

Top ethicist makes the case for COVID-19 vaccine challenge trials

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Human challenge trials intentionally place human subjects in harm's way, so it is imperative that care be taken about when and how they are conducted. One prominent medical ethicist says challenge trials for COVID-19 vaccines might be the way to go, given the enormous morbidity and mortality associated with the infectious disease caused by SARS-CoV-2.

An [“Ethics Talk” videocast](#) from the *AMA Journal of Ethics*[®] ([@JournalofEthics](#)) features an interview with Arthur Caplan, PhD, founding head of the Division of Medical Ethics at NYU Grossman School of Medicine. In his conversation with the journal's editor-in-chief, Audiey Kao, MD, PhD, Caplan talks about the circumstances that make developing and rolling out a SARS-CoV-2 vaccine so emergent.

The AMA and the Centers for Disease Control and Prevention are closely monitoring the COVID-19 pandemic. Learn more at the [AMA COVID-19 resource center](#). Also check out pandemic resources available from the [AMA Code of Medical Ethics](#), [JAMA Network](#)[™] and [AMA Journal of Ethics](#), and consult the [AMA's physician guide to COVID-19](#).

The stakes are high for everyone

Global health and the global economy are both in dire straits, Caplan noted. The conventional path to a SARS-CoV-2 vaccine, which is underway for several vaccine candidates, requires waiting for natural infection to assess the vaccine's efficacy.

“If we're waiting for natural infection in a 30,000-person study ... you're waiting and you're waiting and the virus ebbs and flows,” Caplan said. “And that means people are dying all around the world because of the virus. So it's a dire situation with many deaths.”

In a challenge trial, by contrast, researchers instead launch the study and say to participants, “We're going to test whether a [SARS-CoV-2] vaccine works by giving you a purified form of this virus.”

Learn why top infectious diseases physician Anthony S. Fauci, MD, predicts 2021 may see up to 300 million doses of a COVID-19 vaccine.

Being straight up about the risks

While there are people who have already volunteered, getting proper informed consent is essential for proceeding with any human challenge trial for a SARS-CoV-2 vaccine. This would involve being clear with human subjects that, “Should you become sick, we don't really have anything that will save you. If you're lucky enough to survive on a ventilator or make it through kidney dialysis, we've got this drug that might speed up your recovery a little bit, but we don't have an agent to rescue you,” Caplan said.

Ordinarily, though, researchers wouldn't even consider doing a challenge study without a rescue treatment at hand.

“We've done it with malaria, but we have different types of interventions we can use there to try and rescue somebody,” Caplan said. “We've done it with cholera, [where] we have rehydration, which helps a lot.”

But no rescue medications yet exist for COVID-19.

“So my defense,” Caplan noted, “rests on the idea that you understand what you're doing,” and that the best available medical care is provided to challenge trial human subjects who get sick.

Read more from the AMA about [the medical ethics of vaccine challenge trials](#).

More on COVID-19 vaccines

Caplan also addressed the logistical challenges of manufacturing and distributing millions of vaccines for U.S. patients, whether it would be appropriate to conduct COVID-19 challenge trials in developing countries, where the Public Readiness and Emergency Preparedness Act falls short legally, and how to deal with the anti-vaccination movement when issuing vaccine mandates.



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