

Ethics must not be ignored when testing COVID-19 vaccines

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As human trials begin for potential COVID-19 vaccines, the ethics of human challenge studies must be considered. Credit: Shutterstock

The grassroots organization 1Day Sooner has been [asking people to indicate their willingness to volunteer for human challenge studies of COVID-19](#). Challenge studies, in which healthy people are intentionally exposed to infection, may, they believe, speed vaccine development.

1Day Sooner reports that [more than 35,000 people from 160 countries, including Canada, are ready to volunteer to be exposed to COVID-19](#).

But should we let them?

Many find the idea of [human challenge studies](#) surprising. Why would scientists want to expose [healthy volunteers](#) to an infectious disease? One reason is to efficiently conduct a preliminary test of a new vaccine.

In a vaccine [challenge](#) study, participants are given either a new vaccine or a placebo and then deliberately exposed to the infectious agent. If fewer people who were given the vaccine become ill compared to the placebo group, we have preliminary evidence the vaccine works.

Challenge studies stand traditional clinical trials on their head. In a clinical trial, the patient receives a novel treatment that may improve her medical condition. There are risks from experimental treatment, but those risks are offset by the prospect of direct benefit to the patient.

Challenge studies, by contrast, deliberately seek to make healthy volunteers sick and offer no prospect of direct benefit. Because challenge studies do not benefit volunteers, we limit the risk to which they may be exposed for scientific ends.

Ethical research

Can we ethically conduct a vaccine challenge study involving COVID-19? According to [current ethical guidelines](#), published in 2016 and on which I served as co-author, the ethical permissibility of challenge studies entails a range of requirements, including a compelling scientific rationale, minimization of risks to participants and detailed informed consent ethical guidelines for human challenge studies.

A key provision requires that "volunteers will under no circumstances be exposed to the risks of irreversible, incurable or possibly fatal infections." And while [challenge studies were used to develop vaccines for cholera and malaria](#), this research was permissible because there are drugs that reliably cure both illnesses.

But the proposal to conduct challenge studies of COVID-19 fails to satisfy this key ethical requirement. The [mortality rate for COVID-19 in Canada is 7.3 percent](#). Even if challenge studies were restricted to adults in their 20s, the [risk of death is 0.03 percent, or about one in 3,000 patients](#).

While the primary impact of COVID-19 appears to be on the lungs, it is now clear that the [disease affects many organs](#), leaving some patients with lasting disabilities. As yet, there is no curative

treatment for COVID-19.

Challenging ethics

Researchers have argued that we ought to [change widely accepted ethical standards to allow COVID-19 challenge studies](#), claiming that challenge studies could greatly speed the development of a COVID-19 vaccine and, as a consequence, "the savings in human lives could be in the thousands or conceivably millions."

In a recent [TED talk](#), bioethicist Nir Eyal claims that the threshold for permissible risk in challenge studies is too low. We allow adults to donate a kidney to a person in need of a transplant even though this involves a risk of death of one in 3,000 to the donor.

Why not allow healthy volunteers to agree to similar risks in a COVID-19 challenge study?

Moving forward safely

Neither of these arguments is compelling. There are reasons to doubt that COVID-19 challenge studies would in fact give us a vaccine sooner. One or two years of development is typically required before a challenge study with a new infectious agent can proceed. For COVID-19, [scientists would need to standardize the viral strain](#) and determine a dose that reproducibly causes mild disease but does not cause severe disease.

Meanwhile, standard avenues of vaccine research and development are proceeding quickly. More than [160 vaccine candidates have been identified](#), of which 30 are now being tested in human clinical trials. Two vaccine trials are [enrolling thousands of volunteers in Brazil, South Africa, the United Kingdom and the United States](#).

Philip Dormitzer, chief scientific officer at Pfizer Vaccines Research and Development recently commented: "[I think we can probably be faster by taking these vaccines forward and testing them in a conventional way.](#)"

Preserving trust

What of the claim that the threshold for permissible risk in challenge studies is too low? Here the argument relies on an analogy between donating a kidney and participating in a vaccine challenge study. This assumes the two cases are comparable; they are not.

Decades of experience in kidney transplantation means the [risks to donors are well understood](#). Our experience with COVID-19 is all too brief, and little information is available on the long-term consequences of infection.

Further, a kidney transplant from a closely matched donor has high probability of success. The benefits of a vaccine challenge study are far less likely, since (based on experience with other diseases) only a minority of [vaccine](#) candidates will ultimately be licensed for use.

Over the last 50 years, [thousands of people have volunteered for challenge studies](#). Participants have endured the diarrhea caused by cholera and malarial fevers, but none have died. This is a testament to the skill and extraordinary efforts of scientists to protect volunteers. In drawing the line at "risks of irreversible, incurable or possibly fatal infections," scientists seek not only to protect volunteers but also preserve the public's trust in the scientific enterprise.

If [ethical standards](#) are lowered and COVID-19 challenge studies are allowed to proceed, my fear is that volunteers will suffer irreparable harm and die. This runs the risk of undermining public trust in both research and vaccines. Public trust is now—and will remain—an indispensable element in our efforts to defeat COVID-19.

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