COVID-19 Evidence Accelerator Collaborative
Diagnostics Evidence Accelerator #39
Thursday, November 4, 2021, 12-1 PM ET

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting #39

This week’s Diagnostics Evidence Accelerator meeting consisted of 2 presentation:

1. COVID-19 Testing Strategy Update (Morgan Ripski, NOLA Public Schools)
2. An Interoperability Discussion (Ken Mandl, Harvard Medical School, Ryan Argentieri, HHS ONC, Brett Marquard, Argonaut, Josh Mandel, Microsoft, and Bala Hota, Rush)

As always, thank you to all of the analytic partners, strategic advisors, and scientific advisors that are participating in Project One of Diagnostics Evidence Accelerator.

COVID-19 Testing Strategy Update (Morgan Ripski, NOLA Public Schools)

This presentation discussed the testing strategy that was administered in New Orleans Public Schools (NOLA-PS). The school district consists of 45,000 students and 99 schools. The students are primarily economically disadvantaged and students of color. This understanding and the understanding of how COVID-19 impacted different communities were the primary driving forces behind their problem-solving approach.

Their testing strategy consisted for two tracks: acute responsive testing and routine screening testing. Acute responsive testing was designed for symptomatic and quarantined individuals. With the onset of COVID-19, NOLA Public Schools have adhered closely to the Louisiana State and State Public Health Department guidelines. Since the onset of the Delta variant, the guidelines state that an exposed individual should receive a PCR test immediately and then follow up PCR tests five to seven days later. They have partnered with hospitals, urgent cares, on-call mobile units, and Louisiana Department of Health in order to provide testing to families.

For routine screening testing, the Department of Health secured federal funding in order to provide COVID-19 testing to the community. The Department of Health contracted with a local lab company to conduct weekly testing in schools. The tests that are used for screening are PCR tests with a turn around time for results of 24 hours. The results are shared with parents and schools which significantly helped to reduce quarantine time. Routine screening testing is opt- in, but the school district is seeing 30% of the community participating in testing. In order to encourage testing, the Health Department has incentivized testing by offering individuals that get tested $25 for the first test and $10 for any
subsequent test taken. With the increase in cases due to the Delta variant and Hurricane Ida, the school district saw an increase in participation in testing.

A critical step in ensuring that they were able to provide testing to a greater number of people was having a local lab conduct testing. Additionally, it was beneficial to have an electronic system for reporting and integration. There are areas for improvement for the integration of data. There are student specific fields that are missing from the system. The only data that is collected about the student is their name and test result. This forces schools to report the results twice due to the state department asking for additional information about the student. Additionally, the database does not integrate the vaccine information. Another area for improvement is the implementation of the program such as providing the incentive in a timely manner to students and families. Finally, participation varies by schools, therefore seeing similar participation is an area for improvement.

The next wave of work that NOLA Public Schools will focus on is to use the data that they have and analyze it to make decisions going forward. They are currently collecting vaccination data and schools are able to obtain the data through LINKS to report to the district. The school system is hoping to align on incentives to encourage schools to collect more vaccination data. Currently, they have 95% of staff vaccinated and 30-45% of students vaccinated. Additionally, they are looking at both the testing and vaccination data together to analyze testing participation, vaccination rates, and quarantine data. This will help inform the effectiveness of testing and vaccination and assess the viability of change to operational health and safety protocols.

**Discussion:**

- Test results from the program are exported to the Department of Health. However, only the name of the student and result are exported. This requires the schools to submit the test result with additional student information to the Department of Health and the district.
  - However, the information is moving quickly to the Department of Health compared to last year.
- There is a district-wide communication that discusses the number of students and staff that in quarantine and positive.
- They are using different PCR tests for symptomatic testing and same PCR tests for screening.

**An Interoperability Discussion (Ken Mandl, Harvard Medical School, Ryan Argentieri, HHS ONC, Brett Marquard, Argonaut, Josh Mandel, Microsoft, and Bala Hota, Rush)**

The goal of this discussion was to understand how the prioritized essential data elements, which were defined during the Diagnostics Lab meeting on October 21, 2020, move through the instrument, lab, and EHR. The prioritized data elements were selected during the last meeting. These elements are device identifier, specimen collection date, test result, and test result date. The key discussion points are listed below.

- Federal regulation requires all new devices to submit their unique device identifier (UDI) to the Global Unique Device Identification Database, but that databases is not in the EHR.
- In the United States Core Data for Interoperability (USCDI), UDI is present in FHIR. Therefore, making it a required data element for use cases.
- In USCDI, there are additional data elements that are not part of ONC regulation, but those data elements might of interest to certain organizations such as CDC and CMS.
There is a need for community efforts to come together to identify what essential data elements are needed in order to address use cases. Additionally, we need to be able to understand what elements EHRs can track well. It is important to work directly with organizations like HL7 or with a standards accelerator such as Argonaut accelerator to understand if there is a possibility to write out FHIR profiles that add required data elements.

- If a software does not have the required data element in it, then it will not include it in the exported or shared.
- This will be a place where we could begin looking at incorporating the required data elements.

Argonaut is a consortium of the largest EHR vendors and they have been prioritizing data elements as a community and testing them to ensure that they are supported in the same way. Once they do this, they deploy the elements to their customers.

- At the top level, the USCDI will include all of the required data elements, however, many vendors will prioritize the elements that their customers are interested in. This creates a significant drop in the number of data elements that are provided to the specific customers.
- There are vendors that are working to release support for including additional data elements such as UDI into the EHR.

An idea that was emphasized was that even though the interoperability frameworks and regulations are there, it doesn't mean that everything is going to be easy to use or apply.

If there is a clear mandate or incentives for the required data element, then the IT group will focus on the business use case and begin researching and developing the pipeline to include the data element.

- There is a data supply chain that has to occur in order to get that device ID which is feasible. There is a possibility to link the cost of the products to a use case, for example.
  - If there is a supply chain that can be made, then the development project can take approximately 3-6 months to complete.
- If this is not on its radar, then this effort falls into another area of innovation.
- IT will begin developing a Bulk FHIR output pathway which leverages the data warehouse. Vendors can build in a data pathway using a data warehouse to map the device IDs out into that infrastructure. The ideal goal is always to build it into the EMR and get true information captured at the time that care is provided. This will lead to better data quality.

USCDI is designed to work closely with the guidance that is being developed in collaboration with stakeholders, therefore there is a lot of community input in the development of USCDI.

The goal for USCDI Plus is to understand the use case for COVID-19. They are working with stakeholders to understand what are the essential data elements that need to be captured and develop guidelines that are beneficial to the community.

**Pathway forward:**
- US Core FHIR profile must include UDIs however there is no requirement to include it into an EHR.
- There are many certification and regulatory challenges that exist in order to accomplish the flow. There is a need to look at the current regulations.
- Understanding how each entity (instrument, LIS, and EHR) is capturing and storing the required element is important and is how we can address the issue of data flow. Most data fields are there but could be labeled with different names.
Next Steps

- Continue making data connections through the Evidence Accelerator and through www.EvidenceAccelerator.org.

Next Meeting: Thursday, November 18, 2021 12-1 pm ET