COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #11

Thursday, August 13, 2020, 12:00-1:00 PM ET

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting 11

One of the purposes of this work group is to collaborate on capturing data and using those data to bring EUA to full market authorization by the FDA. Along with collaborating, with the efforts of this work groups, understanding the lessons learned and questions is crucial to combat COVID-19 and future pandemics.

This week's Diagnostics Evidence Accelerator meeting consisted of 3 presentations.

1. Clinical Dx COVID RWE Update (Sue Dahlquist, MDIC Working Group /ThermoFisher Scientific)
2. HHS Reporting and Device Identifier Challenges (David Liebovitz, Northwestern Medicine)
3. Chicago Department of Public Health Data Hub (Bala Hota, Rush University Medical Center)

Clinical Dx COVID RWE Update (Sue Dahlquist, MDIC Working Group /ThermoFisher Scientific)

MDIC is a nonprofit organization that brings together governmental agencies, nonprofits, industries, patient organizations, and integrated health care networks with the objective of advancing regulatory science of medical devices for patient benefits. Their project goal is to have a health care network with well-developed and integrated data systems that are able to generate RWD accepted by the FDA for regulatory submission. They want to gather RWD to bring COVID-19 IVD EUAs to full market authorization for both PCR and serology assays. They are leveraging the work that Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) is doing to improve the semantic interoperability of laboratory data within institutions to better support clinical decision. The primary stakeholders that are involved in this process are federal agencies, *in vitro* diagnostic (IVD) manufacturers, and healthcare networks with well-developed and integrated data systems.

The process that MDIC is taking to approach this project is to develop two bootcamps and integrate them. The two bootcamps are the IVD bootcamp and the SHIELD bootcamp. The IVD bootcamp involves industry and FDA which are gathering data on the PCR and serology assays. To do this, they will connect questions to common data elements and figure out what the data gaps are and how they are able to close those gaps. They are ensuring that they are following all of the HHS laboratory reporting guidelines. The SHIELD bootcamp will have subject matter experts (SME) and will have data from healthcare partners. This boot camp will discuss the coding and the technology that will be required to collect the data elements and answer questions. Once the 2 bootcamps have completed their tasks,

they will merge into a classroom integration where MDIC can look at all of the data collected and apply what they have learned. They are currently in the planning phase of their efforts.

Their overall goal is to have the opportunity to educate on practical RWE use. From their small group learning, they are going to capture the learnings through high quality video productions and disseminate for a broad global use. They have many project deliverables throughout their efforts. For their IVD bootcamp their deliverables are to educate on MDIC IVD RWE Framework, educate on HHS COVID-19 Lab Data Reporting, have questions for EUA PCR and Serology RWE Clinical Study, and MDICx including Q & A from SMEs. For the SHIELD bootcamp, the deliverables are to educate on practical application of SHIELD for healthcare systems and MDICx including Q & A with SMEs. For the COVID RWE Classroom, they will take the learnings of the bootcamps and inform stakeholders. Finally, they will develop a resource library for future education. The potential question areas that they are looking at are common data fields/elements, study end points, data quality, cybersecurity, privacy concerns, and questions we do not yet know to ask, which provides an opportunity to collaborate with MDIC.

HHS Reporting and Device Identifier Challenges (David Liebovitz, Northwestern Medicine)

Northwestern Medicine has 11 hospitals, 4,500+ clinical trials and studies, and serve 1,200,000 patients annually. There are 7 different agencies/organizations that request data in 14 ways with varying frequencies from Northwestern Medicine Hospitals. The data request are clinical details and information about projected capacity. The definition of data elements are inconsistent across reports and changing over time for the various reports. The additional reporting process mandated by Chicago Department of Health does not replace other reporting mandate which presents challenges in reporting data. However, the reporting mandates are a great way to bring the data into one system where it can be analyzed. It was stated that ideally, the collection of data should have been taking place pre-COVID-19 and the efforts to collect all of the necessary data should not be taking place during a pandemic, so there is a lot of potential changes that can take place which is a lesson learned from this pandemic.

Northwestern Medicine is submitting all of the required elements that they are able to send through Electronic Lab Reporting (ELR). Data that are not sent through the interface are manually entered on the portal for each patient. To reduce this, they are working to add a data field for non-existing or variably defined items that are in different places in the chart. Patients are also able to complete a public health survey on their patient portal and the data from the surveys will be collected and entered. Also, the addition of robotic process automation to retrieve data from the EMR and upload it onto the HHS portal will reduce the manual abstraction that is currently required. Northwestern Medicine has 3 Laboratory Information Systems (LIS) across the 11 hospitals. They are actively consolidating the EMR enterprise to Epic Beaker by Summer 2021. They are using the HL7 result interface for the Illinois Department of Health COVID-19 reporting.

Northwestern Medicine has faced many challenges. With their LIS vendors, 2 of the 3 LIS vendors are not prepared to manage device identification. With the instruments used, the challenges were that some instruments lack the capability to embed device ID in result messages, only some include identifier, some do not capture Device Identification data in LIS, and some require significant internal and vendor resources for analyzers and LIS. They face challenges with the middleware layer that have multiple instances of data innovations instrument managers, but they are consolidating to one instance. There are multiple instances of Beckman Remisol, but they are working to reduce the number of instances. They have multiple POC middleware platforms and are working on consolidate them. They are following the HHS guideline to address Device ID and mapping LOINC codes in OCX-17. Information

is always changing as the situation evolves. As new instruments are added, there will be new information and updates that will take place. Dr. David Liebovitz concluded by making the point that having a vision in mind of what needs to be accomplished will help the individuals that are working in the laboratory systems, analytics and researcher know that they are converging on a specific deliverable. Also, he recommended having a national registry for vaccines that could show which patients had serologic test, which patients have antibodies, and which patients are eligible for vaccines.

Chicago Department of Public Health Data Hub (Bala Hota, Rush University Medical Center)

There are two major problems that we as an informatics community need to tackle. One is that there is work that needs to be done at facilities to capture all of the data points for reporting. The second problem is that there needs to be optimization of data so that the systems that need data can receive the data in an efficient way. Rush University Medical Center and Chicago Department of Public Health (CDPH) recognized their data limitations early in the pandemic which helped them greatly. The limitations and data gaps that they saw were race/ethnicity, hospitalization data, underlying conditions were not in the electronic feed, and length of hospital stay. They report 78% of data through ELR submissions but there are very limited data fields and only 22% with provider reports. Not all testing sites were connected to an ELR and the critical data elements to conduct investigations were not being captured in a timely manner. Rush University Medical Center is reporting to 4 different agencies causing administrative burden to add up.

The goals of CDPH COVID Data Hub is to have a complete data set for all COVID tested patients in Chicago, have essential data elements captured when labs are submitting data, capture of bed capacity data to monitor utilization trends across city, have a data dashboard of cases and bed capacity, capture consumer apps data from COVID patients, serve as a mechanism to streamline capture of necessary data from health systems for dissemination to other entities (Federal/state level), and develop a mechanism to capture and utilize other key data sets. CDPH released orders that mandated the reporting of key data elements to the health department by the hospitals. The data sets that need to be reported on are data on lab testing and results (INEDSS records), CCDs as minimal data necessary, NHSN data, and EHR data for anyone tested. Rush University Medical Center partnered with multiple stakeholders to develop the data hub. The data come in from 5 different sources and are pushed into the CDPH Data Hub (MS Azure) where stakeholders are able to access it and use it for regulatory science. This information has allowed them to realize that there should be a development of a clinical registry where there can be an input and output of different data elements.

They have 88,906 CCDA data records and 408,741 ELR data records. LOINC codes are not present in the CCDA data. They are doing a bivariate analysis on the data that they have collected and identified challenges. They are able to analyze test results by month, race/ethnicity, race/ethnicity by age, and the race/ethnicity by test week. The challenges that they faced were to figure out which data elements are standard, using standard vocabulary, standard use of measurements, addition of new data elements, scalability, and the federal reporting changes. There are opportunities that they were able to see during their efforts. They developed a public health home rule, centralized infrastructure and governance.

Discussion

- The discussion was focused on the concept of unique Device Identifier. Researchers and data collectors can utilize TradeName_ManufacturerName, which is a reasonable surrogate until HHS can develop a method for collecting Device Identifier.

From the Chat Box

- MDIC will provide opportunities for the public to attend the classroom integration meetings once both of their bootcamps have finished their research.
- If researchers are interested in participating in MDICs' bootcamps, they can reach out to Carolyn Hiller the MDIC Clinical Dx Program Director at chiller@mdic.org.
- A caller was interested in knowing if the systems being developed at Northwestern could be exported to less well-resourced settings. It would be nice if they did not have to be developed in parallel by other health systems, hospitals, etc.
- The question of how Northwestern Medicine is integrating lab data from across health systems (Walgreens, CVS, UofC, UIC, etc.), was asked. Also, if they are using Epic, are they able to pull in data on patients from other Epic health systems?
    - Answer: Yes - Epic has a tool, CareEverywhere, through which results are available. Where information from Epic sites is available, not only are they "viewable" but we have mapped to COVID-19 flags and decision support for actionability, too. This required additional build work and was not automatic. They also participate in CareQuality, however, many sites' content is neither available via Epic nor CareQuality and not amenable to this approach. Hence the suggestion for a national registry that can piggyback on existing state based, already embedded in EHRs, immunization registries so ALL results would be available to patients' personal physicians and care teams no matter where patients seek care.
- There was a clarification given on device identifiers: In lieu of a formal Device Identifier (DI), 'Test Kit Name_Manufacturer' can be used as a surrogate DI, as denoted in the HHS IG Specifications and within the LIVD file published by CDC. Could people who conduct testing use a package insert with a name of the test? If so, that would be a great step in the right direction.
- Clarification was asked on the difference between device ID and test kit manufacturer. A caller responded stating that if the test doesn't have an FDA-assigned unique device identifier (UDI), using the manufacturer and kit can serve as a surrogate for a device ID.
- A caller brought up that the Medical Device Epidemiology Network (MDEpiNet) public-private partnership has been working on building Coordinated Registry Networks around devices and on implementation of UDI. A major UDI implementation effort was undertaken by AHRMM [Association for Health Care Resource & Materials Management]. There are existing programs that can help move device identification along.
- The idea of encouraging state-based registries would make sense since we already have them for immunization, and PDMP [prescription drug monitoring program] was suggested. It would be technically simple to piggyback PCR/serology results on top of existing immunization registries. Agree "national" too ambitious - but State registries already exist yet this isn't been done yet! Let's build momentum for this idea! Then... as vaccines arise, patients could show up anywhere and their results would be available to determine the best vaccine based on their prior results.

Next Steps

- If researchers are interested in participating in Project One, they can contact Amar Bhat.
- Continue making the data connection and learn about test performance for the next meeting.

Next Meeting: Thursday August 20th, 2020 12-1 pm ET