

## **BRIEF19**

*A daily review of covid-19 research and policy.*

### **POLICY BRIEFING**

#### **Interim guidance on changes in CDC procedures.**

Back in February, *Brief19* [reported](#) on efforts announced by the US Centers for Disease Control and Prevention (CDC) to depoliticize the agency and focus on promoting evidence-based and scientifically-validated recommendations. As a result, the CDC recently [released](#) its review on changes being made across the board at the agency.

The Principal Deputy Director for the CDC, Dr. Anne Schuchat, conducted interviews with incident managers of various Emergency Response task forces within the CDC, public health stakeholders, and career staff. The general findings of existing materials were that many documents were not primarily authored by CDC staff, relied on more suggestive (versus directive) language, and that the data to support some decisions was not consistently readily apparent. The report also included the following changes to existing documentation.

Guidance removed:

- “The Importance of Reopening America’s Schools this Fall.”
- “Overview of Testing for SARS-COV-2.”
- “Opening Up America Again,” linked on the CDC’s website.

Also included were several reports recently (or soon to be) released, covering phased prevention, school guidance, targeted testing, exemption from quarantine following natural exposure versus inoculation, masking, and travel.

As data on potential and currently authorized vaccines are published, the agency will monitor and update its recommendations accordingly.

With regards to science, the CDC’s website has been overhauled to make landing pages cleaner, easier to understand, and optimized to make the supporting science more evident. Overall, this iteration of the agency seems committed to removing or minimizing politics from its process and increasing the transparency of the factors guiding their decisions. *The Centers for Disease Control and Prevention*. [19 March 2021](#).  
—*Brief19 Policy Team*

#### **FDA streamlines path for screening of asymptomatic individuals.**

On Tuesday, March 16, the US Food and Drug Administration announced plans to streamline the path for coronavirus screening for asymptomatic individuals in non-medical settings and provided information to groups establishing testing programs. This news comes at the one-year mark of the public health emergency of this pandemic.

The FDA will allow some developers of the tests to market their products for regular at-home use, with the aim of making it easier to screen Americans returning to school and work as sectors of the economy reopen. FDA medical device director Jeff Shuren and diagnostics director Tim Stenzel said in a joint statement, “We believe this effort will pave the way for further expanding the availability of tests authorized for screening asymptomatic individuals, help bolster existing and new testing programs and increase consumer access to testing.”

While some rapid coronavirus tests are somewhat less accurate in identifying infected but asymptomatic individuals (as compared to symptomatic persons), the FDA’s new policy aim is that with repeated testing over time, there can be improved overall accuracy of results.

The FDA also issued a fact sheet for those interested in setting up screening programs, offering a “streamlined path to emergency use authorization for these important screening tools,” according to Shuren and Stenzel’s joint statement. Companies will now be able to apply for permission to market

an over-the-counter test for at-home use or at the “point-of-care,” in public settings if there is evidence that any particular test performs well in symptomatic individuals and if repeated testing can help to avoid false results. The emphasis on repeat testing is the crux of an argument about rapid tests [covered previously](#) in *Brief19*: testing *regimens* should be evaluated for their ability to rule out infection, not one-off tests.

The FDA sees this streamlined path for test developers as a way to support the serial testing strategy recommended by the US Centers for Disease Control and Prevention, which recommends serial testing at least once per week along with other mitigation measures such as masking and social distancing to reduce transmission of SARS-CoV-2.

However, even as the FDA is now facilitating this serial testing strategy, its fact sheet emphasizes that even serial testing “is of limited value if it is not combined with appropriate mitigations for individuals who test positive (such as quarantine, good contact tracing, and behavioral protocols.” [18 March 2021](#).  
—*Miranda Yaver, PhD*

### **Mass vaccination sites are working. But they require mass coordination.**

The need to vaccinate an entire country—an entire planet—in a short period of time has never been so urgent. As a result, mass vaccination sites have popped up in places like Dodger Stadium in Los Angeles and Gillette Stadium in Boston. These sites have certain advantages. Everyone knows where they are and they are built for high volumes of traffic.

But as my colleagues wrote last week in the [New England Journal of Medicine](#), the logistics around mass vaccination sites are complicated. For covid-19, municipalities have been learning on the fly. The lessons learned can help other jurisdictions ramp up now, and all locales in future pandemics.

The main challenge is coordinating the various actions that lead up to the moment of injection and the ones that follow. (Getting volunteers and a place to give the shots is not quite enough). You need language interpreters. You need to make sure people know how to schedule their booster shots. You need to troubleshoot in real time. Even the flow of movement needs to be anticipated and adjusted as needed. To address problems, managers improvising solutions are needed; one satisfying solution offered to a bottleneck was simply to rotate the registration desks, so as to allow better views for the workers. This was reminiscent of the Homeland Security finding that the single best way to make airport security lines move more quickly was not to add more helpers, or make changes in the flow of movement, but simply to add more tables for people to pile their stuff on to, while awaiting the x-ray machine.

Mass vaccination sites can jumpstart a region’s inoculation program. But they are not meant to be the only way to reach people. Bringing vaccines directly to communities that are less able to reach municipal stadiums is equally important. But the message is clear: if 2021 is going to be mark a return to normalcy, ironing out the logistics of vaccinations for all must be a top priority. [16 March 2021](#).  
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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.