

GENERAL ESSAY 2020

Human Challenge Trials and Ethics

The pandemic of coronavirus disease 2019 (COVID-19), caused by SARS-CoV-2, poses an extraordinary threat to global public health, socioeconomic stability, food security and other social goods. Left unchecked, COVID-19 would probably claim millions of lives and place extreme strain on health care systems worldwide. While control measures such as physical distancing can help to reduce the spread of COVID-19, these measures come at enormous social and economic costs that may be disproportionately borne by underprivileged groups. Major challenge for the current public health response is lack of safe, effective vaccines and treatments.

Controlled human infection studies (or “human challenge studies”) involve the deliberate infection of healthy volunteers. Such studies can be particularly valuable for testing vaccines. They can be substantially faster to conduct than vaccine field trials, in part because far fewer participants need to be exposed to experimental vaccines in order to provide (preliminary) estimates of efficacy and safety. Such studies can be used to compare the efficacy of multiple vaccine candidates and thus select the most promising vaccines for larger studies. Well designed challenge studies might thus not only accelerate COVID-19 vaccine development, but also make it more likely that the vaccines ultimately deployed are more effective. Challenge studies are also used to study processes of infection and immunity from their inception. Such findings could significantly improve the overall public health response to the pandemic.

Ethics of human infection challenge studies

Challenge studies have a long history, including early research with smallpox, yellow fever and malaria that changed the course of global public health. In the last 50 years, challenge studies have been performed safely in tens of thousands of consenting adult volunteers under the oversight of research ethics committees. These studies have recently helped, for example, to accelerate the development of vaccines against typhoid and cholera and influenza.

Research involving the deliberate infection of healthy volunteers may seem unethical, and there are numerous prominent historical examples of unethical research involving deliberate infection of research subjects. However, there is a consensus among ethicists who have reflected upon human challenge studies that the intentional infection of research participants can be ethically acceptable under certain conditions, such as those in which modern challenge studies are conducted. Challenge studies are nonetheless ethically sensitive and must be carefully designed and conducted in order to minimize harm to volunteers and preserve public trust in research. In particular, investigators must adhere to standard research ethics requirements especially where studies involve exposing healthy participants to relatively high risks. Public trust in research is particularly crucial, such as during public health emergencies.

The ethical issues are

It is ethically acceptable because

1. it is voluntary
2. it serves to save an infinitely larger population for generations
3. it happens all the time when volunteer fire fighters rush into burning buildings, relatives donate a live organ to loved ones

It is objectionable because

1. profitable pharma companies benefit most
2. lives lost are those of the young people
3. it is not associated with the promise of spending more on public health

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