

## **The ethics of human challenge trials for Covid-19 vaccines**

From the WHO Working Group on Key criteria for ethical acceptability of COVID-19 human challenge studies (see Jamrozik et al. 2021 article in optional readings):

“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 challenges for the current public health response include (a) a lack of safe, effective vaccines and treatments; and (b) gaps in scientific knowledge regarding pathogenesis, immunity and transmission.

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. They could thus be used to (a) validate tests for immunity to SARS-CoV-2, (b) identify correlates of immune protection, and (c) investigate the risks of transmission posed by infected individuals. Such findings could significantly improve the overall public health response to the pandemic.”

Questions:

1. Would it have been ethically acceptable to undertake human challenge trials for Covid-19 vaccine development before the first vaccines were approved and before there were effective therapies against SARS-CoV-2 infection such as monoclonal antibodies and antivirals?
2. Is it ethically acceptable to undertake such trials in the current environment, with a range of approved vaccines and therapies?
3. Would you volunteer for such trials, and what would you recommend to a family member or friend who asked for advice about whether they should volunteer?