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## **BRIEF19**

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

### **RESEARCH BRIEFING**

#### **Two SARS-CoV-2 vaccine trials report progress in world's first Phase II data.**

As the covid-19 pandemic unfolds and spirals out of control, a two-part strategy remains our only hope in limiting the final number of dead. The first, so-called non-pharmacologic interventions, aim to slow down the spread of the virus. These efforts include physical distancing, mask wearing, and improved hygiene. Taken to extremes, such measures could eradicate the virus. But most countries have not shown the willingness or capability of achieving that with these strategies alone. Therefore, in essence, non-pharmacologic interventions have two purposes. The first is to flatten the curve so that hospital capacity is not a factor in our ability to save lives using finite resources such as mechanical ventilators. The second is to buy time for the other major strategy in getting out of this crisis with the fewest deaths: pharmacologic interventions. While therapeutic drugs play a role—for example, the steroid dexamethasone was recently shown to improve mortality among covid-19 patients requiring mechanical ventilation by 11 percent—it is unlikely that a medicine or even a cocktail of them will be sufficient. No, the great hope remains in a vaccine.

While hundreds of potential candidate vaccines have been identified by researchers all over the world, fewer than a dozen are registered in active clinical trials. Of these, just two have posted results from phase I trials (both covered in *Brief19* [previously](#)) which by definition only assessed a handful of subjects, and with no control arms. The two studies appearing yesterday in *The Lancet* both describe results from Phase II trials, one conducted in the [United Kingdom](#) and one in [China](#). Both studies reported on findings that utilize a similar technology—genetic material is introduced to the body via a weakened common cold virus (called an adenovirus). The “Ad5” virus is specially encoded with the genetic code for an important “spike” protein of SARS-CoV-2. It infects human cells which in turn read the genetic instructions and produce the viral protein. While the virus is not capable of replicating, the eventual protein the cells are co-opted into making is recognized by the body's immune system, which responds to by creating antibodies and, crucially, T cells, which remember the shape of the protein for far longer and, hopefully, ward off future infections. Adenovirus vaccines were not approved for widespread use until recently.

Both of these new trials randomized subjects to receive either the candidate vaccine or a control. Both reported encouraging responses. Signs of vigorous immune responses were observed in each of the trials. In the UK study, a smaller subset of subjects received a booster shot, which also appears to have strengthened the response. It is encouraging that the measured magnitudes of the immune responses found in subjects in both trials was similar in both trials, comprising a kind of immediate replication of the findings found in each study.

While side effects like feeling feverish were very common in both studies (slightly less in the study from China, but both hovering around 50%), the use of the European equivalent of Tylenol/acetaminophen (known as paracetamol) lowered symptoms substantially without a loss in immune response—albeit even with the use of the symptom-relieving drug, rates of many side effects were still high (feeling feverish dropped from 51 percent to 36 percent in the UK study).

Several hurdles remain. While these studies show the overall safety and potential effectiveness of these vaccines, the reality is that there is no guarantee that the responses detected

in cells means that the vaccine recipients will be immune or less likely to either experience a serious future infection by SARS-CoV-2 or be less contagious. That information will only be gleaned from Phase III trials, which are already underway. However, if bothersome side effects, non-serious though they may be, are as frequent as described in these studies, getting people to sign up to receive the vaccine may be another barrier to ending this pandemic.

–Jeremy S. Faust, MD MS

## **POLICY BRIEFING**

### **Congress races to pass a relief package before August recess.**

With only two weeks to go before the yearly August recess, the US House and Senate have only about six working days to [develop](#) and pass the next coronavirus relief package. This fifth package is expected to authorize trillions of dollars in spending, similar to the previous legislation. Where the money will be spent is still in debate.

Republicans including Senate Majority Leader Mitch McConnell of Kentucky have stated they will not pass a relief bill unless liability protections are included. As [described](#) by the GOP, such protections would prevent frivolous lawsuits regarding coronavirus transmission against businesses such as healthcare institutions, grocery stores, and factories so long as they followed public health guidelines that were recommended at the time. Democrats have prioritized continued economic relief for individuals, including extending the increased unemployment insurance payments, although it is unclear if that increased amount will be maintained at \$600 as there have been concerns that the additional payments may have prevented some on unemployment rolls from returning to work. Other priorities for Democrats include measures to support food security, increased aid for state and local governments, and another round of individual stimulus checks. President Trump has been pushing for a payroll tax cut which would increase the take-home pay of those who are still employed. However, that relief would not help Americans who have lost their job as a result of the economic downturn caused by the pandemic.

Lawmakers and their staffs will return to the Capitol this week as cases of covid-19 are increasing in many areas around the United States. Leaders from both parties have been discussing how to protect their members from coronavirus transmission. After yet another Congressman tested positive for covid-19, the House Republican conference will be instituting new rules at all meetings including mandatory masks and temperature checks. House Speaker Nancy Pelosi, a Democrat from California, [previously](#) required that masks be worn at all Committee hearings and on the floor of the House.

–Jordan M. Warchol, MD, MPH

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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.