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BRIEF19

A daily review of covid-19 research and policy.

RESEARCH BRIEFING

Coronavirus vaccine based on genetic material reports Phase 1 results.

There is currently no treatment for covid-19 with full FDA approval in the United States. A safe vaccine that provides long-lasting immunity would quicken the world's recovery from this pandemic.

The authors of [a new study](#) appearing in *The New England Journal of Medicine* published evidence that an mRNA vaccine made by Moderna Therapeutics did not show signs of being toxic, was well-tolerated, and induced the production of antibodies against the Spike protein, a component of the virus thought to be responsible for the virus' increased virulence. In this Phase 1 trial, 45 volunteers with no detectable coronavirus received two shots 28 days apart. The 45 participants were divided into three groups depending on whether they received 25, 100, or 250 micrograms of the vaccine. Three out of 15 participants in the highest dose group had severe adverse effects, including a large red rash and one episode of passing out.

An [mRNA vaccine](#) is a novel approach in the world of biosciences. Moderna's vaccines would be the first approved for human use based on this recent technology. Instead of the usual approach of baiting the immune system with a weakened (or killed) form of a virus, mRNA vaccines act like a patch or software update for the genome of immune cells. One upside of mRNA vaccines is that they do not integrate into the DNA of the host's cells. This means they are less likely to have the side effects associated with similar vaccines that are made from DNA. A downside is that mRNA vaccines are less likely to provide long-lasting immune responses precisely because they don't fully integrate into the host's DNA (genome).

One major gap in the newly published data: the vaccine was not studied in older individuals with pre-existing medical conditions, the part of the population most at risk for death or disability from covid-19. Older individuals may not respond as briskly to these doses of the vaccine, which could force a choice between higher doses that would be accompanied by more adverse effects, and lower doses that are less likely to confer immunity, though would come with fewer side effects.

The results of this study are encouraging, though successful Phase I trials only indicate that a vaccine is not immediately toxic among a small group of healthy volunteers. Clinical trials are divided into three phases. Phase I trials aim to find the best dose of a new drug with the fewest side effects. Phase II trials assess if the therapy treats disease at those safe doses. Phase III assesses if the therapy works better than the standard-of-care, when a standard-of-care exists. Trials testing other vaccines are also underway, targeting different components of SARS-CoV-2. Even if the phase II and phase III trials for Moderna's vaccine are less promising, the development of a preliminarily safe mRNA vaccine is a substantial achievement.

–Michael Chary, MD, PhD

POLICY BRIEFING

Los Angeles and San Diego schools announce online-only plan for the fall.

Despite calls from the White House last week to reopen schools in the fall, California's two largest school districts made [a joint statement](#) on Monday afternoon that the school year will resume on schedule in an online-only capacity. The San Diego and Los Angeles Unified school districts represent some 825,000 students. This announcement was made after Department of Education Secretary Betsy DeVos made a statement last week suggesting that federal funding to states who do not follow the administration's wishes would be cut. District leaders, however, reiterated, "One fact is clear: those countries that have managed to safely reopen schools have done so with declining infection rates and on-demand testing available. California has neither. The skyrocketing infection rates of the past few weeks make it clear the pandemic is not under control."

Both Los Angeles County and San Diego have seen a resurgence of covid-19 cases in recent weeks. As of July 13th, [Los Angeles County reported](#) there were 2,056 people hospitalized, 28 percent of these people are confirmed cases in the ICU and 20 percent are confirmed cases on mechanical ventilators. Both the Los Angeles and San Diego districts state they will continue planning for a return to in-person learning during the 2020-21 academic year, as soon as public health conditions allow.

–Regina Royan, MD, MPH

HHS clarifies taxable status of Provider Relief Fund Payments.

While medical advocacy groups are continuing to petition Congress to [clarify](#) what was assumed to be an oversight in drafting the Provider Relief Fund legislation, the Department of Health and Human Services (HHS) has [updated](#) its Frequently Asked Questions page with a new clarification. The document now states that payments from the Fund count towards gross income under section 61 of the Internal Revenue Service's Code. It goes on to state that while a federally tax-exempt entity that receives a disbursement under the program is still exempt, certain uses for the money may be viewed as taxable. Since the tax rate for such funding can be as high as 21 percent, the need for further clarification from Congress remains. *Various*

–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.