Week in Review: 12 – 16 October 2020

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

The CDC releases "interim considerations" for school-based coronavirus testing.

Nothing projects confidence and authority like a document entitled "Interim Considerations for Testing for K-12 School Administrators and Public Health Officials." Afterall, what else would the United States Centers for Disease Control and Prevention, the world's leading organization of epidemiologists, offer other than "*considerations*," actual guidelines? Perish the thought.

The document does not disappoint. Published this week, more than a month after most schools opened, topics covered include the various types of tests that might be used, when testing "might" be performed, who definitely *not* to test, and some reasonable, if patently obvious, recommendations on who should be prioritized, in the event that testing occurs at all. The conspicuous emphasis on the hypothetical nature of all of this amounts to something less than workable guidance for local officials and more a love letter addressed to the conditional tense.

Some insights on whom to test include offering that for "people in a school setting who show signs or symptoms consistent with COVID-19 while at school," testing "may be considered." Beyond that something-short-of-game-changing pearl of wisdom, the CDC also allows that asymptomatic students might be tested, if moderate to high community transmission is already occurring. While this may seem trivial and uncontroversial, this itself is among the only notable and clarifying statements to be found in this document; it was not long ago that the CDC found itself embroiled in a controversy related to the need for asymptomatic testing, which the agency first spurned before being pilloried by public health experts and quickly completing a hardly face-saving about-face. (Asymptomatic testing is seen by many experts as one of the most effective ways to stop the spread of SARS-CoV-2, which is known to have a contagious period that overlaps with pre-symptomatic and asymptomatic disease).

But the overall mood of this document is an emphasis on the voluntary nature of school-based testing and a good deal of hand-waving. The CDC explicitly mentions that it is illegal to force anyone to be tested but fails to mention that it is perfectly legal to ban students from attending school who refuse to be tested when testing is indicated by a local policy. From there, the document amounts to a series of questions that local officials can ask when determining what to do next given a variety of circumstances and for a range of possible exposures. Other than suggesting that persons who had known close contact --"within 6 feet of an infected person for at least 15 minutes with confirmed or probable COVID-19"--*should* receive testing and should be quarantined as soon as possible for 14 days, a great amount of ink and pixel is spent listing series of options that officials may, can, or might, consider for various competing contingencies. This would seem to be a useful exercise given that scarcely any actionable expert guidance, let alone novel or practical insight, is supplied. *The CDC. 16 October 2020.* *—Jeremy Samuel Faust MD, MS*

FDA seeks to reclaim trust.

It is no secret that the Food and Drug Administration (FDA) has been involved in controversy since the pandemic started, from the White House decrying regulations to retracted statements on therapeutic options. As such, it comes as no surprise that, "vaccine confidence is at an all-time low," according to Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research. In an effort to restore confidence, Dr. Marks partnered with the American Medical Association through a webinar, in order to outline the agency's meticulous approach to product development.

During this session, Dr. Marks outlined some key components of the FDA's strategy. To increase transparency, the FDA requires vaccine candidates make their data public before advisory committee meetings. He also discussed the pathways for product approval by Emergency Use Authorization (EUA) or biologic license application (BLA), as well as the trial data for current applicants and data requirements for consideration. He emphasized the reliance on large data sets and substantial evidence of compelling advocacy. The interview ended with a projected timeline for roll out, with frontline workers possibly seeing a vaccine product by the end of the calendar year, but called this merely, "informed speculation." *Various*. *14 October 2020*. —*Joshua Lesko, MD*

What's in a name? All about Emergency Use Authorizations.

At *Brief19*, we have extensively covered various Emergency Use Authorizations (EUAs) that the Food and Drug Administration (FDA) has issued since the start of the pandemic, but we have not stopped to take a closer look at what an EUA truly is. Until now.

The FDA states that EUA authority allows the FDA "to help strengthen the nation's public health protections against CBRN [chemical, biological, radiological, or nuclear] threats by facilitating the availability and use of MCMs]means medical countermeasure] needed during public health emergencies." The legal ability to issue EUAs was granted to the FDA under the Federal Food, Drug and Cosmetic Act, which allows the FDA commissioner the broad ability to allow unapproved products or unapproved uses during an emergency to diagnose, treat, or prevent serious or life-threatening conditions when there are no "adequate, approved, and available" options. Many of the EUAs granted since the start of the pandemic mention the public health emergency declared on January 31, 2020, but such an announcement itself does not endow the agency with the ability to grant EUAs indiscriminately. Of note, the FDA publishes guidelines for all manufacturers applying for EUAs in terms of data, oversight, and any other requirements for consideration. *The Food and Drug Administration*. *13 October 2020*. —*Joshua Lesko, MD*

FDA issues EUA for first multiplexed diagnostic test.

Late last week GenMark Diagnostics, a laboratory test manufacturer, was granted an Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) for its ePlex Respiratory Antigen Panel 2, a new rapid molecular test that can distinguish between over twenty viruses and bacterias, including the coronavirus SARS-CoV-2 that causes covid-19.

In explaining the decision, the FDA acknowledged that there were other products that test for these same pathogens, but currently no multiplexed tests for "simultaneous qualitative detection and differentiation of nucleic acids" and that a need for such differentiation existed.

Like many other coronavirus tests, this one uses a nasopharyngeal swab sample collected by a healthcare provider and analyzed in a special medium. Because of the method of evaluation, this device is not intended to be a point-of-care product; this means that tests will be run in centralized laboratories that have samples delivered to them. This process can leads to substantial delays between the acquisition of a test and the results. *The Food and Drug Administration. 12 October 2020*. —*Joshua Lesko, MD*

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Brief19 is a daily executive summary of covid-19-related medical research, news, and public policy. It was founded and created by frontline emergency medicine physicians with expertise in medical research critique, health policy, and public policy.