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BRIEF19

A daily review of covid-19 research and policy.

RESEARCH BRIEFING

Why does universal testing for SARS-CoV-2 matter? A [preprint](#) publication in medRxiv describes a large covid-19 outbreak at a homeless shelter in Boston. The report has implications for universal testing as 36 percent of residents were found to be positive for SARS-CoV-2. In late March, a cluster of fifteen cases over a 5-day period were discovered. Each patient was removed from the shelter at time of diagnosis. Researchers then performed SARS-CoV-2 PCR testing on all remaining residents of the shelter over a two-day period. A total of 408 individuals were tested. The mean age was 51 years, 72 percent were male, 33 percent were black or African American, and 19 percent were Hispanic or Latino. Symptoms and signs such as cough, fever, and shortness of breath were uncommon among the positive patients. Among residents testing positive, 8% reported cough, fewer than 1% reported shortness of breath, and 6 percent reported other symptoms including diarrhea. The authors noted the apparent rapid spread of the virus despite infection control vigilance. The remarkably high number of asymptomatic individuals further provides evidence that universal testing may prove beneficial in protecting the homeless population. However, the need to screen as much of the entire population as possible is becoming increasingly apparent.

--Christopher Sampson, MD, FACEP

What's going on with Gilead's remdesivir clinical trial? Concerning news emerged on social media on Friday when some observers noted that Gilead Sciences, the pharmaceutical company that makes remdesivir, has once again [changed the protocol](#) of their phase 3 randomized clinical trial to assess for effectiveness in treating covid-19. (Remdesivir is an investigational drug that is not approved for any condition.) The sample size in the previously published protocol stated that 2,400 patients would be recruited to the study. That plan has now been altered and increased to 6,000 patients. Such an increase in the number of patients the researchers intend to recruit for the study led some [observers](#) to believe that Gilead's preliminary data might be disappointing, and that a larger study might find a smaller but statistically significant benefit. On the surface, this suggests that patients are likely not to be benefiting from the drug in a game-changing way. For example, if patient response was overwhelmingly positive, the trial would have to be halted "for benefit" on ethical grounds, so as not to deprive patients receiving placebo from a treatment that is unequivocally helping the other patients. But by enrolling more people, the researchers might be hoping to salvage the trial, looking for a small signal of benefit. Though speculative, this news is worrisome for those hoping that this medication would turn the tide in this pandemic

--Joshua Niforatos, MD, Research Section Editor.

POLICY BRIEFING

Non-profit vaccine may be available in early 2021. Johnson & Johnson announced during their first quarter earnings call that it hopes to bring a [vaccine](#) for SARS-CoV-2 to market early next year. CEO Alex Gorky said that the company was "committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use." More than \$600 million of government funding has been earmarked for Johnson & Johnson's vaccine and antiviral research and development. The company also announced that they will be scaling up production on its vaccine candidate soon, long before they have Food and Drug Administration

approval to use the vaccine in the United States. Phase I trials to assess safety in a small number of patients are likely to begin in September. *Politico*. --Jordan Warchol, MD, MPH.

Compounded sedation now available. Responding to widespread fears about the availability of sedative, paralytic, and pain medications used for patients on ventilators, the Food and Drug Administration (FDA) has issued [temporary](#) guidance to allow compounding pharmacies to make several drugs in short supply. The Drug Enforcement Agency typically maintains tight control over the manufacture of the medications, including opioids such as fentanyl and hydromorphone, due to the increased risk of misuse or diversion (i.e. the illegal selling of medications obtained by prescription). In its announcement, the FDA acknowledged that increased use of the medications for patients being treated for covid-19 as well as concerns about global supply chains fueled the decision. The list of medications approved for compounding currently includes thirteen drugs, but the list may be expanded if the need arises. *The Food and Drug Administration*. --Jordan Warchol, MD, MPH.

Is Counting Covid-19 Death Toll State Dependent? The covid-19 death toll in the United States is believed to be undercounted due to the limitations in [testing](#). As recently as April 4th, the Centers for Disease Control and Prevention stated that their tallies only include deaths with confirmed laboratory testing--which likely leads to underestimation. In response to recommendations from the Council of State and Territorial Epidemiology, the CDC recently updated its website and now explicitly states that unconfirmed coronavirus cases may be reported and counted. With conflicting information, many states have interpreted policies on counting covid-19 deaths differently. Some have begun rethinking their approaches. Alabama, for example, has determined that 1 in 10 patients who die *with* covid-19 did not die *from* covid-19. Meanwhile, Colorado has included deaths where coronavirus was seen as probably, based on the patient's symptoms and possible exposures. The drastic differences counting methods can make was illustrated by New York City this week when authorities reported that the deaths of individuals suspected of having covid-19 (but who were never tested) may have increased the number of covid-19-related fatalities by over 3,700 people. Some states now report two numbers (probable vs confirmed cases) while others like Pennsylvania include probable cases in the number of total deaths only. While the response coordinator of the White House coronavirus taskforce, Dr. Deborah Birx, in an April 7 briefing stated that the USA is counting deaths of people with underlying conditions as covid-19 deaths unlike other countries, this does not seem to be the case in every state. Furthermore, an Alabama coroner has reported that deaths appearing in the state death toll are taking several days to appear giving people a false sense of security. Health officials in multiple states believe that their approach to counting covid-19 deaths is the most accurate. Without consistency of death counting, it is even more difficult to assess what states and counties need the most help during this pandemic. *The Washington Post*.

--Annie Gensel

*Kimi Chernoby, MD JD, Policy Section Editor. Kane Elfman PhD, Publishing and Design.
Jeremy Samuel Faust MD MS, Editor-in-Chief.*

<http://www.brief19.com/>

Twitter: [@brief_19](#)

submissions@brief19.com

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.