



COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #31

Thursday, June 3, 2021, 12:00-1:00PM ET

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting 31

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

1. Learnings from COVID Testing (Dr. Will Kimbrough, One Medical)
2. Managing an Emerging Pandemic (Dr. Peter McCaffrey and Juan David Garcia, University of Texas Medical Branch)

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.

Evidence Accelerator Announcement: FDA Launches Challenge to Spur Development of Affordable Traceability Tools as Part of Broader Food Safety Efforts

The Food and Drug Administration (FDA) is calling on stakeholders, including technology providers, public health advocates, entrepreneurs, and innovators from all disciplines and from around the world, to develop traceability hardware, software, or data analytics platforms that are low-cost or no-cost to the end-user to evaluate food safety. If the accelerator community is interested in participating in the challenge, please visit Precision FDA Challenge [website](#) for more information on how to participate.



Tech-Enabled Traceability

FDA Launches Challenge to Spur Development of Affordable Traceability Tools as Part of Broader Food Safety Efforts

One of the goals in the [New Era of Smarter Food Safety blueprint](#) is to encourage the development of creative financial models that are low- to no-cost solutions, proportional to benefits derived from participating, and enable human and animal food operations of all sizes to participate in a scalable, cost-effective way. Toward these efforts, the FDA has launched the FDA New Era of Smarter Food Safety Low- or No-Cost Tech-Enabled Traceability Challenge, which runs from **June 1, 2021 at 8 am ET to 5pm ET on July 30th, 2021**.

Who can enter: stakeholders, including technology providers, public health advocates, entrepreneurs, and innovators from all disciplines (not restricted to U.S.)

Submissions include: submission form, video URL, solution summary

What to develop: traceability hardware, software, or data analytics platforms that are low-cost or no-cost to the end user

Challenge to solve: affordability of traceability technology

For whom: primary producers (such as entities involved in farming, fishing, and animal agriculture), importers, manufacturers and processors, distributors, and retailers and foodservice

Winners: Up to 12 winners will be announced at the completion of the challenge.

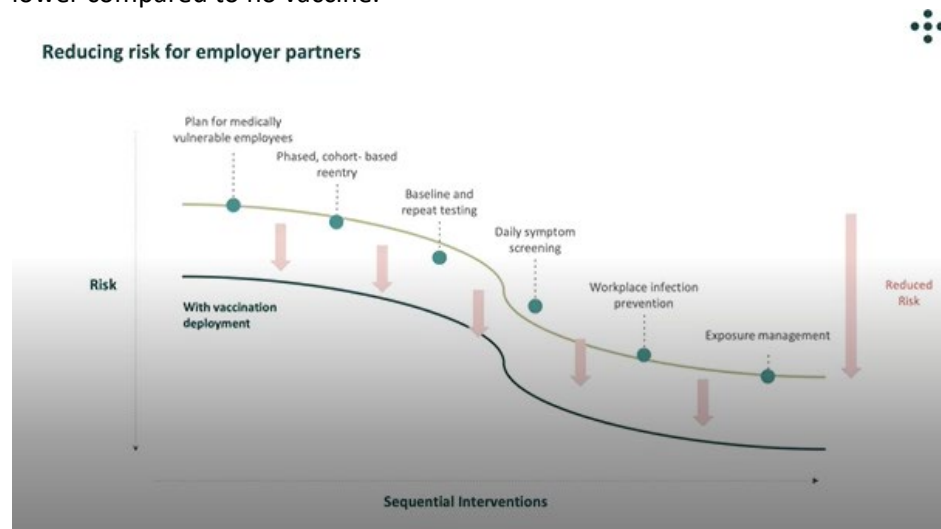
Learnings from COVID Testing (Dr. Will Kimbrough, One Medical)

One Medical is a national organization that focuses on modern primary care. Their patient community includes individuals whose employers have purchased the membership for their employees. At the

beginning of the pandemic, One Medical set up mass testing sites across all cities when COVID-19 testing became available. This has allowed for early testing experience which was leveraged to address testing issues such as employer-based testing.

The clinical framework that was used to approach testing was focused on the Urban areas where COVID-19 cases were significantly higher during the early stages of the pandemic. This allowed the research team at One Medical to understand the disease and disease burden in those areas. Additionally, One Medical partnered with different public health departments across the country to share their experience with setting up mass vaccination sites and gather understanding of how to address the pandemic. Also, One Medical developed COVID-19 educational materials to help keep their provider community informed about the rapidly changing aspects of COVID-19.

Employer based testing, one of use cases for One Medical, was conducted through a stepwise approach. The image below shows how the risk was reduced through the stepwise approach taken. These steps were implemented for One Medical employees also. With the roll out of the vaccination, testing still is essential. The same risk reducing measure are being taken with vaccine deployment, however, the risk is lower compared to no vaccine.



One Medical began deploying tests and setting up testing sites at the beginning of the pandemic. One Medical worked with LabCorp and Quest Labs to plan and adjust the amount of testing that was conducted. During Summer 2020, One Medical began using antibody test. Additionally, they distributed educational materials on antibody and at-home testing to their patients to keep them informed about the rapid changes that were occurring for COVID-19 testing. One Medical began deploying antigen tests during the late summer 2020 when antigen tests were granted an EUA. Finally, in the spring of 2021, over the counter point of care tests received an EUA.

In looking at future of testing after vaccination, One Medication will focus on the following use cases:

- Close proximity settings for employer with low risk tolerance
- Educational settings with unvaccinated students
- First time returning to workplace to help alleviate anxiety
- Ongoing screening for settings of imperfect vaccine uptake and high/moderate community spread
- Enabling rapid testing after an outbreak

Questions and Answers:

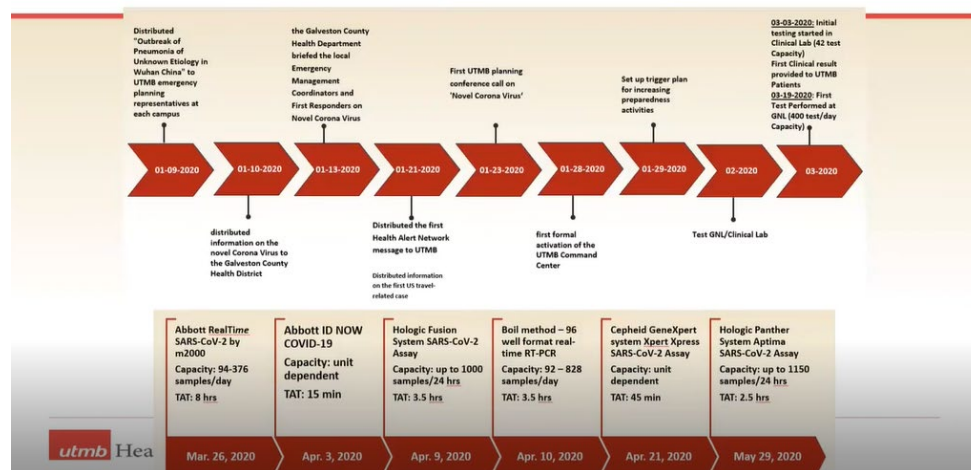
- One Medical is using various testing methods, how do you calibrate those results?
 - One Medical has used 5 different companies that use thermal cycling PCR tests. The lab organizations that they work with are treated as a gold standard when compared to LabCorp and Quest. The way they have calibrated is to match the right platform with the right risk tolerance.
- how is One Medical using serology tests? Through our Evidence Accelerator we are finding that there is a lot of same day molecular -serology testing. We know some of this is for nosocomial infection surveillance. How are clinicians using this?
 - One Medical avoids using same day serology and PCR testing. Currently, serology testing is being used through patient decision. Their hope is to increase the use of serology test in the near future to conduct their use cases.
- Is the data that you capture integrated with other health systems data?
 - There is integration within One Medical's health systems partners, however, not among other health systems partners.

Managing an Emerging Pandemic (Dr. Peter McCaffrey and Juan David Garcia, University of Texas Medical Branch)

University of Texas Medical Branch (UTMB) is a member of the University of Texas system consisting of 13 Academic and health institution. The health system consists of 7 hospitals and the Galveston National Laboratory (biosafety level 4 lab). UTMB has conducted approximately 0.5 million COVID-19 tests.

As early as February 2020, the researchers at UTMB starting addressing the pandemic. By March 2020, they were able to conduct 400 tests per day. Additionally, in March 2021, UTMB designed and implemented a COVID-19 dashboard that captured the number of specimens collected and number of positive specimens. The timeline below shows the events that took place at UTMB to address the pandemic.

SARS-CoV-2 Timeline at UTMB



UTMB communication with and learning from different stakeholders was essential in addressing the pandemic. UTMB worked with the FDA, CDC, Office of the Governor, University President, Texas Medical

Center Executives, Health System Leadership and Laboratory Leadership. The UTMB COVID 19 Dashboard has allowed tracking and trending of COVID-19 cases. The dashboard was essential to the medical and lab professionals to make accurate and evidence-based decisions. The visualization of data included global, country, regional and local and lead indicators, summary plots, and extrapolation. The COVID-19 dashboard consisted of data from multiple databases that were loaded daily and hourly during the peak of COVID-19.

The COVID-19 dashboard provided an opportunity to better understand how to leverage the resources during the COVID-19 Pandemic. This allowed them to address the different challenges that the team encountered during the COVID-19 pandemic. Some of those challenges are staff shortage, reagent shortage, workload volatility, and equipment (e.g., lab analyzers and ventilator) shortage. In order to be prepared for future surges, the research team at UTMB command center used their current model to simulate the number of individuals that will be positive based on the data that they see from previous weeks. If there are deviations to the model, then the team will be able to look into why and implement policy changes as needed.

Leading with data has proven to be important during the pandemic. The COVID-19 Dashboard enabled real-time decisions for staff, supplies, hospitalizations, ICU admissions, and ventilators. Due to this, UTMB was able to safely re-open ORs faster than other local hospitals, meet excess testing demand for other TMC hospitals, and proactively detect infection hotspots. The team is able to look at the data by where there is an uptick in the number of cases and what instrument is being used. This led to policy changes regarding managing COVID-19. The next steps for the team is to understand testing patterns that are seen through their data. Additionally, the team will be working on expanding testing by using robotics to limit human exposures. For COVID-19 vaccine, tracking the data is challenging, however, the team at UTMB is able to track the individuals that have received 1 dose, 2 doses, or no doses.

Questions and Answers:

- How close were the weekly predictions to what was observed subsequently? What were the sources of the variances?
 - The extrapolations were within the 95% confidence interval for positivity. However, there were weeks where the extrapolation was not within the 95% confidence interval. This allowed the teams to observe the deviation and evaluate if this required a policy or behavior change. Additionally, since the team was able to see the location of where the positive test results came from, they were able to advise the location on how to address the increase in cases.

Next Steps

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

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