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## Review Article

### Curing the pandemic of misinformation on COVID-19

**Aseem Malhotra**

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#### Abstract

**Background:** In response to severe acute respiratory syndrome (SARS-CoV-2) administered to billions of people worldwide, including the young, the lack of the pre-clinical and clinical testing of these agents, despite the known risks, has led to a global health crisis.

**Aim:** To gain a better understanding of the true benefits and harms of COVID-19 vaccines.

**Methods:** A narrative review of the evidence from randomised controlled trials of BionTech/Pfizer vaccine.

**Results:** In the non-elderly population the "number needed to vaccinate" to prevent one hospitalised from COVID-19. Pharmacovigilance systems and especially in relation to cardiovascular safety. Mirroring a pot of ambulances in England was seen in 2021, with similar data elsewhere.

**Conclusion:** It cannot be said that the consent to receive the global vaccination policies for COVID-19 is long overdue.

**Contribution:** This article highlights the importance of addressing the risk factor for poor outcomes from COVID-19.

**Keywords:** COVID-19; mRNA vaccine; cardiac arrests; real-world evidence

#### Vaccines save lives

The development of safe and highly effective vaccines during the COVID-19 pandemic is a constant reminder of the importance of vaccines. The prominent scars on my left arm are a constant reminder of the impact of tuberculosis (TB), measles, mumps and rubella to name but a few. Collectively, these diseases have caused more deaths than all other infectious diseases combined (#CIT0001\_71). The greatest success of vaccination was the global eradication of smallpox.

In other words, almost one in three people who contracted it would have died. In contrast, 95 out of 100 individuals being protected from symptomatic COVID-19. Similarly, one dose of the COVID-19 vaccine is assumed to be 95% effective. Similarly, if exposed to chickenpox, only five out of 100 vaccinated individuals would contract the disease.

Vaccines are also some of the safest interventions in the world. They are expected, given that they are being administered to prevent so many deaths.

summer of 2020, several drug companies including both Pfizer and Moderna had developed a vaccine with more than '95% effectiveness' against coronavirus disease 2019 (COVID-19).

### A doctor's experience

Volunteering in a vaccine centre, I was one of the first to receive the vaccine in early 2021. Although I knew my individual risk was small from COVID-19, I wanted to prevent transmission of the virus to my vulnerable patients, especially those patients and people in my social network who were asking me for advice.

I was asked to appear on *Good Morning Britain* after a previous episode where I was also interviewed, explained that I convinced her to take the vaccine.

But a very unexpected and extremely harrowing personal tragedy would ultimately prove to be a revelatory and eye-opening experience. This was to eminent scientists involved in COVID-19 research, vaccine researchers who had previously concluded that contrary to my own initial dogmatic belief, the vaccine was not 95% effective. This critical appraisal is based upon the analytical framework of epidemiology, clinical expertise and/or experience with use of the best available evidence.

### A case study

Case studies are a useful way of conveying complex clinical information in a concise summary results of a clinical trial.

On 26 July 2021, my father, Dr Kailash Chand OBE, former director of a major hospital, also taken both doses of the Pfizer mRNA vaccine six months earlier. A subsequent inquiry revealed that a significant ambulance delay likely contributed to a 75% blockage in his right coronary. Given that he was an elderly man during the whole of lockdown, this was a shock to everyone involved. In detail. My father who had been a keen sportsman all his life, had a heart attack a few years earlier, which had revealed no significant problems. He had lost belly fat, reduced the dose of his blood pressure pills, started taking statins, triglycerides, significantly improving his cholesterol profile.

I couldn't explain his post-mortem findings, especially as this was in my own special area of research. That is, how to delay progression of heart disease through lifestyle changes. <sup>4</sup> (#CIT0004\_71) We emphasize that this was exacerbated by insulin resistance. Then, in November 2021, my father died. Findings. In over 500 middle-aged patients under regular follow-up, insulin resistance correlated with risk of heart attack, the mRNA vaccine was associated with a 25% reduction in risk 2–10 weeks post mRNA vaccine. In a control group, but nevertheless, even if partially correct, that would have been more importantly heart attack risk, within months of taking the vaccine six months earlier, could have contributed to his unexplained death.

### Questioning the data

I recalled a cardiologist colleague of mine informing me, to my surprise, for a number of reasons, including his personal low background COVID-19 risk, short- and longer-term harms. One thing that alarmed him was the data in the supplementary appendix, specifically that there was a 25% reduction in risk (#CIT0007\_71) These figures were small in absolute terms and without further studies it was not possible to rule out this case it could have the effect of causing a surge in cardiac arrhythmias.

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**TABLE 1:** (<https://insulinresistance.org/index.php/jir/article/view/71>)  
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 vaccination by age.

In terms of efficacy, headlines around the world made very big claims, glossing over the big difference between controlled trial and real-world outcomes. To interpret this that if 100 people are vaccinated then 95% of them will not get COVID-19 (CDC) director Rochelle Walensky recently admitted in an interview that it would not significantly stop transmission and infection, but this was later revealed that a person was 95% 'less likely' to catch the virus. To know the true value of any treatment one needs to understand the *absolute individual risk reduction*.

Importantly, it turns out that the trial results suggest that the absolute risk reduction for this was 0.84% (0.88% reduced for every 10 000 people vaccinated in trial 4 would have tested positive in the placebo group, 9912 of the 10 000 (over 99%) would not have tested positive. To prevent one such symptomatic positive person to be vaccinated, you would need to vaccinate 119 people to prevent one such symptomatic positive person beyond the scope of this article).<sup>10 (#CIT0010\_71)</sup>

This absolute risk reduction figure (0.84%) is extremely important. Did you receive the shot? Transparent communication of risk and benefits is essential for informed consent.<sup>11 (#CIT0011\_71)</sup>

The Academy of Medical Royal Colleges made this clear in a report to the chair of the General Medical Council. In fact, in a 2009 World Medical Journal article, it stated, 'It's an ethical imperative that every doctor and patient should be free from unnecessary anxiety and manipulation'.<sup>13 (#CIT0013\_71)</sup>

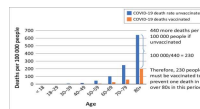
Contrary to popular belief, what the trial did not show was an increase in deaths over the 6-month period of the trial, but the actual numbers were very close. There were 10 deaths from COVID-19 in the placebo group and one death from COVID-19 in the vaccine group. This is actually slightly more deaths<sup>14 (#CIT0014\_71)</sup> in the vaccine group than in the placebo group. The rate of COVID-19 illness classed as severe in the placebo group was 0.00011 and in the vaccine group 0.000011. The illness even in regions chosen for the trial because of perceived high risk.

Finally, the trials in children did not even show a reduction in hospital admissions or deaths. The Food and Drug Administration's (FDA's) own website states that the trials in children did not show a reduction in hospital admissions or deaths.

[R]esults from currently authorised SARS-COV-2 antibody treatments do not show a reduction in hospital admissions or deaths from COVID-19 at any time, and especially after the peak of the Delta wave.

Now that we know what the published trial did and did not show, we can see that the vaccine would be in reducing mortality or any other adverse effects. It would be in reducing symptomatic infection from ancestral variants, then to find the number of people who would need to be vaccinated to prevent one death (from the infection that lead to a single death for each age group. This is the number of people who would need to be vaccinated to prevent one death) from the vaccine. For example, if my risk at age 44 from the infection that lead to a single death for each age group is 1 over 1000, then the vaccine protecting me from death is 1 over 1000.

Of course, even for those people who do become infected the vaccine would be in reducing mortality or any other adverse effects. It would be in reducing symptomatic infection from ancestral variants, then to find the number of people who would need to be vaccinated to prevent one death (#CIT0016\_71) during the Delta wave gives 230 for people over 70 rising to 520 for people in their 70s and 10 000 for people in their 80s. However, these figures will be distorted by inaccuracies in the data. In a paper by John Ioannidis in *BMJ* evidence-based medicine the inference is that the data generated by 'pre-existing immunity, vaccination misclassification, decision, treatment use differences and death attribution'.<sup>18</sup>



(<https://insulinresistance.org/index.php/jir/article/view/10>)

**TABLE 2:** (<https://insulinresistance.org/index.php/jir/article/view/10>) **Number of people who would need to be vaccinated to prevent one death based on death rates and case fatality rates from UKHSA data.**

These numbers are for the whole population of England and Wales, including those with pre-existing conditions.<sup>19 (#CIT0019\_71)</sup> It is also important to note that the death data is biased. For example, the unvaccinated are more likely to die from severe illness or death should they be infected.

Professor Carl Heneghan, the director of the Centre of Evidence-Based Medicine, has noted that some of his own patients who ended up in intensive care units were already suffering from terminal illness.

Given these limitations, the above figures are likely an overestimate and the uncertainty is an essential component of shared decision-making.

What should be part of the shared decision-making informed by these lines: Depending on your age, several people die from the Delta variant of COVID-19 over a year. The younger you are, reaching at least 2600 for people in their 50s. Omicron, which has been shown to be 30% – 50% less lethal than Delta, long any protection actually lasts for is unknown; boosters are also uncertain.

But how many people have had a conversation that even approximates the potential benefits and harms as yet to be fully quantified harms.

Although many have proposed that omicron is intrinsically less lethal (and thus less likely to cause virus) immunity built up by prior exposure protecting against reinfection, whether it is a viral or immune-related phenomenon, the milligram of harm should not be attributed to vaccines. ≤

### What are the harms?

Concerns have already been raised about the under-reporting of adverse events. A reporter Maryanne Demasi analysed the various ways that participants limited to the type of adverse event they could report and those who withdrew from the trial and not reported in the final results. The fact that the vaccine to subjects in the placebo group, essentially torpedoed the pharmacovigilance data.

Such data have shown that one of the most common mRNA (Pfizer) side effects showed an increased risk from mRNA vaccination over background. Myocarditis is more common after COVID-19 infection than after vaccination. The risk of myocarditis in subsequent infection is elusive, and vaccines were rolled out to the younger cohorts having remained the most up-to-date evidence, a paper from Israel<sup>24</sup> (#CIT0024\_7) showed risks of either myocarditis or pericarditis from COVID-19, stroke, and other conditions, with or without COVID-19 infections as an additional risk factor.

Indeed, this reflects my own clinical experience of advising a patient with a history of myocarditis post mRNA vaccination but aren't reporting symptoms like fatigue and shortness of breath on exertion a few weeks after vaccination. Another lady in her 30s experienced similar symptoms. Ventricular impairment was also present on echo and a subsequent MRI scan, which is consistent with damaged heart tissue.

Although vaccine-induced myocarditis is not often fatal in young people, it can cause some degree of myocardial damage.<sup>25</sup> (#CIT0025\_71) ,<sup>26</sup> (#CIT0026\_71) heart muscle injury. It is uncertain how this will play out in the long term or potentially more serious heart rhythm disturbances in the future.

A number of reports have produced concerning rates of myocarditis. A Hong Kong study in male children and adolescents aged 12–17 years (which measured myocarditis cases that have been diagnosed in a hospital setting, which long-term harm cannot be ruled out). In addition, and other studies have shown similar findings.

The United Kingdom relies on the Medicines and Health Regulatory Agency (MHRA) to ensure adequate to cope with a rapid roll-out of a brand new product. The MHRA product in April 2021 for younger people after 9.7 million doses had been administered. The problem after only 150 000 doses had been administered.

In the United Kingdom, since the vaccine roll-out there have been reports of an association with the mRNA COVID-19 vaccinations involving children and young people (at least one dose), the MHRA figures show around 1 in 120 serious adverse reactions (SARs) unclear about the rate and furthermore do not separate out the total number of reports in the modern medical era and equals the total number of reports for all vaccines) up to 2020.<sup>33</sup> (#CIT0033\_71) In comparison, for the year 2020, there was around 1 in 4000, more than thirty times less frequent than in the modern medical era. It does separate out the reported serious adverse reactions and the total number of reports for all products that result in hospitalisation or are life changing.<sup>35</sup> (#CIT0035\_71)

Another, and more useful, source of information (because of Vaccine Adverse Effect Reporting System (VAERS)). As with the vaccines is completely unprecedented. For example, over 24 within 48 h of injection, and half within two weeks. The average given for this is that the COVID-19 vaccine roll-out is unprecedented. The United States has administered 150 million – 200 million vaccinations. An analysis of a sample of 250 early deaths suggested that the VAERS report is a violation of Federal law punishable by fine

Given that VAERS was set up to generate early signals of potential harm, it is perverse to only now criticise it as unreliable when there see

It has been estimated that serious adverse effects that are of the above comments in relation to VAERS reports are considerable, suggesting that as few as 1% of serious adverse events are identified. In the United Kingdom, it has been estimated that only 10% of serious adverse events are reported. A publication co-authored by some of the most trusted medical researchers in the world, data. Accessing data from the FDA and health Canada websites, the authors concluded that the absolute risk of a serious adverse event from COVID-19 hospitalisation in randomised controlled trials.<sup>17</sup> (

What VAERS and other reporting systems (including the yet to be established) miss are potential medium to longer term harms that neither VAERS nor other reporting systems can detect. The risk of a vaccine increases the risk of a coronary event within a few months, and would increase event rates well beyond the first few weeks of follow-up later on.

It is instructive to note that according to ambulance service records, there was a (~20% increase) out-of-hospital cardiac arrest calls compared to before. Information laws from one of the largest ambulance trusts in the UK, thereafter the rise has been seen disproportionately in the years following the introduction of the vaccine.<sup>42</sup> (#CIT0042\_71)

Similarly, a recent paper in *Nature* revealed a 25% increase in hospital admissions significantly associated with administration with the first and second doses.<sup>43</sup> (#CIT0043\_71) The authors state that:

[7]he findings raise concerns regarding vaccine-induced harm, and the established causal relationship between vaccines and harm.

The disturbing findings in this paper have resulted in calls for a review. We would have published a paper with differing assumptions and conclusions.

Many other concerns have been raised about potential harms from the vaccine. If hypothetical, it may be a grave mistake to focus only on what is known.

**What could be the mechanism of harm?**

For 'conventional vaccines', an inert part of the bacteria or virus is used. For the COVID-19 vaccines, spike protein has been shown to be months after vaccination<sup>44</sup> (#CIT0044\_71) and is distributed throughout the body. For respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines, the spike protein is not inert, but rather it is the source of much of the pathology associated with the virus.<sup>45</sup> (#CIT0045\_71) and lung damage. It is instructive to note that potential serious adverse events of special interest that may be associated with the platform, adverse events associated with prior vaccines in general, immunopathogenesis<sup>40</sup> (#CIT0040\_71) (see **Figure 2** (#F0002\_71))



(<https://insulinresistance.org/index.php/jir/article/view/17>)

**Is the vaccine doing more harm than good?**

The most objective determinant of whether the benefits of the vaccine outweigh the thorny issue as to what should be classified as a C-surprising – to say the least – if during an apparently deadly cause mortality.

Pfizer's pivotal mRNA trial in adults did not show any statistically significant difference in mortality, with a slightly higher number of deaths in the treatment arm versus in the placebo arm.

Work by Fenton et al. showed an unusual spike in mortality in the youngest age group. [48 \(#CIT0048\\_71\)](#) The rapid shrinking in the size of the unvaccinated population is likely an artifact. Alternative explanations must include the (more) unvaccinated population: in other words, those counted as 'unvaccinated' (a freedom of information [FOI] request has now confirmed that the population is unvaccinated, creating a misleading picture of efficacy vs deaths).

One has to raise the possibility that the excess cardiac arrest deaths may all be signalling a non-COVID-19 health crisis exacerbated by the pandemic.

Given these observations, and reappraisal of the randomised controlled trial, the vaccine has been net beneficial in all age groups. While a case can be made for the youngest age groups, that case seems tenuous at best in other sections of the population. The overall benefit is considered (especially for multiple injections, robust safety data, and the fact that it is not a reckless gamble. It's important to acknowledge that the risks of COVID-19 as new variants are (1) less virulent and (2) not targeted by the vaccine. A pause and re-evaluation of the vaccine is warranted.

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The author declares that he/she has no financial or personal competing interests.

### Author's contribution

A.M. is the sole author of this article.

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This article followed all ethical standards for research without involving human participants.

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### Data availability

Data sharing is not applicable to this article, as no new data were generated or analysed in support of this research.

### Disclaimer

The views and opinions expressed in this article are those of the authors and do not necessarily reflect those of the agency of the authors.

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