

COVID-19 Evidence Accelerator Collaborative Lab Meeting #2

Thursday, April 23, 2020, 3:00-4:00 pm ET

Call Summary

Update on Parallel Analysis Workstream Progress

- Approximately 25 organizations joined the first standing call of the parallel analysis workstream with the goal of building on previous data element discussions and working towards treatment patterns and outcomes of interest in the COVID-19 pandemic. Thus far this workstream has:
 - Constructed a set of variables and variable definitions by building on the core data elements initially identified by Accelerators
 - Developed an initial scoping document with a starting table of proposed outcome measures and analyses
- Participants in this workstream have been asked to rank the feasibility of collecting the proposed variables and provide comments on the proposed variable definitions, outcome measures, and analyses by Saturday, April 25.
- Important observations already made by members of this workstream include:
 - Differences across datasets will warrant creative, and possibly varied, approaches to conduct parallel analyses
 - COVID-19 efforts will be different in nature from many previous efforts such as the FOCR RWE Pilot Project due to rapidly changing understanding of the disease, uncertainty about which covariates are most important, and the ongoing development of datasets required to answer critical questions
- Those Accelerators interested in participating in the parallel analysis workstream should reach out to Carla (RUF) and/or Jeff (FOCR).

Introduction to Lab Meeting 2

"The COVID-19 Accelerator lab meetings provide a unique opportunity to hear about ongoing COVID-19 research efforts whose learnings can be both specifically incorporated into the parallel analysis workstream and broadly utilized to advance our knowledge of this emerging disease."

Lab Meeting Presentations

- 1. Presentation on the Hackensack Meridian *Health*, COTA, and Berry Consultants COVID-19 Observational Database Collaborative
- Currently, there are over 1800 patients hospitalized with COVID-19 in the Hackensack Meridian healthcare system.
- Although having a clinical trial infrastructure would be ideal, this collaborative was able to mobilize quickly and shift to garnering information from a unified electronic health record

system (EPIC) and to aligning with the CDC on what data elements should be captured in their database.

- These data elements seem to align closely with what has been proposed by the Accelerator parallel analysis workstream.
- Methods:
 - Patients were included in this database if they had a positive SARS-CoV-1 diagnosis by RT-PCR and were hospitalized within the time frame of March 1-April 8, 2020.
 - A convenience sample was abstracted from these SARS-CoV-2 positive patients. Hospital death with follow-up through April 8 was determined to be the primary endpoint.
 - This collaborative noted that analyses of real-world data sets must take into account that patients are not being randomized to a treatment, but rather given a treatment based on a physician's evaluation of their condition and a physician's individual treatment decision-making process. Researchers utilizing real-world data sets must be creative in their analytic approaches and recognize that different approaches may be required for different projects.
 - Multivariate analysis will be of little utility for the evaluation of the treatment effect when numerous variables are incorporated.
 - This collaborative built a risk model which incorporated individual variables in a stepwise fashion.
 - Model took into account risk factors such as gender, age, ICU admission, Ferritin level, Insulin use, and arrhythmia to calculate a risk score.
 - This collaborative found that when looking across their database as a whole, it appears that hydroxychloroquine (HCQ) may benefit patients, but this conclusion does not hold up when taking to account a patient's risk score. Upon further analysis, it became clear that HCQ was being preferentially prescribed to "less risky" patients and that when risk score is accounted for, HCQ provides no clinical benefit to COVID-19 patients in this dataset.
- 2. Presentation on the Epic Insight Initiative
- 3. Presentation on UnitedHealth Group COVID-19 Efforts

As results emerge and are ready for circulation, we will post updates to our Accelerator site: https://www.focr.org/covid19

Next COVID-19 Evidence Accelerator Lab Meeting:

3:00pm EDT Thursday April 30th