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Ideas

**I got an experimental COVID-19 vaccine. I'm willing to put it to the ultimate test.**

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“Challenge studies" could accelerate research, but they come with big ethical questions.

On Tuesday, I received my second and final dose of an experimental coronavirus vaccine. The pharmacist who injected me confessed that seeing the substance inside the syringe had brought a tear to her eye. “It's translucent, she said, “and it just might save the world."

I am one of 45 healthy volunteers taking part in a Phase 1 clinical trial to assess the safety of mRNA-1273, the first COVID-19 vaccine candidate to be given to humans. If found safe, it will be given to more volunteers to see whether it works.

But while even trials like these are cause for hope, they will take many months. With the world in stasis and lives being lost to COVID-19 every day, it would be great if a safe and effective vaccine could come sooner. One way to speed up testing might be so-called “challenge studies," in which vaccinated volunteers get intentionally exposed to the virus.

This is not how vaccines are normally tested. What usually happens is that after a vaccine is deemed safe in Phase 1, vaccinated subjects in Phases 2 and 3 carry on with their day-to-day lives. Months later, scientists check to see whether the vaccinated group as a whole got fewer infections than a group that got a placebo. This is safe, but takes time. In a challenge study, there is no waiting around. Vaccinated volunteers would be exposed to or injected with live virus in a controlled setting.

With limited treatments for COVID-19, such an experiment would obviously be risky. Even so, I would be willing to sign up — if conditions were right.

I do not consider myself a big risk-taker. I am a teetotaler, I follow speed limits, and my last broken bone was in middle school. I did not sign up to be in a Phase 1 study because I do not care about my health; I did it because by taking on a small amount of risk, I might be able to help many others. I'm not alone in this — thousands applied to be in the study I am in, though just 45 volunteers were needed for this stage of this particular trial.

The vaccine injection could have caused an immediate allergic reaction. I had no issues. It may cause my body to produce antibodies that make later coronavirus infection more likely, as has rarely happened with other experimental vaccines. But I am 29 years old and in good health. Even if my odds of catching COVID-19 go up, I would likely have mild illness and then fully recover.

Which brings me to challenge studies.

The idea of exposing volunteers to an infectious agent to definitively assess whether a vaccine is working is not new. It has been done in the United States for influenza and typhoid fever, yielding approved vaccines, and across Africa for malaria, though that parasitic infection can be managed with known antibiotics, which lowers risk for volunteers. All told, more than 6,500 people have participated in challenge studies for diseases other than COVID-19.

Not all challenge studies are ethically equivalent. For each, potential benefit must be weighed against potential harm. A planned challenge study for Zika virus was called off in 2018 in part over objections from a panel of bioethicists who found “substantial uncertainty" about the risks to would-be volunteers. These concerns extended to those in the community where such a trial might take place. Zika's spread is difficult to detect and is linked with birth defects. Can a challenge study be ethical if it puts additional children at risk?

There is a lot we do not know about SARS-CoV-2, the virus behind COVID-19. A challenge study would clearly need to omit pregnant women and people most likely to die from infection. Volunteers would have to be kept in strict isolation, potentially for weeks or months. Experts estimate that 100 healthy subjects would be needed.

A growing number of bioethicists argue that we should seriously consider COVID-19 challenge studies. The public health and economic burden of the pandemic is extraordinary. Even one day shaved off vaccine testing could save many lives.

I would agree to participate in such a challenge trial if three conditions were met.

First, the Food and Drug Administration would have to sign off. This would signify both that the conditions for preparing and handling the virus are up to par with other approved challenge studies and that the country's chief regulatory body is willing to accept the results.

Second, it would need to be clear that no matter the outcome, the experiment would have value. If all the subjects in a challenge avoid infection, then clearly the vaccine should be fast-tracked. If they all get sick, it should be scrapped. But what if protection is only partial, as is the case with many vaccines? Would traditional testing of the vaccine resume? If so, what really would have been gained by the challenge trial? The answers to these questions would need to be decided ahead of time.

Third, I would need to know that I had a good chance of avoiding infection altogether. As of today, I am making no assumption that I am immune. My experimental vaccine, made by Cambridge-based Moderna, may not produce any effect. But if laboratory testing could indicate before a challenge trial that my immune system is already producing neutralizing antibodies as a result of the vaccination, I would consider the personal risk low enough. I know lab testing isn't foolproof, but it would at least put my mind at ease.

You might disagree with the moral calculus I've laid out. To some, human challenge trials are clearly too dangerous, making informed consent impossible. To others, the need to act swiftly — even if it means that exposing 100 volunteers to the coronavirus leads to 100 more COVID-19 cases — makes human challenge studies the obvious choice. In the end, it's a judgment call.

Though no human challenge studies are being planned at the moment, the organization 1DaySooner has begun soliciting volunteers online. More than 10,000 people have said that if enough precautions were in place, they would be willing to sign up — including me.

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Caption:

The second shot of the author's experimental coronavirus vaccine.

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