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Gene-based COVID-19 vaccines: Australian perspectives in a corporate and global context

Peter Rhodes [a,1], Peter Parry [b,c,*]

[a] Independent Researcher, Gonville & Caius College, University of Cambridge, UK, (alma mater), Consultant Specialist Anaesthesia and Intensive Care Medicine, Brisbane, Queensland, Australia
[b] Children's Health Research Clinical Unit, Faculty of Medicine, The University of Queensland, Brisbane, Queensland, Australia
[c] Department of Psychiatry, College of Medicine and Public Health, Flinders University, Adelaide, Australia

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ABSTRACT

Pandemic management requires societal coordination, global orchestration, respect for human rights and defence of ethical principles. Yet some approaches to the COVID-19 pandemic, driven by socioeconomic, corporate, and political interests, have undermined key pillars of ethical medical science. We explore significant mistakes that may have occurred in recent pandemic control, in order to better navigate the future. Within corporate and geopolitical infrastructure, we review the COVID-19 pandemic and novel mRNA and viral-vector DNA COVID-19 vaccines, deployed by wealthy western countries. The pandemic, together with rollouts of unconventional, gene-based vaccine technology, has provided experimental opportunity to engineer social control of entire populations. The haste and scale of development, production, and distribution of these new pharmaceuticals is unprecedented in history. Key phase III clinical trials for these products are yet to be fully completed, despite administration to billions of people. Mass vaccination of workforces has been mandated, and vaccine mandates correlate with excess mortality. Many independent data sets concur - we have experienced a pandemic of viral illness, followed by a pandemic of vaccine injury. For Australia, matters have operated the other way around. Vaccination followed later by the main viral wave. Australian excess mortality data correlates with this. Neither risk nor cost can justify these products for the vast majority of people. Lack of efficacy against infection and transmission, and the equivalent benefits of natural immunity, obviate mandatory therapeutics. With the many gene-based pharmaceuticals planned, a new era of pathology lies ahead. We should pause, reflect, and reaffirm essential freedoms, welcome the end of the COVID-19 pandemic, embrace natural immunity, and lift all mandated medical therapy.

1. Introduction

Capitalist principles of competition, efficiency and profit are supportive of innovation and knowledge growth. Unfettered, they may impinge on other human value systems. They must find balance within strong regulatory frameworks, to protect human rights and fundamental ethical principles.

In public health policy, this interplay is completely dependent on the evidence base, which in turn relies upon accurate, transparent data available for open scientific debate, subservient to the timeless pillars of medical ethics - beneficence, non-maleficence, autonomy, and justice.

Sadly, history is replete with examples in which this balance of optimistic capitalist risk and protective medical ethics has not been achieved.

Sociopathic character traits are well recognised to facilitate control, leadership, capitalist venture, and success in many areas of our highly competitive world, yet they may strain or collide with the realm of humane ethics. Perhaps nowhere are such qualities more in need of restraint by evidence-based oversight and open scientific debate, than in the vast corporate structures that have come to dominate the pharmaceutical industry and medical industrial complex [1,2].

Additionally, while threats to human societies have warranted coordinated, hierarchical, even autocratic responses, such collectivist approaches are not easy to harmonise with ethical principles and the rights

* Corresponding author at: Children's Health Research Clinical Unit, Faculty of Medicine, The University of Queensland, Brisbane, Queensland, Australia.
E-mail address: p.parry1@uq.edu.au (P. Parry).
[1] retired

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of the individual. They may prove counterproductive when decisions are not grounded in the best possible data.

The COVID-19 pandemic, together with social lockdowns and the rollout of novel gene-based mRNA and viral-vector DNA vaccine technology in wealthy countries, allowed for social control of entire populations [3]. It is increasingly apparent that these health policies, with mandates for "Experimental Use Authorisation" (EUA) and "provisionally authorised" experimental vaccines, have not taken full account of the extensive evidence for the pathology caused by the vaccines.

These novel COVID-19 gene-based agents have distinctive features that we now consider in some detail. Appreciation of these characteristics is important to understand their place in the recent pandemic and their contribution towards excess morbidity and mortality.

2. Essential features of novel Gene-based mRNA and viral-vector DNA agents

2.1. Vaccine

'Vaccine' as a broad and familiar term conveys clear implications of safety and protection. Traditional technologies have utilised viral antigens, protected from infection and transmission of disease, and held excellent safety records.

The term vaccine thus carries reassurance and is remarkably prejudicial when used for novel and experimental agents that deploy gene codes. It immediately implies "safe and protective", or "safe and effective", a narrative now understood, in the case of these gene-based products, to be mistaken.

Efficacy has been inconsistent with the traditional sense of 'vaccine', and failure to prevent infection or transmission of the COVID-19 variants eventually led the US Centers for Disease Control and Prevention (CDC) to reinvent their definition for 'vaccine' [4].

In technical, pharmacological design terms, these products are accurately described as "pro-drugs" [5]. Genetic code must enter human cells and undergo translation before intended active outcomes unfold. Unintended consequences are thus possible, as recent reviews attest [6,7].

2.2. Novel

These products are novel. Until as recently as 2020, their technology had been restricted to rare conditions, in which widespread production of foreign proteins could combat uncommon hereditary disease [8]. For the wealthy western nations who have utilised these novel agents in particular, the haste and scale of development, production, distribution, and administration is unprecedented [9].

3. Experimental

These products are also experimental. Broadly, all pharmaceutical products are continuously experimental, observed and tracked by pharmacovigilance systems worldwide.

Specifically, clinical trial work for these products is incomplete and cannot be properly completed given the dissolution of the placebo arms of these studies, despite interim publication in *The New England Journal of Medicine (NEJM)* [10–15].

Concerns exist over the transparency of trial data. Available data from Pfizer and Moderna trials listed at clinicaltrials.gov have been evaluated (NCT04368728 and NCT04470427) [16]. As originally published in *NEJM,* the Pfizer and Moderna mRNA COVID-19 vaccine interim phase III clinical trial reports suggested a favourable risk/benefit ratio. But based on exactly the same data, Fraiman and colleagues, publish in *Vaccine* that:

> 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.

From which they conclude a need for formal risk-benefit analyses.

The FDA has been publicly criticised for their slow response to follow up potential increases in serious adverse events in elderly people related to Pfizer's mRNA COVID-19 vaccine [17].

There are even indications that initial clinical trial work, published in the *NEJM*, may have been performed with mRNA products that differed from those eventually mass-produced [18,19].

With efficacy data from the Pfizer COVID-19 booster trial, Bardosh et al. found that to save one COVID-19 hospitalisation (not necessarily ICU or death) amongst university-aged students, 22,000–30,000 would need vaccination. But a rate of 98 serious to 18 very serious vaccine related adverse events would occur [20].

3.1. Post covid vaccine syndrome (PCVS)

Many studies demonstrate overlap between severe COVID-19 viral illness and gene-based COVID-19 vaccine injury [6,7]. This literature indicates toxicity of the spike protein produced by vaccine genetic code, of the lipid-nanoparticle carrier and also possibly from contaminants. There is a need for official terminology to describe the varied adverse event syndromes that occur post-vaccination, both acute and chronic, and "Post Covid Vaccination Syndrome" (PCVS) has been suggested [7].

3.2. Batch toxicity

The phenomenon of batch toxicity may involve variation in quality. Correlation exists between adverse events and product batch numbers. Most severe injuries and deaths trace to a small minority of batches. Adverse events were lower with batches aged from manufacture date (see: https://howbadismybatch.com/adversesize.pdf). These important observations have been recently confirmed by peer-reviewed research of Danish adverse events reported to the European Medicines Agency pharmacovigilance database that showed just 4.2% of batches correlated with 71% of serious events, while 31% of batches had virtually no serious adverse event reports [21].

Data presented by Pfizer shows significant batch variability in amount and quality of mRNA [18,19]. The upscale to commercial quantities is officially called 'Process 2′, as a contrast to the initial process used to supply clinical trials. Process 2 involves large vats of E. Coli which must be purified and decanted into small vials. This has raised questions about variable dilution and dosage of active mRNA, lipid-nanoparticles and fragments of mRNA (and DNA) [18,19].

Concerns of vaccine contamination and quality variation were raised early in the pandemic [22,23]. In FOI released minutes from the Australian TGA Advisory Committee on Vaccines (19 January 2021, prior to public rollout of the Pfizer vaccine) [24], it is noted that:

> Residual DNA should be part of batch testing; increased DNA contamination has the potential to increased [sic] reactogenicity. (p. 6).

To our knowledge these tests were never performed.

More recently, whole plasmid DNA and dsDNA linearised fragment contamination has been reported with high reproducibility by several laboratories around the world, at concentrations that exceed official FDA safety limits, and which raise concerns about potential genomic integration and oncogenic potential [25–28].

Violation Tracker Industry Summary Page

Industry: pharmaceuticals
Penalty Total since 2000: **$113,889,301,079**
Number of Records: 1,217
Note: The totals include only those entries matched to a parent company. The industry designation is the primary one for the parent's operations overall. The totals are adjusted to account for the fact that each parent's entries may include both agency records and settlement announcements for the same case; or else a penalty covering multiple locations may be listed in the individual records for each of the facilities. They are also adjusted to reflect cases in which federal and state or local agencies cooperated and issued separate announcements of the outcome. Duplicate or overlapping penalty amounts are marked with an asterisk in the individual records list below.

TOP 10 CURRENT PARENT COMPANIES	TOTAL PENALTY $	NUMBER OF RECORDS
Johnson & Johnson	$24,347,639,699	85
Pfizer	$10,945,838,549	96
Merck	$10,654,360,581	86
Teva Pharmaceutical Industries	$9,771,817,455	92
GlaxoSmithKline	$9,572,803,406	50
Purdue Pharma	$9,278,372,787	11
AbbVie	$7,460,350,024	75
Takeda Pharmaceutical	$3,966,166,447	31
Novartis	$2,951,229,570	43
Endo International	$2,847,090,667	29

Fig. 1. : Total of fines levied against the pharmaceutical industry in criminal court cases from 2000 to August 2023.
Source: https://violationtracker.goodjobsfirst.org/summary?major_industry_sum=pharmaceuticals.

Violation Tracker Current Parent Company Summary

Current Parent Company Name: Pfizer
Ownership Structure: publicly traded (ticker symbol PFE)
Headquartered in: New York
Major Industry: pharmaceuticals
Specific Industry: pharmaceuticals
Penalty total since 2000: **$10,945,838,549**
Number of records: 96

TOP 5 OFFENSE GROUPS (GROUPS DEFINED)	PENALTY TOTAL	NUMBER OF RECORDS
safety-related offenses	$5,637,014,255	15
healthcare-related offenses	$3,373,675,000	10
government-contracting-related offenses	$1,148,191,225	20
competition-related offenses	$775,381,952	14
environment-related offenses	$5,629,098	26

TOP 5 PRIMARY OFFENSE TYPES	PENALTY TOTAL	NUMBER OF RECORDS
drug or medical equipment safety violation	$5,636,840,000	9
off-label or unapproved promotion of medical products	$3,373,675,000	10
False Claims Act and related	$1,148,191,225	20
price-fixing or anti-competitive practices	$680,465,384	8
Foreign Corrupt Practices Act	$60,216,568	3

Fig. 2. : Fines levied against Pfizer and its subsidiary companies from 2000 to August 2023, top offences listed.
Source: https://violationtracker.goodjobsfirst.org/parent/pfizer.

3.3. Corporate integrity and data transparency

Concerns exist related to data transparency, access to raw data, and the potential for hidden data, deleted data or indeed failure to record data [29]. The track record of the pharmaceutical industry in these areas has been weak [30]. Internal industry documents released after criminal convictions (Fig. 1 and 2) reveal a systemic pattern geared towards 'marketing-based medicine' that is at odds with 'evidence-based medicine' [31].

Conflicted and circular relationships are rife within the corporate world. Pharmaceutical giants, media outlets, charities and academic institutions work in concert to orchestrate public opinion. Such conflicts of interest may have spilt over to the regulatory agencies themselves [32]. A Pfizer pharmacovigilance report from December 2020 to February 2021 was publicly released by FOI in 2022 [33]. The US Food & Drugs Administration (FDA) had pleaded in Court that such information be withheld for up to 75 years [34]. In less than three months, the summary table noted 42,086 people had reported adverse events, many had not resolved and 1223 were recorded as fatal. Fig. 2.

The medical profession practices under an "illusion of evidence-based medicine" [35]. The evidence base for clinical and public health decisions has long been corrupted, as described by Marcia Angell, former chief editor of *The New England Journal of Medicine* [36] and Richard Horton of *The Lancet* [37]. The former *BMJ* chief-editor Richard Smith describes medical journals as "an extension of the marketing arm of pharmaceutical companies" [38].

Distorted data is regularly published in medical journals. A meta-analysis found across a range of specialties that a 4-fold odds ratio exists for a sponsored drug trial to find in favour of the drug versus an independent trial for the same agent [39]. The global pandemic response in wealthy western countries has relied on clinical trials published by wealthy sponsors.

Three *BMJ* senior editors in an article titled "COVID-19 vaccines and treatments: we must have raw data, now", have called for a full release of anonymised clinical trial data, decried the slow release of data by the manufacturers Pfizer, Moderna and AstraZeneca, and noted loss of trust "in the system" [29].

3.4. Corporate funds for vaccine mandates

Investigative journalist Lee Fang has tracked Pfizer's financial disclosures to discover that in the first 6 months of 2021 the company gave many $millions to more than 500 medical associations, universities, and community organisations, often for such groups to lobby for COVID-19 vaccine mandates. Virtually none of the organisations disclosed their links with Pfizer [40].

Consequences of the corruption of Medicine and Academia through conflicts of interest with the pharmaceutical industry are enormous in both economic and health impacts.

3.5. Mandate of mRNA and viral-vector DNA COVID-19 agents

Evidence indicates that these agents should not have been mandated. Ethical norms established in the wake of World War II have been contravened. Such ethical codes, enshrined in human rights declarations, indicate that coercion must not be brought to bear against informed, educated, individual personal non-consent, hesitancy, or refusal [41,42]. These have been incorporated into immunisation handbooks and guidelines such as the Australian Immunisation Handbook [43].

To mandate experimental medical therapy of any kind is to violate fundamental individual human rights of autonomy, and to trample historic professional relationships between individual patients and the medical profession.

Ethical implications are profound. While COVID-19 remains of significant concern for our very elderly and our frail, it is of negligible lethality in most age groups. To violate protective professional relationships, with an autocratic mandate for a novel, experimental product, targeted against a virus that is ever less clinically relevant, could be considered unethical.

Current adverse event pharmacovigilance data, global excess mortality data, and the suppression of this information should cause concern. These gene-based therapeutics are potential major contributors to these data [44]. Yet corporate attitudes are dismissive. Perhaps indicative of an agenda of exuberant optimism or even one of wilful blindness [45].

3.6. Australia as a remarkable showcase

In many countries, the COVID-19 pandemic came well before the introduction of vaccines and mandates. Thus, for such nations, excess mortality data needs to be understood in the context of long-term averages, then a viral illness, and then finally the introduction of novel therapeutics.

But in Australia, matters operated the other way around. Social lockdown and vaccination preceded the main viral pandemic.

Australia has therefore provided a case study for COVID-19, vaccine rollouts, adverse events, and excess mortality. Most COVID-19 related deaths in Australia occurred between September 2021 and September 2022. Prior to this, COVID-19 related deaths were below 1000 for 2020, and only 1300 for 2021. Yet over 10,000 excess deaths occurred in the country in 2021 (for a population of 25.5 M). Therefore around 90% of excess deaths were non-COVID deaths. Australian COVID-19 vaccination campaigns began pre-pandemic, in March 2021, shortly before increased excess deaths from May 2021 onwards.

Information from the Western Australia Vaccine Safety Surveillance (WAVSS) annual report 2021 has been released and notes 264 adverse events per 100,000 population, to be compared with a 'norm' of 11/100,000 for other vaccines [46]. More than a 20-fold increase. The WAVSS report states, that:

The number of adverse events (after) immunisation reported to WAVSS was significantly higher in 2021 than in previous years (10,726 compared with an average of 276 per year for the 2017–2020 period) due to the introduction of the COVID-19 vaccination programme.Fig. 3.

These numbers should be understood in the context of under-reported pharmacovigilance data – a well-recognised and widely accepted phenomenon [44,47,48]. Both the *active* surveillance US "V-Safe" [49] – obtained via FOI court order [50], and Australian "AusVaxSafety" [51] surveys reported much greater numbers of adverse events to the COVID-19 vaccines than the *passive* pharmacovigilance of the US CDC's VAERS (Vaccine Adverse Events Reporting System) and the Australian TGA's DAEN (Database of Adverse Events Notifications). Despite 983 death reports to the DAEN, the TGA officially only recognised 14 of them, as of April 2023 [52].

The US VAERS database records 35,911 death reports from the COVID-19 vaccines through 11 August 2023, which is triple the number of death reports from all vaccines combined since 1990. It also reveals that death report rates per dose in the USA alone since 2006 for all vaccines are orders of magnitude higher for the gene-based COVID-19 vaccines and this is not a factor of more doses due to mandates (Fig. 4).

Failure of authorities to act may represent the phenomenon of "wilful blindness" [45] to the red flags of surveillance. Coupled with mandates and other government attitudes that have ridiculed, bullied, and coerced the vaccine injured, one arrives at a hypothesis of either negligence, or of suppression driven by fear of political embarrassment [53].

3.7. Youth

Of still greater concern, these products have been mandated for the young, fit, and healthy in the workplace, with disastrous consequences for some, whose lives have been cut short.

Mass vaccination has been forced upon the millennial generation and

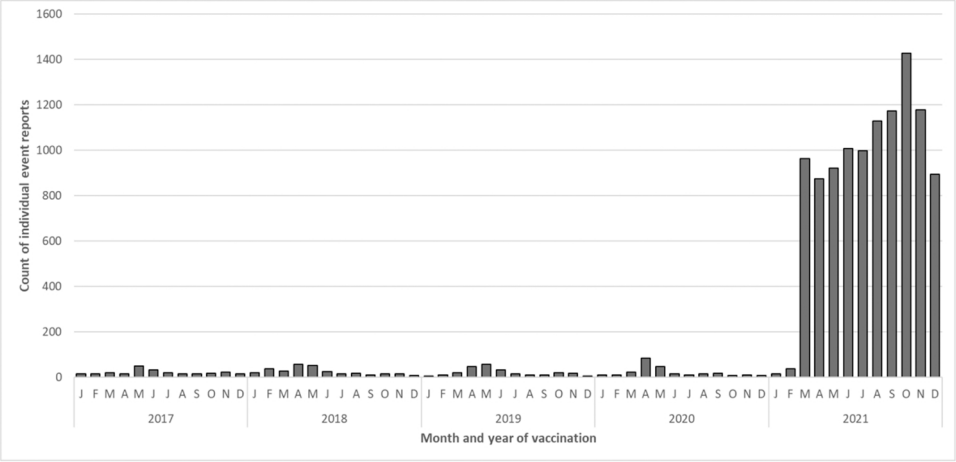

Fig. 3. : Western Australian Vaccine Safety Surveillance (WAVSS) Report for 2021: Page 8, Fig. 2: Adverse events following immunisation reported to WAVSS by month, 2017–2021, excluding active surveillance reports for routine vaccination adverse events.
Source: https://www.health.wa.gov.au/~/media/Corp/Documents/Health-for/Immunisation/Western-Australia-Vaccine-Safety-Surveillance-Annual-Report-2021.pdf.

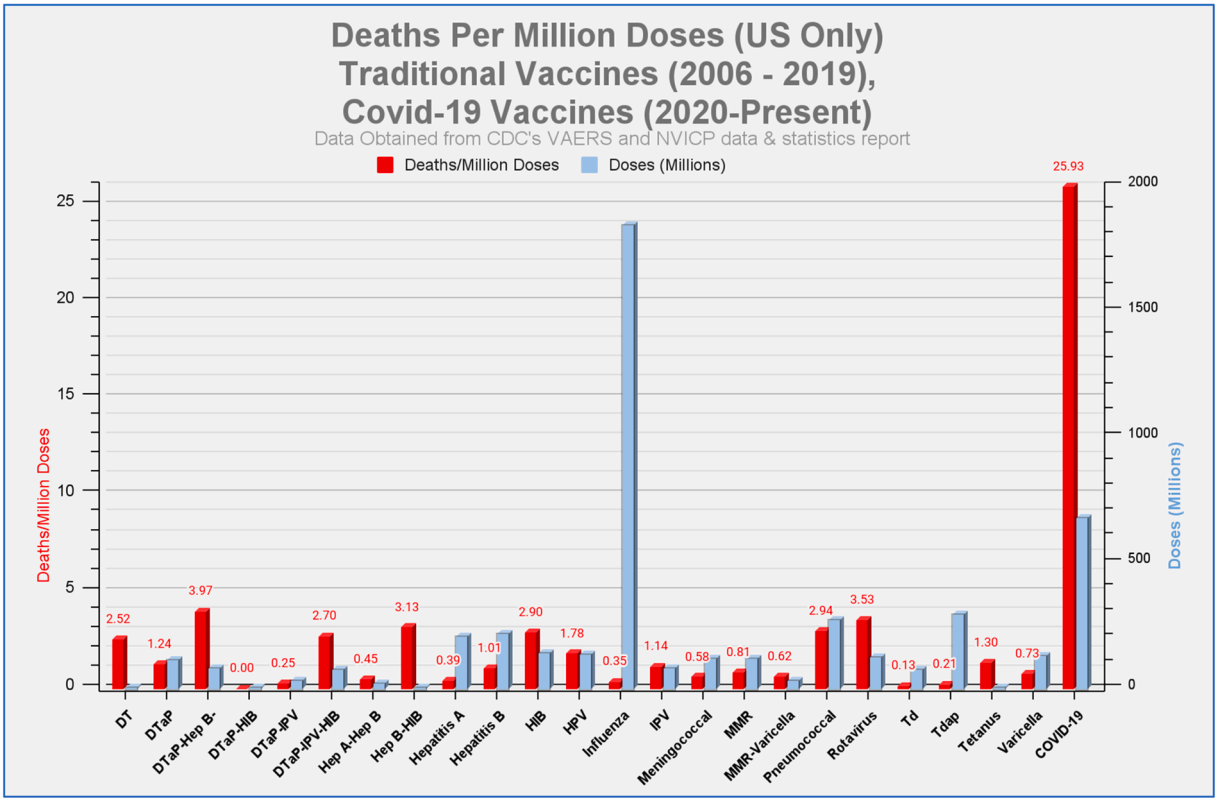

Fig. 4. : Rate of death reports per million doses associated with vaccines to the US CDC's VAERS pharmacovigilance database from 2006 to 11 August 2023.
Source: VAERS Analysis: https://vaersanalysis.info/2023/08/18/vaers-summary-for-covid-19-vaccines-through-8–11–2023/.

mandates correlate with excess mortality [44]. In the USA, all-cause mortality increased contemporaneously with imposition of COVID-19 vaccine mandates. Independent datasets concur [44]. European, international, and global datasets also concur and demonstrate two clear phases of excess death - the COVID-19 pandemic (Year 1) – and mass vaccination (Year 2 and beyond). This can be fairly stated as two pandemics, reversed in order in Australia.

We have a pandemic of the vaccinated. We must open our eyes to this global tragedy.

Myocarditis in the young and healthy is of particular concern. Prospective studies of myocarditis / cardiac inflammation (mostly subclinical) found a 2.3% rate after the second Pfizer mRNA vaccine in adolescents in Thailand [54], a 2.8% rate after the Moderna booster dose in Swiss healthcare workers, [55], and a 0.62% rate after the second Pfizer booster dose in Israeli healthcare workers [56], though higher rates of chest pain (3.7%) and palpitations (2.16%).

Even mild subclinical myocarditis is of concern as a 12-month follow-up study in Hong Kong showed 58% had late gadolinium enhancement, thus possible myocardial scar tissue, arrhythmogenic foci and potential for ventricular fibrillation [57]. Italian case reports show

post-vaccine myocarditis recurs after apparent "full clinical recovery" [58].

Recent histopathology has now clearly demonstrated involvement of vaccine spike protein in this dangerous inflammatory condition [59].

All-cause mortality data continue elevated in many countries to this day.

Youth are at greater risk of harm from these agents than the elderly, yet they are at negligible risk from the COVID-19 viruses themselves and show robust natural immunity.

3.8. Natural immunity

It may not be commonly considered, but natural immunity is a form of individual freedom. It is a natural and profoundly important aspect of our health. Natural immunity is also the context in which all vaccine development should take place. The principal therapeutic aim must be to better what nature provides.

Natural immunity for the SARS-CoV-1 (one) outbreak in 2003 proved long-lasting [60].

Most recently, an extensive systematic review and meta-analysis by the COVID-19 Forecasting Team published in *The Lancet*, estimated protection from past infection by variant type and by time since infection. Sixty-five studies from 19 countries were included and the summary analysis suggests the level of protection afforded by past infection by variant and over time is at least equivalent if not greater than that provided by two dose mRNA vaccines of Moderna and Pfizer [61].

Poor vaccine efficacy against infection and transmission, coupled with equivalent or greater benefits of natural immunity, forfend any rationale for government mandated therapy. While scientifically it is no surprise to find the human immune system equal to or better than a newly experimental mRNA-based agent, we have politically been afforded two opportunities by the science.

The first would be to champion the benefits of natural immunity and to welcome this highly protective and natural response. A form of freedom.

The second would be to lift government mandated medical therapy for all employment sectors still subjected to this.

3.9. Conformity, official narrative, and behavioural Insights

Conformity and authority biases are adaptations to threat. A unified response to a dangerous virus is laudable, if based on the best evidence in science. Unfortunately, the broadcast official narrative of 'safe and effective' COVID-19 gene-based therapeutics was based on flawed data [16].

The British government Behavioural Insights Team (BIT), the "Nudge Unit" [1], was reinforced by the "Trusted News Initiative", a collective of global media led by the BBC, Reuters, and most major news and social media platforms [62]. To date the mainstream narrative has obscured the obvious – that if the spike protein is pathogenic as part of the virus, then it is likely to be pathogenic when produced by gene-based vaccines. Media discussion of gene-based COVID-19 vaccine pathogenicity has just begun. An article titled "The Spike" points towards the spike protein, whether replicated by the virus or by injected gene codes and notes, "scientists are sounding the alarm about the risks of both COVID and its cures" [63].

3.10. Future concerns, further mRNA technologies

Failure of agencies and governmental public health policies is now evident. Ebullient and optimistic corporate pharmaceutical forces, draconian vaccine policies, manipulation and repression of data, and censorship of contrarian evidence-based opinion, even if well-intentioned, have created an historic public health disaster.

Unnecessary layers of tragic complication have been added, well beyond the risks of the COVID-19 viral pandemic itself.

Still more remarkable, the individual person, with individual freedoms, rights, and bodily autonomy, is partially deleted from the new WHO amended version of their "Pandemic Preparedness Treaty" and the term "informed consent" does not appear [64]. A narrow and indeed elitist group may seek to decide on behalf of a subordinate majority.

With many gene-based therapeutic technologies planned, a vast new era of pathology may lie ahead, and pharmacovigilance will need to be heightened.

4. Conclusion

We are in a unique period of medical history. Central medical assumptions are threatened. Whether the morals and ethics of individualised care, localised professional relationships between patients and their doctors, or the right to open discussion and debate of raw data and transparent scientific literature. Data on vaccine related injury and excess mortality continue to mount. Mandates, if not lifted, will become a serious political embarrassment. A survey of ours, currently in preprint, is indicative of the harms that can be caused by mandated experimental vaccines [65]. With the significant expansion of gene-based technologies already visible ahead, it is high time to reaffirm previously established medical ethics and the freedoms of the human condition.

CRediT authorship contribution statement

Peter Rhodes: Conceptualization, Writing – original draft, Writing – review & editing. **Peter I Parry:** Writing – review & editing.

Declaration of Competing Interest

None.

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