COVID-19 Evidence Accelerator Collaborative

Thursday*, May 28, 2020, 12:00-1:00 pm ET*

Diagnostic Accelerator Call Summary

Evidence Accelerator Model:

The goal of the Evidence Accelerator Collaborative is to bring together the vast experience and expertise from the healthcare services research community to spark innovation. The Evidence Accelerator will provide many opportunities, through the use of real-world data, to provide guidance, answer questions, and increase innovations to combat COVID-19.

There were 4 presentations given at the first Diagnostic Accelerator meeting. Those presentations are as followed:

1. EA Model and Diagnostics Approach by Amy Abernethy and Jeff Allen
2. NIH's Efforts in diagnostic Testing by Ned Sharpless, Bruce Tromberg, and Lynne Penberthy
3. Discussion of Research Questions by Carla Rodriguez-Watson, Jeff Allen, and Sean Tunis
4. Discussion of Standards by Sara Brenner and Michael Waters

EA Model and Diagnostics Approach by Amy Abernethy and Jeff Allen

Reagan-Udall Foundation for the FDA and Friends of Cancer Research have provided a safe space for researchers to work together to advance real world data in service to COVID-19. This partnership brings together key tools and questions prioritized by the FDA with data partners and analytic teams to address those critical questions. The Evidence Accelerator operates through the use of common data elements, translation tables to translate common data elements between different models, and a shared space to work together and learn from one another.

The Evidence Accelerator has two primary components. The Laboratory Meeting Model allows researchers and partners to share the lessons learned and ideas. The Parallel Analysis Model allows experts to work together on answering a common critical question, to develop a common analytic plan, and answer the research question with multiple data sets to ensure replicability of findings and develop a master protocol that can be used centrally and repurposed to answer different core questions.

These models can be used as a framework to look at the diagnostic testing elements of COVID-19 using real world data. The regular interactions will allow experts to share strategies and ask questions. The goal is to bring in different data elements to answer the core questions that have been prioritized to create a bigger picture and work together faster rather than in isolation.

NIH's Efforts in diagnostic Testing by Ned Sharpless, Bruce Tromberg, and Lynne Penberthy

Ned Sharpless, the National Cancer Institute (NCI) shared that they received funding from Congress to develop, validate, improve, and implement serological testing. The NCI is setting up a Proposed Serological Science Network to create centers and grants to support serology testing capacity and address research questions related to serology. There is a recent RFI that has been announced. **The industry call is Friday May 29, 2020 at 2**

pm. This RFI is associated with both NCI and NIBIB. NCI along with NIBIB created contracts to allow for experts to supply solutions to move forward with these crucial questions. NCI envisions that there will be many innovative tools that will be developed such as understanding how testing platforms can be integrated and creating an application to receive wearable data and contact tracing.

Bruce Tromberg and his team are working with the NCI and other partners to develop a digital backbone to integrate information across sources. They have developed a Rapid Acceleration of Diagnostic (RADx) Initiative with the goal to introduce innovation into diagnostic technology to expand the number, type, access, throughput of testing technologies for the virus. By introducing innovations, they will like to optimize technology performance for a range of essential use cases such as home-based Point of Care (POC), hospital, and testing laboratory. With the knowledge that they had gained with Point of Care Technologies Research Network (POCTRN) program, they were able to launch RADx quickly. The POCTRN program created point of care technology in infectious disease, sexually transmitted diseases, and heart, lung, and blood monitoring. Within this program, there are five locations that accept new ideas from researchers and analyze them from multiple diagnostic points from clinical needs to standard of care. The four technology centers located in Georgia Tech/ Emory, Johns Hopkins University, Northwestern University, University of Massachusetts that have experts that look at core resources such as validations, clinical testing, articulation of use cases, and the matching of the use cases with the performance issues relations to validation and use cases.

With the creation of RADx, there is a call of proposals for innovations. The RADx Tech Innovation Funnel was developed to sort through the innovations in a timely manner. The funnel is a multistep process to ensure that the innovations that are being developed will have the maximum impact to combat COVID-19. So far there have been 1900+ proposals initiated, 350 proposal completed, 50+ proposals in the shark tank process or the deep dive with an expert plan, and couple of projects that are in the work package 1 where risk and validation of the project is evaluated. Proposal contributor consist of small businesses, academics, startups, mid-size business, large businesses, others, and nonprofit labs/CRO. The proposals that are coming in are requesting support and requesting sample type other than nasal pharyngeal swabs.

NIH has implemented the RADx initiative also. There are 4 different types of RADx funnels that NIH is using. There are RADx Tech where support for technology is given. There is RADx-UP for underserved population that focuses on providing testing to the underserved and vulnerable population. There is RADx-Radical that emphasizes innovation that may not be able to be deployed before the deadline of fall 2020. Finally, RADx Advanced Testing Program (RADx-ATP) funds advanced technologies to increase rapidity and enhanced and validate throughput to prepare for the flu season. They developed a digital health platform that can capture input devices and technologies across community.

Lynne Penberthy and the NCI are focusing on the key question of does a positive serology test provide protection against subsequent COVID-19 infection and for how long. They believe that they can use real world data to answer that question rather than using clinical trials. NCI is looking at real world data to identify a cohort of patients that may test positive for COVID-19 serology and follow them longitudinally to access the subsequent risk of infection. For them, It is important to replicate results. The key factors that they want to be part of their study include using test results that include test type and manufacturer due to the large variation in sensitivity and specificity across the tests and a significant cohort size that can support the overall analyses and sub analyses. The sub analyses that they want to focus on is to evaluate patients that had a prior PCR positive COVID-19 test or positive diagnostic code that they can follow longitudinally and look at patients that had orthogonal testing and perform risk analysis across test type. They are looking at large data aggregator to follow patients longitudinal and evaluating individual data sources.

Discussion of Research Questions by Carla Rodriguez-Watson, Jeff Allen, and Sean Tunis

Clinical trials are going to be essential for evaluating the diagnostic accuracy of tests. The hope of the Evidence Accelerator is to provide a coordinated program of diagnostic testing research using RWD that could generate useful information that can be used for public health and policy decisions.

The FDA has developed 4 objectives and focus to move forward with the diagnostic accelerator. Listed below are the objectives:

- **TEST**: To generate evidence on real world test performance of SARS-CoV-2 molecular diagnostics, direct antigen, and antibody tests
- **PATIENT**: To improve understanding of the pathophysiology of disease including the development of antibodies, immune response, and immunity in patients with SARS-CoV-2 infection (by diagnostic testing and/or clinical assessment)
- **POPULATION**: To estimate the prevalence of SARS-CoV-2 infection, recovery (presence and persistence of antibodies over time) and reinfection for different populations, analyzed by geography, public health interventions, and other characteristics
- **SYSTEM:** To promote the uptake of COVID SHIELD data standards within clinical labs to improve the ability to address diagnostic testing questions

We developed a worksheet to collect feedback on an initial list of critical questions and data elements. The group was asked to review and return feedback on the sheet by June 1st, 2020. The feedback will be incorporated and discussed at the next DX Accelerator meeting, with the goal of quickly turning it into a work plan that could be used as a protocol to answer the first critical question.

The purpose of the worksheet is to provoke thinking. Experts were asked if they add any additional questions or comments, they can write on the worksheet.

Discussion of Standards by Sara Brenner and Michael Waters

Sara Brenner discussed the test performance and data in regard to the test. There are three main pieces in terms of the data underlying the tests. The first is harmonizing data that is underlying the diagnostic test. The second piece is integrating core data elements across different components: the diagnostic test platform, the specimen, and the patient demographic data. The third piece is integrating new technology quickly and harmonize data. Their focus was to answer the "Test" metric in the worksheet.

Key Points:

- Collaboration and harmonizing the core data elements is crucial moving forward with the Diagnostic Accelerator.
- This group can provide opportunities to use real-world data to provide guidance to answer questions and increase innovations to combat COVID-19.
- The goal is to bring in different data elements to answer the core questions that have been prioritized to create a bigger picture and work together faster rather than in isolation.
- Complete the diagnostic accelerator worksheet to gain insight on the questions that need to be answered to combat COVID-19 and develop a work plan for additional work groups.

Next Steps:

1. Please review and comment and provide feedback on the research question worksheets (e.g. priority level, the time period that the question can be answered, and the feasibility of answering the questions) **by Monday June 1st, 2020.**
2. Review feedback and identify the first critical question at the next meeting.

NEXT MEETING- THURSDAY JUNE 4TH, 2020 (12-1 pm ET)