



COVID-19 Evidence Accelerator Collaborative Diagnostics Evidence Accelerator #23

Thursday, February 4, 2021, 12:00-1:00PM ET

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting 23

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

- 1. Workplace Employer Alliance for COVID-19 Testing (WE ACT) (Amy Rosenbaum, PhD, CVS Health)
- 2. K-12 Testing Insights from the Parabola Project (Asaf Bitton M.D., MPH, Ariadne Labs, and Beth Rabbitt, Ed.L.D, The Learning Accelerator)
- 3. Ct Value Preliminary Results (Cindy Wang, PhD & Qingqing Mao, PhD, Dascena)

As always, thank you to all of the analytic partners, strategic advisors, and scientific advisors that are participating in this project. As of the week of February 1, 2021 we are on step 4 where Accelerators are refining Aim 2: Positive Percent Agreement & Risk of Seropositivity protocol.

Workplace Employer Alliance for COVID-19 Testing (WE ACT) (Amy Rosenbaum, PhD, CVS Health)

The mission of WE ACT is to advocate for employer-based testing programs to keep employees safe during the public health emergency and to serve as a resource for public health officials by working to increase COVID-19 testing programs in communities and businesses interested in launching employer-based testing programs. CVS Health has set up free testing sites to increase testing in communities with a high rate of underinsured and uninsured individuals.

WE ACT started off as an informal coalition to discuss how to provide testing, now, it has become a coalition to discuss different testing strategies. Through the program, they make sure that individuals that need testing frequently receive tests. Dr. Rosenbaum mentioned that there are federal regulation for testing such as programs reimbursed through Medicare. Individuals at long term care facilities are required to get testing twice a week as per Medicare guideline.

Once they developed an official coalitions, they established objectives for WE ACT. Those objectives are as followed:

- A comprehensive testing strategy: WE ACT supports a comprehensive national testing strategy that include guidelines for testing implementation and results reporting.
- Expanded access to high quality, FDA authorized tests: Some members of the coalition struggled
 with acquiring high quality, FDA authorized tests. therefore, this became one of the objects of
 WE ACT to increase the number of tests that all members of the coalition have access to.

• Resources for data sharing: There are great benefits for sharing data and lessons learned from different COVID-19 testing strategies among the government and private employers.

CVS health is conducting testing for other employer and governments through their Pharmacy Benefit Management (PBM) program. They are testing employees that are going back to work by setting up rapid testing sites at the employer sites. The tests that they are using for this is the Abbott rapid test. They conduct PCR and Point of Care (POC) tests at their CVS locations by setting aside a number of appointment for employers and states to increase testing for that cohort. To share the lessons learned and best practices with others, CVS Health is engaging with the Biden Administration and Capitol Hill to provide them with those lesson.

K-12 Testing Insights from the Parabola Project (Asaf Bitton M.D., MPH, Ariadne Labs, and Beth Rabbitt, Ed.L.D, The Learning Accelerator)

In partnership with Ariadne Labs, The Learning Accelerator sought to answer the question of how to reengage in-person learning safely. This opportunity brought together a cross section between education and healthcare to support school leaders. Dr. Rabbitt shared a background on the school systems during the presentation. There are more than 15,000 unique school districts or systems with 131,000 school across the 50 states. However, there are 1 in 4 schools that do not have a nurse on staff which prevents the school from address health issues on site. Also, the average expenditure is \$13,000 per student per year, however, the actual expenditure varies in each district and funding will be stagnant or decline in the next year.

Currently, nearly half of the students are in a remote instruction setting and individuals that are in lower income and minoritized subgroups are less likely to have access to in-person school. Sadly, areas where there is in-person schooling, the incidence rate of COVID-19 is higher compared to area where there is virtual learning. Through their analysis, they found that there are approximately 3 million students that have not had contact with formal education. This presents an urgency to open in-person learning.

Testing availability and interpretation has had a significant impact on educational perceptions, policies, and practice. This has presented challenges when trying to open school causing school districts to be sued by the city over teachers not being able to resume in-person learning. Dr. Bitton presented data on schools and community transmission. Studies suggest that seroprevalence is lower for children than adults, although, this understanding is still evolving as new data is collected. It was found that there is minimal transmission from child or teacher in three school based contact tracing studies. A CDC-authored JAMA Viewpoint, published on Jan 26, 2021, recommended mitigation strategies to be used to continue to minimize the spread of COVID-19.

The <u>Parabola Project</u> was convened to offer education leaders actionable guidance, tools, and strategies to understand and minimize risks while maximizing learning and wellness. To approach this, they focused on:

- Getting kids back to in-person learning requires the best combination of public health and education expertise.
- Schools need to take a comprehensive view of health and educational risks and implement measures to maximize learning and wellness.
- Each community must take into consideration its unique local contexts, but there are common principles that we can organize around.

- Parabola Project resources and tools can help stakeholders and decision makers reflect on the decision to reopen and provides resources if they decide to do so.
- These resources will continue to be relevant into the next school year.

It was stated that the project is not a replacement for state and federal guidelines around school reopening and not a checklist that needs to be implemented. It is a resource for the state and federal government to help them make guided decisions about school reopening.

The decisions around the return to school must reflect a comprehensive view of risk. There must be balance of risks such as the risks of COVID-19 infection, loss of learning, social and emotional impact, reduced detection of child abuse, nutritional insecurity, loss of parental employment and lack of access to essential services. However, through mitigation strategies, this risk can be addressed. With the help of their public health colleagues, they have developed 9 core principles that fall into 3 categories to keep schools safe. Those principles are district/ network level: leadership and culture, risk stratification and prevention, and testing and tracing; school building level: screening and triage, space layout and air quality, and cohorting and scheduling; classroom level: masks and PPE, hygiene, and density and distance.

One challenge that school leaders face is implementation. The Parabola Project has developed a school reopening readiness guide, tools, and examples from other schools. One of the key considerations that need to be taken into account is what is being achieved with testing. The overall goal for testing is to rapidly get students and teachers back to school with minimized disruptions caused by suspected cases and cohort quarantining. The second key consideration is what do school leaders need. Through the analysis, they found that school leaders need clarity on strategies and procedures; testing approaches for different scenarios; and the ability to talk about case rates within a balanced risk viewpoint

CDC has developed guidance and risk assessment variables to guide schools, however, they are not always actionable at the district and school level. Dr. Bitton discussed that there are 3 types of testing (diagnostics, screening, and surveillance) for use in schools that have different purposes and use cases. There have been different testing scenarios that have displayed that strategies vary by the frequency of administration, test sensitivity, and time to result return. In simulation studies, test frequency and time to return were most important in reducing school transmission. Finally, Dr. Bitton shared three testing programs that have been implemented in New York City Public Schools, Los Angeles Unified School District, and Wellesley Public Schools, MA.

Ct Value Preliminary Results (Cindy Wang, PhD & Qingqing Mao, PhD, Dascena)

Dascena COVID-19 PCR testing facilities are broadly recognized for speed, accuracy and efficiency. The COVID-29 testing facility was established with the NIH RadX grant. It is CLIA-certifies, operational 24 hours, 7 days a week, provides results in 24-48 hours, and consists of testing capacity of 20,000 tests per day. Dascena has opened consumer drive thru stations in 10 cities and patients can register for the test and find testing locations via www.Mycovidtest.me. Dascena is the primary testing facility for El Paso Department of Public Health. They have performed more than 150,000 tests since September 2020 in El Paso, Texas. Cycle threshold (Ct) values are the number of PCR cycles needed to detect a positive sample. Theoretically, a lower Ct value means more starting genetic material and a higher viral load. This gave them an opportunity to understand Ct value correlations in a population setting.

There tests targeted three genes from mid-September 2020 through January 2021. Since the N gene is the strongest gene, it is used to measure Ct value. They found that there was a strong variation of Ct value over time. Through their data, they observed strong correlations between the Ct value and the daily Rt and did not see significant lag between the Ct and the Rt values. Dascena did not observe strong Ct fluctuation and correlations in other areas which could be due to the testing coverage and density difference in the El Paso, Texas compared to other cities.

Their next steps consist of combining the Ct measurements with EHR data to study the correlation between Ct and patient outcomes and working on the analysis of Ct values in closed communities such as nursing homes. They are open to collaborations if accelerators are interested.

From the Chat Box

- A caller stated in the chat box that it is true ELR reporting varies by jurisdiction, even though the ELR Implementation Guide. The HHS requirements are tailored to any entity performing COVID. ELR IG was in Meaningful and federal rulemaking/regulations.
- An accelerator asked if the information generated by CVS Health is shared with each of the corresponding EHR systems giving health care to individuals?
 - The presenter responded by stating that federal regulations require all COVID results to be reported to public health departments with HHS elements. However, employee systems are often separate from employee's patient EHRs
 - As a follow up question, an accelerator asked what method is used for reporting to public health? Are the data from the Abbot test being stored in an electronic format for batch reporting?
 - The presenter responded by stating that they do report positive tests to the Department of Health.
 - The presenters collogue stated that Yes, they use the state and federal reporting processes in place--so do the state, per their requirements, and then to the CDC
 - Another caller asked if reporting include negative and indeterminate results too.
 - The presenter stated that it is only the positive tests that are reported but they can check and let the accelerators know.
- Another accelerator stated that as a consumer, you have used your online system intuitive and easy to use; drive through was equally seamless; unfortunately availability still seems to be challenge; having Aetna as my insurer the results were available on my patient portal.
- An accelerator stated availability is a problem in some regions, and in others we have seen demand drop remarkably.
- Another accelerator stated it is very good to see the integration of risks addressed as part of the
 equation rather than just focusing on infection and mortality rates. This is a terribly complex
 situation, and all factors must be considered rather than optimizing policy to a single outcome.
- A caller asked how is the Parabola Project integrating these learnings with other national efforts at dissemination of policy implications? (e.g. David Rubin's CHOP Policy lab https://policylab.chop.edu/project/responding-covid-19).
 - The presenters stated that they are integrated with other public and private partnerships to share lessons learned. They are working with different educational groups also. They presenters stated that they are open to more collaborations and can reach out to the presenters.

- Another accelerator asked what is being done to ensure schools have accurate test methods (i.e. not high false positives or false negatives). Also, surveillance testing on individuals must be performed under CLIA #, and is reportable to public health. (A number of entities don't realize this yet.)
 - Yes, they are performed under CLIA numbers.
- Another participant asked if the Parabola Project is finding that antigen testing programs are seeking confirmatory PCR tests for antigen positive results?
- An accelerator shared that <10 year old with lower rates of infection and spread, some have postulated that may be attributed to less mixing of the population (e.g. not as much switching of classrooms). However, regardless of age, school sports have been associated with transmission.
- Another accelerator asked is there a positivity test rate within a school that is considered so high that it should dictate a school shutdown and going back to virtual?
 - The guideline was 5%, however, this has not been widely enforced. Therefore, there is a lot of confusion as to what is considered high.
- Another accelerator asked are the positive test results being integrated with the EHRs of the individuals?
 - The presenter stated that there is not a regular integration of tests with EHRs unless the testing is done at a health system.
- The presenter stated that states are issuing different guidance on closure rules, most focusing on individual non-related cases within specified schools or cohorts. Unfortunately, school principals are typically doing that contact tracing.
- The presenters for the Parabola Project asked accelerators to reach out if they have any questions
 via email: bitton@ariadnelabs.org and beth.rabbitt@learningaccelerator.org and to check out the
 project at www.parabolaproject.org.
- An accelerators asked Dascena what PCR instrumentation are they using.
 - o The presenter stated that they use Thermofisher Quantstudio 7 machines.

Next Steps

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

Next Meeting: Thursday, February 18, 2021 12-1 pm ET