COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #40

Thursday, *November 18, 2021, 12-1 PM ET*

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting #40

This week's Diagnostics Evidence Accelerator meeting consisted of 3 presentation:

1. Updates from CDRH (Dr. Sara Brenner, FDA/CDRH)
2. Minimum Data Elements (Dr. Carla Rodriguez-Watson, Reagan-Udall Foundation for the FDA)
3. Using Various Timestamps in the Context of HIE and the Indiana COVID-19 Response (Dr. Shaun Grannis, Regenstrief Institute)

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.

Updates from CDRH (Dr. Sara Brenner, FDA/CDRH)

On Monday November 15, 2021, HHS Secretary Xavier Beccerra released a statement withdrawing HHS's policy on Laboratory Developed Tests (LDTs). The statement stated that HHS no longer has a policy on LDTs that is separate from FDA's approach. Additionally, FDA/CDRH released new updates to the guidance on testing polices to help ensure accuracy and reliability of tests and increase access to at-home testing. The policy areas that were updated are Prioritization of Review of EUA Request for Tests (Section IV.A), State Authorization (Section IV.B), Distribution and Offering of Tests During FDA Review (Section IV.C), and Modification to EUA-Authorized Diagnostic COVID-19 Tests (Section IV.D).

During the presentation, a high-level overview was provided for each of the policy areas that were updated. Specifically for Prioritization of Review of EUA Request for Tests (Section IV.A), figure 1 shows the process of how FDA prioritizes the review of EUA requests for molecular, antigen, and serology tests.

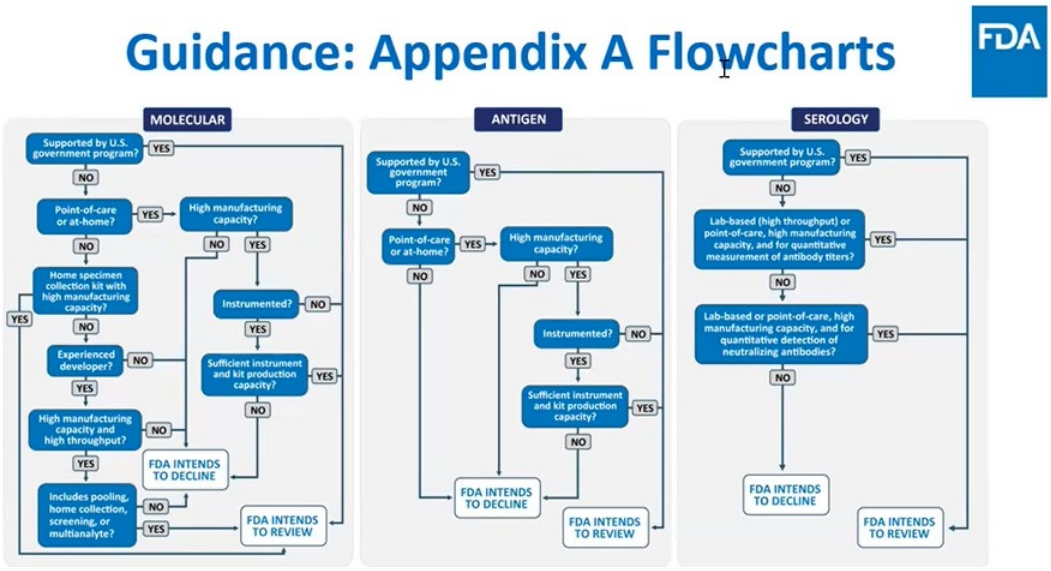

Figure 1: General overview of the policies in Section IV.A.

Additionally, updates were made to the FAQs on testing for SARS-CoV-2, Coronavirus (COVID-19) and Medical Devices page, and other EUA Related pages. Finally, there were reissuance of the March 2020 EUA for certain molecular diagnostic tests and the July 2020 VTM guidance.

With the increase in the numbers of at-home testing and point-of-care testing, it is increasingly important to have diagnostic data elements that are consistent and harmonized. Therefore, CDRH, in collaboration with SHIELD and other stakeholders is working to harmonize the data elements captured. They have defined the data element and developed a playbook to guide industry on what needs to be collected and sent to the state and federal government.

Minimum Data Elements (Dr. Carla Rodriguez-Watson, Reagan-Udall Foundation for the FDA)

During the October 21, 2021 Lab meeting, we aligned on data elements 4 key data elements that could help us understand the priority use cases. The data elements are device identifier, specimen collection date, test result, and test result date. Figure 2 shows the priority use cases on the left and the key data elements on circled in green.

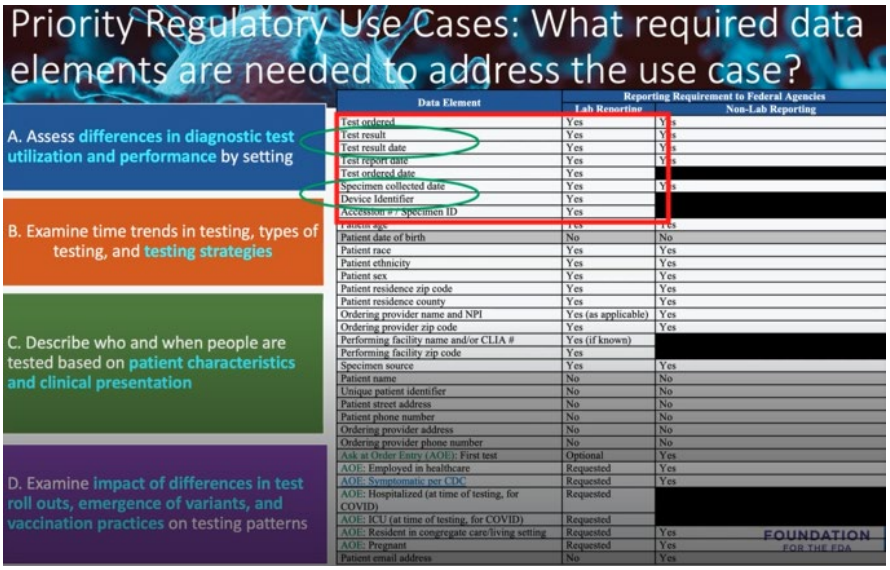

Figure 2: Priority use cases and the essential data to define the use cases.

During the November 4, 2021 meeting, we began discussing where the key data elements lie in the system and whether the elements move from instrument, lab, and EHR. One of the elements that did not move was specimen collection date.

Using Various Timestamps in the Context of HIE and the Indiana COVID-19 Response (Dr. Shaun Grannis, Regenstrief Institute)

Dr. Shaun Grannis discussed how they were able to move the key data elements across their system. Regenstrief Institute receives data from many sources and the data is also accessed and used by many sources. Figure 3 shows where the data is coming in from, being accessed from, and being used by.

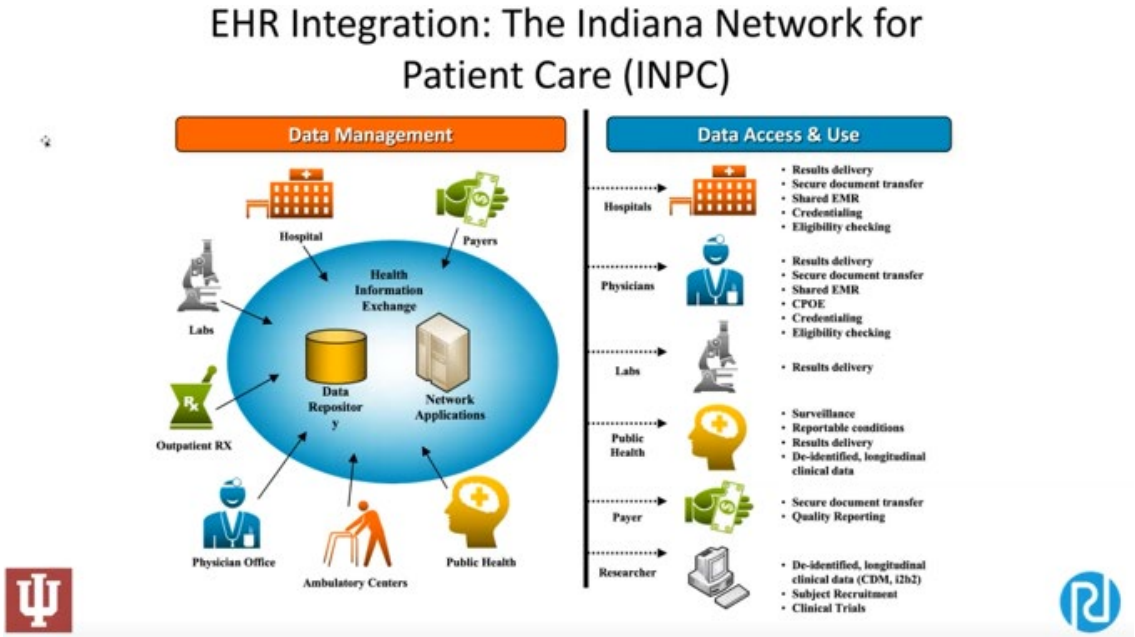

Figure 3: The Indiana Network for Patient Care (INPC).

One way that Regenstrief Institute is handling the influx of data is through their Notifiable Condition Detector. All of the data or transactions that is coming into the Notifiable Condition Detector is evaluated for its reportability to public health and stakeholders. Figure 4 shows how the transaction flows through the Notifiable Condition Detector.

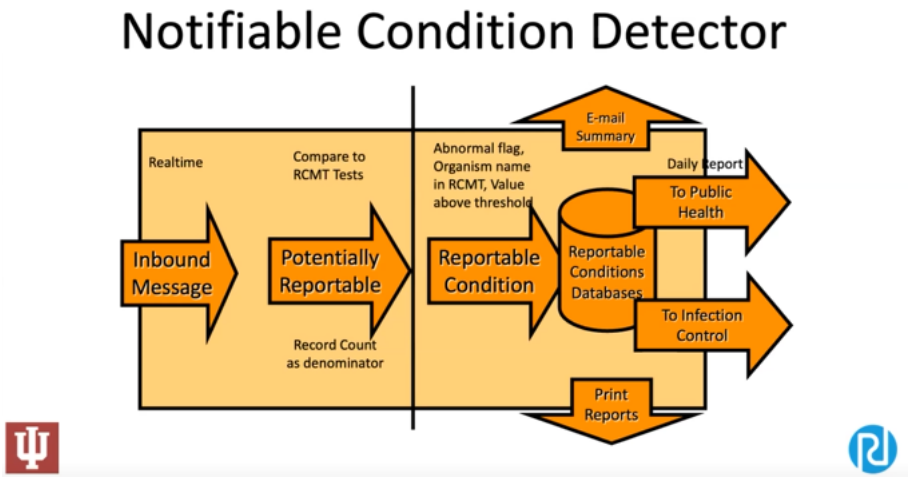

Figure 4: Flow of transaction through the Notifiable Condition Detector.

However, as the COVID-19 continued, there was data from other sources that was being collected and being used. This led Regenstrief Institute to notice that there was a lag in the data being transferred to the health exchange and there were different data elements being collected such as the date of specimen collection and date of result. Due to this, they began analyzing and addressing this issue.

In their system, they saw that majority of the transactions are in the standard HL7 version 2. However, they also saw that there were multiple kinds of dates being reported at different stages in the process. They saw that there was an observation date/time (OBR-7), specimen received date/time (OBR-14), date/time of observation (OBX-14), and date/time of analysis (OBX-19). The observation date/time represents the field shall represent the date and time the specimen was collected or obtained. The specimen received date/time is the actual log in time at the diagnostics service. Date/time of observation is the relevant date-time is the specimen's collection date-time. Date/time of analysis is the result date. Given the different types of dates that are reported, it is important to understand what each date that is reported signifies.

Upon further investigation, they examined the state department only had one date that was being reported. This date was the specimen collection time/date. Also, only 80% of the partners using the health information exchange were putting the correct date (specimen collection date) in the right place. The remaining were adding the date in other fields. However, the date that the other partners were adding was the specimen collection date.

Only after they understood what dates the state department and health information exchange (HIE) were collect, Regenstrief Institute, in close collaboration with different stakeholders, leadership, and technical team, were able to reconcile the dates and standards. However, not all of the partners are using the correct standard. This is due to the amount of data that is flowing into the system and the amount of time that it will take to completely address this issue. Currently, they are 80% of the partners that are using the standards correctly, however, for the remaining 20% or partners, they do know where to look to find the correct timestamp.

Interoperability Connection Discussion:

- In order to begin addressing this issue
    - The people that need to be at the table are the data consumers (end users). The way that Regenstrief Institute was able to identify this issue was through the analysts that were comparing the data from the HIE and state department. Additionally, organizational leadership need to be at the table so that this issue can be prioritized and supported. Finally, the technical team that understand the data flow need to be at the table.
    - Additionally, the language that is used in the standards is unclear. Clarifying this language could help ensure that all stakeholders are using the standards and data fields in the same way. This was an issue with the date coming in from the Indiana State Department. Analyst believed that this was the date that the state department received the result whereas it was the specimen collection date.
- Adopting and implementing the standards takes time. We have to be accommodating to the partners that are lagging and be cognizant of the time and resources it takes to fully implement all of the standards.
- All health systems vary in the way they are organized and operate. The individual that understands this issue will be in demand, therefore, in order to address this issue, there will be a need to prioritize from leadership and technical team.
- If a certain data element is not there, then adding it should be a priority. This will take additional resources, but all data elements are important as they are part of the story.
- Test result (OBX-11) and test result date (OBX-19) are in Regenstrief Institute's system.

Next Steps

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

Next Meeting: Thursday, December 2, 2021 12-1 pm ET