Case Discussion

To date, the World Health Organisation, has approved seven COVID-19 vaccines [https://covid19.trackvaccines.org/agency/who/] . Two of these vaccines (Pfizer-BioNTech's COMIRNATY and Moderna's mRNA-1273), which are based on a relatively new platform using messenger RNA, seem to be the most effective, but they have only been tested in two countries, require at least 2 doses several weeks apart, and require a "cold chain" from the time of production to vaccination. Following the designation of an Emergency Use Authorization from the US Food and Drug Administration, in the US alone over 235 million doses of the Pfizer vaccine and 153 million doses of the Moderna vaccine have been given, providing substantial evidence of safety[1] [https://www.statista.com/statistics/1198516/covid-19-vaccinations-administered-us-by-company/]. Nevertheless, global vaccination rates are uneven and substantial proportion of the global population remain unvaccinated, contributing to morbidity, mortality and persistence of the pandemic. Therefore, scaling up and distributing available vaccines is critical, but having additional vaccines could be very important for global public health control of the pandemic. For example, scientists wonder if it might be possible to develop a vaccine product that is as effective, or almost as effective, as the mRNA vaccines developed by Pfizer and Moderna while not requiring the deep freezer cold chain storage that these vaccines require. Additional questions have emerged about whether another one-dose vaccine is possible, which would make roll out remarkably easier and enable outreach to many more individuals in a given time period. And just having additional safe and effective products on the market — especially ones that are responsive to emerging variants of concern — may be helpful to address the vast global need. The ethics question—now that safe and effective vaccines do exist—is how to ethically design a trial for a new candidate vaccine.

When the initial vaccines now in use were tested for safety and efficacy, large placebo-controlled clinical trials were conducted. There were no vaccine products on the market, and participants were randomly assigned to receive either the "real" experimental vaccine or a placebo vaccine that looked the same. This was done in a "masked" fashion; that is, neither the participants nor the investigators knew whether any given individual participant was receiving the "real" vaccine or the placebo.
In most parts of the globe, access to any existing vaccine is months and months away. This is due to a complex combination of woefully inadequate supply of the vaccine globally and some distribution mechanisms not being fully identified, especially for vaccines requiring the type of cold chain technology that the mRNA vaccines require. Mostly, it remains a problem of inadequate supply for the world's populations.

Some have suggested that additional vaccine candidates could be studied in parts of the globe where the vaccines currently known to be safe and effective are unavailable. No one would be denied any known, effective vaccine that was otherwise available to them, and participation in the trial might actually provide access to vaccine sooner. Provisions could be made for those in placebo groups in such trials to receive the "real" vaccine after the trial was completed if it turned out to be safe and effective. Others object to this type of design, stating that it is exploitive to go to areas of the world—often overlapping with regions of high poverty—to test new products when good products already exist.

[1] https://www.statista.com/statistics/1198516/covid-19-vaccinations-administered-us-by-company/

Imagine an investigator is planning a trial of a new vaccine candidate that seemed to be safe and effective with animal models and is ready for human trials. Researchers want to now do a placebo-controlled trial in a country where vaccines will not be available to most of the public for at least 6-8 months. Is this ethically acceptable or not?