Why Many People Are Not Getting a COVID Vaccine: Part V

According to an article published in the British Medical Journal in October 2020, the COVID-19 vaccine trials were not designed to determine if the vaccines were safe or effective.**[1]** This was a problem since the primary reason for getting any vaccine should be because it has been proven to be safe and to prevent serious illness, hospitalization, and death.

The author, Peter Doshi, is associate editor of the journal. He begins by stating that while Anthony Fauci and the FDA assured the public that only safe and effective vaccines would be made available, this was not possible due to study design.

The phase III trials of the Moderna and Pfizer vaccines were designed to end after 150-160 "events" were reported. The definition of an event was quite liberal and could include a person with a cough and a positive lab test. Mild symptoms and a test with a very high false positive rate (see articles on this topic in the Health Briefs Library) made it easy to record the required number of events, end the trial early, and apply for Emergency Use Authorization. This might be good for drug company sales, but what about consumers?

Doshi gives the drug companies the benefit if the doubt on study design, pointing out that one of the reasons for categorizing mild symptoms and a test as an event might have been that the rate of severe illness and hospitalization due to COVID-19 was so low - only 3.4% overall. This means that even trials with tens of thousands of patients would only show a few cases of severe illness. And these trials were much smaller. Of course, a reasonable person might ask why a vaccine is needed for a disease that has a such a low rate of severe illness and hospitalization and an overall survival rate of 99.98%. But as we have learned during the last 15 months, reasonable people are not in charge of our government right now.

Doshi reports that the drug companies acknowledged the limitations of the trials. Tal Zaks, chief medical officer of Moderna, admitted that the trial could not determine whether or not the vaccine reduced hospitalizations based on its size and duration. This did not stop Moderna from reporting to the media that hospital admissions were a "key secondary endpoint."

Zaks also admitted that the trial could not determine whether or not the vaccine reduced the risk of death from COVID, stating "Would I like to know that this prevents mortality? Sure, because I believe it does. I just don’t think it’s feasible within the timeframe [of the trial]…"

And then Zaks admitted that the trials would not even demonstrate that the vaccine would prevent transmission because a trial that would evaluate this endpoint would take too long and would be too expensive. Really? Moderna received almost a billion dollars from The Biomedical Advanced Research and Development Authority (BARDA), which is part of the Department of Health and Human Services. The taxpayers funded the development of this vaccine and Moderna is arguing that proving efficacy is too expensive.**[2]** Really?

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But that's not all. the federal government also committed $1.5 billion for 100 million doses of the Moderna vaccine. Americans did not get a vaccine that was safe and effective, but we did make Moderna executives rich. Stock sales that coincided with announcements of trial results totaled $100 million dollars for just three executives.**[3]**

in addition to providing funding, the U.S. government assisted Moderna by distributing false information about the trials. A press release from the National Institutes of Health stated that Moderna's trial "aims to study whether the vaccine can prevent severe covid-19" and "seeks to answer if the vaccine can prevent death caused by covid-19."

Doshi writes that most of the general public assumes that the point of the trials is to test safety and efficacy, and asks Zaks, "How do you reconcile that?"

I give Zaks credit for honesty. He replied, "Very simply…we have a bad outcome as our endpoint. It's covid-19 disease." In other words, NIH press releases concerning the Moderna vaccine were patently false, and the trial was a charade.

Doshi points out that issues with study design for trials of flu vaccines are not new. He reports that only two placebo-controlled trials including elderly people living in community settings have ever been conducted, and neither was designed to evaluate differences in hospital admissions or deaths. A further limitation is that increased uptake of flu vaccines has not led to a reduction in mortality from flu.

Shockingly, Peter Marks, an FDA official involved with vaccine approvals agreed, stating that flu vaccines only prevent flu in about half of the people who get them.

Perhaps most alarming is Doshi's warning about adverse events resulting from vaccines that were rushed to market in the past – like the COVID vaccines. Examples include contaminated polio vaccines in 1955, cases of Guillain Barre as a result of flu vaccines in 1976, and narcolepsy which was a side effect of one flu vaccine in 2009.**[4]**

The only reason a person would agree to receive one of these vaccines is ignorance of the facts, and the government and vaccine makers are working very hard to make sure that people do not have access to factual information.

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[1] Doshi P. "Will COVID vaccines save lives? Current trials aren't designed to tell us." BMJ 2020;371:m4037
[2] Judy Stone. The People's Vaccine – Moderna's Coronavirus Vaccine Was Largely Funded By Taxpayer Dollars. Forbes December 3 2020
[3] IBID
[4] Doshi P. "Will COVID vaccines save lives? Current trials aren't designed to tell us." BMJ 2020;371:m4037