Certification for vaccine clinical trial participants for international travel and other purposes

As a group of individuals who have provided science advice to various governments we write to raise the issue of certification for vaccine clinical trial participants for international travel and other uses. We are concerned that under current arrangements participants in clinical trials of vaccines are not recognised as having been vaccinated and therefore are not eligible for vaccine certification. This is both unfair to them and will have a negative effect on participation in future trials.

Clinical trials of COVID-19 vaccinations have been critical for responding to COVID-19 and are a global public health good. Those who volunteer to take part in trials are selflessly creating great benefit for all of us. Of course trials will continue to be needed to improve vaccine design and coverage, especially as the virus mutates and evolves. Anything that acts as a disincentive to participate in trials will be to the detriment of public health.

Because only vaccination with approved vaccines is recognised for certification some participants in ongoing COVID-19 vaccine trials are withdrawing prematurely and seeking vaccination with approved vaccines so that they can be certificated and travel. This is both wrong for the individual who may be unnecessarily exposed to multiple vaccines when it is not clinically needed, and impacts the integrity of the clinical trial.

To mitigate this, and allow trials to continue at pace, we propose that for international travel purposes vaccine clinical trial participants in late-stage COVID-19 clinical trials approved by regulators should be treated in an equivalent way to people who have been fully vaccinated with an approved vaccine including being granted a COVID-19 'certificate' or 'passport'. This should include people who have received unlicenced vaccines, heterologous combinations, and those who may have received placebo as part of the trial design. Given the numbers of trial participants globally the population contribution of admitting a small number of placebo recipients in trials will be trivial in terms of public health and national disease epidemiology. Of course, once the trials have completed and been unblinded volunteers who received placebo or less effective vaccine would at that stage be eligible for vaccination with an approved vaccine.

The public health risk of not being able to complete vaccine trials in a timely way is a major one, and is much greater than the very small risk of a trial participant importing infections.

Vaccine clinical trial volunteers have given their time freely to help others, and clinical trials are the way in which the world can understand which vaccines work and are safe. There is a moral and ethical obligation to treat volunteers in a way that feels fair to them and to the wider public. It is the right thing to do.

Signed:

Steven Van Gucht - BE
Mona Nemer - CA
Martin Ackermann - CH
Roman Stocker - CH
Sarah Tschudin Sutter - CH
Lothar Wieler - DE
Fernando Simon - ES
Peter Piot - EU
Bruno Lina - FR
Mark Ferguson - IE
Silvio Brusaferro - IT
Jaap van Dissel - NL
Patrick Vallance - UK
Chris Whitty - UK

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