Human challenge studies: What we've learned from intentionally infecting people with COVID

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When COVID began to spread rapidly in 2020, sending the UK and other countries into lockdowns, many people asked what they could do to help. While millions of people found novel ways to help others in their communities, a large number became interested in volunteering for

medical research.

This presented an interesting situation for researchers who normally struggle to recruit participants. Suddenly there was significant enthusiasm from the public to volunteer for research studies. This included a willingness to volunteer for potentially risky "human challenge trials" that would intentionally expose participants to SARS-CoV-2, the virus that causes COVID.

Many people hoped, or even assumed, that deliberately exposing themselves to the virus in the name of medical research would speed up the production of pandemic-ending vaccines. But the reality was a bit more complex.

Beginning in 2021, scientists in the UK embarked on three SARS-CoV-2 human challenge studies with healthy young adult participants. However, none hastened the production of the vaccines in use today. So what did these studies tell us?

The science

One main difficulty in human challenge studies is how quickly the challenge agent (for example, a virus such as SARS-CoV-2) mutates. Challenge studies rely on the safe production of a well-characterized agent, but since this can take months, the risk is that by the time the infectious agent has been created for research, the dominant virus in circulation may be quite a different variant.

This was indeed the case with SARS-CoV-2, where the first and second challenge studies were conducted with the alpha variant about a year after it was the main variant of concern. The third challenge study, which is currently recruiting, is using the delta variant, and is facing a similar problem.

Could the challenge agent have been created more quickly? Perhaps, but with SARS-CoV-2, the high level of community infections meant that more traditional placebo-controlled studies (where people are given either an active or inactive vaccine and subsequent infections are recorded) were far more effective, and easy to conduct, for scientists trying to develop vaccines.

So, contrary to many people's expectations, and despite their track record in accelerating vaccine development for diseases such as malaria, the SARS-CoV-2 challenge studies didn't speed up the immediate development of vaccines.

The studies are, however, still very useful, as they were able to follow the infection closely from first exposure through to the development of symptoms and subsequent recovery. They revealed just how infectious the virus is, as participants exposed to even the smallest dose became infected. They also provided a useful validation of the sensitivity of rapid antigen tests.

The ethics

It wasn't a surprise that the UK was the first country to conduct SARS-CoV-2 challenge studies. The UK has a history of conducting challenge studies dating back to the "flu camps" of the 1940s and has several active research groups with experience using this approach.

The healthcare system in the UK is also well set up for providing lifelong care through the NHS should any participants be harmed in a research study. One reason such studies were considered unethical in the US was the more individualized insurance-based healthcare system and subsequent lack of guaranteed long-term care from the state.

In the UK most medical research is reviewed by one of a network of

about 60 research ethics committees coordinated through the Health Research Authority. The role of these committees is to balance the enthusiasm of researchers with the rights, safety and well-being of the potential participants.

In July 2020, the Health Research Authority established a new specialist research ethics committee ready to review any SARS-CoV-2 human challenge studies, of which I was a member. This was in parallel with the World Health Organization publishing ethical guidelines for any country conducting SARS-CoV-2 challenge studies (to date only the UK has).

On the specialist committee we did consider whether the challenge model was the most effective way to rapidly develop treatments. However, this was not our primary ethical concern, because we knew the studies would generate a wealth of other useful scientific knowledge.

Instead, we were more focused on the participants themselves, and the conditions that were required to conduct the studies in an ethically robust way. These included informed consent and how participants would be looked after in the isolation unit.

The practical experience of our specialist committee also offered a useful opportunity to engage internationally with the bioethics community and the substantial debate the challenge studies raised. Specifically, we have been able to closely consider the best ways to screen and recruit people for contentious studies like these and help develop new guidance for use in future studies.

Were these studies worthwhile?

The COVID human challenge studies have undoubtedly been worthwhile, though perhaps not in the way many people originally expected. Challenge models enable the study of viral infection and

disease progression in a carefully controlled environment and have a proven track record. But for a rapidly changing virus like SARS-CoV-2, they have been less helpful in the development of treatments and vaccines.

However, this may not be the case in future pandemics. The practical and ethical lessons learned from the challenge studies this time around could be invaluable next time we need to respond rapidly to a pandemic threat.

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