AN OPEN LETTER FROM COVID-19 VACCINE TRIAL PARTICIPANTS

December 8, 2020

We, the undersigned, are participants in various COVID-19 vaccine trials and we would like to share our thoughts with you about the future unblinding of these studies. On October 22, 2020, the Vaccines and Related Biological Products Advisory Committee ("VRBPAC") met to discuss principles for the development and approval of vaccines to prevent COVID-19. This meeting was live-streamed to the public online.

One of the points of discussion at this meeting was whether participants in the trials who are eligible to receive the vaccine under an Emergency Use Authorization ("EUA") should be unblinded. Those eligible for the vaccine under the EUA are likely to include healthcare workers, especially those interacting with COVID-19 patients, and people most at risk of severe COVID-19 disease. Unblinding this subset of trial participants would mean notifying members of the placebo arms of these studies that they received the placebo and should therefore consider getting the newly-authorized vaccine.

Another point of discussion both at, and following, the VRBPAC meeting was whether vaccine developers may choose to unblind their own studies, after demonstrating efficacy and safety, and allow participants in the placebo arm of the study the option of crossing over to the vaccine arm of the study.

At the VRBPAC meeting, representatives of the FDA made clear that the FDA wants the companies currently in vaccine trials to develop strategies to prevent trial participants who are eligible for the vaccine, under an EUA, from withdrawing from the study to get the vaccine. Likewise, representatives of the FDA made clear their preference that the placebo arms of such studies should continue for as long as practicable.

As participants in these studies, we are concerned by both of these notions, for the following reasons:

First, the American Medical Association's Code of Medical Ethics states, in section 7.3.1,[1] that researchers should "design studies to minimize the amount of time participants are on placebo without compromising the scientific integrity of the study or the value of study data," and "ensure that interim data analysis and monitoring are in place to allow researchers to terminate a study because of either positive or negative results, thus protecting participants from remaining on placebo longer than needed to ensure the scientific integrity of the study."

This is important. Many Americans, especially persons of color, are suspicious of medical research, given examples like the Tuskegee Syphilis Study, in which antibiotics were withheld from Black men with syphilis in order to study the progress of the disease. If the FDA wants to build trust with the public, they should hold themselves to the ethical standards designed to prevent this sort of ethical disaster.

Second, the World Health Organization has suggested that those who are willing to risk their health for the advancement of science and participate in experimental trials should also be the ones to be rewarded first. Additionally, Dr. Anthony Fauci in an interview with Kaiser Health

[1] https://www.ama-assn.org/delivering-care/ethics/ethical-use-placebo-controls-research

News on September 1, 2020, stated that when the trials end, there is “a moral obligation”[2] to make the active vaccine available to everyone in the study, including those who had been given placebos. This is not simply a noble ideal, it is a practical choice. By providing special care for those who are willing to “roll up their sleeves” in a time of need, the next generation of vaccine trial participants learns that there are practical benefits to participating.

Although maintaining a larger placebo group for a longer period of time would provide more data, in this case, it would do so at the cost of preventing people at high risk of contracting the virus, or high risk of having a severe outcome from the virus, from seeking a potentially life-saving vaccine. It would also undermine trust in the FDA at a time when the FDA most needs that trust.

For example, one of the leading COVID-19 vaccine trials announced on October 19, 2020, that a 28-year-old Brazilian doctor who worked with COVID-19 patients had passed away while in the placebo group of the trial. This incident highlights the risk that even young medical professionals are taking during the pandemic. If, in the future, a vaccine receives EUA, it would be unethical to withhold it from other medical professionals who could be saved.

Additionally, there is the likelihood of massive participant dropouts, especially from the later trials, due to high-risk participants who believe they received a placebo (due to lack of side effects) and wanting to be inoculated. This would jeopardize these later trials and risk the potential development of a more effective COVID-19 vaccine; some of the later trial companies have already expressed concern about this.

The majority (if not all, by now) of U.S. states have submitted their initial COVID-19 distribution plans to the CDC, giving priority to essential personnel and individuals at high-risk. We suggest that those who are qualified by their state's distribution plan should be unblinded first as they would be qualified if they had not participated in the trial. If you fail to do so, the likely outcome will be that people who intuit that they were in the placebo arm of a vaccine trial will simply quit the trial and seek the approved vaccine. Such a result would be disorderly and would be to the detriment of ongoing trials.

In summary, the majority of the volunteers who risk their health for science in these trials are also often people in high-risk categories. While we understand the importance of the data we are providing, we respectfully suggest the following steps;

- As a vaccine developer achieves EUA, it should be permitted and indeed encouraged to unblind members of its placebo arms who would naturally qualify for vaccination under their state vaccine distribution plan.
- The remaining blinded participants should be given priority after the initial high-risk population is inoculated and before the general population.
- Continue COVID-19 vaccine trial studies by using the initial approved vaccines as a comparator for the control group instead of a placebo.

Thank you for your careful consideration of our suggestions. For inquiries please email CovidTrialParticipants@gmail.com.

Signed,

[2] https://khn.org/news/dr-fauci-says-covid-vaccine-trials-could-end-early-if-results-are-overwhelming

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