



## **COVID-19 Evidence Accelerator Collaborative**

### **Diagnostics Evidence Accelerator #27**

*Thursday, April 1, 2021, 12:00-1:00PM ET*

#### **Call Summary**

#### **Introduction to Diagnostics Evidence Accelerator Meeting 27**

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

1. HHS Design-a-thon At-Home Diagnostics (Kristen Honey, HHS and Sara Brenner, FDA/CDRH)
2. COVID-19 Testing and Vaccine Update (Sree Chagaturu, CVS Health)

As always, thank you to all of the analytic partners, strategic advisors, and scientific advisors that are participating in Project One. As of the week of March 29, 2021, Accelerators are on step 6 where they are revising Aim 1 manuscript on testing characterization and on step 9 where Accelerators are running their Aim 2 analysis.

#### **HHS Design-a-thon At-Home Diagnostics (Kristen Honey, HHS and Sara Brenner, FDA/CDRH)**

Design-a-thon has two objectives: 1. To conceive and design solutions to capture test and patient data in automated, harmonized, and wireless means; 2. To establish a government developed device/systems-agnostic interface between HHS Protect and various reporting systems. This solution is called WATERS (Wireless Automated Transmission for Electronic Report Systems). The second phase of the Design-a-thon is TOPx. The goals of TOPx is to build and extend the products or technology that were being developed in the Design-a-thon. Additionally, HHS's goal was to allow industry to run and build their own tools and work with industry for long term sustainability.

When the project was launched, they had asked anyone from industry to submit their ideas and products to advance digital solutions for reporting. Submissions were made to <https://waters.crowdicity.com/>. The Design-a-thon submissions were due in November 2020 and the winners were announced by December 2020. Sixteen (16) out the 30 submissions moved on to TOPx which began in January 2021 and final demos were presented on April 1, 2021. In order to protect the sensitive data sharing while preserving interoperability, they worked closely with HHS PROTECT. This allowed them to build the digital infrastructure to include the intake of the different reporting mechanisms so the industry solutions can be docked into the federal infrastructure. The demos were not shared publicly and were shared on Demo day (date TBD). However, HHS has been transparent about the solutions that have been developed through the Design-a-thon and TOPx.

The COVID-19 TOPx tech teams were allocated into 3 tracks: data capture from diagnostic workflow, severity/risk scoring and health passports, and secure data storage and exchange. As testing options

outside of labs increases, FDA/CDRH’s goal is to increase technology solutions and data capture for non-lab-based diagnostics. Some of the organizations and their efforts were highlighted during the presentation. Safe Health Systems solution is one of the first solution that is engineered for interoperability to capture and harmonize the data elements required by HHS. Lifepoint Informatics is using the diagnostic data captured by Ellume which was the first over-the-counter test to receive an emergency use authorization (EUA). The Department of Defense (DOD) is investing \$232 million to expand US production to 640,000 tests per day. U-Do Test developed a workforce-based solution. They developed an at-home testing software platform that allows employees to order tests. IBM facilitates health data exchange by individuals setting and implementing data sharing polices by creating a health passport.

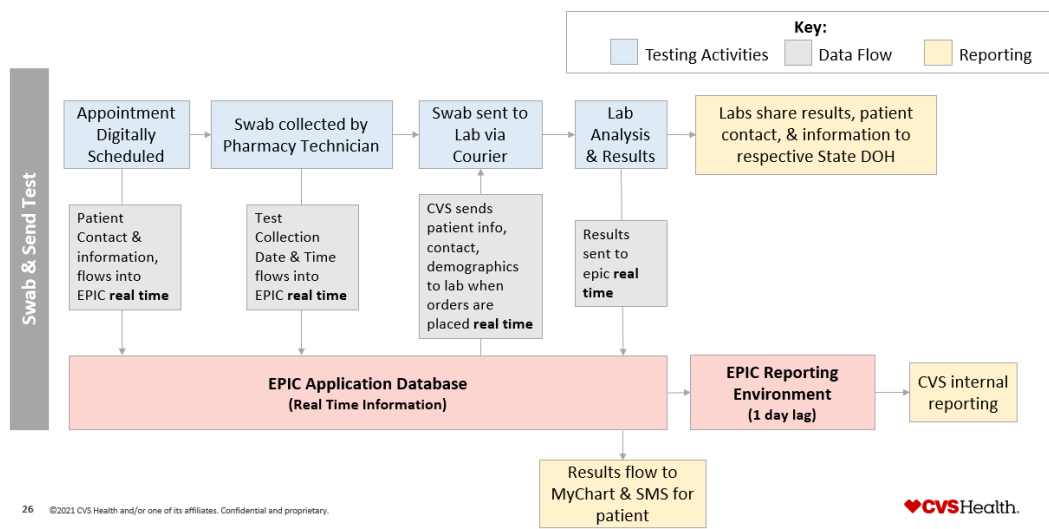
All of the teams have onboarded into the WATERS system, which is an interface where harmonized COVID-19 diagnostics data will be flowing to the federal government. FDA/CDRH is working on rerouting the information captured to the states to conduct contact tracing and develop public health interventions.

**COVID-19 Testing and Vaccine Update (Sree Chaguturu, CVS Health)**

The presentation discussed both testing and vaccine data in a real-world setting. CVS Health entered created large community-based testing sites in attempt to expand testing from the traditional hospital setting. They expanded to 4,000+ locations where they partnered with central reference laboratory (e.g. LabCorp, Quest) in order to administer COVID-19 testing. Over time, as point of care test became more assessible, they converted some locations to point of care testing for communities. CVS Health worked with underserved communities to identify the communities that needed additional testing deployment.

CVS Health has conducted more than 15 million tests, and has a digitized data flow. An appointment is digitally scheduled which allows for the collection of demographic information, comorbidities, and symptoms. This is transferred to EPIC and communicated to the patient through MyChart. The EPIC data is used for CVS internal reporting. By having their own data, they are able to look at the overall testing and positivity rates for each state. The flow chart below shows the data flow and testing process for CVS Health.

**Testing Process & Data Flow (Swab & Send)**



CVS Health generated 4 models from the data they collected with varying lists of variables and subsequent performance that can be decided upon by the business. They saw that as more data elements are added, the accuracy of the positive prediction increased. However, not many data elements are needed to be added in order for the model to prove effective. Symptoms such as new loss of taste or smell and number of symptoms are the most impactful data variables in model. They are careful not to create inequities in the models that they proposed. CVS Health’s proposed models are shown in the image below. CVS Health recommends models 3 and 4 based on accuracy and feasibility of obtaining data.

## Refined Model Options (Different Input Variables)

We generated 4 models with varying lists of variables and subsequent performance, that can be decided upon by the business. **We recommend 3 & 4 based on accuracy and feasibility of obtaining information.**

	1	2	3	4	
	All Variables Included (32 variables)	All Positive Factors Only (16 Variables)	All Positive Factors Except Race (14 Variables)	Symptoms & Age Only (8 variables)	Current Screening Form
Variables Included	<ul style="list-style-type: none"> <li>✓ Symptoms (same as from 4)</li> <li>✓ COVID-19 Incidence (same as from 3)</li> <li>✓ Demographics (same as from 2)</li> <li>✓ Risk factors               <ul style="list-style-type: none"> <li>- Caregiver / first responder</li> <li>- Living situation (nursing home or congregate setting)</li> <li>- Existing conditions: weakened immune system, asthma / lung disease, obesity, liver issues, heart condition, pregnancy, diabetes)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>✓ Symptoms               <ul style="list-style-type: none"> <li>- Loss of smell / taste</li> <li>- Fever</li> <li>- Chills</li> <li>- Cough</li> <li>- Muscle pain</li> <li>- Sore throat</li> <li>- # of symptoms</li> </ul> </li> <li>✓ COVID-19 Incidence               <ul style="list-style-type: none"> <li>- New cases by state</li> <li>- Tests distributed</li> <li>- % Positive tests</li> </ul> </li> <li>✓ Demographics               <ul style="list-style-type: none"> <li>- Age / Gender</li> <li>- Race</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>✓ Symptoms               <ul style="list-style-type: none"> <li>- Loss of smell / taste</li> <li>- Fever</li> <li>- Chills</li> <li>- Cough</li> <li>- Muscle pain</li> <li>- Sore throat</li> <li>- # of symptoms</li> </ul> </li> <li>✓ COVID-19 Incidence               <ul style="list-style-type: none"> <li>- New cases by state</li> <li>- Tests distributed</li> <li>- % Positive tests</li> </ul> </li> <li>✓ Age</li> </ul>	<ul style="list-style-type: none"> <li>✓ Symptoms               <ul style="list-style-type: none"> <li>- Loss of smell / taste</li> <li>- Fever</li> <li>- Chills</li> <li>- Cough</li> <li>- Muscle pain</li> <li>- Sore throat</li> <li>- # of symptoms</li> </ul> </li> <li>✓ Age</li> </ul>	<ul style="list-style-type: none"> <li>✓ Symptoms               <ul style="list-style-type: none"> <li>- Fever</li> <li>- Cough</li> <li>- Shortness of Breath</li> </ul> </li> </ul>
Accuracy	Class. Accuracy: 75% AUC: 80-82%	Class. Accuracy: 75% AUC: 79-81%	Class. Accuracy: 74% AUC: 77-80%	Class. Accuracy: 73% AUC: 77-79%	Class. Accuracy: 49% AUC: N/A

<sup>27</sup> Note: Classification Accuracy for models are provided at 0.11 threshold (Population average probability)  
 'AUC' is a area under the ROC curve, which shows the summary of both sensitivity & specificity, also known as "c-statistic"



To date, CVS Health has administered over 10 million COVID-19 vaccines. CVS Health has a digital scheduler similar to the testing scheduler. Additionally, they have 10,000 locations and widely distributed in the country which is important for operability for the program. They have used the lessons learned from this year’s flu season and COVID-19 testing to distribute vaccines efficiently. For CVS pharmacies, there are 2 community vaccination programs: long term care program and federal pharmacy program. For the long-term care program, Long Term Care (LTC) facilities enrolled and selected CVS as their partner to go onsite and administer vaccines over the course of 3 visits. There are 45,000+ LTC facilities in the program. CVS Health has administered 4.6 million doses.

CVS Health a conducted 2 analytics projects: Long-term depot selection, and the retail pharmacy program. For the LTC program, it is important to pick a pharmacy that opens 7 day per week, is centrally located to the LTC facilities, has a layout compatible with vaccine product storage, and has TempAlert capability and reliable network. They had a subset of locations that were able to provide space to administer vaccines which they Geo-mapped to include the LTC facilities close to a CVS location. Additionally, the established back up depots if needed, so if the primary site was unable to provide the vaccine, the LTC facility would be able to receive the vaccine as scheduled at the backup location. For their retail pharmacy program, they receive a weekly allotment of vaccines from the CDC proportionate to the state’s population. Then, CVS Health can decide which pharmacy will the vaccines by using the Social Vulnerability Index (SVI) and consumer data to conduct store selection and administer the vaccine.

## From the Chat Box

- An accelerator asked if HHS is planning to build multiple prototypes using real world data captured from multiple settings.
  - The presenter stated that they are using real-world data captured from multiple settings.
- Another accelerator asked if the data was coming from centrally calibrated test.
  - The diagnostics developers and their team are using the guidelines that were published for technical standards for the core data elements identified under the CARES Act and HHS guidance. Therefore, the data is harmonized and centralized even though each developer is working on its own solution. FDA/CDRH does not want to restrict innovations and would like solutions (high quality and harmonized) on the market.
- If HIPAA doesn't apply to employers, how is patient privacy protected?
  - The data is HIPAA protected. However, it depends on individual policies between employer and employees. Therefore, FDA/CDRH address it based on the situation.
- Are there incentives being offered to increase uptake and adoption?
  - FDA have been working to reroute funding for diagnostics to accelerate innovation. FDA/CDRH is working aggressively to do that.
- Do test capture variants on positive tests? If yes, do the employers receive employee-identifiable results?
  - The presenter responded by stating the tests themselves do not capture or sequence variants; however, CDC is working on genetic surveillance sequencing strategies in tandem with testing
- The presenter shared the website for accelerators to learn more about the Design-a-thon and TOPx: <https://waters.crowdicity.com/>.
- An accelerator asked assuming all CVS Epic data is available to patient providers/health teams via CareEverywhere too.
  - CVS Health asks the consumers using their facilities if they are okay sharing this data with their provider and health teams.
- Curious if any consumer/purchasing info or data was ever added into the CVS prediction model?
  - Yes, such data was used to plan for vaccine deployment. However, CVS Health does not connect front store (consumer data) with back store (pharmacy data). For vaccine deployment, the consumer data was not connected at a patient level. It allowed CVS Health to understand the demographics of the consumers for each store to improve targeting of vulnerable communities.
- Any insights into why so many long-term health care workers have been hesitant about being vaccinated?
  - They have published 2 white papers on vaccine hesitancy. They saw that over the first couple months they saw increased hesitancy. The last couple of weeks they saw a softening of hesitancy among healthcare workers. They saw this in LTC and in the general population. When they analyzed why individuals want to get vaccinated, they stated that they want to get back to some sort of normalcy in life and a network effect (they know someone else who received the vaccine with little or no adverse events and were therefore assured of safety).
- Given the 10 million vaccinations, what is experience with immediate adverse reactions (within the 15 minutes)?
  - CVS Health does collect the safety data which they report internally and to CDC. They can look at specific stores and operational issues. They have a quality operational team that

would step in and address any issues that arise. They have this data for both testing and vaccines.

- Is vaccination data available to non-Epic EHRs, e.g., Cerner, athenahealth, etc., perhaps via the bi-directional FHIR Immunization resource (HL7 uses the terms vaccination and immunization interchangeably)?
  - They are working with the emerging vaccine credential initiatives to allow for the interoperability.
  - An accelerator stated Interoperability with employee health, patient EHRs (health org/provider perspective), and vaccine administrators (public health, pharmacies, others) as they are all not interoperable yet.
- How does CVS Health collect data on race and ethnicity of people coming into the store?
  - The data are taken from the US Census datasets. This allows CVS Health to understand the consumers that reside near a specific store.
- On a similar note, how does the test team and vaccination data get back into the patient's medical records?
- Regarding centrally calibrated diagnostic testing: We could centrally distribute calibrated pertinent positive and negative samples.
- The consumer, retail data mentioned earlier has historically no been available to the public health community - suggestions for how to change this?

#### **Next Steps**

- Continue making data connections through the Evidence Accelerator and through [www.EvidenceAccelerator.org](http://www.EvidenceAccelerator.org).

**Next Meeting: Thursday, April 15, 2021 12-1 pm ET**