Week in Review: 5 – 9 October 2020

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

Here we go again. Are we seeing the feared Fall surge?

A new analysis of case data through Tuesday gathered by Johns Hopkins University's covid-19 tracking website shows thirty-nine states around the country are once again facing rising numbers, reporting more weekly cases than the week prior. As if this were not enough, nine states (Alaska, Indiana, Kansas, Kentucky, Minnesota, Montana, North Dakota, Utah, Wyoming) set state records. In similarly grim milestones, North Dakota and South Dakota now hold the record for most per-capita coronavirus cases in the United States.

Across the country, stricter enforcement of social distancing measures, extension of Personal Protective Equipment use requirements and the return of business closures are just some of the measures being deployed in an effort to slow or stop the spread. Many states' contact tracing programs are buckling under the new load and rural locations are starting to activate alternative treatment sites as the number of hospitalized patients is climbing. All of this comes ahead of influenza season, making the coming months possibly more daunting. The 1918 H1N1 pandemic saw astronomical case surges in October and November. *Various. 9 October 2020. —Joshua Lesko, MD*

Turning the screws on hospitals not reporting data to HHS.

In late September, the Centers for Medicare and Medicaid Services (CMS) confirmed that they would begin halting Medicare funding to hospitals that did not report daily coronavirus data to the Department of Health and Human Services (HHS) online portal. This past summer, hospitals were instructed to bypass the usual reporting to the Centers for Disease Control and Prevention, and instead provide data to HHS, an agency with far less experience and far less equipped to carry out such epidemiologic functions.

In a call earlier this week with reporters, CMS Administrator Seema Verma announced hospitals had fourteen weeks to come into compliance or all funding would cease. Additionally, relevant influenza data would need to be included in the updates. Given that most treatment facilities were already opposed to an unfunded mandate requiring extensive administrative resources in the middle of a pandemic, this addition will likely be met with similar apprehension and frustration. *Various. 9 October 2020. —Joshua Lesko, MD*

Confirmation of new transmission vector; CDC says some airborne spread possible.

The Centers for Disease Control and Prevention (CDC) has been under significant scrutiny during the pandemic, most recently for conflicting messaging on whether or not the novel coronavirus can be transmitted by airborne methods.

On Monday, the CDC updated its transmission page, confirming the possibility or airborne transmission. While acknowledging that there are some instances wherein particles can remain in the air for hours, the agency implies this is limited to situations where infected individuals are breathing heavily, as when exercising and when in enclosed spaces, but emphasizes that the primary method of transmission remains through extended close contact. This close contact still includes spread through the air, though; the distinction is whether viral particles are transmitted in the air from one person directly to the next (droplet spread) or whether particles floating for hours can infect others who have not been in close physical contact with an infected person.

Despite this new information, the CDC has made no changes to any physical or social distancing recommendations. *The CDC. 7 October 2020. —Joshua Lesko, MD*

Vaccine update: White House turns on its own Food and Drug Administration.

The Food and Drug Administration has squandered enormous credibility throughout the covid-19 pandemic. The main source of its perceived dysfunction has been several emergency use authorizations granted during the national emergency. These authorizations have included the use of hydroxychloroquine (later revoked), permitting unvetted coronavirus antibody tests to be marketed and sold (later revoked), and other unwise moves including what many experts consider to be unwise actions related to permitting the emergency use of convalescent plasma without ample evidence and while downplaying substantial known risks.

Now the White House is moving to block the FDA's attempt to maintain control of the vaccine approval process. A strict guideline proposed by the FDA and sent to the White House has been "deep sixed"—meaning the administration is killing and burying it.

This leaves two major options that might prevent the White House from all but forcing the FDA to approve a vaccine before adequate safety and efficacy data are known. The FDA might be able to get its guideline approved by outside experts (an "end around"); alternatively, the biotechnology companies may heed messages like those in an open letter written by Dr. Zeke Emanuel (signed by 60 others, myself included), requesting that companies police themselves and not release premature data. *The New York Times. 6 October 2020.* *—Jeremy Samuel Faust MD MS*

"Warp Speed" may have blown past solutions.

Since President Trump's hospitalization, there has been a renewed focus on different coronavirus treatment modalities. Monoclonal antibodies in particular have drawn interest, as therapy experts are now saying was passed over by Operation Warp Speed given its narrow focus on developing a vaccine. While a vaccine would eventually prevent future outbreaks, treatments would allow for reactive solutions to limit the spread of confirmed cases and serve as an augmentation to a prevention campaign.

Monoclonal antibody therapy mimics the body's natural immune response and shows promise as a therapy and potential prophylaxis for high risk populations. While currently under development, President Trump was treated with monoclonals developed by Regeneron under a special access program. Like most of the efforts in diagnosis and therapy during the pandemic, wider use would require an Emergency Use Authorization by the Food and Drug Administration, which allows a line-jumping of sorts, while more rigorous data is collected to confirm efficacy.

Under Operation Warp Speed, the administration has spent less than $1 billion on therapeutic options, representing just 10 percent of vaccine development spending. Despite the limited federal funding, pharmaceutical companies say variations in infection prevalence have also delayed their efforts in enrolling adequate patients for study. Finally, even if an EUA is granted, initial supply scarcity and a high price tag may limit the actual benefits. *Politico. 5 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.