



COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #43

Thursday, January 20, 2021, 12-1 PM ET

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting #43

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

1. COVID-19 Test with Consumer-Collected Sample and Data Flow/Data Opportunities (Savitha Arokiarmy, Amazon Dx, and Jim Daniel and Dr. Taha Kass-Hout, Amazon Web Services)
2. Funding Announcement (Reagan-Udall Foundation for the FDA)

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 Test with Consumer-Collected Sample and Data Flow/Data Opportunities (Savitha Arokiarmy, Amazon Dx, and Jim Daniel and Dr. Taha Kass-Hout, Amazon Web Services)

The public health reporting (PHR) team at Amazon Dx is responsible for reporting COVID-19 test results to all state public health leaders and reporting authorities. In order to achieve this, the team uses their internal reporting service engine where they established an electronic reporting process with all 50 states and DC. The electronic laboratory reporting (ELR) system is a transport mechanism used by the state agencies to share data, and in this case, the results of PCR-based COVID-19 testing. This reporting structure has three mechanisms: Secure File Transfer Protocol (SFTP), Simple Object Access Protocol (SOAP) and Public Health Information Network Messaging System (PHINMS). Using the transport mechanisms, PHR shares the data via HL7, with the state reporting authorities. HL7 is a file type contains strings of data such as patients' demographics and test information and collates into a single report. HL7 bridges the gap between the different health IT applications and allows the sharing of the data.

PHR has also cooperated with Public Health Authorities in the UK Germany, Spain, and Ireland to report test results and contribute towards public efforts to minimize the impacts of this pandemic. Amazon is listed with the UK Department of Health and Social Care (DHSC) as general, day 2, day 8, and Test to Release COVID-19 testing provider. 98.1% of their test results were reported within 24 hours or less to the US state agencies. The majority of the longer reporting times are due to requests from a few states for Amazon to provide once per day reporting. PHR/Amazon Dx faced many challenges as they on boarded the states. The challenges and their solutions are listed below:

- **Challenge:** At the beginning, they had trouble reporting the device ID to the states because the reporting field had a number of components associated with it which made it difficult to capture all of the data in a 20-character field.

- **Solution:** Amazon Dx partnered with Association of Public Health Laboratories (APHL) to help them include device ID into their reporting system. They were able to align on the data structure and format of the device ID by truncating the character limit, below the original 20 characters allotted in the device ID field, so that you can only add the device ID into the device ID field. The additional fields such as testing product information was provided in the notes section of the report. Additionally, they customized the device ID based on the EUA number of the testing product. This allows the state health reporting authority to differentiate the test result base on the test type. They included state specific reporting requirements in to their reporting system.
- **Challenge:** The use of PHINMS is cumbersome. PHINMS is a CDC-provided software that fulfills this critical need for public health reporting. There were five states that were using PHINMS. The challenge with its use was that it is difficult to automate as the system requires manual updates, its cumbersome to use, and that it was not supported by AWS.
 - **Solution:** PHR worked with the state reporting agencies to help them transition from the PHINMS to SFTP. For the state of Delaware, for example, they are using a third-party Health Information Exchange (HIE) called Delaware Health Information Network (DHIN) to report results. This is the first time that Amazon Dx's PHR team is partnering with a HIE. Additionally, for Iowa, they onboarded the state onto an Amazon-owned SFTP. They are looking into expanding this option to other states that express interest.
- **Challenge:** Amazon Dx's PHR team launched their first direct-to-consumer COVID-19 test collection kits in July 2021. With an increase in FDA-authorized at-home COVID-19 tests (both rapid antigen and PCR), some states expressed concerns about at-home tests, particularly as it relates to public health reporting.
 - **Solution:** In order to address their concerns, Amazon Dx hosted two Q&A sessions with the state health reporting authorities and provided context about their product. Additionally, they offered one-on-one calls to follow-up and provide additional insights, as requested. This allowed for an open line of communication for the departments to ask questions related specifically to Amazon's direct-to-consumer test collection kit. Amazon Dx also modified their reporting to help states identify the direct to consumer at-home tests by including the EUA number in the device ID field.
- **Challenge:** State response time for reporting changes varied. There were some states that provided feedback quickly, while others had longer response times which delayed the process of incorporating the feedback into their reporting.
 - **Solution:** Amazon Dx's PHR team is working to develop and incorporate configuration and reporting changes that more effectively integrate into state reporting mechanisms and streamline these processes. Amazon Dx and PHR are committed to building strategic relationships with the state health reporting agencies and continuing to improving two-way communication with these partners.

Amazon Dx's future work includes:

- As industry moves towards FHIR, PHR/Amazon Dx is working on their tech systems to be able to adopt FHIR as soon as possible.
- Working with New York State, and others, to adopt a common reporting system similar to the reporting system of other states.
- Working on ways to make agency configurations more accessible and easily implemented.
- Working with states to automate report correction.

- Continuing to partner with states to support continued tracking and reporting of AmazonDx-produced test results.

Collaboration with Persivia

AWS is collaborating with companies where they are working with local and state health department to streamline the electronic lab reporting system. With the volume of COVID-19 tests coming in, the state's lab reporting system is unable to handle the volume of test. Therefore, the states worked with companies that are running AWS, such as [Persivia](#), to adopt the scalability and be able to handle the large amount of test result volume.

One challenge that Persivia was able to help address is the opportunity of variability in the accepting of the standard HL7251 message. For states that are working with Persivia, Persivia works with the lab to conduct mapping on the variables, so that the labs can keep the same reporting vocabulary that they are used to. As the data passes through the Persivia ELR engine, the codes will translate into the codes that the health department is expecting. An example of this is the mapping of LOINC and SNOMED codes to the codes that public health department use.

Additionally, Persivia was able to add facilities such as long-term care facilities and pop-up COVID-19 testing sites on to AWS. They were able to help translate the files format that the facilities provided into a format that public health departments were able to accept. They were able to translate the text and paper reports and translate that into HL7251 messages that was supported by AWS.

Amazon Health Lake (Taha Kass-Hout, Amazon Web Services)

[Amazon Health Lake](#) provides a center-based API. The stored information adheres to FHIR. Most of the data comes in an unstructured format, therefore, Amazon structures the data. Rush University built their population health platform on Amazon Health Lake during the wake of COVID-19. They were able to add their hospital systems to one area and analyze the data in the standard API. Additionally, Amazon Health Lake can be scaled to apply machine learning tools.

Question and Answer:

- Are you able to link the tests results with the clinical data of each person that had a test done?
 - The clinical data consist of the test result and the location of where the test result was generated. PHR does not capture broader clinical data.
- Is AWS looking to/able to provide reporting services for lab products other than your own?
- Is AWS running any analytics in addition to the reporting?
 - Yes, AWS does. They will also be providing the reporting service to Healthcare products other than their own.
- Does the AWS BAA (Business Associate Agreement) allow AWS to execute clinical analytics under the HIPAA treatment safe harbor?
- How is AWS handling LOINC and reportable disease semantic Interoperability — direct crosswalks, UMLS-based DAG?
 - The Persivia product has the capacity for reporting labs to create simple crosswalks through a UI.

Funding Announcement (Reagan-Udall Foundation for the FDA)

As the pandemic has continued, the role of accurate and reliable SARS-CoV-2 diagnostics tests remain a critical component of the COVID-19 response. Some of the needs were assessed in Project One and we learned about important trends in sero-testing and performance of serological tests. Additionally, through Project One we learned a lot from our limitations such as the lack of interoperability to link manufacturer information with clinical and demographic data left us with a good deal of missing data on the actual test name and race.

Therefore, the FDA Foundation is announcing a new program¹ that can help us dig into the limitations from Project One. The purpose of the funding is to

- Improve the use, interpretation, and performance of diagnostic tests as a means to:
 - improve the medical products available to patients
 - enable critical public health decision-making
- Expedite advances in knowledge regarding IVD performance, including strengths and limitations for use in different settings or subpopulations
- Enable a more rapid regulatory review process relative to current pre- and post-market data approaches
- Increase knowledge of real-world performance of SARS-CoV-2 IVDs
- Inform a framework for IVD test developers to collect and analyze data for regulatory submission
- Can lead to regulatory submissions from SARS-CoV-2 IVD manufacturers for Emergency Use Authorization (EUA) or Full Market Approval (FMA)

Key dates for the funding opportunity can be seen in Figure 1 below. More information on the announcement can be found [here](#).



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| Funding Announcement Publication | January 20, 2022, 1pm ET |
| Letter of Intent Deadline | January 31, 2022 5pm ET |
| Application Deadline | February 17, 2022 5pm ET |
| Merit Review | February 18-27, 2022 |
| Awards Announced | February 28, 2022* |
| Anticipated Project Start Date | March 1, 2022 |
| Anticipated Project Period | March 1, 2022, to January 31, 2023 |

* Subject to the availability of funds

Figure 1: Key dates for funding announcement application.

¹ Subject to availability of funding

Next Steps

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

Next Meeting: Thursday, February 17, 2021 12-1 pm ET