



# The ethical case for allowing medical trials that deliberately infect humans with COVID-19

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Could intentionally infecting volunteers in COVID-19 trials speed up a vaccine? AP Photo/Ted S. Warren

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Despite the urgent need to beat COVID-19, health officials may be delaying the development of an effective vaccine.

Authorities in the U.S. and elsewhere are yet to authorize an ethically charged research procedure called “human challenge trials.” Challenge trials entail deliberately infecting volunteers with the disease – which explains the official reticence – but they could substantially expedite the development of a vaccine.

The debate over human challenge trials has been raging for months among health professionals and academics. But only now – some eight months into the pandemic – are authorities in the U.S. beginning to consider them in a bid to speed up the vaccine-development process.

## Sitting and waiting

A vaccine has to go through multiple stages before it can be rolled out. After establishing its ability to trigger an immune response and its safety, developers must test it for efficacy. Inefficient vaccines may not justify the tiny risk inherent even in safe vaccines, may be enormously wasteful, may divert resources from better alternatives and may harm immunization rates.

There are two principal ways with which to measure efficacy. Under the conventional method, researchers vaccinate tens of thousands of volunteers and then passively wait for some of them to get infected. The frequency of infection is then compared to a non-vaccinated control group.

In the second method, human challenge trials, a much smaller group of volunteers is intentionally infected after receiving the experimental vaccine or a placebo. This allows for a much faster and efficient determination of vaccine efficacy.

To date, more than 33,000 people from 151 countries have volunteered to be part of such a procedure. But there is no official authorization for human challenge trials for COVID-19 in the U.S. or other Western countries. This means that vaccine developers are forced to vaccinate many more volunteers – typically about 30,000 are involved for each candidate vaccine – and then release them into the general population, with the hope that enough data would soon accumulate.

This is where we presently are in the U.S.: waiting for enough participating volunteers to catch the virus by happenstance.

Paradoxically, these giant and expensive studies – American taxpayers have already spent billions of dollars on vaccine development – are slowed down by government efforts to minimize infection rates through quarantines, closures, masks usage or social distancing. Back in May, leading developers of potential COVID-19 vaccines, including the biotechnology company Moderna and Oxford University, issued a warning that low-level infections among their volunteers may delay the development of their vaccines.

It is possible, of course, that the conventional studies will yield the required data. But there is a distinct possibility that challenge trials could speed up things.

## Medical ethics

Opposition to human challenge studies for COVID-19 is based, first and foremost, on ethical considerations. Since at present there is no cure for COVID-19, intentional infection can result in death or serious impairments. It is therefore argued by people like Michael Rosenblatt, a former dean of Tufts University School of Medicine and a present adviser to Moderna, that the risks are too high, and that volunteers cannot give a valid “informed consent” for intentional infection.

The argument that willing adults cannot consent to risking their health for the greater good is, we believe, inconsistent with how society views other acts of volunteerism. Volunteer firefighters, for example, also face unknown dangers. Moreover, few countries refrain from risking the health and lives of their young citizens on the world’s battlefields, if they deem that the common good requires such sacrifice. And while COVID-19 human challenge trials would include only volunteers, most battlefields also include people who are forced into service.

Delaying a vaccine may also endanger volunteering health care workers. Current estimates put the number of U.S. health care workers’ deaths from COVID-19 at around 1,000. Health care volunteers continue risking their lives as long as vaccine development is delayed.

The opposition to human challenge trials derives from justified sensitivity to medical experiments on humans, and the horrific history of such experiments – which often ignored the interests and rights of their subjects. These included the experiments performed by the Nazis on prisoners or the notorious Tuskegee Study of untreated syphilis, which was conducted on unsuspecting African Americans. And of course, even medical experiments that subjects consent to can go terribly wrong.

## Lives at stake

But rapid development of an effective vaccine could save hundreds of thousands of lives worldwide. At present, more than 5,000 people die of COVID-19 each day. At that rate, every month of delay in vaccine availability costs 150,000 lives.

The indirect costs are tremendous as well. For example, the United Nations recently announced that pandemic-linked hunger is tied to 10,000 child deaths each month. From these perspectives, the arguments against human challenge trials appear far less convincing.

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We believe that the decision to allow human challenge trials for COVID-19 should not be examined solely through the narrow lens of medical ethics – with its cardinal principal of doing no harm to the individual patient or the volunteer. The COVID-19 epidemic is a global disaster, and decisions concerning it should be made with the wider perspectives of public health and general morality. In other words, the decision may be more suitable for high level policymakers than for medical ethics committees.

In April, some American lawmakers did weigh in: 35 members of the U.S. House of Representatives sent a letter to the heads of the U.S. Food and Drug Administration and the Department of Health and Human Services, voicing support for human challenge trials. So far, however, this effort has had no effect.

There is no doubt that human challenge trials carry significant risks for volunteers; but they also carry the chance of significant benefits for humanity. Instead of regarding these volunteers as uninformed, society may do better to valorize their altruism and heroism. We believe that, given present circumstances, human challenge trials for COVID-19 are not morally wrong: To the contrary, they express humanity’s most noble values.

- Vaccines
- Ethics
- Medical ethics
- Coronavirus
- Vaccine trials
- Biomedical ethics
- Vaccine safety
- COVID-19
- Clinical trial

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