Week in Review: 27-31 July 2020

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

Health justice demands global supply of remdesivir. If not for patients in Liberia, Guinea and the Democratic Republic of Congo, no large-scale clinical trials of remdesivir would exist right now. A commentary traces the history of remdesivir and its origins as a novel treatment for the Ebola virus. Because of these willing patients, Gilead (the company that manufactures the drug) was able to conduct necessary safety trials, ultimately proving the drug was safe for humans, although it was not found to be effective against Ebola. With human safety trials therefore already having been completed years ago, Gilead was able to quickly secure orphan drug approval from the FDA in March and subsequently proceed to effectiveness trials. In a cruel twist however, the very same patients who risked their health as participants in early clinical trials for Ebola have no current access to the drug during the covid-19 pandemic, as the U.S. has purchased the entire global supply and has shown no indication of any willingness to share it. The issue of global access to costly drugs is not new to Gilead, as the company has faced criticism of its distribution of HIV and Hepatitis C drugs in the past, even finding ways to reap benefit by donating some of its products. The commentary authors suggest that Gilead place the patent for remdesivir in a United Nations patent pool that would facilitate low-cost generic manufacturing of the drug. Regardless of the lingering questions as to remdesivir's effectiveness, it seems unconscionable to deploy the drug domestically knowing that those who paved the way lack access themselves. *28 July 2020*. —*Kimberly Chernoby, MD JD*

The FDA seeks home-based coronavirus tests. Will they work?

The United States Food and Drug Administration released a statement Wednesday calling for commercial developers to create and send proposals for home-based SARS-CoV-2 tests. The FDA specified that the tests should be able to be completely performed at home or anywhere that is not a laboratory or medical facility and that interpreting the results should not require any external help. In other words, non-medical professionals should be able to take the tests themselves and read the results, without any additional assistance other than what the test kit contains. Interested companies are invited to send the FDA proposals.

The agency also released a document with a template and guidelines for would-be manufacturers of such tests. Among other requirements, manufacturers must describe to the FDA how the tests work. The tests would not necessarily require a prescription and could be sold over-the-counter. The FDA outlined different requirements depending on whether the tests are intended for symptomatic for asymptomatic people. For example, tests intended for symptomatic people only would be available by prescription while tests meant for both symptomatic and symptom-free persons would not necessarily require a prescription. For each type of test, the manufacturers must report the product's agreement with existing tests that have already been approved. While agreement of positive results must be at least 80 or 90% with established tests currently on the market, negative results must be more than 99% in agreement with currently approved tests. This makes sense as the implications of a false positive are less dangerous than false negatives. Additionally, for every test, there must a clear way for persons taking the test report positive test results to officials. Finally, applicants must have evaluated how the tests perform (and whether they remain accurate) in various temperatures, humidity, and light. Given all of the complexities (and in some cases software for apps that would be used for reporting of results), some experts worry that the FDA's template will be too difficult for most manufacturers to achieve in a way that is not prohibitively expensive for most people. *The Food and Drug Administration. Abbreviated from Brief19 for 30 July 2020.*

—Jeremy Samuel Faust, MD MS

The CDC updates its isolation guidelines.

Last week the Centers for Disease Control and Prevention (CDC) updated its isolation guidelines based on updated epidemiologic data. The new supporting evidence essentially shows that viral load and the chances of replication-capable transmission (i.e. contagion) decreases after symptom onset. The data also suggest that serologic evidence of infection–blood tests for antibodies which indicate prior infection and which likely imply some level of immunity–may persist for months. To date there have been no confirmed documented cases of reinfection, though experts have debated whether some patients who recovered from covid-19 who later had similar symptoms and who retested positive for SARS-CoV-2 were actually reinfected, or whether the causes of these second illnesses were unrelated, but just occurring in patients who were still shedding detectable though not contagious levels of the novel coronavirus.

Based on all of this, the CDC's new recommendations are as follows: for most coronavirus infections, isolation may be terminated ten days after symptom onset and twenty four hours after the last occurrence of a fever; those with confirmed infections who never display symptoms may now cease quarantine ten days after their first positive test. In general, serology-based decisions (blood tests for antibodies) to end quarantine are only recommended in severely immunocompromised patients and in consultation with infectious disease experts, or when the results would indicate that it would be safe to discontinue isolation before the ten day period had elapsed. The CDC is discouraging routine serologic retesting within three months, with exceptions for patients who develop new symptoms without an alternate explanation. Finally, serologic testing should not be used to establish presence or absence of infection. *The Centers for Disease Control and Prevention. 27 July 2020.*

–Joshua Lesko, MD

CDC releases school reopening statements. No specific guidelines provided.

After initially delaying the release of its school reopening guidelines under reported pressure from the White House, the Centers for Disease Control and Prevention (CDC) has published the new recommendations. Without specifically recommending re-opening, the document strikes a pro-opening tone, citing the decreased rate of infection and mortality among children, as well as the emotional and behavioral harm incurred by school closures, especially for underprivileged children or those with disabilities. The paper discusses reports low rates of transmission between student and teacher, with the important caveat that this has only been demonstrated in areas with low community transmission. The argument for re-opening focuses on the role in-person education plays in student education, safety, nutrition, and physical activity. Missing from this document, unfortunately, are any concrete steps or recommendations for how schools can achieve safe reopening, from use of social distancing to sanitization procedures. *The Centers for Disease Control and Prevention*. *29 July 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.