Week in Review: 17-21 August 2020

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

Plasma therapy not ready for prime time.

Last week, the Food and Drug Administration was on the verge of completing an Emergency Use Authorization (EUA) to allow blood plasma from recovered coronavirus patients to be used as a treatment for the virus, when a group of federal health experts banded together in an effort to stop its finalization. Led by Dr. Francis Collins, the Director of the National Institutes of Health (NIH), Dr. Anthony Fauci, the director of the National Institute of Allergy and Infectious Disease (NIAID), Dr. H. Clifford Lane (NIAID), and members of the White House coronavirus task force, this group believes that the data on plasma efficacy is not yet robust enough to warrant an EUA issuance. The main concern is that many of the published studies have conflicting results on the true benefit of plasma, with differences in time to intervention, concentration of plasma components, and the severity of patient illness in the trials, all of which complicate the overall picture.

A randomized trial assessing the use of convalescent plasma (antibodies recovered from patients who have survived covid-19) for the treatment of covid-19 published in *JAMA* in June showed no benefit. A recent non-peer-reviewed article (published on a preprint server) that combined results from multiple studies of plasma purported to show that the treatment works; however, two of the three major studies included in the paper's main analysis have themselves not been peer reviewed, creating an unusual situation in which a preprinted review article heavily relied on data from preprinted research articles. In addition, the methods of at least one of the major articles included in the review have come under fire; the authors of a study conducted in Iraq claimed they performed a randomized controlled trial (RCT) of the effect of plasma on patients with serious covid-19, when in fact it appears that the methods used were not truly consistent with RCTs.

However, Drs. Collins, Fauci, and Lane focused their arguments against moving forward with an FDA emergency use authorization for convalescent plasma largely on the fact that the support for plasma relies on shaky historic evidence of plasma's effectiveness, animal studies, and a few human studies. These experts requested more time be given in order to review the pool of existing and emerging data and to develop rigorous study protocols that would definitively ensure that plasma provides benefit to covid-19 patients. There are multiple trials of plasma currently underway in several nations around the world. *The New York Times and others. 21 August 2020.*

New pilot for rural healthcare. The Centers for Medicare and Medicaid Services (CMS) has announced a new pilot program called the Community Health Access and Rural Transformation (CHART), aimed at improving rural healthcare systems. As nearly twenty percent of Americans live in rural communities with a disproportionate number of comorbidities, covid-19 cases are rising (as *Brief19* covered in April). With a significant number of hospitals facing closure due to financial strain, the covid-19 pandemic has had an especially devastating effect on access to care in these communities. To combat this, CMS has developed two models under this new pilot. The Community Transformation Track will provide up to $5 million up front to fifteen organizations with follow-on capitated payments. The Accountable Care Organization (ACO) Transformation Track will give twenty ACOs advanced payments as part of the Medicare Shared Savings Program. The goal of this split aim is to investigate whether these organizations benefit more from early investment or faster payments for existing services. *Various. 19 August 2020.*

Salivating for samples. A new test for SARS-CoV-2 moves forward. Over the weekend the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for a novel means of testing for coronavirus, specifically using saliva samples. Developed by the Yale School for Public Health, the "SalivaDirect" process has several features that make it an attractive alternative for testing: any sterile specimen container may be used for collection, it bypasses a nucleic acid extraction step (often the equipment-limiting phase causing delays in other tests), and has been validated and authorized on a variety of reagents and equipment, allowing greater generalizability. It does not require any special swabs, which has been a bottleneck in some areas. The protocol has been released (and is open source). Because it does not require any proprietary equipment or materials, the new test should be easily integrated into most testing facilities. A prepublication release of a study on the test's effectiveness showed greater than 94 percent concurrence with nasopharyngeal swabs. However, prepublication releases of research findings have not been vetted via the traditional peer review process and as such outside verification is still necessary *The FDA. 17 August 2020.*

—Joshua Lesko, MD

Americans get more than ballots by mail. They also get their medications. The Trump Administration has claimed that voting by mail might compromise the integrity of the general election in November, despite the fact that there is no evidence to suggest widespread fraud has occurred in the past or will occur. Nevertheless, the administration has turned undermining the United States Postal Service into a political tool, with reports of mailboxes being removed all over the country last week. Here's the problem. Many Americans rely on the mail to receive their prescription drugs (let alone their paychecks and bills). Policies that intentionally slow down the delivery of mail could lead millions of Americans to lose access to medications that they rely on, ranging from medications that reduce the odds of heart attacks and strokes to diabetic crises. This could cause a massive increase in demand in Urgent Care clinics, doctors offices, and emergency rooms. A slowdown in the flow of mail--which we note is a completely preventable choice being made by government officials in Washington--could not come at a worse time. As the fall approaches, cold and flu season is expected to increase demand for all kinds of medical services, regardless of the continued extent of the covid-19 crisis. The American College of Physicians (ACP) released a statement yesterday highlighting these problems. The ACP has over 163,000 internal medicine physicians (internists) as members and is the largest medical specialty organization in the United States. It is unusual for the ACP to make statements related to public policy that are not explicitly related to health and medicine. However, in this case, the ACP has correctly identified the potential for medical mayhem that the administration's reckless policy stands to impart. After substantial outcry from the public, it was announced that no more mailboxes would be removed from city streets for now. However, removal of mail sorting machines, which are away from the public eye, may continue. With the health of millions of Americans on the line, it is worth noting that those over 60 years old have traditionally had the highest rates of voting. Older voters are also the most likely to use vote-by-mail options. *18 August 2020.* *—Jeremy Samuel Faust, MD MS*

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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.