COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #9

Thursday, *July 30, 2020, 12:00-1:00PM ET*

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting 9

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

1. Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) (Rachael Fleurence, PhD, NIH/OD, Special Assistant to the NIH Director for COVID-19 Diagnostics; Susan Gregurick, NIH/OD)
2. Data Reporting (Andrew Trister, Gates Foundation)
3. Connecting the Dots Back to Project One (Amy Abernethy, FDA/OC; Susan Winckler, Reagan-Udall Foundation for the FDA)

Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) (Rachael Fleurence, PhD, NIH/OD, Special Assistant to the NIH Director for COVID-19 Diagnostics; Susan Gregurick, NIH/OD)

Rapid Acceleration of Diagnostics (RADx) Initiative was designed to address the need for accurate, reliable, and accessible testing on a massive scale. Therefore, testing must be inexpensive, user friendly, widely accessible in different locations, and able to detect asymptomatic patients. The goal of the program is to accelerate innovation, develop and commercialize, and implement COVID-19 testing. The approach that they are taking is funding early innovative diagnostic technologies, advance late-stage diagnostic technologies to expand testing infrastructure, identify effective testing implementation strategies in underserved populations, and work closely with other government agencies. There are multiple RADx projects that are in development. Those projects are RADx Tech, RADx Underserved Populations (RADx-UP), RADx Radical (RADx-Rad), RADx Advanced Testing Program (RADx-ATP), and Data Management Support.

RADx-ATP's goal is to increase capacity for point-of-care (POC) testing platforms and support high-throughput laboratories, or mega-labs, by Fall 2020. They plan on having contracts in place by August 2020 with 2-3 POC companies and 1-3 high throughput laboratories. The approach that they are taking for RADx-ATP is to 1) scale up late stage technologies and 2) support scale up of high throughput labs to add capacity by developing next gen labs and using robotics. They have certain requirements for POC companies and tests and high throughput laboratories which are located on their website. However, they do want high throughput laboratories to be able to process 100,000 to 250,000 test per day and have capability for using FHIR-based APIs for standardized electronic data transmission. They published an article called "Rapid Scaling Up of Covid-19 Diagnostic Testing in the United States - The NIH RADx

[Initiative](#)" which discusses the program. They will work with companies to support the appropriate data to support future linkage of demographic data with clinical data and with the goal of supporting a robust data infrastructure. They will scale up activities in August 2020. (Update: First contracts have been announced on July 31st. More information can be found on [NIH's website](#).

Susan Gregurick states that there are a number of use cases that they are collaborating on. She highlighted a use case that forecasts the trajectory of the pandemic. This team looks at data on a 4-6 week basis. They also look at data surrounding transmission intensity among sub populations such as race/ethnicity, rural/urban, and low/high income populations. This group is optimizing the combination of interventions tailored to specific sub-population. NIH has initiatives that fall under the extramural and intramural programs to address the COVID-19 pandemic. There are other projects that Susan Gregurick is heading, and those projects are the Jumpstart Project and COVID-19 Clinical Data Resource. They have developed recommended policies for promoting participation and research data sharing.

RADx Data Hub's vision is to provide an access point to de-identified COVID-19 RADx and related data, algorithms, and other capabilities generated by digital health solutions and technologies. The Data Hub will be able to provide research data repository for researchers and work with NIH supported COVID programs to develop and/or implement standards, CDEs, CDMs and best practices. Their data sources include RADx-tech, RADx-UP, an integration strategy for the Data Warehouse effort related to the aggregation of clinical data from NIH supported CTSAs, CTSRs, and clinical trial networks, and existing and future data and information sources. The intention of this project is to be accretive to existing IC-led initiatives. The work will be guided by a selection of prioritized use cases and the technical architecture will utilize cloud technology. There are many aspects of their workstream and currently they are on the development of communication and stakeholder engagement plan step in the workstream.

They are in phase 2 of their RADx-Tech Innovation funnel. There are a number of projects that are going through the Guidance and Impact Tracking System (GAITS). The public version of the system is available at www.GAITS.org. They are in week 3 of their RADx Data Hub project. The data will be coming into the data hub in the next 2 weeks. In the next week, they will build prototypes, and then they will leverage this project to vendors. The question of how stakeholders can leverage the data from the RADx Data Hub to make decision and identify interventions was asked. For RADx-ATP, they are integrating systems so that all of the pipes are connected early, so they can be used to make decisions when it is needed.

Data Reporting (Andrew Trister, Gates Foundation)

The Gates Foundation is looking at questions that focus on how they can leverage common elements, inform, allocate resources, and deliver care in low and middle income countries. They are taking the same approach for the US. In low resource setting, they are focusing on the point of care, molecular, and antigen tests. They are thinking of ways to leverage the recommendations that have been made for individuals. The high turnaround times may preclude action that is taken by the individual and population to curve the epidemiological spread, therefore point of care devices are critical. Data collection for an individual is important so they have actionable information. Given the areas that they are working in, it is difficult to collect common data elements. The Gates Foundation is finding space to have discussions like the ones in this workgroup to better understand the data needed. Also, legislation is behind on the efforts that are needed to combat COVID-19. Having a regulatory sense and legislation is an important aspect to consider along with the aggregated data.

Connecting the Dots Back to Project One (Amy Abernethy, FDA/OC; Susan Winckler, Reagan- Udall Foundation for the FDA)

For Project One, this workgroup will be taking a cohort of positive molecular test results that have a subsequent serology test and using that data to look at clinical and demographic data. Along with this data, this workgroup will be able to evaluate how test sensitivity varies by different demographic and clinical factors and how the timing of a positive serology result varies. To answer this question, the data that we will need is information on manufacturer, the type of test used, laboratory results, and information on the patient and patient population. Linking this data is key to understanding COVID-19 and future impacts.

Discussion
- Ensuring that appropriate data is collected and processed correctly is important. It is a critical to have clean data to look for the bigger picture.
- The idea that there are many competing models and thoughts about which test we should use was raised.
- To consider moving forward, we should start with the effectiveness of a test instead of efficacy.
- Patient that receive serology tests are not chosen at random, therefore, it is important to think about research design as the data may not represent a random group.
- Clinical testing is not the same as community surveillance because there is a selection bias in who is tested which may not be a complete indicator of what is happening in a community.
- The purpose of Project One is to connect the data pipes, so we are able to ask complex questions in the future.
- NIH and other organizations such as CDC are coordinating activities to develop use cases and inform decisions.

From the Chat Box
- It was made clear that the HHS reporting requirement under CARES Act is for laboratories; however, certain data elements are clinical and will therefore require the clinical community (e.g. order providers, healthcare systems, clinicians) to collect and transmit those data elements to labs so they can be reported along with the IVD/test specific data elements.
- A caller raised the idea that there is value in thinking through the real-world data and confounders in Stage 1 RADx-Tech. If the device or system is not built with capturing those elements, then it might be too late to add them by the time the researcher goes into regulatory decision making given design lock.
- Common data elements are critical, but there should be an eye to extensibility since different elements may matter for different test formats.
- The idea of one trying to regulate the data capture was raised as there are structure in place as part of the regulatory process.
- The methodologic concerns about observational studies are real but can't be used to prevent us from making use of real world data
- To understand the clinical predictive performance of each one of the 750+ diagnostic tests in use (by version and lot), we need a centralized system that can provide unique identifiers for each diagnostic test and lot, possibly in a similar manner as vaccine lots are managed.
- A caller stated that he liked the biphasic approach of starting with a small, practical study while at the same time visioning where we are going. It's been their experience that they learn about real world data by working with it.

<u>Next Steps</u>

- Recruit additional researchers that are interested in participating in Project One. If researchers are interested, they can contact Amar Bhat at abhat@reaganudall.org.
- Continue making the data connection and learn about test performance for the next meeting.

Next Meeting: Thursday August 6th, 2020 12-1 pm ET