Statement

COVID-19 Vaccines Safety and Efficacy

by Dr Aseem Malhotra MD for Mika Vauhkala

Short Biodata:

Dr Aseem Malhotra is an NHS trained Consultant Cardiologist and an internationally renowned expert in the prevention, diagnosis and management of heart disease. His areas of expertise include evidence-based medicine and collaborative shared decision-making with patients.

From 2018 - 2023 he was visiting professor of evidence-based medicine at the Bahiana school of medicine and public health, Salvador, Brazil. He is a founding member of Action on Sugar and was the lead campaigner highlighting the harm caused by excess sugar consumption in the United Kingdom, particularly its role in type 2 diabetes and obesity. In 2015 he helped co-ordinate the Choosing Wisely campaign by the Academy of Medical Royal Colleges as lead author in a BMJ paper to highlight the risks of overuse of medical treatments. In the same year he became the youngest member to be appointed to the board of trustees of UK health think tank, The King's Fund that advises government on health policy. Aseem is a frequent expert commentator in print and broadcast media and he has written scores of articles for a number of publications including the BMJ, British Journal of Sports Medicine, BMJ Open Heart, JAMA Internal Medicine, Prescriber, The Pharmaceutical Journal, European Scientist, The Guardian and Observer, BBC online, Huffington Post, The Daily Mirror, Daily Mail, The Daily Telegraph and the Washington Post. He is serves on the editorial board of the Journal of Metabolic Health.

Aseem has appeared in the Health Service Journal's list of top 50 BME pioneers, and has won a number of awards for his work to raise awareness of diet-related illness both in the UK and internationally. He is a pioneer of the lifestyle medicine movement in the UK and has had feature articles written about him in the New York Times, The Guardian, The Telegraph, The i, and Healthcare Leader. In 2018 he was ranked by software company Onalytica as the number 1 doctor in the world influencing obesity thinking.

In 2016 he was named in the Sunday Times Debrett's list as one of the most influential people in science and medicine in the UK in a list that included Professor Stephen Hawking. His total Altmetric score (measure of impact and reach) of his medical journal publications since 2013 is over 10,000 making it one of the highest in the World for a clinical doctor during this period. His first book co-authored with Donal O' Neill, The Pioppi Diet, has become an international best seller. His second book, the 21 day immunity plan is a Sunday Times best seller. During the first year of the Covid pandemic he was asked by the Secretary of State for Health, Matt Hancock to advice on the link between covid and obesity and how best to reduce population risk to infection. His recently published third book A Statin Free Life is already a best seller.

Award winning American Science Journalist Gary Taubes describes Aseem as someone who has "probably done more in the UK to inject sanity in to nutrition science and the pharmaceutical industry debate than any human being alive".

Sir Richard Thompson, Past President of the Royal College of Physicians and former personal physician to her majesty The Queen said "Dr Aseem Malhotra is changing the face of medicine and his revolutionary book the Pioppi Diet should be read by everyone".

The Mayor of Manchester Andy Burnham said " He's really making people think differently about what they eat and how they live their life. Through his work he's going to change many thousands of lives, millions of lives for the better".

https://draseemmalhotra.co.uk/

Summary

In response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), several new pharmaceutical agents have been administered to billions of people worldwide, including the young and healthy at little risk from the virus. Considerable leeway has been afforded in terms of the pre-clinical and clinical testing of these agents, despite an entirely novel mechanism of action and concerning biodistribution characteristics.

Re-analysis of randomised controlled trials using the messenger ribonucleic acid (mRNA) technology suggests a greater risk of serious adverse events from the vaccines than being hospitalised from COVID-19. Pharmacovigilance systems and real-world safety data, coupled with plausible mechanisms of harm, are deeply concerning, especially in relation to cardiovascular safety. 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.

In parallel, authorities and sections of the medical profession have supported unethical, coercive, and misinformed policies such as vaccine mandates and vaccine passports, undermining the principles of ethical evidence-based medical practice and informed consent. These regrettable actions are a symptom of the 'medical information mess': The tip of a mortality iceberg where prescribed medications are estimated to be the third most common cause of death globally after heart disease and cancer. Underlying causes for this failure include regulatory capture – guardians that are supposed to protect the public are in fact funded by the corporations that stand to gain from the sale of those medications.

To gain a better understanding of the true benefits and potential harms of the messenger ribonucleic acid (mRNA) coronavirus disease (COVID) vaccines, I conducted a narrative review of the evidence from randomised trials and real world data of the COVID mRNA products with special emphasis on BioNTech/Pfizer vaccine[1].

In a second published review, I identified the major root causes of these public health failures, it was found that the public health messaging has also resulted in wanton waste of resources and a missed opportunity to help individuals lead healthier lives with relatively simple – and low cost – lifestyle changes[2].

Key aspects of these reviews for 2020-2021 will be developed here for the case of Mr Vauhkala.

I - Safety and Efficacy of the COVID-19 Vaccines up to end 2021

A doctor's experience

Volunteering in a vaccine centre, I was one of the first to receive two doses of Pfizer's messenger ribonucleic acid (mRNA) vaccine, at the end of January 2021. Although I knew my individual risk was small from COVID-19 at age 43 with optimal metabolic health, the main reason I took the jab was to prevent transmission of the virus to my vulnerable patients. During early 2021, I was both surprised and concerned by a number of my vaccine-hesitant patients and people in my social network who were asking me to comment on what I regarded at the time as merely 'anti-vax' propaganda.

But a very unexpected and extremely harrowing personal tragedy was to happen a few months later that would be the start of my own journey into 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.

This critical appraisal is based upon the analytical framework for practicing and teaching evidence-based medicine, specifically utilising individual clinical expertise and/or experience

[1] Malhotra, A. (2022a). Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 1. Journal of Metabolic Health, 5(1), 8 pages. doi:https://doi.org/10.4102/jir.v5i1.71

[2] Malhotra, A. (2022b). Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 2. Journal of Metabolic Health, 5(1), 10 pages. doi: https://doi.org/10.4102/jir.v5i1.72

with use of the best available evidence and taking into consideration patient preferences and values.

A case study

Case studies are a useful way of conveying complex clinical information and can elicit useful data that would be lost or not be made apparent in the summary results of a clinical trial.

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. A subsequent inquiry revealed that a significant ambulance delay likely contributed to his death[3]. But 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.

I couldn't explain his post-mortem findings, especially as there was no evidence of an actual heart attack but with severe blockages. This was precisely my own special area of research. That is, how to delay progression of heart disease and even potentially reverse it. In fact, in my own clinic, I successfully prescribe a lifestyle protocol to my patients on the best available evidence on how to achieve this. I've even co-authored a high-impact peer-reviewed paper with two internationally reputed cardiologists (both editors of medical journals) on shifting the paradigm on how to most effectively prevent heart disease through lifestyle changes[4].We emphasised the fact that coronary artery disease is a chronic inflammatory condition that is exacerbated by insulin resistance.

In November 2021, I was made aware of a peer-reviewed abstract published in *Circulation*, with 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 predictive risk[5] of a coronary event within five years from 11% pre-mRNA vaccine to 25% 2–10 weeks post mRNA vaccine**. An early and relevant criticism of the validity of the findings was that there was no control group, but nevertheless, even if partially correct, that would mean that there would be a large acceleration in progression of coronary artery disease, and more importantly heart attack risk, within months of taking the jab[6]. I wondered whether my father's Pfizer vaccination, which he received six months earlier, could have contributed to his unexplained premature death and so I began to critically appraise the data.

Questioning the Data

I recalled a cardiologist colleague of mine informing me, to my astonishment at the time, that he had made a decision not to take the vaccine for a number of reasons, including his

[3] Gallagher P. The death of Dr Kailash Chand: How a lethal mix of NHS privatisation and lack of resources led to tragedy [Homepage]. iNews. 2021 [accessed 2023 Nov 17]. https://inews.co.uk/news/health/the-death-of-dr-kailash-chand-how-a-lethal-mix-of-nhs-privatisation-and-lack-of-resources-led-to-tragedy-1303449

[4] Malhotra A, Redberg RF, Meier P. Saturated fat does not clog the arteries: Coronary heart disease is a chronic inflammatory condition, the risk of which can be effectively reduced from healthy lifestyle interventions. Br J Sports Med. 2017;51(15):1111–1112. https://doi.org/10.1136/bjsports-2016-097285

[5] *Predictive risk*: this study used the PULS Cardiac Test (Predictive Health Diagnostics Co., Irvine, CA) a clinically utilized measurement of multiple protein biomarkers, which generates a score predicting the 5 year risk (percentage chance) of a new Acute Coronary Syndrome (ACS) called the PULS Score. This clinic has been using the PULS Cardiac Test (Predictive Health Diagnostics Co., Irvine, CA) a clinically utilized measurement of multiple protein biomarkers, which generates a score predicting the 5 yr risk (percentage chance) of a new Acute Coronary Syndrome (ACS) called the PULS Score.

[6] Gundry SR. Abstract 10712: Observational findings of PULS cardiac test findings for inflammatory markers in patients receiving mRNA vaccines. Circulation. 2021;144(Suppl_1):A10712. https://doi.org/10.1161/circ.144.suppl_1.10712

personal low background COVID-19 risk[7,8] and concerns regarding unknown short- and longer-term harms. One thing that alarmed him about Pfizer's pivotal mRNA trial published in *The New England Journal of Medicine,* in December 2020, was the data in the supplementary appendix, specifically that there were four cardiac arrests in those who took the vaccine versus only one in the placebo group[9].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. In terms of efficacy, headlines around the world made very bold claims of 95% effectiveness, the interchangeable use of 'efficacy' and 'effectiveness' glossing over the big difference between controlled trial and real-world conditions[10].

Contrary to popular belief**, what the Pfizer pivotal efficacy trial did not show was any statistically significant reduction in serious illness or COVID-19 mortality from the vaccine over the 6-month period of the trial**, **but the actual numbers of deaths (attributed to COVID-19) are still important to note**. There were only two deaths from COVID-19 in the placebo group and one death from COVID-19 in the vaccine group. Looking at all-cause mortality over a longer period, there were actually slightly more deaths[11] in the vaccine group (19 deaths) than in the placebo group (17 deaths). Also of note was the extremely low rate of COVID-19 illness classified as severe in the placebo group (nine severe cases out of 21 686 subjects, 0.04%), reflecting a very low risk of severe illness even in regions chosen for the trial because of perceived high prevalence of infection.

Now that we know what the published trial did and did not show in terms of the vaccine efficacy, we can attempt to extrapolate what the effect of the vaccine would be in reducing mortality or any other adverse outcome from the virus.

Clinical Harms

Concerns have already been raised about the under-reporting of adverse events in the clinical trials for the COVID-19 vaccines. Investigative medical reporter Maryanne Demasi analysed the various ways that the pivotal mRNA trials failed to account for serious harms[12]. Not only were trial participants limited to the type of adverse event they could report on their digital apps, but some participants who were hospitalised after inoculation were withdrawn from the trial and not reported in the final results. After two months into the pivotal trials, the FDA allowed vaccine 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.

Such data have shown that one of the most common mRNA COVID-19 vaccine-induced harms is myocarditis. A study across several Nordic countries showed an increased risk from mRNA vaccination over background, especially in young males[13]. Authorities have repeatedly maintained that myocarditis is more common after COVID-19 infection than after vaccination[14]. However, trial data demonstrating that vaccination reduces the risk of myocarditis in subsequent infection is elusive, and in fact the risks may be additive. Incidence

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[7] Axfors C, Ioannidis JPA. Infection fatality rate of COVID-19 in community-dwelling elderly populations. Eur J Epidemiol. In press 2022;37(3):235–249. https://doi.org/10.1007/s10654-022-00853-w

[8] Axfors C, Ioannidis JPA. Infection fatality rate of COVID-19 in community-dwelling populations with emphasis on the elderly: An overview. medRxiv, 2021.07.08.21260210; doi: https://doi.org/10.1101/2021.07.08.21260210

[9] Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. N Engl J Med. 2020;383(27):2603–2615. https://doi.org/10.1056/NEJMoa2034577

[10] Burches E, Burches M. Efficacy, effectiveness and efficiency in the health care: The need for an agreement to clarify its meaning. Int Arch Public Health Community Med. 2020;4:35. https://doi.org/10.23937/2643-4512/1710035

[11] Wollersheim S, Schwartz A. BLA Clinical Review Memorandum* [Homepage]. 2021 [accessed 2023 Nov 17]. https://www.fda.gov/media/152256/download

[12] Demasi M. Are adverse events in Covid-19 vaccine trials under-reported? [homepage]. Investigative Journalism. Nov 2021 [accessed 2023 Nov 17]. Available from https://maryannedemasi.com/publications/f/are-adverse-events-in-covid-19-vaccine-trials-under-reported

[13] Karlstad Ø, Hovi P, Husby A, et al. SARS-CoV-2 vaccination and myocarditis in a Nordic cohort study of 23 million residents. JAMA Cardiol. 2022;7(6):600–612. https://doi.org/10.1001/jamacardio.2022.0583

[14] Patone M, Mei XW, Handunnetthi L, et al. Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection. Nat Med 2022;28:410422. .https://doi.org/10.1038/s41591-021-01630-0
Note:the same authors had already warned about this risk earlier in 2021 https://www.phc.ox.ac.uk/publications/1225727

of myocarditis rocketed from spring 2021 when vaccines were rolled out to the younger cohorts having remained within normal levels for the full year prior, despite COVID-19[15], with the most up-to-date evidence, a paper from Israel[16] presented the results of a large population-based retrospective cohort study of 196,992 adults after COVID-19 infection in Clalit Health Services members in Israel between March 2020 and January 2021. The study found that the infection itself, prior to roll-out of the vaccine, conferred no increase in the risks of either myocarditis or pericarditis from COVID-19, strongly suggesting that the increases observed in earlier studies were because of the mRNA vaccines, with or without COVID-19 infections as an additional risk in the vaccinated[16].

Indeed, this reflects my own clinical experience of advising and managing several patients in the community who presented with a clear suggestion from the history of myocarditis post mRNA vaccination but aren't necessarily unwell enough to require hospital admission. Many case studies can be presented to demonstrate this.

II – Evidence-based Medical & Public Health Decision-Making in question

Health System Indicators

A number of reports and retrospective studies on 2020-2021 have produced concerning rates of myocarditis, depending on age, ranging from 1 in 6000 in Israel[17] to 1 in 2700 in a Hong Kong study in male children and adolescents aged 12–17 years[18]. Most of the epidemiology studies that have been carried out have measured myocarditis cases that have been diagnosed in a hospital setting, and do not claim to be a comprehensive measure of more mild cases (from which long-term harm cannot be ruled out). In addition, under-reporting of adverse events is the scourge of pharmacovigilance data[19].

It is instructive to note that according to ambulance service data**, in 2021 (the year of the vaccine roll-out), there were approximately an extra 20 000 (~20% increase) out-of-hospital cardiac arrest calls compared to 2019, and approximately 14 000 more than in 2020**. Data obtained under Freedom of Information laws from one of the largest ambulance trusts in England suggest that **there was no increase from November 2020 to March 2021, and thereafter the rise has been seen disproportionately in the young**[20]. This is a huge signal that surely needs investigating with some urgency[21].

Similarly, a scientific report published in *Nature*, comparing cardiovascular emergency events during January–May 2021 with the years 2019–2020[22] on the basis of Israel Government Data base Portal vaccination data revealed a **25% increase in both acute coronary syndrome and cardiac arrest calls in the 16- to 39-year-old age groups significantly associated with administration with the first and second doses of the mRNA vaccines but no association with COVID-19 infection**[23].

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[15] Diaz GA, Parsons GT, Gering SK, Meier AR, Hutchinson IV, Robicsek A. Myocarditis and pericarditis after vaccination for COVID-19. JAMA. 2021;326(12):1210–1212. https://doi.org/10.1001/jama.2021.13443

[16] Tuvali O, Tshori S, Derazne E, et al. The incidence of myocarditis and pericarditis in post COVID-19 unvaccinated patients-a large population-based study. J Clin Med Res. 2022;11(8):2219. https://doi.org/10.3390/jcm11082219

[17] Fronza M, Thavendiranathan P, Chan V, et al. Myocardial injury pattern at MRI in COVID-19 vaccine-associated myocarditis. Radiology. 2022;304(3):553–562. https://doi.org/10.1148/radiol.212559
Note: included In this retrospective cohort study, consecutive adult patients with myocarditis with at least one T1-based and at least one T2-based abnormality at cardiac MRI performed at a tertiary referral hospital from December 2019 to November 2021.

[18] Chua GT, Kwan MYW, Chui CSL, et al. Epidemiology of acute myocarditis/pericarditis in Hong Kong adolescents following comirnaty vaccination. Clin Infect Dis. 2021; ciab989. https://doi.org/10.1093/cid/ciab989

[19] Gahr M, Eller J, Connemann BJ, Schönfeldt-Lecuona C. Underreporting of adverse drug reactions: Results from a survey among physicians. Eur Psychiatry. 2017;41:S369. https://doi.org/10.1016/j.eurpsy.2017.02.377

[20] Patients with heart conditions/strokes from 2017-present day [homepage]. WhatDoTheyKnow; 2022 [accessed 2023 Nov 17]. https://www.whatdotheyknow.com/request/patients_with_heart_conditionsst

[21] HART. An epidemic of cardiac arrests [Homepage]. HART. HART Group; 2022 [accessed 2023 Nov 17]. https://www.hartgroup.org/an-epidemic-of-cardiac-arrests/

[22] Data on the vaccinations and COVID-19 cases were obtained from the online Israel Government Database Portal (https://info.data.gov.il/datagov/home/). These data include the number of daily administered 1st and 2nd vaccination doses by age group, as well as the weekly number of new confirmed COVID-19 cases by age group, across all of Israel

[23] Sun CLF, Jaffe E, Levi R. Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third COVID-19 wave. Scientific Reports, Nature 2022;12(1):6978. https://doi.org/10.1038/s41598-022-10928-z

The authors state that:

"The findings raise concerns regarding vaccine-induced undetected severe cardiovascular side effects and underscore the already established causal relationship between vaccines and myocarditis, a frequent cause of unexpected cardiac arrest in young individuals".

Reporting Systems Data

The United Kingdom relies on the Medicines and Health Regulatory Agency's (MHRAs) 'Yellow Card' reporting system[24], which is far from adequate to cope with a rapid roll-out of a brand-new product. It only detected the clotting problems that resulted in the withdrawal of the AstraZeneca product in April 2021 for younger people after 9.7 million doses had been given in the United Kingdom[25]; in contrast, Denmark detected the problem after only 150 000 doses had been administered[26].

In the United Kingdom, since the vaccine roll-out there have been almost 500 000 adverse event reports recorded (via the Yellow Card system) in association with the mRNA COVID-19 vaccinations involving over 150 000 individuals. In terms of the number of reports per person (i.e. having received at least one dose), the MHRA figures show around 1 in 120 suffering a likely adverse event that is beyond mild[27]. However, the MHRA are unclear about the rate and furthermore do not separate out the serious adverse events. Nevertheless, this level of reporting is unprecedented in the modern medical era and equals the total number of reports received in the first 40 years of the Yellow Card reporting system (for all medicines – not just vaccines) up to 2020[28]. In comparison, for the measles, mumps and rubella (MMR) vaccine, the number of reports per person vaccinated was around 1 in 4000, more than thirty times less frequent than the 1 in 120 Yellow Card reports for COVID-19 vaccine recipients[28].

Norway does separate out the reported serious adverse reactions and has shown a rate of approximately 1 in 1000 after two doses of BioNTech/Pfizer mRNA product that result in hospitalisation or are life changing[29].

Another, and more useful, source of information (because of the level of detail for each report made available to the public) is **the United States (US) Vaccine Adverse Effect Reporting System (VAERS)**. As with the UK's system, the level of reports – including serious ones – associated with COVID-19 vaccines is completely unprecedented. For example, over 24 000 deaths had been recorded in VAERS as of 02 March 2022; 29% of these occurred within 48 h of injection, and half within two weeks. Earlier as of 15 October 2021, 17'128 deaths had already been recorded, of which 818'044 injuries cases and 26'199 permanent disabilities. An analysis published on 8 September 2021 by Hoeg et al. from this database shows that young people aged 12 to 17 are exposed to a higher cardiac risk (myocarditis type) than the risk of hospitalisation for COVID-19. The group with the most severe risk of heart problems after experimental vaccination is the youngest group of 12-15 year olds

The average reporting rate prior to 2020 was less than 300 deaths per annum. One explanation often given for this is that the COVID-19 vaccine roll-out is unprecedented in

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[24] Coronavirus vaccine – Weekly summary of Yellow Card reporting [Homepage]. GOV.UK. [accessed 2023 Nov 17]. https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

[25] Yellow Card reports compared for Oxford/AstraZeneca and PfizerBioNTech product (2021). Covid-19: European countries suspend use of Oxford-AstraZeneca vaccine after reports of blood clots. *BMJ:*372:N699 - doi: https://doi.org/10.1136/bmj.n699 (Published 11 March 2021)

[26] BBC News. AstraZeneca vaccine: Denmark stops rollout completely. BBC [serial online]. 2021 [accessed 2023 Nov 17]; https://www.bbc.co.uk/news/world-europe-56744474

[27] Coronavirus vaccine – Weekly summary of Yellow Card reporting [Homepage]. GOV.UK. [accessed 2023 Nov 17]. https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

[28] Medicines and Healthcare products Regulatory Agency. All spontaneous suspected UK Adverse Drug Reaction (ADR) reports associated with the MMR vaccine in 2020 [homepage]. 2021 [accessed 2023 Nov 17] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1041736/FOI_21-877-4.pdf

[29] Norwegian Medicines Agency. Reported suspected adverse reactions to COVID19 vaccines as of 04.01.2022 [Homepage]. 2022 [accessed 2023 Nov 17]. https://legemiddelverket.no/Documents/English/Covid-19/20220107%20Reported%20suspected%20adverse%20reactions%20coronavirus%20vaccines%20-%20updated%2020220113.pdf

Hoeg T.B., Krug A., Stevenson J. and Mandrola J. (2021). SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis, medRxiv 2021.08.30.21262866; doi: https://doi.org/10.1101/2021.08.30.21262866.

scope; however, this is not valid, since (for the last decade at any rate) the United States has administered 150 million – 200 million vaccinations annually. Another criticism of VAERS is that 'anyone can make an entry', yet, in fact, an analysis of a sample of 250 early deaths suggested that the vast majority are hospital or physician entries[30], and knowingly filing a false VAERS report is a violation of Federal law punishable by fine and imprisonment[31]. Given that **VAERS was set up to generate early signals of potential harm for new vaccines, and was instrumental in doing so for several products, it seems perverse to only now criticise it as unreliable when there seem to have been no changes in the way it operates**.

It has been estimated that serious adverse effects that are officially reported are actually a gross underestimate, and this should be borne in mind when the above comments in relation to VAERS reports are considered. For example, a paper by David Kessler (a former FDA Commissioner) cites data suggesting that as few as 1% of serious adverse events are reported to the FDA[32]. Similarly in relation to the Yellow Card scheme in the United Kingdom, it has been estimated that only 10% of serious adverse effects are reported[33,34]. A pre-print publication co-authored by some of the most trusted medical scientists in the world in relation to data transparency adds validity to pharmacovigilance data. Accessing data from the FDA and Health Canada websites and combining results from journal articles that published the Pfizer and Moderna trials, the authors concluded that the absolute risk of a serious adverse event from the mRNA vaccines (a rate of one in 800) significantly exceeded the risk of COVID-19 hospitalisation in randomised controlled trials[35,36].

What VAERS and other reporting systems will miss are potential medium to longer term harms that neither patients nor doctors will automatically attribute to the drug. For example, if the mRNA vaccine increases the risk of a coronary event within a few months (in what was a likely contributory factor in my father's sudden cardiac death), then this would increase event rates well beyond the first few weeks of the jab yet linking it back to the vaccine, and thus reporting it is highly unlikely to occur later on.

Biological mechanism of harm

For 'conventional vaccines', an inert part of the bacteria or virus is used to 'educate' the immune system. The immune stimulus is limited, localised and short-lived. For the COVID-19 vaccines, spike protein has been shown to be produced continuously (and in unpredictable amounts) for at least four months after vaccination[37] and is distributed throughout the body after intramuscular injection[38]. For the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines, the spike protein was chosen, possibly because it enables cell entry. However, this protein is not inert, but rather it is the source of much of the pathology associated with severe COVID-19, including endothelial damage[39], clotting abnormalities[40] and lung damage. It is instructive to note that prior to roll-out of the mRNA products, the WHO endorsed a priority list of potential serious adverse

[30] McLachlan S, Dube K, Osman M, Chiketero PP. (June 2021). Analysis of COVID-19 vaccine death reports from the Vaccine Adverse Events Reporting System (VAERS) Database: Interim Results and analysis. ResearchGate. https://doi.org/10.13140/RG.2.2.26987.26402

[31] VAERS. Report an adverse event [homepage]. [accessed 2023 Nov 17]. https://vaers.hhs.gov/reportevent.html

[32] Kessler DA. Introducing MEDWatch. A new approach to reporting medication and device adverse effects and product problems. JAMA. 1993;269(21):2765–2768. https://doi.org/10.1001/jama.1993.03500210065033

[33] Rawlins MD. Pharmacovigilance: Paradise lost, regained or postponed? The William Withering Lecture 1994. J R Coll Physicians Lond. 1995;29(1):41–49.

[34] Yellow Card: Please help to reverse the decline in reporting of suspected adverse drug reactions [homepage]. GOV.UK; 2019 [accessed 2023 Nov 17]. https://www.gov.uk/drug-safety-update/yellow-card-please-help-to-reverse-the-decline-in-reporting-of-suspected-adverse-drug-reactions

[35] Fraiman J, Erviti J, Jones M, et al. Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. Vaccine. 2022 Aug 30:S0264-410X(22)01028-3.

[36] Note for clarity: "the results of both studies reported all data at the time of data cutoff (14 Nov 2020 for Pfizer, 25 Nov 2020 for Moderna)" cited from above reference by Fraiman et al.

[37] Bansal S, Perincheri S, Fleming T, et al. Cutting edge: Circulating exosomes with covid spike protein are induced by BNT162b2 (Pfizer-BioNTech) vaccination prior to development of antibodies: A novel mechanism for immune activation by mRNA vaccines. J Immunol. 2021;207(10):2405–2410. https://doi.org/10.4049/jimmunol.2100637

[38] Seneff S, Nigh G, Kyriakopoulos AM, McCullough PA. Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs. Food Chem Toxicol. 2022;164:113008. https://doi.org/10.1016/j.fct.2022.113008

[39] Lei Y, Zhang J, Schiavon CR, et al. SARS-CoV-2 spike protein impairs endothelial function via downregulation of ACE 2. Circ Res. 2021;128(9):1323–1326. https://doi.org/10.1161/CIRCRESAHA.121.318902

events of special interest that may occur as a direct result of COVID-19 vaccines. The list was based upon the specific vaccine platform, adverse events associated with prior vaccines in general, theoretical associations based upon animal models and COVID-19-specific immunopathogenesis[41].

Evidence-based medicine and COVID-19 vaccine roll-out

Neither the drug regulators nor the vaccine manufacturers have yet to share all the raw data from the pivotal trials for the COVID-19 vaccines[42]. The raw data from clinical trials comprise thousands of pages that have yet to be released for independent scrutiny. This is important because historically when independent researchers have on occasion gained access to this data then it can completely overturn the conclusions of the published trials: A case in point is Tamiflu[43]. Getting access to clinical case reports for Tamiflu ultimately revealed that the drug was no more effective than paracetamol for influenza and also came with small but significant harms. The UK government had spent half a billion dollars stockpiling a drug that in effect proved to be useless despite claims by the manufacturers (Roche, Basel, Switzerland) that it shortened the duration and severity of the illness. The independent researchers who were able to analyse the data concluded that all industry-sponsored research should be considered marketing until proven otherwise.

It is against this backdrop that transparency advocates sued the Food and Drug Administration (FDA) to gain access to the data upon which the Pfizer (BNT162b2) vaccine was granted emergency use authorisation[44]. The FDA wanted a US Federal court judge to allow the agency 55 years to release this data[45]. Why would the FDA – 'which is responsible for the oversight of more than $2.7 trillion in consumption of food, medical products, and tobacco[46]' – do this? Secrecy should never surround any public health intervention. The lawyer acting on behalf of the plaintiff Aaron Siri reported that:

The government also sought to delay full release of the data it relied upon to license this product until almost every American alive today is dead. That form of governance is destructive to liberty and antithetical to the openness required in a democratic society[47].

Instead, the judge ordered the FDA to release the data over a period of eight months after all commercially sensitive information has been redacted.

A major risk factor for failure to protect the public from such harms is lack of independence of the regulator. The FDA's Centre for Drug Evaluation Research (CDER) receives 65% of its funding from the pharmaceutical industry (mainly in the form of user fees)[48]. For example, as part of the approval process for its COVID-19 vaccine, Pfizer made a wire transfer to the FDA

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of $2 875 842 million in May 2021[49] under the *Prescription Drug User Fee Act* of 1992[50]. Full FDA approval for Pfizer's COVID-19 injection duly followed in August 2021[51] despite evidence emerging a few months later that the original RCT data suggested a greater risk of serious adverse events from the vaccine than from hospitalisation because of COVID-19.

Shortcomings of informed decision making in the medical profession

According to Professor Carl Heneghan and urgent care General Practitioner, the director of the University of Oxford's Centre of Evidence-Based Medicine: '*with every intervention you do as a doctor you must ask yourself two questions: how much difference does it make? How do I know this?*[52]'

Building on the Academy of Medical Royal Colleges Choosing Wisely campaign[53], it is instructive to note that the General Medical Council in 2020 issued guidance on the duty of doctors to engage in Shared Decision Making with patients, underpinned by informed consent[54].

There are six components essential to informed decision making:

(1) description of the nature of the decision;

(2) discussion of alternatives;

(3) discussion of risks and benefits (in absolute terms);

(4) discussion of related uncertainties;

(5) assessment of the patient's understanding; and

(6) elicitation of the patient's preference.

If the administration of the vaccine did not adhere to these principles (which is likely widespread, consistent with historical evidence[55]), then it is also a significant breach of General Medical Council duties of a doctor to 'give patients the information they want or need in a way that they can understand'[56].

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In conclusion

There was never any evidence justifying any COVID-19 vaccine mandates, passports or any of the other coercive measures adopted by various governments worldwide. Every patient who was offered any COVID-19 vaccine should have been made aware of what their risk from COVID-19 is according to age and risk factors. In keeping with ethical medical practice, doctors should have informed patients of their absolute risk reduction for infection from previous more lethal variant being approximately 0.84% or 1 in 119 (based on non-transparent data) and that this level of protection only lasts for a few months. They should also have provided more precise and robust data on what the actual absolute individual risk reduction of COVID-19 death from the vaccine is, what the true rates of serious adverse events (such as permanent disability, hospitalisation or death) are. It is only when doctors and patients have all this information that they can then be empowered to have frank decision making conversations on whether any treatment – including this vaccine – is right for them. The profession must explain that optimising metabolic health will give patients the best chance for ensuring they are not just resilient to infection but reducing their risk of chronic disease including heart disease, cancer and dementia.

The time has come to stop misleading evidence flowing downstream into media reporting and clinical decision making and resulting in unethical and unscientific policy decisions. It's time for real evidence-based medicine[57]

The most objective determinant of whether the benefits of the vaccines outweigh the harms is by analysing its effects on 'all-cause mortality'. This gets round the thorny issue as to what should be classified as a COVID-19 death, and also takes full account of any negative effects of the vaccine. It would be surprising – to say the least – if during an apparently deadly pandemic, an effective vaccine could not clearly and unequivocally be shown to reduce all-cause mortality.

Pfizer's pivotal mRNA trial in adults did not show any statistically significant reduction in all-cause mortality, and in absolute terms there were actually more deaths in the treatment arm versus in the placebo.

There is also a strong scientific, ethical and moral case to be made that the current mRNA vaccine administration must stop until Pfizer releases all the raw data for independent scrutiny[58].This will allow a more accurate understanding of which groups are more likely to potentially benefit from the vaccine versus those who are more likely to be harmed. A pause and reappraisal of vaccination Policies for COVID-19 is long overdue[59].

The above reviews of data and studies conducted in 2020-2021 present the evidence that the risks of adverse events from the vaccine remain constant, whereas the benefits reduce over time, as new variants are (1) less virulent and (2) not targeted by an outdated product.

From my medical experience and the review of sound data and scientific basis, I can confirm that in December 2021 the medical and scientific communities should have known that COVID-19 vaccines were proven to be far from safe or effective and far from preventing transmission of COVID-19 or severe form of COVID-19. Most of them did not know. Although the results were available and showed early on in 2021 a higher risk of deleterious reactions such as cardiovascular events. The COVID-19 vaccine study should have ethically been halted and reconsidered.

Looking to the future the medical and public health professions must recognise these failings and eschew the tainted dollar of the medical-industrial complex. It will take a lot of time and effort to rebuild trust in these institutions, but the health – of both humanity and the medical profession – depends on it[60].

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Dr Aseem Malhotra MD

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