HHS National COVID-19 Testing Implementation Forum (NTIF)

Meeting #2

Teleconference

Thursday, August 13, 2020

2-3:30 p.m. EDT

The Office of the Assistant Secretary for Health hosted the second meeting of the National COVID-19 Testing Implementation Forum (NTIF). These meetings are being held to gather individual input from a wide range of stakeholders. This meeting focused on surveillance and reopening strategies.

PRESENTATIONS FROM FEDERAL PARTICIPANTS:

The Food & Drug Administration presented on its oversight on testing for diagnostic/screening versus surveillance purposes, stating that it does not typically regulate tests used for surveillance, i.e., monitoring infection levels in a population. The FDA does regulate tests used for individual level diagnosis or screening (when a person has no symptoms or known exposure). In the present emergency, the FDA is allowing test developers to validate tests, including tests for screening asymptomatic individuals, while pursuing FDA approval.

The Centers for Disease Control and Prevention presented on recommendations for testing for COVID-19 in the context of reopening schools. The CDC recommends testing individuals with symptoms of COVID-19 and those who have been in close contact with someone with COVID-19, and isolating them. The CDC does not recommend universal entry testing in schools because such testing poses challenges and has not been systematically studied to show that it would improve disease containment. Policies and guidance are evolving as the situation changes.

The Assistant Secretary for Health said the federal government expects results from surveillance testing in non- Clinical Laboratory Improvement Amendments (CLIA) certified environments not to be treated as diagnostic, and results are not to be reported to individuals. However, it is appropriate to refer individuals who are part of a positive pool to diagnostic testing.

DISCUSSION:

The discussion included clarifications of CDC definition of congregate settings and the FDA definition of rapid tests. The FDA also discussed additional labeling options for test developers. HHS informed the participants that recommendations for how surveillance testing should be linked to the public health system will be written, and there was discussion about the appropriateness of antigen tests for asymptomatic testing in certain contexts.

PRESENTATIONS ON SURVEILLANCE TESTING:

A presenter from University of California San Francisco discussed reopening strategies, stating that it can be considered an engineering problem to solve using existing resources. A fundamental challenge of testing to reopen is that tests from high-risk people (with symptoms or exposure) are being pooled with tests from low-risk people. The demand for screening far exceeds the available testing capacity, and screening tests are clogging the testing system. Samples should be triaged as high vs. low risk, and low-risk samples can be screened in regional high-throughput hubs separate from the diagnostic testing system.

The Rockefeller Foundation presented on its ongoing surveillance testing initiatives, and it believes that aggressively developing a separate screening system would respond to market demand, help institutions like schools reopen, and relieve pressure on the clinical testing system. Industry partners should consider how to dramatically expand screening capacity in time for winter.

DISCUSSION:

The participants discussed the need to sort out issues around test funding, and the fear that loosened testing restrictions could be exploited by unethical actors after the pandemic. An example of using machine learning to predict positive tests results was discussed as an inexpensive approach to help surveillance efforts.

Action Items

- Continuing rapid work is needed to develop COVID-19 screening systems.
- The meeting of NTIF on August 27 will focus on reaching minority communities.
- Further comments or questions may be directed to ntif@hhs.gov.