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Have People Been Given the Wrong Vaccine?

BY MARTIN KULLDORFF APRIL 22, 2022 VACCINES 5 MINUTE READ

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andomized controlled trials show all-cause mortality reduction from the Covid adenovirus-vector vaccines (RR=0.37, 95%CI: 0.19-0.70) but not from the mRNA vaccines (RR=1.03, 95%CI 0.63-1.71).

That is the verdict from a new Danish study by Dr. Christine Benn and colleagues. Have people been given vaccines that don't work (Pfizer/Moderna) instead of vaccines that do work (AstraZeneca/Johnson & Johnson)? Let's put this study into context and then delve into the numbers.

In medicine, the gold standard for evidence is randomized controlled trials (RCT), as they avoid study bias for or against the vaccine. Moreover, the key outcome is death. Do these vaccines save lives? Hence, the Danish study answers the right question with the right data.

It is the first study to do so.

When the Pfizer and Moderna mRNA vaccines were approved by the US Food and Drug Administration (FDA), that decision was based on RCTs.

The RCTs submitted to the FDA showed that the vaccines reduce symptomatic Covid infections. By recruiting mostly younger and middleaged adults, who are unlikely to die from Covid no matter what, the studies were not designed to determine whether the vaccines also reduce mortality.

That was assumed as a corollary, although it may or may not be true. Neither were the RCTs designed to determine whether the vaccines reduce transmission, but that is a different story for another time.

The vaccines were developed for Covid, but to properly evaluate a vaccine, we must look at non-Covid deaths as well. Are there unintended adverse reactions leading to death? We do not want a vaccine that saves the lives of some people but kills an equal number of other people. There may also be unintended benefits, such as incidental protection against other infections. For a fair comparison, that should also be part of the equation.

While each individual RCT was unable to determine whether the Covid vaccine reduced mortality, the RCTs recorded all deaths, and to increase sample size, the Danish study pooled multiple RCTs. There are two different types of Covid vaccines, adenovirus-vector vaccines (AstraZeneca, Johnson & Johnson, Sputnik) and mRNA vaccines (Pfizer and Moderna), and they did one pooled analysis for each type. Here are the results:

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| Vaccine Type | Deaths / Vaccinated | Deaths / Controls | Relative Risk | 95% Confidence Interval |
|-----------------------|------------------------|-------------------|---------------|-------------------------|
| Adenovirus- vector | 16 / 72138 | 30 / 50026 | 0.37 | 0.19 – 0.70 |
| mRNA | 31/37110 | 30 / 37083 | 1.03 | 0.63 - 1.71 |

There is clear evidence that the adenovirus-vector vaccines reduced mortality. For every 100 deaths in the unvaccinated, there are only 37 deaths among the vaccinated, with a 95% confidence interval of 19 to 70 deaths. This result comes from five different RCTs for three different vaccines, but it is primarily driven by the AstraZeneca and Johnson & Johnson vaccines.

For the mRNA vaccines, on the other hand, there was no evidence of a mortality reduction. For every 100 deaths among the unvaccinated, there are 103 deaths among the vaccinated, with a 95% confidence interval of 63 to 171 deaths. That is, the mRNA vaccines may reduce mortality a little bit, or they may increase it; we do not know. The Pfizer and Moderna vaccines contributed equally to this result, so there is no evidence that one is better or worse than the other.

While all-cause mortality is what matters for public health, there is scientific interest in knowing how the different vaccines affect different types of mortality. The Danish scientists contacted RCT investigators to get information on whether each death was due to Covid, cardiovascular disease, accidents, or other causes.

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For the mRNA vaccines, there was a reduction in Covid deaths but an increase in cardiovascular deaths, but neither was statistically significant. So, either result could be due to random chance. Alternatively, the vaccines may reduce the risk for Covid deaths while increasing the risk for cardiovascular deaths. We do not know, and Pfizer and Moderna did not design the RCTs to let us know.

For the adenovirus-vector vaccines, there were statistically significant decreases in both Covid and cardiovascular deaths, unlikely to be due to chance. There was a slight decrease in other deaths, which may be due to chance.

The strength of the Danish study is that it is based on randomized controlled trials. The primary weakness is that the follow-up time is short. This is because the manufacturers ended the clinical trials prematurely, after the vaccines received emergency use authorization. Another weakness is that the data does not allow us to determine how these results may differ by age. While anyone can get infected, there is more than a <u>thousand-fold difference</u> in the risk of dying from Covid between the old and the young.

Are the vaccines primarily reducing deaths in older people? That is a reasonable guess. What about younger people? We don't know. This is not the fault of the Danish investigators. They have done a brilliant job extracting as much information as possible from the industry-sponsored RCTs.

Some may criticize the Danish study for not yet being peer-reviewed, but it has been. It was peer-reviewed by me and several colleagues, and all of us have decades of experience with these types of studies. That it has not yet been peer-reviewed by anonymous journal reviewers is inconsequential.

The mRNA vaccines were approved based on a reduction in symptomatic infections instead of mortality. That Pfizer and Moderna did not design their RCTs to determine whether the vaccines reduced mortality is inexcusable, as they could easily have done so.

That the FDA still approved them for emergency use is understandable. Many older Americans were dying from Covid, and they had to base the decision on whatever information was available at the time. Now we know more. If Pfizer and Moderna want to continue to sell these vaccines, we should demand that they conduct a proper randomized clinical trial that proves that the vaccines reduce mortality.

Equally important, the government, corporations and universities should stop mandating vaccines when randomized controlled trials show a null result for mortality.

Author



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