Cardiologist Calls for Global Pause of mRNA COVID-19 Vaccines After Father's Sudden Cardiac Death Led to Analysis of Pfizer Trial Data



A prominent UK cardiologist who was once an outspoken supporter of COVID-19 vaccination is calling on health authorities to pause messenger ribonucleic acid (mRNA) COVID-19 vaccines until independent researchers are given access to the raw data from clinical trials.

He contends that based on the data, there's a greater risk of experiencing a serious adverse event from a vaccine than being hospitalized with COVID-19, and informed consent is "not being given to people to receive these agents."

In a <u>paper</u> published on Sept. 26, Dr. Aseem Malhotra sought to gain a better understanding of the real benefits and possible harms of mRNA COVID-19 vaccines — with a special interest in

the Pfizer-BioNTech vaccine.

"While a case can be made that the vaccines may have saved some lives in the elderly or otherwise vulnerable groups, that case seems tenuous at best in other sections of the population, and when the possible short-, medium- and unknown longer-term harms are considered (especially for multiple injections, robust safety data for which simply does not exist), the roll-out into the entire population seems, at best, a reckless gamble," Malhotra wrote.

For the non-elderly population, the "number needed to treat" to prevent a single COVID-19 death runs into the thousands.

"Pharmacovigilance systems and real-world safety data, coupled with plausible mechanisms of harm, are deeply concerning, especially in relation to cardiovascular safety," Malhotra found. "Mirroring a potential signal from the Pfizer Phase 3 trial, a significant rise in cardiac arrest calls to ambulances in England was seen in 2021, with similar data emerging from Israel in the 16–39-year-old age group."

Maholtra questions COVID-19 vaccines after father's sudden cardiac death

Maholtra, in January 2021, was one of the first in the UK to receive two doses of Pfizer's COVID-19 vaccine. He worked in a vaccine center and said his main motivation for taking the jab was because he believed it prevented transmission of the virus to his vulnerable patients, something that has since proven to be unfounded.

Malhotra says he was surprised and concerned by the number of vaccine-hesitant patients and people asked him to comment on what he considered to be "anti-vax propaganda" at the time.

Maholtra even appeared on "Good Morning Britain" to convince Indian film director Gurinder Chadha to take the jab, which he did shortly after.

Everything changed when Maholtra's father, a previously healthy man with no heart issues, died suddenly of cardiac arrest after receiving a COVID-19 vaccine. This is what led him to investigate whether COVID-19 vaccines were as safe and effective as the U.S. health agencies claimed they were.

"On 26 July 2021, my father, Dr. Kailash Chand OBE, former deputy chair of the British Medical Association (BMA) and its honorary vice president (who had also taken both doses of the Pfizer mRNA vaccine six months earlier) suffered a cardiac arrest at home after experiencing chest pain," Maholtra wrote.

This started my journey to "what would ultimately prove to be a revelatory and eye-opening experience so profound that after six months of critically appraising the data myself, speaking to eminent scientists involved in COVID-19 research, vaccine safety and development and two investigative medical journalists, I have slowly and reluctantly concluded that contrary to my own initial dogmatic beliefs, Pfizer's mRNA vaccine is far from being as safe and effective as we first thought."

As a cardiologist, Maholtra had seen his father's diagnostic test results prior to receiving the shots and said there was no rational explanation for the blockages found in his father's arteries after his death:

"His post-mortem findings are what I found particularly shocking and inexplicable. Two of his three major arteries had severe blockages: 90% blockage in his left anterior descending artery and a 75% blockage in his right coronary. Given that he was an extremely fit and active 73-year-old man, having walked an average of 10–15 000 steps/day during the whole of lockdown, this was a shock to everyone who knew

him, but most of all to me.

"I knew his medical history and lifestyle habits in great detail. My father who had been a keen sportsman all his life, was fitter than the overwhelming majority of men his age. Since the previous heart scans (a few years earlier, which had revealed no significant problems with perfect blood flow throughout his arteries and only mild furring), he had quit sugar, lost belly fat, reduced the dose of his blood pressure pills, started regular meditation, reversed his prediabetes and even massively dropped his blood triglycerides, significantly improving his cholesterol profile."

Malhotra said he couldn't explain his father's post-mortem findings, especially because there was no evidence of an actual heart attack despite severe blockages. Then in November 2021, Maholtra was made aware of a peer-reviewed abstract published in "Circulation," that showed concerning findings:

"In over 500 middle-aged patients under regular follow-up, using a predictive score model based on inflammatory markers that are strongly correlated with risk of heart attack, the mRNA vaccine was associated with significantly increasing the risk of a coronary event within five years from 11% pre-mRNA vaccine to 25% 2–10 weeks post mRNA vaccine."

Although some criticized the validity of the study's findings, Maholtra felt that even if partially correct, it would mean a large acceleration in the progression of coronary artery disease and heart attack risk within months of taking the jab.

Maholtra began to wonder whether his father's Pfizer vaccination could have contributed to his unexplained premature death and decided to critically analyze the data.

Cardiologist finds flaws with Pfizer's mRNA vaccine trial

Malhotra recalled that one of his colleagues, also a cardiologist, had chosen not to receive a COVID-19 vaccine for a number of reasons, including concerns regarding the unknown short- and long-term harms.

One thing that alarmed him about <u>Pfizer's COVID-19 vaccine</u> <u>clinical trial</u> published in The New England Journal of Medicine was the data in the supplementary appendix showing four cardiac arrests in those who took the vaccine compared to only one in the placebo group.

"These figures were small in absolute terms and did not reach statistical significance in the trial, suggesting that it may just be coincidence, but without further studies, it was not possible to rule out this being a genuinely causal relationship (especially without access to the raw data), in which case it could have the effect of causing a surge in cardiac arrests once the vaccine was rolled out to tens of millions of people across the globe," Maholtra wrote.

Another thing Maholtra took issue with was the misleading claims parroted in the mainstream media that Pfizer's COVID-19 vaccine was "95% effective."

What happened, he said, was that the word "efficacy" and "effectiveness" were made interchangeable and people began to believe that for every 100 people vaccinated, 95 people would be protected from actually getting the infection.

What Pfizer's original trial actually showed is that a person was 95% "less likely" to catch the fall 2020 COVID-19 variant.

"This is known in medical speak as relative risk reduction, but to know the true value of any treatment one needs to understand for that person, by how much is their individual risk reduced by the intervention — that is, the absolute individual risk reduction," Malhotra said.

Pfizer's trial results actually indicate the vaccine was only "preventing a person from having a symptomatic positive test, and the absolute risk reduction for this was 0.84% (0.88% reduced to 0.04%)."

In other words, assuming 10,000 people were vaccinated and 10,000 people were not, for every 10,000 vaccinated during the clinical trial, 4 would have tested positive with symptoms compared to 88 who were unvaccinated, he said.

"Even in the unvaccinated group, 9,912 of the 10,000 (over 99%) would not have tested positive during the trial period," Malhotra said. "Another way of expressing this is that you would need to vaccinate 119 people to prevent one such symptomatic positive test (assumed to be indicative of an infection, which, in itself, is potentially misleading but beyond the scope of this article)."

Malhotra said the absolute risk reduction figure of only 0.84% is "extremely important" for doctors and patients to know, but patients weren't given this information when they received the shot.

"Transparent communication of risk and benefit of any intervention is a core principle of ethical evidence-based medical practice and informed consent," Malhotra said.

Contrary to popular belief, Pfizer's clinical trial did not show "any statistically significant reduction in serious illness or COVID-19 mortality from the vaccine over the 6-month period of the trial," Maholtra noted.

Looking at COVID deaths, there were only two deaths from COVID-19 in the placebo group compared to one death in the vaccine group. Looking at all-cause mortality over a longer period, there were actually slightly more deaths in the

vaccine group (19 deaths) than in the placebo group (17 deaths).

There was also an "extremely low rate of COVID-19 illness classified as severe" in the placebo group. Only nine cases (0.04%) out of 21,686 subjects were severe.

Pfizer's clinical trials in children "did not even show a reduction in symptomatic infections but instead used the surrogate measure of antibody levels in the blood to define efficacy, even though the relationship between Wuhan-spike vaccine-induced antibody levels and protection from infection is tenuous, at best," Malhotra added.

Effect of Pfizer vaccine on mortality reduction or other adverse outcomes from COVID-19

Once you know what the published trial did and did not show as it relates to vaccine efficacy, the real effect of the vaccine on mortality reduction or any other adverse outcome from the virus can be calculated, Malhotra said.

According to the <u>study</u>, if there is a 1 in 119 chance the vaccine protects you from getting a symptomatic infection from ancestral variants, then to find the protection against death, this figure (n = 119) must be multiplied by the number of infections that lead to a single death for each age group.

This would give — for up to two months after vaccination — the absolute risk reduction for death from the vaccine.

"For example, if my risk at age 44 from dying from Delta (should I get infected with it) is 1 in 3000, then the absolute risk reduction from the vaccine protecting me from death is 1 over 3000 multiplied by 119, that is, 1 per 357 000," Maholtra explained. "Of course, even for those people

who do become infected the vaccination may provide some protection against death."

From observational data it is possible to calculate the number who would need to be vaccinated to prevent a COVID-19 death; however, these figures will be distorted by inaccuracies in the measure of the size of the unvaccinated population and bias generated by "pre-existing immunity, vaccination misclassification, exposure differences, testing, disease risk factor confounding, hospital admission decision, treatment use differences and death attribution."

Maholtra noted that 95% of those who died from COVID-19 in England were people with pre-existing conditions. In addition, the vaccinated and unvaccinated populations differ in ways that could further bias death data.

Given these limitations, the individual benefit of vaccination has likely been overstated," he concluded.

Malhotra said what should be part of a shared decision-making informed consent discussion with any member of the public considering taking the shot is something along these lines:

"Depending on your age, several hundreds or thousands of people like you would need to be injected in order to prevent one person from dying from the Delta variant of COVID-19 over a period of around three months. For the over 80s, this figure is at least 230, but it rises the younger you are, reaching at least 2600 for people in their 50s, 10,000 for those in their 40s and 93 000 for those between 18 and 29 years.

"For omicron, which has been shown to be 30% — 50% less lethal, meaning significantly more people would need to be vaccinated to prevent one death. How long any protection actually lasts for is unknown; boosters are currently being recommended after as short a period as 4 months in some

"But how many people have had a conversation that even approaches an explanation similar to that?" He asked.

Calculating the harms of Pfizer's COVID-19 vaccine

In his study, Maholtra raised several concerns regarding the safety of COVID-19 vaccines including under-reporting of adverse events during clinical trials, the failure of pivotal mRNA trials to account for serious harms, the limitations placed on trial participants when it came to reporting their adverse events on digital apps and the fact that some participants who were hospitalized after vaccination during the clinical trial were withdrawn from the trial and excluded from the final results.

Then, two months into the clinical trials, the U.S. Food and Drug Administration allowed pharmaceutical companies to offer the vaccine to subjects in the placebo group, essentially "torpedoing any chance of properly recording adverse events from that point on, forcing a reliance of pharmacovigilance data."

Pfizer's clinical trial data showed that one of the most common harms reported following vaccination was myocarditis.

<u>Myocarditis</u> is inflammation of the heart muscle that can lead to cardiac arrhythmia and death. According to the <u>National Organization for Rare Disorders</u>, myocarditis can result from infections, but "more commonly the myocarditis is a result of the body's immune reaction to the initial heart damage."

Numerous studies have shown an increased risk of myocarditis with mRNA vaccination over that of the background rate, especially in young males, yet it has been repeatedly asserted

that myocarditis is more common after COVID-19 infection compared to COVID-19 vaccination.

Malhotra says trial data demonstrating vaccination reduces the risk of myocarditis is "elusive" and the risks may actually be higher.

"Although vaccine-induced myocarditis is not often fatal in young adults, MRI scans reveal that, of the ones admitted to hospital, approximately 80% have some degree of myocardial damage," Maholtra wrote. "It is like suffering a small heart attack and sustaining some — likely permanent — heart muscle injury. It is uncertain how this will play out in the longer-term, including if, and to what degree, it will increase the risk of poor quality of life or potentially more serious heart rhythm disturbances in the future."

Malhotra said after analyzing clinical trial data, research studies and the Vaccine Adverse Event Reporting System, the risk of adverse events from COVID-19 vaccines remains constant, whereas any benefit derived from a vaccine reduces over time.

Having analyzed the data, it is a "real possibility" that my father's sudden cardiac death was related to his Pfizer shot, he added.