



COVID-19 Evidence Accelerator
Thursday, April 16, 2020, 3:00 – 4:30 pm ET

Call Summary

Background

Prior to the initiation of this call, 41 organizations were provided a list of draft core data elements and key questions to encourage additional feedback and characterization of key questions. Over 25 responses were collected through the course of three days and rapidly incorporated into a master document that reflects a comprehensive list of key questions across stakeholders and core data elements necessary to address them.

The responses provided to the initial core data elements and key questions have revealed several potential opportunities that could be implemented in different venues. In evaluating the feedback, the key question series below was identified as immediate and feasible and may be a prime candidate for multi-stakeholder collaboration:

How can real world data improve our initial understanding of safety and effectiveness of therapies used for COVID-19? In particular safety and effectiveness of hydroxychloroquine and chloroquine, with or without azithromycin (dosing, treatment patterns, patient selection, unique safety concerns)

This initial query indicated that several groups are exploring a variety of the identified key questions and signaled that they could be addressed in a rapid nature.

COVID-19 Evidence Accelerator Collaborative

This is a rapidly evolving space and one core objective of the COVID-19 Evidence Accelerator Collaborative is to provide a venue to share findings and strategize on what additional analyses should be addressed. To accomplish this objective, there will be two interactive workstreams:

1) Parallel Analysis: Develop a key research question that multiple organizations and teams can address simultaneously.

Initial activities of this workstream would include (1) rapidly revising a list of core data elements; (2) identifying those critical to answering the primary question; and (3) establishing uniform collection parameters. It will be necessary to work collaboratively to determine how data elements are being extracted and how they are being defined to operationalize a platform

that can answer questions now, but also inform how such activities could be conducted in the future.

Repeating analyses through different analytical techniques and data sources will help strengthen findings and learnings. Furthermore, this effort will help elucidate the role of RWE for rapidly learning patient characteristics, treatment patterns and management strategies for COVID-19.

2) Lab meetings: Share findings from interested data partners on critical questions

Results are coming out in many different ways and using different methods and data sources. Lab meetings will provide a venue to discuss data generated from quick turnaround queries and share results with experts from FDA, major data organizations, academic research institutions, professional societies, and health systems to help accelerate, and potentially even confirm, findings from different data sources and leverage existing expertise.

Lab Meeting Presentations

Precisely Practicing Medicine from 700 Trillion Points of University of California Health Data

Atul Butte, MD, PhD, University of California Health system

- The University of California Health system has been able to successfully extract data across six of the UC medical schools and systems (5 academic medical centers) for aggregation in a health data warehouse built using OMOP (UC San Diego Health, UCR Health, UCI Health, UCLA Health, UCSF Health, and UC Davis Health).
- Data collection, aggregation, and mapping efforts were rapidly adapted to include data elements of increased importance during the COVID-19 pandemic. The UC efforts demonstrate the complexity of the collection, aggregation, and mapping of data elements.
 - Ex. Within the UC system, there are 24 different ways for a COVID-19 viral test to be ordered, including sending the samples to external providers.
 - Ex. At UCSF, it takes 300 lines of code to determine whether or not a patient is on a ventilator.
- Thus far, UC data shows:
 - Approximately 20,000 patients in this population have been tested so far.
 - The doubling time of positive cases is shrinking, already beyond two weeks.
 - End stage renal disease is a preliminary strong predictor of which SARS-CoV-2 positive patients will be admitted to the hospital.

- The SARS-CoV-2 tested rates are slightly higher than expected among Asian and Black patients.

COVID-19 Testing, Hospital Admission, and Intensive Care Among 2,026,227 Veterans Aged 54-75 Years

Amy Justice, MD, VA Connecticut Healthcare System; Yale School of Medicine

- The US Department of Veterans Affairs has used EHR data systems to create specific cohorts that have been previously characterized. This previous characterization has allowed them to move quickly to link these cohorts to COVID-19 testing.
- Using a previously defined cohort, the VA has observed these associations:
 - Black veterans are substantially more likely to be tested for COVID-19 and to test positive for COVID-19.
 - Black veterans are slightly more likely to go to the ICU and be intubated as well as have higher death rates.
- The VA has tested 29,000 people and over 4,00 people have tested positive.
- The VA has been providing daily updates on observed treatment patterns to inform the FDA of risks in surges in product demand and risks of shortages of therapies due to COVID-19 prescribing practices.

OHDSI COVID-19 Study-A-Thon and Evaluation of Safety of Hydroxychloroquine in RA Patients

Patrick Ryan, PhD, Janssen Research and Development; Columbia University Irving Medical Center

Link to YouTube presentation: <https://youtu.be/m7mGWmZpnoE>

- OHDSI, a global open science community, has created a network comprising 152 databases in 18 countries and covering approximately 600M patient records
- OHDSI held a virtual COVID-19 study-a-thon for researchers to collaborate on the use of observational data to answer important questions.
 - OHDSI reached out to public health organizations to get a better understanding of the priority research questions needing to be answered. These were classified into three categories: characterization, prediction, and estimation.

- In three days, tremendous progress was made on all identified research questions across the research paradigm (Literature review and protocol development, Phenotype development and evaluation, Study package development, Study execution across network, Clinical review and dissemination). This effort led to:
 - The first large-scale characterization of COVID-19 patients in US and Asia
 - The first prediction model externally validated on COVID-19 patients to support triage to ‘flatten the curve’
 - The largest study ever on the safety of hydroxychloroquine using historical data aggregated across 14 partners. This study observed:
 - HCQ appears safe in short-term use for rheumatoid arthritis, but long-term use may be associated with increased cardiovascular mortality.
 - HCQ + azithromycin increases 30-day risk of heart failure and cardiovascular mortality

Discussion

- Common theme across each presentation involved mapping data to a common data model to allow work to go faster
- Strategy is to be able to distribute brief summary of presentations as way to enable regular communications and generate additional hypotheses
- A lot of data may exist that has not been designed for research. Prioritizing data elements will help inform hospitals of critical data to collect

Next Steps

- This will be a regularly occurring call on Thursdays from 3-4pm EDT
- Please let us know if there is interest in the idea of conducting parallel analyses and/or have refinements to the key question
- We will explore logistics of sharing information from these meetings and implementing processes for presenting data during the lab meeting