Moderna, Pfizer Studies Don't Support COVID Vaccine Mandates, Physician Says

The Occupational Safety and Health Administration's (OSHA) controversial plan to enforce COVID-19 vaccinations for large businesses—recently enjoined by the Fifth Circuit Court of Appeals— was ostensibly designed to minimize "deadly outbreaks of COVID-19." The ability of COVID-19 vaccines to protect life is at the heart of the OSHA mandate and the fierce debate over similar mandates now embroiling much of the world.

Nearly 18,000 scientific papers have been published since last year on COVID-19 and vaccines, so the task of sifting through the evidence to help critically evaluate whether vaccines reduce risk of death seems daunting. It turns out, though, that two studies stand so far above the rest in terms of rigor and quality that they are uniquely suited to help us address the question of vaccine protection.

These two studies, published last month in the *New England Journal of Medicine*, are fundamentally distinct from the other

studies in that they are the only clinical trials yet reported to randomize adults to receive either a COVID-19 vaccine (Pfizer or Moderna) or a placebo injection and then follow them over time. Why is this important? Because the randomized controlled study design they used is the gold standard and most rigorous scientific tool available to examine cause and effect relationships between an intervention and outcome (vaccination and death, in this case).

This design also limits as much as possible the influence of other factors, whether known or unknown, that could affect the outcome. Many studies have used other designs to try and understand how well the COVID-19 vaccine protects against death, but no matter how well planned or executed, none of these studies approaches the level of scientific rigor that a well-conducted randomized controlled trial offers.

So did these two clinical trials find that vaccination reduced the risk of dying from COVID-19? The Moderna study reported one death from COVID-19 in the vaccinated group and three in the unvaccinated group, far too few to make any statistical conclusion. The Pfizer trial was even more inconclusive because the findings published in the New England Journal report (one COVID-19 death in the vaccinated group and two in the unvaccinated group) differed from what Pfizer later reported to the Food and Drug Administration, and the FDA update did not specify the number of COVID-19 deaths.

Regardless, the most relevant study endpoint is not death from COVID-19 but all-cause mortality, which counts every death that occurred during the study period. All-cause mortality is the key outcome of interest not simply because it circumvents the oftentimes subjective decision as to why someone died but also because it balances all the possible effects of a COVID-19 vaccine, both good and bad, that could influence risk of death. In other words, it allows us to quantify lives saved by the COVID-19 vaccine while taking into account potential lives lost from vaccine-related heart disease, blood clots,

severe allergic reactions, and perhaps other causes.

Because results from the two trials were so similar regardless of the type of vaccine used it is helpful to merge the results. Following a combined total of 74,580 individuals, half given the COVID-19 vaccination and half given a placebo shot, over six to seven months, the two studies reported that thirty-seven people who were vaccinated died as compared to thirty-three people who received placebo.

Simply put, the very best scientific evidence currently available to mankind does not support the widely held contention that COVID-19 vaccination using the Pfizer or Moderna brands lowers risk of death, at least over the first half-year after vaccination. Interestingly, these striking findings were not reported in the main body of the papers but in supplemental sections.

There are several additional points to consider.

First, the studies' findings were limited by the fact that their design did not take into consideration previous infection leading to subsequent immunity from COVID-19 infection, which could very well have lowered risk of death in one or both study groups.

Second, there are serious concerns over falsification of data and other data integrity issues in the Pfizer trial so this could also have influenced results. Importantly, because both trials mostly excluded groups at highest risk of dying from COVID-19 such as the frail elderly, the very obese, or those with serious chronic illnesses, we cannot assume that the vaccines do not protect against death in these populations.

Based on my clinical judgment and lesser quality supportive evidence, I generally assume when treating such patients that the vaccine's benefits outweigh its risks and so advocate for their use, though I cannot be absolutely certain they offer protection against death because of the lack of randomized

controlled evidence.

Finally, the very low rates of death from COVID-19 observed in both studies should serve to remind us of how minimal this risk is in the general population.

Perhaps the key takeaway message is that absolutist, rigid COVID-19 vaccine mandates such as that put forth by OSHA are not based on best science. Such mandates run counter to the universal medical dictum of risk stratification, whereby treatment is tailored to individuals based on individual risks and benefits to be accrued. They also violate the dominant philosophy of evidence-based medicine, which supports the use of current best evidence when making decisions about patient care.

The Pfizer and Moderna trials show that in lower risk populations (which account for most of society) COVID-19 vaccines do not reduce mortality. Therefore, vaccine mandates, which are enormously costly and terribly divisive, are a cure worse than the disease.