COVID: U.S. Should Follow UK's Lead on Human Challenge Trials

By Alex Berezow, PhD — September 28, 2020

Given that more than 200,000 Americans have died (at least in part) due to COVID-19, there seems little to lose and much to gain by green-lighting human challenge trials in which volunteers are vaccinated and then deliberately infected with coronavirus. The U.S. should follow the UK’s lead.

Several months ago, I wrote an article about how UK health authorities have more guts than their U.S. counterparts. Specifically, they are much more likely to be honest and forthcoming on controversial topics like alternative medicine, vaping, and “three-parent” embryos than American officials.

The Brits have done it again. The Financial Times has reported that the UK will allow human challenge trials to proceed in order to help hasten the development of a coronavirus vaccine. This is good news, and hopefully it will prompt the U.S. to do the same.

Challenge trials are different from clinical trials. In the latter, volunteers are given a vaccine or a placebo and then told to go about their normal lives. Over the course of months or years, scientists follow them to determine if the vaccine worked (to prevent disease) and if there are any side effects. A challenge trial is different in that volunteers are deliberately exposed to a disease-
causing agent to determine if the vaccine worked.

Thus, challenge trials can greatly speed up the process of vaccine production. However, they also carry risk, mostly in regard to safety, though some believe there are ethical risks as well.

**An Ethical Risk for Human Challenge Trials?**

One bioethicist argued [4] that human challenge trials are unethical on several grounds, the most persuasive of which is that fully informed consent is not possible since so much remains unknown about the virus and its long-term health effects. The bioethicist then proposes one very specific scenario under which human challenge trials would be ethical, but the conditions are so restrictive that challenge trials probably never would occur.

Overall, the argument is unconvincing. Some people, like astronauts, knowingly take enormous risks for the benefit of humanity. Is it really possible for an astronaut to give fully informed consent? There are countless things that could go wrong -- both foreseeable and unforeseeable -- with a launch, spacewalk, or re-entry. The only relevant point is that the astronaut is aware that he or she may not return to Earth in one piece.

Likewise, if a human challenge trial volunteer is fully aware that he or she may die or suffer from some unknown long-term health effect, then that seems sufficient to satisfy any ethical quandaries. Therefore, the only risk posed by challenge trials is safety.

**Human Challenge Trials Pose Multiple Safety Risks**

First, there's the obvious safety threat that human challenge trials pose to volunteers: Deliberate infection with the coronavirus might harm or kill the volunteer, and the vaccine itself may have dangerous side effects. To ameliorate these risks, challenge trials can be done in quarantine, and medical staff should be prepared to administer life-saving aid if needed.

But there are other risks. Most likely, the people who will be enrolled in a challenge trial will be young and healthy. That means the only data scientists can collect will be on the safety and efficacy of a vaccine in people who are unlikely to die or suffer other long-term health consequences. Any data is better than no data, but the insights will probably not be limited to younger, healthier demographics. We won't know if the elderly or those with underlying health conditions will benefit or be harmed by a vaccine.

Another safety risk is that scientists will not collect information on the long-term efficacy of the vaccine. According to the aforementioned FT article, volunteers will be challenged with the coronavirus one month after receiving a vaccine. If the immune benefits of a vaccine wear off after a year, the challenge trial won't detect it.

**Human Challenge Trials: The Benefits Outweigh the Risks**

All together, a strong case can be made in favor of challenge trials. Given that more than 200,000 Americans have died (at least in part) due to COVID-19, there seems little to lose and much to gain by green lighting the trials. The U.S. should follow the UK's lead.

Links
[3] https://www.ft.com/content/b782f666-6847-4487-986c-56d3f5e46c0b