support understanding of COVID-19, which has been a major motivational factor towards participation.
- It is important to engage participants as stakeholders in the research process and develop processes to feedback results of the study to the community.
- Study retention beyond acute enrollments has been a challenge, but instituting processes for improved communication including a variety of approaches from phone calls, messages, and e-mails, as well as incentives has helped improve retention.
- Teamwork has been critical for making this bio-repository a success and has included collaboration across clinical, enrollment, abstraction, and laboratory teams as well as scientific investigators.
- Establishing systems for coordination including through many team workers working virtually through the pandemic is important for a successful project. This includes establishing clear defined roles and virtual systems and databases that allow teams to work both on-site and remotely.

References

- Alcendor DJ. Racial Disparities-Associated COVID-19 Mortality among Minority Populations in the US. Journal of clinical medicine. 2020;9(8). Epub 2020/08/06. doi: 10.3390/jcm9082442. PubMed PMID: 32751633; PubMed Central PMCID: PMC7466083.
- CDC (2020). Cases in US. Accessed Mar 25.
- Tan et al (2020). Known coronavirus cases in DC, MD and VA. Washington Post. Accessed Mar 25.
- CDC (2020). Healthcare professionals: FAQs and answers. Accessed Mar 22.
- CDC (2020). Interim guidelines for collecting, handling, and testing clinical specimens from persons for coronavirus disease 2019 (COVID-19). Accessed Mar 19.
- Henry, B. M., de Oliveira, M. H. S., Benoit, S., Plebani, M., & Lippi, G. (2020). Hematologic, biochemical and immune biomarker abnormalities associated with severe illness and mortality in coronavirus disease 2019 (COVID-19): a meta-analysis. [Meta-Analysis Review]. Clin Chem Lab Med, 58(7), 1021-1028. doi: 10.1515/cclm-2020-0369
- Lazzerini M et al (2020). COVID-19 in Italy. Lancet Glob Health.
- NIH (2020). Clinical Spectrum of SARS-CoV-2 Infection. Accessed Mar 25.
- WHO (2020). Coronavirus disease (COVID-19) outbreak situation. Accessed Mar 25.