COVID-19 Working Group Meeting 7/10/2020

Any old business/ updates

- None

Re-visit R01 aims based on team expertise

- Dr. Dodani recapped that the group had some concern about making clear the differences between our proposed study and what the All of Us Study is doing on COVID.
- We want to consider how to best revise our aims and who can best contribute on which aspects.
- We reviewed the table of expertise that Sarah created based on the biosketches that were provided.
- Dr. Dodani emphasized that now there are more NIH-funded studies on health disparities.
- When considering what we can add, Keith suggested that the idea of county-level and neighborhood-level inequities seems very important.
- Amira stressed that we need to further define a target population. We need to have the existing infrastructure, which we are trying to build in the IRB application.
- Brian echoed the relevance of neighborhood and contextual factors. However, the challenge is to think about what neighborhood factors are of relevance to COVID specifically.
- Josh Sill emphasized that our aims may be best strengthened by starting with preliminary data collection first in order to best target the areas of need.
- HADSI do expect to receive clinical data from Sentara on COVID positive admitted patients within a weeksin order to have some preliminary data to strengthen our position.
- Generally, the feedback we have gotten from NIH is positive, but we do feel that we need to bring more innovation in.
- The group concluded that we should wait and get some pilot data to support where we want to go.
- Amira suggested for the Sentara patients as well as GMU free clinic patients, mapping their locations, assessing comorbidities, and looking at sociodemographic factors. This could be a great way to move forward with some preliminary data. From their MAP clinics they have found disproportionate rates of COVID-19 among the Hispanic population.
- Keith brought us back to the idea of focusing on COVID-positive patients and tracking their outcomes going forward. We could target COVID positive patients, and then get retrospective data from their electronic medical records but also looking at collecting prospective data.
- Amria referenced the national survey they did in April as a possible comparison group, or patients with *another* health condition in the EMR (such as flu or ICU patients in general). We want to be sure that we are looking at the effects of COVID specifically.
- The census pulse survey is putting out weekly mental health data that could be used as a benchmark: https://www.cdc.gov/nchs/covid19/pulse/mental-health.htm.
- We can also look at using historical controls, particularly for a pilot study.

Registry update- Address IRB Qs

Consent

- Please reconcile the benefits between key information sheet and main consent. We stated in the protocol that some incentives may be included in the future (reimbursement for participation tier system). The IRB would like clarification in the consent form exactly when this will be (if ever).
    - *Right now, the plan is to not give incentives. We can submit an amendment if we get funding.*
- Is it the intention of the investigators to notify the patients of the results and what might apply individually?
    - *No. We decided it would be best to avoid this extra component.*
- Did we make a final decision on if we would like to include additional mental health parameters? If so, we will need to establish mechanisms of contacting individuals separately.
    - *Vibrent may be able to provide guidance on these elements. One consideration is who would be handling any incoming calls and questions. Another would be how to respond to potential crisis situations. It may be best to remove any questions that would be so sensitive that they would need to invoke some kind of action or reporting. We could also include a basic resource list just to cover all that (include both mental health and COVID resources). Vibrent may already have some of this in place.*

Protocol

- Page 3/9 – Please provide all advertising materials including scripts for television and radio, posters, letters, etc and define where they will be posted. I submitted scripts for the emails and texts that will be distributed. Have any scripts previously been created for letters, facebook, etc. they we would like to submit at this time?
    - *For facebook, twitter, insagram, etc., we should create those scripts now. We could also submit an amendment later if needed.*
- Please provide letters of support from all partners. We will need a letter of support from GMU and Vibrent.

Action items

- HADSI will analyze Sentara COVID positive admitted patient data once available. If data results are available before July 18 meeting, Sarah and Josh will share the preliminary findings with the group, otherwise July 18th meeting will be canceled (Dr. Dodani is out on July 18th)
- Amira to get data from GMU clinics as well—we will come back to the data sharing plan.
- Josh with teams input will revise the IRB protocol and will resubmit after addressing their concerns.
- Working group collectively will review and discuss how to collect prospective data from COVID positive patients as well. Discussion topic for next meeting

We will plan to have the meeting next week if HADSI has received the Sentara data and have it cleaned up and have some basic analysis. Otherwise meeting will be canceled.