COVID Revisited

Lessons Learned, Challenges Faced, and the Road Ahead.

This conference was set up to equip participants with valuable insights for more effective and transparent approaches to public health and medical interventions in the face of future pandemics.

Papers by:

Professor James Allan
Associate Professor Peter Parry
Dr. Phillip Altman
Dr. Melissa McCann
Dr. Jeyanthi Kunadhasan
Dr. John Campbell
Professor Colleen Aldous
Professor Gigi Foster
Emeritus Professor Ramesh Thakur
Emeritus Professor Robert Clancy AM

Event supported by:

Professor Phillip Morris AM
Former Barrister Julian Gillespie
Professor Wendy Hoy
Professor Nikolai Petrovsky

Presented by:

acnem Australasian College of Nutritional and Environmental Medicine
Children's Health Defense AUSTRALIA CHAPTER
AMPS Australian Medical Professionals' Society
NIIM National Institute of Integrative Medicine
WOW

Please visit: https://amps.redunion.com.au/covid_revisited

COVID Revisited

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COVID Revisited – Lessons Learned, Challenges Faced, and the Road Ahead.

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Red Union publishing
41 Campbell Street
Bowen Hills
QLD 4006
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First edition 2024

First printing, May 2024
Canberra, Australia
ISBN 978-0-646-89662-5
Cover design: Gary Delahunty

National Library of Australia http://nla.gov.au.obj-135682653
Cover design: Gary Delahunty

Typeset: Gary Delahunty

Foreword

Philip Morris AM

Welcome to a stepping stone in a journey marked by unwavering dedication to truth, accountability, and the pursuit of knowledge. The Australian Medical Professionals Society (AMPS) presents the preceedings from: 'COVID Revisited – Lessons Learned, Challenges Faced, and the Road Ahead', a conference in Sydney, held on April 2nd, 2024.

This meeting aimed to foster a comprehensive and critical understanding regarding the management of the COVID-19 pandemic from both public health and medical perspectives. The conference shed light on the strengths and weaknesses inherent in the approaches adopted, emphasizing the consequences of pivotal decisions such as community-wide lockdowns, the prohibition of readily available anti-COVID-19 repurposed drugs, the limited regulatory assessment and monitoring of novel vaccines, and the imposition of vaccination mandates for continued employment.

The main goal of the conference was to equip participants with valuable insights that will guide more effective and transparent approaches to public health and medical interventions when we are confronted with future pandemics.

Through shared knowledge and collaborative discourse, the meeting endeavoured to contribute to the development of resilient and adaptable strategies, ensuring the well-being of our communities in the face of emerging health crises. These published proceedings are a record of the incisive and thoughtful presentations made by experts in the field.

As the pages of this volume unfold, they reveal a tapestry woven with threads of defiance, resilience, and unwavering commitment to truth. Through painstaking research and determination, independent researchers have unearthed evidence that challenges the prevailing narrative and demands scrutiny.

From the corridors of bureaucratic indifference to the halls of scientific inquiry, this booklet serves as a clarion call for accountability, transparency, and a re-evaluation of prevailing

orthodoxies. It is a testament to the power of dissent, the pursuit of truth, and the unyielding spirit of those who refuse to accept silence as an answer.

Be prepared to confront uncomfortable truths, challenge entrenched beliefs, and embrace the profound responsibility that comes with bearing witness to history in the making. The time for silence has passed; reckoning is at hand.

Professor Philip Morris AM

MBBS, BSc(med), and PhD

...is qualified in psychiatry and addiction medicine in Australia and is a Fellow of the Royal Australian and New Zealand College of Psychiatrists (FRANZCP). He is a Fellow of the Australasian Chapter of Addiction Medicine (FAChAM) of the Royal Australasian College of Physicians (RACP). He is qualified in general adult psychiatry and geriatric psychiatry and addiction medicine in Australia, and in the USA is Board Certified by the American Board of Psychiatry and Neurology (ABPN) in general psychiatry and geriatric psychiatry. Professor Morris AM is visiting Professor of Psychiatry at Bond University. He is President of the Australian and New Zealand Mental Health Association, President of the National Association of Practising Psychiatrists, and President of the Gold Coast Medical Association. He is a Distinguished Fellow, Treasurer and Board Director of the Pacific Rim College of Psychiatrists.

Conference Overview

Robert Clancy AM

So, what was discussed in our COVID meeting?

The aim was to provide comprehensive coverage of the way Australia performed through a very difficult time, what lessons can be learnt and how we can do better. The following essays tease out these issues across a wide spectrum of experiences. These are the central themes:

1 Communication and leadership

John Campbell stated that traditional communication channels for evidence-based health information failed the health professions and the public, from the 'trusted journals' to the 'trusted news initiative' of the legacy press. The popularity of his Youtube programs serves to underline the importance of third-channel mechanisms for evidence-based communication. Colleen Aldous delved into the narrow approach of the pharmaceutical industry to control both therapy and opinion, dismissing the integrity of such contrived mechanisms as the Randomised Controlled Trial. She introduced a balanced approach considering wide portals into health information, with her novel wheel-of-data approach, and using the torrid tale of ivermectin to illustrate the value of thinking outside Randomised Controlled Trials.

High-quality leadership traditionally underpins communication: most speakers commented on the breakdown in the quality of leadership at every level. James Allan was harsh on those substituting power for leadership: those he called 'Principleless; Panicked; and Power hungry'. As a professor of law, he felt obliged to include the legal profession in this category.

2 The Medical Model: where did it go wrong?

Robert Clancy AM focused on the carefully-honed plan developed over many years for managing a pandemic: define the epidemiology, identify those at risk, develop a vaccine as an ancillary tool, use whatever works and is available. Reviewing an article written in late 2020, he noted the breaking of every principle on which the plan was based. The failure to make repurposed drugs available when they were safe and effective leaves us with an appalling

memory of the worst of decisions. The failure to use early epidemiological data within months underpins the Great Barrington Declaration: protect the vulnerable; isolate those infected; use sensible measures to avoid infection, but carry on education and work in a sensible manner; use safe, effective drugs and a vaccine when available. Limitations on any systemic vaccine attempting to control infection within the respiratory tract were discussed; vaccination was never going to prevent infection, prevent transmission, and have more than a small effect on serious disease. Closely-spaced vaccinations were fraught with danger, through immune suppression, more frequent infections and more severe ones. That is what happened. Negative immunity followed three or more closely-spaced injections. Melissa McCann reinforced these issues as seen from family practice, while emphasising the great difficulties in caring for patients when the community was in lockdown. Most importantly she addressed the enormous concerns for patients with severe adverse events from the genetic vaccines, the causes related to systemic spread of mRNA and therefore spike protein, causing toxicity from the spike protein, which also acted as a foreign antigen, as a target of T cell-mediated damage. The concern for serious adverse events, now well documented even in the traditional medical press, and broadly discussed on John Campbell's channel, is evident in increased unexplained death rates across the vaccinated world – yet public, press, and political outlets refuse to discuss the problem. Nikolai Petrovsky gave an erudite counter to the genetic vaccine story, showing the value of a modern antigen vaccine, used without significant adverse events, but with equal efficacy, in Eastern Europe; the sad addendum was that this vaccine was Australian, yet completely neglected and destroyed within Australian institutions.[1]

3 Failure of responsibility to keep us safe

Peter Parry summarised a litany of pharmaceutical company corrupt behaviours linking their spurious claims and statements with the genetic vaccines which had a long line of similar bad-behaviour events with court-based decisions costing a huge amount of money (but which was so much less than earnings that fines were simply a 'cost of doing business'). Phillip Altman continued the sorry tale to include the regulatory bodies whose job it is to keep us safe. He identified a chain of events from batch variation, contaminants, and poor assessment of both efficacy and adverse events; the list went on. That this failure crossed many lines was a concept reinforced by other speakers, including James Allan and Gigi Foster.

4 Costs were not confined to medical outcomes

Gigi Foster gave a powerful indictment of failed leadership, misinformation at several levels, and suppression of free speech and dissenting views. The costs of these mistakes were outlined in economic terms, complementing the medical issues discussed by others. She gave solutions that should be in place for the next pandemic.

1 The South Australian government has terminated Professor Petrovsky's position as Director of Endocrinology at Flinders Medical Centre, and Flinders University removed his academic status. The story is here: https://www.spectator.com.au/2024/04/punishing-petrovsky/

Conclusion

The collected papers give splendid coverage of where decision-making went wrong in the recent pandemic, with extraordinary medical and economic costs to the Australian population. That appropriate lessons are not being learnt is perhaps the greatest indictment of all. Mandates remain, vaccine success is shouted from many sources, and repurposed drugs remain in purgatory. Tertiary education centres, focused on money, tolerate no alternative view or activity. The brutal treatment of one of very few scientists who have performed remarkably well during the pandemic (Professor Petrovsky) has resulted in his being stripped of his position. The authorities obtained a court order to remove him from his laboratory with 24 hours' notice. All this was to protect their piece of the mRNA funding pie. Doctors continue to be muzzled for trusting science over narrative.

Patients bear the brunt of all of this.

Emeritus Professor Robert Clancy AM

AM FRS(N), BSc(Med), MB BS, PhD, DSc, FRACP, FRCP(A), FRCP(C)

Foundation Professor Pathology, Medical School, Newcastle

...is a clinical immunologist with over 300 publications. He and two others began Clinical Immunology in Australia as a discipline. He established Clinical Immunology departments in McMaster University (Canada), RPAH Sydney, and John Hunter Hospital in Newcastle. He has been Chief College examiner in Clinical Immunology and continues to practise. He established the Newcastle Mucosal Immunology Group and was awarded the DSc by the University of Newcastle. He developed the idea of mucosal resilience and immunobiotics.

Introductory Comments

The conference represented by these published proceedings took place in Sydney on April 2nd, 2024. Before it can be adequately introduced, it is fitting to return to the inquiry held by the Australian Medical Professionals Society (AMPS) on October 18th, 2023.

In the time following that event, the end of October through to the year's end, this organisation tried continually to make contact with health officials at the highest level. It had been established with crystal clarity that our all-cause mortality rates were, to use a muted piece of medical jargon, unacceptably high. They were, in fact, at levels to be expected in wartime. A more fitting description than the bland 'unacceptably high' would be to call them hideous. For Australians to be found dying in peacetime at levels appropriate for the combat of war ought to be the principal subject of discussion throughout the entire national media, and the prime focus of concomitant action by the government. The numbers of these deaths have been so troubling that AMPS saw no other option but to ignore government and bureaucratic paralysis, opting to hold a properly independent inquiry and to publish the results – and in doing so, to marvel at the way invitations to attend and bring a paper, directed to office-holders prominent in the health hierarchy, were simply ignored.

In the promotion of these results, and after sending out over 30,000 digital and hard copies of the book *Too Many Dead – an Inquiry into Australia's Excess Mortality*, AMPS made several attempts to have its database of 3600 case histories and peer-reviewed studies transferred to the Federal Health Minister and to the Prime Minister for active consideration and review. These documents find very heavily against the COVID injections. Having attempted numerous times to open intelligent discussion with the Therapeutic Goods Administration (TGA) and having been ignored again and again, AMPS then in that pre-Christmas period tried to catch Prime Minister Albanese, with a view to handing over the database to him. A visit to his office in Parliament House allowed the transfer to take place by hand rather than by mail. Unfortunately, though, and while he issued a statement about the deplorable loss of 1,139 lives in the terrorist attack on Israel, no acknowledgement was ever issued about his receipt of these data, nor of the number of people dying here in his own country's excess deaths, and the figure is at least thirty times greater than the Israeli one. Nobody so much as mentioned the database. The silence is damning and distressing.

There are those among us who find this highly unsatisfactory.

The whole of the bureaucratic response so far has been one of systems defence. The realities are being ignored, because the work is not being done by those who bear the responsibility. It is increasingly important to consider new ways, more expansive and holistic ways, of thinking about and incorporating scientific evidence. We need to turn from the so-called gold standard, pharmaceutically-funded, double blind, placebo-controlled randomized trials that can often lead to incorrect conclusions. We need instead to be in the habit of considering the totality of evidential sources. (See Aldous, below.)

A low-key interview with an Australian embalmer recently produced the information that now, since the roll-out of the injections, about twenty percent of deceased people prepared for burial in his premises are found with the hitherto unknown rubbery material of amyloid clots in their veins. And as the occasional bureaucratic responses are drawn slowly and reluctantly out of the medical system, not a mention is ever made of vitally important issues such as this. It is not as though this phenomenon is irrelevant to health. It is not as though the leaders in the health system have only a theoretical role to play in management.

Without adequate investigation from the official medical orthodoxy, people who lose loved ones are forced to turn to the internet. When they do, they find pictures like this. One wonders how medical bureaucrats would like to have this stuff in their veins. No amount of ivory-tower denial will make the questions go away. (See Altman, Campbell, and Clancy AM, below.) And it seems no amount of persuasion short of the law is going to move the medical system to do its proper investigations. When did anyone last hear a chief medical officer or a health minister go onto the evening news with a plausible reason for the existence of this phenomenon?

In the trickle of documentation AMPS has managed to accrue from the system, there have been only allegations of science, not science itself. There have been denials aplenty, but again no science. There have been protestations about which arm of which medical body is

responsible for what, but no science in answer to even a fraction of our own as published in *Too Many Dead*.

Martin Luther in 1517 nailed his 95 theses to the door of the Castle church in Wittenburg, and so began the Reformation. He decided where he stood. We need some more of that today. The Australian Medical Professionals Society deplores the fact that as we contact them and add actual science to what is known about the excess death rates, our medical masters fail to respond in kind and at the same time suspend from practice competent doctors who offer sound medical opinion. We continue to ask why that is so. We find that while rarified medical argument is necessary, and we do provide yet more as a result of this latest conference, the basic facts are being copiously provided by our side of the argument and paraded before an apparently uninterested medical hierarchy and an only vaguely aware political one. It is beyond reasonable expectation of everyday Australians that blanket denial of responsibility should be allowed to occur at all, let alone continue as it has. (See Kunadhasan, below.)

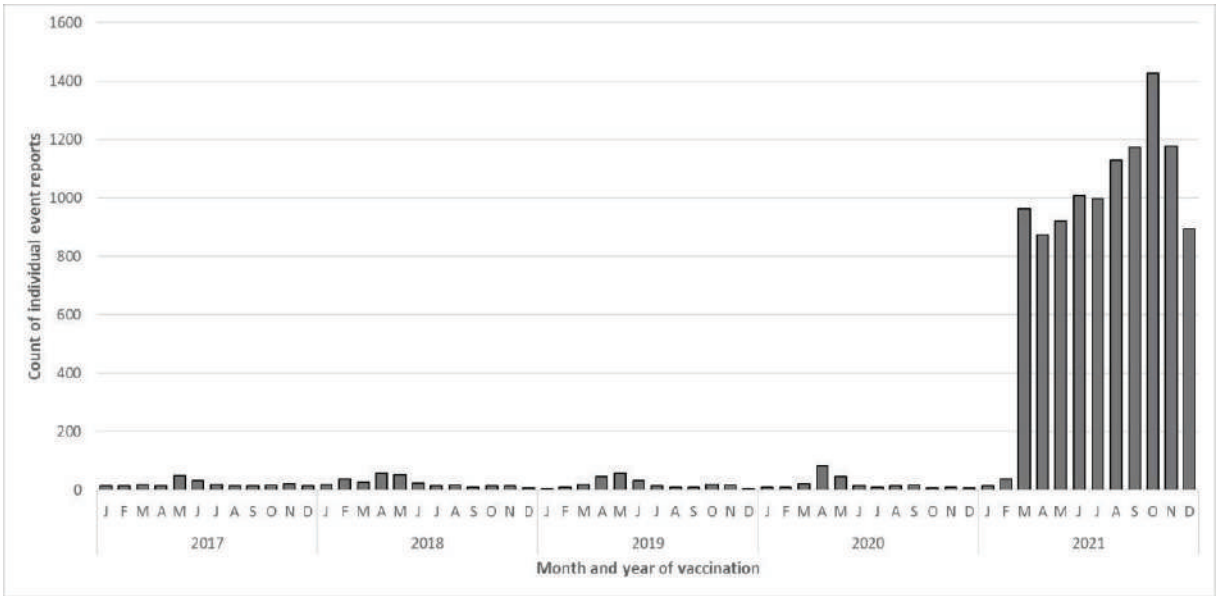
When the many doctors and nurses combined their medical experience and their life-learned wisdom to refuse to take the COVID injections forced on them by the system, they knew they were wilfully running towards danger. They did it to their own detriment because they believed that the evidence showed the injections were neither safe nor effective, and they then had to pay with their livelihoods as the health bureaucrats suspended and then terminated them. Now, as increasing amounts of evidence come forward, with the independent science the argument is going to shift further towards the humanities and to the law. (See Thakur, below.) There is, in fact, so much science that we ought to be seeing a lay-down misère.

> The decision to ban hydroxychloroquine (HCQ) and ivermectin for use in early treatment and prevention of COVID-19 cost many lives, drove divisions within the health care fraternity that may never be repaired, and led to health professionals losing their jobs. (See Clancy AM, below.)

Cost-benefit analyses had been produced by 2022, finding strongly against the lockdown policies, but this was to no avail. Apart from the damage done to employment within the health-related occupations, Foster (below) calls Australia's COVID policy response a 'catastrophic over-reaction', and 'the worst peace-time policy-making the country has ever seen'. The influence of big pharma is described (Parry) in the way fiduciary responsibility has overtaken the incentive to provide adequate medical service. 'Meanwhile,' he says, 'the pharmaceutical industry paid US$116 billion in criminal fines from January 2000 to March 2024, for felonies such as off-label marketing, data suppression and kickbacks and bribery.' The 'results of pharmaceutical industry-sponsored clinical trials exaggerate the safety and benefits of their products' (Thakur). There is good reason for lack of trust.

In Australia the Database of Adverse Event Notifications (DAEN) is a voluntary reporting system that exists to keep track of, obviously, adverse events. Equally obviously, being voluntary it has only a tiny likelihood of scooping up all the incidence rates of anything. Despite this limitation, the data it does list are steadfastly ignored in every statement and letter from ministerial and senior bureaucratic levels. The COVID 'vaccines' as at June 1st 2023 are listed by this government facility as having caused in Australia the following (and more):

- Cardiac disorders, 16,438
- Pericarditis, 3808
- Myocarditis, 1321
- Blood and lymphatic system disorders, 7439
- Immune system disorders, 2606
- Pulmonary embolism, 1593
- Eye disorders, 5739
- Ear disorders, 4303



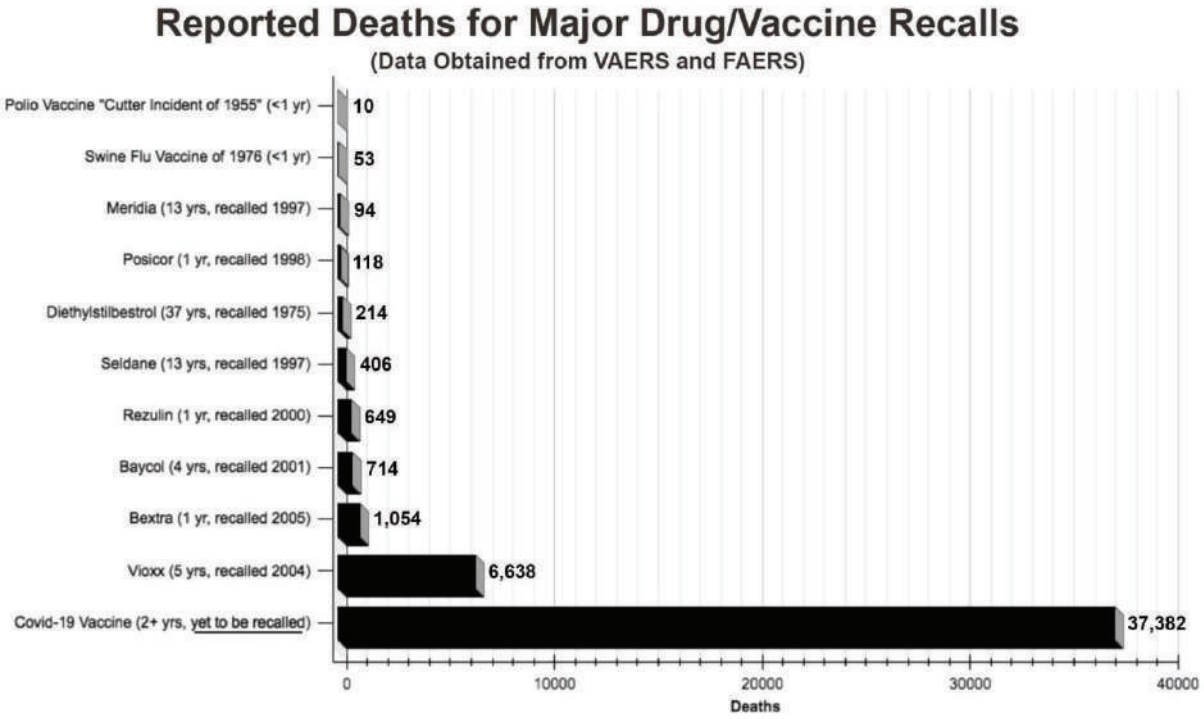
As these Western Australian figures clearly show, the damage burst on the scene not with COVID – WA had none at this early point – but from the beginning of the vaccine roll-out.

A letter directed to the Prime Minister and asking for an audience to discuss these disturbing figures was answered (21-12-23) not by him but by Acting Assistant-Secretary Kim Dobbie, from the Department of Health, saying the PM '…receives numerous meeting requests from individuals and organisations across Australia. Unfortunately, it is impossible for the Prime Minister to accept all of the meeting requests. I regret that the Prime Minister cannot accept your meeting request in this instance.' Do we dare to speculate on whether the many other people he has to meet with are likely to hand him the information about why Australia has suddenly produced sixteen thousand cases of cardiac disorders at the same time as embalmers are being baffled by dead folk with rubbery and fibrous clots in their veins? 'During COVID we fell under the rule of the biosecurity state wherein citizens were regarded as disease-carrying biohazards,' says Thakhur, below.

The Dobbie letter explained that the Commonwealth helpfully offers a scheme which '….. provides compensation of $1,000 and above due to an adverse event that is recognised to be caused by a COVID-19 vaccination.' Allan, below, says 'Those imposing these sometimes inane and often unprecedented public health measures virtually never paid the costs of what they were imposing.' According to DAEN, the governmental agency, and ignored by the TGA, there are over 139,000 of the injured.

There is now a class action (see McCann, below) under way on behalf of the vaccine-injured, people who may never be the same again after the damaging injections delivered to them under mandate by a system well and truly established through scientific investigation to have failed the Australian people to a level never before known. Where cost-benefit and risk-benefit analysis has been entirely deficient, the medical system will increasingly have its methods tested at law. This class action is still open, the biggest ever brought in this country.

Is it really necessary to have a medical degree to understand the extraordinary urgency that needs to be applied to the information now in common circulation? (See Parr, below.)

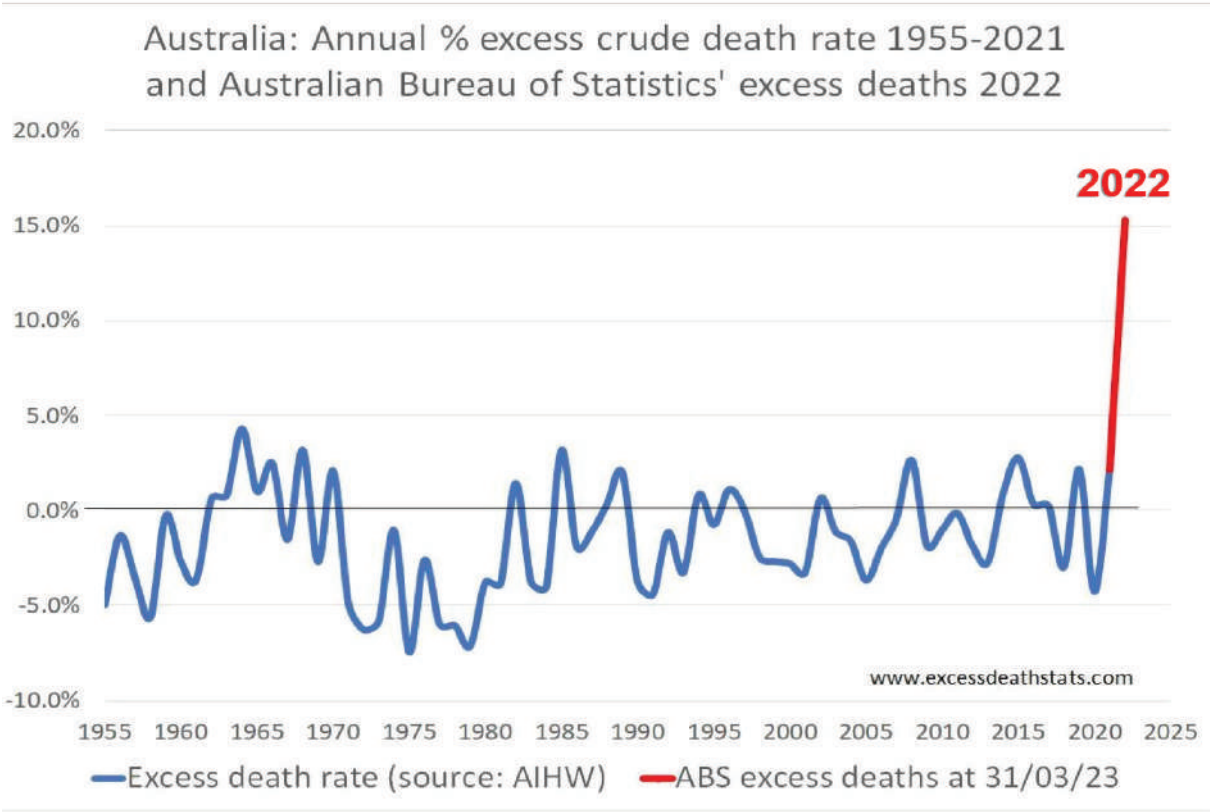


It is not possible to overstate the amount of independent evidence that continues to accrue, and continues to be ignored by the established medical system. It does not seem to be too much to expect that regardless of background or position, an ordinary person, tinker, tailor, soldier, spy, might wonder out loud at what could be done to understand and interpret numbers such as those on the charts displayed in this document above. It was 'false narratives (that) formed the basis of the unsupportable vaccine mandates which continue to this day' (Altman, below). Yet proper and warranted investigations such as by *post mortem* examination and transparent circulation of data simply do not exist. In every exchange, all the medical service chooses to do is to deny, defend, and deflect, and to practise the art of feeble response.

The facts are demonstrated by substantial amassed scientific evidence, the independent kind. Here are some of them:

- The government's policy response to COVID-19 appears to have been made using poor-quality pharmaceutical-company-sponsored data passed off as evidence;
- The modelling of COVID-19 the disease was pessimistic and inaccurate;
- The modelling of the benefits of the COVID-19 vaccines has been equally inaccurate, but wildly over-optimistic;
- Testing methods have been inaccurate;
- Enforced mandates were unscientific and unjustified;
- There has been misinformation on safety and efficacy of provisionally-approved vaccines;
- The suppression of cheap, repurposed, fully-approved and promising COVID-19 early treatment options is deeply concerning. This included such as hydroxychloroquine (the destruction of millions of doses sourced by Mr Clive Palmer), ivermectin, doxycycline, zinc, vitamins D and C, all suppressed in favour of provisionally-approved drugs such as paxlovid, molnupiravir and gene-based vaccines;
- Data collection has been very poor;
- Pharmacovigilance has been of an extremely low standard;
- Throughout there has been absence of decision-making transparency;
- It is the Commonwealth's duty, according to Section 51 [xi] of the Australian Constitution, to provide national statistics. The Australian Statistician CEO of the ABS, David Gruen, failed to collect vaccination data nationally. The ABS does not publish data on vaccination, and in the absence of these data it leaves the government with no idea how vaccines may be linked to the deaths;
- The political environment has been nothing short of outrageous in the way it has intimidated all doctors and scientists, and there have been many, who set out to raise concerns regarding patient safety.

This conference has gone on to draw together once again independent researchers who are not frightened to deal with the facts. When asked by AMPS to produce work of publishable quality, they did just that, and we present it here. At the time of this writing, a Senate inquiry has been promised. This is likely to prove just the beginning of substantial questioning of some of those in authority who have so far resisted the exposure of their actions to the light of day. This process is



necessary. Let us not forget that while it goes on, excess numbers of Australian people are dying.

It now only remains for the reader to begin with our first paper, an exchange comprising four documents, an exchange which is of a kind that has shown itself all too common. Questions have been asked about where the truth really lies, and they have not been answered. These questions, good examples, are to be found at the end of the first letter in this next paper. Here they are:

1. Did the TGA know about the hidden deaths in the vaccinated arm of the trial that were not declared prior to the issuing of the EUA?
2. If the TGA did not know about these hidden deaths, had due diligence been followed by direct scrutiny of the trial data?
3. Alternatively, did the TGA instead choose to rely on the FDA, which in turn had relied on Pfizer?

Questions like this need to be asked because they light the way to a fuller understanding of just how many ways in which the medical, political and regulatory systems have failed us. Are the Australian people going to endure this death rate with no answers about it from the health authorities?

Further, this next document neatly demonstrates the kind of problems that competent and independent researchers have had as they attempt to confront the authorities with information that is not congenial to the official position.

Discussion is what has been sought. So, reader, make up your own mind. Is this discussion being granted? Read on.

Hidden Deaths – a correspondence

Jeyanthi Kunadhasan

The first paper in our report is composed of four separate documents.

1. This is a letter from The Australian Medical Professionals Society to Professor Anthony Lawler, copied to four other people, Professor Paul Kelly, Dr Blair Comley, Professor Nigel Crawford, and Minister Mark Butler. The subject is hidden deaths. There are three questions.
2. This is the response from Professor Anthony Lawler.
3. Then comes a second letter from AMPS to Professor Lawler, again copied to the others, with further concerns regarding the hidden deaths, and also containing two more questions.
4. We then have a reply from Professor Lawler.

Document - 1

20-3-24

Dr Tony Lawler, head of the TGA
Anthony.lawler@health.gov.au

Copied to:
Professor Paul Kelly, Paul.kelly@health.gov.au
Dr Blair Comley, Chair of the Department of Health, Blair.Comley@health.gov.au
Professor Nigel Crawford ATAGI, nigel.crawford@mcri.edu.au
Minister Mark Butler, minister.butler@health.gov.au

RE: Undisclosed Deaths in C4591001 Trial at the Vaccine and Related Biological Products Advisory Committee (VRBPAC) on December 10, 2020.

Dear Dr Tony Lawler

You will find at the end of this paper three specific questions which are being directed to you. This letter comes to you not only on my own behalf, but on behalf of The Australian Medical Professionals Society.

I am Dr. Jeyanthi Kunadhasan, an anaesthetist and perioperative physician. I investigated the data, released on the Public Health and Medical Professionals for Transparency website,[1] which formed the basis of the Food and Drug Administration's emergency use authorization (EUA) of Pfizer-BioNTech's BNT162b2 mRNA COVID vaccine. Additionally, I serve as Treasurer of the Australian Medical Professionals Society.[2]

I co-authored Pfizer reports 42[3] and 76[4], available on dailyclout.io. Additionally, I contributed as a coauthor of "Forensic Analysis of the 38 Subject deaths in the 6-Month Interim Report of the Pfizer-BioNTech BNT162b2 mRNA Vaccine Clinical Trial."[5] This analysis of the Pfizer's COVID vaccine represents the inaugural examination of the original trial data by a group unaffiliated with clinical trial sponsorship.

I wish to highlight two undisclosed deaths of American trial participants in the BNT162b2-vaccinated arm of Pfizer's clinical trial. Pfizer's nondisclosure of these deaths occurred before Pfizer's data cut-off date for its EUA submission to the FDA (Michels et al., 2023).

The clinical trial data reportedly supporting the safety and efficacy of the BNT162b2 mRNA vaccine have been published twice. Polack et al. released their findings, 'Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine,' [6] on December 10, 2020, one day before the FDA issued Pfizer's EUA. Subsequently, on September 15, 2021, Stephen J. Thomas, MD, et al. published, 'Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through

6 Months.'[7] The Polack publication in the *New England Journal of Medicine* stated, 'All the trial data were available to all the authors, who vouch for its accuracy and completeness and for adherence of the trial to the protocol, which is available with the full text of this article at NEJM.org. An independent data and safety monitoring board reviewed efficacy and unblinded safety data' (Polack et al., 2020).

The Polack paper disclosed six deaths — two in the BNT162b2 arm and four in the placebo arm. Both the journal article and the EUA approval documentation[8] showed the six deaths during the period of July 27, 2020, till November 14, 2020. This letter will demonstrate that Pfizer-BioNTech had records showing eight deaths, four in the BNT162b2 arm and four in the placebo arm, that Pfizer should have disclosed to the FDA. Additionally, the two undisclosed deaths indicated a cardiac event signal in the clinical trial's BNT162b2 recipients (Michels et al., 2023).

Pfizer's clinical trial protocol required prompt reporting – immediately upon awareness and, under no circumstances, to exceed 24 hours – of serious adverse events (SAE), via the Vaccine SAE Reporting Form, to Pfizer Safety.[9] Investigators were responsible for documenting all directly observed and spontaneously reported adverse events, including serious adverse events reported by participants, into the patient's Case Report Form (CRF). In the unfortunate event of a death, the next of kin or emergency contact had the responsibility to promptly inform the clinical trial site, distinguishing it from the self-reporting process for other adverse events. The clinical trial site's swift notification about an SAE to the trial sponsor, BioNTech in this instance, played a crucial role in meeting legal obligations and ethical responsibilities concerning participant safety and the study intervention under clinical investigation. BioNTech, as the sponsor, bore the legal duty to quickly notify both the local regulatory authority and other regulatory agencies about the safety of the study intervention under clinical investigation. Compliance with country-specific regulatory requirements for safety reporting to the regulatory authority, Independent Review Boards (IRBs)/Ethics Committees (ECs), and investigators was also obligatory.

Examining the table below, which is adapted from the 'Forensic Analysis of the 38 Subject deaths in the 6-Month Interim Report of the Pfizer-BioNTech BNT162b2 mRNA Vaccine Clinical Trial' (Michels et al., 2023), reveals that as of the data cut-off date of November 14, 2020, a total of 11 deaths (six deaths in the vaccinated arm of the study and five in the placebo arm) were recorded. This stands in contrast to the six deaths publicly disclosed at the VRBPAC meeting and in the Polack article. The capture rate seems to be 33% in the vaccinated arm (two reported deaths out of six) and 80% in the placebo arm (four reported deaths out of five).

Days of delay in recording subject deaths

BNT162b2 arm

Period	Subject ID	Date of Death	Officially Recorded Date (from Case Report Form)	Delay Recording Death (Days)
#P-C	11621327	13Sept2020	24Sept2020	11
P-C	11141050	19Oct2020	25Nov2020	37
#P-C	10071101	21Oct2020	5Nov2020	15
P-C	11201050	07Nov2020	3Dec2020	26
P-C	11521497	11Nov2020	18Nov2020	7
P-C	10891073	12Nov2020	4Dec2020	22

Placebo arm

Period	Subject ID	Date of Death	Officially Recorded Date (from Case Report Form)	Delay Recording Death (Days)
#P-C	11521085	26Aug2020	27Aug2020	1
#P-C	12313972	28Sept2020	1Oct2020	3
P-C	11561124	02Nov2020	19Nov2020	17
#P-C	10661350	03Nov2020	10Nov2020	7
#P-C	10811194	04Nov2020	11Nov2020	7
O-L, F	11681083	18Nov2020	19Nov2020	1

To unravel the discrepancies in reported deaths, my co-authors and I initiated our investigation with the assumption that, as of November 14, 2020, Pfizer-BioNTech had no knowledge of any deaths during the trial. The only way to convincingly disprove this was to demonstrate, through publicly available records, that Pfizer-BioNTech had knowledge of the deaths. By examination of these records, we were able to show Pfizer-BioNTech indeed did possess knowledge of them. Scrutinizing each patient's notes accessible on the Public Health and Medical Professionals for Transparency (PHMPT) website, we identified the six deceased subjects, whose deaths were reported in the initial Polack publication and at the VRBPAC meeting on December 10, 2020. These subjects include vaccinated patients 11621327 and 10071101 along with the unvaccinated subjects 11521085, 12313972, 10661350, and 10811194. Their deaths occurred prior to November 14, 2020, and the documentation of their deaths was available in their respective Case Report Forms (CRFs) prior to November 14, 2020.

Below are two BNT162b2 subjects whose deaths were included in the EUA submission:

Subject ID	Actual Date of Death	Date Pfizer Had Knowledge of the Death	Did Pfizer Have Knowledge of the Death Prior to the 11/14/20 EUA Data Cut-Off?	Source for Pfizer's Knowledge of the Death
11621327	13-SEP-20	24-SEP-20	YES	Subject's Case Report File, 10/15/2020, page 123, 10/2/2020 07:36:13 page 122 notes that death was listed in Safety DB but missing in the CRF. Notification of death noted as 9/24/2020 on page 122.[10]
10071101	21-OCT-20	5-NOV-20	YES	Subject's Case Report File, 11/5/2020 16:40:57 page 188, Nov-05-2020 16:39:49 page 196 of the CRF.[11]

Below are the four placebo subjects whose deaths were included in the EUA submission:

Subject ID	Actual Date of Death	Date Pfizer Had Knowledge of the Death	Did Pfizer Have Knowledge of the Death Prior to the 11/14/20 EUA Data Cut-Off?	Source for Pfizer's Knowledge of the Death
11521085	26-Aug-20	27-Aug-20	YES	Subject's Case Report File, Page 118 Aug-27-2020 09:33:16.[12]
12313972	28-Sep-20	01-Oct-20	YES	Subject's Case Report File, Oct-01-2020 16:07:36 page 149-150, Oct-01-2020 16:08:33 page 156.[13]
10661350	3-Nov-20	10-Nov-20	YES	Subject's Case Report File, Nov-10-2020 13:41:45 page 121, Nov-10-2020 13:41:02 page 122.[14]
10811194	4-Nov-20	11-Nov-20	YES	Subject's Case Report File, Nov-11-2020 15:19:14 page 343, Nov-12-2020 07:51:29 mentions 11Nov202 as the date of notification of death.[15]

The examination of the CRFs for the remaining 32 deaths did not reveal any additional notifications of death prior to the November 14, 2020, data cut-off date. (Reference Appendix A.) Our investigation confirmed that Pfizer-BioNTech relied on the data entry of the death notification in the CRF as perhaps the sole determinant used to include a death as reportable. However, our investigation of publicly available records at that time could not elucidate why the other deaths were not reported.

Nonetheless, the September 2023 Pfizer-BioNTech data released by the FDA introduced a document named '125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf,'[16] which included information revealing that Pfizer-BioNTech was, in fact, informed of two additional deaths in the BNT162b2 arm of the trial well before the EUA data cut-off date, and that Pfizer-BioNTech did not disclose those deaths to the FDA. If the deaths had been disclosed in the EUA submission, they would have shown that the BNT162b2 mRNA COVID vaccine intervention did not reduce deaths.

Subject 11141050[17] from Alliance for Multispecialty Research LLC , Newton, Kansas[18], in the vaccinated arm of the study, died on October 19, 2020. Contrary to Pfizer-BioNTech's clinical trial protocol, neither Polack et al., nor the EUA submission documentation, nor the VRBPAC meeting on December 10, 2020[19], disclosed this patient's death.

The death occurred well before the data cut-off date of November 14, 2020. The public lacks access to any of the original clinical trial records, specifically Pfizer Safety's Vaccine SAE Reporting Form for subjects. However, from the patient narratives (Pfizer, 2023, p. 71), it is evident that the emergency contact confirmed on the day of death (October 19, 2020) that the subject had died. The narrative documents further state that the subject had an autopsy, determining the cause of death to be 'sudden cardiac death.'

Upon reviewing this subject's Case Report Form (CRF), I found the specific diagnosis 'sudden cardiac death' was mentioned on December 9, 2020.[20] On page 71 of this subject's CRF, the date of death notification was November 25, 2020. Since the clinical site had been informed by the emergency contact on the day the patient died, we know there was a 37-day delay in

recording this death in the CRF, violating Pfizer's trial protocol. As this death occurred well before the data cut-off date of November 14, 2020, and was known to Pfizer on November 25, 2020, there was ample opportunity to disclose this subject's death, and possibly the autopsy results, at the December 10, 2020, VRBPAC meeting.

Compound: PF-07302048; Protocol: C4591001 **Page 71 of 157**
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1114 11141050; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 18AUG2020; Date of Last Dose: 08SEP2020

Narrative Comment
Subject C4591001 1114 11141050, a 63-year-old white female with a pertinent medical history of depression (since 01 Jan 1984), intervertebral disc degeneration (since 18 Aug 2005), hypertension (since 01 Jan 2010), generalized rheumatoid arthritis (since 01 Jan 2010), and sleep apnea syndrome (since 01 Jan 2016), received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject experienced sudden cardiac death on 19 Oct 2020, 41 days after receiving Dose 2. Concomitant medications included trazodone (since 01 Jan 2005) for depression, pregabalin (since 01 Jan 2005) for degenerative disc disease, amlodipine (since 01 Jan 2010) for hypertension, baclofen (since 01 Jan 2018) for degenerative disc disease, hydralazine (since 01 Feb 2020) for hypertension, and sertraline (since 01 Jul 2020) for depression. On 19 Oct 2020 (Day 63), the emergency contact confirmed that the subject died. An autopsy determined the cause of death as sudden cardiac death. Of note, the subject had risk factors of hypertension and obesity, which put her at high risk for cardiac/acute myocardial infarction death. In the opinion of the investigator, there was no reasonable possibility that the sudden cardiac death was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

I also want to highlight another undisclosed death of a vaccinated subject. Subject 11201050, from Meridian Clinical Research LLC, Savannah, Georgia, died on November 7, 2020. The patient narratives explicitly state that the clinical site received notification of the subject's death on November 7, 2020, from her husband (Pfizer 2023, p. 75). This information is further supported by documentation found in that patient's CRF clearly stating that the death notification occurred on November 7, 2020.[21]

Given these established facts, it is puzzling that the death of this subject was not included with the other data to the FDA when seeking EUA. Moreover, it was not disclosed by the clinical trial investigators to the regulators during the December 10, 2020, VRBPAC meeting (Vaccines and Related Biological Products Advisory Committee, 2020). This is particularly perplexing as the death occurred and was acknowledged as known before the November 14, 2020, data cut-off date.

Compound: PF-07302048; Protocol: C4591001 **Page 75 of 157**
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1120 11201050; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 04AUG2020; Date of Last Dose: 27AUG2020

Narrative Comment
Subject C4591001 1120 11201050, a 58-year-old white female with a pertinent medical history of chronic back pain (since 2015), hypertension (since 2017), anxiety (since 2018), and type 2 diabetes mellitus (since 2018), received Dose 1 on 04 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 24). The subject died of cardiac arrest on 07 Nov 2020, 72 days after receiving Dose 2. Concomitant medications included metformin (since 2017) for type 2 diabetes mellitus; lisinopril (since 2017) and clonidine (since 2018) both for hypertension; and lorazepam (since 2018) for anxiety. On 07 Nov 2020 (Day 96), the subject's husband notified the site that the subject had died in her sleep. The subject's husband reported that the night before her death, she had taken an unspecified muscle relaxant and diazepam (Valium) for her chronic back pain; these medications were previously used by the subject. No symptoms or illnesses leading to the subject's death were reported. The subject was not seen in the hospital. The coroner was called to pronounce death; an autopsy was not performed. On 04 Dec 2020 (Day 123), the subject's husband stated that the cause of death on the death certificate was cardiac arrest (also described as cardiopulmonary arrest). In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201050.pdf, p. 74

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1120	**Site Name:** (1120) Meridian Clinical Research
Subject No: 11201050	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 11:09

eCRF Audit Trail History

Death Details		
1.	Date of Collection / Notification of Death:	Nov/7/2020
Cause of Death		
2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[cardiac arrest]

We have documentation in the publicly available Pfizer clinical trial documents that confirms the patients' loved ones promptly communicated the subjects' deaths to the clinical trial sites. However, in violation of legal requirements, the regulatory authorities were apparently not informed of these deaths within the specified time frame. The critical time period under scrutiny is the issuance of the EUA on December 11, 2020, which relied upon the clinical trial data collected through November 14, 2020. Beyond the ethical issues raised, which I have highlighted, there are legal obligations to promptly report deaths to local regulatory authorities, a practice essential for ensuring trial subjects' safety.

The public does not have access to records that would demonstrate the actual notifications of death for the other undisclosed deaths that occurred before November 14, 2020 — specifically, two BNT162b2-vaccinated subjects (11521497 and 10891073) and placebo subject 11561124. It is currently not possible to determine whether there were any additional errors in reporting during this period. Compelling Pfizer-BioNTech and the clinical trial sites to provide all available information is essential to establish the facts and a correct timeline.

During the December 10, 2020, VRBPAC meeting, one reason cited for vaccine approval was 'the known and potential benefits of the vaccine outweigh the known and potential risks of the vaccine when used for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older' (Vaccines and Related Biological Products Advisory Committee, 2020). Patients who volunteered for the clinical trial likely did so, at least in part, in service of humanity. The failure to disclose the patients' deaths, despite timely notification by loved ones, constitutes a betrayal of their altruism and trust and deserves further investigation. Further, and even more notably, the omission of the two deaths from the vaccinated arm of the study at this critical juncture of EUA issuance raises substantial concerns about the overall safety reporting of Pfizer's clinical trial.

Accordingly, we ask:

1. Did the TGA know about the hidden deaths in the vaccinated arm of the trial that were not declared prior to the issuing of the EUA?

2. If the TGA did not know about these hidden deaths, had due diligence been followed by direct scrutiny of the trial data?

3. Alternatively, did the TGA instead choose to rely on the FDA, which in turn had relied on Pfizer?

In closing, we wish to make it perfectly clear: this letter, as you have seen, is copied to a number of others, but considering your responsibility in checking the evidence of efficacy is valid, these questions are specifically for you.

Sincerely,

Dr Jeyanthi Kunadhasan

MD (UKM), MMed (AnaesUM), FANZCA MMED (Monash)

Appendix A

1. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1114-11141050.pdf
2. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201050.pdf
3. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1152-11521497.pdf
4. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1089-10891073.pdf
5. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1039-10391010.pdf
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9. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1097-10971023.pdf
10. https://phmpt.org/wp-content/uploads/2023/06/125742_S1_M5_CRF_c4591001-1156-11561160.pdf
11. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1252-12521010.pdf
12. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1140-11401117.pdf
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17. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1088-10881139.pdf
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19. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1168-11681083.pdf
20. https://phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1128-11281009-reissue.pdf
21. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1088-10881126.pdf
22. https://phmpt.org/wp-content/uploads/2023/06/125742_S1_M5_CRF_c4591001-1231-12314987.pdf
23. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1019-10191146.pdf
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Footnotes

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Document - 2

Australian Government

Department of Health and Aged Care

Deputy Secretary

Dr Jeyanthi Kunadhasan
Treasurer
Australian Medical Professionals' Society
41 Campbell Street
BOWEN HILLS QLD 4006

Dear Dr Kunadhasan

Thank you for your letter, dated 21 March 2024, concerning undisclosed deaths in C4591001 Trial.

First, I would like to clarify that while the Therapeutic Goods Administration (TGA) does work closely with international counterparts, including the US Food and Drug Administration (FDA), the TGA independently reviews data submitted as part of a submission to register a medicine or vaccine, and makes its own decision based on the Australian context. Questions pertaining to the FDA's conduct of its own investigations are best directed to the FDA itself.

Second, the TGA is not aware of any 'hidden deaths'. At the time of provisional approval, the interim report provided to the TGA included 6 deaths. This is articulated on page 29 of the Australian Public Assessment Report (AusPAR) for COMIRNATY (accessible at: www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125.pdf). Subsequently, the final report of the trial, with updated figures on safety outcomes including deaths over the 6-month double-blind period and subsequent open-label follow-up, has been provided to the TGA.

Large, multicentre clinical trials in humans present complex logistic challenges and despite preplanned protocols, detailed procedures and strict monitoring, similar errors and protocol deviations are commonly reported in clinical trials. These are not considered a breach of Good Clinical Practice or 'hidden deaths'. The subsequent reports or supplementary addenda capture or correct any missing or incorrectly reported data and if needed revised reports are issued.

Phone: (02) 6289 4200 **Email:** anthony.lawler@health.gov.au
Gulgana Building, 27 Scherger Drive, Fairbairn ACT 2609 - PO Box 100 Woden ACT 2606 - **www.tga.gov.au**

It is reassuring to note that, in this case, none of the deaths in the trial have been attributed to the vaccine and the initial conclusions remain valid. The accumulating published evidence over time continues to support the significant public health benefit of the safety and efficacy of mRNA vaccines, as well as an overwhelmingly favourable risk/benefit ratio.

I would like to emphasise that the TGA takes the issue of data integrity very seriously. It is not possible to audit all clinical trials routinely, however random or targeted inspections are conducted when appropriate. In addition, information is shared across various regulators where significant issues are suspected. In the case of this clinical trial, there has not been any evidence or suggestion of impropriety that would have required such action or revision of findings.

I thank you for your effort in corresponding and hope to have addressed your concerns.

Yours sincerely

Professor Anthony Lawler
Health Products Regulation Group

27 March 2024

Document - 3

April 6, 2024

Dear Professor Lawler

Re: Undisclosed Deaths in C4591001 Trial at the Vaccine and Related Biological Products Advisory Committee (VRBPAC) on December 10, 2020.

Thank you for your reply dated 27th March 2024.

An important feature of pharmaco-vigilance is continuous reappraisal of data when it is provided. I would like to again draw your attention to the two undisclosed deaths (hidden deaths) at the point of the consideration of the Pfizer COVID-19 vaccine approval in the United States in December 2020. The data that I highlight with regard to timelines and date stamps, whilst it would not necessarily have been available to the TGA at the point of vaccine approval in December 2020, was certainly accessible at the 6-month safety report, and this would have been available from April 2021 onwards.

The TGA in its own independent review of the data would have come across the data I am about to highlight again. I understand not all clinical trials can be audited extensively. However, because of the immense societal, economic, and psychological implications of the rollout of COVID-19 vaccination, where people's livelihoods were dependent upon receiving approved vaccination, the onus on ensuring data integrity would have been higher with trial C4591001. At the 6-month data review, the TGA team investigating the C4591001 trial data would have found that up until the data cut-off date of November 14th 2020, there had been a gross misrepresentation in what had thus far been presented to the public. Instead of 6 deaths, with more deaths in the placebo arm (4 deaths) compared to the vaccinated arm (2 deaths), there were actually 11 deaths with more deaths in the vaccinated arm (6 deaths) compared to the placebo (5 deaths). Whilst not statistically significant because of the small numbers involved, it would have been harder to persuade the public to take a drug where more people died in the supposedly life-saving intervention arm.

Subject 11141050 died on October 19th 2020. This was certainly well before the data cut-off date of November 14th 2020. I have highlighted that we have documentation to the effect the emergency contact notified the clinical site of the death on October 19th itself. Once the clinical site had been notified, as per protocol requirements, this was to be notified to Pfizer via the Vaccine SAE form no later than 24 hours after. This death was not one of those disclosed publicly. Why? Why was there a 37-day delay to entering this patient's death into their notes? Has the TGA's team uncovered any reasons for this? Why is this not a breach of Good Clinical Practice?

Compound: PF-07302048; Protocol: C4591001 **Page 71 of 157**
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1114 11141050; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 18AUG2020; Date of Last Dose: 08SEP2020

Narrative Comment
Subject C4591001 1114 11141050, a 63-year-old white female with a pertinent medical history of depression (since 01 Jan 1984), intervertebral disc degeneration (since 18 Aug 2005), hypertension (since 01 Jan 2010), generalized rheumatoid arthritis (since 01 Jan 2010), and sleep apnea syndrome (since 01 Jan 2016), received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject experienced sudden cardiac death on 19 Oct 2020, 41 days after receiving Dose 2. Concomitant medications included trazodone (since 01 Jan 2005) for depression, pregabalin (since 01 Jan 2005) for degenerative disc disease, amlodipine (since 01 Jan 2010) for hypertension, baclofen (since 01 Jan 2018) for degenerative disc disease, hydralazine (since 01 Feb 2020) for hypertension, and sertraline (since 01 Jul 2020) for depression. On 19 Oct 2020 (Day 63), the emergency contact confirmed that the subject died. An autopsy determined the cause of death as sudden cardiac death. Of note, the subject had risk factors of hypertension and obesity, which put her at high risk for cardiac/acute myocardial infarction death. In the opinion of the investigator, there was no reasonable possibility that the sudden cardiac death was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

I would like to probe further into the TGA's conclusion that this undisclosed death in the vaccinated arm was not due to the vaccine. On what basis was this determination made? This patient had an autopsy result that is not publicly available. Has the TGA had access to this autopsy result? If so, I argue it is in the public interest that this autopsy result be publicly available for independent scrutiny.

This patient's cause of death as per the autopsy was 'sudden cardiac death' with her risk factors of hypertension and obesity putting her at high risk of cardiac-acute myocardial infarct. The specific diagnosis of 'sudden cardiac death' was entered into her notes on Dec 9th 2020, the day before the VRBPAC meeting of Dec 10th 2020, which suggests that this hidden death also had autopsy results available at the critical juncture of consideration of vaccine approval.

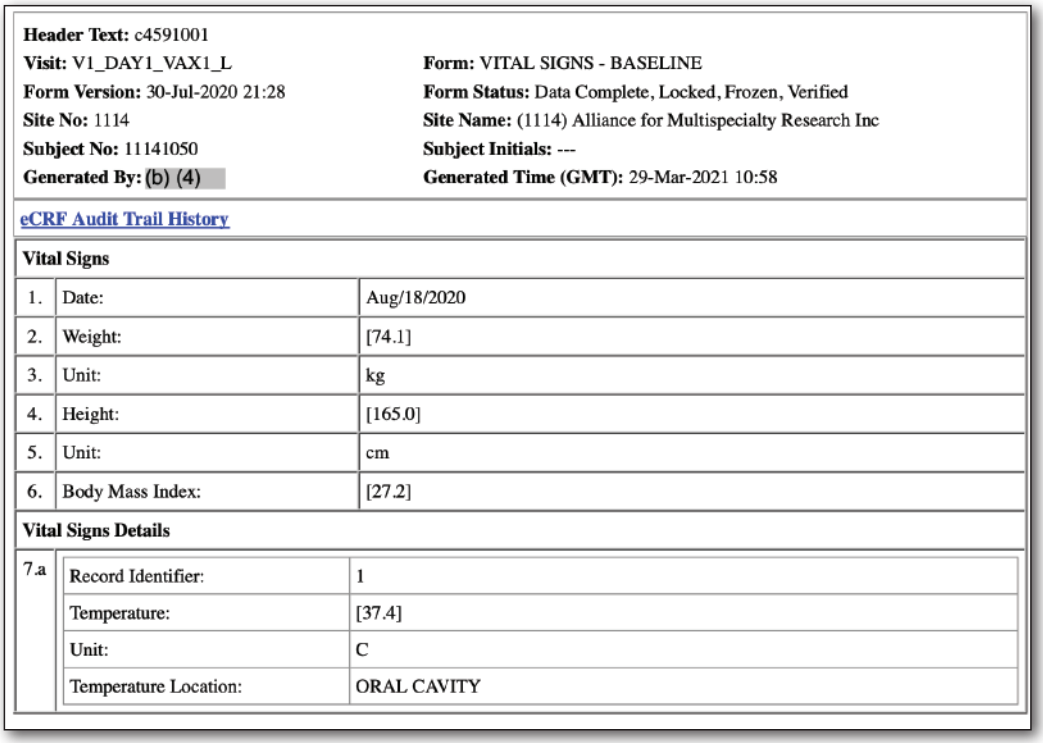
Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen, Verified
Site No: 1114
Site Name: (1114) Alliance for Multispecialty Research Inc
Subject No: 11141050
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:58

Dec-09-2020 16:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-09-2020 16:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	New Information
Dec-09-2020 16:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Sudden cardiac death	New Information
Dec-09-2020 06:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020468218, the term in Safety database was updated to Sudden cardiac death while retained as death-cause unknownin AE CRF.Please confirm correct term. If safety update is required, please submit a follow-up form.
Nov-29-2020 22:47:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	to follow up: pending records
Nov-27-2020 09:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Correct as entered pending records
Nov-26-2020 02:34:36 (UTC-06:00) Central Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6247063;This 'Adverse Event' contains the term DEATH. If known, please provide the cause of

https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1114-11141050.pdf page 128

I cannot find a blood pressure reading in her publicly available case notes, let alone one that would have been worryingly high. A criterion for enrolment in this clinical trial was to admit healthy participants who were determined by medical history and physical examination (if required); they needed the approving clinical judgement of the investigator to be eligible for inclusion in the study. Healthy participants with pre-existing stable disease were defined as having disease not requiring significant change in therapy or hospitalization for worsening of the condition during the six weeks before enrolment. I believe I can be forgiven for making the assumption that the patient's blood pressure which she had since Jan 1st 2010 was well controlled at her enrolment into the trial.

Her weight was noted to be 74.1 kg, and her height 165 cm, hence her BMI is 27.2 which puts her in the overweight category, not obese. Does the TGA readily accept that someone with these anthropometric readings is at high risk of sudden cardiac death, without perusal of any autopsy results? She died 41 days after dose 2 of the vaccine. On what basis was this intervention discounted as a cause of death?



Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VITAL SIGNS - BASELINE
Form Version: 30-Jul-2020 21:28
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1114
Site Name: (1114) Alliance for Multispecialty Research Inc
Subject No: 11141050
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:58

eCRF Audit Trail History

Vital Signs

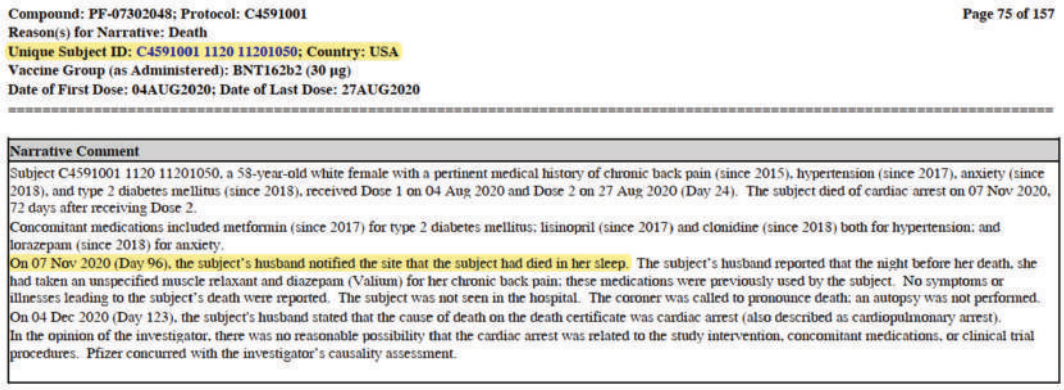
1.	Date:	Aug/18/2020
2.	Weight:	[74.1]
3.	Unit:	kg
4.	Height:	[165.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY

https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1114-11141050.pdf page 10

Subject 11201050 died on November 7th 2020. Her husband reported her death to the clinical site on November 7th 2020. She had been found dead in her sleep 72 days after receiving dose 2 of the vaccine. She was not seen in the hospital and had no autopsy performed. A coroner was called to pronounce her death. The cause recorded on the death certificate was cardiac arrest.



Compound: PF-07302048; Protocol: C4591001 Page 75 of 157
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1120 11201050; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 04AUG2020; Date of Last Dose: 27AUG2020

Narrative Comment
Subject C4591001 1120 11201050, a 58-year-old white female with a pertinent medical history of chronic back pain (since 2015), hypertension (since 2017), anxiety (since 2018), and type 2 diabetes mellitus (since 2018), received Dose 1 on 04 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 24). The subject died of cardiac arrest on 07 Nov 2020, 72 days after receiving Dose 2. Concomitant medications included metformin (since 2017) for type 2 diabetes mellitus; lisinopril (since 2017) and clonidine (since 2018) both for hypertension; and lorazepam (since 2018) for anxiety. On 07 Nov 2020 (Day 96), the subject's husband notified the site that the subject had died in her sleep. The subject's husband reported that the night before her death, she had taken an unspecified muscle relaxant and diazepam (Valium) for her chronic back pain; these medications were previously used by the subject. No symptoms or illnesses leading to the subject's death were reported. The subject was not seen in the hospital. The coroner was called to pronounce death; an autopsy was not performed. On 04 Dec 2020 (Day 123), the subject's husband stated that the cause of death on the death certificate was cardiac arrest (also described as cardiopulmonary arrest). In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201050.pdf, p. 74

I would like to be enlightened as to how to the TGA was able to conclude that this death could not be attributed to the vaccine, as no autopsy results were available. Is the TGA similarly incurious for other 58-year-old women suddenly dying in their sleep, when they have signed up for other clinical trials? Pfizer has documented that they received notification of her death on November 7th 2020. As this was well before the data cut-off date, does the TGA have an explanation as to why this death from the vaccinated arm of the study was not disclosed either at the December 10th VRBPAC meeting or in the Polack *NEJM* publication? Could I not be justified in seeing this as hidden deaths?

I continue to highlight the hidden deaths in this trial to draw attention to a larger issue that my co-authors and I found in our forensic paper. Given the large number of participants in the clinical trial, the 38 deaths reported in the 6-Month Interim Report was surprisingly low (18% of the expected number). Did the TGA come to a similar conclusion in their scrutiny of the data? The number of subjects lost to follow-up at Nov 14th 2020 was already 203 (this was higher than the primary endpoint population of 170, from which the 95% efficacy claim came).

The cardiac adverse event signal was obscured by delays in reporting the accurate date of subject death that was known to Pfizer-BioNTech in the subject's Narrative Report. The first 4 deaths in the vaccinated arm of this trial were adults aged 56-64, who were found dead. Two of those patients (subject 11141050 and 11201050) are those that I have highlighted in my letter. Has the TGA investigated why there was a delay in recording their deaths in violation of trial protocol?

I am grateful for your correspondence thus far and look forward to your reply to the issues that I have further raised. I hope you agree with me that there are important issues in the safety reporting of this trial that need to be further addressed.

Yours sincerely

Dr Jeyanthi Kunadhasan

Document - 4

On Sun, 7 Apr 2024 at 11:49, LAWLER, Tony <Anthony.LAWLER@health.gov.au> wrote:

Ms Thomas

Thank you for forwarding this correspondence.

For the completeness of your records and the accuracy of any future correspondence, the correct titles of the recipients are:

- Professor Anthony Lawler, Deputy Secretary Health Products Regulation, Department of Health and Aged Care
- Professor Paul Kelly, Chief Medical Officer, Department of Health and Aged Care
- Mr Blair Comley PSM, Secretary, Department of Health and Aged Care
- Professor Nigel Crawford, Chair, Australian Therapeutic Advisory Group on Immunisation
- The Hon Mark Butler MP, Minister for Health and Aged Care.

Kind regards

Professor Anthony Lawler FACEM, FRACMA, MBBS, BMedSci, MBA (Health Mgmt)

Deputy Secretary, Health Products Regulation Group

Australian Government Department of Health and Aged Care

PO Box 100 Woden ACT 2606 AUSTRALIA

The Health Products Regulation Group comprises the Therapeutic Goods Administration, the Office of Drug Control, the Office of the Gene Technology Regulator, and the Australian Industrial Chemicals Introduction Scheme.

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Dr Jeyanthi Kunadhasan

MD (UKM) MMED (UM) FANZCA MMED (MONASH)

Anaesthetist and Perioperative Physician

...has been a consultant anaesthetist at a major regional Victorian public hospital and was in practice for more than 12 years. She has a clinical interest in patient blood management where she spearheaded many initiatives that sustainably brought down the unnecessary transfusion rates in major surgeries, leading to improved patient outcomes and lower cost to the health system.

A Kaleidoscopic Review of the COVID Craziness

Ramesh Thakur

The public policy madness of the COVID years seems less and less believable with each passing week and month. And yet, many incidents and scenes will be instantly recalled by most of us who lived through it all as soon as they are mentioned. This paper offers a few representative but not comprehensive snapshots of some of the more telling ones.

1 The Absurd, the Idiotic and the Farcical

To begin with, some were so absurd and farcical that, if presented in a work of fiction, they would be dismissed as too creative. There were photos of police tapes around rocks in public parks to warn people against sitting on them in case they got infected. There were photos of young children in primary school all masked up and anti-socially distanced, which was nothing less than child abuse. Sole occupant drivers were stopped by cops for being maskless. There were photos of election rallies in India with people crowding together, some masked, some with masks pulled below chins, some maskless.

Canada's chief medical officer advised people to put their masks on during sex. There were virus-free eating areas where a mask was not required when sitting but had to be worn when standing up or going to the lavatory. A lonely farmer operating his tractor in a paddock, miles from another human being, had to wear a mask. The supermarket had a check-out Plexiglas safety screen. The police, with tape measures in hand, enforced density limits for shops and it resulted in long queues outside supermarkets.

And the winner is: South Australia's Chief Public Health Officer. She closed down the whole state based on a lie told by a man with COVID-19 about his link to a pizza[1] shop. The pizza box must be highly infectious! She also advised footy fans to 'duck and do not touch'[2] any errant football that came their way over the fence at Adelaide Oval because it might have been infected with the virus from Collingwood players coming from the plague state over the border. A COVID flunkey subsequently explained that her remark had been taken out of context and people could safely touch the ball if they used hand sanitiser.

You really could not make up any of this stuff in the pre-COVID era, before 2020.

1 https://www.abc.net.au/news/2021-09-08/woodville-pizza-bar-owner-reflects-on-sa-covid-19-lockdown/100425432
2 https://www.abc.net.au/news/2021-06-02/nicola-spurrier-urges-afl-fans-to-duck-to-avoid-football/100185804

2 The Many Faces of a Police State

Comical as these incidents were, the COVID excesses were no laughing matter. In many respects what we experienced was martial law dressed up as a medical emergency, a police state where far too many individual coppers were given free rein to indulge their inner bullies. And unfortunately, Australia led the world in this descent into authoritarianism, validating the *bon mot* from Clive James that its problem is not too many convict ancestors so much as too many prison guard ancestors.

Military joined police to patrol our major cities. Heavily armed riot police in full battle gear and menacing-looking vehicles confronted peaceful protestors (but Black Lives Matter protests were okay because, well, racism is an even more lethal health risk). Rubber bullets were fired into crowds of protestors at Melbourne's Shrine of Remembrance. A young pregnant mother was arrested in her pyjamas in the presence of her shocked and distressed family for the crime of posting a link on Facebook about a peaceful protest with proper social distancing and masks. A man was dumped hard on the pavement while engaged in a conversation with another police officer. A woman on the beach was surrounded by five riot squad officers. Another sitting by herself on a bench in a park was accosted by two officers and told to move on. Riot police charged through Melbourne's Queen Victoria Market.

3 The Cruel and the Heartless

Unfortunately, the public health clerisy were determined to match police brutality with their own examples of cruelty and heartlessness. Examples that spring to mind begin with the heart-breaking image of the masked-up Queen sitting in a corner all alone in her grief at her beloved husband's funeral service. And the photo of the man in Milton Keynes, UK who went to comfort his mother during his father's funeral when an officious man interrupted the service to put him right. There were thousands who were forced to endure parents and grandparents dying lonely deaths in isolation wards, and loved ones with dementia looking out from behind glass windows with pain and confusion plainly written on their faces. There were missed family birthdays, anniversary reunions, wedding ceremonies.

Hospitals were closed off because Queensland hospitals are for Queenslanders. There was the resulting death of one unborn twin[3] because the paperwork and other red tape hassles in crossing from Ballina NSW into Queensland and catching flights from Brisbane to Sydney caused too much wretched delay. There were poignant scenes of families reaching over the plastic barriers at the Tweed Heads (NSW)-Coolangatta (QLD) border. Australian citizens were prevented from returning home from India. There was delay of a visit to Queensland by a California-based son to see his dying father, even though he had been allowed to enter Australia and was already in Sydney, willing to charter a private plane.

4 The Hypocrisy

What incensed the people even more was how the harshness and cruelty imposed on the general public was overridden by the elites when it came to their own behaviour. Sports and entertainment A-lister celebrities were exempted from many of the restrictions in order to give

3 https://7news.com.au/lifestyle/health-wellbeing/nsw-woman-denied-queensland-border-exemption-for-emergency-case-loses-unborn-twin-c-1272490

the public their weekly dose of bread and circuses. The Prime Minister made multiple overseas trips. A state chief health officer exempted himself from travel restrictions he had laid down for everyone else in order to attend a function in Canberra where his contributions were honoured. Politicians in the US enjoyed themselves in fancy French restaurants sans masks and in breach of physical distancing requirements for everyone else, or in sunny locations mid-winter while exhorting their citizens to stay home. Many donned masks for photo-ops before returning to enjoy their group cocktails – for example, the world's ruling elites at the G7 summit in Cornwall or Alexandria Ocasio-Cortez who danced merrily without a mask but put it on for a group photo. American politicians and celebrities mingled at ritzy functions without masks while the serving staff had to wear masks or risk being fired.

5 Science and Data Illiteracy

Pandemics are relatively rare occurrences in history. Including COVID-19, there have only been five outbreaks since the First World War. Over that same period, advances in medical knowledge and technology have greatly expanded the toolkits of prevention, treatment and palliative care. There have also been major advances in medical education, training and research. Alongside these developments, countries learned from one another and cooperated to build national and international public health infrastructure to promote people's health around the world. In September 2019, the World Health Organisation (WHO) published a report that summarised the 'state of the art' policy advice for governments on health interventions to deal with pandemics. Many governments, including Australia, wrote their own pandemic preparedness plans that drew on the century's worth of science, data, and experience.

These were the best-practice contingency plans for the outbreak of pandemics as low-probability but high-impact 'black swan' events. Why were they abandoned just when most needed in early 2020? The science and evidence base did not change in that short timeframe.

Doctors combine their formal training, clinical knowledge, best available evidence, and familiarity with patients' medical history. Most importantly, they also take into consideration individual patient preferences and values in order to treat illness, manage risks, and relieve suffering. All this too was thrown out in favour of commands from centralised health bureaucracies. Why?

Modelling was all too often mistaken for scientific research and modelled scenarios for hard data and scientific conclusions. This was the basis for claiming that lockdowns, mask and vaccine recommendations-cum-mandates were based on the science. A wide-ranging survey conducted by *The Telegraph* and Censuswide and published[4] in *The Telegraph* on March 2 found that a third (33%) of scientists believe that officials had focused on only a minority of opinions, wrongly equating scientific scepticism with science denialism. Science is always work in progress, never an encyclopaedia of immutable facts. The sceptics had considerable tacit support in the scientific community. 'This was, however, muted by concerns about loss of patronage, access to research grants and difficulty in publication as the cost of speaking out', says Prof. Robert Dingwall.

6 Misinformation, Disinformation, Gaslighting

The threat from COVID-19 to the general population was greatly exaggerated. Between them, the real-life examples from the cruise ship the *Diamond Princess* and the US and French

4 https://www.telegraph.co.uk/news/2024/03/02/leading-scientists-government-harm-covid-lockdowns/

warships the *Theodore Roosevelt* and *Charles de Gaulle* showed two things. In the first case, even under the worst possible conditions with mostly elderly people engaged in constant social interactions in close physical proximity, the mortality rate was quite low. In the latter two cases, involving healthy and fit mostly young men, the mortality risk was negligible. But to instil fear, the infection and case fatality rates, the distinction between dying with and from COVID, and that between absolute and relative risk reductions, were all blurred.

People were bombarded with slick propaganda messages saying that the threat was very grave for everyone. The effectiveness of interventions was exaggerated, the risk of collateral harms was seriously downgraded, the standard QALY (quality adjusted life years) metric for assessing the benefits of interventions were jettisoned, and the requirement for rigorous cost-benefit analyses was ignored. The media were bribed, bullied and otherwise co-opted into amplifying the pandemic fear porn.

Drug companies have a fiduciary duty to maximise returns for shareholders but no corresponding legal obligation to give the best treatment to citizens. The corporatisation of the healthcare sector has arguably compromised ethical standards. With rare exception, the results of pharmaceutical industry-sponsored clinical trials exaggerate the safety and benefits of their products,[5] leading to lack of fully-informed consent. This is further compounded by the fact that because of commercial confidentiality the raw data from clinical trials are rarely made available for independent analysis. Too many regulators of pharmaceutical products are dependent on the industry itself for their operating budgets and many of their personnel end up working for the drug manufacturers once they have served their term.

7 Harms

At the height of the pandemic, only a few dissenting scientific voices spoke out to highlight the health and economic risks from lockdowns, masks and vaccines. Now, the *Telegraph* poll cited earlier shows that 68 per cent of British scientists believe more consideration should have been given to the fallout caused by shutting down the country. As national health services collapsed into *de facto* single service COVID-only health services, treatment of other illnesses was deferred and screening of detectable and treatable illnesses was postponed to an indefinite future. A study from University College London in February estimated that 12,000 quality adjusted life years had been lost[6] in Britain and over 100,000 across Europe because of delays in diagnosing melanoma alone during COVID lockdowns.

Millions in the third world aspiring to join the lower middle class were instead flung back into harsh poverty. Financial strains and school closures put many children and women back into increased risk of domestic violence, child trafficking and sex trafficking. Hundreds of millions missed out on childhood immunisation with proved benefits and long-term safety profiles. Multiple studies have shown that lockdown increased developmental and learning delays. The vast amounts of money thrown at keeping individuals and businesses afloat through the shutdowns have pumped money into circulation to fuel inflation, add to the cost-of-living pressures, and rob today's children of secure debt-free futures.

5 https://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-12-249
6 https://www.telegraph.co.uk/news/2024/02/16/covid-lockdown-diagnosis-delays-12000-years-life-lost/

Almost all highly-vaccinated countries have experienced high excess death rates that coincide with their vaccination campaigns. Yet, the general response from governing and public health authorities is that of the three wise monkeys: see no evil, hear no evil, speak no evil.

8 The Sinister

In the beginning many of us assumed that the institutional checks on abuse of power would come into play as self-correcting mechanisms, that the powers that be and the public would soon realise the error of their ways, and COVID-19 would be regarded by public health authorities and the people as just another endemic respiratory illness and infectious disease not meriting extraordinary interventions.

How wrong we were.

As weeks turned into months and months into years, what initially had seemed like well-intentioned incompetence and mistakes began to take on more sinister manifestations. The surprise at just how easy it had proved for governments to secure mass buy-in of the pandemic scare and near-universal compliance with lockdown, mask and vaccine diktats turned into apprehension at the growing number of medical and human rights, civil liberties and political freedoms that were trampled.

Compliance with official regulations turned into the more sinister transformation of civil society into the snitch societies reminiscent of Stasi East Germany, Stalinist Russia and Maoist China, with citizens enthusiastically reporting possible breaches of the regulations by colleagues, neighbours and even family members. As vaccine apartheid took hold, many public commentators and intellectuals openly contemplated denying to the unvaccinated jobs, entry into public spaces and even medical and hospital care for life-threatening illnesses.

Nor has the era passed of 'nudging' one's own citizens through techniques of behavioural psychological manipulation, compulsion and coercion. On the contrary, having learned how easily mass public opinion can be mobilised in service of the official narrative, there is every prospect of serial repeats of public emergencies across many sectors of human life. Meanwhile the World Health Organisation is preparing for a *de facto* coup to centralise unprecedented power and resources by means of a new pandemic treaty and amendments to the existing International Health Regulations. This is less of a globalist coup against sovereign states than a power grab by elites in collusion across state borders against the world's deplorables.

Perhaps the era of liberal democracy that underpinned growing prosperity and improved health outcomes for everyone has peaked and we have begun the descent into Dystopia.

9 State Power and COVID Crimes

In effect we are witness to the culmination of a long-term trend since the Second World War. The Cold War saw the rise of the national security state. Then we had the growth of the administrative state with technocrats and bureaucrats being delegated more and more legislative, executive and judicial functions with correspondingly diminished public accountability. This was followed by the creation and spread of the surveillance state as governments harnessed the

power of technology to spy on their own people even more than on alleged enemies. Finally, during COVID we fell under the rule of the biosecurity state wherein citizens were regarded as disease-carrying biohazards. The national security elite entered into an active, mutually-beneficial partnership with the pharmaceutical, media, and technological leaders in society. The end result is not just the censorship industrial complex but the fusion of Big State, Big Pharma, Big Media and Big Tech to create an oppressive and suffocating ruling class.

10 What Is to be Done?

Has the public worm turned? A mere 3.3%[7] of Australians aged 18-64 were 'fully immunised' as at February 2024 and only a third (33.6%) of people over 75 have taken the recommended up-to-date booster.

If public disenchantment is replacing trust in the competence and good faith of the public health clerisy, it might be an opportune time to resurrect the campaign for a duly empowered Royal Commission, helmed by credible people with the appropriate mix of qualifications, experience, expertise, and integrity, who are not tainted with conflicts of interest, to conduct an independent, impartial and rigorous inquiry.

In addition, those responsible for the extraordinarily damaging pandemic policies need to be identified, prosecuted and, if convicted, punished. Only this can satisfy people's innate sense of justice, bring emotional closure to the victims and families of those who suffered grave harms, and act as an effective deterrent to comparable acts of malfeasance in the future.

Emeritus Professor Ramesh Thakur

Ph.D, LID, (hc)

...is an Emeritus Professor in the Crawford School of Public Policy, The Australian National University. He is a former United Nations Assistant Secretary-General, and a Brownstone Institute Senior Scholar. Born in India and educated in India and Canada, he has held full time academic appointments in Fiji, New Zealand, Canada, and Australia and been a consultant to the Australian, New Zealand and Norwegian governments on international security issues. He has served on the international advisory boards of policy-oriented research institutes in Africa, Asia, Europe, and North America. He has written and edited more than 50 books.

7 https://www.health.gov.au/resources/publications/covid-19-vaccine-rollout-update-9-february-2024?language=en

Evidence-Based Communication

John Campbell

Evidence-based communication (EBC) of course is not new. However, traditional modalities of medical and scientific communication have now been deleteriously influenced by powerful vested interests. While this pernicious influence has probably been developing in strength over the past 20 years, the recent pandemic, or specifically the responses to the pandemic, have brought the problem into sharp focus.

Evidence-based medicine (EBM) has a long history but was concisely defined by David Sackett in the early 1990s. Sackett identified the three essential components of EBM as best available evidence, expert-consensus opinion and patient preferences and choices. However, it is now argued that true EBM is difficult or impossible to attain in the current international climate.

First, best available evidence is problematic because the research that is done is the research that is paid for. Vested interest can often dictate the research that is commissioned and equally importantly, the research that is not commissioned. Research is pragmatically aimed at new products which can be commercially exploited. Equally, potentially efficacious interventions, ones that do not have prospective financial returns, are ignored or actively supressed.

Secondly, expert opinion is also compromised by who pays for it. Medicine regulators around the world are largely funded by industry-based vested interests. The infamous revolving door conveying well-paid people from industry to regulators and from regulators to industry continues to spin apace. Of course, we are assured by regulators that this extreme financial compromise in no way affects the objectivity of their decisions while in office. In other words, he who pays the fiddler has no influence whatsoever in the choice of the tune.

So, if patients do not have access to the best available evidence and the expert opinion they receive is potentially compromised, this means they cannot be well informed. If a person is not properly informed, how can they give informed consent? Preference cannot be expressed if no alternative narratives are presented. You can have your car any colour you want, as long as it is black: the choice of Henry Ford and Hobson.

Given the failures of implementation in current EBM, new modalities of evidence presentation are needed. New methods of collating expert opinion are now needed. New ways of informing individuals to empower them into independent decision making are now needed.

Evidence-based communication can present data and draw on first-person testimony; experts can be consulted and their evidence evaluated. Networks of trust can grow, physical and photographic evidence can be collated and applications made plain in non-specialised language. There can be direct communication between world-leading experts and needy people. Peer review can be electronically evaluated within hours. For us, as health care providers, if we have the audacity to intervene, this must always be on the best available evidence.

One example of the need for independent interrogation has been the COVID vaccines. While a lot of time could be devoted to a debate on terminology, such as differentiating between the term vaccine and novel, experimental, genetically-modified gene therapy, there is no doubt that adverse reactions to vaccines are higher than they have ever been. Surely this deserves evaluation of the interventions that have been given. This is basic; we assess, plan, implement and evaluate. The results of this evaluation feed back into the next cycle of planning and implementation. It is strange that this has not been done.

Another new phenomenon worth examination is an apparent new pathology, first identified by embalmers. We have photographic evidence and specimens of a new form of protein-based clot being extricated from arteries and veins of the recently deceased. These are real physical objects, they exist, can be felt, seen, chemically examined and viewed under a microscope. As such, their presence needs to be communicated and causative explanations sought. These 'clots' were not seen before 2020, very rarely seen in 2020, but have been commonly seen in the years since.

Excess deaths are another international issue that has been essentially ignored by governments and main stream (legacy) media. However, multiple data sources confirm this continuing international disaster. In Australia, for example, excess deaths in 2023 were over 16% above expectation. Are there potential temporal correlations with a plausible dose-dependent, consistent, specific pathophysiological mechanism which could be examined as aetiological?

In evidence-based communications we are also free to ask questions. Sometimes it is the simplest and most naïve questions which can lead to the most important answers. We feel free to challenge dogmatic narrative as long as the challenges are rooted in plausible scientific theory and mechanisms.

Another theme of EBC is the desire to pick low-hanging fruit. This fruit usually lacks randomized control trial evidence. However, it is often preferred by patients. It is generally inexpensive, available to all, not under patent, has a good risk to benefit analysis, may be natural or repurposed, can be given by non-specialised personnel and has empirical and scientific consistency.

An obvious example of low-hanging fruit is the potential to make the world's population vitamin D replete. Optimising vitamin D levels would have extraordinary benefit in a wide range of diseases as it is needed for the effective operation of probably 3,000 genes. As vitamin D takes time to activate after oral administration or sun exposure, giving the activated form calcifediol may be lifesaving in acute illness.

Ivermectin has been given to over three billion people around the world with a known very good safety profile. Considering that about 250 million humans still take ivermectin every year it seems strange to see an international regulator describe this wonder drug as 'horse paste'. Clinicians globally have seen big improvements in ill people after ivermectin administration. After the people who discovered and developed ivermectin were jointly awarded the Nobel prize in 2015, it seems unfortunate that sponsored research has proved it to be ineffective.

Another example of very low-hanging fruit is the development of immunobiotics. Immunologist Professor Clancy AM has developed an oral preparation based on simple dead bacteria which greatly increases the immunity of the mucosal surfaces around the body, such as those lining the lungs or genital tracts. Oncologist Professor Dalgleish has conducted clinical trials on an immunobiotic, again consisting of simple killed bacteria. This injection increases the function of the immune T lymphocyte system. Effective T lymphocytes not only combat all infections, they also prevent most cancers. Despite physiological and empirical trial evidence, the British Medicines and Healthcare Products Regulatory Agency refuses to authorise this potential great leap forward in medicine. While EBC cannot authorise these simple interventions, we can offer education to encourage pressure for authorisation and change.

The potential for functional mushrooms in health care is also considered a low-hanging fruit. For example, the mushroom 'lion's mane' does contain nerve grown factors. This represents a possible revolution in the therapeutically-challenged field of neurology. Of course, mushrooms are difficult to patent, so why spend the ten million dollars on a clinical trial? In the UK, the psychotherapeutic potential of psilocybin mushrooms is already being (informally) exploited by many thousands. It is intriguing to speculate what would have happened had Professor Marshall discovered the role of Helicobacter Pylori in peptic ulceration today. Would this also have been suppressed?

In conclusion EBC suggests we turn, look and see, so that we shine some scientific light into darkness. It suggests that we refuse to conform to the dictated narrative and stand tall, and that we take the dangerous path less trodden and that even if we are a lone voice crying in the wilderness, that's fine, more will soon follow when they hear the truth.

Dr John Campbell

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The COVID Policy Analysis Australia Should Have Done - and what's needed to avoid a repeat of the catastrophe

Gigi Foster

Abstract

Australia's leadership cadre in COVID times wrought unprecedented destruction upon the Australian population in their charge. Their actions were informed only by incomplete and policitised sources of information, while dissenting voices were denigrated and suppressed. The process by which this poor policy-making gripped the country for over two years is illustrative of the problems in governance and in our wider society that will continue to damage Australia unless we see and act on the need for change. In this paper, I review the present best estimates of the costs of Australia's COVID policy response to the country's health and wealth, and contextualise the analysis capable of recovering such estimates within a broader view of what types of reforms are required in order to avoid a similar tragedy the next time that a perceived health crisis arrives. Particular attention is paid to the proposal of embedding more direct democratic elements into our present polity.

Introduction

How did Australia's leadership get the country's COVID policy response so wrong? In this short paper, I explore from a broad social scientific perspective what happened in our 'lucky country' during the COVID era, both within leadership circles and at the grassroots level, and sketch what might have happened instead. I briefly review the reasons why a health-and wealth-promoting policy response to COVID did not occur, summarise our best estimates of the costs of the response that did transpire, and close with ideas for what must change for the country to have any hope of avoiding a similar tragedy in future.

What happened, and what should we have done instead?

In *The Great Covid Panic: What happened, why, and what to do next* (Frijters et al 2021), my coauthors and I detail the many dimensions of vulnerability present in Western societies prior to 2020, and the particular forces that tipped both Australia and most of the Western world into a catastrophic over-reaction starting in March 2020 to a new respiratory virus preying mainly

on the old and infirm. I summarise some of our arguments below.

Australia in early 2020 was a *de jure* representative social democracy where *de facto*, corruption was embedded in many industries (Murray and Frijters 2022), with public offices often held by career politicians and a bloated Commonwealth government with far more say in running the country's affairs than had been presaged at the time of Federation.[1] Inequality had been increasing for years, with the wealthy and well-connected pulling away from the rest of the population mainly because of the aforementioned corruption (Frijters and Foster 2015). A two-class society had emerged, though not well-advertised amongst the less advantaged, for obvious reasons, with elites at the top of government and industry preying upon grassroots Australians in order to retain their positions and get even richer and more powerful.

In the lead-up to mid-March 2020, the Australian population – like most populations of the West – moved steadily into a state of near-total petrification about the new coronavirus, fed by catastrophist computer modelling and media from around the world filled with images of healthy people falling over dead in the streets, hospitals overflowing, and societal chaos. Addicted to their digital devices, culturally primed to look to authority figures in a crisis (Foster 2021), and unused to doing their own research about complex phenomena (particularly when plenty of 'experts' were on hand to fill in the blanks), the Australian people were sitting ducks for a mass social and psychological takeover by COVID hysteria and a subsequent betrayal by the elites in charge.

By late March, the Australian political class could see the population were panicked and clamouring to be saved from COVID, and in that moment, they had a clear choice.

Alternative One was that they could opt to tamp down the fear, disseminate within and outside the government accurate knowledge about the virus (which was known even then not to be particularly dangerous to the young and healthy), and arm the population with information to help them mount a robust defence in case they were exposed. This could be done by building their immune system: getting enough sleep, exercise, and healthy food; spending time with friends and family; regularly relaxing, rejuvenating, and releasing anxiety – and also by reminding their families of the types of health behaviours that have worked against respiratory pathogens for generations, such as following good hygiene practices, absorbing plenty of vitamin D and other supplements as needed, and taking in fresh air. In short, they could have sought to re-introduce perspective to the petrified populace and make them feel empowered to fight the disease when it came, while also focussing special policy attention on those segments of society likeliest to be hard-hit by COVID – namely, the aged care centres and older, sicker people wherever in society they lived. Creative staffing plans, ventilation system audits, activity rosters, menu audits and supplement reviews could have been invested in for aged care centres; flexi-work plans and health guidelines drawn up and publicly funded for the morbidly obese or otherwise sick and still in the workforce who wished to self-isolate; and many other initiatives embarked upon for the express purpose of preparing and protecting the most vulnerable elderly and sick members of our society. COVID would arrive, but the idea could have been to create a situation in which those it reached first were those least likely to fall ill or die from it. Thereby our young and healthy would develop immunity as early as possible, the better to protect our older and sicker as the disease penetrated through society and some flavour of it became endemic, as tends to occur with respiratory viruses. At each step on the journey, our leaders could have

1 https://www.scienceandfreedom.org/articles/can-federalising-central-governments-fixfederalism/

subjected their policy options to rigorous cost-benefit analysis based on real data as they came in – not on narrowly-focussed computer simulations, or empty slogans like 'flattening the curve' – and selected only those policies that in expectation would deliver positive net benefits for the Australian people, adapting and adjusting their choices along the way as new information became available.

Alternative Two – something not even considered viable in the pandemic management plans in place before the arrival of COVID – was for Australian governments at every level to hoist themselves into the imaginary throne of 'Protectors from COVID' and to set about closing down the Australian way of life via the abuse of emergency powers and the bloated machinery of state to which they had access, all justified outwardly by the fearsomeness of the threat the population believed it faced. In a coordinated effort across government departments, with coordinated outward-facing messaging, Australian leaders displayed damning cowardice, and chose this option. They closed the national and domestic borders and plunged the Australian people into months of suspended economic animation and lockdowns of varying severity and duration across the states and territories, in which businesses, places of worship, community and sport facilities, and schools had their normal activities acutely disrupted or entirely shuttered. Eighteen months of this sort of abuse were followed by the introduction with great fanfare of novel vaccines against COVID and a country-wide campaign to coerce everyone over a certain age into accepting them, despite substantial irregularities in testing and concerning initial results from animal studies of the technology being used.[2] The vaccine saviour story continued for years after that, with fractures in professions, families, and communities between those who had bought the story being sold by the elites that the vaccines were the only way out of the torturous existence they had been ushered into by those same elites, and those who at some point along the way realised that they were being had, refused the vaccines, and thereby found themselves excluded from broad social acceptance and from many normal social and work activities.

The Costs of the Policy Mistakes

As the lockdowns raged on, and the Australian people morphed by April or May 2020 into an obsessive crowd of fanatics evidently bent on destroying its way of life in order to supposedly save itself from COVID, most of Australia's economics profession stood mutely by or cheered on the destruction of the crowd (Foster and Frijters 2024). Even now, mainstream economists still cling to the story that lockdowns were not that bad, and that they were needed to save lives (Foster and Sabhlok 2023) – in spite of the lack of evidence, either in March 2020 or to this day, linking lockdowns with better health outcomes. Yet economics is exactly the discipline charged with using its understanding of the functioning of markets and society to come up with cool-headed, data-driven policy advice that factors in the costs and benefits to everyone involved, and in all relevant dimensions, of a given government policy.

Sanjeev Sabhlok, who worked in the Victorian Treasury at the outbreak of COVID, tried to get his superiors to listen to exactly this sort of analysis of lockdowns. He failed, and subsequently quit his job when he was told by his employer to stop posting publicly on social media about his disagreement with government policy, as he documents in Sabhlok 2020.

I appeared on national radio and television repeatedly, starting in March 2020, to voice the

2 https://dailysceptic.org/2021/03/09/is-the-mhras-yellow-card-reporting-system-safeguarding-the-uk-public/?highlight=vaccine%20animal%20trial

argument that lockdowns were a poor policy choice, and I also provided the Victorian state parliament with a sense of the reasons why in the form of a skeletal cost-benefit analysis in August 2020.[3] I also wrote academic articles about the biased decision-making that had led to Australia's COVID policy response (Foster 2020a), and the alarming negative effects that could already be seen and be predicted to occur in the future as a result of school closures and economic disruption (Foster 2020b). The repeated warnings given by me and those of the precious few other loud dissident voices in Australia, who were regularly pilloried and denigrated on social and mainstream media, failed to stop the catastrophe.

By 2022, several thorough cost-benefit analyses of lockdown policies had been written around the world, including for Australia, with none of them finding that the benefits of lockdowns were remotely worth their costs. In my analysis with Sanjeev Sabhlok (Foster with Sabhlok 2022) we enumerate the many categories of costs and benefits that should be counted in a proper evaluation of lockdowns, and find that Australian lockdowns cost a minimum of 68 times the value of the benefits they could possibly have delivered, with those costs easily reaching several hundred billion dollars in a country whose annual GDP is only around $1.6 trillion. Martin Lally, using a different currency and methodology, similarly finds that lockdowns were not justifiable according to conventional policy evaluation criteria (Lally 2022).

Lockdowns destroyed mental and physical health in the short run, while the government's excess COVID-related expenditure – including the fiscal stimulus provided through programs like JobKeeper – mortgaged the growth and well-being of the future. Normal child development and human capital formation were disrupted, people lost their confidence in a bright future, and bad habits developed that are still with us today. The health effects of the lockdowns and of the ill-advised mass roll-out of experimental vaccines are still being felt, with the labour market disruptions and tens of thousands of excess deaths Australia has experienced since mid-2021 not even counted in the 68:1 ratio of costs to benefits cited above. All of these harms occurred in order to achieve benefits amounting to, at best, a couple of hundred young people saved from traffic accidents and homicides in 2020-2021, and the prolongation of life for a few years at most for perhaps 10,000 mostly elderly and sick people. The benefits pale in comparison to the enormous cost.

Australia's COVID policy response constituted the worst peace-time policy-making the country has ever seen (Foster and Frijters 2024).

How to avoid a similar tragedy in future

In *The Great Covid Panic: What happened, why, and what to do next*, my coauthors and I sketch the beginnings of our ideas for reform that might protect our societies against a repeat of the descent into madness and destruction that we saw in the COVID era. Since that book's publication, we have expanded these ideas, including in blogs for our publisher Brownstone Institute,[4] and in book chapters (for example, Foster and Frijters 2023).

Our essential conclusion as broad-minded social scientists who were studying power, loyalty, corruption and social influence long before the arrival of COVID, and who have now lived

3 See under Wednesday, August 12th at https://www.parliament.vic.gov.au/get-involved/inquiries/inquiry-into-the-victorian-governments-response-to-the-covid-19-pandemic/hearings

4 https://brownstone.org/author/gigifoster/

through this horrific and educative period, is that radical changes are needed to our institutions if we are to restore an Australia healthy and strong enough to resist another disaster the next time a supposed health emergency comes along. Power must be wrested from the elites and returned in far greater amounts and far more robustly to the people; corruption must be expressly designed against in building a new federalism; our health, education, and media sectors must be populated with alternative means of meeting the fundamental needs of people in these arenas while embracing modern technology only where it truly advances human thriving.

We have offered proposals to establish citizen juries whose job would be to appoint leaders of public-sector institutions which are presently staffed by elites appointed by politicians; to establish citizen media channels to prevent the emergence of a single, unchallengeable narrative aligned with elite interests; and to reorganise taxation, our legal system, and our system of federation. We have founded a new free think-tank concerned with generating, discussing, and then implementing new alternatives in the many areas of life where corrupt and complicit institutions now loom, and are actively holding in-person events to draw out these ideas;[5] and we are putting our own money and effort toward building radically alternative educational systems.[6]

If you love Australia and agree that our beloved society has deep problems, there is merit in considering organisations such as scienceandfreedom.org, novacad.org, AMPS and the Red Union Employee Associations for Nurses, Teachers, Police and Independent Workers. All would benefit from your lending a hand to our events, projects and initiatives.

A better life for yourself and your children will not be forthcoming from the decisions of those presently in power, nor from the moribund institutions they lead, even if a whole new cadre of leaders were magically to take over. It is we who must build a better life, while accepting the role of stewards of our freedom and our moral principles, a role that has gone unfilled for too long and opened our societies to decay. Our rebuilding effort begins with believing in ourselves and giving ourselves permission to design and set up better systems, informed by wisdom and love.

What an opportunity.

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The Disquisitive Narrative of COVID-19 (or, Where have all the leaders gone?)

Robert Clancy AM

1 Australia's long tradition with pandemics

Australia has a proud history of managing pandemics. That history includes the bubonic plague in 1900 and a series of influenza pandemics dating from the Spanish flu (1918-19) followed by pandemics marked by genetic shifts in 1957, 1968, and 2009. A central characteristic was an outcome of the strong national medical and scientific leadership, characterised by the progressive strengthening of both public health and scientific bases. This leadership, not always without moments of indecision, would shape political agendas and the mainstream press support, not always without moments of conflict. Towering figures that through their contributions guided public health development equal to that found anywhere in the world included John Ashburton Thompson who, as President of the NSW Board of Health, changed the world's approach to plague management, and John Cumpston, Foundation Director-General of the Commonwealth Department of Health from 1921, responsible for the good quality Health Service moulded following the Spanish flu pandemic. Equally important to the international position Australia commanded in the field of infection and health was the line of leading research workers whose studies followed pandemic disease: from Macfarlane Burnet who founded study of influenza biology and vaccine development while initiating research into the host response, through Frank Fenner and the extinction of smallpox, to Peter Doherty's resolution of respective roles of self and non-self in viral eradication. These continuous strands of medical and research activity resulted in the development of a finely-honed plan aimed at controlling the next respiratory virus pandemic, while limiting its effects. The most recent update was in 2019.

2 Key lessons from Australian pandemic experience

Underpinning the Australian experience learnt through pandemics were three principles upon which the Pandemic Plan would be built.

First is to understand the epidemiology of the disease, as the basic science formative to public health response. Each pandemic reinforced the value of being late into the pandemic scene, by virtue of Australia's remote and island-continent geography. Those observations reflected

the natural history of reduced vigour of pandemic pathogens over time, as a result of both attenuation and antigen drift. The critical value of understanding epidemiology of any infection was poignantly shown by Ashburton Thompson, when he identified zoonosis (or clinical infection in rats) as the precursor to flea-borne transmission of microbes to man. By screening the residential rat population of Sydney Harbour involving 50,000 rats per year, a positive blood culture heralded human disease. By his 'test and eradicate' strategy in rats he changed public health from quarantine of patients (and contacts) to 'quarantine' of zoonotic rats, reducing deaths in humans by 90% and the economic cost to the city, by 80%.

Eighty years of vaccine development for influenza in parallel over a similar period, with study of the immunology system of local immunity, gave clear understanding of what injected vaccines can and cannot do in the context of a pandemic due to inhaled virus. Systemic vaccination for pandemics due to inhaled virus would always be important, but never centre stage, because of dominant systemic and mucosal immune suppression generated following any inhaled antigen, to protect against excessive inflammatory response that would otherwise occur as a result of mucosal surfaces being bathed in microbes (now called the 'microbiome').

Prediction for outcomes of injected vaccines from the influenza model is protection against 'escape' of the pathogen into the gas-exchange apparatus of the lungs; thus there is little to no protection from injected vaccines from primary infection, or pathogen transmission, but a switch from more severe disease to less severe disease (then asymptomatic infection).

A second lesson was the observation that repeated vaccination drives a dominant downregulation with immune suppression both locally and systemically, mediated by T reg (suppressor) cells, a mechanism used by allergists offering repeated antigen injection to benefit from the downregulation by minimising allergic hypersensitivity symptoms.

Third, and central to pandemic management, was the doctor-patient relationship, guided by the medical and scientific prowess available within Australian institutions. This was the environment for individual decisions in patient management. As it is with all medical challenges, every patient is different, and the use of safe available off-label drugs would be tried, until and unless science produced evidence-based products clearly superior to re-utilised medications. In this spirit bacterial vaccines were used with claimed benefit in Australia in both the bubonic plague and Spanish flu pandemics, while others used quinine to treat influenza in 1918 with benefit claimed by Dr Burrows (of Burrows Welcome fame).

These three legs formed the basis of the Australian (and WHO) Pandemic Plans, updated to 2019.

3 Fast forward to 2020: COVID-19 appears

By March:

(i) The SARS-CoV-19 virus is sequenced, making possible cloned antigen or genetic vaccine production. By mid-2021 both antigen and genetic vaccines are available.

(ii) The epidemiology is defined by Stanford University: highly infectious and moderately severe with a clearly defined high-risk group (3% infected; 40% asymptomatic; >70

years and or collateral disease are high risk). By October in place was the Great Barrington Declaration model formulated by world leading epidemiologists based on epidemiology.

(iii) Extensive screening identifies two available drugs with anti-viral activity (hydroxychloroquine and ivermectin), followed by numerous supporting studies.

By year's end, the three legs of the existing Pandemic Plan had been satisfied.

4 An extraordinary thing happened: the narrative replaced the science

One hundred years of pandemic experience was negated, and 80 years of influenza vaccine experience neglected (COVID-19: A realistic approach to community management. *Quadrant*: 17/1/2021).

A narrative based on an untested mRNA vaccine, and the importance of protecting it by ensuring no competitive therapy existed, dominated the COVID scene. Decisions were made by a pharma-political complex outside of Australia, while the web of public figures and institutions responsible for guidance and management of medical practice in Australia were as rabbits in headlights, while health professionals followed believing the narrative mantra. There was mass cognitive dissonance.

How did the 'three legs' play out in 2020–2024?

5 The epidemiology

The narrative called for lockdown isolation; the 'plan' social distancing, protection of the vulnerable, isolation if infected to protect those at risk while slowing spread, allowing natural immunity to grow. Schooling and work otherwise continued much as before. This 'advisory' approach was incorporated into the Great Barrington Declaration, and was the basis of management in Sweden.

The pattern of clinical infection in Australia contrasted with Sweden: few cases and few deaths in the lockdown period to late 2021, by which time most were vaccinated. Following release from lockdowns, the case numbers and deaths ballooned despite the less virulent strain Omicron dominating, with most double-vaccinated about to have their first booster vaccine. Differences between narrative and science are reflected in three-fold more infections in Australia per capita than Sweden (over three years), but less than half the mortality. Most deaths in Sweden occurred during the alpha variant (the most aggressive variant) phase; at the end of the lockdown period in Australia (October 2022) 6% of COVID deaths had occurred, compared to 60% in Sweden over the same time. 90% of the Swedish deaths were over 70 years old, with 80% in care situations. All-cause mortality is considered the best monitor of pandemic effect: that for Sweden was lower over the pandemic period than for nearly all (46) other European countries and Australia. Schools and businesses in Sweden largely stayed open, with education effects minimal, and the economic hit less than in Australia. For example, economic contraction in Australia was 7.0% of GDP compared to 2.2% in Sweden; there was an economic stimulus package of 4% of GDP in Sweden compared with 7.0% in Australia.

It can be concluded that the 'advisory' approach used in Sweden was successful to the extent it was efficiently prosecuted. Sweden failed its vulnerable population, reflected in the high mortality during the early pandemic. The respective total number of infections was significantly less in Sweden per 100,000 than Australia, supporting the value of cohort natural immunity. The lockdowns in Australia with geographic isolation shifted the pandemic impact to 2022, when the more benign isolate Omicron dominated; this had no effect on total number of infections over the period of the pandemic (which in fact were substantially higher), but there was less mortality. The social and economic parameters of the 'advisory' system favoured Sweden over Australia. The success of Sweden in containing the pandemic was tempered by its failure to protect its vulnerable and elderly. Yet at no time was there an excess mortality over past norms.

6 The vaccine

One unacceptable outcome is the mantra that characterised the first two-plus years of the pandemic in Australia:

"So you have COVID. Sorry, but there's no treatment. Isolate at home. If breathless, go to hospital and be given oxygen." But – "Hang around, because we've got a vaccine that will eradicate COVID."

7 Rules of immunology define vaccine value

COVID Immunology 101:

(i) Immune protection is compartment dependent. The systemic compartment is protected by IgG antibody and T cells, always aiming at sterility. The mucosal compartment includes the airway and the gut, both of which are naturally associated with microbes (the microbiota); protection is more about control, invoking a dominant suppression system. Antigen (virus, allergen etc) inhaled, is aspirated into the gut, taken up into Peyer's patches from where T and B cells migrate via the blood stream to the airway. There they control pathogens within the microbiome. To minimise any associated inflammation which would cause innocent-bystander damage to tissues, T reg cells downregulate immunity, in both the mucosa and the systemic immune system.

(ii) In COVID-19 infection, virus is inhaled and the mucosal immune system determines primary infection and viral transmission. If it fails to contain the virus to within the mucosal compartment, on one hand a stressed and inappropriate mucosal immune response manifests as production of purulent sputum, and on the other, as the virus enters the alveolar or gas-exchange system of the lung, the systemic immune system is engaged. The outcome depends on the antigen-antibody balance: if antibody dominates, virus is neutralised; if virus (antigen) dominates, a vigorous inflammatory response follows with pneumonia, even a cytokine storm and dissemination of virus, with microthrombi and small vessel damage.

(iii) Injected vaccines follow the influenza model: short term (up to six months) protection, with a shift in clinical outcome towards less severe disease. Closely spaced vaccination produces progressive downregulation, with negative immunity a risk characterised by more frequent and more severe infections.

(iv) Genetic vaccines for COVID: these offer no advantage in protection over classic antigen vaccines (tested by comparing outcomes in Hong Kong). An important outcome of mRNA vaccines is that they spread potentially to every cell in the body, causing an unknown and highly variable amount of spike protein (the antigen) to be produced. This creates variable response, greater immune suppression, and a shorter period of protection with repeated dosing followed by negative immunity. UK data show those with one booster, at 40 days, develop negative immunity; repeated vaccination in this circumstance can be understood as a requirement to prevent impaired COVID immunity. The dissemination of protracted spike protein (at least months) creates foreign protein on cell surfaces (or circulating as antigen), enabling T-cell-induced pathology, or circulating pathogenic immune complexes to form. mRNA from vaccines dominates cellular machinery, with mis-read constructs from frame-shifting, and reversion into host DNA. The consequence of reversal into DNA is unknown, though turbo-cancers and intergenerational expression are discussed. The high incidence of 'mixed' chronic fatigue illness with structural damage constituting post-vaccination syndromes reflects this pathophysiology and dynamics of mRNA dissemination.

In summary, no reason for genetic vaccines has ever been given; mRNA vaccines are particularly liable to immune suppression and multiple adverse events; excess deaths of 10-15% across the vaccinated world correlating closely with mRNA vaccine use remain otherwise unexplained; and no advantage over classic antigen vaccines has been given. Taking 4-5 vaccinations in a couple of years then getting more frequent COVID is a common outcome.

8 The curious tale of repurposed drugs as a metaphor for distortion of efficient clinical practice

Off-label drug use is a longstanding component of patient management reflecting on one hand the central role of the physician in decision-making for patient care, and on the other, the reality that all patient management is individualised within a doctor-patient relationship given that every subject is different and 'one size fits all' doesn't work in clinical practice. The political capture of this relationship by the narrative-driven agenda with cancelling of existing safe and effective medications was, simply, inexcusable. The decision to ban hydroxychloroquine (HCQ) and ivermectin for use in early treatment and prevention of COVID-19 cost many lives, drove divisions within the health care fraternity that may never be repaired, and led to health professionals losing their jobs.

The sequence in this 'curious tale' can be followed with HCQ.

Immediately the pandemic appeared, Chinese scientists screened existing drugs for anti-COVID activity. They (and others) identified chloroquine as highly effective. This drug and its safer analogue, HCQ, were known to be trapped within intracellular endosomal compartments. Here, upon ionization as a weak base, increased pH negated the hydrolytic effect of proteases essential for autophagy, which, in turn, was essential for viral takeover of the cell's synthetic machinery.

Numerous small studies including those by Raoult in France and Zelenko in the US quickly confirmed clinical benefit attracting immediate backlash which included misinformation with unprecedented personal attack. The international press under its newly minted 'Trusted News

Initiative' format became the attack dogs for the narrative. *The New York Times* chimed in with comments such as 'Falsehoods collide with fragile information' to ensure a level of cognitive dissonance amongst professionals and public alike. The major Australian news outlets appeared incapable of responsible reporting, with articles and comments both ridiculous in content while targeting individuals with disinformation claims. Our professional colleagues wasted no time in conducting large studies designed to fail, by treating seriously sick hospital patients with mortalities over 20%. Every member of the public knows that treating any viral illness with anti-viral therapy must begin within two to three days (note cold sores and shingles). Three historic studies of thousands of sick hospitalised patients confirmed that HCQ was not only useless in treating COVID, but possibly dangerous. These studies (the Surgisphere, Solidarity and Recovery Trials) were published in the most respected of journals: *The Lancet* and *The New England Medical Journal*. *The Lancet* was forced to withdraw the Surgisphere study because it was corrupted. The political response in Australia was swift: in Queensland doctors could be jailed for prescribing HCQ to treat COVID.

Fast forward to 2023, when six observations gave sanity and support to the disinformation cycle that had been so destructive to medical practice and of such damage to those with COVID. In brief, screening studies identified HCQ as a highly effective block to the chaperone function of Sig-1R essential for SARS-CoV-2 movement into the cell and in navigating the endosomal network. In turn, this connects to the endosomal pH effect noted above, clearly linking antiviral mechanisms mediated by HCQ. Professor Harvey Risch (Yale University) emphasised the importance of early treatment of subjects bearing high risk factors. He used nine controlled trials of patients with these characteristics in a meta-analysis to demonstrate a highly significant reduction in mortality in those treated with HCQ. Two important studies identified outcomes with author bias: 86% of those without conflict gave positive outcomes, compared to only 5% of those with conflict. A review of the Marseille experience treating 30,000 with COVID-19 infection showed a 70% reduced mortality in those where treatment included HCQ. These four factors added to an additional two that became clear by late 2022: synthesised antiviral drugs at $A1000 per course and rushed through regulatory hurdles were at best disappointing (Molnupiravir was no more effective than placebo in the UK Panorama study of 25,000 in reducing hospitalisation or death while creating transmissible mutants; Paxlovid was marginally better but active only in a limited age range, had high rebound disease, and was incompatible with numerous drugs including statins). Recognition of the realities of limited vaccine efficacy and its high incidence of adverse effects was blunting enthusiasm that the genetic vaccines would save the world from COVID (and the Astra Zeneca DNA-vector vaccine was being quietly removed from the market). Somewhat cynically, the repurposed drugs HCQ and IVM had risen above the very reason for their government embargo, with the pharmaceutical *res publica* failing (medically if not commercially) to imprint their mark on COVID with their synthetic antiviral drugs developed to cover vaccine failure.

Now for three comments on IVM, a truly remarkable drug.

First a combination of clinical and sophisticated scientific studies provided clarity of drug effect, putting to rest any (if indeed it existed) residual doubt as to its benefit in COVID-19 infection. Three studies showed normalisation of oxygen desaturation within 24 hours of starting IVM therapy, followed by demonstration that spike protein bound to glycans to facilitate entry into cells, and then to agglutinate erythrocytes within the capillaries of the gas apparatus.

Second, regional studies in India and South America complemented clinical trials to add strong support to the efficacy of IVM: impressive was the correlation of all-cause deaths in Peru with legislated use of IVM – a 14-fold decrease following introduction of IVM use, followed by a 13-fold increase immediately the drug was withdrawn.

Third, the emerging evidence of substantial improvement of clinical features of both post-infection and post-vaccine Long COVID, following treatment with IVM (identifying long-term spike protein expression in both circumstances).

9 Are there new ideas for the future?

(i) Much learnt from the recent COVID pandemic should have been already known. Nearly all the conclusions made here were predictable. Perhaps the most important conclusions are to avoid precipitous novel developments with inherent and predictable dangers, until safety, efficacy and the science are clear, particularly when there is no clear purpose for their replacement of existing technology. To otherwise impose on the world drugs or vaccines for unclear reasons short of even the shallowest of investigation is contrary to all held sacred in medical practice. The experiment involved 72% of the world population with a total of more than 5.55 billion subjects injected, most with mRNA vaccines, with an average number of vaccinations of 170 per each 100 subjects). With the vaccinated world experiencing otherwise unexplained increases of between 10-15% in all-cause mortality, and exposed to the systemic spread of spike protein mRNA persisting for unknown periods, with DNA and SV40 (oncogenic DNA sequences) contaminating batches of vaccine with unacceptable quality control, and no concept of the downside of reverse transcription into DNA in the injected population and their progeny, it beggars belief that genetic vaccines continue to be available. Recent recognition in Hong Kong that mRNA vaccines offer no advantage over antigen vaccines should make pausing genetic vaccine production pending review a very easy decision. There is concerning deception involved in huge amounts of money passing from industry and government to support mRNA commercial development, without resolving question safety resulting from the COVID-19 vaccination rollout. Three months after a Nobel prize was awarded in 2023 for unique modification of mRNA to increase efficacy, Cambridge scientists confirmed that the nucleotide base substitution was the cause of frame shifting and production of potentially pathogenic proteins. The use in individualising tumour therapy has more supporting argument than can be offered for any vaccine, but even here much more needs to be understood regarding safety and pharmacodynamics, given the recent data showing transmission of mRNA vaccines via the placenta and breast milk.

(ii) The Australian paradigm of health care, finely honed to be as good as any, was shattered by the pharmaco-political power plays of the COVID era. Whether the medical profession can recover from the cognitive dissonance imposed by the broadside narrative with its replacement to a degree in patient care decisions, to regain its long held cherished position of influence, is further challenged by the current move by the WHO to control world health. The government handling of repurposed drugs through the COVID pandemic was discussed as a metaphor for medical control. The failure to immediately define the epidemiology of COVID in Australia led to the inappropriate restrictions with their health and economic costs. There is a need for the best epidemiologists to be

organised and prepared to immediately set up and monitor infection parameters when the next pandemic arrives, along the lines used by the Stanford group.

(iii) Pandemics in Australia have been closely linked to progressive science related to infection control. Australia must seek to have in place focussed and relevant research to maintain its scientific credibility. This means restructuring the way ideas are managed and funded – the current situation where academic institutions and government funding are chasing genetic vaccine production is how not to do it. The starting point is to identify non-conflicted high-quality scientists charged with broadly examining ideas and obtaining opinion outside the narrow band of conflicted academia who to date have followed rather than led, and shown to be overly influenced by the pharmaceutical industry.

Here is one idea, clearly close to my interests, a novel yet tested idea of enhancing airway immune resilience, whereby there is a shift in the host-pathogen relationship within healthy subjects, with the outcome of infection more benign – even asymptomatic – as a consequence. Airway immunity is driven by delivery of T cells from Peyer's patches in the gut wall, stimulated by swallowed respiratory microbiome (about 100 ml of secretions from the airway are swallowed each day). This is a random and imperfect process in about 25% of normal subjects. Oral administration of inactivated components of the airway microbiome reverses defective T-cell delivery by optimising uptake of antigen into the Peyer's patches. Enhanced immune resilience protects against airway inflammation following inhalation of microbial pathogens: (https://doi.org/10.3390/vaccines11071251)

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The T-EBM Wheel: Transforming Evidence Synthesis for Better Healthcare

Colleen Aldous, Barry Dancis, Jerry Dancis, Phil Oldfield

We propose a new way of thinking about medical research called Wheel Thinking, which challenges traditional methods that often only consider the 'gold standard' of clinical trials (Aldous et al. 2024). Wheel Thinking suggests that we should look at all kinds of research, not just the most strictly controlled experiments, to make healthcare decisions. This approach is especially important during emergencies like the COVID-19 pandemic, where waiting for perfect data could cost lives. We introduce the 'T-EBM Wheel,' a tool that helps visualize and consider different types of medical evidence when deciding on treatments. This new approach aims to make healthcare more responsive and effective by acknowledging the value of a wider range of scientific studies. The paper discusses the benefits of this inclusive approach and considers how it could change for the better medical practice, research and education.

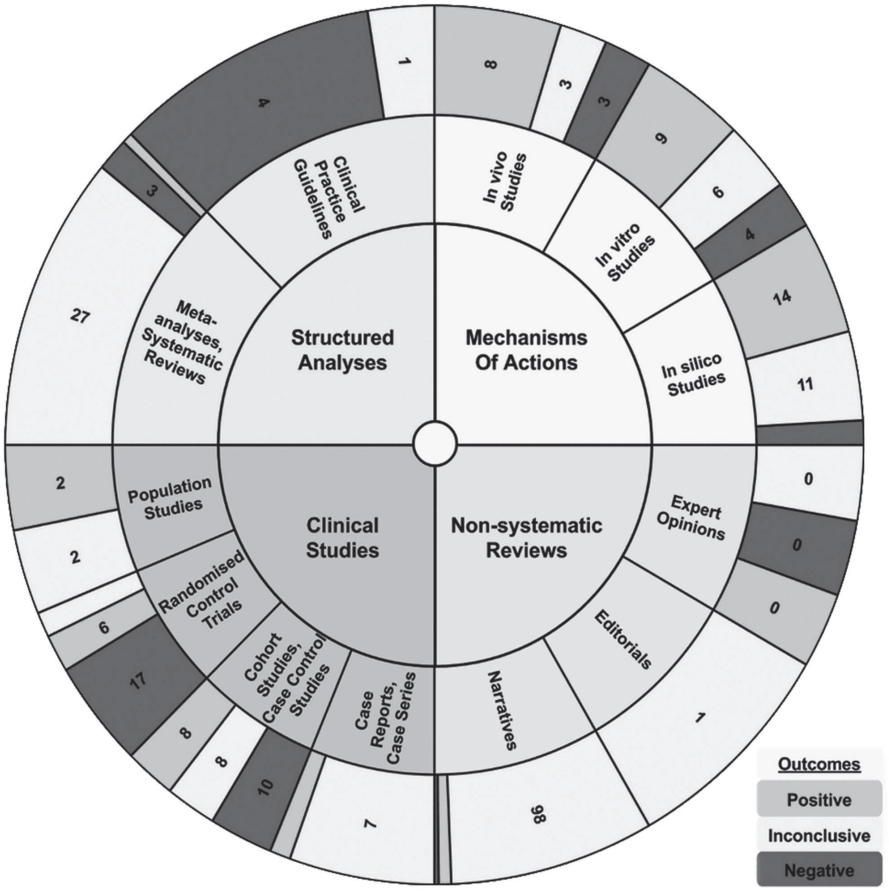
1 Introduction

Evidence-based medicine (EBM) is a foundational principle in healthcare that emphasises the use of the best available research findings from well-designed and conducted research as the basis for making clinical decisions. EBM integrates clinical expertise with the most current and relevant research evidence and patient values to guide the care of patients. From its inception, EBM has encouraged the common practice of what we call Gold Standard Thinking, namely the dichotomy between studies to be lauded (Randomized Controlled Trials and their meta-studies) and those to be played down or ignored (everything else).

In 2021, Deaton (the winner of the 2015 Nobel Prize in Economics) and Cartwright analysed RCTs and determined they had serious limitations including failure to balance confounders, and found little practical value of unbiasedness compared to precision. They highlighted their conclusion that 'RCT results can serve science but are weak ground for inferring "what works" [clinically] (Deaton A, and Cartwright N., 2018).' Against narrow Gold Standard Thinking, the US Congress mandated the consideration of real-world evidence (RWE), namely non-gold-standard evidence, especially for repurposing drugs. In general, RWE generates results much faster and less expensively than Gold Standard studies. The COVID-19 pandemic accentuated the limitations of Gold Standard Thinking, as the urgent need for effective treatments and preventive measures outpaced the availability of high-quality RCTs, stressing

the necessity for a comprehensive approach that could rapidly incorporate emerging evidence of all types, that is, the totality of the evidence.

In response to these challenges, we propose Wheel Thinking as a new EBM framework for making medical decisions that is visually modelled by the T-EBM Wheel (Figure 1). Wheel Thinking is the holistic consideration of the totality of evidence and the degree of medical equipoise for each study type. It overcomes the limitations of Gold Standard Thinking by also including RWE (observational studies, mechanistic studies, and expert opinions) and also by recognising that each type of evidence can contribute its own type of valuable insights. This is especially useful in a rapidly evolving situation like the COVID-19 pandemic. Thus, Wheel Thinking encourages the integration of the totality of evidence from the totality of study types in an unbiased, and comprehensive way.



Extracted from DOI: https://doi.org/10.5334/aogh.4341

Figure 1 As an example, here is the T-EBM Wheel for the efficacy of ivermectin-based treatments of COVID-19. The inner ring of the wheel catalogues reports into four types: 1) mechanisms of action and 2) clinical studies, both of which are sources of primary evidence, and 3) structured analyses of primary data and 4) reviews, both of which are the secondary reports based on the primary evidence. Each inner ring section is disaggregated into several middle ring sections with the same grey scale. In turn, each middle ring section is disaggregated into three outer ring sections by the outcomes of its reports, namely: 'positive', 'inconclusive', and 'negative'. The legend in the lower right-hand corner of the figure shows the grey scale associated with each of the outcomes. For each middle ring section, the size of its three outcome sections in the outer ring is proportional to its number of reports in the literature and the order of those three outcome sections is clockwise from largest to smallest and not by outcome. Data are from peer-reviewed published reports listed in PubMed® and searched for by 'ivermectin' and for either 'covid' or 'sars'. The number displayed in each outer ring section is the number of its reports. Numbers are omitted when the section is too narrow for display.

2 Gold Standard Thinking and the Quality of Evidence Pyramid

The traditional framework of EBM initially and hierarchically ranked the quality of medical evidence by the methodological rigour and susceptibility to bias (certainty of evidence) of their study types. The ranking has been visualised for the last two decades as the Quality of Evidence (QoE) Pyramid (Fig 2B). For EBM, however, the quality of each individual study must then be adjusted based on the quality of its evidence (Guyatt, et al., 2008). Thus, the final grade for the quality of a study is not determined by its level in a pyramid which is based solely on its study type. In addition, the QoE Pyramid excludes evidence from population, *in vitro* and *in silico* studies, amongst others. And lastly, the QoE Pyramid reinforces the common practice of Gold Standard Thinking by having Gold Standard studies at the top. Gold Standard Thinking is strongly repudiated by the fact that the collective results of observational studies are actually similar to those of RCTs (Anglemyer A, et al., 2014; Doidge N., 2020). In the case of COVID-19, this was true, even from different sources across the globe. Gold Standard Thinking, however, has been evident during the pandemic when health regulators referred to studies other than RCTs or their systematic reviews, as being *a priori* insufficient in evidence or merely anecdotal. They did accept selective RCT evidence regardless of poor study design and unreliable findings.

3 The Need for a New Framework

The COVID-19 pandemic exposed challenges to the global healthcare system. The rapid spread of the virus, the urgent need for effective treatments, and the evolving nature of scientific knowledge about the disease demanded quick decision-making when there was limited high-certainty evidence available.

An enormous amount of research came out during the pandemic, quickly inundating the medical community. This surge, coupled with the limits of Gold Standard Thinking, posed challenges to assimilate new findings quickly and effectively into clinical practice. RWE, including preprints, crucial for their speed to publication, were dismissed by health regulators as 'insufficient evidence'.

Clinicians and policymakers should instead have used the totality of evidence, including the population studies, case studies and mechanistic studies of RWE to generate well-informed decisions. However, Gold Standard Thinking ignored most of the diverse and rapidly expanding body of pandemic-related research. There was a critical need for a comprehensive and more adaptable approach to evaluating evidence for treating COVID-19, an approach that was capable of efficiently navigating the complexities and urgencies of a pandemic and for directing clinical practice, the next round of research and regulatory recommendations.

4 Introduction to the T-EBM Wheel

Wheel Thinking, visualized in the T-EBM Wheel, is designed to overcome the limitations of Pyramid Thinking (Figure 2A) and the even more restrictive Gold Standard Thinking by providing a comprehensive and holistic approach to evaluating medical evidence.

Description of the T-EBM Wheel

The T-EBM Qualitative Wheel visualizes the multifaceted nature of medical research (Figure 2B). The inner ring displays all the major categories of study types within the totality of evidence. In the next ring, each major category is partitioned into its specific study types. This design reflects a core principle of Wheel Thinking: no single type of study is inherently superior to another; instead, each study type contributes in its own unique way.

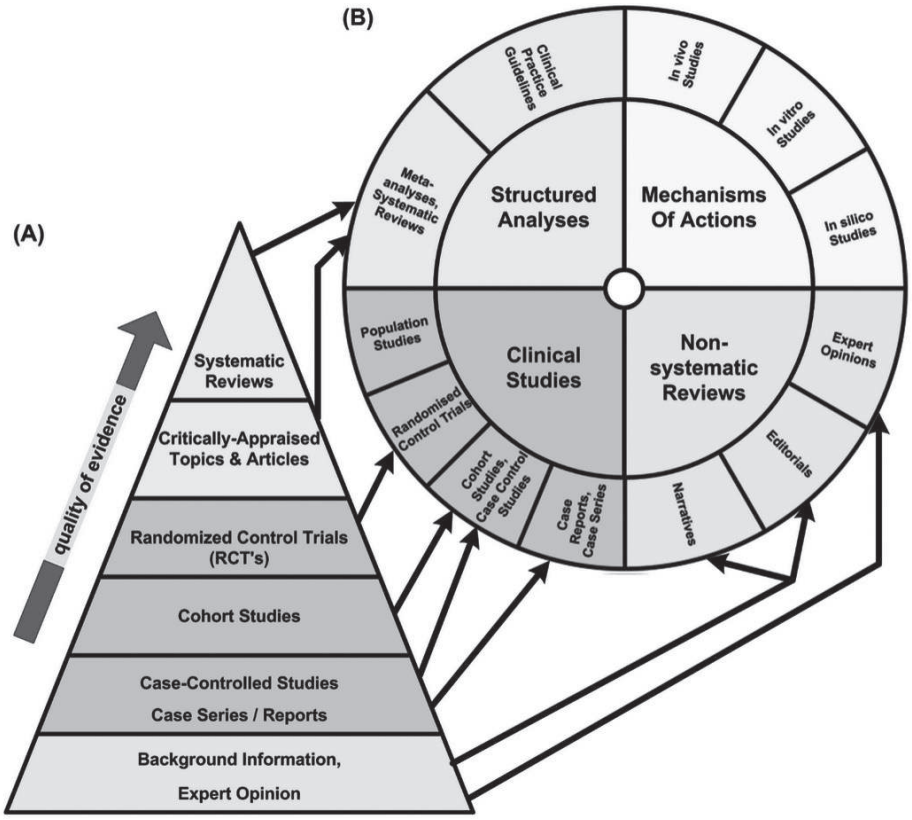


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Figure 2 Correspondence of traditional QoE Pyramid with T-EBM Qualitative Wheel. (A) QoE Pyramid. The pyramid represents a hierarchy of ever-increasing purported quality. The grey scale of each level of the pyramid was chosen to match its corresponding section of the wheel. (B) T-EBM Qualitative Wheel. Rings show various types of reports. Arrows link each level of the pyramid with its corresponding section in the outer ring of the T-EBM Qualitative Wheel.

The entire T-EBM Wheel (Figure 2) is simply the T-EBM Qualitative Wheel surrounded by an additional outer ring that displays grey scale coded sections with the number of positive, inconclusive, and negative outcomes for each study type.

Benefits of the T-EBM Wheel

The T-EBM Wheel presents all study types in an unranked display in opposition to the false quality hierarchy restricted to a limited subset of study types in the QoE Pyramid. Additionally, the T-EBM Wheel includes evidence from population, *in vitro* and *in silico* studies, amongst others that are excluded from the QoE Pyramid. This can be seen in Figure 2 where the T-EBM Qualitative Wheel contains a proper superset of the data and information found in the QoE Pyramid without that pyramid's false quality hierarchy. Ignoring everything other than RCTs and their meta-studies makes Gold Standard Thinking even more restrictive than Pyramid

Thinking. Wheel Thinking, with its totality of evidence viewpoint, includes much valuable evidence and many important signals of clinical benefit previously overlooked or neglected thereby delaying and or preventing effective treatments, especially when using repurposed drugs.

The novel outer ring allows medical decision-makers to estimate medical equipoise (the proportion of relative successes and failures of a treatment) at a single glance across the totality of study types. This forces the user to form an instant initial sense of the degree of equipoise from the totality of evidence. Such an impression would thereby encourage the creation and integration of insights from the results of observational studies, qualitative research, case reports, and even expert opinions alongside those from more traditional forms of accepted evidence. As an example, mechanistic studies should help explain and predict the results of clinical trials. The more sections containing positive results, the more that further research should be encouraged and be guided by integrating the results from multiple sections.

Thus, Wheel Thinking is a new paradigm for medical education, research, regulation and practice. It promotes a comprehensive understanding and integration of evidence, facilitating quicker and better decision-making, thereby potentially fast-tracking the adoption of effective treatments and phasing out those found ineffective or harmful. The visual impact of the wheel itself deters cherry-picking decisions based on a few anomalous RCTs, as those RCTS would disappear under the weight of the totality of evidence summarised in the outer ring. By adopting the framework of Wheel Thinking, the medical community can have a holistic and dynamic approach to the practice of EBM.

5 Case Study - Ivermectin and COVID-19

During the COVID-19 pandemic, ivermectin became controversial as a potential treatment against SARS-CoV-2. Interest in using ivermectin was sparked by early *in vitro* studies suggesting antiviral capabilities, leading to its early adoption in some regions based on a mix of preliminary findings from preprints, observational studies, and small-scale RCTs – evidence types in the QoE Pyramid that are traditionally ignored. In some places, the urgency for treatment solutions amidst the pandemic drove the use of ivermectin despite the lack of conclusive high-quality RCT evidence. This resulted in a heated debate among healthcare professionals and public health officials over its efficacy, reflecting the broader challenges of evidence evaluation in emergencies. Critics highlighted the mixed quality and methodological limitations of the supporting studies, arguing against its widespread use without robust large-scale RCT evidence. Conversely, some practitioners were spurred on by their own and others' successes in treating and preventing COVID-19 infection. They and other proponents cited the pressing need for immediate treatment options and the then cumulative weight of available positive evidence as justification for its use.

Influence of Gold Standard Thinking and the QoE Pyramid

Given the absence of large, conclusive RCTs supporting ivermectin's efficacy in treating COVID-19, the WHO, the FDA, and the CDC along with most other leading health authorities not only did not endorse ivermectin's use for COVID-19 treatment outside of clinical trials, they recommended against its use. Their stance was based on Gold Standard Thinking, where the available evidence for ivermectin, primarily from small RCTs and non-RCT sources like

observational studies, was deemed insufficient, but evidence against ivermectin from a few large RCTs was deemed convincing regardless of their poor study design and unreliable findings. The ivermectin trial on the TOGETHER platform (Reis, et al., 2022) was a high-profile RCT concluding that ivermectin was not effective for treating patients with COVID-19. However, that trial was poorly designed and executed (COVID-19 Early Treatment, n.d.). And yet, this RCT was extensively referenced by the media and government policy recommendations as proof that ivermectin was ineffective against COVID-19. In contrast, a clinical observational trial at a long-term care facility in France (Bernigaud, et al., 2021) had definitively shown that ivermectin used to treat patients was safe and effective; the integrity of the data can be easily verified and was never questioned. The above illustrates how Gold Standard Thinking may lead to incorrect conclusions.

6 Effect on Medical Decision-Makers

The adoption of Wheel Thinking would have far-reaching implications for the medical decision-makers including practitioners, researchers and policymakers. The shift from Gold Standard Thinking to the expansive and holistic approach to evidence evaluation of Wheel Thinking not only changes the way evidence is understood and applied but also fosters a culture of critical thinking and adaptability within the medical community. This new paradigm encourages decisions based on consideration of the totality of evidence sources, thereby promoting the integration of information from a variety of studies and a practical approach to healthcare delivery and policy formulation.

Since the ever-evolving landscape of medical evidence is reflected in the continually changing outcome counts and proportions in the outer ring, that reflection underscores the usefulness of the T-EBM Wheel. The wheel can also display possible medical equipoise and when it does, there should be different responses depending upon the type of responder. Medical practitioners should be guided by the positive signals for treatment and by the negative signals for what to avoid. Clinical researchers should perform further studies to improve efficacy and or help select among regimens. Governmental and medical authorities should initially present the collection of different findings while remaining neutral concerning any pronouncements on treatments, and then modify their neutrality accordingly when new reports decrease the degree of medical equipoise. The bases for those pronouncements should be the totality of evidence – clinical studies (both observational studies and RCTs), structured analyses, mechanistic studies, and non-systematic reviews.

Thus, medical decision-makers using Wheel Thinking will make better decisions.

7 Implications for Medical Education

The implementation of Wheel Thinking would transform evidence evaluation in medical education by training students to critically analyse and synthesise evidence from the totality of study types. This would require curricula to give serious weight to observational and mechanistic studies and to have a better understanding of the unique strengths and weaknesses inherent in individual study types. The new curricula would provide a more holistic education, preparing future healthcare providers to better meet the demands of real-world medical decision-making. Such changes could begin with retiring the QoE Pyramid and replacing it with the T-EBM

Wheel. By integrating this comprehensive approach to evidence evaluation, medical education can produce practitioners ready to apply evidence from the totality of study types. Comparable changes would need to occur in the curricula of continuing education courses which would update practitioners on how to apply the evidence from the totality of study types.

8 Challenges to Implementation

Implementing Wheel Thinking will encounter several challenges. These include resistance from the champions and adherents of Gold Standard Thinking in the medical community, the development of new curricula and textbooks for medical education relating to evidence evaluation and summary presentation, the need to now evaluate the quality and relevance of the totality of evidence, including RWE, the development of new guidelines for medical practitioners on how to productively spend their limited time keeping up with the literature and maybe first and foremost, replacing the QoE Pyramid with the T-EBM Wheel. Addressing these challenges requires strategic approaches to facilitate acceptance and holds the promise of fostering a comprehensive and more adaptive approach to EBM, ultimately enhancing healthcare outcomes and the quality of care.

9 Future Perspectives

Looking to the future, several key developments, modifications, and areas of research are likely to shape the trajectory of EBM and the role of Wheel Thinking within it.

Future Research

The integration of Wheel Thinking into clinical practice and policymaking will mark an important area of focus for future research initiatives. Establishing criteria and developing standardised tools to measure the quality of reports for each study type in the totality of study types is fundamental to preserve the integrity of the totality of evidence incorporated within each T-EBM Wheel. Including in a T-EBM wheel only reports that adhere to high standards will facilitate reliable and effective clinical and policy-making decisions.

Future Modifications to the Visualization of Wheel Thinking

There are potential enhancements to the T-EBM Wheel that will increase its utility and effectiveness in clinical practice and policymaking. A single T-EBM Wheel could have multiple outer rings to display: 1) different aspects of a given drug (for example, prevention, treatment, and safety) or 2) individual results of several drugs or supplements (such as ivermectin, hydroxychloroquine and vitamin D), 3) different protocols (such as different adjuncts), or 4) disaggregation of results by demographic characteristics (for example, comorbidities and ages). Such a wheel would facilitate taking in even greater amounts of information at a single glance to quickly locate areas for designing better protocols and further study. Thus, there might be several wheels for a given drug or disease.

The application of artificial intelligence (AI) to create and update T-EBM Wheels is a forward-thinking approach to managing the enormous volume of medical data. AI could

dramatically streamline the process of identifying relevant reports and individually rating their outcomes for summary in the outer rings.

Advanced visualisation and decision support tools could automate the construction of wheels on web pages in real time where, for instance, users could click on a wheel section to get the list of all its papers, including links, to get summaries of protocols for a wheel section, and to find disaggregated summaries of patient demographics and responses to treatment. Such real-time wheels will assist clinicians and policymakers to navigate the complexities of the evidence landscape. Providing intuitive, user-friendly interfaces that aid in the collation and interpretation of data will promote the integration of the evidence, ultimately facilitating more effective healthcare decisions.

Emerging and Evolving Healthcare Challenges

The COVID-19 pandemic has highlighted the critical need for frameworks of evidence synthesis and decision-making that can swiftly adapt to the dynamics of global health crises. Wheel Thinking stands as a framework for addressing newly-emerging and ever-evolving healthcare challenges. It facilitates public health officials to rapidly integrate new evidence, potentially in real time, and to help guide them to effective responses. This framework's capacity to accommodate the totality of evidence types makes it particularly adept at responding to the urgent demands of pandemics, promoting timely and effective interventions.

10 Conclusion

We propose Wheel Thinking as a new paradigm and holistic EBM framework for integrating and synthesizing medical evidence from the totality of study types in order to make better informed medical decisions. It advocates a comprehensive and dynamic approach to evidence evaluation in healthcare. The framework is visualised in the T-EBM Wheel where each type of study, from RCTs and systematic reviews to observational studies, case reports, mechanistic studies, and expert opinions, contributes its own unique and valuable type of evidence.

In contrast, classical Pyramid Thinking and Gold Standard Thinking are very narrow decision-making processes that sometimes deprive patients of the more effective treatments that could have been based on the evidence from the totality of study types. Unlike the QoE Pyramid, each T-EBM Wheel also visualizes the degree of equipoise in its novel outer ring that can be immediately understood at a glance. Such an impression encourages the creation and integration of insights from RWE alongside those from RCTs making the wheel particularly adept at responding to the urgent demands of pandemics and promoting timely and effective interventions.

We propose that Wheel Thinking with its T-EBM Wheel replace Pyramid Thinking with its QoE Pyramid as well as the even more restrictive Gold Standard Thinking in medical education and decision-making. The comprehensive approach of Wheel Thinking and its T-EBM Wheel promotes a broader understanding and integration of the totality of medical evidence, creating agile clinical decision-making leading to improved patient care.

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‘Trusting the Science’ in an Era of Marketing-Based Medicine

Peter Parry

In recent decades, pharmaceutical vested interests extended their influence over medicine[1] at all levels: journals, research, academic institutions, guidelines committees, and clinical practice. Even though ethical well-intentioned professionals predominate, such systemic influence is insidious, starting with control of research data upon which Evidence-Based Medicine relies.

Meanwhile, the pharmaceutical industry paid US$116 Billion in criminal fines[2] from January 2000 to March 2024, for felonies[3] such as off-label marketing, data suppression and ‘kickbacks and bribery’.[4] This does not include vast sums in class action settlements[5] (including for the recent US opioid crisis[6]) to patients injured but insufficiently forewarned of adverse events. Data suppression has prevented clinicians from providing appropriate informed consent to patients. These billions of dollars are referred to as the cost of business, as pharmaceutical revenue over the same period exceeds US$20 trillion.[7] This is the era of Marketing-Based Medicine.[8]

In this global corporate context[9] modern medicine finds itself now cornered and ushered into narratives conducive to prescribing lucrative on-patent drugs and novel ‘warp speed’-developed mRNA vaccines that bolster the industry’s bottom line. ‘Evidence-Based Medicine’ has generally been reduced to what large randomised controlled trials (RCTs) find statistically significant. Only Big Pharma can afford to conduct them, outsourcing to contract clinical and contract research organisations[10] (CROs) which outsource data management to medical writing firms who ghost author[11] first drafts. Academic and clinical role authors for papers on the RCT often receive ghost-written drafts to edit for final manuscript submission to journals. For Big

1 https://davidhealy.org/pharmageddon-is-the-story-of-a-tragedy/
2 https://violationtracker.goodjobsfirst.org/summary?major_industry_sum=pharmaceuticals
3 https://projects.propublica.org/graphics/bigpharma#:~:text=In%20the%20last%20few%20years,the%20Food%2and%20Drug%20Administration.
4 https://violationtracker.goodjobsfirst.org/violation-tracker/-pfizer-inc-10
5 https://www.smh.com.au/world/merck-reaches-485-billion-dollar-vioxx-settlement-deal-20071110-197n.html
6 https://www.npr.org/2022/02/25/1082901958/opioid-settlement-johnson-26-billion
7 https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/
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10 https://guides.clarahealth.com/top-clinical-research-organizations/
11 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3190555/

Pharma's big new RCTs these will be prestigious journals like *The New England Journal of Medicine (NEJM)* or *The Lancet*.

Even a little boy watching a naked emperor parade by can see the corruption such a scenario allows for.[12] Although CROs and medical writing firms employ well-meaning people, 'who pays the piper calls the tune' still applies. Lack of transparent data[13] is the root rot infesting the whole tree of modern medicine and pharmacy. Articles[14] in the *British Medical Journal*[15] *(BMJ)* indicate this is not a fringe perspective. As I discovered in my doctoral research and have lectured on for years, a substantial academic medical literature[16] contends that we cannot trust the academic medical literature.

One of the most cited papers in Medicine is titled 'Why most published research findings are false'.[17] The author John Ioannidis, professor of four faculties at Stanford University, Medicine, Epidemiology, Statistics, and Biomedical Data Science, argued this conclusion was due not only to flaws in statistical analyses and trial design, but inherent bias – from both favoured perspectives of researchers and commercial conflicts of interest.

Fellow of the Canadian Academy of Health Sciences emeritus professor Joel Lexchin and colleagues published in the *BMJ* a meta-analysis finding a four-fold odds ratio of a clinical trial finding favourable results for a drug if that trial was sponsored[18] by the pharmaceutical manufacturer, compared to an independent study of the same drug. Thus, peer-reviewed published research demonstrated that peer-reviewed industry-sponsored research literature cannot be trusted.

Chief-editors of major medical journals have addressed the commercial bias problem. Marcia Angell resigned as chief-editor of the *NEJM* to write what she had gleaned. Her book, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*[19] described the financial and persuasive marketing power of the pharmaceutical industry she witnessed at the helm of the *NEJM*. She noted the capture of academic medicine and the profession via corporate-sponsored research and medical education, and this capture extended to the agency charged with regulating the industry – the Food and Drugs Administration (FDA). Angell followed in *JAMA* with 'Industry sponsored research: a broken system',[20] and a 2009 media piece 'Drug Companies and Doctors: A Story of Corruption'.[21]

The NEJM is where Pfizer,[22] Moderna,[23] AstraZeneca,[24] Janssen[25] and Novavax[26] all published their COVID-19 vaccine clinical trial papers. The current editor-in-chief, Eric Rubin, was on

12 https://www.center4research.org/ghostbusting-exposing-drug-company-hired-ghostwriters-medical-journals/
13 https://www.alltrials.net/find-out-more/why-this-matters/
14 https://www.bmj.com/content/346/bmj.f2865
15 https://www.bmj.com/content/345/bmj.e7303
16 https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050217
17 https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124
18 https://www.bmj.com/content/326/7400/1167
19 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC521592/
20 https://jamanetwork.com/journals/jama/article-abstract/182478
21 https://www.nybooks.com/articles/2009/01/15/drug-companies-doctorsa-story-of-corruption/
22 https://www.nejm.org/doi/full/10.1056/nejmoa2034577
23 https://www.nejm.org/doi/full/10.1056/nejmoa2035389
24 https://www.nejm.org/doi/full/10.1056/NEJMoa2105290
25 https://www.nejm.org/doi/full/10.1056/NEJMoa2101544
26 https://www.nejm.org/doi/full/10.1056/NEJMoa2107659

the FDA's Vaccine & Related Biological Products Advisory Committee (VRBPAC), and as VRBPAC voted on 29 October 2021 approving Pfizer's COVID-19 vaccine for children,[27] he noted the risk of myocarditis stating, 'We're never gonna learn how safe the vaccine is until we start giving it.'

Richard Horton, chief-editor of *The Lancet* in an editorial 'How tainted has medicine become?'[28] answered his rhetorical question, 'heavily, and damagingly so.' He expanded on this in 'What is medicine's 5 sigma?',[29] referring to the physics standard for accepting a result as not due to chance being 5 standard deviations or 1 in 3.5 million. Medicine relies on a p (probability) value of 0.05 or 1 in 20 risk of chance and as Horton described, many factors can enable erroneous research over that low bar:

> The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness.

Despite the chief-editor's sceptical eye, *The Lancet* suffered an egregious example of his description. 'Lancetgate' refers to a large study from over 600 hospitals worldwide that purported to find hydroxychloroquine, a 60-year-old off-patent medication, had no benefit in COVID-19. But most patients did not exist. The study, largely fiction, was retracted.[30] The fraudulent data had been contrived by a CRO and writing company, Surgisphere.[31] The WHO halted all trials of hydroxychloroquine, only to do a 180-degree turnaround. However, a media narrative had damned hydroxychloroquine, which then posed no further risk to Marketing-Based Medicine.

It is a truism of Marketing-Based Medicine that off-patent drugs can threaten pharmaceutical industry profits from on-patent products. Former *BMJ* chief-editor Richard Smith titled a paper, 'Medical journals are an extension of the marketing arm of pharmaceutical companies'[32] where he noted RCT methodologies designed to disparage old off-patent competitor drugs.

Following hydroxychloroquine, another such competitor was ivermectin,[33] an antiparasitic with broad antimicrobial properties[34] whose discoverers won the 2015 Nobel Prize[35] in Medicine for ivermectin's safety and efficacy record. Although a review[36] indicated likely efficacy for COVID-19, ivermectin was disparaged by drug regulators and media as dangerous and ineffective. This website details all the studies on ivermectin for COVID-19[37], overwhelmingly positive but for a few large well-funded RCTs, which the website reviews[38] as having critical methodological flaws. The

27 https://www.theepochtimes.com/health/fda-adviser-explains-why-he-abstained-from-vote-on-pfizers-covid-19-vaccine-for-young-children-4074913
28 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(02)08198-9/fulltext
29 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)60696-1/fulltext
30 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31324-6/fulltext
31 https://www.theguardian.com/world/surgisphere
32 https://journals.plos.org/plosmedicine/article/info:doi/10.1371/journal.pmed.0020138
33 https://www.nature.com/articles/ja201711
34 https://www.sciencedirect.com/science/article/pii/S0168365920305800?via%3Dihub
35 https://link.springer.com/article/10.1186/s40249-015-0091-8
36 https://www.sciencedirect.com/science/article/pii/S2052297521000883?via%3Dihub
37 https://c19ivm.org/
38 https://c19ivm.org/meta.html

FDA appears to have conceded defeat in a legal settlement,[39] and ordered to withdraw all critical commentary[40] the agency made against ivermectin.

The TGA restricted ivermectin in September 2021;[41] one concern was its use could increase 'vaccine hesitancy' to the gene-based COVID-19 vaccines. Australian doctors lost practising licences over this. Getting a manuscript[42] reviewing favourable evidence for ivermectin's use in COVID-19 accepted in journals became nigh impossible.

A Pittsburgh and Carnegie-Mellon university-funded survey[43] in early 2021 found 'vaccine hesitancy' towards the lipid-nanoparticle encased modified mRNA (LNP-modRNA) and adenovectorDNA gene-therapy technologies used in Pfizer, Moderna, AstraZeneca and Janssen's COVID-19 vaccines was (in terms of education qualifications) highest among medical PhD holders for those with post-high school qualifications. In terms of occupation, paramedics with 45.6%[44] hesitancy were the highest among all healthcare workers. Having completed a PhD – 'Paediatric Bipolar Disorder': Why did it occur, the iatrogenic consequences, and the implications for medical ethics and psychiatric nosology[45] – on a pharmaceutical industry-funded academic child psychiatry-driven overdiagnosis epidemic of bipolar disorder in hundreds of thousands of prepubertal children including toddlers, where many children died of adult psychiatric medication regimes, I was a hesitant medical doctorate holder. As work colleagues were hospitalised shortly post-vaccine with myo-pericarditis my hesitancy increased.

During my doctoral research, I coined the term 'Marketing-Based Medicine' in a 2010 paper, 'From Evidence-Based Medicine to Marketing-Based Medicine: Evidence from internal industry documents'.[46] In the wake of multiple Big Pharma corruption 'of' medicine scandals,[47] legal discovery exposed internal company documents disclosing data suppression and manipulation. My co-author and I read over 400 documents concerning antipsychotic and antidepressant medications from six major pharmaceutical companies. I recall a journey of cognitive dissonance through shock and outrage as to the level of systematic fraud. I have lectured on these documents for 15 years; a 2014 version is on YouTube;[48] more documents are compiled at this webpage,[49] and the UCSF library has a large Drug Industry Documents Archive[50] (DIDA).

I had not always been so sceptical. As a GP straight from a mid-1980s three-year stint as a medical officer in the Royal Australian Navy, I was keen to see pharmaceutical sales representatives who could tell me about medications for geriatric and paediatric patients I'd not experienced during Navy service. As well as accruing free pens, notepads, and coffee mugs, I was likely being profiled by pharmaceutical companies[51] for marketing strategies.

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39 https://www.courthousenews.com/fifth-circuit-sides-with-ivermectin-prescribing-doctors-in-their-quarrel-with-the-fda/
40 https://covid19criticalcare.com/wp-content/uploads/2024/03/Stipulation-of-Dismissal.pdf
41 https://www.tga.gov.au/news/media-releases/new-restrictions-prescribing-ivermectin-covid-19
42 https://www.drphilipmorris.com/repurposed-drugs-to-treat-covid-19-ivermectin/
43 https://www.medrxiv.org/content/10.1101/2021.07.20.21260795v2.article-info
44 https://www.sciencedirect.com/science/article/pii/S221133552100259X?via%3Dihub
45 https://theses.flinders.edu.au/view/e8c15152-a279-4e61-88ce-e96080a908da/1
46 https://www.researchgate.net/publication/225663511_From_Evidence-Based_Medicine_to_Marketing-Based_Medicine_Evidence_from_Internal_Industry_Documents
47 https://www.enjuris.com/blog/resources/largest-pharmaceutical-settlements-lawsuits/
48 https://www.youtube.com/watch?v=AXS_oiEzeTw&t=2s
49 https://www.healthyskepticism.org/global/news/int/hsin2009-12
50 https://www.industrydocuments.ucsf.edu/drug/
51 https://www.acpjournals.org/doi/10.7326/0003-4819-146-10-200705150-00008

I believed, erroneously like the majority of clinicians,[52] I would see through any marketing spin and glean important information to save me reading time.

To some extent I possibly did, but I was naïve and likely fooled on several points but with no way to know which. That realisation grew early in my career as a child and adolescent psychiatrist in a tertiary referral mood-disorders clinic for young people. I was confronted by clear cases of selective serotonin reuptake inhibitor (SSRI) antidepressant-induced agitation and suicidality in adolescent and young adult patients.

Initially the marketing narrative was that this exacerbation of suicidality was either a very rare side effect, or simply the underlying illness. While at times it probably was the depression, temporal proximity of agitation-akathisia[53] and increased suicidality to SSRI dose initiation, change and stoppage was often obvious, and not dissimilar to reports these days of serious adverse events to COVID-19 vaccines. A prominent NIH study of fluoxetine for adolescent depression[54] seemed to suggest safety, but our letter to the *BMJ*[55] outlined methodological flaws obscuring suicidality. By 2004 under pressure of compelling case reports from clinicians and bereaved parents, the FDA issued a black box warning[56] label that this adverse event was indeed real. SSRIs have not met their marketing hype[57] though can be effective for high anxiety and severe depression. Informed consent and judicious prescribing on a risk-benefit basis particularly in young people remains, and evidence supports the black box labelling.[58]

GlaxoSmithKline (GSK) was convicted of data fraud that included its SSRI drug paroxetine in two GSK (formerly SmithKlineBeecham SKB) RCTs for adolescents with depression: studies 329 and 377. Internal SKB/GSK documents[59] revealed the company suppressed study 377 where paroxetine 'failed [to] demonstrate any separation of Seroxat/Paxil [paroxetine] from placebo', and cherry-picked secondary endpoint data in study 329 which 'failed to demonstrate a statistically significant difference from placebo on the primary efficacy measures'. These secondary data were published in 2001[60] in *The Journal of the American Academy of Child & Adolescent Psychiatry (JAACAP)*, touting paroxetine as 'generally well tolerated and effective'.

However, following a US$3 billion fine, as a sign of goodwill, GSK allowed restricted access to raw data from study 329[61] to an independent group of researchers; several of these I knew and could follow their work. In 2015 these independent researchers published their analysis of the study 329 RCT data in the *BMJ*.[62] Key findings were that paroxetine showed 'increased harms' (specifically a four-fold increase in suicidality) and 'no efficacy'.

RCT studies summarise data in clinical study reports (CSRs) that are submitted to regulators such as the FDA and from which data are extracted to write manuscripts to submit to peer-reviewed journals. Raw participant level data are held in the form of case report forms (CRFs). The hidden paroxetine suicidality data were in the CRFs – normally not shared with regulators like FDA and

52 https://link.springer.com/article/10.1007/s11606-009-0989-6
53 https://rxisk.org/akathisia/
54 https://jamanetwork.com/journals/jama/fullarticle/199274
55 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC534889/
56 https://antidepressantsfacts.com/2004-10-15-FDA-Black-Box-SSRIs-suicide.htm
57 https://www.mja.com.au/journal/2016/204/9/unfulfilled-promise-antidepressant-medications
58 https://www.frontiersin.org/journals/psychiatry/articles/10.3389/fpsyt.2020.00018/full
59 https://www.industrydocuments.ucsf.edu/docs/#id=xrfw0217
60 https://www.jaacap.org/article/S0890-8567(09)60309-9/abstract
61 https://study329.org/
62 https://www.bmj.com/content/351/bmj.h4320

TGA, named authors, peer-reviewers and editors of journals.

The *JAACAP* has declined repeated calls to retract or correct[63] the RCT paper. Thus, based on the same RCT data, two papers in prestigious peer-reviewed medical journals present contradictory results.

Something similar has happened with the Pfizer and Moderna mRNA vaccine RCTs published in *NEJM*. The papers claimed 95% and 94% 'efficacy in preventing COVID-19' and adverse events were 'similar in the vaccine and placebo groups'[64] and 'no [serious systemic] safety concerns were identified'.[65] Primarily because of these two papers, and similar RCTs in *NEJM* concerning the AstraZeneca, Janssen and Novavax RCTs, echoing what regulators say they saw of the data, governments instituted vaccine mandates, with significant economic and psychosocial consequences.[66]

However, both RCTs' summary data had been posted to www.clinicaltrials.gov website, a recommended practice to allow some degree of independent vetting, even though mainly CSR not CRF level data. An independent group of researchers including senior *BMJ* editor Peter Doshi analysed these Pfizer and Moderna RCT data and published on the safety data in the journal *Vaccine*, not as prestigious as *NEJM* but nonetheless the leading vaccinology journal. Their analysis found:

> Pfizer and Moderna mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest 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 excess risk of serious adverse events of special interest of 12.5 per 10,000 vaccinated.

Doshi was involved in the *BMJ*'s editorship of GSK study 329 rewrite and aware of the need for raw patient level data to truly know the safety risks. They concluded:

> Full transparency of the COVID-19 vaccine clinical trial data is needed to properly evaluate these questions. Unfortunately, as we approach 2 years after release of COVID-19 vaccines, participant level data remain inaccessible.

Aware this data credibility issue applies to the COVID-19 vaccines, Doshi along with immediate past and current *BMJ* editors-in-chief Fiona Godlee and Kamran Abbasi published an editorial titled 'COVID-19 vaccines and treatments: we must have raw data, now'.

Access to the FDA's copies of the Pfizer and Moderna RCT data has been achieved by US court-ordered enforcement of FOI request by Public Health and Medical Professionals for Transparency, and volunteers have started analysing and publishing these data. The FDA had made its EUA decision within weeks based on these data, but argued (unsuccessfully) in court for 75 years to release it to PHMPT. Such resistance to transparency adds weight to the questioning title of a *BMJ* article: 'From FDA to MHRA: are drug regulators for hire?'

63 https://study329.org/request-to-retract-study-329/
64 https://www.nejm.org/doi/full/10.1056/NEJMoa2034577
65 https://www.nejm.org/doi/full/10.1056/NEJMoa2035389
66 https://www.fortunejournals.com/articles/economic-and-psychosocial-impact-of-covid19-vaccine-noncompliance-amongst-australian-healthcare-workers.html

A key Pfizer-FDA document showed voluntary reports of suspected adverse events collected by Pfizer between mRNA vaccine launch in December 2020 and end of February 2021 included 1,223 reports of fatal adverse events among 42,086 cases. Reports of serious adverse events to national pharmacovigilance databases like the US VAERS, Australian DAEN, UK Yellow Card and others, or to the WHO VigiAccess, all show gene-based COVID-19 vaccines suspected adverse events are orders of magnitude above normal antigen-based vaccines including antigen-based COVID-19 vaccines. In the past, product market recall would have occurred. This has indeed now happened for adenovector-DNA vaccines AstraZeneca and Janssen, but not as yet for the mRNA vaccines. Could this relate to sunk cost investments in mRNA technology, or the Bill Gates statement about the ease and cheapness of mRNA manufacturing?

Ease and cost-efficiency are desirable, but ethically should not be prioritised above safety and efficacy.

The Vioxx scandal was a prominent medicinal product withdrawal for adverse events reasons, among around 500 such market recalls. The FDA approved Vioxx, an anti-inflammatory analgesic in 1999, based on Merck's data and *NEJM* RCT paper. Despite a paper in *JAMA* (like that in *Vaccine*) showing greater safety risk than the *NEJM* paper, the FDA only recalled Vioxx in 2004 after further data suppression of heart attacks exposed by an FDA scientist who published in *The Lancet* despite FDA pressure on *The Lancet* to reject the paper.

Estimates of global strokes and heart attacks were 160,000 per 10 million, and an estimated 80 million were prescribed Vioxx. Cardiovascular deaths were around 60,000 in the USA although only 6,638 were reported to the FAERS pharmacovigilance database (Figure 1). This like all other pharmacovigilance research indicates these databases have under-reporting biases, yet inexplicably regulators argue there has been over-reporting of COVID-19 mRNA and adenovector DNA vaccines, the TGA only affirming 14 (1.5%) of 1006 death reports.

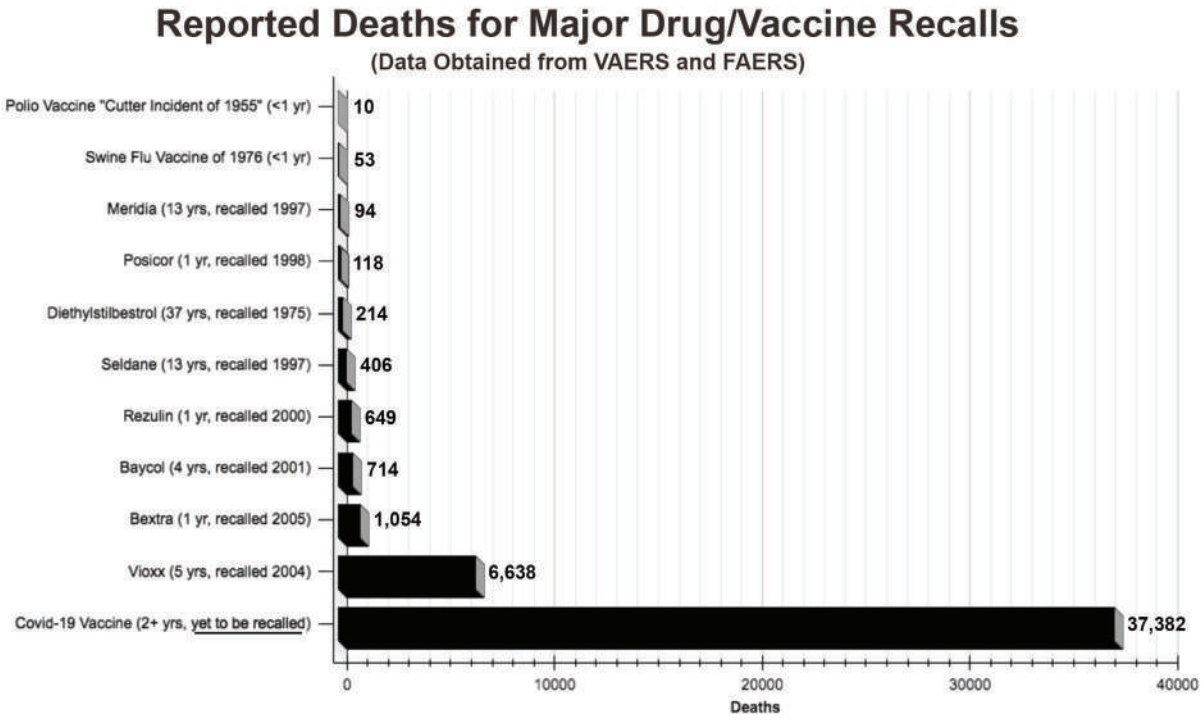

Figure 1. Major drug and vaccine recalls (FAERS & VAERS data).
As of 23 Feb 2024, www.vaersanalysis.info

Merck settled a class action and internal documents revealed plans to harass and silence dissenting doctors and scientists and create a fake journal touting Vioxx. In this pandemic, Merck has criticised its Nobel Prize winning but now financially worthless off-patent ivermectin, which could compete with its lucrative on-patent antiviral molnupiravir.

Similar to the *NEJM* RCT that failed to report three heart attacks on Vioxx, four subjects with serious adverse events were not reported in the *NEJM* COVID-19 vaccine RCT papers. These were: Augusto Roux (peri-myocarditis, hepatic injury; Pfizer); Brianne Dressen (chronic demyelinating polyneuropathy; AstraZeneca); Catherine Olivia Tesinar (shoulder inflammation, tendon rupture near injection site, axillary lymphadenopathy, neurological symptoms and rapid T-cell lymphoma; Moderna); and Maddie de Garay (neurological injuries including paralysis; Pfizer adolescent trial). The first three were excluded from the RCTs and their adverse events were not recorded in the *NEJM* papers despite correspondence with the editor-in-chief; the fourth was recorded as 'functional abdominal pain'.

Roux and Dressen are co-authors of a peer-reviewed paper on their RCT experiences. Doshi in the *BMJ* reports FDA documents show that an inexplicable excess of Pfizer subjects over placebo subjects (311 v 60) were excluded. Roux claims he knew another unreported exclusion with cardiac adverse effect; Tesinar says she knew another Moderna RCT participant with stroke. Could these exclusions include others? Doshi also noted out of approximately 22,000 in each of Pfizer and placebo arms, only 8 Pfizer and 162 placebo were PCR-positive participants (hence '95%' effective) but over 3,000 other participants had COVID-like symptoms, and PCR false negatives could have skewed the efficacy rate downwards.

Brook Jackson, trialsite manager for a CRO running one of Pfizer's RCT trial sites, along with two anonymous whistleblowers informed the *BMJ* of serious irregularities including unblinding of whether participants received Pfizer or placebo. She was sacked by her CRO soon after reporting the irregularities to the FDA. Whether such unblinding relates to the imbalance in exclusions is an unanswered question.

The *NEJM* is the most prestigious medical journal, but dependent on pharmaceutical industry funding. An opinion paper in a medical ethics journal argued that the *NEJM's* 'commercial conflict of interest' influenced its handling of the Vioxx RCT paper for which Merck paid $US697,000 for preprints. The author concluded:

> Indeed, as the Vioxx scandal illustrates, the stakes are too high to either downplay or turn a blind eye to the problem of commercial COI. What is disconcerting is that the conditions that gave rise to the Vioxx scandal remain intact.

The AllTrials campaign, led by the *BMJ* and other eminent British medical institutions, sought to bring transparency and honesty back to medical research. This was so we could truly trust it when a clinical trial published in a medical journal proclaimed a medicine 'safe and effective'. Following scandals like study 329 and Vioxx, AllTrials had momentum, garnering signature support from over 700 medical organisations and colleges, including

our own RANZCP after a group of us lobbied it in 2014-2015. Unfortunately, AllTrials appears to have run out of steam, and has not updated since the start of Covid.

As there is dissipation of the mass fear and groupthink from the COVID pandemic, magnified via media and social media strategies coordinated by the Trusted News Initiative and psychological strategies from 'nudge units', more people are realising that Marketing-Based rather than Evidence-Based Medicine skewed our public health responses. This realisation can reinvigorate the goals of something like Alltrials towards true patient-level (with privacy protections) RCT data transparency. Only then does Evidence-Based Medicine have a chance, resulting in true informed consent on risk and safety decisions for all clinicians and patients, as well as properly informed public health directives.

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Associate Professor Peter Parry

...is an associate professor and a child & adolescent psychiatrist whose career encompasses that of a medical officer in the Royal Australian Navy, and GP and palliative care, prior to training in psychiatry from 1990. He was until recently a senior psychiatrist with Children's Health Queensland, a position terminated for not being able to conscientiously consent to a gene-based vaccine based on the information he was aware of (the principle of informed consent) and he currently works as a locum psychiatrist with interstate health services that recognise the protein-based vaccine Spikogen he received in a clinical trial. He has research and teaching interests in developmental psychology, lifestyle factors in mental health, the history and politics of psychiatric nosology, and conflict-of-interest issues between psychiatry-medicine and the pharmaceutical industry.

COVID-19 'Vaccines': A Failure of the Drug Regulatory System

Phillip M. Altman

Introduction

Prior to the COVID pandemic, Australia's drug regulator, the Therapeutic Goods Administration (TGA), was highly regarded internationally for its rigorous application of the most stringent international standards of drug quality, safety and efficacy. However, in assessing the quality, safety and efficacy of data submitted in support of the gene-based COVID 'vaccines', these standards were seriously compromised in many fundamental and critically important ways. Given the serious quality, safety and efficacy problems now well-known and widely reported in relation to the COVID 'vaccines', it has been argued by many experts that these gene-based injections should never have been approved by the TGA. A detailed description of the TGA's failures to properly evaluate these injections will be described in this presentation.

In the past, the relationship between the pharmaceutical industry and the government regulator could best be described as adversarial. Put simply, the industry was focused on profits while the drug regulator was focused on safety. In dealing with the TGA it was always assumed that industry was guilty until proven innocent. It was essentially a relationship of checks and balances. The heavy burden of proof of quality, safety and efficacy for new drugs required many years of research and billions of dollars of investment.

The public, by default, has placed its trust in the TGA to ensure that new drugs meet the stringent and complicated standards of quality, safety and efficacy, the details of which are fully known to very few people.

The COVID-19 'vaccines' presented a unique challenge to the drug regulators. Such gene-based products and lipid nanoparticle delivery system had never before been used. Gene-based genetic products present very special safety concerns and the development of such products usually takes many years. Because of safety concerns, these products are typically reserved to treat serious genetic defects or rare cancers where the risk of serious side effects might be justified. In this case, normal safety testing usually demanded for gene-based products was lacking.

It is my opinion, based on more than 40 years of experience in international drug regulation,

that our TGA and other regulatory agencies around the world such as the US Food and Drug Administration (FDA), the UK's Medical Health Regulatory Agency (MHRA), the European Medicines Agency (EMA) and other national drug regulatory agencies have been derelict in their duty to properly evaluate and approve these so-called 'vaccines' prior to their release. Furthermore, it is my opinion that given the numerous serious clinical safety signals that have been reported worldwide, these regulatory agencies have failed in their duty to act immediately to investigate, suspend or withdraw these dangerous gene-based therapies which, by many measures, are doing more harm than good.

For clarity, I have divided these regulatory failings into:

a) Regulatory failures to adequately and properly evaluate and assess the risk of the COVID-19 vaccines and risk-benefit prior to release, and
b) Regulatory failure to adequately assess and respond to emerging safety data signals post-release.

Definition of 'Vaccine' – Protection against infection and transmission

What is a 'Vaccine'?

- **Most would presume that vaccines prevent infection & prevent transmission of infection**
- **But the COVID-19 'vaccines' do not prevent infection nor do they prevent transmission of infection**

COVID-19 'vaccines' as a therapeutic fall under the US Food and Drug Administration (FDA) Office of Cellular, Tissue, and Gene Therapies' definition of "gene therapy products", in that it involves "introducing a new or modified gene into the body to help treat a disease".

What is Gene Therapy? (25/7/2018) US-FDA https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy

Most people presume that vaccines both prevent infection and transmission of infection and, following years of industry persuasion, most people believe that vaccines are generally safe. However, vaccines are serious pharmaceutical products and many have been withdrawn because of their serious adverse events, including death.[1] Some vaccines have been withdrawn for as few as 10 related deaths.

In contrast to conventional vaccines, the COVID-19 'vaccines' were developed in record time over a few months in 2020. They employed for the first time an experimental gene-based technology never before used in vaccines, and a technology and delivery system normally reserved to treat serious genetic defects or for rare cancers because of the inherent and significant safety risks recognised with genetic therapies.

1 Historical Vaccine Safety Concerns – US Centers for Disease Control and Prevention. September 4 2020. https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html

In fact, the so-called COVID-19 vaccines were not really 'vaccines' in that, as we now know, these injections do not prevent infection nor do they prevent transmission of infection.

Our TGA knew or should have known that the COVID-19 injections did not prevent transmission of infection, but they remained silent while this false claim was made repeatedly by senior health bureaucrats and politicians alike. The FDA Press Release of December 11th 2020 made this point very clear.

FDA News Release 11 Dec. 2020

'FDA takes key action in fight against covid-19 by issuing emergency use authorization for first COVID-19 vaccine' [Pfizer]

'At this time, data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person.'

https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

The fact that these COVID-19 injections did not prevent infection of the virus was clearly shown in the official state governments' hospital statistics. On a *per capita* basis, those people most COVID-'vaccinated' were the ones more likely to be admitted to hospital with COVID-19.

In fact, these disappointing statistics became such an embarrassment to the government that publication of these weekly statistics ceased in New South Wales, on December 31st 2023. These statistics are presented in the government-published table below.

Failure to Recognise Negative Vaccine Efficacy

NSW COVID-19 WEEKLY DATA OVERVIEW – Weeks 51 and 52 ending 31 Dec. 2-22
www.health.nsw.gov.au/coronavirus

ADMISSIONS TO INTENSIVE CARE

- **No Dose - 0**
- **One Dose - 1**
- **Two Doses - 17**
- **Three Doses - 29**
- **Four Or More Doses - 58**

In addition, a Pfizer senior executive, Janine Small, who was President of International Developed Markets, was asked by MP Rob Roos on October 10 2022 the question whether the Pfizer vaccine was 'tested on stopping the transmission of the virus before it entered the market.' Testifying before the European Parliament, she answered, 'No'….the company had to 'move at the speed of science'.[2]

2 Source: European Union Parliament via Twitter. 9 min. 51 sec. European Union MP Rob Roos questioning Janine Small on 10 October 2022. https://youtu.be/J6VbI8gOnUM?si=NgwX9UU_OvTdtakk (last viewed 4 Feb. 2024).

The failure of the TGA to correct COVID-19 vaccine misinformation regarding prevention of disease and transmission of disease permitted these destructive false narratives to be accepted and from there to sweep through our society. These false narratives formed the basis of the unsupportable vaccine mandates which continue to this day.

Failure to require appropriate gene therapy safety guidelines

Failure to Require Gene Therapy Safety Guidelines

- **Officially classified as 'countermeasures' under US Emergency drug regulatory framework**
- **No Australian drug regulatory equivalent**
- **Australia has a provisional approval system**
- **Critical lack of carcinogenicity, mutagenicity, genotoxicity, reliable reproductive toxicology and evidence to rule out reverse transcription**

Altman, P. et al: Did National Security Imperatives Compromise COVID-19 Vaccine Safety? Brownstone Institute Articles, 5 January 2023. https://brownstone.org/articles/did-national-security-imperatives-compromise-covid-19-vaccine-safety/

Under Emergency Use Authorisation Regulations in the US, the COVID-19 so-called 'vaccines' were released with minimal safety data.[3] There is no Australian equivalent to the US emergency drug-regulatory framework, but since 2018 Australia introduced a Provisional Approval drug-regulatory system which also permitted the release of drugs without comprehensive quality, safety and efficacy testing pending the supply of outstanding required data for up to six years. [4]

The net result of these regulatory frameworks was that the COVID-19 so-called 'vaccines' were released with a critical lack of research on carcinogenicity, mutagenicity, genotoxicity and reliable reproductive toxicology in appropriate animal species. In particular, there was a lack of critical data on the potential for reverse transcription of the mRNA genetic material into a person's DNA, which may have intergenerational adverse consequences.

The scientific literature contains evidence of potential genetic damage and potential genetic integration *in vitro* in human liver cells,[5] human kidney cells[6] and human blood cells.[7] The consequences of these biochemical events could include an increased incidence of cancer and miscarriages.

In addition, these COVID-19 so-called 'vaccines' fell under the definition of gene therapy by the US FDA as recently as 25 July 2018 in that these products involved '…introducing a new

3 Altman, P. et al: Did National Security Imperatives Compromise COVID-19 Vaccine Safety? Brownstone Institute Articles, 5 January 2023. https://brownstone.org/articles/did-national-security-imperatives-compromise-covid-19-vaccine-safety/

4 Australian Government – dept of Health and Aged Care: Provisional approval pathway: prescription medicines. 20 March 2018. https://www.tga.gov.au/provisional-approval-pathway-prescription-medicines

5 Alden et al ntracellular ReverseTranscription of Pfizer BioNTech COVID-l9 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. 25 Februaru 2022. Preprint: Curr. Issues Mol. Biol. 2022, 44, 1115-1126.

6 Hui Jiang and ya-Fang Mei SARS-CoV-2 Spike Impairs DNA Damage Repair and Inhibits V(D)J Recombination in-vitro. Viruses: 2021 Oct 13:13(10):2056. doi:10.3390/v13102056

7 Dhuli, K. et al: Presence of viral spike protein and vaccinal spike protein in the blood serum of patients with long-COVID syndrome. Eur Rev. Med. Pharmacol. Sci 2023; 27 (6 Suppl): 13-19. Doi: 10.26355/eurev_202312_34685.

or modified gene into the body to help treat a disease'.[8] In the past, gene therapy used the same vector delivery systems utilised by the COVID-19 'vaccines', that is, either a virus (such as the AstraZeneca injections) or a lipid-nanoparticle vector (for example, Pfizer and Moderna injections) to deliver genetic material to cells.

Some would argue that the term gene therapy should not apply to these 'vaccines' because there is no intention of repairing or inserting permanently genetic material for therapeutic purposes. However, semantic demarcation cannot disguise the fact that new genetic material is being inserted into the body's cells to help treat a disease and therefore these injections should, more appropriately, be described as 'gene therapy'. The public was not advised of this important information.

Never before has a gene-based product been released with so little quality, safety and efficacy testing. Never before has a gene-based product been released for population-wide use in healthy people, in pregnancy, in infants and children. This is why there are more adverse and serious adverse events reported for the COVID vaccines than for the total number of all vaccines combined over the past 32 years which greatly exceed the total number of COVID-19 injections.

The unanticipated high level of serious adverse events including death associated with the COVID-19 so-called 'vaccines' might have been predicted because of the unreliable and poorly designed and reported clinical trial data and a lack of normally-required safety testing, but it is also due to the failure to properly evaluate the pharmacology and toxicology of the spike protein itself which is produced by the gene-based COVID injections. It is the spike protein which is the active entity of the injections that elicits the immune response and, along with the lipid nanoparticle delivery system, is responsible for the reported toxicity of the injections. The literature now contains more than 3,000 papers regarding safety issues surrounding the COVID-19 so-called 'vaccines'.

Failure to investigate allegations of fraud

There is evidence of fraud in relation to the conduct and reporting of the clinical trials which supported the initial registration of these COVID-19 injections. These allegations appear to be well founded, placing doubt upon the data supporting the claimed safety and efficacy of the injections, yet our TGA appears unconcerned.

Failure to adequately assess the safety of the lipid-nanoparticle (LNP) delivery system

Both the Pfizer and Moderna COVID-19 'vaccines' use a synthetic mRNA encased in a lipid-nanoparticle (LNP) delivery system. Nanoparticles are of dimensions around 100 nanometres (100 millionth of a millimetre) or smaller. These LNPs employ positively charged lipids which do not occur in nature. Their use in pharmaceutical chemistry only dates back to the 1990s.[9] There is a well-established history of safety concerns regarding LNPs in that they have organ toxicity in their own right and cause inflammatory reactions. The first LNPs encapsulating

8 What is Gene Therapy? (25/7/2018) US-FDA https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy

9 Xucheng, H. et al: Lipid nanoparticles for mRNA delivery. Nature Reviews Materials 6, 1078-1094 (2021). https://www.nature.com/articles/s41578-021-00358-0

small antibiotic molecules were approved by the FDA in 1995. However, LNPs are poorly regulated with no specific safety testing recommendations. It may well be that many of the adverse effects of the COVID-19 'vaccines', such as myocarditis, may be attributable to the LNPs in the vaccine formulations. Regulatory agencies failed to require detailed biodistribution and pharmacokinetic studies as well as comprehensive toxicological studies on the LNPs themselves. We now know there is accumulation of LNPs in the ovaries following mRNA COVID-19 'vaccine' administration. This is of particular concern, especially in light of reports of an increased incidence in miscarriage rates.

LNPs by their very physicochemical nature would be expected to distribute widely to every part of the body, and not remain at the site of injection in the deltoid muscle of the arm as we were all told. The use of LNPs means that virtually every cell of the body can become a factory to produce toxic spike protein on its surface. This means that every organ, every tissue and every body-compartment potentially sustains toxic effects from the spike protein. This is why we are seeing such a diverse range of reported adverse effects including cardiovascular, neurological, immunological, autoimmune and oncogenic effects.

Claim: 'Safe and effective'

Many pharmaceutical drugs have been approved and considered relatively safe only to be subsequently withdrawn as a result of serious adverse events reported in post-marketing adverse drug-reaction reporting systems. A total of 462 medicinal products have been withdrawn from the market between 1950 and 2013 using post-marketing surveillance,[10] and this includes many vaccines.[11]

There is overwhelming evidence that the COVID-19 so-called 'vaccines' are not 'safe'. These so-called 'vaccines' have produced more serious side effects per million injections than any vaccine in history, according to various vaccine adverse-event reporting systems including the CDC's VAERS.[12]

CDC VAERS COVID-19 Vaccine Adverse Event Reports

1,630,913 REPORTS THROUGH FEBRUARY 23, 2024
https://www.openvaers.com/covid-data

- **37,321 Deaths**
- **214,906 Hospitalisations**
- **154,245 Urgent Care**
- **28,214 Myocarditis/Pericarditis**
- **21,524 Heart Attacks**

Under-reporting Factor 40X to 100X

10 Onakpoya, I, J. et al: Post-marketing withdrawal of 462 medicinal products because of adverse drug reactions: a systematic review of the world literature. DOI 10.1186/s12916-016-0553-2

11 US Centers for Disease Control and Prevention (CDC): Historical Vaccine Safety Concerns. https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html

12 US Centers for Disease Control and Prevention (CDC): Vaccine Adverse Event Reporting System (VAERS) data presented in openvaers.com.

In the case of our own national adverse drug reaction reporting system, DAEN (Database of Adverse Event Notifications), there have been 140,000 adverse events reported in relation to the COVID-19 'vaccines'. There have been 140,000 adverse event cases, 22,000 serious cases and 1010 deaths in DAEN but the government admits to only 14 vaccine-related deaths.[13] DAEN also reports a total of nine children have died in relation to the administration of the COVID so-called 'vaccines'.[14]

The TGA says myocarditis from the COVID-19 'vaccines' is 'rare'. But a study showed biomarker evidence of cardiac damage in 2.3% of adolescents and a 30% incidence of cardiovascular adverse events in adolescents following COVID-19 vaccination.[15]

Failure To Respond To Amyloid Rubbery Casts Never Before Seen

- **A new disease or vaccine injury?**
- **Not seen prior to 'vaccine' rollouts**
- **Observed by embalmers (~ 25% in some series)**
- **Also reportedly observed by vascular surgeons**
- **Prion related?**

Campbell, J.: Youtube Channel (6 min). 7 Feb. 2024.
https://youtu.be/z06xBRCwGp0?si=fx-XMTR2SSpfBvnZ

More recently, as Dr. Campbell knows,[16] embalmers are reporting the presence of white amyloid rubbery clots extracted from the blood vessels of COVID-vaccinated people. Such observations were not known prior to the vaccine rollout.

Three recognised prion sites of about 20 amino acid sequences each have been identified within the spike protein produced by the COVID 'vaccines[17] and these sites potentially may cause the misfolding of other proteins and lead to the rubbery amyloid clots. Yet there is no sign the TGA has done anything to investigate these frightening observations.

The number of serious events and deaths reported in the DAEN system are probably only one or two per cent of the true incidence of adverse events and death because health practitioners are reluctant to report adverse events – or do not even know they can report, or do not know how to report, or do not have time to report.

13 COVID-19 vaccine safety report – 2 Nov. 2023. Australian Government – Therapeutic Goods Administration. https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-02-11-23#summary

14 Personal communication: Case numbers 616124, 647663, 659048, 719838, 724023, 733723, 734187, 744306 and 762472

15 Mansanguan, S. et al: Cardiovascular Effects of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents. 8 August 2022. https://www.preprints.org/manuscript/202208.0151/v1

16 Campbell, J.: Youtube Channel (6 min). 7 Feb. 2024. https://youtu.be/z06xBRCwGp0?si=fx-XMTR2SSpfBvnZ

17 Nostrum, S. and Hammarstrom, P: Amyloidogensis of SARS-CoV-2 Spike Protein. J. Am. Chem. Soc. 2022, 144, 20, 8945-8950. https://pubmed.ncbi.nlm.nih.gov/35579205/

Failure to recognise the importance of the excess deaths safety signal reported worldwide

Failure to Recognise the Importance of the Excess Deaths Safety Signal Reported Worldwide

- **How is Excess Death measured?**
- **Excess Mortality is measured as the difference between the reported number of deaths in a given week or month in 2020-2024 and an estimate of the expected deaths for that period had the COVID-19 Pandemic not occurred**
- **Excess Deaths = Reported Deaths less Expected Deaths**

In Australia and around the world these All-Cause Mortality statistics have shown a disturbing trend up to about 16-20% Excess Deaths since the rollout of the COVID 'vaccines' in 2021 but not in 2020 when there were no COVID 'vaccines' and the SARS-CoV-2 virus was at its most virulent. The majority of these Excess Deaths in 2021 and 2022 were non-COVID-19 deaths and include heart attacks, strokes, diabetes, dementia and other neurological conditions.

A Bradford Hill analysis of Excess Mortality in Australia in relation to the COVID 'vaccines' showed mass vaccination was strongly correlated with Excess Deaths.[18]

Some of the most convincing evidence that COVID-19 'vaccines' are causing a surge in Excess Deaths comes from surveys of European countries which plot the Excess Death rate versus the vaccination rate for individual countries.

COVID-19 Vaccination Rates Correlate with Excess Deaths

Chudov, Igor: Excess Mortality Positively Associated with COVID Vaccination Rates
https://www.igor-chudov.com/p/2023-excess-mortality-positively?utm_campaign=post&utm_medium=web

- **Excess Deaths for weeks 1-40 in 2023 for 26 countries show positive correlation between national Vax Rates and Excess Deaths**
- **Pattern was the same in 2022**
- **1.3% Probability of the relationship occurring by chance**
- **Also - systematic review of 325 autopsies post-c19 vax found 73.9% due to COVID-19 vaccines, mean time to death 14.3 Days, 53% cardiovascular cause identified**

Hulscher, N. et al: A Systematic Review of Autopsy Findings in Deaths After COVID-19 Vaccination. https://zenodo.org/record/8120771

A Norwegian analysis found a statistically significant link between COVID-19 vaccination rates in Europe based on the all-cause mortality officially reported by Eurostat in 2022 and vaccination rates derived from Our World in Data.[19]

18 Sy, W.: Australian COVID-19 pandemic: A Bradford Hill Analysis of Iatrogenic Excess Mortality. J. Clin. Exp. Immunol. 2023, Vol 8, Issue 2, 542-556. 1 April 2023. https://www.opastpublishers.com/peer-review/australian-covid19-pandemic-a-bradford-hill-analysis-of-iatrogenic-excess-mortality-5339.html

19 Aarstad, J. and Kvitastein, O.A.: Is there a Link between the 2021 COVID-19 Vaccination Uptake in Europe and 2022 Excess All-Cause Mortality? Preprints **2023**, 2023020350. https://doi.org/10.20944/preprints202302.0350.v1

A more recent detailed analysis covering Excess Deaths for weeks 1-40 in 2023 for 26 countries confirmed this previous survey, positively correlating national vaccination rates with Excess Deaths.[20] The correlation pattern vaccination and Excess Deaths was similar to that found in 2022 by the same author. The statistical correlation was highly significant with a P value of 0.013, that is a 1.3% chance that the relationship occurred by chance.

Autopsies are the most powerful diagnostic tool to establish with a high degree of certainty whether the COVID-19 'vaccines' are the cause of unexpected sudden death following vaccination, but autopsies and autopsy studies are generally not encouraged by health authorities. However, one of the biggest systematic reviews of published autopsy reports relating to COVID-19 vaccination up to May 18 2023 identified 44 papers that contained 325 autopsy cases.[21] Independent review by a panel of physicians found that 240 deaths (73.9%) were due to the COVID-19 vaccines. The mean time from vaccination to death was 14.3 days, and in 53% of cases the cardiovascular system was involved.

Failure to investigate and act in relation to serious quality control problems of the COVID-19 vaccines

Failure to Investigate and Act In Relation to Serious Quality Control Problems of the COVID-19 Vaccines

Schmeling, M.et al: Batch-dependent safety of the BNT162b2 mRNA COVID-19 Vaccine. March 26 2023. Eur J Clin Invest. 2023;53:e13998. doi:10.1111/eci.13998

- **3 major quality safety issues**
- **The commercial batches were made by a different process**
- **Contaminating plasmid (circular) DNA and endotoxins**
- **52 Pfizer batches in Denmark covering 11 million doses showed 71% of all serious adverse events and 47% of all deaths occurred in 4% of batches**

There have been three major safety issues in relation to the manufacturing of COVID-19 'vaccines'.

The COVID-19 'vaccines' sold commercially were not the same as the ones used in the original clinical trials. The commercial lots were manufactured using a completely different process called Process 2. This was an E. coli bacterial fermentation process which utilised plasmid (circular) DNA to produce the mRNA. Unfortunately, it has now been widely reported that commercial lots of the mRNA 'vaccines' contain plasmid DNA which should have been removed in the manufacturing process. This genetic material has the potential to integrate into the patient's own DNA. The Canadian drug regulator has acknowledged the DNA contamination which far exceeds both the FDA and European Medicines Agency's (EMA's) official limits and accounts for up to 20-35% of the nucleic acids contained in the vaccine batches.[22]

20 Chudov, Igor: Excess Mortality Positively Associated with COVID Vaccination Rates https://www.igor-chudov.com/p/2023-excess-mortality-positively?utm_campaign=post&utm_medium=web

21 Hulscher, N. et al: A Systematic Review of Autopsy Findings in Deaths After COVID-19 Vaccination. https://zenodo.org/record/8120771

22 Palmer, M. and Gilthorpe, J.: COVID-19 mRNA vaccines contain excessive quantities of bacterial DNA: evidence and implications. April 5 2023. https://doctors4covidethics.org/covid-19-mrna-vaccines-contain-excessive-quantities-of-

Indeed, a survey has been published of the rates of serious adverse events reported per thousand doses between 52 different batches of Pfizer COVID-19 'vaccine' administered to four million persons covering nearly 11 million doses in Denmark up to January 2022[23] – 4% of batches were reported to be associated with more than 70% of the serious adverse events.

The shift in production method to bacterial fermentation using toxic E. coli bacteria instead of Real Time-Polymerase Chain Reaction (RT-PCR) for the commercial vaccine products has also been responsible for the presence of endotoxin in the final product.[24] Endotoxin is one of the world's most potent and deadly toxins. Endotoxin contamination in the vaccines could cause septic shock and death. Arbitrary allowable limits of DNA and endotoxins have both been adjusted upwards by drug regulators thus presenting a substantial safety risk.

Conclusions

COVID-19 'Vaccines': Drug Regulatory Failures

- **Inadequate clinical trial quality, safety and efficacy data**
- **Failure to investigate alleged corporate fraud**
- **False claims of prevention of infection and transmission of infection**
- **False claim that the 'vaccine' would remain at the site of injection**
- **Failure to investigate continuing and unexplained non-COVID excess deaths**
- **Failure to investigate highest ever incidence of adverse reactions**
- **Failure to investigate reported batch to batch variations linked to mortality**
- **Failure to investigate contamination with dna plasmids and endotoxin**
- **Failure to require safety data on potential genotoxicity**

Despite the poorly designed and inadequate original clinical trial safety and efficacy data, despite the allegations of corporate fraud, despite the failure of the COVID 'vaccines' to prevent infection or transmission of infection, despite the continuing above-average unexplained rise of non-COVID Excess Deaths, despite the highest ever reported incidence of serious adverse drug reaction reports for any vaccine or drug in history, despite the widely reported cardiac injury and heart attacks, despite the alarming batch-related mortality and despite serious concerns about genotoxicity and toxic impurities...

Despite all this, there are still those who say 'the COVID vaccines saved lives.'

There has never been a stronger case for the immediate suspension of any other drug in the history of the pharmaceutical industry.

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bacterial-dna-evidence-and-implications/

23 Schmeling, M.et al: Batch-dependent safety of the BNT162b2 mRNA COVID-19 Vaccine. 26 March 2023. Eur J Clin Invest. 2023;53:e13998. doi:10.1111/eci.13998 https://pubmed.ncbi.nlm.nih.gov/36997290/

24 Geoff Pain Substack 29 Jan. 2023. https://open.substack.com/pub/geoffpain/p/production-of-the-pfizer-biontech?r=10pxn5&utm_campaign=post&utm_medium=web and https://open.substack.com/pub/geoffpain/p/extreme-toxicity-of-endotoxins-in?r=10pxn5&utm_campaign=post&utm_medium=web

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COVID-19 Vaccine Adverse Events – pathological mechanisms and the experiences of the injured and bereaved

Melissa McCann

During the pandemic there was little time to think collectedly, and no time to analyze procedures, and even now it is far from easy to determine what things were done wisely and what things were of no practical value. There exists the greatest difference of opinion as to what measures should again be used when the need arises, and what ones should be discarded. For instance, there are confirmed exponents of prophylactic vaccines, and equally able men who are convinced of their uselessness; enthusiastic advocates of the face mask, and almost as many objectors; those who would close schools, churches, theatres, etc., and those who claim that such measures serve only to prolong the epidemic. One naval officer is said to have stated that he had accumulated figures either to prove or to disprove the usefulness of any preventive measure yet recommended. There is, in short, a chaos of opinions with followers who vary from the one extreme of believing there is 'virtue in all things' to those of the other extreme who state that every susceptible person develops the disease in the degree of his susceptibility, regardless of any and all preventive measures used. While there remain so many points on which definite, concrete knowledge is lacking, and so much controversy over the relative value of various measures, this paper can do little more than state the facts and discuss their bearing on prevention as impartially as possible.

Publications from the University of Pittsburgh School of Medicine, Studies on Epidemic Influenza comprising Clinical and Laboratory Investigations, By Members of the Faculty of the School of Medicine, University of Pittsburgh, 1919.

The extract above was not published last year, but is from a paper over 100 years ago, by the Faculty of the University of Pittsburgh School of Medicine in reference to the so-called Spanish flu epidemic of the early 1900s and it is sobering to reflect on how our management of the COVID-19 period may be judged by our descendants, 100 years from now.

As I approached the COVID-19 virus outbreak my perspective of pandemic management was based on a number of my pre-conceived foundational concepts of medicine, but these quickly became a distant memory as the pandemic progressed.

I believed:

- First, that respiratory viruses are managed in early and non-severe stages using simple over-the-counter remedies, rest, hydration, healthy eating, avoiding social contact and using basic infection control principles such as handwashing to limit transmission.
- That severe illness, ICU admissions and deaths from respiratory infections were mostly limited to medically at-risk patients, but could complicate viral infections such as influenza even in the fit, healthy and young.
- That these severe complications were in almost all cases a consequence of exuberant inflammatory immune response or to secondary bacterial infection, and that steroids and antibiotics might be successfully used for moderate disease to reduce the risk of disease progression and of hospital and ICU admission.
- That off-label use of various medications is common and acceptable clinical practice, though requiring open discussion with a patient for use outside of approved indications.
- That clinical judgement is the ultimate responsibility and requirement of every medical practitioner – it would never be defensible to blindly adhere to a guideline without taking into account the individual patient circumstances.
- That privacy of personal medical information is paramount with legislative protections and requirements for information-sharing.
- That patient autonomy and the right of patients to make their own healthcare decisions were absolutely protected rights, with very few exceptions for any form of involuntary treatment and only in extreme cases such as loss of cognitive ability or function.
- That behind the doors of the consultation room was a place of perhaps the highest possible trust between two people outside of personal relationships – patients share their most private and intimate thoughts, fears and experiences. Patients submit to at times invasive examinations or to procedures that may be painful. Such trust is only ever possible when a patient knows their doctor has the health, wellbeing and best interests of patients as their first and only concern.
- That AHPRA and the Medical Boards have a legislated role to maintain the register of practitioners and to investigate and take action against practitioners only when in the public interest to do so and by taking the minimal regulatory action to protect the public.

I also had a preconceived notion of how pandemics were managed, (public health forming an important part of my medical education and training), and management plans are well established in national Government guidelines, such as the Australian Health Management Plan for Pandemic Influenza 2019 (AHMPPI).

The ethical framework outlined in this AHMPPI, which was agreed in 2008 by the Australian Health Protection Principal Committee, was also destined to the archives of memory.

This ethical framework included the following:

> **Individual liberty:** ensuring that the rights of the individual are upheld as much as possible;

Privacy and confidentiality of individuals: is important and should be protected, (under extraordinary conditions during a pandemic it may be necessary for some elements to be overridden to protect others);

Proportionality: ensuring that measures taken are proportional to the threat;

Provision of care: ensuring that healthcare workers are able to deliver care appropriate to the situation, commensurate with good practice and their profession's code of ethics;

Stewardship: that leaders strive to make good decisions based on best available evidence;

Trust: that health decisionmakers strive to communicate in a timely and transparent manner to the public and those within the health system.

It is difficult to conceive a pandemic response that deviated further from those ethical principles.

The protection of individual rights and liberties became the denial of medical care across state borders, with families separated for months between states, shameful examples of police violence against the public, and patients separated from their families and unable to attend weddings, funerals and unable to be with their loved ones in hospital or in their final hours.

Protection of privacy and confidentiality became public humiliation when COVID-positive patients not only had their medical information disclosed but also had their activities publicly announced in the name of contact tracing.

Once vaccine mandates were introduced, private medical information was required to be disclosed to one's employer, to restaurant staff and shop attendants.

A response proportional to the threat became a pervasive publicity campaign inflating the risk of COVID-19 infection, seemingly in order to engender fear and compliance. Few would be aware that a case fatality rate in the overall population was known to be 0.4% at May 2020 as reported by the CDC. This was as the public statements made by government officials continuously asserted that COVID-19 was a 'deadly virus' with a fatality rate much higher than influenza or other respiratory viruses.

Ensuring health care workers are able to deliver care appropriate to the situation and commensurate with their code of ethics changed. It turned into threatening doctors in one state, Queensland, with six months of prison time if the off-label treatment hydroxychloroquine for COVID-19 was prescribed, taking action to immediately suspend doctors who prescribed Ivermectin, and emailing all health practitioners in the country the statement from AHPRA in March 2021, the statement which threatened regulatory action for any health practitioner who dared make comments adverse to the COVID-19 immunisation campaign.

Leaders striving to make good decisions based on the best available evidence became leaders delivering emotionally unhinged tirades attacking those who questioned government policy. They encouraged the public ostracism of the unvaccinated.

Transparent communication by health decisionmakers in order to build trust turned into the formation of National Cabinet with all decision-making exempt from scrutiny or from Freedom of Information, and repeated denial of information release or publication from the Therapeutic Goods Administration (TGA) the Department of Health; this was on the basis that information unfavourable to the vaccination campaign might 'undermine public confidence'.

The AHMPPI was disregarded on almost all counts. The reader might perhaps wish to search this document to see if the word 'lockdown' appears. (Spoiler warning – no.) Lockdowns have in fact never been utilised in pandemic responses prior to COVID-19. Lockdowns are universally understood to do more harm than good, from perspectives of economic, mental health, social and infection control.

Pandemic management has previously used the common-sense approach of quarantining the unwell and perhaps close contacts, not locking down the asymptomatic and the well general population.

People in Melbourne witnessed the trauma of months of one of the most draconian lockdown measures on earth, including the implementation of a curfew and citizens being unable to travel more than a few kilometres from their home and at times not being able to have even one person visiting. It is difficult to imagine the horror for those living alone, entirely isolated, unable to leave their homes and unable to have visitors; it was an atmosphere of deprivation akin to solitary confinement.

Deviation from established legislation, procedures and protocols also characterised the COVID-19 vaccination program, Operation Covid Shield, which program was administered outside of the well-established National Immunisation Program (NIP).

According to the National Health Act 1953, vaccine listing for the NIP requires a recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC), confirming that a vaccine is clinically and cost effective for the NIP; it requires that before a vaccine is provided without charge through the NIP or subsidised under the Pharmaceutical Benefits Scheme, the PBAC must undertake a thorough and objective assessment of its clinical efficacy and cost-effectiveness, its value for money, in comparison with other available treatments.

The COVID-19 vaccines to this day remain unlisted as 'Designated Vaccines' under the National Health Act 1953, and have been administered outside of the established governance arrangements of the National Immunisation Program. Yet the Australian Government has now purchased over 196 million doses of COVID-19 vaccines, in total investing over 18 billion dollars in Australia's vaccine and treatment supply as part of the COVID-19 health response.

It is difficult to imagine a less successful vaccination campaign. A successful vaccine will prevent the overwhelming majority of vaccinated people from contracting the disease. It will prevent severe disease and death, and will result in a reduced overall mortality from the pandemic. It will ideally prevent transmission of the disease. What we received was a vaccine that was never approved for the indication of the prevention of transmission, and yet inexplicable mandatory vaccination policies were supported by every level of government and the 'official health advice'. When the timing is examined, it is apparent that increases in COVID-19 cases and deaths closely followed in timing the increases in vaccination doses given.

Excess deaths figures, not prior to the vaccination program but only after the widespread uptake, are shocking evidence of a failure of the vaccines to reduce the overall mortality of the pandemic. Being a country with one of the highest vaccination uptakes on earth did not protect Australia from the COVID-19 pandemic; which could be best characterised as a pandemic of vaccination failure or 'breakthrough infections', whereby the majority contracted COVID-19 (sometimes multiple times) despite vaccination.

Safety concerns and the adverse event profile of the COVID-19 vaccines together deserve a textbook of their own and will probably be a topic for academic and legal scholarship for generations to come.

As I summarise the adverse events I have seen in patients and some of the underlying pathophysiological mechanisms as presented in the clinical literature, I find this by no means an exhaustive list and I am certain we will discover further mechanisms with time. But understanding the pathological basis for these events is really one of the first steps in acknowledgement for the patients who have suffered them, and to further research on treatment. Understanding the underlying mechanisms will also help us affirm the patient experiences of adverse events that so many are suffering.

I conceptualise these adverse event mechanisms into several categories:

1 General concepts and mechanism
2 ASIA / Lipid Nanoparticles
3 Protein production – spike and or off-target proteins
4 Autoimmunity
5 Endotoxin and or DNA contamination
6 VAED

1. *General concepts and mechanisms.* Trougakos et al. (1) present the 'spike hypothesis', and they discuss the inflammatory effects including cytokine and T-cell- mediated effects, immune imprinting and circulatory shedding of the spike protein as well as the inflammatory effects of the lipid nanoparticles. Gionotta et al. (2) also summarise several of the mechanisms. These authors focus on the pro-inflammatory cytokine production after vaccination, and describe the multisystem inflammatory syndrome, and inflammatory mediators leading to cardiac arrythmias and myopericarditis, endothelial dysfunction and inflammation. Their model of inflammation is conceptualised using onset time latency for each of the inflammatory effects, and I think it is very useful to conceptualise in this way. Obtaining a history from the patient examining the time course from vaccination to their symptoms and the symptom progression over time I believe provides valuable insights into the underlying pathogenesis.

2. *ASIA Syndrome and the Lipid Nanoparticles*. Ndeupen et al. (3) note the LNP platform is highly inflammatory, stating that 'The Lipid nanoparticles activate multiple inflammatory pathways and induce IL1b and IL-6 which could be responsible for some of the side effects.' The authors report robust lung inflammation from intranasal delivery, and inflammation from intramuscular delivery, which is precisely the opposite

effect to what would be desired from vaccination to prevent lung inflammation from a respiratory virus. The ASIA syndrome, or autoimmune-inflammatory syndrome induced by adjuvants, which has been described following other adjuvanted traditional vaccines, was recently reviewed by authors Seida et al. (4) and the authors discuss the potential for the lipid adjuvants in the COVID-19 vaccines to trigger this syndrome. They write that the ASIA syndrome unites the variety of symptoms, related to autoimmunity, caused not by the vaccine itself, but rather by the adjuvant part of the vaccine such as aluminum, among others. And the authors detail the cellular responses to synthetic lipids such as silicone or mineral oils or the COVID-19 vaccine synthetic lipid adjuvants, and the variety of mechanisms for triggering inflammatory tissue damage. There are major criteria for diagnosis of the ASIA syndrome (bear in mind this predates the COVID-19 vaccines):

1 Exposure to external stimuli (infection, vaccine, silicone, adjuvant) before the onset of clinical symptoms;
2 The appearance of typical clinical manifestations:
   a. Myalgia, myositis, or muscle weakness;
   b. Arthralgia and or arthritis;
   c. Chronic fatigue, un-refreshing sleep, or sleep disturbances;
   d. Neurological manifestations (especially associated with demyelination);
   e. Cognitive impairment, memory loss.

Patients reporting these symptoms to the TGA database number in the thousands. I certainly know personally of hundreds who would fulfil these major criteria.

3. *Effects related to the spike protein and production, and production of off-target proteins*. We are told in the vaccination approval data that the mRNA sequence encodes the full length S1S2 spike protein, with two amino acid modifications compared to the viral spike protein. The sponsor provides a detailed three-dimensional diagram which seems to indicate the structural characteristics of the produced spike protein have been evaluated and confirmed. In fact, the only study to date provided to the TGA on the structural and biophysiological characteristics was not using the mRNA vaccine product, but rather a modified DNA construct. So neither the sponsors nor the TGA have confirmed the biophysiological properties or structure of the spike protein produced in humans from the vaccine.

4 Authors Malroney et al. (5) in fact recently published data confirming that frameshifting due to the pseudouridine modification did result in off-target proteins being produced after vaccination. In other words, some peptides or proteins that are not spike protein are being produced. We are apparently expected to believe these off-label proteins are of no consequence. In fact it is known that aberrant protein production and protein misfolding have the potential to lead to amyloid and other aberrant protein accumulation, potentially leading to degenerative disorders such as Parkinson and Alzheimer's disease. McAlary et al. (6) discuss the prion-like potential of misfolded proteins. This is where misfolded proteins cause normal healthy proteins to become misfolded and display virus-like behaviour and detail the potential for aberrant self-protein production to lead

to amyloidosis, lateral sclerosis and prion disease. Authors Stroylova et al. (7) report that key amyloidogenic proteins with SARS-CoV-2 proteins may be one of the causes of expanding and delayed post-COVID-19 neurodegenerative processes. Furthermore, such abnormal effects can be caused by proteins and their fragments circulating in the body during vaccination and they describe the mechanisms for syneuclopathies after COVID vaccination.

5 Authors Leung et al. (8) review the mechanisms for amyloidosis after COVID vaccination and present cases of cardiac amyloidosis leading to myocarditis and cardiomyopathy, and renal amyloidosis leading to acute renal injury. Autoimmunity is another pathological mechanism for vaccine-induced harm. Guo et al. (9) review the mechanism for autoimmune disease after vaccination. The authors detail several pathways including molecular mimicry resulting from shared peptides between the SARS CoV 2 glycoprotein and human proteins as well as adjuvants acting on toll-like receptors and triggering innate immune activation. Autoimmune diseases feature on the Database of Adverse Events – myocarditis, multiple sclerosis, type 1 diabetes, rheumatoid arthritis and autoimmune hepatitis. In retrospect, we can question the wisdom of self-production of a foreign protein in all cells and tissues of the body, which logically would lead to potential for immune activation against all organs and tissues.

6 Endotoxin or DNA contamination from the plasmid DNA production platform using E coli is a further mechanism for harm. Buckhaults and McKernan (10,11) presented evidence to the US Senate, regarding contamination of the vaccine products with plasmid DNA. Potential genome integration could have catastrophic consequences given that it is known the products distribute to the germline cells of the ovaries and testes and this has the potential to cause muti-generational genetic modification of the human species.

7 Finally, Vaccine-Associated Enhanced Disease. This well-described phenomenon was actually examined by the Brighton collaboration before the vaccines were developed (12), highlighting it as a risk for COVID vaccine development. It is a phenomenon that occurs when the vaccine triggers the immune system, such that a vaccinated person who later contracts COVID becomes more unwell than if they were not vaccinated – in other words, the exact opposite of what vaccination ought to do. They describe the inflammatory responses that can occur in a vaccinated person when they later come into contact with the virus; these include heart attacks, heart failure, severe fatigue, arrythmias, multiorgan inflammatory syndrome, death, seizures, liver failure, clotting events and pro-inflammatory state. I have personally heard from hundreds of people who may have had some side effects after vaccination, or may have had none, but who contracted COVID despite being vaccinated and became extremely unwell. These have developed new or worsening symptoms after COVID and would meet this Brighton Collaboration case definition of VAED.

My personal observations of adverse events in patients and in the community are what has

Here are some of the many people of the class action about their COVID-19 'vaccine' damage.

prompted me to work for the past two years to bring a federal class action on behalf of vaccine injured and bereaved. This matter now has over 1000 group members who have joined and is the largest personal injuries class action ever to have been filed in Australia. It is the first action in the world to seek compensation for COVID-19 vaccine injuries against the medical regulator, health department and government. The case remains open for injured to join.

How can we as doctors and health professionals help these patients?

We can assist by directing patients to some of the suggested management strategies for these side effects, including the work from the FLCCC who provide evidence-based management suggestions. The peer-reviewed paper by Halma et al. also outlines potential management strategies.

In my opinion, one of the most important things we can do is to listen to our patients, take a careful history of their adverse events and current symptoms, and provide appropriate investigations and specialist referrals. We can refer to support groups such as CoVerse and React-19, which provide advocacy and peer support for the injured and bereaved, as well as driving research and change at the political level.

Perhaps the most important thing that we can do as health care professionals is to turn back to our obligations to our patients and our communities, and to resume our absolute adherence to the principles of medical ethics.

What are the pillars and principles of medical ethics?

Non-Maleficence – to do no harm;

Beneficence – to do good;

Autonomy – to respect our patients' rights to their own healthcare decisions;

Justice – the fair and equitable use of the finite health-care dollar.

Our code of conduct sets out the principles that characterise good medical practice and makes explicit the standards of ethical and professional conduct expected of doctors by their professional peers and the community. Our Code states we are required to make the care of our patients our first concern and that we have a responsibility to be open and honest in communication with patients. Our Code requires that we support our patients' rights to their own healthcare decisions, and we do whatever we can to alleviate patient suffering, whether or not a cure is possible.

We must never again lose our way as a profession, and grounding our practice of medicine on these ethical principles will ensure the errors of the past three years are never repeated.

For what does it truly mean to be a doctor? I believe it is an unwavering and conscious acknowledgement that it is a privilege and honour to hold this position of trust and regard. A commitment to lifelong learning means we recognise that we are far from having all of the answers, that we reflect upon and learn from the lessons of history and we remain ever cognizant of the most important lesson of all – *that the science is never settled.*

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Principleless, Panicked and Power-Hungry: The Three Ps of Society's Elites During COVID

James Allan

It is important to admit when one has been wrong, and more so when one has been badly wrong. So let me start with myself. I go back to the years before the COVID pandemic. For a long-time part of my work-related, peer-reviewed legal writings had focused on the failings around the English-speaking world of bills of rights and of the judges – committees of unelected ex-lawyers if we wish to be precise – and, indeed, of the lawyerly caste itself. And I believed that things were only going to get worse. That was in part due to what was happening in the law schools around the anglosphere. Let us just say that the law schools, and universities more generally, were uncontestably getting more woke while viewpoint diversity was collapsing – just look at last year's Voice referendum and the fact that this country has some three dozen law schools yet the number of law professors across the whole country who came out openly against the proposal could be counted on one hand, one machine operator's hand in fact. But the country as a whole voted nearly 61 percent 'No'. In short, I was a fully signed-up member to the well-known sentiment that William Buckley had conveyed some years back when he said that he would rather be governed by the first 2,000 people in the Boston telephone directory than by the Harvard University faculty. For me, make that also the lawyerly caste that gives us our top judges. Put differently again, I was no great fan of juristocracy or of kritarchy or of lawyers as a group when it comes to driving public policy.

But before 2020 I had been quite a big fan of the doctorly caste. During my seven or eight years on New Zealand's University of Otago ethics committee, and from interactions more generally, I believed as a general proposition that doctors tended to focus on the evidence. That they did not tend to over-moralise and then attempt to impose their own moral worldviews on others. That they were better at standing up to groupthink and panic, and certainly better than the lawyerly caste. They put a hefty weight on individual autonomy, sometimes through the prism of the doctrine of 'informed consent' (about which I have grave doubts, as it happens, since ten plus years of education is really not able to be summed up in a ten-minute little overview so the patient can give 'informed' consent – the proper question to the doctor is 'what would you do if this were your son?') but nevertheless I reckoned doctors valued individual autonomy and a large degree of patient choice. They also, as an aside of sorts, seemed to me to take a real interest in the arts and literature in a way that is dying out in the universities – including in those parts of our universities supposedly devoted to them such as history, literature, classics, even philosophy and which are

dying out in part because the academics who staff them want to deconstruct and woke-ify even their own fields of expertise. Still, and in summary, I was big fan of doctors and the doctorly caste. I certainly thought that as a group they were better than the lawyers.

And here's where we come back to my starting claim, the importance of admitting when one has been wrong. Because let's face it. Boy, was I wrong about doctors! The pandemic and COVID plainly showed the preponderance of them, as a class, to have been as pusillanimous, panicked and even principleless as the rest of our elites. Let us take the risk of having all of our blood pressure readings go through the roof and recall the nearly three years of governmental thuggery, heavy-handedness, imposition of idiotic and often irrational rules and resort to lockdown lunacy – not to mention that those imposing these sometimes inane and often unprecedented public health measures virtually never paid the costs of what they were imposing. The police heavy-handedness verging on thuggery did not affect them. The school closures that shut down schools in a way that will see many children, especially the poor ones, disadvantaged for life did not much affect them. In late March, 2024, a new study out of Stanford University's Hoover Institute came out and found that the total cost to the US economy of the educational loss from COVID school closures will be US$31 trillion, leave aside that the closures were completely needless and ineffective at preventing COVID transmission. There will be a proportionally enormous cost here in this country. And don't forget that Australia's educational results pre-COVID were already woeful – we scored below Kazakhstan – so it's not as though we could afford any drops in scores and attainment, let alone precipitous ones. In addition to the police thuggery and school closures the people who brought us lockdowns did not pay the costs of devastating the small business sector. Somehow that seems worse when it is a supposedly right-of-centre political party doing the devastating of its core constituency in favour of the public service and while fostering an ongoing 'work from home' mindset across society that has gutted productivity – no serious person really believes that working from home, in general terms, produces as much as working from the office – and that led to last year's biggest drop in living standards in this country in decades. Nor did a single public health type or politician or top bureaucrat take a big pay cut, or even a small one, all while seemingly flipping coins to decide which were, and which were not, essential businesses. Let us not forget that while doing all this they were mouthing the inane, false (but rhetorically effective) phrase 'we're all in this together', a phrase that was factually wrong on all sorts of levels including poor *versus* rich, young *versus* old, and private sector *versus* public sector. Basically, the lockdown imposers had no skin in the game, to borrow a phrase from Nassim Taleb. They did not bear the costs of their decision-making. If they had, we would have had different, more liberal decisions.

Or what about the sort of massive government spending and increased debt and all the money printing during the lockdown lunacy? These measures effectively – in part via asset inflation – transferred huge wealth from the young to the old and from the poor to the rich. The pandemic years were the best years ever to be a billionaire. Again, the decision-makers had no skin in the game. Or what about, in a comparative blink of the eye, throwing away everything I had ever heard about the importance of informed consent during my years on a university ethics committee, in order to push vaccine mandates? All in all, these years amounted to 'the biggest inroads on our civil liberties in at least two hundred years' to paraphrase the retired UK Supreme Court judge Jonathan Sumption.

Which takes us back to doctors. The pandemic response was largely brought to you by public health types and by modellers. Imperial College's Neil Ferguson was the modeller who years earlier had given us modelled predictions as regards BSE ('mad cow disease') and foot-and-mouth disease that

grossly over-estimated everything – by orders of magnitude. This was well-known at the start of the COVID pandemic. Yet it made no difference at all to the British and American governments' willingness to treat Professor Ferguson's forecasts wholly unsceptically and almost as holy writ. Apparently hugely over-estimating what the actual deaths will turn out to be, however repeatedly, does not affect one's career as a feted epidemiological modeller one iota; it seems, in fact, to bolster one's position and burnish one's credentials. Perhaps, though, if instead of over-estimating actual outcomes by orders of magnitude one were to under-estimate by just one death, well then we'd see some ramifications.

I need also to mention the incredible inroads into free speech and the marketplace of ideas during the pandemic-censorship, shadow bans, social media blackouts, the legacy press operating more as a latter-day *Pravda* running the lockdownista line on everything and without even a hint of a trace of a soupcon of an echo of scepticism and questioning as regards that day's offerings from the public health cadre and government ministers. I even had a couple of published, peer-reviewed law articles offering a sceptical view of the pandemic response rejected for listing by Social Science Research Network (presumably because only public health types were then deemed suitable to comment on this fiasco, and only lockdown cheerleader ones at that). Or consider the vitriolic response to anyone who suggested that the virus that was found a few hundred yards from the front door of a laboratory – the only known lab in that country – doing research on that sort of virus might have actually escaped from that lab. 'Racism' was the accepted line or response from our elites, along with mocking anyone who suggested this as the source. Even a former head of MI5 was censored and banned on social media. Or remember how the three authors of the Great Barrington Declaration were treated by their university colleagues, by the press, by social media. Mr. Fauci called these three 'fringe epidemiologists', although one day before the pandemic started Professor Sunetra Gupta of Oxford University would have been widely picked as the world's most eminent epidemiologist. And the other two would have made the top ten list, those two being Professor Jay Bhattacharya of Stanford University and Professor Martin Kulldorff of Harvard University (then, not now, as Harvard recently fired him for being right about everything). During the frenzied panic and demand for conformity of the lockdown mania years even the most credentialled people in the world were censored, shadow-banned and threatened with losing their jobs if they proffered an opinion outside the government and public health line. So much for any concern about free speech. It was even a political party with the name 'Liberal' and a Prime Minister Morrison that to their eternal shame offered up the first iteration of the free speech suppressing and truly woeful ACMA bill, the one that uses the bogus notions of misinformation and disinformation to try to put up a privileged set of people who will tell us what is and is not true – despite the fact that Professor Bhattacharya maintains to this day that the biggest source of disinformation throughout the pandemic was government. These are bleak times for freedom of expression.

And so, being sufficiently depressed, we are nearly ready to turn to the occupations and castes who in general terms were principleless, panicked and power-hungry. These were the various types of elites who let us all down so badly during the pandemic in this country and across the democratic world outside of Sweden, Florida, South Dakota and a tiny few other jurisdictions. First, though, let me just pre-emptively deal with a response one hears regularly. This is the line that goes something like: 'Well, yes, in retrospect we made a fair few errors but at the time, in conditions of uncertainty, we made the safe, responsible choices that uncertainty demanded.' This is simply wrong. It is public policy nonsense, in fact. Indeed, right from the start it seemed silly to me, verging on crazy, to think that in conditions of great uncertainty what we ought to do is to

proceed directly to some version of the precautionary principle on steroids, thereby mimicking the authoritarian response of the Chinese politburo – and in the process throw away a hundred years of data that informed the then pandemic plans of the British government (and the WHO for that matter) and that unambiguously rejected lockdowns. The smart response in an information vacuum is to carry on making changes at the margins to protect those most at risk, and at the same time waiting for more information. This is how virtually all of us behave all the time in general life. Nor do we focus obsessively on just one cause of death – let us say from car accidents – and so impose 5km/h speed limits that would undoubtedly save a decent number of lives currently lost in car crashes, but at the same time cause markedly more deaths (rising to myriad more) through returning us all to the Middle Ages in terms of being able to move goods and people around efficiently. And anyway, from very early on it was known that this virus was over a thousand times more deadly to the very old than to the under thirties. In most countries, for most of the pandemic, the average age of those dying from COVID was over the country's life expectancy. For governments to proclaim that 'we are all in this together' was not true in any sense that could lead to the sort of policy response we saw everywhere in the democratic world outside of Sweden, Florida, South Dakota and a few other outliers that got their responses more or less correct (a fact that today's cumulative excess deaths data, from start of the pandemic to today, bring home in the bluntest fashion going). Put directly, nothing that we knew in March 2020 justified going down the incredibly authoritarian, 'Let's run government on the Chinese Politburo model' path that our elites opted to take. It was not caution. It was stupidity, a complete lack of commitment to both the liberal and the democratic components of 'liberal democracy', an incredible naivete about how handing huge, unfettered power to government and public health cadres affects the likelihood of their ever-confining lockdowns to just a fortnight, and – let's be honest – an awful lot of cowardice on the part of an awful lot of people.

And lest anyone thinks this is all pure hindsight on Allan's part, I will remind doubters that from virtually day one this native born Canadian, who has lived in Australia for two decades, was an open sceptic of the lockdowns in the pages of the *Spectator Australia*, the British *Lockdown Sceptic* website (now *Daily Sceptic*) and once or twice in *Law & Liberty* in the US and in *The Australian* here. In fact, it was that early scepticism that led me to meet the incredibly insightful Ramesh Thakur, also published in this conference, as we were fellow travellers right from the start. I think we got just about everything right, if I do say so for myself and Ramesh.

I now comment quickly on the various castes most responsible for the panicked, power-hungry, pusillanimous and principleless (four Ps, not three) response to COVID in Australia and around the non-Swedish, non-Florida democratic world. This is highly contestable but in terms of the Top Five of occupations as regards being panicked, principleless, power-hungry and pusillanimous my rankings, finishing with the very worst occupation and so starting with the least worst, now follow:

5th Worst: Lawyers, Judges and the Lawyerly Caste. Yes, there was next to no chance litigants anywhere in the democratic world were going to be able to use a bill of rights to roll back thuggish, heavy-handed governmental COVID regulations through the courts. I said so in print at the start of the crisis and I believe events have proved that true. My take was that we would have to wait till everyone calmed down and the panic subsided and then it would be possible to see the judges discover a tiny bit of a willingness to overturn some of these rules and regulations. But as far as the COVID years were concerned the entire edifice of human rights law, and all its accoutrements, was totally useless. Worse than useless in fact, thereby going a long way to proving the enervated,

emasculated worth of bills of rights. You buy one and you are simply buying the views of the unelected judges. And they panicked as much as the rest of our elites. But the lawyers and judges come least bad in my list because I do not think we really should even want to live in a world where the lawyerly caste could decide these sorts of issues through the courts. And that is true even when we strongly, even vociferously, disagree with what the government is doing, as I did throughout the pandemic. The remedy here had to be political. Elect a Ron DeSantis or the Social Democratic government of Sweden and let them stand up to the panic and show what should be done. There would be nothing left for democracy if a handful of unelected judges could dictate policy here. So only fifth worst.

4th Worst: Here I put the university caste, including the modellers at Imperial College. Yes, many of them disgracefully imposed vaccine mandates (explicitly or implicitly). Yes, the treatment of your Bhattacharyas and Guptas at the world's top universities was shameful. But the competition here is fierce so I score them just outside a podium finish.

3rd Worst: Doctors get the bronze medal for the four 'P's of being panicked, pusillanimous, principleless and power-hungry. Sure, the public health wing of the doctorly caste carried more than its fair share of the load here. And maybe this scoring was a little affected by our disappointment with an occupation that had looked so good before COVID. But it's more likely that the gold and silver positions were denied the doctors because at least a noticeable chunk of them were dissidents and sceptics, including the terrific Anders Tegnell. Some even lost their practising certificates because of their bravery. And that would influence anyone's scorecard.

2nd Worst: This was a tough call. But in the end I gave the silver medal for most pusillanimously panicked and power-hungry to the politicians. A good few who had come into politics preaching their commitment to freedom and to the individual showed that these protestations weren't worth the paper they hadn't been written on. They were too lazy and too fearful to do their jobs the way Governor DeSantis of Florida did. Or the way the Swedish government did. In fact, they shamed themselves while pretending they had implemented good policies. They deserve to be voted out everywhere.

Absolute Worst: The Jimbo gold medal goes to the journalistic caste. Here is a profession or occupation supposedly dedicated to questioning power and to bringing a sceptical mind to all assertions but especially those by government. It is a job that values an open mind and not taking on trust what the elites are telling them. It is an occupation that is meant to be fearless, not cravenly fearful. So in a close finish it is the journalists who get the gold medal for being pusillanimous, panicked and principleless.

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