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Academy of Medical Royal Colleges – Obesity Steering Group 2011-2014
Action on Sugar – Founding Member (Science Director 2013-2016)

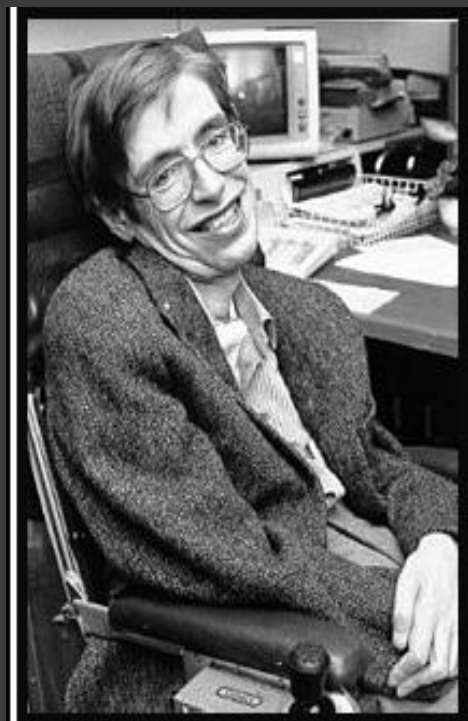
# CURING THE PANDEMIC OF MISINFORMATION ON COVID-19 MRNA VACCINES THROUGH REAL EVIDENCE BASED MEDICINE

MARGARET HEFFERNAN

# Wilful Blindness

'A polemic against the dangers of docility and "groupthink" in every walk of life'
*Financial Times*

'Entertaining and compellingly argued'
*Sunday Times*



The greatest enemy of knowledge is not ignorance,
it is the illusion of knowledge.

(Stephen Hawking)


AOSIS
OPEN ACCESS
PUBLISHED RESEARCH:
'Curing the pandemic of misinformation on Covid-19 mRNA vaccines through REAL evidence-based medicine'
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Coronavirus
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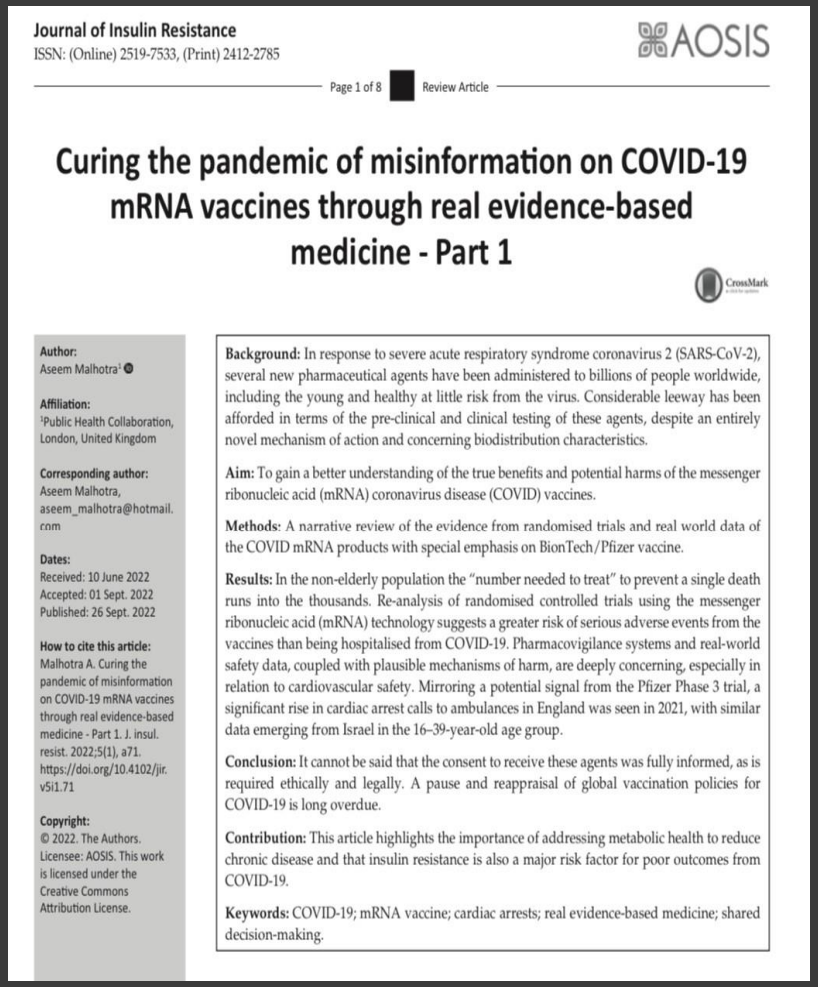
Vaccine
Injection Only
JOURNAL OF
INSULIN RESISTANCE
Author: Aseem Malhotra

# Journal of Insulin Resistance



Journal of Insulin Resistance
ISSN: (Online) 2519-7533, (Print) 2412-2785

AOSIS

Page 1 of 8 Review Article

## Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 1

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**Dates:**
Received: 10 June 2022
Accepted: 01 Sept. 2022
Published: 26 Sept. 2022

**How to cite this article:**
Malhotra A. Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 1. J. insul. resist. 2022;5(1), a71. https://doi.org/10.4102/jir.v5i1.71



**Background:** 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.

**Aim:** To gain a better understanding of the true benefits and potential harms of the messenger ribonucleic acid (mRNA) coronavirus disease (COVID) vaccines.

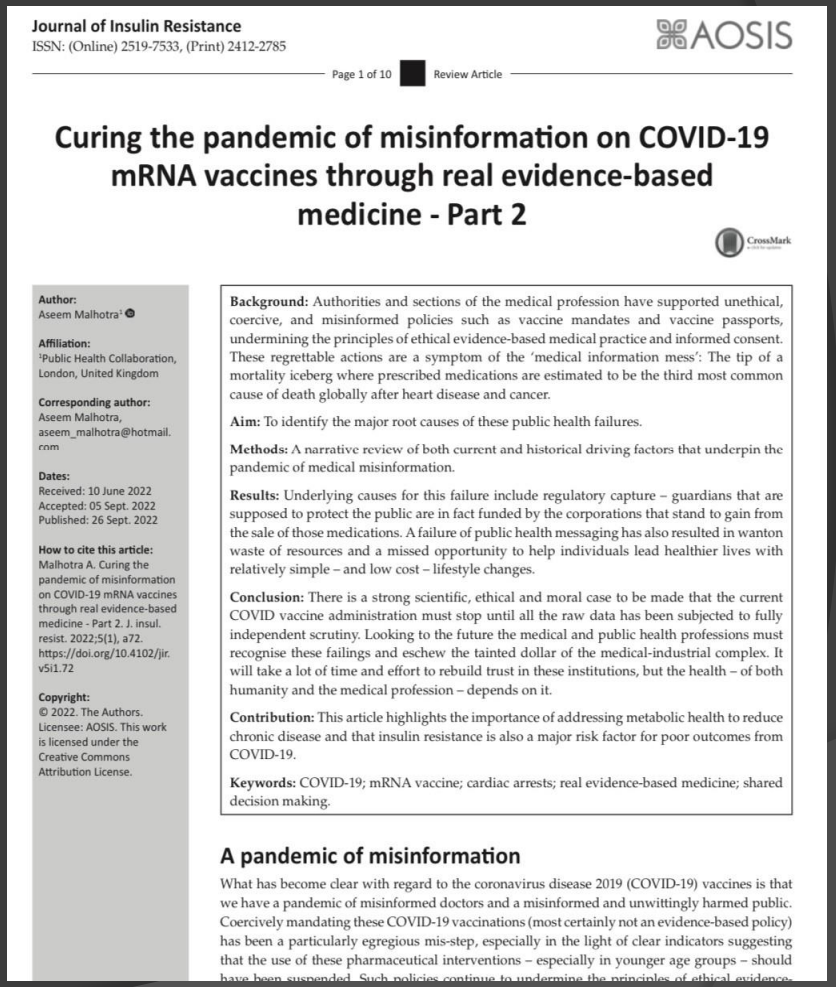
**Methods:** A narrative review of the evidence from randomised trials and real world data of the COVID mRNA products with special emphasis on BionTech/Pfizer vaccine.

**Results:** In the non-elderly population the "number needed to treat" to prevent a single death runs into the thousands. 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.

**Conclusion:** It cannot be said that the consent to receive these agents was fully informed, as is required ethically and legally. A pause and reappraisal of global vaccination policies for COVID-19 is long overdue.

**Contribution:** This article highlights the importance of addressing metabolic health to reduce chronic disease and that insulin resistance is also a major risk factor for poor outcomes from COVID-19.

**Keywords:** COVID-19; mRNA vaccine; cardiac arrests; real evidence-based medicine; shared decision-making.



Journal of Insulin Resistance
ISSN: (Online) 2519-7533, (Print) 2412-2785

AOSIS

Page 1 of 10 Review Article

## Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 2

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**Dates:**
Received: 10 June 2022
Accepted: 05 Sept. 2022
Published: 26 Sept. 2022

**How to cite this article:**
Malhotra A. Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 2. J. insul. resist. 2022;5(1), a72. https://doi.org/10.4102/jir.v5i1.72



**Background:** 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.

**Aim:** To identify the major root causes of these public health failures.

**Methods:** A narrative review of both current and historical driving factors that underpin the pandemic of medical misinformation.

**Results:** 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. A failure of 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.

**Conclusion:** There is a strong scientific, ethical and moral case to be made that the current COVID vaccine administration must stop until all the raw data has been subjected to fully independent scrutiny. 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.

**Contribution:** This article highlights the importance of addressing metabolic health to reduce chronic disease and that insulin resistance is also a major risk factor for poor outcomes from COVID-19.

**Keywords:** COVID-19; mRNA vaccine; cardiac arrests; real evidence-based medicine; shared decision making.

### A pandemic of misinformation

What has become clear with regard to the coronavirus disease 2019 (COVID-19) vaccines is that we have a pandemic of misinformed doctors and a misinformed and unwittingly harmed public. Coercively mandating these COVID-19 vaccinations (most certainly not an evidence-based policy) has been a particularly egregious mis-step, especially in the light of clear indicators suggesting that the use of these pharmaceutical interventions – especially in younger age groups – should have been suspended. Such policies continue to undermine the principles of ethical evidence-

# The Evidence-Based Medicine triad

(see D.L. Sackett et al, BMJ 1996; 312: 71-72)

# Efficient Health Care Requires Informed Doctors and Patients

Seven Sins that contribute to Lack of knowledge

- Biased funding of research (research funded because it is likely to be profitable, not because it is likely to be beneficial for patients)
- Biased reporting in medical journals
- Biased patient pamphlets
- Biased reporting in the media
- Commercial Conflicts of interest
- Defensive medicine
- Medical curricula that fail to teach doctors how to comprehend and communicate health statistics.

Ref: G. Gigerenzer, J.A Muir Gray. Better Doctors, Better Patients, Better Decisions, Envisioning Healthcare 2020,

DOI: 10.1111/eci.12834

PERSPECTIVE

# How to survive the medical misinformation mess

John P. A. Ioannidis[*,†,‡], Michael E. Stuart[§,¶], Shannon Brownlee[**,††] and Sheri A. Strite[¶]

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- 1. Much published research is not reliable, offers no benefit to patients, or is not useful to decision makers
- 2. Most healthcare professionals ARE NOT AWARE of this problem
- 3.They also lack the necessary skills to evaluate the reliability and usefulness of medical science
- 4. Patients and families frequently lack relevant, accurate medical evidence and skilled guidance at the time of medical decision making

- “ ignorance of this problem even at the highest levels of academic and clinical leadership is profound”

# Best available evidence

Open access, freely available online

Essay

## Why Most Published Research Findings Are False

John P. A. Ioannidis

**Summary**

There is increasing concern that most current published research findings are false. The probability that a research claim is true may depend on study power and bias, the number of other studies on the same question, and, importantly, the ratio of true to no relationships among the relationships probed in each scientific field. In this framework, a research finding is less likely to be true when the studies conducted in a field are smaller; when effect sizes are smaller; when there is a greater number and lesser preselection of tested relationships; where there is greater flexibility in designs, definitions, outcomes, and analytical modes; when there is greater financial and other interest and prejudice; and when more teams are involved in a scientific field in chase of statistical significance. Simulations show that for most study designs and settings, it is more likely for a research claim to be false than true. Moreover, for many current scientific fields, claimed research findings may often be simply accurate measures of the prevailing bias. In this essay, I discuss the implications of these problems for the conduct and interpretation of research.

factors that influence this problem and some corollaries thereof.

### Modeling the Framework for False Positive Findings

Several methodologists have pointed out [9–11] that the high rate of nonreplication (lack of confirmation) of research discoveries is a consequence of the convenient, yet ill-founded strategy of claiming conclusive research findings solely on the basis of a single study assessed by formal statistical significance, typically for a *p*-value less than 0.05. Research is not most appropriately represented and summarized by *p*-values, but, unfortunately, there is a widespread notion that medical research articles

**It can be proven that most claimed research findings are false.**

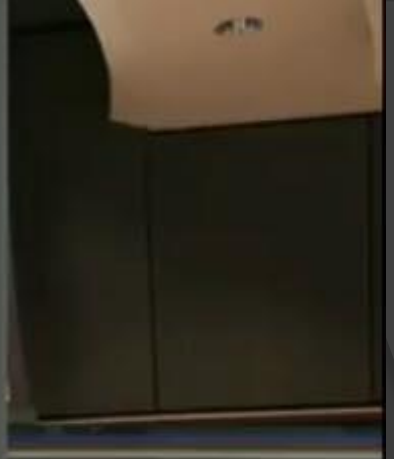
should be interpreted based only on *p*-values. Research findings are defined here as any relationship reaching formal statistical significance, e.g., effective interventions, informative predictors, risk factors, or associations. "Negative" research is also very useful. "Negative" is actually a misnomer, and the misinterpretation is widespread

is characteristic of the field and can vary a lot depending on whether the field targets highly likely relationships or searches for only one or a few true relationships among thousands and millions of hypotheses that may be postulated. Let us also consider, for computational simplicity, circumscribed fields where either there is only one true relationship (among many that can be hypothesized) or the power is similar to find any of the several existing true relationships. The pre-study probability of a relationship being true is $R/(R + 1)$. The probability of a study finding a true relationship reflects the power $1 - \beta$ (one minus the Type II error rate). The probability of claiming a relationship when none truly exists reflects the Type I error rate, $\alpha$. Assuming that $c$ relationships are being probed in the field, the expected values of the $2 \times 2$ table are given in Table 1. After a research finding has been claimed based on achieving formal statistical significance, the post-study probability that it is true is the positive predictive value, PPV. The PPV is also the complementary probability of what Wacholder et al. have called the false positive report probability [10]. According to the $2 \times 2$ table, one gets $PPV = (1 - \beta)R/(R - \beta R + \alpha)$. A research finding is thus

- " The greater the financial and other interests and prejudices in a scientific field, the less likely the research findings are to be true"

## Peter Wilmshurst – Centre of Evidence Based Medicine, Oxford 2014

- Pharmaceutical companies and medical device companies have a fiduciary obligation as businesses to make a profit and declare a shareholder dividend by selling their product.
- They are not required to sell consumers ( patients and doctors) the best treatment, though many of us would like that to be the case.
- REAL SCANDALS: 1. Regulators fail to prevent misconduct by industry and 2.Doctors, institutions and journals that have responsibilities to patients and scientific integrity collude with industry for financial gain



"Honest doctors can no longer practice honest medicine. We have a complete healthcare system failure and an epidemic of misinformed doctors and misinformed and harmed patients."

~Dr Aseem Malhotra

April 12, 2018 European Parliament, Brussels

tinyurl.com/FullVideoKillingForProfit

bmj.com

PERSONAL VIEW

# Big pharma often commits corporate crime, and this must be stopped

Tougher sanctions are needed, says **Peter C Gøtzsche**

When a drug company commits a serious crime, the standard response from the industry is that there are bad apples in any enterprise. Sure, but the interesting question is whether drug companies routinely break the law.

drugs, also in 2009, the company entered into a corporate integrity agreement with the US Department of Health and Human Services to detect and avoid such problems in future. Pfizer had previously entered into three such agreements in the past decade.[2]

Of the top 10 drug companies, in July 2012 only

page for each company. The most common recent crimes were illegal marketing by recommending drugs for non-approved (off-label) uses, misrepresentation of research results, hiding data on harms, and Medicaid and Medicare fraud.[1] All cases were

It is time to introduce tougher sanctions, as the number of crimes, not the detection rate, seems to be increasing.[8] Fines need to be so large that companies risk going bankrupt. Top executives should be held personally accountable so that they would need to think of the risk of imprisonment when they consider performing or acquiescing in crimes.

# Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs

*Donald W. Light, Joel Lexchin, and Jonathan J. Darrow*

Institutional corruption is a normative concept of growing importance that embodies the systemic dependencies and informal practices that distort an institution's societal mission. An extensive range of studies and lawsuits already documents strategies by which pharmaceutical companies hide, ignore, or misrepresent evidence about new drugs; distort the medical literature; and misrepresent products to prescribing physicians.[1] We focus on the consequences for patients: millions of adverse reactions. After defining institutional corruption, we focus on evidence that it lies behind the epidemic of harms and the paucity of benefits.

It is our thesis that institutional corruption has occurred at three levels. First, through large-scale lobbying and political contributions, the pharmaceutical industry has influenced Congress to pass legislation that has compromised the mission of the Food and Drug Administration (FDA). Second, largely as a result of industry pressure, Congress has underfunded FDA enforcement capacities since 1906, and turning to industry-paid "user fees" since 1992 has biased funding to limit the FDA's ability to protect the public from serious adverse reactions to drugs that have few offsetting advantages. Finally, industry has commercialized the role of physicians and undermined their position as independent, trusted advisers to patients.

## Institutional Integrity: The Baseline of Corruption

If "corruption" is defined as an impairment of integrity or moral principle, then institutional corruption is an institution's deviation from a baseline of integrity. In the case of Congress, integrity demands that democratically elected representatives should be dedicated solely to the best interests of the people they represent. According to seminal essays on institutional corruption by Dennis Thompson and Larry Lessig,[2] this baseline of integrity is corrupted because elections are not publicly funded. As a result, congressional representatives must constantly raise funds from a tiny percent of the population and respond to their priorities. This dependency corruption creates an "economy

**Donald W. Light, Ph.D.,** *is a fellow for 2012-2013 at the Edmond J. Safra Center for Ethics at Harvard University in Cambridge, MA. He received his Ph.D. in sociology from Brandeis University and is a professor of comparative health policy at Rowan University, School of Osteopathic Medicine.* **Joel Lexchin, M.Sc., M.D.,** *has been teaching health policy for 12 years at York University in Toronto, ON. He received his M.D. from the University of Toronto in 1977 and since 1988 has been an emergency physician at the University Health Network in Toronto.* **Jonathan J. Darrow, J.D., M.B.A., LL.M., S.J.D.,** *is a research fellow at Harvard Medical School and a lecturer on law at Bentley University in Waltham, MA. He received his S.J.D. from Harvard in 2013.*



Figure 1

**Therapeutic Value of Drugs Marketed in France, 2002-2011***

| Category | Number | Percent |
|---|---|---|
| Major advance in a new area; breakthrough | 2 | 0.2 |
| Significant clinical advance | 13 | 1.4 |
| Some added therapeutic value | 61 | 6.4 |
| Minimal added value | 205 | 21.7 |
| No added value | 517 | 54.7 |
| More risk of harm than benefit | 148 | 15.6 |
| Total | 946 | 100.0 |
| Inadequate data to judge | 48 | |

Source: "New drugs and indications in 2011." *Prescrire International*: 2012 (Apr); 21(126):107.
*Assessments based on a rigorous evaluation using a wide range of data by the independent French drug bulletin *La revue Prescrire*.

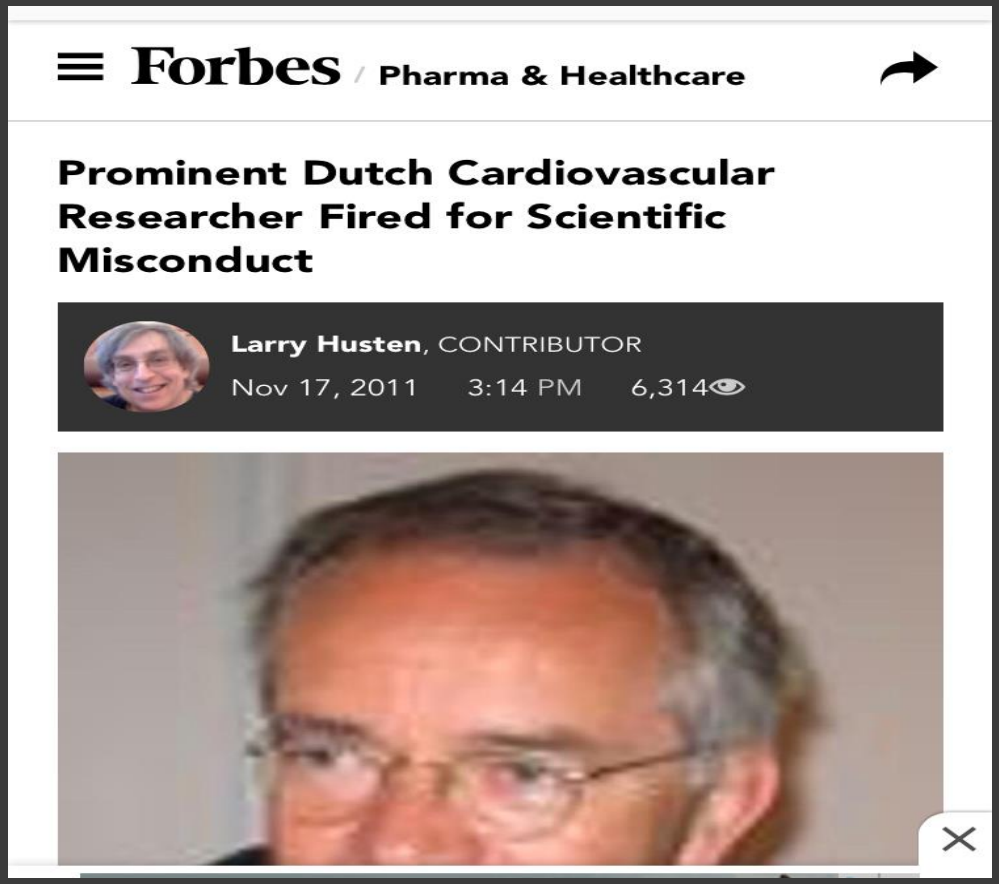
# The Illusion of “innovation”

- Of 667 new drugs approved by the FDA between 2000 and 2008 only 11% truly innovative. 75% essentially copies of old ones. Drug companies spend twice as much on marketing than they do on research and development. Twenty times more on marketing than researching new molecular entities

- “ It is no longer possible to trust much of the clinical research that is published or to rely on the judgement of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of The New England Journal of Medicine” Dr Marcia Angell

- “possibly half of the published literature may simply be untrue” Richard Horton, editor of the Lancet - 2015

- Several recent scandals including universities covering up research misconduct “ Something is rotten in the state of British Medicine and has been for a long time” Richard Smith (2016)




- It has been estimated that use of beta-blockers in the clinical setting recommended in the ESC guidelines increased patient mortality by 27%.[15] Some estimates suggest that there may have been 800,000 excess patient deaths in Europe of which 10% (i.e. approximately 10,000 excess patient deaths per year for eight years) are believed to have been in the UK. In the Polderman's case, the ESC was slow to amend the guidelines, the journals that published the trials have been tardy at retracting the publications, and Erasmus University were slow to act until the scandal was widely publicised

thebmj

*BMJ* 2015;350:h2308 doi: 10.1136/bmj.h2308 (Published 12 May 2015)



ANALYSIS

# Choosing Wisely in the UK: the Academy of Medical Royal Colleges' initiative to reduce the harms of too much medicine



**A Malhotra and colleagues** explain how and why a US initiative to get doctors to stop using interventions with no benefit is being brought to the UK

A Malhotra *consultant clinical associate*[1], D Maughan *Royal College of Psychiatrists sustainability fellow*[2], J Ansell *advanced trainee in general surgery*[3], R Lehman *senior research fellow*[4], A Henderson *chief executive*[1], M Gray *director*[5], T Stephenson *former chair*[1 6], S Bailey *chair*[1]

[1]Academy of Medical Royal Colleges, London, UK; [2]Centre For Sustainable Healthcare, Oxford, UK; [3]Welsh Institute for Minimal Access Therapy, Cardiff Medicentre, Cardiff, UK; [4]Department of Primary Health Care, University Of Oxford, Oxford, UK; [5]Better Value Healthcare, Oxford, UK; [6]Institute of Child Health, London, UK

AoMRC: “doctors have an ethical responsibility to reduce this wasted use of clinical resource because, in a healthcare system with finite resources, one doctor’s waste is another patient’s delay”

# Misleading health statistics

- There are many ways of presenting a benefit. RRR, ARR or NNT
- Communicating relative risks as opposed to absolute risk or NNT ( numbers needed to treat) can lead laypeople and doctors to overestimate the benefit of medical interventions.
- For example in high risk type 2 diabetics primary prevention with Atorvastatin 10mg, RRR 48% in stroke over 4 years.
- Reduces risk of suffering a stroke from 28 in 1000 to 15 in 1000 i.e 13 in 1000 or ARR od 1.3%
- NNT – need to treat 77 to prevent 1 stroke.
- Mismatched framing in medical journals compounds the issue.
- If treatment A reduces the risk of developing disease from 10 to 7 in 1000 but increases the risk of disease B from 7 to 10 in 1000 the journal article reports the benefit as a 30% risk reduction but the harm as an increase of 3 in 1000 or 0.3%!
- One third of articles in the Lancet, BMJ and JAMA between 2004 and 2006 used mismatched framing
- Such asymmetric presentation of data for benefits and harms is likely to bias toward showing greater benefits and diminishing the importance of the harms

# WHO Bulletin 2009

"It is an ethical imperative that every doctor and patient understand the difference between absolute and relative risks to protect patients against unnecessary anxiety and manipulation"

Gerd Gigerenzer, Director of Harding center for risk literacy, Berlin.

# Tackling vaccine hesitancy Feb 2021 – GMB

**Good Morning Brit...** · 05/02/2021

'Vaccines have saved millions of lives over the years.'

Director @GurinderC, who was initially hesitant to receive the jab, explains how 'science gave her reassurance' after doing research and talking to Dr Aseem Malhotra.

She says she 'feels safer' now she's had the vaccine.


**Good Morning Britain**
@GMB

'We need to understand where this vaccine hesitancy is coming from.'

@DrAseemMalhotra explains that 'rational concerns' need to be understood 'in order to move forward in a better way.'

He says 'trust needs to be restored' and that 'vaccines by far are the safest.'

World Health Organization

Home / Newsroom / Facts in pictures / Detail / Immunization

# Immunization

5 December 2019

中文 | Français | Русский | Español

Immunization is one of modern medicine's greatest success stories. Time and again, the international community has endorsed the value of vaccines and immunization to prevent and control a large number of infectious and, increasingly, cancers and other chronic diseases.


# Covid: Report reveals increase in risk of heart attack following the mRNA COVID...

1.1M views · 10 mo ago

# NNT – 119 to prevent infection, but no reduction in covid deaths

**Are the Covid-19 vaccines effective and safe?**

EVIDENCE BITE: We believe trial data hint at high efficacy and short-term safety. We have lingering concerns about limitations in the data, lack of transparency, and in particular a jarring lack of evidence showing reductions in hospitalizations and mortality—the outcomes public health authorities and citizens of the world care about most.

SUMMARY:

Efficacy: According to a report in the New England Journal of Medicine from an early Pfizer vaccine trial, among 37,000 subjects 170 developed COVID-19 (8 vaccine group; 162 placebo group). Infection rates were therefore 0.04% vs. 0.88%, a *relative* efficacy of >95%. The absolute difference between groups was 0.84%, meaning in this trial the vaccine prevented one COVID-19 infection for every 119 people vaccinated. Moderna, AZ, and J&J vaccines have shown similar results.

Oddly, however, the question of whether the vaccine reduces hospitalizations and deaths is unanswered by most trial data. As in the Pfizer trial, hospitalizations are strangely absent from most papers ('severe' COVID-19 has often been used as an unhelpful proxy), and too few deaths occurred to find differences. Instead,

# Antibodies are an unreliable surrogate for protection


**Date Issued:** May 19, 2021

The U.S. Food and Drug Administration (FDA) is reminding the public and health care providers that results from currently authorized SARS-CoV-2 antibody tests should not be used to evaluate a person's level of immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination.

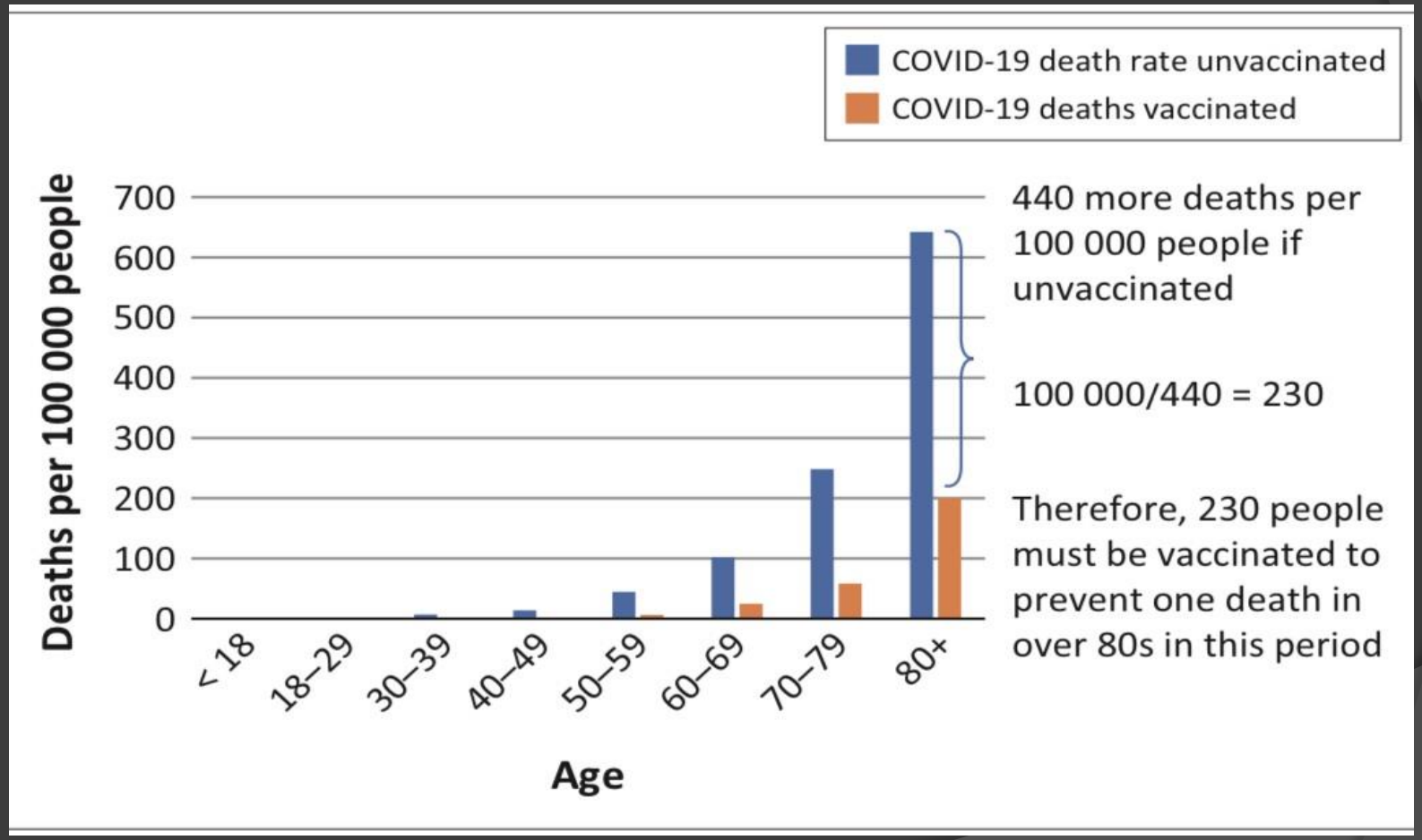

COVID-19 death rate unvaccinated
COVID-19 deaths vaccinated
Deaths per 100 000 people
700
600
500
400
300
200
100
0
< 18
18–29
30–39
40–49
50–59
60–69
70–79
80+
Age
440 more deaths per 100 000 people if unvaccinated
100 000/440 = 230
Therefore, 230 people must be vaccinated to prevent one death in over 80s in this period

**TABLE 1:** Infection fatality rate of ancestral variants of COVID-19 pre-vaccination by age.

| Age | Median IFR % | Median IFR (absolute) | Survival rate estimate (%) |
|---|---|---|---|
| 0–19 | 0.0027 | 1 in 37 037 | 99.9973 |
| 20–29 | 0.0140 | 1 in 7143 | 99.9860 |
| 30–39 | 0.0310 | 1 in 3225 | 99.9690 |
| 40–49 | 0.0820 | 1 in 1220 | 99.9180 |
| 50–59 | 0.2700 | 1 in 370 | 99.7300 |
| 60–69 | 0.5900 | 1 in 169 | 99.4100 |
| > 70 community | 2.4000 | 1 in 42 | 97.6000 |
| > 70 overall | 5.5000 | 1 in 18 | 94.5000 |

*Source*: Adapted from 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

IFR, infection fatality rate.

**TABLE 2:** Deaths prevented, and number needed to vaccinate to prevent a death based on death rates and case fatality rates from UKHSA data for England during Delta wave.

| Age | Deaths prevented (in England) based on differences in death rates per 100 000 | Number needed to vaccinate per death prevented based on differences in death rates per 100 000 |
|---|---|---|
| < 18 | -0.1 | Negative |
| 18–29 | 70 | 93 000 |
| 30–39 | 240 | 27 000 |
| 40–49 | 640 | 10 000 |
| 50–59 | 2740 | 2600 |
| 60–69 | 4580 | 1300 |
| 70–79 | 9100 | 520 |
| 80+ | 11 900 | 230 |
| **Total** | **29 270** | - |

*Source*: Adapted from HART. How many injections to prevent one covid death? [homepage on the Internet]. No date. Available from: https://www.hartgroup.org/number-needed-to-vaccinate/

UKHSA, United Kingdom Health Security Agency.

# Benefit of mRNA vaccine against omicron is close to non-existent.

| Age | Covid deaths prevented based on differences in covid death rates per 100kDELTA (27th Aug – 16th Dec 2021) | Number needed to vaccinate per covid death prevented based on differences in covid death rates per 100kDELTA | Covid deaths prevented based on differences in covid death rates per 100kOMICRON(3rd Jan – 27th Mar 2022) | Number needed to vaccinate per covid death prevented based on differences in covid death rates per 100kOMICRON |
|---|---|---|---|---|
| **<18** | -0.9 | Negative | Negative | Negative |
| **18–29** | 70 | 93000 | 21 | 785000 |
| **30–39** | 240 | 27000 | 50 | 338000 |
| **40–49** | 640 | 10000 | 161 | 167000 |
| **50–59** | 2740 | 2600 | 870 | 63000 |
| **60–69** | 4580 | 1300 | 2160 | 30000 |
| **70–79** | 9100 | 520 | 5600 | 17000 |
| **80+** | 11900 | 230 | 7800 | 7300 |
| **Total** | 29,270 | | 16,662 | |

*Table 1: Covid deaths prevented and number needed to vaccinate to prevent a covid death based on covid death rates from UKHSA data.*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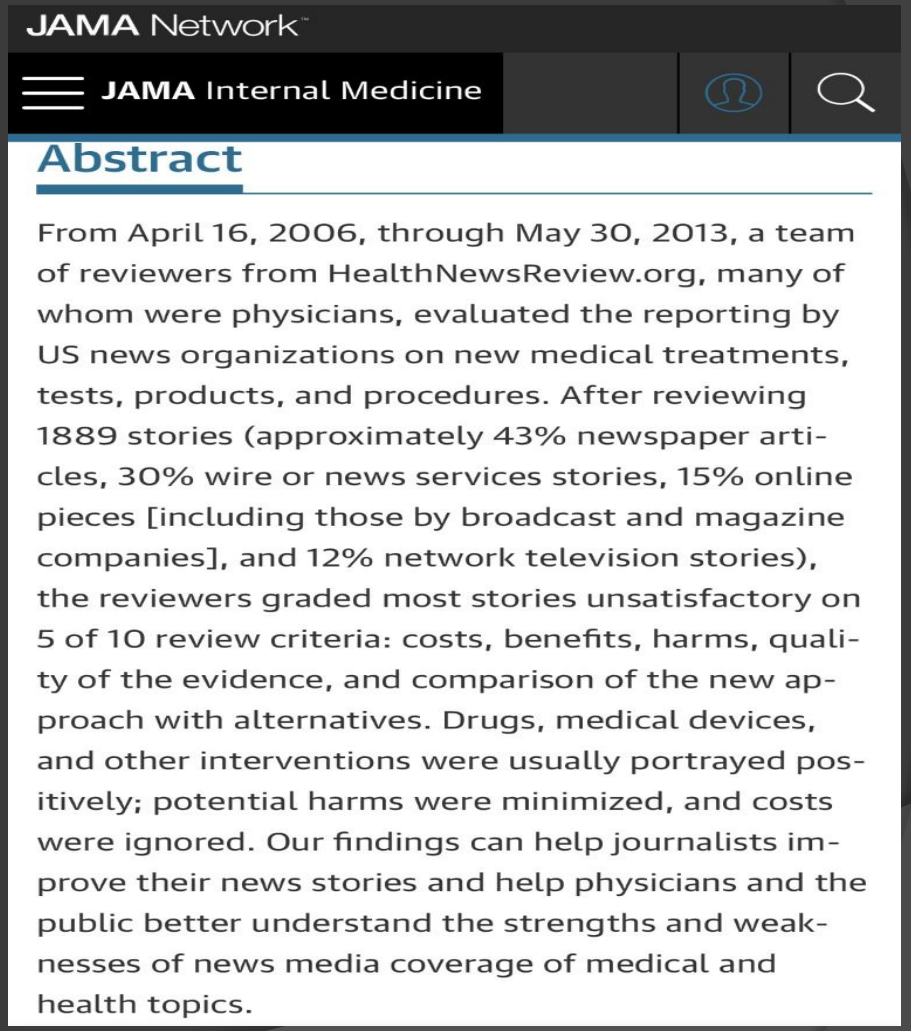
Gary Schwitzer, BA[1]
Author Affiliations
JAMA Intern Med. 2014;174(7):1183-1186. doi:10.1001/jamainternmed.2014.1359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JAMA Internal Medicine
Abstract
From April 16, 2006, through May 30, 2013, a team of reviewers from HealthNewsReview.org, many of whom were physicians, evaluated the reporting by US news organizations on new medical treatments, tests, products, and procedures. After reviewing 1889 stories (approximately 43% newspaper articles, 30% wire or news services stories, 15% online pieces [including those by broadcast and magazine companies], and 12% network television stories), the reviewers graded most stories unsatisfactory on 5 of 10 review criteria: costs, benefits, harms, quality of the evidence, and comparison of the new approach with alternatives. Drugs, medical devices, and other interventions were usually portrayed positively; potential harms were minimized, and costs were ignored. Our findings can help journalists improve their news stories and help physicians and the public better understand the strengths and weaknesses of news media coverage of medical and health topics.

# Can we trust the regulators?





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Cite this as: *BMJ* 2022;377:o1538
http://dx.doi.org/10.1136/bmj.o1538
Published: 29 June 2022

BMJ INVESTIGATION

## From FDA to MHRA: are drug regulators for hire?

**Patients and doctors expect drug regulators to provide an unbiased, rigorous assessment of investigational medicines before they hit the market. But do they have sufficient independence from the companies they are meant to regulate? Maryanne Demasi investigates**

Maryanne Demasi *investigative journalist*

Over the past decades, regulatory agencies have seen large proportions of their budgets funded by the industry they are sworn to regulate.

In 1992, the US Congress passed the Prescription Drug User Fee Act (PDUFA), allowing industry to fund the US Food and Drug Administration (FDA) directly through "user fees" intended to support the cost of swiftly reviewing drug applications. With the act, the FDA moved from a fully taxpayer funded entity to one supplemented by industry money. Net PDUFA fees collected have increased 30 fold—from around $29m in 1993 to $884m in 2016.[1]

In Europe, industry fees funded 20% of the new EU-wide regulator, the European Medicines Agency (EMA), in 1995. By 2010 that had risen to 75%; today it is 89%.[2]

In 2005 in the UK, the House of Commons' health committee evaluated the influence of the drug industry on health policy, including the Medicines and Healthcare Products Regulatory Agency (MHRA).[3] The committee was concerned that industry funding could lead the agency to "lose sight of the need to protect and promote public health above all else as it seeks to win fee income from the companies." But nearly two decades on, little has changed, and industry funding of drug regulators has become the international norm.

*The BMJ* asked six leading regulators, in Australia, Canada, Europe, Japan, the UK, and US, a series of questions about their funding, transparency in their decision making (and of data), and the rate at which new drugs are approved. We found that industry money permeates the globe's leading regulators, raising questions about their independence, especially in the wake of a string of drug and device scandals.

### Industry fees

Industry money saturates the globe's leading regulators. *The BMJ* found that the majority of regulators' budget—particularly the portion focused on drugs—is derived from industry fees (table 1).

FEATURE

Table 1 | How the regulators compare

| | Australia TGA | Europe EMA | UK MHRA | Japan PMDA | USA FDA | Canada HC |
|---|---|---|---|---|---|---|
| Budgets and fees | | | | | | |
| Proportion of budget derived from industry♁ | 96% | 89% | 86% | 85% | 65% | 50.5% |
| Total annual budget† | AU$170m (£95m) | €386m (£331m) | £159m | ¥29.1bn (£175m) | US$6.1bn (£5bn) | C$2.7bn (£1.7bn) |
| Transparency, COIs, and data | | | | | | |
| Proportion of covid-19 vaccine committee members that declared financial COIs | 50% | 3% | 32% | 75% | <10% | 0% |
| Declared COIs available as public information | No | Yes | Yes | Yes | Yes | No |
| Regulator routinely receives patient level datasets* | No | No | No | Yes | Yes | No |
| Drug approvals | | | | | | |
| Proportion of decisions to approve new medicines (*v* not approve) | 94% | 88% | 98.5% | Not disclosed | 69%^ 29%# | 83% |
| Proportion of new drugs approved through expedited pathways in 2020 | 20% | 50% | 36%† | 26% | 68% | 16% |

Note: Data sources and methods are detailed in the supplemental file

† Data refer to the year 2021 calendar year or 2020-2021 fiscal year

♁ Many agencies regulate beyond medical products (for example, food); where possible (US, Canada), we used the proportion of the human drugs budget

FDA: US Food and Drug Administration; EMA: European Medicines Agency; TGA: Therapeutic Goods Administration; HC: Health Canada; MHRA: Medicines and Healthcare Products Regulatory Agency; PMDA: Pharmaceuticals and Medical Devices Agency

* Agencies still have the ability to request patient level datasets from sponsors

^ FDA Center for Drug Evaluation and Research

# FDA Center for Biologics Evaluation and Research

# Can we trust the regulators? NO

- “ It’s the opposite of having a trustworthy organisation independently and rigorously assessing medicines. They’re not rigorous, they’re not independent, they are selective and they withhold data. Doctors and patients must appreciate how deeply and extensively drug regulators can’t be trusted so long as they’re captured by industry funding” Donald Light

# More likely to suffer SAE from mRNA jab than be hospitalised from covid.

**Serious adverse events of special interest following mRNA vaccination in randomized trials**


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Mark Jones, PhD[3]
Sander Greenland, MA, MS, DrPH, C Stat[4]
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**ABSTRACT**

**Introduction.** In 2020, prior to COVID-19 vaccine rollout, the Coalition for Epidemic Preparedness Innovations and Brighton Collaboration created a priority list, endorsed by the World Health Organization, of potential adverse events relevant to COVID-19 vaccines. We leveraged the Brighton Collaboration list to evaluate serious adverse events of special interest observed in phase III randomized trials of mRNA COVID-19 vaccines.

**Methods.** Secondary analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines (NCT04368728 and NCT04470427), focusing analysis on potential adverse events of special interest identified by the Brighton Collaboration.

**Results.** Pfizer and Moderna mRNA COVID-19 vaccines were associated with an increased risk of serious adverse events of special interest, with an absolute risk increase of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95% CI -0.4 to 20.6 and -3.6 to 33.8), respectively. Combined, the mRNA vaccines were associated with an absolute risk increase of serious adverse events of special interest of 12.5 per 10,000 (95% CI 2.1 to 22.9). The excess risk of serious adverse events of special interest surpassed the risk reduction for COVID-19 hospitalization relative to the placebo group in both Pfizer and Moderna trials (2.3 and 6.4 per 10,000 participants, respectively).

**Discussion.** The excess risk of serious adverse events found in our study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID-19 outcomes such as hospitalization or death.



**Funding.** This study had no funding support.

**Supplemental Table 1. Included and excluded SAE types across both trials**

**Included SAE types (matching AESI list):** Abdominal pain, Abdominal pain upper, Abscess, Abscess intestinal, Acute coronary syndrome, Acute kidney injury, Acute left ventricular failure, Acute myocardial infarction, Acute respiratory failure, Anaemia, Anaphylactic reaction, Anaphylactic shock, Angina pectoris, Angina unstable, Angioedema, Aortic aneurysm, Aortic valve incompetence, Arrhythmia supraventricular, Arteriospasm coronary, Arthritis, Atrial fibrillation, Atrial flutter, Axillary vein thrombosis, Basal ganglia haemorrhage, Bile duct stone, Blood loss anaemia, Bradycardia, Brain abscess, Cardiac failure, Cardiac failure acute, Cardiac failure congestive, Cardiac stress test abnormal, Cardio-respiratory arrest, Cerebral infarction, Cerebrovascular accident, Chest pain, Cholecystitis, Cholecystitis acute, Cholelithiasis, Colitis, Coronary artery disease, Coronary artery dissection, Coronary artery occlusion, Coronary artery thrombosis, Deep vein thrombosis, Dermatitis bullous, Diabetic ketoacidosis, Diarrhoea, Diplegia, Dyspnoea, Embolic stroke, Empyema, Facial paralysis, Fluid retention, Gastroenteritis, Gastrointestinal haemorrhage, Haematoma, Haemorrhagic stroke, Hemiplegic migraine, Hepatic enzyme increased, Hyperglycaemia, Hyponatraemia, Hypoxia, Ischaemic stroke, Laryngeal oedema, Multiple sclerosis, Myocardial infarction, Non-cardiac chest pain, Oedema peripheral, Pancreatitis, Pancreatitis acute, Pericarditis, Peripheral artery aneurysm, Peritoneal abscess, Pleuritic pain, Pneumothorax, Post procedural haematoma, Post procedural haemorrhage, Postoperative abscess, Procedural haemorrhage, Psychotic disorder, Pulmonary embolism, Rash, Rash vesicular, Respiratory failure, Retinal artery occlusion, Rhabdomyolysis, Rheumatoid arthritis, Schizoaffective disorder, Seizure, Subarachnoid haemorrhage, Subcapsular renal haematoma, Subdural haematoma, Tachyarrhythmia, Tachycardia, Thrombocytopenia, Thyroid disorder, Toxic encephalopathy, Transaminases increased, Transient ischaemic attack, Traumatic intracranial haemorrhage, Type 2 diabetes mellitus, Uraemic encephalopathy, Uterine haemorrhage, Vascular stent occlusion, Ventricular arrhythmia

**Excluded SAE types (not matching AESI list):** Abdominal adhesions, Abortion

CellPress

Trends in
Molecular Medicine

Opinion

# Adverse effects of COVID-19 mRNA vaccines: the spike hypothesis

Ioannis P. Trougakos,[1,*] Evangelos Terpos,[2] Harry Alexopoulos,[1] Marianna Politou,[3] Dimitrios Paraskevis,[4] Andreas Scorilas,[5] Efstathios Kastritis,[2] Evangelos Andreakos,[6] and Meletios A. Dimopoulos[2]

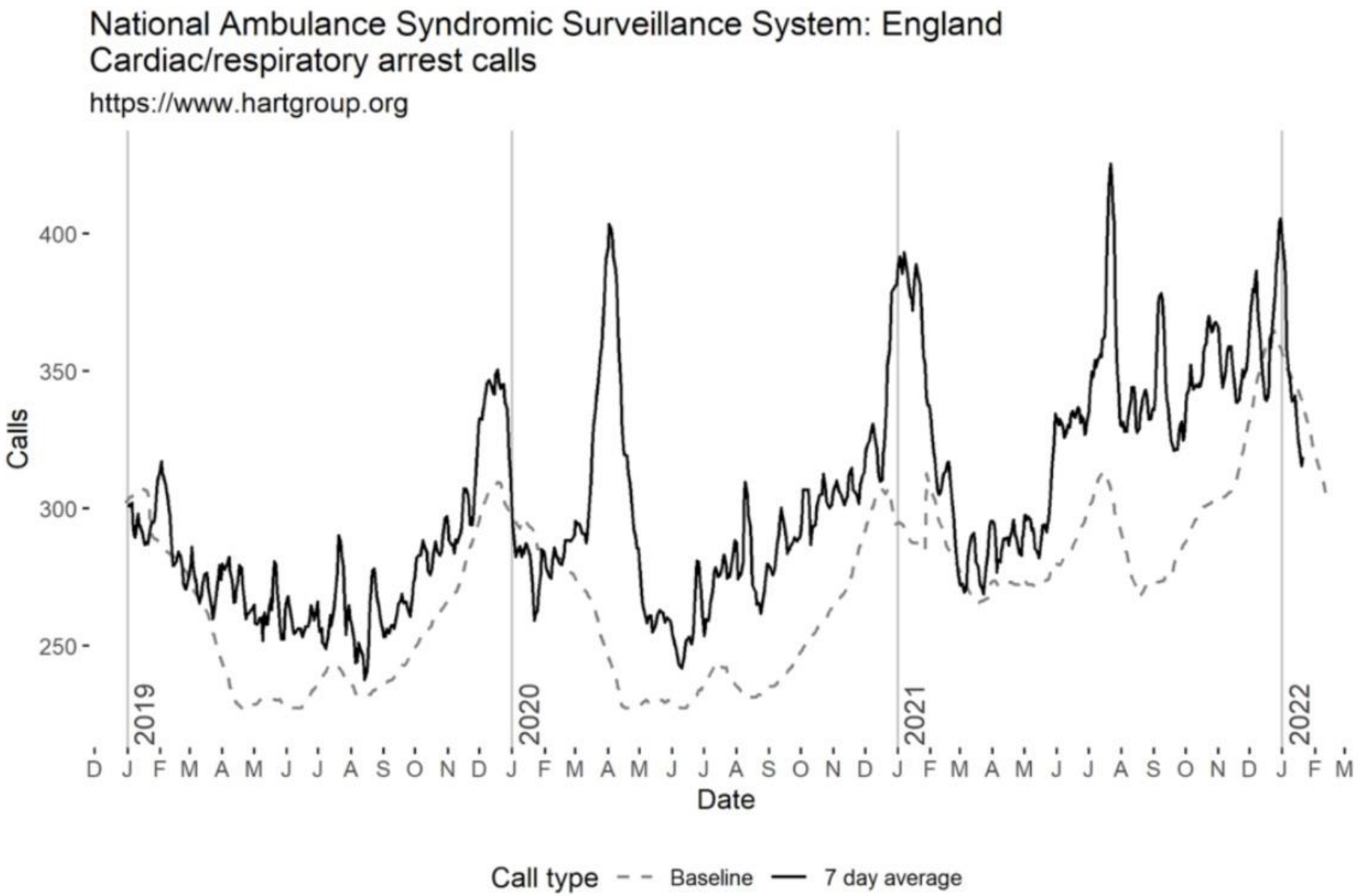
**Vaccination is a major tool for mitigating the coronavirus disease 2019 (COVID-19) pandemic, and mRNA vaccines are central to the ongoing vaccination campaign that is undoubtedly saving thousands of lives. However, adverse effects (AEs) following vaccination have been noted which may relate to a proinflammatory action of the lipid nanoparticles used or the delivered mRNA (i.e., the vaccine formulation), as well as to the unique nature, expression pattern, binding profile, and proinflammatory effects of the produced antigens – spike (S) protein and/or its subunits/peptide fragments – in human tissues or organs. Current knowledge on this topic originates mostly from cell-based assays or from model organisms; further research on the cellular/molecular basis of the mRNA vaccine-induced AEs will therefore promise safety, maintain trust, and direct health policies.**

## Highlights

Coronavirus disease 2019 (COVID-19) mRNA vaccines induce robust immune responses against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), yet their cellular/molecular mode of action and the etiology of the induced adverse events (AEs) remain elusive.

Lipid nanoparticles (LNPs) probably have a broad distribution in human tissues/organs; they may also (along with the packaged mRNA) exert a proinflammatory action.

COVID-19 mRNA vaccines encode a


National Ambulance Syndromic Surveillance System: England
Cardiac/respiratory arrest calls
https://www.hartgroup.org
Calls
400
350
300
250
2019
2020
2021
2022
D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M
Date
Call type
Baseline
7 day average
Graph source: UK Health Security Agency/Public Health England

scientific reports



OPEN

# Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third COVID-19 wave

Christopher L. F. Sun[1,2], Eli Jaffe[3,4] & Retsef Levi[1]✉

**Cardiovascular adverse conditions are caused by coronavirus disease 2019 (COVID-19) infections and reported as side-effects of the COVID-19 vaccines. Enriching current vaccine safety surveillance systems with additional data sources may improve the understanding of COVID-19 vaccine safety. Using a unique dataset from Israel National Emergency Medical Services (EMS) from 2019 to 2021, the study aims to evaluate the association between the volume of cardiac arrest and acute coronary syndrome EMS calls in the 16–39-year-old population with potential factors including COVID-19 infection and vaccination rates. An increase of over 25% was detected in both call types during January–May 2021, compared with the years 2019–2020. Using Negative Binomial regression models, the weekly emergency call counts were significantly associated with the rates of 1st and 2nd vaccine doses administered to this age group but were not with COVID-19 infection rates. While not establishing causal relationships, 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. Surveillance of potential vaccine side-effects and COVID-19 outcomes should incorporate EMS and other health data to identify public health trends (e.g., increased in EMS calls), and promptly investigate potential underlying causes.**


October 7, 2022

# State Surgeon General Dr. Joseph A. Ladapo Issues New mRNA COVID-19 Vaccine Guidance

**TALLAHASSEE, Fla.** – Today, State Surgeon General Dr. Joseph A. Ladapo has announced new guidance regarding mRNA vaccines. The Florida Department of Health (Department) conducted an analysis through a self-controlled case series, which is a technique originally developed to evaluate vaccine safety.

This analysis found that there is an 84% increase in the relative incidence of cardiac-related death among males 18-39 years old within 28 days following mRNA vaccination. With a high level of global immunity to COVID-19, the benefit of vaccination is likely outweighed by this abnormally high risk of cardiac-related death among men in this age group. Non-mRNA vaccines were not found to have these increased risks.

As such, the State Surgeon General recommends against males aged 18 to 39 from receiving mRNA COVID-19 vaccines. Those with preexisting cardiac conditions, such as myocarditis and pericarditis, should take particular caution when making this decision.

***Cardiac-related deaths following vaccination***

In the 28 days following vaccination, a statistically significant increase in cardiac-related deaths was detected for the entire study population (RI = 1.07, 95% CI = 1.03 - 1.12). Stratifying by age group revealed RIs were significantly higher for age groups 25 - 39 (RI = 2.16, 95% CI = 1.35 - 3.47) and 60 or older (RI = 1.05, 95% CI = 1.01 - 1.10). The remaining age groups failed to reach statistical significance.

***Cardiac-related deaths by age group, vaccination type, and sex following vaccination***

To determine which group may be driving the increased risk of cardiac-related deaths in the primary analysis, the vaccination analysis was further stratified by sex, vaccination type, and age groups. Tables 2 and 3 present the sex specific results for cardiac-related deaths following vaccination stratified by age group and vaccination type. Risk was significantly higher during the risk period for males (RI = 1.09, 95% CI = 1.03 - 1.15) but not for females (RI = 1.05, 95% CI = 0.98 - 1.11). Concerning vaccination type, males receiving mRNA vaccination had significantly higher risk (RI = 1.11, 95% CI = 1.05 - 1.18), while males receiving vaccinations that were not mRNA/unknown had significantly lower risk (RI = 0.75, 95% CI = 0.58 - 0.98). RIs for females stratified by vaccination type revealed a similar pattern, with lower, non-

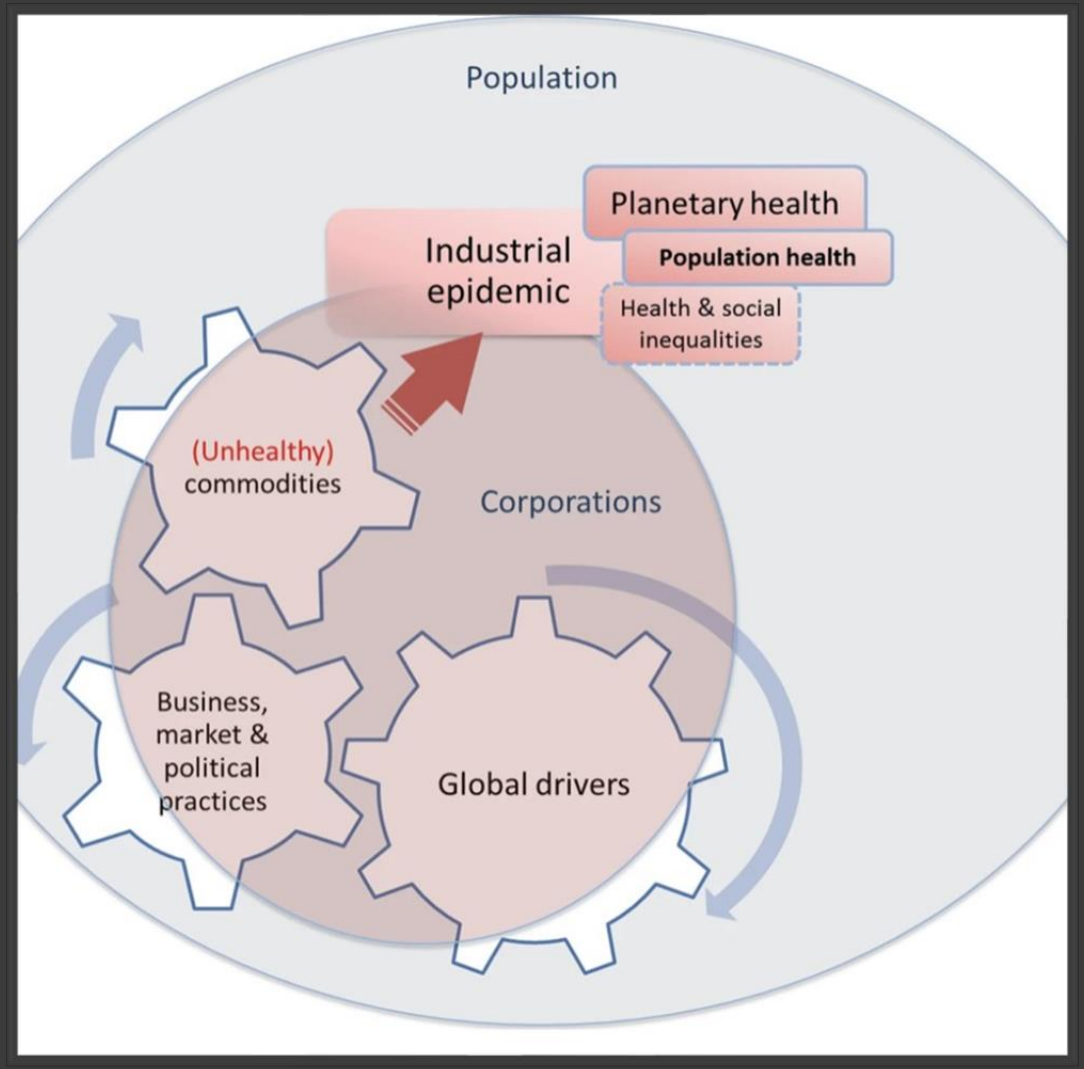
significant estimates. Among the subgroups evaluated, males aged 18 - 39 had the highest risk (RI = 1.97, 95% CI = 1.16 - 3.35).

**Discussion/Conclusion**

In this statewide study of vaccinated Florida residents aged 18 years or older, COVID-vaccination was not associated with an elevated risk for all-cause mortality. COVID-19 vaccination was associated with a modestly increased risk for cardiac-related mortality 28 days following vaccination. Results from the stratified analysis for cardiac-related death following vaccination suggests mRNA vaccination may be driving the increased risk in males, especially among males aged 18 - 39. Risk for both all-cause and cardiac-related deaths was substantially higher 28 days following COVID-19 infection. The risk associated with mRNA vaccination should be weighed against the risk associated with COVID-19 infection.

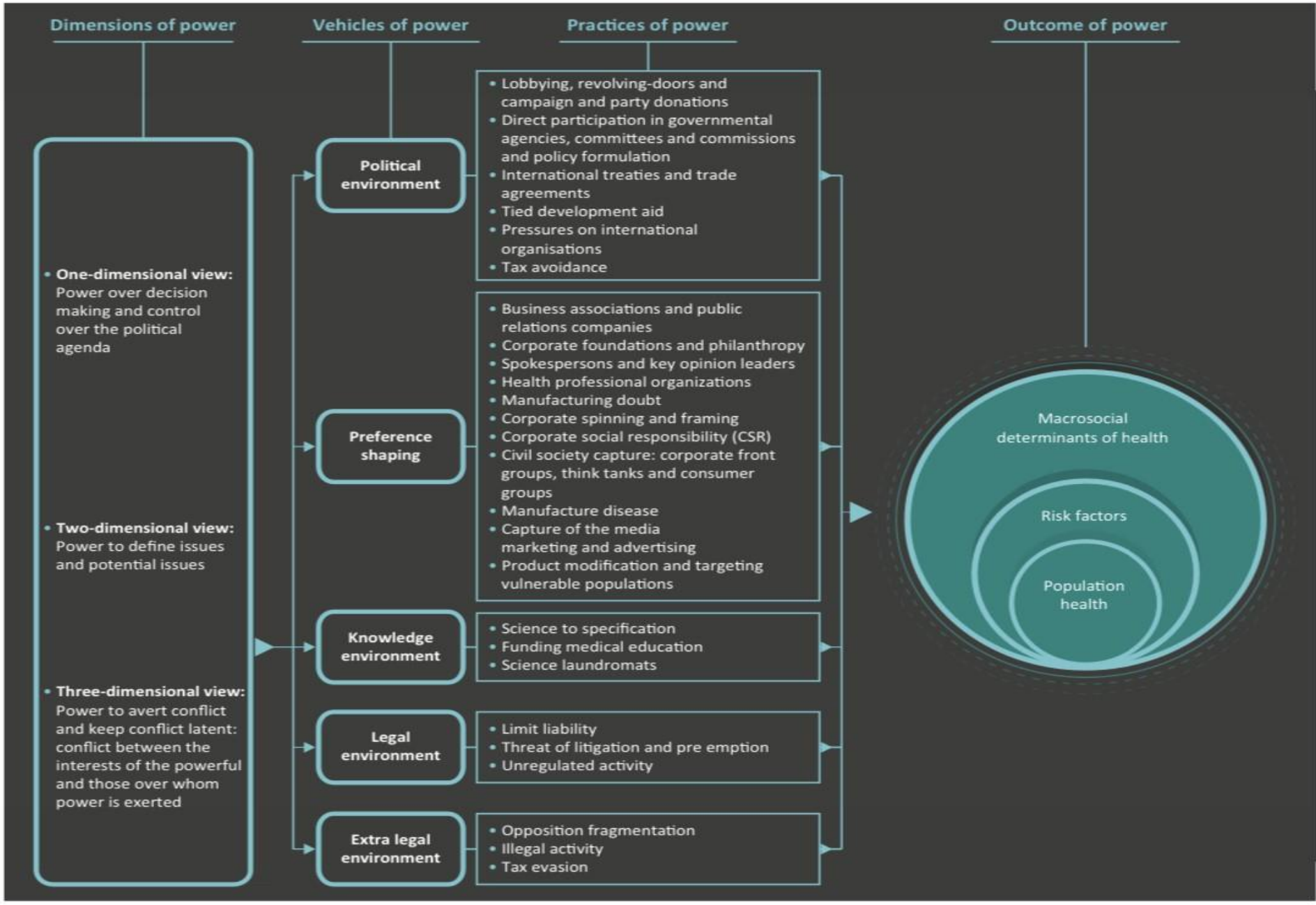
# Key facts on vaccine based on highest quality data and best available evidence

- No protection from infection now
- Initial protection from ancestral more lethal variant in 1 in 119?
- No reduction in Covid mortality/all cause mortality from RCT
- RCT's that led to approval of the mRNA product suggesting more serious harm from vaccine (1 in 800) than from covid hospitalisations of more lethal Wuhan strain.
- Best case scenario for protecting those over 80 from a covid death from Delta variant is 1 in 230 . Omicron 1 in 7300.
- In those under 50 NNT is 1 in 10,000 to prevent a covid death
- Unprecedented harms reported by yellow card scheme.
- Rate of harm requiring hospitalisation from real world data is close to 1 in 1000 within a couple of months of mRNA jab (likely a significant underestimate of real serious harms)




## THE COMMERCIAL DETERMINANTS OF HEALTH

"Strategies and approaches adopted by the private sector to promote products and choices that are detrimental to health"




*Source*: Madureira Lima J, Galea S. Corporate practices and health: A framework and mechanisms. Global Health. 2018;14(1):21

**FIGURE 1:** Diagram of dimensions, vehicles, practices and outcomes of power.

BMJ

*BMJ* 2012;345:e5124 doi: 10.1136/bmj.e5124 (Published 21 August 2012)



ANALYSIS

# Why corporate power is a public health priority

The marketing campaigns of multinational corporations are harming our physical, mental, and collective wellbeing. **Gerard Hastings** urges the public health movement to take action

Gerard Hastings *director*

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The work of Professor Richard Doll provides two key lessons for public health. The first, that we must do all we can to eradicate the use of tobacco, has been well learnt and is being energetically acted upon. The second, more subtle learning—that our economic system has deep flaws—remains largely ignored. And yet, lethal though tobacco is, the harm being done to public health by our economic system is far greater.

## Industrial epidemics

Furthermore, the two are intimately connected: tobacco has remained such an intractable problem only because our economic system allows free ranging corporations to market it. The same applies to the other two "industrial epidemics"[1] that constitute such a large share of the public health burden: alcohol misuse and obesity. In each case evocative promotion, ubiquitous distribution, perpetual new product development, and seductive pricing strategies are used to encourage unhealthy consumption. And in each case painstaking research and review have shown the obvious truth that this marketing effort succeeds, especially with the young.[2-4] The consequence has been the inevitable escalation of lifestyle illnesses such as cancer, heart disease, cirrhosis, and diabetes.

However, the impact of marketing on public health goes much deeper than this. Marketing textbooks lionise the consumer: our complete satisfaction is the essence of successful business (provided we can afford to pay). The result is an unstinting hunt for new needs and wants (or, increasingly, whims) to satisfy, and a population that has a burgeoning sense of entitlement. The damaging effect of this favouritism is shown in the pharmaceutical business, which pays more attention to the trivial complaints of the rich than the life threatening sicknesses of the poor. As Bakan points out, "Of the 1400 new drugs developed between 1975 and 1999, only 13 were designed to treat or prevent tropical diseases and three to treat tuberculosis. In the year 2000, no drugs were being developed to treat tuberculosis, compared to eight for impotence or erectile dysfunction and 7 for baldness."[5] This dangerously indulgent focus starts at birth, because children offer the corporate marketer a lifetime of profitability (box 1).

Sadly, as any philosopher or theologian would predict, such pampering does not bring happiness. Once basic needs are satisfied, the correlation between material possessions and contentment rapidly dissipates. But marketing keeps us craving more: the paradox of a system devoted to our satisfaction is that it depends on our perpetual dissatisfaction; after all once we are satisfied we stop shopping. In this way it undermines our mental as well as our physical wellbeing.

## The customer always comes second

Furthermore, the corporate marketers' focus on customer satisfaction is in reality specious; the fiduciary duty of corporations gives them a legal obligation to prioritise the needs, not of the consumer, but of the shareholder. How else could we have tobacco companies, who are consummate marketers, continuing to produce products that kill one in two of their most loyal customers? The corporate marketers' self centred purpose, then, is "to recognise and achieve an economic advantage which endures."[7] Not an economic advantage for the customer—just for the company. This is the same single minded and dysfunctional principle that continues to drive the financial sector.

A key function of marketing is to mask these uncomfortable truths by disguising inanimate corporate monoliths as benign friends under the guise of branding. The role of branding in youth smoking[8] and drinking[9] has been well documented, and a recent study in California among 3-5 year olds showed that children's food preferences are being moulded by McDonald's branding even before they have learnt to tie their shoelaces.[10] Items that came in McDonald's wrappers were thought to taste better, even if they were foods like carrots; on the other hand McDonald's products didn't taste as good without the liveried packaging. These effects were apparent across the group, but most marked among those who had been most exposed to McDonald's and its advertising. Marketers are clearly succeeding in their aim "to start building up their brand consciousness and loyalty as early as possible."[6]

However, susceptibility to the "emotional benefits" of branding reaches way beyond toddlers and teens; it touches us all. The

# Why corporate power is a public health priority

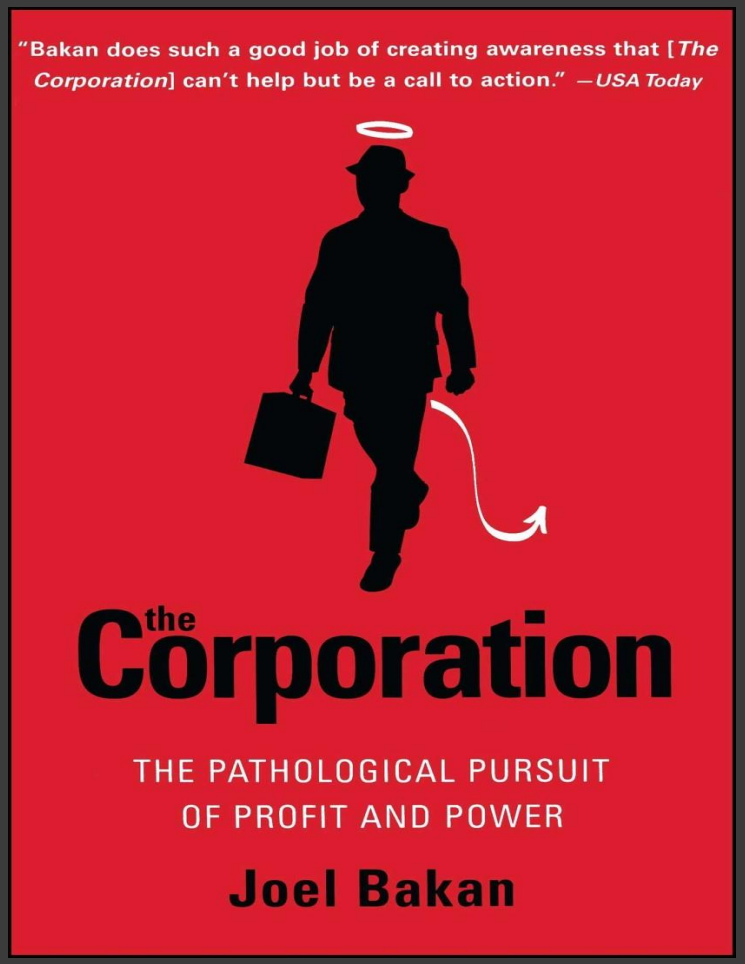
- “ We have to take the lead in a movement away from a world driven by abeyance to the corporate bottom line and the enrichment of an elite to one that prioritises physical, mental, social, and planetary wellbeing”

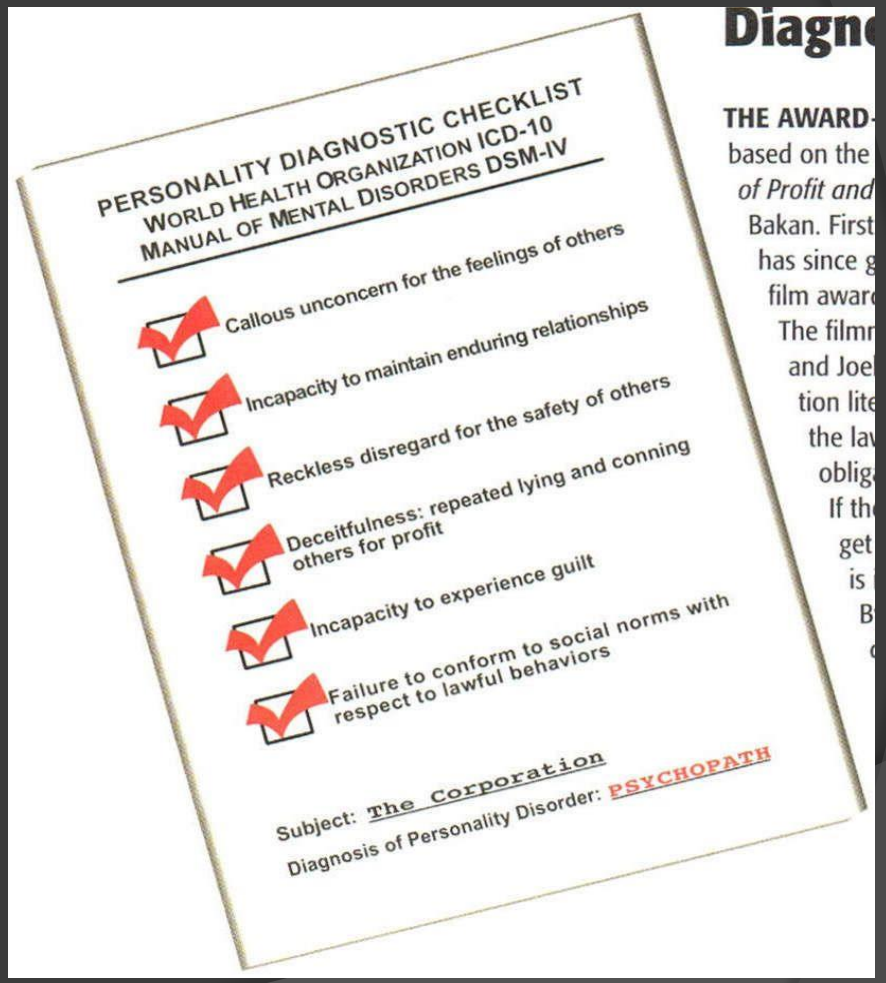
Joe Rogan " You can make a billion dollars from lying ?!"

John Abramson paraphrasing chief scientist of Merck "it's a shame that the cardiovascular effect is there but the drug will do well and we will do well"

# Vioxx scandal – estimated to have killed 40-60k American citizens.

# The "Psychopathic" Determinants of Health



# Facebook, Merck commit $40 m for Alliance for Advancing Health Online

Friday 11 June , 2021 health news

**By Marwa Nassar -**

Facebook and Merck have committed $40 million – half-half – to a multi-year initiative of establishing the Alliance for Advancing Health Online. The initiative will initially focus on addressing vaccine hesitancy and vaccine equity among underserved communities.

# Victims of a failing system

65p

2019 MEDIA BRAND OF THE YEAR • BRITAIN'S MOST TRUSTED DIGITAL NEWS BRAND 2018

i

THURSDAY
5 DECEMBER 2019
Number 2818

'A big heart on the pitch and a sweet guy'
Tributes to England cricket hero Bob Willis
P56

INSIDE
2019 voting guide - part 2
Party by party, on every major issue
Today: Environment
PULL-OUT - CENTRE PAGES

# NHS cuts killed my mother

EXCLUSIVE
**Leading heart doctor warns that 'systemic political failure' is crippling health service**

» Dr Aseem Malhotra says: 'A GP who dedicated 25 years of her life to the NHS was failed by it'
» Family of NHS medics say that Anisha suffered hospital setbacks which led to her premature death
» 'The system is broken and money alone cannot fix it. No one should suffer like my mother'
» Tories promise £34bn budget increase by 2024 will be enshrined in law - while Labour pledges £40bn

Report P7, comment by Dr Aseem Malhotra, P15

**The pill may alter structure of women's brains**
P5

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- Chequers gifted to homeless under a Corbyn government
- Johnson toughens UK position against Chinese tech
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**The gift of reading**
i's charity appeal
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**United make Mourinho's Old Trafford return an unhappy one**
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It's the end of your career! Oh no it isn't!
Les Dennis and other stars on the 2019 panto season
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PUZZLES P44 | GETTING PISTE – SKIERS BEWARE P30 | KIM SENGUPTA ON A NATO TANTRUM P6

8 NEWS

PEOPLE

# Doctor's family want review of his death after ambulance delay

Exclusive
By Paul Gallagher
HEALTH CORRESPONDENT

The family of a former top doctor and lifelong NHS campaigner have called for an investigation into his death after it took paramedics more than half an hour to arrive at his home despite operators being told he was suffering a cardiac arrest.

Professor Kailash Chand, the former vice chair of the British Medical Association (BMA), had complained of chest pains before one of his neighbours, a consultant anaesthetist at Manchester Royal Infirmary, called 111 for help.

He told the call handler within three minutes that he believed his friend was having a cardiac arrest.

"I was answering their questions when Kailash's eyes began rolling and he slipped into unconsciousness. That's when I said 'this looks like a cardiac arrest' and to upgrade the call.

"They kept asking questions as I started CPR and asked for an urgent ambulance. That was two or two and a half minutes into the call.

"My wife, who is also a doctor, arrived and she took over CPR while I kept asking where the ambulance was. We kept going but I couldn't feel Kailash's pulse and there was no sign of life. He never regained consciousness."

Evidence seen by i showed that it then took 30 minutes for the paramedics to arrive at Professor Chand's flat in Didsbury, Greater Manchester. This included a 10-minute gap between arriving "on scene" and being "at patient" after paramedics were given the wrong address and could not immediately locate Professor Chand's home.

National standards for ambulance trusts show that they must respond to category 1 calls – those that are classified as life-threatening and needing immediate intervention and/or resuscitation, such as cardiac or respiratory arrest – in seven minutes on average, and respond to 90 per cent of such calls in 15 minutes.

The neighbour's phone records showed that he called 111 at 17.29 on 29 July and was on the phone for 33 minutes and 31 seconds. The North West Ambulance Service (NWAS) diagnosis of death certificate states that the "call date" of the incident was 17.42 before being "received" by the service at 17.45.

The paramedic crew was "mobile" a minute later before arriving "on scene" at 17.54 but they did not enter the flat until 18.04 due to having a wrong address. They attempted resuscitation but Professor Chand was declared dead at the scene at 18.46. He was 78.

Professor Chand, a former GP described as a "fearless defender" of the NHS, lived in a flat at Quantum House in Kensal Drive.

But the NWAS certificate shows that the crew had been given "Randel Kensal" as the scene and that there were "no signs to indicate address: location" – despite the neighbour being on the phone continuously to the operator.

CCTV shows the ambulance pulling up at 18.02 but it is a further two minutes before three NWAS staff walk in, two of whom are in full personal protective equipment.

Professor Chand's son, the anti-obesity campaigner and London-based cardiologist Dr Aseem Malhotra, has asked the Manchester coroner to investigate the circumstances surrounding his father's death.

Dr Chand Nagpaul, BMA council chair, said: "Chronic underfunding, workforce shortages and lack of capacity is resulting in an NHS that cannot always meet the urgent needs of its population.

HEALTH

## Ambulance trusts receiving 'record levels' of demand

By Paul Gallagher

North West Ambulance Service is currently the subject of the seventh series of the popular BBC One show *Ambulance*. Last night's episode showed the service "busier than ever" and even being asked to take calls from Scotland to help overstretched services there. NWAS has also been asked to take calls from London Ambulance Service who have also been overwhelmed with demand.

Last month, nearly 100 members of the Army were brought in to help four ambulance trusts in England look after patients. High demand and staffing shortages mean they are being used to work alongside NHS staff in the South Central, South West, North East and East areas of England. The union, Unison, said it was a "sign things are not right" within the ambulance service.

In a letter to ambulance trust chief executives last month, Unison officials warned the health of paramedics and 999 call centre staff is being put at risk because of the "unsustainable demand" on the NHS.

All 10 ambulance trusts across England were operating at their highest level of demand the week before the letter was sent.

Latest figures show that more than one million 999 calls were answered in July in a new record for emergency services in England. July also saw the highest ever number of ambulance callouts for life-threatening conditions with 82,000 calls - 8,000 more than the previous record high in June.

Dr Chand Nagpaul, BMA council chair, said: "It is alarming that ambulance services are now receiving record levels of calls, with no national ambulance waiting time standards being met in July in England. In fact, for category 2 patients, which can include people who have had a stroke or chest pain, the average response time was over 40 minutes, more than double the agreed standard of 18 minutes.

"It is vital the Government urgently puts forward an action plan to address this deficit in emergency care infrastructure, so that no person has to endure waits beyond specified standards."

CAMPAIGN



Dr Aseem Malhotra with his father Kailash Chand, who died in July

## 'I was grappling with anger that he shouldn't have died so suddenly'

**Dr Aseem Malhotra** recounts how an ambulance delay cost his father his life

Sitting alone in my London flat, I prepared myself to travel to Manchester to say goodbye to my father, my best friend and the last surviving member of my immediate family. I was also grappling with profound anger, knowing he to hospital now." Knowing that he would need to be monitored and have a blood test to exclude a heart attack, I rushed to be with him. I kept calling until a friend of Dad's, a consultant physician, answered saying: "Aseem, your dad has

He was gone. I asked the coroner for a post mortem. There was no evidence of heart attack but he had experienced unstable angina, where the blood supply to the myocardium is significantly reduced but not enough to cause damage to his heart muscle. This made it even more likely that he almost certainly would have survived had the ambulance arrived within the acceptable response time: seven minutes.

Unfortunately, this is not an isolated case. A few weeks prior, a very senior nurse at NHS England's own husband, suffered cardiac-sounding chest discomfort whilst playing football. Knowing there would be a significant delay she told me that she didn't even call 999. She drove as fast as she could to the nearest A&E where an ECG diagnosed a heart attack.

A colleague of hers relayed that several NHS trusts in regions in England have asked the Government to call in the army to assist

### 999 Delayed responses

When I spent a day inside the control room of the South Central Ambulance Service, the staff told me they were 'stacking' life threatening calls on a daily basis. That was almost three years ago.

Since then demand on ambulance trusts around the country continues to rise. Part of the problem is how the public perceive the 999 service.

"So many more people assume the service is there to help with their social or domestic issues, rather than an emergency," Maurice McGinlay, the night control shift officer, told me back then. "The demand over the last few years has been incredible and I think's only going to increase."

He was right. In July, more than one million 999 calls were answered by NHS staff in England – a new record.

The unprecedented number of calls has come over a year into the pandemic, as exhausted staff deal

**BOX 4:** Defining real evidence-based medicine and actions to deliver it.

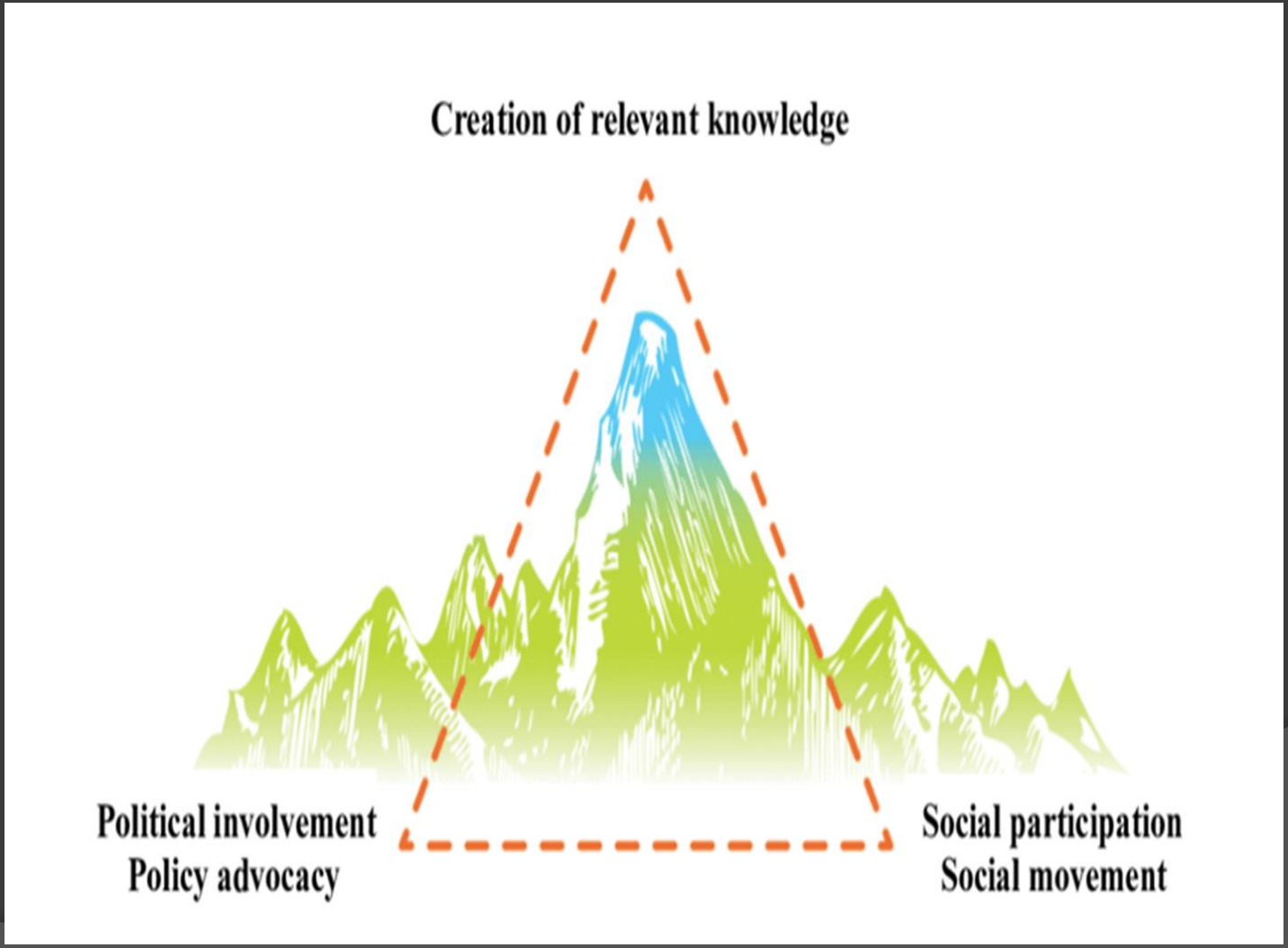
1. Is the application of individual clinical expertise with best available evidence and taking into consideration patient preferences and values in order to improve patient outcomes (relieve suffering and pain, treat illness and address risks to health)
2. Makes the ethical care of the patient it's top priority
3. Demands individualised evidence in a format that clinicians and patients can understand
4. Is characterised by expert judgement rather than mechanical rule following
5. Shares decisions with patients through meaningful conversations
6. Builds on a strong clinician–patient relationship and the human aspect of care
7. Applies these principles at community level for evidence-based public health

**Actions to deliver real evidence-based medicine**

1. Although the pharmaceutical industry plays an important role in developing new drugs, they should play no role in testing them
2. All results of all trials that involve humans must be made publicly available
3. Regulators such as the FDA and MHRA must be publicly funded, and not receive any money from the pharmaceutical industry
4. Independent researchers must increasingly shape the production, synthesis and dissemination of high-quality clinical and public health evidence
5. Medical education should not be funded or sponsored by the pharmaceutical industry
6. Patients must demand better evidence, better presented (using absolute and not relative risk), better explained and applied in a more personalised way

*Source*: Adapted from Greenhalgh T, Howick J, Maskrey N. Evidence based medicine Renaissance Group. Evidence based medicine: A movement in crisis? *BMJ*. 2014;348:g3725. https://doi.org/10.1136/bmj.g3725

# The Triangle That Moves The Mountain

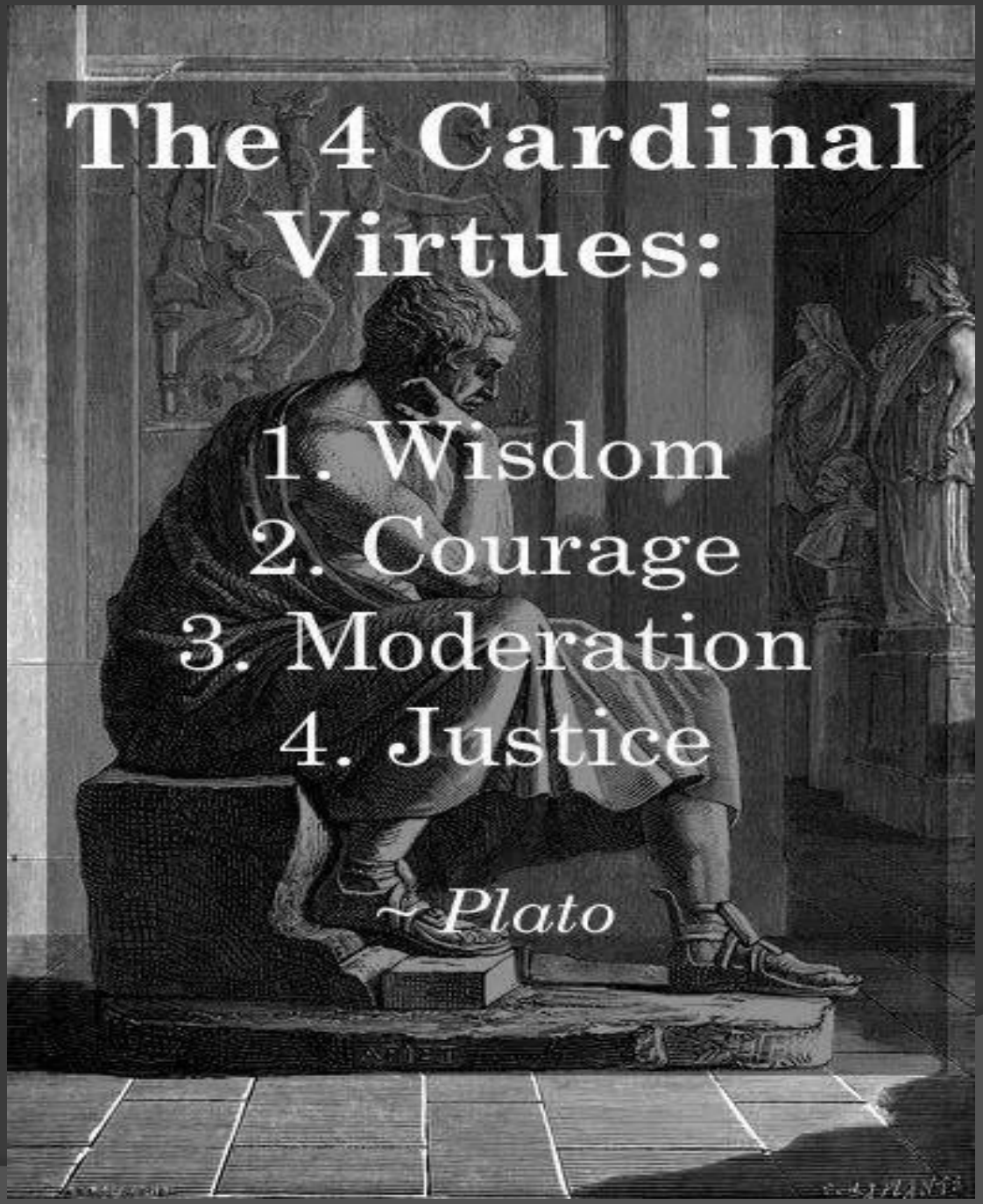


# Public Health Advocacy

- “ careers are often built on lifetime commitment to particular phases of evidence. But if the evidence changes, it is absolutely critical for public trust in the integrity of public health that we acknowledge the facts have changed and accordingly that we have changed our minds too”

# Conclusions

- Overwhelming evidence that current mRNA Pfizer vaccine needs to be suspended until all of the raw data is released for independent scrutiny.


The 4 Cardinal Virtues:
1. Wisdom
2. Courage
3. Moderation
4. Justice
~ Plato

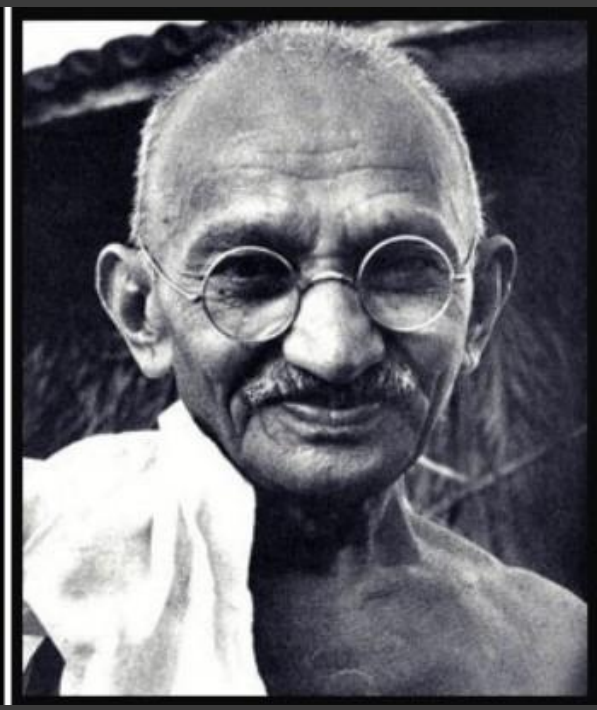
Courage is the most important of all the virtues, because without courage you can't practice any other virtue consistently. You can practice any virtue erratically, but nothing consistently without courage.

(Maya Angelou)

"I see in the near future a crisis approaching that unnerves me and causes me to tremble for the safety of my country... corporations have been enthroned and an era of corruption in high places will follow, and the money power of the country will endeavor to prolong its reign by working upon the prejudices of the people until all wealth is aggregated in a few hands and the Republic is destroyed."

~ ABRAHAM LINCOLN


Rise up with me against
the organisation of misery.
Pablo Neruda
quotefancy



It is health that is real wealth and not pieces of gold and silver.

(Mahatma Gandhi)