COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #8

Thursday*, July 23, 2020, 12:00-1:00PM ET*

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting 8

The Diagnostics Evidence Accelerator is part of the RWD community designed to answer critical questions surrounding COVID-19. This community is focusing on the issue of connecting data pipes by collecting manufacturer data, laboratory data, and clinical data so that we can understand the real world performance of diagnostic tests and answer population based COVID-19 questions.

This week's Diagnostics Evidence Accelerator meeting consisted of 4 presentations.

1. Updates on Connecting the Pipes (Amy Abernethy, FDA; Gina Valo, FDA/OC; Susan Winckler, Reagan-Udall Foundation)
2. A Window into the California COVID-19 Testing Experience (Bob Kocher, Member of California Testing Task Force, Non-Resident Senior Fellow at USC Schaeffer Center, and Partner at Venrock.)
3. Health Information Exchanges- CRISP (David Horrocks, President of Chesapeake Regional Information System for our Patients)
4. Health Information Exchange- Regenstrief Institute (Chris Frederick, Director of Strategic Partnerships, Regenstrief Institute)

Update on Connecting the Pipes (Amy Abernethy, FDA; Gina Valo, FDA/OC; Susan Winckler, Reagan-Udall Foundation)

For Project One, this workgroup will be taking a cohort of positive molecular test results that have a subsequent serology test and using that data to look at clinical and demographic data. Along with this data, this workgroup will be able to evaluate how test sensitivity varies by different demographic and clinical factors and how the timing of a positive serology result varies.

Gina Valo discussed the efforts that are taking place at the FDA for tackling Project One. She states that some of the data produced by the instruments flows back to the manufacturer for their use and some of the data flows into the Laboratory Information System (LIS). From the LIS, the data flows into the EHR as results for the clinicians. Test manufacturer information such as the test ran for the patient is lost as the data goes into the EHR.

For the projects that the FDA is working on, they have 4 large health systems and 3 data aggregators. They are looking at 3 questions with the 7 groups that are involved. The requirements they are assessing

are 1) do the groups have lab results, 2) do the groups have device manufacturer data, and 3) are these two data elements connected at the patient level. All of the groups have lab results but there are only a few that have device manufacturer data. Currently one group, Data Aggregator A, has been able to connect the data elements, which is promising.

A Window into the California COVID-19 Testing Experience (Bob Kocher, Member of California Testing Task Force, Non-Resident Senior Fellow at USC Schaeffer Center, and Partner at Venrock.)

California is having challenges in accessing sample collection, acquiring testing supplies, reducing testing cost, having poor visibility into future supply and demand, and having a high risk of system failure as testing demands grow. California launched a public and private partnership to develop and implement a state testing strategy with the goal of rapidly scaling up testing supply and ensuring that all Californians have access to testing. California scaled up testing from 2,000 to 125,000 tests per day, opened more than 120 state operated sample collections sites, expanded sample collection to pharmacists, procured 22 million sample collection kits and 250,000 PCR kits, and integrated testing with contact tracing.

The state of California faced many challenges along the way. Their reporting system, CalRedie, was not very extensible to accept the high volume of COVID-19 testing data or to add new data fields. A great deal of lab data had to be manually collected and lots of data exist in non-integrated data set. So far, California has conducted approximately 6.6 million tests. The positivity rate increased as the number of positive cases increased indicating accelerating community transmission.

Their approach to improve testing was to figure out where testing facilities were located, and which tests the labs were running. They called every lab in the state to determine testing capacity in each lab. They created new testing guidelines since the CDC guidelines did not account for asymptomatic testing. Then, they set up a statewide network of collection sites targeting the undeserved population. They secured sufficient supplies for sample collection. They expanded capacity for PCR tests processing by creating new state labs. They are identifying and scaling new tests for future use. They rebuilt their reporting and data capture system to track results. Finally, they will communicate aggregated results to the public.

There were many lessons learned by the State of California. They learned that they did not need to develop new labs since the preestablished labs had the capacity of running 400,000 PCR tests per day. The issue that they had was collecting sample data because many samples were taken in facilities that were not connected with the state system. Also, they had more than half of the data come in via fax, but the data that was coming in from big lab companies and state run labs was flowing directly into the state system. Their in-state labs had no backlog, but the large national lab companies have had frequent backlogs. Despite backlogs, they have not been successful at rerouting samples. They also believe that pooling will be crucial as testing demand, particularly from employers, grows. Finally, they learned that sequencing is very helpful for contact tracing and tailoring county level public health NPIs.

The current challenge California is facing is that almost all of the sample collection sites and labs are at risk of lacking supplies since manufacturing of supplies is not keeping up with demand growth. California only receives a fraction of PCR kits that they request because of demand across the country. Also, the areas with COVID-19 outbreak did not correlated with testing access – which is why he majority of the state funded sample collection sites are in these areas.

The data that that the State receives is the total number of tests, positive tests, and which lab the test was conducted at. For positive tests, they get patient contact information. They only receive demographic and symptom information on the patients that had sample collected at a state funded facility. They receive machine utilization information directly from the manufacturers, but they do not know which machine ran which test for a patient. They have data on supplies being requested so they are aware of where there is a supply shortage. They only get sequencing data from UCSF but not from other facilities. Some of the data that they wish they had were sample collection locations and the time the sample was collected, lab turnaround time, Point of Care machine data, antigen and serology test reporting, next gen sequencing test reporting, population health symptoms and geolocation that are connectable to testing data, manufacturer supply forecast, and data on test performance.

There was a discussion on lab turnaround time. The lab measures turnaround time from the moment that they receive the test, not from when the sample was collected so patients experience turnaround times that are longer than labs report. Bob Kocher's view is that the intensity of the crisis makes it unlikely that investments in new IT systems and connectivity will be prioritized. As a result, he expects faxing and PDFs to remain in widespread use.

Health Information Exchanges- CRISP (David Horrocks, President of Chesapeake Regional Information System for Our Patients)

CRISP is an HIE serving Maryland, West Virginia, and D.C. via affiliation. David Horrocks focused on Maryland's public health efforts for this presentation. The services that CRISP conducts is point of care, care coordination, population health, public health support, and program administration. HIE is needed to link data between organizations for a single patient. CRISP is able to deliver information to public health officials, clinicians, government, and care managers. They are developing a research file that can be used for the efforts of this workgroup. They are combining data from labs with reportable conditions which creates a data set that can be provided to the State Health Department. They are linking that with clinical data, claims data, and survey data from hospitals. They are able to calculate data such as length of stay and connect it to a single patient. CRISP are collecting data on the volume of lab results by specimen collection date. They collect this data at a county and ZIP Code level. They are not receiving data on test manufacturer; however, they are receiving data on where the test was conducted and at what time the test was conducted. They are receiving serology test results. They are able to combine data sets within minutes by using data from claims and clinics to view a complete picture of a patient.

Health Information Exchange- Regenstrief Institute (Chris Frederick, Director of Strategic Partnerships, Regenstrief Institute)

The overall goal is to improve data interoperability and exchange to support COVID-19 containment. Also, the Regenstrief Institute wants to do better disease surveillance, laboratory testing collection, public health reporting, and clinical data collection. Through their goals, they will identify infection clusters and localize hotspots, alert providers to patient's test results, and coordinate patient care from the start of testing. Chris Frederick believes that there is a way to connect the pipes that will enhance existing infrastructure. Strategic Health Information Exchange Collaborative (SHIEC) is a collaboration of various HIEs around the country. Some HIEs that are part of SHIEC are Arizona's HIE, Health Current, which sends real time alerts on test results, Reliance eHealth Collaborative COVID-19 Response which focuses on enhancing data reporting and analytics, NEHII launched COVID-19 Alerts and Reporting Program, and San Diego Health Connect helps EMS providers face COVID-19. It was stated that it is

important that all the HIEs should be able to talk to one another. SHIEC started an initiative called Patient Centered Data Home that is able to aggregate patient data through patient ZIP Codes.

Indiana is the home to the nation's largest inter-organizational clinical data repository. They had used LOINC to bring the data together to become the largest repository. The Indiana Health Information Exchange (IHIE) is a collaboration between many entities in Indiana. IHIE consists of a notifiable condition detector, visual data dashboard, population level surveillance reports, and results delivery communication to hospitals. The State of Indiana refers individuals to the institute when they want to understand the clinical linkage of the test. The Regenstrief Institute has a dashboard that shows hospitalizations, emergency visits, ICU admits, recovery, and hospital mortality. The aim of this dashboard is to provide a complete picture of the pandemic in Indiana and assist lawmakers to make evidence based decisions for the state. The link to the dashboard is https://www.regenstrief.org/covid-dashboard/.

It is important to match patient records. With a legislation that is in Congress for allowing the use of patient identifiers, a unique patient identifier will be key to seeing a complete picture on a patient. The next steps for the institute will be to continue improving their COVID-19 research cohort, addressing gaps in the data coverage, expanding their dashboard, utilizing NLP to extract unstructured clinical test features, and providing data access beyond their partner organization. Regenstrief Institute is willing to participate in Project One.

From the Chat Box

- The question of why health systems send lab reports via PDFs was raised when they have great lab information systems. Also, it was asked if there are systems that send lab data electronically to the state.
- A reminder that we as an Evidence Accelerator community have important work to do. We should think about what is possible now and then contemplate how we can solve subsequent problems in the future.
- The key idea of reporting value was raised. The description of infrequent and incomplete reporting from labs speaks to a larger problem of public health reporting. The role of public health in outbreak investigation is not often valued. There is absolutely a role - as we see here. If reporting compliance was high, State Health Departments could be a repository for integrated lab and demographic data.
- Callers agreed that it is an assumption that all PCR test are operating the same. We don't know what bias is injected into the positivity rates if a test does not perform the same and we make future decisions based on that data.
- There is a limit of detecting information on most PCR tests. A low positive result may be a result of either low viral load or poor sampling which complicates interpretations.

Next Steps:

- Develop a list of researchers that are interested in participating in Project One. If researchers are interested, they can contact Amar Bhat at abhat@reaganudall.org.
- Continue making the data connection for the next meeting.

Next Meeting: Thursday July 30th, 2020 12-1 pm ET