



COVID-19 Evidence Accelerator Collaborative

Thursday, June 18, 2020, 12:00-1:00 pm ET

4th Diagnostic Accelerator Call Summary

There were 4 presentations given at the 4th Diagnostic Accelerator meeting. Those presentations are as followed:

1. Real-World Performance of Diagnostics and Outcomes: Connecting the Pipes (FDA)
2. Solutions to Common Challenges with RWD and IVDs (FDA/CDRH)
3. Aggregating Real World Data Sources using a Patient Centered Data Sharing Platform (Yale/ Mayo Clinic)
4. Data Sharing and Informatics (LabCorp and Quest Diagnostics)

Real-World Performance of Diagnostics and Outcomes: Connecting the Pipes (FDA)

One of the goals of the Diagnostic Evidence Accelerator is to develop linkages within the research community and provide additional resources to achieve the outcomes that are needed to answer questions that the community has in regard to COVID-19 test performance. The framework for diagnostics tests consists of 4 aspects in order to understand real world performance. First, the test needs to be interrelated with the outcome. Second, consideration of data points such as the test manufacturer, test type, test collection date, test return date, and test results are important. Third, additional data points such as information about individual patient, prior exposure, and population data are needed to better understand real world performance of tests. Finally, knowing the type of data (e.g. passive, prospective, EHR, and lab) collected is an important consideration in test performance. An important question to consider is how is the data that we are collecting is going to come together to answer the questions that the research community has about COVID-19 when linking the resources that we have so far.

Common RWD Challenges and Opportunities for IVDs (FDA/CDRH)

The FDA and CDRH believes that there is a need to increase data quality so RWE can be understood and be reliable to be useful in answering questions. There is an infrastructure that has been set up for the real-world space across FDA. The main goal of it is to find “fit for purpose” information where the data is complete, consistent, accurate, and contains all of the critical data elements that are needed to evaluate a medical device and its claims. This will allow the FDA to conduct a benefit and risk analysis in regard to the healthcare. The FDA/CDRH has developed a guide for the community to better understand the challenges and solutions that the research community has so they can help other researchers develop better study protocols.

Aggregating Real World Data Sources using a Patient Centered Data Sharing Platform (Yale/ Mayo Clinic)

The Yale-Mayo Clinic Center of Excellence in Regulatory Science and Innovation (CERSI) is a joint effort between Yale University, Mayo Clinic and the FDA to conduct research to address gaps in knowledge and develop tools to support regulatory decision making and the overall mission of the FDA. The pilot study that they worked on tested the feasibility of using a patient centered health platform named Hugo Health to aggregate information across electronic health sources. Through the Hugo platform, the researchers were able to evaluate the patients that underwent the procedures and see post op activities such as weight loss, daily steps, and daily heart rates. The platform links patient reported outcome measures (PROMs), pharmacy data, electronic health record data, and personal digital device data. There were 60 patients enrolled on the platform with 15 patients per procedure (bariatric surgery and catheter-based atrial fibrillation ablation) per site (Yale and Mayo Clinic). There were 59 patients that underwent the procedures and completed an 8 week follow up. The enrollment procedure consisted of signing the patient up for the Hugo platform, linking the patients EHR, pharmacy record and the Fitbit and additional personal digital device that was given to the patient at the start of the study.

Yale and Mayo Clinic received health record for 100% of the enrolled patients. 55% of patients had primary care visits based at Yale or Mayo Clinic which uploaded into the platform. 10 patients linked 13 additional portals from other health systems. 40% of patients connected CVS or Walgreens pharmacy accounts with their medication information. Walmart pharmacy is now available to link too. The data passively aggregated into the Hugo platform after the initial enrollment allowing for a real time streaming of data. They were able to see different data points such as the daily steps that a patient takes and weight loss. They conducted surveys that asked post procedure questions and disease specific questions through the platform and the research team was able to get many individuals to answer those questions. To read more about this study, please visit <https://www.nature.com/articles/s41746-020-0265-z>.

Recently, they proposed a study to develop real-world data source characterizing the experience of minority and other vulnerable patients diagnosed with COVID-19 to better understand disease progression and symptom burden. They are prospectively enrolling 600 patients who are undergoing testing for SARS-CoV-2 at CVS health testing sites in New Haven, CT and Atlanta, GA. These patients will be enrolled in Hugo for PROM surveys and there will be a 180 day follow up period.

Data Sharing and Informatics (LabCorp and Quest Diagnostics)

LabCorp acquired Covance which performs clinical trials for pharmaceutical and biotech companies presenting LabCorp with additional data sets that they can use. They believe that there is a linkage between diagnostic testing and drug therapy. LabCorp is conducting both the PCR test and the serology test. LabCorp prints the name of the test manufacturer responsible for PCR test on the receipt allowing for researchers to gather additional data points for research. Currently, LabCorp is running over 90 studies for drugs and vaccine development.

Quest Diagnostics is gathering data on serology tests conducted along with the PCR test. They saw that there were 93% of patients that were positive for COVID-19 after a positive NAAT test. Also, there were more males testing positive compared to females and the age range that was positive was mainly adults 35-74 years old. There was a discussion of a previous study that examined trends in laboratory detection of Rotavirus among vaccinated and unvaccinated children. This study could be the basis of studies conducted when a vaccine for COVID-19 is approved. Quest Diagnostics has the ability to match other datasets with its own data sets as seen in their study looking at HCV antibody positivity rates.

Discussion:

The key takeaways from the discussion were

- The need to ask critical questions about how testing is done.
- The need for reliable data.
- The need to map the data to ensure that what data collected is the actual data needed for the study.
- The need to leverage tools that are given and integrate and link those tools to better understand COVID-19.

Next steps:

- Contribute ideas and data sets to develop a parallel analysis meeting.
- Work together to better understand the impact of COVID-19

From the Chat Box:

- It would still be good to have access to the molecular test developed in Germany for WHO, so we could perform “compared to what” analyses.
- We see a lot of data loss when results go from the lab to the EHR. Would be great if we could create a patient-centric view in which we could link shared patients. We'd love to partner on this
- It would be helpful if timing between RT-PCR and Serology tests could be provided - certainly we know there is a relationship vis a vis timing of infection - can that be captured with RWE
- So to put out a provocative data integration concept: Can I Hugo my Sentinel CDM claims data with my PCORnet CDM EHR data (curated with high quality QA packages) with my CVS minute clinic tests (in EPIC) and my out of PCORnet network EHR ED visits and all of my Cerner and/or athena EHR records?
- On patient-centric platforms, like HUGO:
 - No, we didn't see differences in ease of data standardization (across familiar vs. unfamiliar data sources) because the data are aggregated through patients, integrating their personal electronic health data made available via their MyChart, no institutional permissions are needed. Please feel free to email me directly with questions: joseph.ross@yale.edu.

If you have thoughts on any of these issues, please email them to Amar Bhat (abhat@reaganudall.org) and we will be sure to share on a slide at the next DX Evidence Accelerator Meeting.

Next meeting: June 25, 2020 12- 1 PM ET