

## *COVID-19 Modified mRNA “Vaccines”: Lessons Learned from Clinical Trials, Mass Vaccination, and Censorship by the Bio-Pharmaceutical Complex, Part 1*

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### Abstract

Our understanding of COVID-19 synthetic, modified mRNA (modmRNA) products and their public health impact has evolved substantially since December 2020. Published reports from the original randomized placebo-controlled trials concluded that the modmRNA injections could greatly reduce COVID-19 symptoms. However, the premature termination of both trials obviated any reliable assessment of potential adverse events due to an insufficient timeframe for proper safety evaluation. Following authorization of the modmRNA products for global distribution, problems with the methods and execution of the trials have emerged. The usual safety testing protocols and toxicology requirements were bypassed. Many key trial findings were either misreported or omitted entirely from published trial reports. By implication, the secondary estimates of excess morbidity and mortality in both trials must be deemed underestimates. Rigorous re-analyses of trial data and post-marketing surveillance studies indicate a substantial degree of modmRNA-related harms than was initially reported. Confidential Pfizer documents had revealed 1.6 million adverse events by August 2022. A third were serious injuries to cardiovascular, neurological, thrombotic, immunological, and reproductive systems, along with an alarming increase in cancers. Moreover, well-designed studies have shown that repeated modmRNA injections cause immune dysfunction, thereby potentially contributing to heightened susceptibility to SARS-CoV-2 infections and increased risks of COVID-19. This paper also discusses the insidious influence of the Bio-Pharmaceutical Complex, a closely coordinated collaboration between public health organizations, pharmaceutical companies, and regulatory agencies. We recommend a global moratorium on the modmRNA products until proper safety and toxicological studies are conducted.

**Keywords:** *adverse events, COVID-19 modified mRNA vaccines, COVID-19 registrational trials, immunity, serious adverse events, genetic therapy products, safe and effective, all-cause-mortality*

## Introduction

Knowledge concerning coronavirus disease 2019 (COVID-19) genetic “vaccinations” and their impact on disease and mortality outcomes has evolved substantially since the first rollouts in December 2020. Early investigations claimed these biologicals could prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Based on the first randomized controlled trials sponsored by Pfizer-BioNTech (New York, United States; Mainz, Germany) and Moderna (Massachusetts, US), a 95% relative risk reduction of symptomatic COVID-19 was announced (Polack et al., 2020; Baden et al., 2021). The overlapping relative risk finding between the two trials prompted the US Food and Drug Administration (FDA) to allow the use of the COVID-19 modified mRNA (modmRNA) products under Emergency Use Authorization on December 11, 2020, a decision that was followed by early unblinding and cessation of the trials (Singh et al., 2021).

Prior to the rapid authorization process, no vaccine had been permitted for market release without undergoing a testing period of at least four years, the record set by Merck & Co., Inc. (New Jersey, US) in 1967 with the development of the world’s first mumps vaccine (Kaplan et al., 1988). Pfizer’s vaccine (BNT162b2) completed the process in seven months. Previous timeframes for phase 3 trial testing averaged 10 years (Vaccine Research & Development, 2023). Health departments have stated that 10-15 years is the normal timeframe for evaluating vaccine safety (New York State Department of Health, 2023). With the COVID-19 products, safety was never assessed in a manner commensurate with previously established scientific standards, as numerous safety testing and toxicology protocols typically followed by the FDA were sidestepped (Altman et al., 2023; McCullough, 2023). Preclinical studies of the biodistribution and potential toxicities from repeated doses of the modmRNA product to simulate multiple modmRNA inoculations, all were circumvented to enable acceleration of the clinical testing (Wagner et al., 2021). Perhaps the most important trial benchmark obviated by the rapid authorization process was the minimum 6-12 month observation period typically recommended for identifying possible longer-term adverse effects in the intervention versus placebo groups (Wagner et al., 2021).

The previously established 10-15-year timeframe for clinical evaluation of vaccines was deemed necessary to ensure adequate time for monitoring the development of adverse events such as cancers and autoimmune disorders (Conklin et al., 2021; Alqatari et al., 2023). To be expeditious, the coordinators of Pfizer and Moderna trials prioritized symptomatic COVID-19 risk reduction over severe adverse events and mortality concerns. In retrospect, this was a grave misstep. Historical accounts bear witness to instances where vaccines were prematurely introduced to the market under immense pressure, only to reveal disabling or even fatal adverse events later on. Examples include: the 1955 contamination of polio vaccines, instances of Guillain-Barré syndrome observed in flu vaccine recipients in 1976, and the connection between narcolepsy and a specific flu vaccine in 2009 (Stratton et al., 2002; Buonocore et al., 2022; Greenstreet et al., 1984). Against this backdrop, it is not surprising that so many medical and public health experts voiced concerns about the COVID-19 modmRNA products having bypassed the normal safety testing process (Doshi, 2021a; 2021b; Thorp, 2020; Torrelee, 2020). For instance, the essay by Torrelee (2020) in the *British Medical Journal (BMJ)* observed logically that testing the modmRNA product’s efficacy with a short-term trial might only indicate short-term protection against COVID-19. Others warned that the expedited trials could overlook long-term adverse events or health consequences that might remain undetected until months or even years after the Emergency Use Authorization (Jiang, 2020). In a 2020 commentary for *The Hill*, McCullough referred to Operation Warp Speed as “one of the greatest gambles in

modern history” and predicted that the modmRNA products “will be hurried to market only to be partially effective and the uptake and population benefit will remain uncertain” (2020).

Political and financial incentives may have played a key role in undermining the scientific evaluation process leading up to the Emergency Use Authorization. Lalani and colleagues documented the major investments made by the US government well before authorization (Lalani et al., 2023). Even prior to the pandemic, the US National Institutes of Health invested \$116 million (35%) in the modmRNA technology, the Biomedical Advanced Research and Development Authority (BARDA) had invested \$148 million (44%), while the Department of Defense (DOD) contributed \$72 million (21%) to modmRNA product development. BARDA and the DOD also collaborated closely in the co-development of Moderna’s modmRNA injectable, dedicating over \$18 billion, which included guaranteed purchases of the modmRNA products (Lalani et al., 2023). This entailed pre-purchasing hundreds of millions of modmRNA doses, alongside direct financial support for the clinical trials and the expansion of Moderna’s manufacturing capabilities. The public funding provided for developing these products through Operation Warp Speed surpassed investments in any prior public initiative (Nayak et al., 2021). Once the pandemic was declared, \$29.2 billion (92% of which came from US public funds) was dedicated to the purchase of COVID-19 modmRNA products; another \$2.2 billion (7%) was channeled into supporting clinical trials, and \$108 million (less than 1%) was allocated for manufacturing and basic research (Lalani et al., 2023). This profuse spending of taxpayer dollars continued throughout the pandemic: BARDA spent another \$40 billion in 2021 alone (Biomedical Advanced Research and Development Authority, 2022).

Using US taxpayer money to purchase so many doses in advance would suggest that US federal agencies were strongly biased toward successful outcomes for the registrational trials well before they resorted to the Emergency Use Authorization process. Moreover, it is reasonable to infer that such extensive vested interests could have influenced the decision to prematurely halt the registrational trials. Unblinding essentially nullified the “placebo-controlled” element of the trials, eliminating the control group and thus undermining the ability to objectively assess the modmRNA products’ safety profile and potential serious adverse events. Thus, while the accelerated authorization showcased the government’s dedication to provide these novel products, it also raised concerns among many experts regarding risk-benefit issues and effectively eliminated the opportunity to learn about the potential long-range harms of the modmRNA inoculations. The political pressures to rapidly deliver a solution compromised the thoroughness and integrity of the scientific evaluation process while downplaying and obfuscating scientific concerns about the potential risks associated with modmRNA technology.

Problematic and flawed safety testing violated the usual regulatory approval standards and practices. Although we employ the terms “vaccine” and “vaccination” throughout this paper, the COVID-19 modmRNA products are more accurately termed genetic therapy products (Banoun, 2023). They are fundamentally different from traditional vaccines which rely on an inactivated or a weakened form of the pathogen. European regulations mandate the inclusion of an antigen in vaccines, but these immunogenic proteins are not intrinsic to the modmRNA injectables (Guerriaud & Kohli, 2022). Instead of directly injecting an antigen, the COVID-19 products introduce nucleic acids (either synthetic, modified mRNA or viral vector DNA) that are meant to instruct the ribosomal organelles in the body’s cells to produce the SARS-CoV-2 spike protein that is, according to the standard narrative, the intended antigen. In the case of the modmRNA “vaccines”, billions of replicas of the artificially modified mRNA strands, encapsulated within a protective lipid nanoparticle vehicle, are presented to the body’s protein manufacturing systems for translation into the spike protein of the

SARS-CoV-2 virus. Subsequently, according to the theoretical narrative behind the COVID-19 modmRNA products, this protein subsequently stimulates the immune system to produce antibodies against SARS-CoV-2.

The gene therapy platform has been studied for over 30 years as an experimental cancer treatment, and the terms *gene therapy* and *mRNA vaccination* are often used interchangeably (Van Lint et al., 2015). According to the FDA: “Human gene therapy/gene transfer is the administration of nucleic acids, viruses, or genetically engineered microorganisms that mediate their effect by transcription and/or translation of the transferred genetic material, and/or by integrating into the host genome. Cells may be modified in these ways *ex vivo* for subsequent administration to the recipient or altered *in vivo* by gene therapy products administered directly to the recipient” (FDA, 2022). Wiseman et al. (2021) suggested that the modmRNA products might therefore be appropriately referred to as “Gene Therapy Vaccines”. They may also be accurately referred to as “*prodrugs*” because the COVID-19 products aim to stimulate the recipient’s cells to manufacture the targeted spike protein of SARS-CoV-2 (Cosentino & Marino, 2022). As there were no specific regulations at the time of the rapid approval process, regulatory agencies quickly generalized the definition of “vaccine” to incorporate gene therapies for Emergency Use Authorization for the first time ever against a viral pathogen. However, the rationale for regulating the modmRNA products as vaccines and excluding them from regulatory oversight as gene therapy products lacks scientific or ethical justification (Banoun, 2023).

Due to the reclassification of gene therapy products as vaccines, none of their components have been thoroughly evaluated for safety in a manner commensurate with the testing of genetic products. The main concern, in a nutshell, is that these modmRNA injectables are designed to transform cells into viral protein factories. As Trougakos et al., (2022), and Acevedo-Whitehouse and Bruno (2023) have pointed out, the factories are not provided with any off-switch. There is no built-in system to prevent indefinite proliferation of the spike protein replicas. Also there is no guarantee that the intended replicas will actually consist of identical spike sequences or of similar stereoscopic conformations once they are produced by the body’s ribosomes. Protracted production of even perfect spike proteins can, in theory, result in chronic, systemic inflammation and immune dysfunction, both of which can result in numerous disease outcomes, some of them with long latency (Seneff et al., 2022; Qin et al., 2022; Klingel et al., 2023; Giannotta et al., 2023). However, if the billions of supposedly perfect coding sequences delivered to the recipient’s cells in the payload of the injectables are themselves imperfect to begin with, allowing what is termed “frameshifting”, for instance, as demonstrated by Mulrone et al. (2023), the buildup of proliferating imperfect proteinaceous material can in theory result in the catastrophically harmful clots being documented and discussed by other researchers (Nyström, S., & Hammarström, P., 2022; Santiago & Oller, 2023).

In theory, the spike protein was initially supposed by genetic engineers to be the common denominator between the coronavirus and the COVID-19 injectable products. Given that the spike protein was also identified as the basis for enabling COVID-19 infections, it should have surprised no one that the synthetically manufactured proteins generated by modmRNA would become associated with adverse events evidently generated by the inoculations (Parry et al., 2023; Trougakos et al., 2022). Nevertheless, there are some fundamental differences. The modmRNA-induced spike protein is more immunogenic than its coronavirus counterpart; and yet, the increased humoral response elicited by the injectables (as indicated by higher antibody titers) is also associated with more severe immunopathology, reactogenicity, and various adverse events (Brisotto et al., 2023; Çalık et al., 2022; Debes et al. 2021; Kobashi et al., 2022; Levy et al., 2022; Naaber et al., 2021; Pozdnyakova et al., 2022; Rechavi et al., 2021; Sugiyama et al., 2022; Takeuchi et al., 2021; Uwamino



et al., 2022). Thus, from a putative risk-benefit perspective, while the modmRNA-induced spike protein is linked with an amplified adaptive immune response, it also merits careful consideration of the potential for increased adverse events and immunopathology, particularly in the context of a low infection fatality rate (0.05% for people under age 70; 0.1-0.3% for more elderly individuals; Pezzullo et al., 2023). The spike protein found on the original SARS-CoV-2 Wuhan strain had a 141kD weight, but the spike protein generated by the modmRNA is 180kD, possibly due to glycosylation factors (Veenstra et al., 2022). The modmRNA-induced spike protein is distinct from the wild-type or ancestral version due to specific amino acid modifications, which supposedly help keep the protein in a prefusion state, thus more immunogenic (Heinz et al., 2021). Nucleic acids in the modmRNA injectables also exhibit enhanced base-pairing stability over natural nucleic acids (Duffy et al., 2020). The substitution of N1-methylpseudouridine for uracil in the modmRNA product supposedly results in greater resistance to enzymatic degradation, and may also help account for the persistence of the modmRNA and spike protein in the body (Bansal, 2021; Brogna, 2023; Ho et al., 2024; Nance & Meier, 2021). Spike protein was recently found to persist in immune cells for about 245 days following the modmRNA injection (Patterson et al. 2024). When the spike protein enters the bloodstream and disseminates systemically, it becomes a contributing factor to diverse adverse events (Troughakos et al., 2022). Systemic distribution of the modmRNA is also problematic, since the N1-methylpseudouridine modification has been shown to promote a diversity of errors (Kim et al., 2022). As we discuss in Part 2, even marginal transcription errors have the potential to result in significantly harmful disease-related effects in both the short- and long-term. Disastrous results can occur when scaled to a large population (Gutschi, 2022), and this particular gene-based prodrug has been distributed to at least 80% of the population in developed countries (Pharmaceutical Technology, 2024).

In this two-part narrative review, we revisit the registrational trials and review analyses of the adverse events from these trials and other relevant studies. Most of the revelations have only recently come to light. We believe this is because of extensive censorship of healthcare professionals and research scientists who have been challenging the prevailing narrative set forth by the vaccine enterprise (Shaw, 2020; Shir-Raz et al., 2022; Bhattacharya & Kulldorff, 2024). This paper (Part 1) starts with an examination of the Pfizer and Moderna registrational trials that led to the Emergency Use Authorization, focusing on the safety and efficacy issues identified in them. We also discuss follow-up research and re-analyses that have exposed crucial problems with the trials.

We show how flawed research and misinformation spread by trialists, federal agencies, and subsequent observational studies misled the public and medical professionals. Additionally, we address the role of censorship in suppressing scientific discourse and the sharing of crucial information about injuries and deaths related to modmRNA products. The censorship of research challenging mainstream “vaccine dogma” has been going on for a long time (Shaw 2020; Oller & Shaw, 2020; Oller et al., 2020) but has been amped up with COVID-19 products by the Bio-Pharmaceutical Complex which is constituted by the closely coordinated collaboration between public health organizations, vaccine manufacturers, and regulatory agencies. All of them were ready and waiting in 2020 for prompt approval for the modmRNA injectables without proper risk evaluation or efficient large-scale production management programs (Leake & McCullough, 2022). Part 2 provides an in-depth overview of the various adverse impacts of the modmRNA inoculations. In a post-“pandemic” context in which the media-created illusion of immediate urgency has subsided, exploratory narrative reviews such as this one can play an important role in

helping us re-evaluate the scientific basis for the well-founded safety concerns of the general public regarding the COVID-19 modmRNA products.

## Revisiting the Registrational Trials

Early in the pandemic, US public health officials promised that the phase 3 trials would prove the COVID-19 modmRNA products were “safe and effective”. They promised a reduction in severe disease, hospitalization, and death, with a secondary endpoint of preventing transmission and infection (Doshi, 2020). Nine vaccine manufacturers issued an unprecedented joint statement pledging not to prematurely seek regulatory review (Pfizer, 2020). Both sets of assurances were delivered to a population already suffering from pandemic fatigue, mostly attributable to lockdowns, masking, social distancing, and other restrictions imposed by the same agencies responsible for ushering in the COVID-19 “vaccination” program. Despite the rhetoric, no large randomized double-blind placebo-controlled trials have ever demonstrated reductions in SARS-CoV-2 transmission, hospitalization, or death. On the contrary, sensible analyses looking at Our World in Data across all the reliably reporting entities seem to show that the “pandemic” occurred after, not before, the rollout of the injectables (Rancourt et al. 2023a, 2023b, Beattie, 2021).

Looking back to the study designs for the Pfizer and Moderna trials leading to Emergency Use Authorization we can see that they were never intended to determine whether the modmRNA products could help prevent severe disease or premature death (Doshi, 2020). They had insufficient statistical power for experimentally assessing these possibilities (Meo et al., 2021). Basing the power calculation solely on the reduction of COVID-19 symptoms was a fatal flaw in itself. An additional limitation involved selectively recruiting young, healthy trial participants in the 18-55-year age group. There were also very few reported clinical infections in the intervention arms of the trials. There were only 8 cases reported in Pfizer and 11 in Moderna (Polack et al., 2020; Baden et al., 2021). Whereas the Pfizer trial recorded just 1 instance of severe COVID-19, the Moderna trial reported 0 (zero), leading the company to proclaim 100% efficacy against severe illness (Cohen, 2020). Moderna also reported 1 COVID-19 death, in the placebo group (Baden et al., 2021). Thus, between the two trials, there was only 1 death attributed to COVID-19 among more than 73,000 trial participants (Polack et al., 2020; Baden et al., 2021).

After announcing trial results, Pfizer extended its study by four months. Trial participants were unblinded by week 20, and placebo volunteers were invited to receive the modmRNA injections. Pfizer’s announcement of the efficacy of its modmRNA product was based on 162 out of 22,000 placebo recipients contracting COVID-19, compared to only 8 out of 22,000 vaccine recipients. None of the 162 placebo recipients who contracted COVID-19 died from the disease (Thomas et al., 2021). The numbers of cases were too small to justify general conclusions with regard to COVID-19 morbidity and mortality (Risch, 2022). Contrast them, however, with the findings of researchers such as Rancourt et al. (2023a, 2023b), and Beattie (2021). From the worldwide distribution of the injectables a firm causal conclusion can be inferred: the rollout of injectables preceded and caused cases and deaths from COVID-19. A causal relation between number of doses and trends in cases and deaths over time must be inferred from what is virtually a universal pattern throughout all the reliably reporting entities in the Our World in Data system.

Nevertheless, the Pfizer trial data do suggest an unfavorable trade-off between the false promise of increased protection against SARS-CoV-2 infection on the one hand and the demonstrated real increased risk of COVID-19 injectable-induced serious adverse events on the other. Polack et al.,

(2020) reported that injecting 21,720 people with the primary series of BNT162b2 prevented 8 cases of severe COVID-19 over the six-week period of observation, but merely preventing 1 severe case of COVID-19, would require injecting about 2,700 individuals with the primary series with a probability of severely injuring 16 of them. As shown in Table S3 of Pfizer's published report (Polack et al., 2020), participants in the BNT162b2 arm experienced 127 serious adverse events. This indicates a 0.6% ( $127/21,720=0.0058$ ) chance of a serious adverse event for any recipient. Essentially, for every case of severe COVID-19 purportedly prevented, there were 16 serious adverse events (127/8). Stated differently, recipients of the primary BNT162b2 series have a 1 in 2,700 chance of being protected against severe COVID-19, but also have a 1 in 167 (or 6 in 1,000) chance of experiencing a serious adverse event (including death and life-threatening diseases). Moreover, whereas the hypothetical "efficacy" of the modmRNA product wanes within a few months, the frequency of very real and serious adverse events can only increase over time. With a longer observation period, it stands to reason that the primary series will yield exponentially increasing injuries as contrasted with the rapidly vanishing hypothetical benefits (Setty, 2023).

Moreover, the 170 confirmed case count based on polymerase chain reactions (PCR) diverts attention from the much larger number of cases identified during the study that fell under the category of "suspected COVID-19", where individuals exhibited symptomatic COVID-19 but lacked a positive PCR test (Doshi, 2021a; 2021b). More to the point, the PCR tests used in the trials, though widely accepted for detecting SARS-CoV-2 were fundamentally flawed, leading to high rates of false positives and false negatives (Franchi et al., 2023; Kämmerer et al., 2023a, 2023b). A total of 3,410 cases of suspected, unconfirmed COVID-19 were identified, a 20-fold difference between suspected and confirmed cases. There were 1,594 such cases in the intervention group, and 1,816 in the placebo. When factoring in both confirmed and suspected cases, vaccine efficacy against developing symptoms drops to only 19%, far below the 50% relative risk reduction threshold required for regulatory authorization (Doshi, 2021a; 2021b). Even when removing cases occurring within seven days of the injection to account for short-term vaccine reactogenicity (rather than true infections), efficacy would be only 29%.

Similarly, it is important to emphasize that the FDA had allowed Pfizer and Moderna to focus on incorrect or suboptimal outcomes over absurdly short time spans. The "cases" being counted in the trials were PCR-positive patients supposedly with mild infections, not moderate to severe illnesses. Thus, a cough, or mild respiratory symptom, would qualify as a criterial endpoint infection (Pfizer, 2021; Moderna, 2020). The temporal finishing point of the trial was predicated on a mere 100 COVID-19 "cases" recorded within the placebo group (Doshi, 2020). Once the trial reached that number, it was anticipated that efficacy would be declared, and participants in the placebo group would be offered the modmRNA injection. This was the very scenario that transpired. Pfizer concluded its blinded phase at two months and Moderna ended theirs at three months, forever shortening the blinded randomized follow-up period, and greatly limiting any risk-benefit evaluations over any longer time frame (see our **Appendix 1**).

The absence of any method to evaluate severe illness in the trials reflected the real-world fact: namely that the likelihood of severe COVID-19, hospitalization, and dying from an infection has always been very low. Stratifying by age, the infection fatality rate in 2021 showed an age gradient with approximately a three to four-fold increase for each decade, starting as low as 0.0003% (nearly zero) among children and adolescents, increasing to 0.5% in those aged 60-69 (Pezzullo et al., 2023). Even in older age groups (>70 years), the infection fatality rate varies from 1-5% depending on comorbidities and treatment access. As a basic principle, all-cause mortality (ACM) tends to increase

with age. In the case of COVID-19, the presence of comorbid disease greatly modifies the influence of age on mortality (Chenchula et al., 2023). For younger generations (<40 years), SARS-CoV-2 infection severity and fatality rates since 2020 have been comparable to those of influenza (Thornley et al., 2020). Even in countries that showed excess mortality in 2020, death rates among children were extremely low (Islam et al., 2021). In Sweden, where 1.8 million children were allowed to freely attend school in 2020, zero COVID-19 deaths were recorded among them by summer 2021 (Baral et al., 2021).

Although randomized controlled trials are viewed as the gold standard for testing the safety and efficacy of medical products, in this case, the trials excluded key sub-groups, notably children, pregnant women, frail elderly persons, and immunocompromised individuals, as well as those with cancer, autoimmune disease, and other chronic inflammatory conditions (Barbari, 2021). Rather than assess these well-known safety and comorbid risk concerns, the focus was narrowly placed on the potential for inflammatory lung injury as had been seen in COVID-19 patients and, many years earlier, in immunized animal models infected with SARS-CoV (Thames et al., 2020). We recognize the folly of this narrow focus, as millions of severe and life-threatening events associated with the COVID-19 modmRNA products continue to be documented in the medical literature (Montano, 2021; Yan et al., 2022; Classen, 2021; Fraiman et al., 2022; Mörl et al., 2022).

With respect to all-cause mortality for the Pfizer and Moderna trials, Benn and colleagues found 61 deaths total — 31 in the modmRNA group, 30 in the placebo — and a mortality risk ratio of 1.03 (0.63-1.71), comparing the modmRNA to placebo (Benn et al., 2023). These findings can be interpreted as “no significant difference” or no gold-standard evidence showing these COVID-19 modmRNA products reduce mortality. The lack of significant differences in deaths between the study arms is noteworthy. The true mortality impact remains unknown in this context, and this fact alone is relevant, as it would be preferable to take a modmRNA injectable with good trial evidence of reduced mortality than to take the same product where trial evidence does not show convincing evidence of improved survival (Kuldorff, 2022). Similarly, a subsequent analysis of the Pfizer trial data concluded that mortality rates were comparable between modmRNA and placebo groups during the initial 20-week period of the randomized trial (Michels et al., 2023). The fact that the COVID-19 modmRNA injections did not lead to a reduction in overall mortality implies that, if the injections were indeed averting deaths specifically attributable to COVID-19, any such reduction was buried under the much greater increase in mortality from serious adverse events.

Even the six-month Pfizer trial failed to show any reduction in all-cause mortality (Thomas et al., 2021). Indeed, a reanalysis of the post-marketing data provided to the FDA suggests the opposite effect. The extended portion of the trial included four months of an unblinded period, in which most placebo participants crossed over to the modmRNA group. During this phase, there were 5 additional deaths, including 3 in the original modmRNA group and 2 among the placebo participants who chose the modmRNA injection (Thomas et al., 2021). When these 5 deaths are included as “vaccinated” deaths, the total count becomes 20 deaths in the modmRNA group and 14 deaths in the placebo group, which would represent a 43% increase in deaths (not statistically significant due to small counts). In the FDA documents, however, a total of 38 deaths were reported, with 21 in the modmRNA group and 17 in the placebo group, representing a 23.5% increase in all-cause deaths among those who received the two-dose primary series of BNT162b2 (US Food and Drug Administration, 2021; US Food and Drug Administration, 2021b). This suggests that the 2 placebo participants who died after the modmRNA injections were counted twice (i.e., both deaths were counted in each arm of the trial). To properly account for the 5 extra



deaths, however, one should adjust the analysis based on person-months spent in each group. Applying this method, the total count was 37 deaths: 21 in the BNT162b2 arm and 16 in the placebo arm. Calculating the relative all-cause mortality risk, the modmRNA group had a mortality rate of 0.105% (21 deaths out of 20,030), while the placebo group had a mortality rate of 0.0799% (16 deaths out of 20,030). The relative risk equation yielded a value of 1.3125 (95%CI 0.6851-2.5144,  $p = 0.41$ ), indicating a 31% higher all-cause mortality risk in the BNT162b2 group compared to the placebo group. The estimate may be considered conservative, as it does not assume that all placebo recipients chose to get the modmRNA injection during the open-label phase of the trial.

For the Pfizer and Moderna registrational trials, Benn et al. (2023) also reported a 45% increase in cardiovascular deaths (relative risk=1.45; 95% CI 0.67-3.13) in the modmRNA arms of the trials. This finding is consistent with numerous reports of COVID-19 modmRNA-related cardiovascular pathology among both young and old segments of the population (Jeet Kaur et al., 2021; Oster et al., 2022; Almas et al., 2022; Rees, 2022; Shiravi et al., 2022; Gao et al., 2023; Yasmin et al., 2023). Although none of the mortality estimates from the trials are statistically significant, the upward trends for both all-cause and cardiovascular mortality are problematic. If the Pfizer trial had not been prematurely discontinued, and assuming death rates remain the same in both arms as observed in the first six months, the all-cause mortality difference would reach the standard threshold for statistical significance ( $p < 0.05$ ) at approximately 2.8 years (34 months). The  $p$ -value is 0.065 at 2.5 years and 0.053 at 2.75 years (see Appendix 1). These calculations were independently confirmed by Masterjohn (2022).

## **Absolute Risk and the “Number Needed to Vaccinate”**

One of the often-overlooked shortcomings of the registrational trials was the exclusive focus of the final report on relative risk while omitting absolute risk reduction. The latter measure gives a better indication of a drug's clinical utility because it is scaled by the sample size (Brown, 2021). Relative risk is the ratio of COVID-19 symptom rates in the modmRNA versus placebo groups, which was reported as 95% and 94.5% for the Pfizer and Moderna products, BNT162b2 and mRNA-1273, respectively (Polack et al., 2020; Baden et al., 2021). Absolute risk refers to the probability of an outcome (in this case, symptoms of clinical infection), based on the number of people experiencing the outcome in relation to the population at large. It is typically calculated as the number of events that occurred in a study population divided by the number of people in that population. Both types of risk estimation are required to avoid reporting bias and to provide a more comprehensive perspective on vaccine efficacy (Brown, 2021). Omitting absolute risk leads to overestimation of the clinical benefits of the modmRNA products (Olliaro et al., 2021). In contrast with the 95% relative risk figure, the absolute risk reductions for BNT162b2 and mRNA-1273 were 0.7% and 1.1%, respectively (Ali et al., 2021). These estimates were derived from publicly available data that ultimately led to Emergency Use Authorization for the modmRNA injectables being granted by the FDA Vaccines and Related Biological Products Advisory Committee (US Food and Drug Administration, 2020). However, the data reviewed by that committee did not include absolute risk reduction measures, thus deviating from FDA guidelines, which state that both approaches are crucial in order to avoid the misguided use of pharmaceuticals (Fischhoff et al., 2011). Again, failing to provide the absolute risk and instead fixating only on relative risk generally results in an overestimation of modmRNA benefits. Absolute risk statistics are also valuable when assessing and comparing safety measures such as adverse event rates.

An absolute risk reduction of approximately 1% for the modmRNA injectables meant that many individuals would need to be injected in order to prevent a single mild-to-moderate case of COVID-19. Specifically, the number needed to vaccinate to prevent 1 case of COVID-19 would be 142 (range 122-170) for the BNT162b2 injection and 88 (range 76-104) for the mRNA-1273 injection, respectively (Brown, 2021). These numbers increase with age and the SARS-CoV-2 variant targeted (Adams et al., 2023). The number needed to vaccinate is an interpretable and salient metric for assessing real-world impact, enabling us to gauge the potential benefits derived from the modmRNA inoculation. For any relatively healthy population (with minimal comorbidities), the risk-benefit profile with a high number needed to vaccinate could easily point to excessive harms.

It is imperative to carefully weigh all potential risks associated with the COVID-19 modmRNA products. Should substantial harms be linked to their use, the perceived “reward” conveyed by the number needed to vaccinate would necessitate a re-appraisal. For example, assuming a number needed to vaccinate of 119 and an infection fatality ratio of 0.23% (both being conservative estimates), approximately 52,000 modmRNA injections would be needed to prevent 1 COVID-19-related death. Thus, for the BNT162b2 injection, a generous estimate would be 2 lives saved from COVID-19 for every 100,000 injections. Given the evidence of flawed trial designs and failed execution along with misconduct in reporting and data integrity problems (see next section), we suggest that this estimate is an “upper bound”, and therefore the true benefit is likely to be much lower, in fact, negative. Regarding potential harms, assuming 30% false-positive reports and a moderate under-reporting factor of 21, we calculate a risk of 27 deaths per 100,000 doses of BNT162b2. Thus, applying these reasonable, conservative assumptions, the estimated injuries caused by the COVID-19 modmRNA products greatly outnumber the hypothetical rewards promised: for every life saved, there would have been nearly 14 times more deaths caused by the modmRNA injections (for details, see Appendix 2). The net outcome reduces to a serious negative efficacy.

## **Underreporting of Injuries and Data Integrity Issues**

Underreporting of severe harms, including serious adverse events, is another important concern that often garners scant attention in the public domain. Notably, severe harms that significantly impede daily activities and quality of life are universally underreported in randomized trials, particularly in industry-sponsored studies (Götzsche & Demasi, 2022). Such adverse events may be most common in modmRNA-injected individuals who are subsequently infected with SARS-CoV-2. While, in principle, systematic reviews of randomized trials serve as a reliable source of evidence, the reporting of serious harms is invariably missing from the drug trial reports (Götzsche, 2013). This dearth of reporting seems exceptionally evident in the context of vaccine trials (Götzsche, 2020; Demasi, 2021; Götzsche, 2022), a fact that only benefits the Bio-Pharmaceutical Complex and its numerous ongoing vaccination campaigns. In the case of the registrational trials, the underreporting was also situational, as participants were unblinded in the open-label phase of the Pfizer trial, and placebo recipients were offered the modmRNA injection within only a few weeks of the Emergency Use Authorization. The early unblinding occurred without allowing sufficient time to identify late-occurring or diagnosed harms associated with the modmRNA products (Doshi, 2021a; 2021b). Was this necessary, given that none of the deaths in the Pfizer trial were attributed to COVID-19 as the primary cause, and given the very low infection fatality ratio for a relatively healthy population (Pezzullo et al., 2023)?

Classen (2021) notes that the trial coordinators employed a haphazard approach to adverse event monitoring and thus the potential harmful impact of these biologicals on health outcomes was more

substantial than is usually acknowledged. Investigators prioritized the documentation of COVID-19 events while prospectively tracking patients for “solicited” adverse events for a duration of approximately seven days post immunization. “Unsolicited” adverse events were subsequently reported for a period of 30-60 days. Among the trial participants were individuals with limited education and elderly individuals, possibly with cognitive impairment (Classen, 2021). The ability of such individuals to competently recognize and report serious adverse events is questionable. Moreover, the original trial reports did not include data on serious non-infectious events, including fatalities, that occurred beyond the 30-60-day reporting period (Classen, 2021). By contrast, COVID-19 infections were continuously monitored from the time of immunization (a form of information bias). Both Pfizer and Janssen showed leniency in recording adverse events, restricting the documentation of “solicited” events to a safety cohort representing less than 20% of the overall study population. These findings align with prior studies showing that only a small proportion, generally 5%, of adverse events are typically reported in pharmaceutical company-sponsored trials (Hazell & Shakir, 2006).

To make matters worse, the public was never allowed access to the raw data of the registrational trial, thus precluding independent verification of adverse events by the scientific community (these were revealed later on, after widespread distribution of the inoculations; Johnson et al., 2020). Such secrecy may have enabled the industry to more easily present an inflated and distorted estimate of the genetic injection benefits, along with a gross underestimation of future harm.

A recent forensic analysis of Pfizer’s six-month trial data revealed that many deaths in the trial occurred after the cutoff date used to create the briefing booklet reviewed by the FDA and resulting in the authorization of the modmRNA products; this effectively concealed mortality data from the decision-making part of the Emergency Use Authorization process (Michels et al., 2023). Pfizer’s original application for the Emergency Use Authorization described the trial results only up to the record-keeping cutoff date of November 14, 2020. However, deaths and other serious adverse events continued to occur afterward, even before the definitive Vaccines and Related Biological Products Advisory Committee meeting to authorize the modmRNA injectables.

During the initial 33 weeks of Pfizer-BioNTech Clinical Trial CA4591001, which spanned 153 clinical trial sites in more than seven different countries, a total of 38 subjects passed away. The 38 trial subjects were listed in the Pfizer-BioNTech six-month Interim Report (Thomas et al., 2021). These events occurred in chronological order within the 33-week period commencing on July 27, 2020 and concluding on March 13, 2021. To visually represent this data, Michels et al. (2023) created a bar graph illustrating the number of subject deaths per week (Figure 1). The number of subject deaths in both the BNT162b2 (“vaccinated”) and placebo arms of the trial is depicted separately. The graph also includes a plot illustrating the cumulative number of deaths in each arm, measured at the end of each week. Solid bars represent subjects who received the BNT162b2 injection, while gray bars represent those who received a placebo, and hatched bars represent subjects who initially received a placebo but were unblinded and subsequently administered BNT162b2. Additionally, the authors included a linear graph that displays the cumulative number of deaths in each trial arm. A solid line corresponds to BNT162b2-injected subjects, while a dotted line represents the placebo group (Michels et al., 2023).

Notably, the unblinded placebo recipients who later received BNT162b2 are combined with the BNT162b2 “vaccine group” for this analysis (Michels et al., 2023). To provide context, the registrational trial can be divided into three distinct periods. The first is the “Blinded placebo-

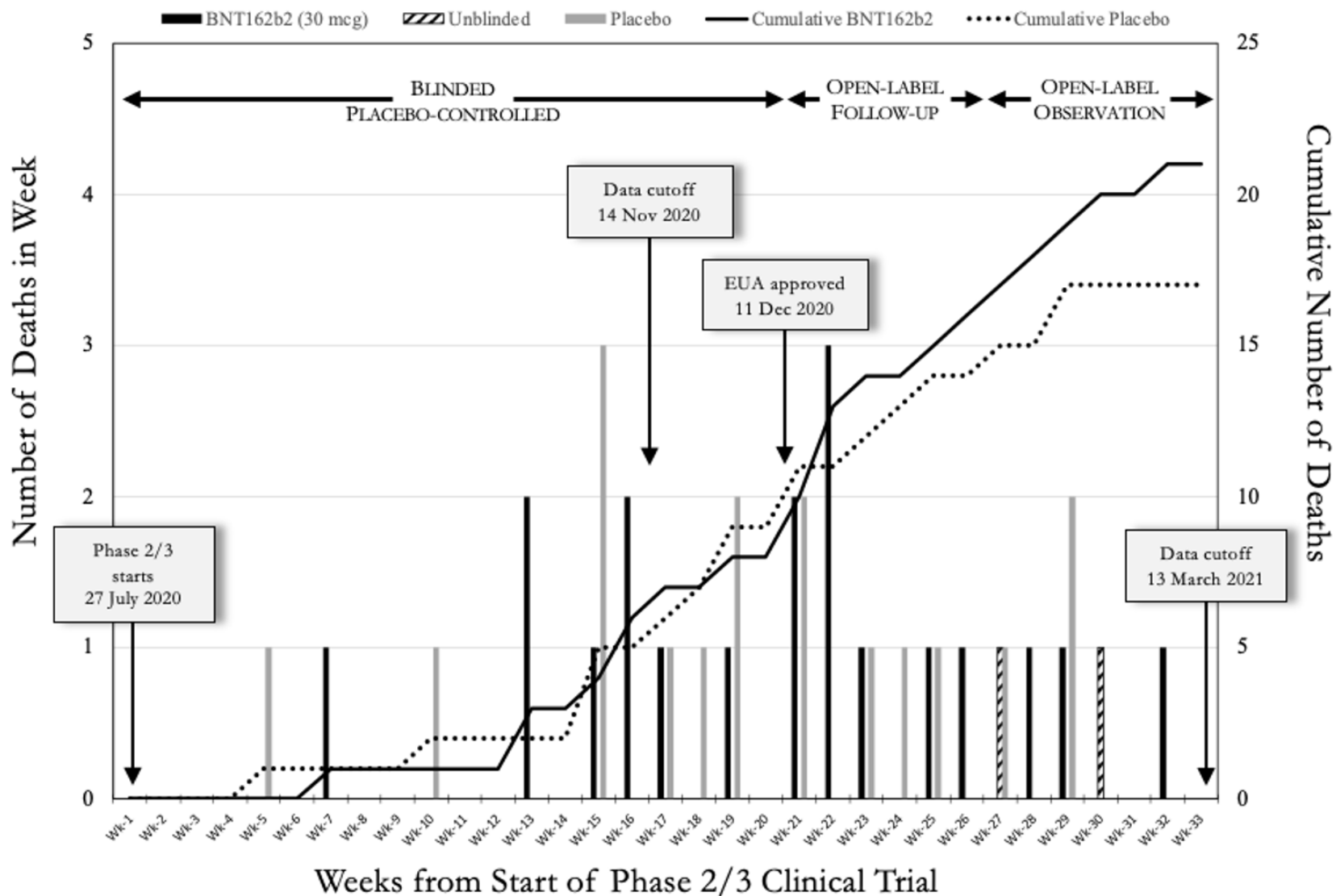


Figure 1. Analysis of weekly mortality in the Pfizer trial over a 33-week period. This representation of the Pfizer trial by Michels *et al.* (2023) showcases the weekly count of subject deaths from July 27, 2020, to March 13, 2021. Solid black bars denote BNT162b2 recipients; gray bars the placebo group; and hatched bars represent unblinded placebo subjects who later received BNT162b2. The solid line represents the cumulative death count for the BNT162b2 group and the dotted line the same for the placebo group. *Image Source:* Michels et al., 2023; Published with permission by authors under CC BY-NC-ND 4.0.



controlled period,” which spanned from July 27, 2020, to December 10, 2020. The second phase is the “Open-label follow-up period,” encompassing the timeframe from December 11, 2020, to January 24, 2021. The final period is the “Open-label observation period,” which extended from January 25, 2021, to May 13, 2021 (Thomas et al., 2021; Pfizer, 2021b). The initial placebo subject death was recorded in Week 5, while the first death among BNT162b2 subjects occurred in Week 7.

The first 12 weeks of the trial saw very few deaths, likely due to ongoing enrolment of new subjects. The plots illustrating the cumulative number of deaths in both arms appear to closely align until around Week 20, after which they diverge (Figure 1). Beyond Week 20, the rate of deaths in the placebo arm decreased and eventually stabilized by Week 30. In contrast, the number of deaths among BNT162b2 subjects continued to rise at a consistent rate. This reduced rate in the placebo arm was likely a result of the diminishing number of non-injected placebo subjects remaining in the trial, stemming from the unblinding and modmRNA inoculation process initiated after December 11. Despite the low overall death count, it is likely that the general public’s perception of the modmRNA injectables would have been far less favorable had they known that the mortality rate had continued to increase among the injected participants (Michels et al., 2023). The data for Figure 1 by Michels et al. (2023) were obtained directly from Pfizer’s Six-Month Interim Report (Thomas et al., 2021). Moreover, Michels et al. (2023) compared the reported number of deaths to an age-stratified estimated number based on US data from 2019 (Murphy et al., 2021) and determined that Pfizer’s reported number of 38 deaths is about 17% of what would be expected for the US population.

Alarmingly, drawing from Pfizer’s Six-Month Interim Report, Michels and colleagues found evidence of a substantial increase in the number of deaths due to cardiovascular events in BNT162b2 recipients that Pfizer did not report (Michels et al., 2023). For their published peer-reviewed analysis, the researchers were able to access the narrative reports on a few critical subjects that provided explicit notification of the subject’s date of death prior to November 14, 2020 (Michels et al., 2023). Protocol C4591001 required immediate reporting of serious adverse events, including death or hospitalization, within a 24-hour window, a guideline likely followed by the trial site staff. Nevertheless, Pfizer used the dates that the death was recorded in the subject’s Case Report Forms, which Pfizer maintained. The Michels et al. (2023) investigation uncovered a consistent pattern of reporting delays of the date of death on Case Report Forms across the entire trial. These delays were greatest in modmRNA-injected subjects who died prior to November 14, 2020. If Pfizer had used the actual death dates in their Emergency Use Authorization application, two additional modmRNA-injected subjects would have been included in the Emergency Use Authorization application. This discrepancy was crucial, as all modmRNA subject deaths (four of four) and half the placebo deaths (two of four) were cardiac-related. The forensic analysis revealed that 75% of the deaths in modmRNA subjects and 33.3% of those in the placebo group were cardiac-related (Michels et al., 2023). Among the 14 subjects experiencing cardiac serious adverse events, 11 were individuals who received the BNT162b2 vaccine, and three were from the placebo-only trial arm, a 3.7-fold increase (OR 3.7, 95% CI 1.02-13.2,  $p = 0.03$ ) (Michels et al., 2023). It is noteworthy that neither the original trial paper by Thomas et al. (2021) nor Pfizer’s Summary Clinical Safety report (2021b) acknowledged or commented on this crucial warning signal. In hindsight, the previously undisclosed observation that twice as many cardiac deaths occurred proportionately among modmRNA recipients compared to placebo subjects in the Pfizer trial would likely have prompted re-evaluation by the FDA, especially considering the later accumulated data by December 10, 2020, where 17 deaths had occurred (Michels et al., 2023). Delays in documenting these fatalities in Case

Report Files, coupled with the omission of the actual date of death, effectively concealed these deaths during the crucial phase of the Emergency Use Authorization approval process, masking the cardiac serious adverse event warning signal (Michels et al., 2023). In short, the various reporting delays and omissions, if they had been openly discussed and considered by the Vaccines and Related Biological Products Advisory Committee, might have prolonged the authorization process. The improper reporting and insufficient scrutiny by the Vaccines and Related Biological Products Advisory Committee may have ultimately enabled Pfizer to manipulate the trial results and obscure the cardiac death signal. Recent *in vivo* animal studies demonstrate that “in isolated cardiomyocytes, both mRNA-1273 and BNT162b2 induce specific dysfunctions that correlate pathophysiologically to cardiomyopathy” (Schreckenberget al., 2024). In principle, then, cardiomyocytes cannot be excluded from the biodistribution of the lipid nanoparticle modmRNA, and every new modmRNA product has the potential to cause life-threatening heart problems, including cardiomyopathy and cardiac arrest.

Beyond these omissions in serious adverse event reporting, the official reporting of trial results was also problematic. The trial data Pfizer submitted for the Emergency Use Authorization application revealed a puzzling trend when comparing COVID-19 incidence between the mRNA-injected and placebo groups: a striking divergence after day 12 following the first BNT162b2 dose (FDA Briefing Document, 2020; Palmer et al., 2023). While the placebo group continued to see new cases, the BNT162b2 group infection rate abruptly halted, suggesting sudden, uniform immunity onset at day 12. Such an abrupt and complete response on day 12 contradicts biological plausibility, given that such immunological responses would realistically tend to register in a more gradual way in a group context. Moreover, Pfizer failed to provide the data for individuals receiving only one dose. Figure 2 from the same trial report (European Medicines Agency, 2021), adapted by Palmer et al. (2023), showing neutralizing antibody titres on the day of the first injection and various subsequent days, depicts the gradual rise of neutralizing antibodies to SARS-CoV-2 following the mRNA inoculation. This contradicts the notion of rapid, full clinical immunity. By day 21, after the 1<sup>st</sup> dose, neutralizing antibodies only slightly increased, peaking on day 28, well after most individuals would have received their 2<sup>nd</sup> dose. This inconsistency between clinical and antibody data raises doubts about the graphic depiction of sudden immunity on day 12, casting suspicion on its validity. Figure 2 shows two charts sourced from the European Medicines Agency (EMA) assessment report on Pfizer trial data (European Medicines Agency, 2021).

When the Pfizer Six-Month Interim Report of Adverse Events (C4591001) revealed a total death count of 38 (Thomas et al., 2021), the number seemed unexpectedly low for a clinical trial involving 44,060 participants amidst a pandemic. To investigate, Michels and colleagues estimated the anticipated deaths based on US mortality rates in 2020, presuming comparability across participating countries (Michels et al., 2023). With 132 trial sites in the US and 80% of subjects, they estimated that 222 deaths were expected to occur between July 27, 2020, and March 13, 2021, making the observed 38 deaths only 17% of the more realistic projected number. Most of the trial sites had fewer deaths than anticipated, possibly attributed to a considerable percentage of “Lost to Follow-up” subjects (4.2% of randomized subjects), including 395 unique subjects within the study period. While some sites recorded negligible losses, others exhibited substantial figures, up to 5% of the subjects on site (Michels et al., 2023). These numbers likely contributed to the seemingly low overall death count and should have prompted increased efforts to locate these individuals. Losing track of nearly 400 study participants in the follow-up observation period could have substantially compromised the validity and generalizability of the results. The missing data can produce biased

estimates, leading to invalid conclusions. This could result in underestimation of serious adverse events (including deaths), thus misrepresenting the unsafe profile of the mRNA products. In

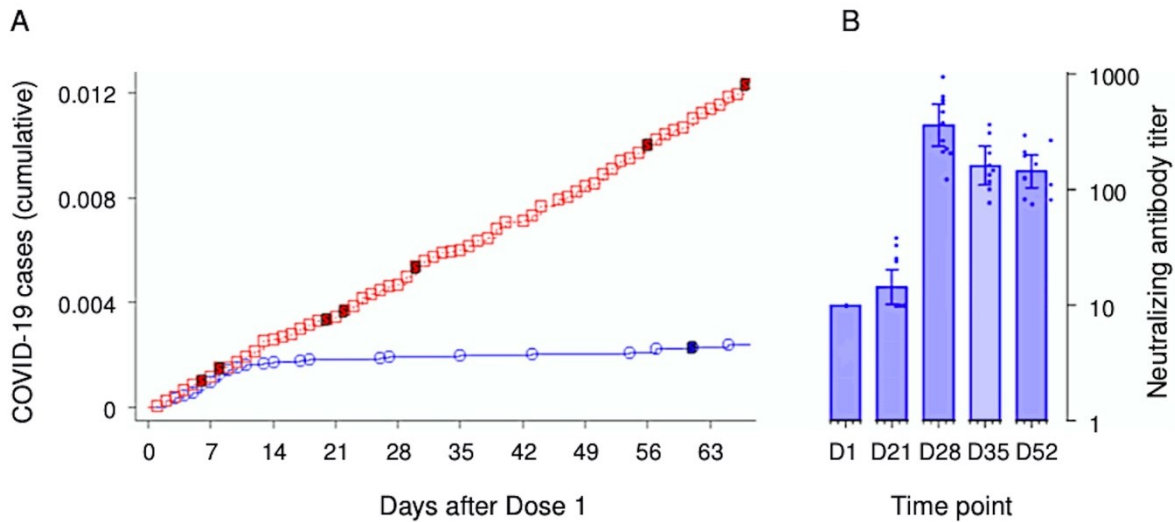


Figure 2. Charts A and B illustrate Pfizer trial irregularities in reporting of COVID-19 cases and humoral immune responses (antibody titers). Chart A indicates an unusual pattern 12 days after the BNT162b2 injection. While the placebo group continued experiencing cases, the BNT162b2 group showed a sudden decline in infection rates, suggesting unexpected immediate immunity. *Image source:* Palmer M, et al. (2023); reproduced under Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License (CC BY-NC-SA 4.0). Data was extracted from the European Medicines Agency report, referencing Figures 9, A, and Figure 7, B (European Medicines Agency, 2021).

short, Pfizer's failure to minimize participant attrition, seriously undermined its six-month study conclusions.

According to a retrospective analysis by Gulbrandsen and colleagues, the Pfizer trial data showed a significant association between the mortality rate and time since the injection in both the modmRNA and placebo arms (Gulbrandsen et al., 2023). A minimal number of deaths were recorded during the initial 80 days, but a significant mortality increase was observed around the 100-day mark post-injection, indicating a pattern that cannot be attributed to chance. Remarkably irregular trends are also evident in the cardiac serious adverse events within the trial. Nearly half of all the cardiac events manifested within the initial 50 days following the injection, despite the constant risk exposure anticipated for the first 140 days. Oddly, a dramatic surge in serious cardiac adverse events was observed around the 100-day mark from the 1<sup>st</sup> injection in both the modmRNA and placebo groups, coinciding with the heightened death rate. Examining the predominant medical diagnoses before participation in the trial revealed yet another aberrant trend: all 9 of the most prevalent pre-existing diagnoses were more commonly found among participants in the placebo arm. Moreover, there was a notable contrast in the ages of deceased participants between the two groups. These observed patterns were unlikely to occur randomly. The only plausible explanation for these anomalous trends was that the serious adverse event records among modmRNA recipients were altered, relocating them to the placebo arm after the fact (Gulbrandsen et al., 2023).

These concerns are further compounded by revelations concerning substandard research practices and inadequate data management in the pivotal trials. A whistleblower report by a former employee of the contract research organization responsible for enrolling patients in Pfizer's pivotal trial raises

significant questions regarding data integrity and the safety of trial participants (Thacker, 2021). Among the trial conduct issues documented were failure to report protocol deviations, improper storage of the modmRNA products, mislabelling of laboratory specimens, and lack of timely follow-up for patients experiencing adverse events, possibly leading to underreporting. In terms of regulatory oversight, the FDA inspected only 9 out of the 153 study sites involved in the Pfizer trial (Godlee, 2021).

Finally, an unblinding of participants occurred early in the trial, potentially on a wide scale across different study sites. Participants were not presented with clear information regarding potential adverse events in both trial protocols and consent forms (Cardozo & Veazey, 2021). Some parts of the consent form were misleading apparently to elicit participation that might not otherwise have occurred. If the volunteers had been made aware that what was promised in theory or “on paper” was unlikely to happen in reality, they probably would have refused to participate (Cardozo & Veazey, 2021). As a result, they could not give informed consent because the potential injuries and adverse events most likely to be caused by the modmRNA injections were never openly stated.

This lack of informed consent carried over into the real-world setting following the Emergency Use Authorization. For example, not publicly disclosing the Pfizer trial’s exclusion of pregnant women is arguably among the CDC’s most egregious oversights when asserting the safety of COVID-19 modmRNA injections during pregnancy (Polack et al., 2020). The Nuremberg Code established every patient’s right to voluntary informed consent in the aftermath of World War II (Annas, 2018). US courts consistently support informed consent as a fundamental right for patient autonomy (Healy et al., 2023). Informed consent procedures must provide clear distinctions between risks that are frequently observed, risks that occur rarely, and the more obvious risk of lack of effectiveness or waning immunity, which is separate from the risk of serious adverse events. Whether in a clinical trial or free-living real-world setting, informed consent is essential to providing a clear understanding of the potential risks associated with receiving a gene-based prodrug such as the modmRNA injectable. Throughout the pandemic, healthcare workers were duty-bound to provide clear risk-benefit information to patients. In practice, however, informed consent was non-existent, as information sheets were blank (Swenson, 2021), and modmRNA recipients were never informed of potential risks beforehand.

## **Shifting Narratives, Illusions of Protection**

The power to prevent or greatly limit infection is generally considered essential to vaccine effectiveness. Nevertheless, the registrational trials by Pfizer and Moderna were not designed to address this issue. The endpoint of the trials was the reduction of symptoms associated with COVID-19 (Polack et al., 2020; Baden et al., 2021), even though the public was subsequently told by the CDC that the COVID-19 products would stop transmission (National Center for Immunization and Respiratory Diseases, 2021). Moreover, asymptomatic transmission was shown to be extremely minuscule (Madewell et al., 2020). Since 2021, the scientific community has known that the COVID-19 mRNA products do not prevent either transmission or infection (Mostaghimi et al., 2022). Even experts sponsored by the vaccine industry admitted to a maximum reduction in transmission of 61% in 2021 (Lipsitch & Kahn, 2021). The Omicron subvariants are associated with a 30-50% reduction in transmission following administration of the boosters (Maeda et al., 2023; Allen et al., 2023; Menegale et al., 2023). The benefit is incremental and transient, with protection against Omicron infection lasting only a few months (Mostaghimi et al., 2022). Even though antibody titers against SARS-CoV-2 are higher following the injection, these levels decline faster in



the mRNA recipients compared to individuals with natural infection (Abou-Saleh et al., 2022). The impact of reduced disease severity among COVID-19 modmRNA recipients on the risk of causing secondary infections has never been systematically investigated in controlled clinical trials (Mostaghimi et al., 2022).

The best evidence for the failure of the modmRNA to confer protection against COVID-19 comes from three large cohort studies of employees within the Cleveland Clinic Health System after the bivalent modmRNA boosters became available (Shrestha et al., 2023; Shrestha et al., 2023b). Cleveland Clinic Health System data are widely regarded as reliable and high quality due to the renowned reputation of that institution for robust data collection methodologies and adherence to rigorous research standards. In the first study ( $n = 51,017$ ), COVID-19 occurred in 4,424 people (8.7%) during the 26-week observation period (Shrestha et al., 2023). In terms of preventing infections by the three prevailing Omicron subvariants, the vaccine efficacy was 29%, 20%, and a non-significant 4%, respectively (Shrestha et al., 2023). No protection was provided when the XBB lineages of the Omicron COVID-19 variants were dominant. Notably, the risk of “breakthrough” infection was significantly higher among those who received the earlier injection, and a higher frequency of modmRNA inoculations resulted in a greater risk of COVID-19 (Shrestha et al., 2023b). In a second Cleveland Clinic Health System cohort study ( $n = 48,344$ ), adults who were “not up-to-date” by the CDC definition had a 23% lower incidence of COVID-19 than those “up-to-date” with their “vaccinations” (Shrestha et al., 2023b). These findings are further reinforced by multiple real-world studies showing rapidly waning protection against Omicron infection after the boosters (National Institutes of Health, 2022). The vaccine efficacy against laboratory-confirmed Omicron infection and symptomatic disease rapidly waned within three months of the primary modmRNA injection cycle and booster dose (Menegale et al., 2023).

Figures 3-4 present the surprising findings from the first Cleveland Clinic studies. Figure 3 displays the findings of the first study, with a cumulative incidence of COVID-19 for study participants stratified by the number of modmRNA doses previously received. Day 0 was September 12, 2022, the date the bivalent modmRNA product was first offered to Cleveland Clinic Health System employees. Case rates were clearly increasing in tandem with greater frequency of mRNA injections (Shrestha et al., 2023b). Figure 4 presents another unexpected finding, this time from the second Cleveland Clinic study, with a Simon-Makuch hazard plot comparing the cumulative COVID-19 incidence in the “up-to-date” and “not up-to-date” with respect to CDC-defined vaccination status. Day 0 was January 29, 2023, the day the XBB lineages of Omicron became dominant in Ohio. For both charts, point estimates and 95% CIs are shown along the x-axis (Shrestha et al., 2023b).

A third Cleveland Clinic investigation, this time enrolling 47,561 working-age employees, confirmed once again that people who received more doses were at greater risk of COVID-19 (Shrestha et al., 2024). The researchers found that the 2023-2024 COVID-19 modmRNA injections were 23% effective against the JN.1 strain of SARS-CoV-2. However, the study also revealed that individuals with a greater number of previous modmRNA injections faced an increased risk of contracting the virus. Specifically, the risk of COVID-19 was 1.5 times higher for those who had received 2 modmRNA doses, 1.95 times higher for those with 3 doses, and 2.5 times higher for those with more than 3 doses, compared to those who had received 0 or 1 dose. This suggests an inverse dose-response relationship in terms of protection against COVID-19 protection, the very disease this product is supposed to prevent.

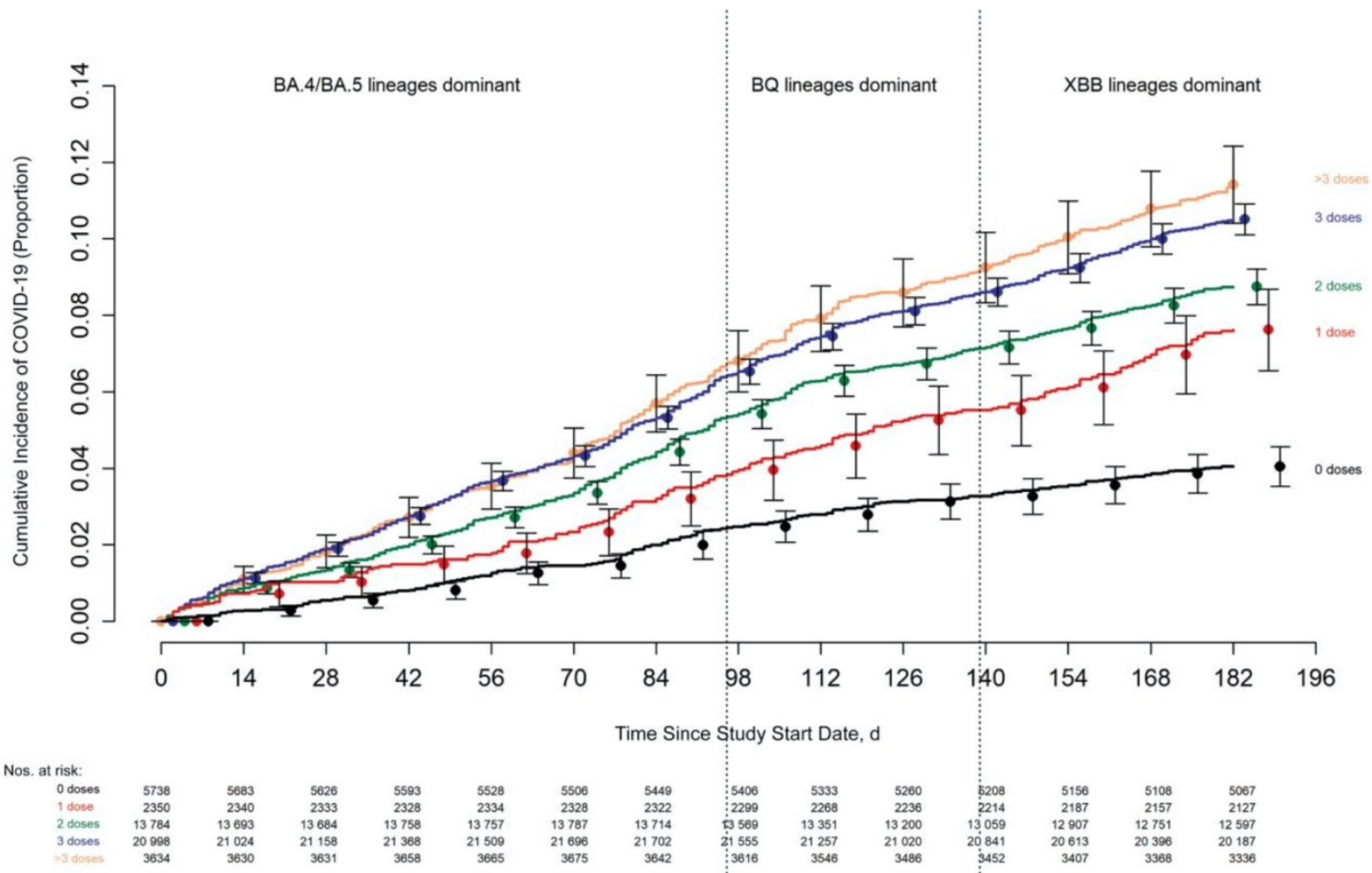
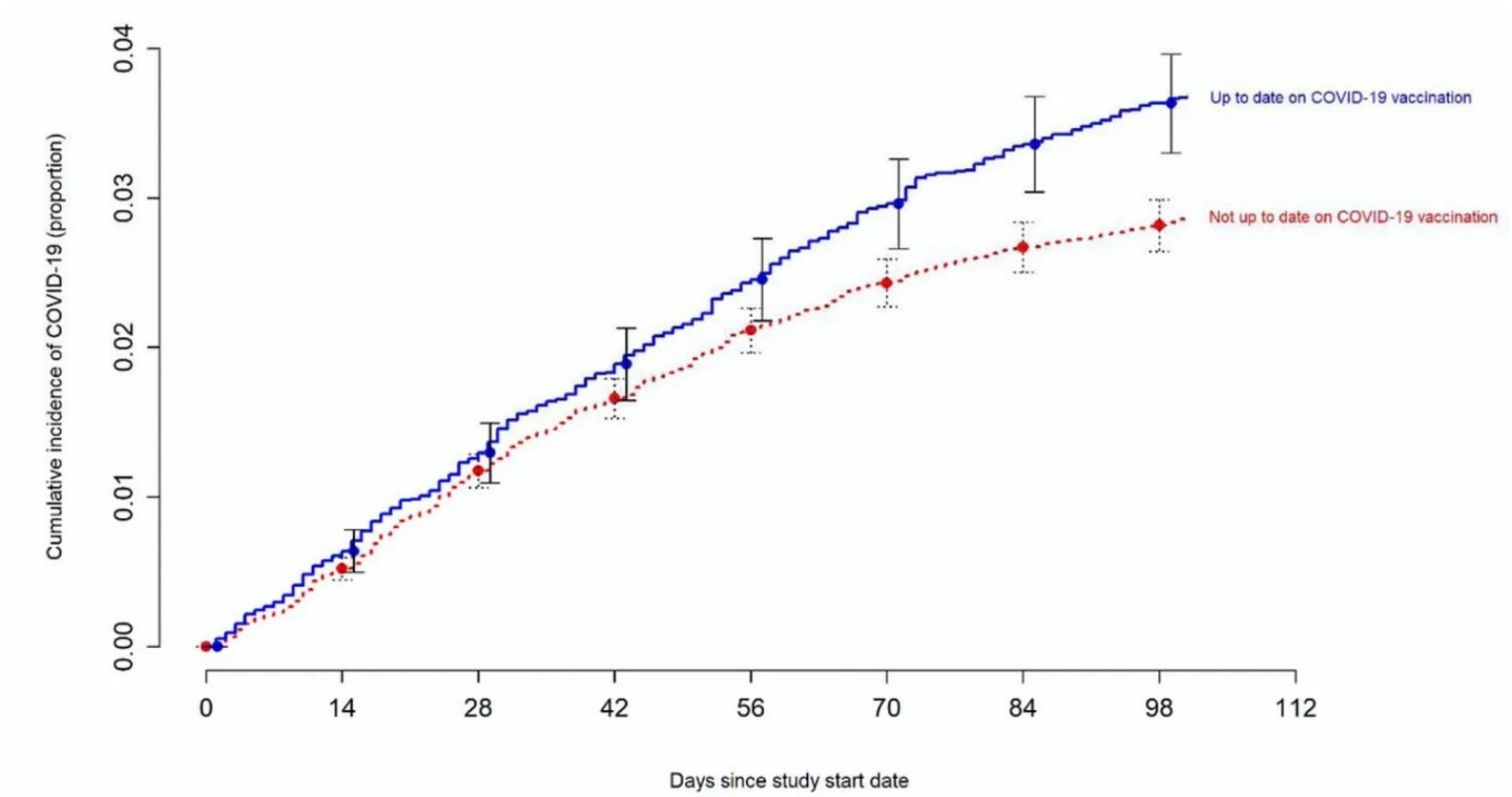


Figure 3. Cleveland Clinic study showing increasing COVID-19 cases with increasing modmRNA injections. Cleveland Clinic study demonstrating COVID-19 incidence among participants based on the number of prior modmRNA doses received. The study shows rising case rates associated with increased modmRNA doses. Image Source: Shrestha et al. (2023); Open Access article with public sector information, licensed under the Open Government Licence v3.0.



Numbers at risk:

	0	14	28	42	56	70	84	98
Not up to date	36344	35771	35223	34712	34310	33928	33595	33350
Up to date	11990	12058	12107	12113	12116	12091	12089	12096

Figure 4. Cleveland Clinic study showing increased COVID-19 cases for subjects most “up to date” with modmRNA injections. Cleveland Clinic study comparing cumulative COVID-19 incidence between “up-to-date” and “not up-to-date” individuals based on CDC-defined vaccination status. The plot includes point estimates and 95% confidence intervals along the x-axis. *Image Credit:* Shrestha et al., 2023b; Open access, licensed under CC BY 4.0 Deed (Attribution 4.0 International).

These remarkably consistent Cleveland Clinic findings offer insight into real-world observations of worsening protection associated with COVID-19 modmRNA injections in various populations.

United Kingdom (UK) Health Security Agency data showed a significant increase in COVID-19 susceptibility among modmRNA-injected compared to non-injected individuals (see Figure 1A, B, and C, UK Health Security Agency, 2022). After an initial six-month period, every age group of modmRNA recipients experienced a higher risk of COVID-19 when compared to their non-injected counterparts (COVID-19 Vaccine Surveillance Report, 2022). A cohort study in Iceland estimated the proportion of persons who became re-infected with SARS-CoV-2 during the Omicron wave in Iceland, finding that 2 or more doses of the COVID-19 injectables were associated with a higher probability of reinfection compared with 1 dose or none (Eythorsson et al., 2022). New Zealand Health data indicate that those individuals who received 3 COVID-19 modmRNA injections were more susceptible to SARS-CoV-2 infection and hospitalization than their non-injected counterparts (Hatchard, 2022). A study of 100,000 people in Qatar revealed that individuals who received 2 doses of either the Pfizer or Moderna mRNA products were more susceptible to Omicron infection compared to non-injected persons. Six months following the 2<sup>nd</sup> dose, the efficacy of both modmRNA injectables declined into negative figures, with the Pfizer product falling to -3.4% and Moderna to -10.3% (Altarawneh et al., 2022).

In a large Israeli study of 32,000 modmRNA recipients, there was a 27-fold higher risk of developing symptomatic COVID-19 along with an 8-fold higher risk of hospitalization when compared to non-injected patients within the same healthcare system (Gazit et al., 2022). Hospitalization is typically correlated with an increased risk of premature mortality. Two additional studies focusing on modmRNA recipients admitted to hospitals suggested that mortality rates may increase with additional doses of the COVID-19 modmRNA (Rzymiski et al., 2021; Adhikari et al., 2024). In retrospect, the possibility of such a backfiring of the modmRNA technology had been suggested early on in the pandemic, albeit based on indirect evidence: animal studies performed decades earlier had suggested that classical vaccines might elevate the risk of contracting the coronavirus infection that causes severe acute respiratory syndrome (SARS; Jiang, 2020).

With the product efficacy profile now firmly in question, the vaccine enterprise has embraced two narratives to justify the ongoing use of COVID-19 modmRNA injections. The first is that, while the modmRNA products may not block infections, the injections still protect against severe disease, hospitalization, and mortality. The second narrative states that the protection associated with the mRNA inoculation, when combined with natural infection, is superior to natural infection, and thus better than natural immunity alone.

The first narrative posits a counterintuitive dichotomy between the two forms of protection, protection against infection versus protection against severe disease, and seems to imply their independence. As an encapsulation of this dichotomy, a 2022 Israeli study report states that the “protection against confirmed infection appeared short-lived, whereas protection against severe illness did not wane during the study period” (Bar-On et al., 2022). However, is it reasonable to contend that protection against severe illness and mortality remains intact even after the rapid decline in protection against infections? To address this issue, Ophir et al. (2023) and colleagues conducted a meticulous analysis of prominent data from clinical trials, large observational studies from Israel, and contemporary dashboards of statistics. The authors noted “multiple methodological and representational constraints, including short, and sometimes arbitrary or uneven follow-up periods, uneven exclusion criteria and COVID-19 testing levels, selection biases, and selective



reporting of results. But most importantly, the documented, conditional probability of death and severe illness (i.e., the percentage of severe illness and death cases among those infected with the virus) did not differ between the treatment and the control groups of the various clinical and observational efficacy studies". The authors concluded that there was no valid evidence to substantiate the claim that getting a 2<sup>nd</sup> COVID-19 mRNA booster effectively prevents severe illness and mortality (Ophir et al., 2023).

The second alternative narrative regarding protection focuses on the phenomenon of hybrid immunity, the combined protection obtained from natural infection followed by the booster. In those individuals recently exposed to SARS-CoV-2 infections, COVID-19 modmRNA-induced immunity is believed to surpass natural immunity because it generates a stronger antibody response and broadens the spectrum of antibodies generated (Pilz et al., 2022). These robust, broad-based humoral responses entail the production of memory B cells at levels 5-10 times higher than those achieved through either infection or modmRNA injection alone (Spinardi & Srivastava, 2023). By the end of 2023, most if not all individuals in developed countries had been infected by SARS-CoV-2. Once informed of the additional protection afforded by hybrid immunity, laypersons cognizant of having a history of infection may be more inclined to embrace ongoing boosters. Nonetheless, given the relatively low severity of Omicron, is the additional antibody production truly necessary?

One also needs to consider the underlying causes and potential risks of the observed increase in antibody production. The potential overproduction of non-neutralizing antibodies could lead to the phenomenon of vaccine-associated enhanced disease, which is based in part on antibody-dependent enhancement (Bigay et al., 2022). To date, there have been only a few reports of mild vaccine-associated enhanced disease following COVID-19 modmRNA injections in animal models and no documented cases in humans (Gartlan et al., 2022). With repeated boosters, however, vaccine-associated enhanced disease could eventually impact the long-term safety of the modmRNA products.

In the context of hybrid immunity, the most serious immunological pitfall pertains to SARS-CoV-2 infection occurring *after* the COVID-19 modmRNA injection, when spike protein production is already systemically increased. It was originally assumed that prior administration of the modmRNA injectable might lessen the severity of the infection and reduce the risk of severe COVID-19 illness. In the post-injection period, the immune system would be primed for responding more robustly to a subsequent infection within a few weeks after completing the full series. However, the opposite scenario can also unfold due to the circumvention of innate immune responses, together with the above-mentioned overproduction of non-neutralizing antibodies and inadequate protection against severe disease (Bossche, 2023). COVID-19 modmRNA injections are known to cause innate immune suppression via profound impairment in type I interferon signalling along with disruption of regulatory control of protein synthesis and cancer surveillance (Seneff et al., 2022). Excessive production of non-neutralizing antibodies could increase the risk of autoimmune reactions by cross-reacting with host tissues instead of the virus, thereby triggering inflammatory autoimmune reactions via molecular mimicry (Rodríguez et al., 2022; Rojas et al., 2023; Talotta, 2021). These mechanisms may collectively raise the risk of autoimmune inflammatory pathologies, including cancers, cardiovascular diseases, and many other diseases with a chronic inflammatory etiology (Akinosoglou et al., 2021; Polykretis et al., 2023).

Up to this point, when considering serious adverse events, we have focused primarily on those effects associated with Pfizer's BNT162b2, drawing from the six-month trial data as well as the 393-page confidential document released on August 2022, revealing close to 1.6 million adverse events (Pfizer, 2022). In the context of hybrid immunity, it is important to note that the Moderna product, mRNA-1273, generates a substantially stronger immune response, resulting in lower rates of symptomatic infection and severe COVID-19 outcomes when compared to BNT162b2 (Wang et al., 2022). Those who fixate on these infection-preventing benefits, however, may tend to overlook the potential harm: mRNA-1273 has exhibited significantly higher risks of serious adverse events compared to BNT162b2, according to clinical trials, survey-based studies, and a government-sponsored surveillance study (Polack et al., 2020; Baden et al., 2021; Beatty et al., 2021; Kitagawa et al., 2022; Valera-Rubio et al., 2022; Chapin-Bardales et al., 2021; Chapin-Bardales et al., 2021b). This again shows the unsavory trade-off between increased protection against Omicron infection on the one hand and a substantial risk of modmRNA-induced serious adverse events on the other.

In a recent study of nearly 5 million adults, those who had a SARS-CoV-2 infection within 21 days post injection showed an 8-fold increased risk of ischemic stroke (OR=8.00, 95%CI 4.18-15.31) and a 5-fold increased risk of haemorrhagic stroke when compared to modmRNA recipients without concurrent infection (OR=5.23, 95% CI 1.11-24.64) (Nahab et al., 2023). The risk was highest for those receiving the mRNA-1273 injections. Thus, SARS-CoV-2 infection close to the time of modmRNA injection produced a strong association with early incidence of ischemic and haemorrhagic strokes (Nahab et al., 2023). Again, with a hybrid immunity approach, the potential harms may greatly outweigh the rewards.

Natural immunity carries none of these risks and is more than sufficient against the mild virulence of Omicron subvariants. Much evidence now indicates that natural immunity confers robust, durable, and high-level protection against COVID-19 severe illness (Gazit et al., 2022; Wang et al., 2021; Gallais et al., 2021; Hall et al., 2021; Harvey et al., 2021). A large UK study of over 30,000 healthcare workers, having a prior history of SARS-CoV-2 infection, showed an 84% reduced risk of reinfection, with a median protective period of seven months (Hall et al., 2021). In a large observational study in Israel, previously infected individuals who decided to forgo the modmRNA injections were 6-13 times less likely to contract the virus compared to those who received the modmRNA injections (Gazit et al., 2022). Hospitalization data from New York and California suggest that having had a previous COVID-19 infection means one's risk of serious COVID-19 disease outcomes following reinfection are astonishingly low (León et al., 2022).

After recovering from COVID-19, the body harbours long-lived memory immune cells, indicating an enduring capacity to respond to new infections, potentially lasting many years (Turner et al., 2021). Mounting evidence suggests that the training of antibodies and induction of T-cell memory resulting from repeated natural infection with Omicron can augment the mitigation of future infections (Wang et al., 2021b; Reynolds et al., 2022). In a recent cohort study, children who had experienced prior infection showed long-lasting protection against reinfection with SARS-CoV-2 for a minimum of 18 months (Patalon et al., 2023). Such children between the ages of 5 and 11 years demonstrated no decline in protection during the entire study, while those aged 12-18 experienced a mild yet measurable decline in protection over time (Patalon et al., 2023). For these younger generations in particular, natural immunity is more than sufficient and of course vastly safer than the modmRNA inoculations.

## Serious Harm to Humans

We now review what is known about the adverse events and serious adverse events reported in the registrational trials, including data that regulatory agencies and drug safety surveillance studies revealed following the Emergency Use Authorization. As early as 2014, Sahin and colleagues had warned of the potential dangers of the modmRNA technology, specifically cautioning that the encoded antigen should be investigated for multiple disease risks (Sahin et al., 2014). Surveys show that the primary concern expressed by parents regarding their children receiving the COVID-19 modmRNA injections is not vaccine efficacy but rather the potential adverse events (Majzoub et al., 2023; Dudley et al., 2023). In a survey of US parents, concerns about the unprecedented speed of the modmRNA products' development (and, by implication, the rapid authorization process) were ranked just above concerns about harmful side effects (Dudley et al., 2023). The risks may vary depending on the number and frequency of modmRNA doses. Whereas some authors have observed fewer adverse events after the 2<sup>nd</sup> dose (Abdulkader & Merza, 2023), others have reported an increased incidence (Beatty et al., 2021). Sultana et al. (2023) reported varying trends in adverse events after the 2<sup>nd</sup> dose for both modmRNA products, albeit with a higher frequency of adverse events following the 2<sup>nd</sup> dose of the Moderna product.

The most compelling revelations regarding the adverse impacts of these products have come from a comprehensive re-analysis of the trial data, with a primary focus on the more serious outcomes, including fatalities. Applying rigorous methodology, Fraiman and colleagues conducted an in-depth investigation and analyzed the interim datasets for the Pfizer and Moderna trials, encompassing approximately four months of observation following the commencement of the trials (Fraiman et al., 2022). serious adverse events were defined as events that led to any of the following outcomes: death, life-threatening conditions, inpatient hospitalization or extension of existing hospitalization, persistent or significant disability/incapacity, a congenital anomaly/birth defect, or a medically significant event based on medical judgment. The risk of serious adverse events was divided into general serious adverse events and “adverse events of special interest”, as identified by the Brighton Collaboration criteria adopted by the World Health Organization (Brighton Collaboration, 2020).

For both the Pfizer and Moderna trials combined, there were about 125 serious adverse events per 100,000 modmRNA recipients, which translates into one serious adverse event for every 800 modmRNA recipients (Fraiman et al., 2022). Because the trials avoided the most frail as participants, one would expect to see even higher proportions of serious adverse events in the population-wide rollouts. Remarkably, the Pfizer trial exhibited a 36% higher risk of serious adverse events in the modmRNA group compared to the placebo, with a risk difference of 18.0 (95%CI 1.2-34.9) per 10,000 modmRNA recipients; risk ratio 1.36 (95%CI 1.02-1.83). These findings stand in sharp contrast with the FDA claim that serious adverse events reported by the two pivotal trials were “balanced between treatment groups” (Doshi, 2021a; Fraiman et al., 2022). The discrepancy may be partly explained by the fact that the FDA was focusing only on individual participant data, and yet many of those individuals were experiencing multiple serious adverse events. Instead of analyzing individuals, Fraiman et al. (2022) focused on total serious adverse events to take into account the multiple, concurrent events. When the serious adverse events were viewed collectively, the risks in the modmRNA group were substantially elevated beyond those previously determined by the FDA.

For their risk-benefit assessment, Fraiman's team considered the excess risk of serious adverse events of special interest in the modmRNA group versus the risk of COVID-19 hospitalization in the placebo group (Fraiman et al., 2022). This analysis was based on published reports from the

drug companies' sponsors and FDA presentations. Remarkably, according to Fraiman et al., the Pfizer trial exhibited a > 4-fold higher risk of serious adverse events of special interest compared to the risk of COVID-19 hospitalizations (10.1 adverse events of special interest vs. 2.3 hospitalizations per 10,000 participants, respectively), while the Moderna trial demonstrated a more than 2-fold higher risk (15.1 adverse events of special interest vs. 6.4 hospitalizations per 10,000 participants, respectively). These findings indicate a much stronger degree of modmRNA-related harm than initially estimated during the time of Emergency Use Authorization. To put these findings in perspective, the official serious adverse event rate for other vaccines is only 1-2 per million (U.S. Department of Health & Human Services, 2022). Fraiman et al.'s (2022) estimate based on the Pfizer trial data (1,250 serious adverse events per million) exceeds this benchmark by at least 600-fold.

Analyses of two large drug safety reporting systems in the US and Europe revealed over 7.8 million adverse events reported by approximately 1.6 million individuals who had received the COVID-19 modmRNA injections (Montano, 2021). When compared to individuals aged 18-64 years, the older age groups exhibited a higher frequency of death, hospitalizations, and life-threatening reactions, with relative risk estimates ranging from 1.49 (99% CI 1.44-1.55) to 8.61 (99% CI 8.02-9.23). Signals were identified for myocardial infarction, pulmonary embolism, cardio-respiratory arrest, cerebral infarction, and cerebral hemorrhage associated with both modmRNA products. These signals, along with ischemic strokes, were confirmed by a large disproportionality analysis (Yan et al., 2022). In an independent risk-benefit analysis, BNT162b2 produced 25 times more serious adverse events than the number of severe COVID-19 cases prevented (Mörl et al., 2022). Such an uneven risk-benefit calculus reinforces the findings from the Skidmore survey, which estimated that the total number of US fatalities due to COVID-19 modmRNA injectables in 2021 alone was 289,789 (95% CI 229,319-344,319; Skidmore, 2023). A physician and survey research specialist helped to validate the survey, and the sample (obtained by Dynata, the world's largest first-party data platform, based in Connecticut, US) was deemed representative of the US population (Skidmore, 2023).

Finally, autopsy studies have provided additional evidence of serious harm. In a comprehensive systematic review with full independent adjudication, 74% of autopsy findings (240 out of 325 cases), were judged to have been caused by the COVID-19 modmRNA products (Hulscher et al., 2024). The mean time from injection to death was 14.3 days, and the vast majority of deaths had the cardiovascular system as the single fatal organ system injury to the body. These findings are reinforced by those of a more recent adjudicated autopsy review of modmRNA-induced myocarditis (28 deaths, all of which were attributed to the injections; Hulscher et al., 2024) as well as a previous autopsy study of modmRNA injectable recipients that did not have the advantage of independent adjudication (Schwab et al., 2023). Based on multiple autopsy studies, German pathologists led by the late Arne Burkhardt have documented the presence of COVID-19 modmRNA injection-generated spike proteins in blood vessel walls and brain tissues through immunohistopathological-staining (Wünstel, 2020; Sanning, 2022). These findings help explain the wide range of well-documented COVID-19 modmRNA-induced toxicities that impact the nervous, gastrointestinal, hepatic, renal, hematological, immune, and reproductive systems (Trogakos et al., 2022; Seneff et al., 2023; Blaylock, 2022). Post-mortem examinations are critical for identifying potential serious adverse events of the modmRNA inoculations. However, as clinics and hospital administrations have a large vested financial interest in the COVID-19 modmRNA product distribution, the common administrative practice of discouraging autopsies and postponing autopsy



reports only serves to undermine comprehensive risk assessment, perpetuate public misconceptions regarding safety, and weaken public health policymaking (Blaylock, 2022).

## Immunologic Basis for COVID-19 modmRNA Failure

The biomedical purpose of the COVID-19 modmRNA “vaccination” is basically twofold: (1) to leverage the body’s immune defenses against infection by SARS-CoV-2, and (2) to reduce the risk of severe disease and its consequences. Following intramuscular injection with the modmRNA product, the spike protein-encoding modmRNA is delivered via LNPs to human cells that generate spike proteins and/or related antigens that resemble those present on the surface of the coronavirus (Trougakos et al., 2022). These antigens then theoretically stimulate the production of memory T-cells and B-cells, with the latter subsequently producing antibodies that bind to specific epitopes of the virus. Consequently, if an injected individual encounters SARS-CoV-2, their immune system will mount a robust adaptive immune response in the short term, theoretically reducing the severity of the infection. This reduction in COVID-19 symptoms represents the intended clinical benefit of these biologicals.

The above explanation, however, connotes an immunological disconnect between the systemic effects of the COVID-19 modmRNA injection and the protection naturally afforded by lung mucosal immunity. SARS-CoV-2 is primarily an airborne virus that enters the human body via the upper respiratory tract. Thus, the immune system’s first encounter with the pathogen usually occurs in the nasal passages and tonsils, inducing the production of secretory IgA antibodies in saliva, nasal fluid, tears, and other secretions within just four days of the initial exposure (Russell et al., 2022). The virus is then successfully confined to the upper respiratory tract, resulting in either asymptomatic infection or mild symptoms such as a cough or sneeze (Russell et al., 2022). The combination of secretory IgA and activated tissue-resident T-cells in mucosal areas can halt the infection altogether, rather than just limiting the infection and curbing disease symptoms (Lavelle & Ward, 2022). Moreover, based on studies of SARS-CoV (the presumed predecessor to SARS-CoV-2), the cellular immunity that accompanies the initial respiratory infection may persist for up to 17 years, even without a detectable humoral component (Primorac et al., 2022). In research involving human participants who consented to exposure to the H1N1 flu virus, pre-existing mucosal IgA provided better protection against severe illness than systemic IgG (Gould et al., 2017), suggesting that high circulating IgG titers might not correlate with robust protection. The lung mucosa produce an array of innate immune factors (e.g., complement, proteases, lactoferrin, and antimicrobial peptides) that work in synchrony with secretory antibodies (sIgA and sIgM) to limit the entry of foreign microbes and particles (Mettelman et al., 2022). During infection, neutrophils are the predominant responders, releasing IL-8 and elastase to enhance the recruitment of natural killer cells, monocytes, and eosinophils from the circulation (Mettelman et al., 2022).

Given this immunological context, it is reasonable to suppose that the natural mucosal immunity against SARS-CoV-2 and other respiratory viruses may typically lead to more comprehensive, long-lasting protection compared to the systemic immune responses elicited by the COVID-19 modmRNA injectables. Whereas SARS-CoV-2 infection induces both mucosal and systemic immune responses, the COVID-19 modmRNA products, as currently administered, are ineffectual in terms of inducing mucosal immunity (Alu et al., 2022; Mettelman et al., 2022). The presumed benefits of modmRNA-induced immunity are further counterbalanced by the serious adverse event risks discussed previously. It cannot be overemphasized that these risks pertain to the entire population,



the vast majority of whom have the capacity to eliminate SARS-CoV-2 without succumbing to severe morbidity or premature death.

When federal officials said repeatedly that the “COVID-19 vaccines are safe and effective”, they often added that the products were “95% effective against the infection”. Nonetheless, later studies showed that any protective benefit was short-lived, with immunity waning after only a few months (Feng et al., 2022; 230. Lyke et al., 2022). This waning effect becomes more pronounced with successive boosters (Tamandjou et al., 2023). There is a logical explanation for this phenomenon. First, due to viral evolution, SARS-CoV-2 variants are constantly mutating, and numerous mutations have occurred in the spike protein, the intended target for neutralizing antibodies. These mutations, mostly concentrated in the vicinity of the receptor-binding domain, create constant opportunities for the generation of new escape variants (i.e., those that evade neutralizing antibodies), thus enabling immune evasion in subsequent modmRNA inoculations. Second, confrontation with novel antigens on escape variants is associated with “original antigenic sin”, the production of cross-reactive antibodies that may not be effective against the new antigen or pathogen due to prior exposure to predecessor strains (McCarthy, 2022; Noori et al., 2022). Although cross-neutralization is a rare event, cross-reactivity in antibody binding to spike protein is common in the context of SARS-CoV-2 infection (Lv et al., 2020). Additionally, other research indicates a degree of cross-reactivity between seasonal coronaviruses and SARS-CoV-2 (Shrock et al., 2020).

When the immune system becomes entrained on pre-existing SARS-CoV-2 variants, there is, in theory at least, a progressive narrowing of the antibody response to the current, prevailing variants. This imprinting phenomenon has been demonstrated with respect to both SARS-CoV-2 infection and COVID-19 modmRNA injections (Röltgen et al., 2022). A 2021 pilot study found robust increases in humoral responses in SARS-CoV-2-naïve individuals following each dose of BNT162b2, whereas previously infected individuals showed strong humoral responses to the 1<sup>st</sup> dose of the mRNA injection but muted responses to the 2<sup>nd</sup> dose (Samanovic et al., 2021). Immune imprinting was also identified as the underlying factor contributing to the unanticipated decrease in the effectiveness of the bivalent COVID-19 modmRNA injections since the “immune systems of people immunized with the bivalent [modmRNA booster], all of whom had previously been vaccinated, were primed to respond to the ancestral strain of SARS-CoV-2” (Offit, 2023).

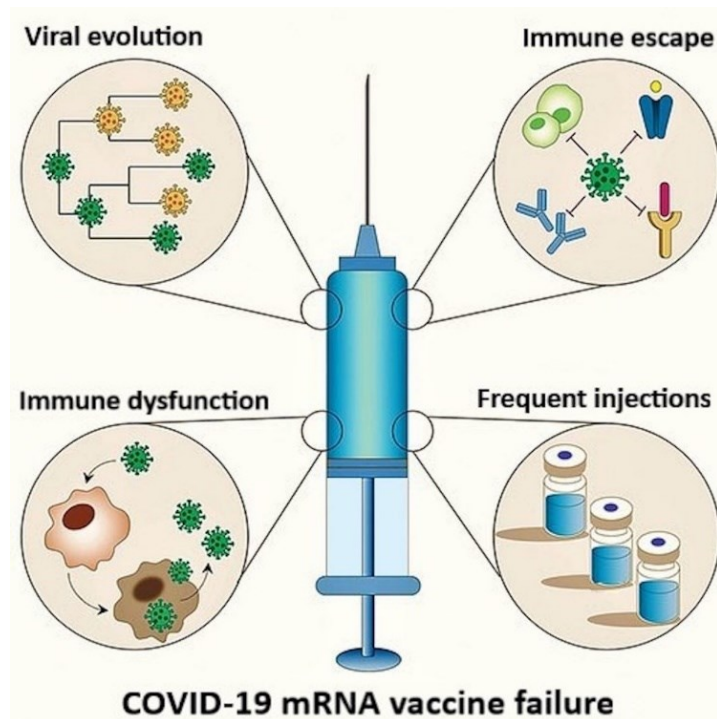
At least part of the immunological basis for COVID-19 modmRNA injectable failure is known and can be summarized as follows. The SARS-CoV-2 spike protein binds to the ACE2 receptor, which is believed to set up a scenario for strong selective immune pressure prompting the spike gene to mutate and find new viral escape paths. According to some researchers, using molecular modeling and 3D docking experiments (Changeux, et al., 2020; Dormoy, et al., 2020; Farsalinos, et al., 2020; Oliveira, et al. 2020, 2021) parts of the spike protein can also bind to the ubiquitous and little understood nicotinic acetylcholine receptors, or nAChRs. If those researchers are correct, such bindings are likely to be involved in many adverse events following COVID-19 injections although those possibilities are beyond the scope of this paper. Because the majority of SARS-CoV-2 modmRNA products are designed using the spike protein sequence from the initial Wuhan strain, whatever escape mutants do arise may, in theory at least, also evade the immune responses triggered by the modmRNA injectables. Any such evasions, regardless of their source, must lead to reduced effectiveness of all subsequent injections with modmRNA products using the unmutated original spike protein sequence, or any other particular mutant or set of them (Gao et al., 2022; Reina, 2022; Röltgen et al., 2022).

Periodic additional COVID-19 modmRNA inoculations, therefore, may adversely impact viral ecology and encourage the ongoing emergence of more immune escape variants ultimately rendering the modmRNA products ineffective. Such diminishing returns were observed in the Cleveland Clinic studies discussed earlier in this paper (Shrestha et al., 2023; Shrestha et al., 2023b). Additionally, ongoing boosters are likely to cause immune dysfunction and antibody class-switching to IgG4, thereby diminishing antiviral and microbial protection while promoting autoimmune disease and accelerated cancer progression, as documented in Part 2 of this paper (Mead, et al., 2024b).

Given the ongoing genetic changes in SARS-CoV-2 driven by both natural viral evolution and modmRNA-induced selective pressure on the immune system, it is likely that frequent COVID-19 modmRNA injections would need to be administered in the coming years to address new prevailing variants. However, the immune imprinting noted above could limit the ability to achieve robust protection and could potentially facilitate viral transmission even with population-wide vaccination (Reina, 2022). Immune evasion by new or emerging SARS-CoV-2 variants in individuals vaccinated against former variants will continue indefinitely, due to antibody cross-reactivity and immune imprinting.

Somewhat ironically, then, the power of the COVID-19 modmRNA to perpetuate the emergence of new variants also tends to perpetuate the perception among the general public that a new round of boosters is necessary. This, in turn, sets up the endless “vaccine-escape variant cycle”, a feedback loop whereby the actions taken to address the issue (more vaccinations) inadvertently contribute to ongoing inefficacy. Mutations in the viral spike protein provide resistance against antibody responses, and this selection process underlies the larger phenomenon in which new dominant variants are emerging (Dumonteil & Herrera, 2020; Shahhosseini et al., 2021; Beeraka et al., 2022). Mass modmRNA inoculations result in the natural selection of highly infectious immune-evading SARS coronavirus variants that successfully bypass modmRNA-induced immunity, leading to a dramatic rise in the prevalence of these variants (Bossche, 2023).

In summary, the large-scale emergence of dominant variants was an adaptive



**Figure 5.** Factors contributing to failure of the COVID-19 modmRNA injections. COVID-19 modmRNA products may lose efficacy in part by inducing SARS-CoV-2 mutations that lead to new immune escape variants, thus ultimately limiting protection against subsequent coronavirus infections. Periodic COVID-19 modmRNA injections could elicit a diverse range of mechanisms associated with immune dysfunction (mostly due to subversion of innate immunity), resulting in a heightened risk of cancers, infections, and autoimmune disorders (as discussed in Part 2). *Image Credit:* Azim Majumder and Razzaque, 2022; adapted with permission from authors.

response to the selection pressure exerted by the mass vaccination campaign, a response further heightened in immunosuppressed individuals (López-Cortés et al., 2022). Importantly, the immune-escape mutants are developing primarily in modmRNA-injected individuals, not in the non-injected (Seneff & Nigh, 2021; Chakraborty et al., 2022). Mechanisms underlying modmRNA-induced immune dysfunction (see preceding section) contribute further to the inefficacy of these products. The main factors involved in the failure of COVID-19 modmRNA injectables are summarized in Figure 5 (Azim Majumder & Razzaque, 2022).

## Scientific Censorship, Retractions, and the Authors' Experience

Prior to the pandemic, with few exceptions, a published paper was only retracted or removed from a journal when there was some form of wrongdoing or misconduct, such as data fabrication, or substantial plagiarism. Criteria for retraction have been established in the Committee on Publication Ethics Guidelines (Graham & Lane, 2018). Since 2020, however, retractions of scientific papers have escalated, with well over 430 COVID-19 papers undergoing retraction as of March 2024 (Retraction Watch). The publicized purpose of these retractions has been to curb the spread of “potentially harmful misinformation”, with the content of that misinformation being defined by the Bio-Pharmaceutical Complex. Nonetheless, retractions during the COVID era have often assumed a pronounced political dimension, with high-quality papers getting retracted when they challenge government-industry strategies for managing COVID-19, particularly in the context of safety concerns associated with the mRNA products. Many research scientists have faced the threat of retractions whenever their findings seriously questioned the safety and effectiveness of the mRNA products and other public health strategies. The practice of truth-finding through discussion and testing of hypotheses, underpinnings of the scientific method, seem to have been largely abandoned.

In 2020, researchers worldwide explored promising early treatment protocols for COVID-19, including hydroxychloroquine and ivermectin. Hydroxychloroquine initially showed promise based on several studies (Gautret et al., 2020; Prodromos and Rumschlag, 2020; McCabe et al., 2021). Nevertheless, later studies using flawed analyses and (in some instances) toxic doses of hydroxychloroquine led to misconceptions regarding its safety and effectiveness (Recovery Collaborative Group et al., 2020). Concerns about the toxicity of hydroxychloroquine were overstated, fueled by what were found out to be deliberately flawed studies like the retracted *Lancet* publication — a justified retraction — due to the fraudulent study design (Mehra et al., 2020).

Similar issues arose with ivermectin research, where collusion and fraudulent-research-conduct tainted the trials (Naggie et al., 2022). Government agencies and academic institutions misled the public and physicians, suppressing dissenting voices and manipulating data (Malhotra 2022a, 2022b). Although numerous studies were released, only problematic studies reporting inefficacy were selectively published in influential journals, leading readers to reach invalid conclusions. Such propaganda led to a false consensus, driven by biopharmaceutical interests, that both hydroxychloroquine and ivermectin were ineffective and unsafe. Under the aggressive influence of vested interests, mainstream media and social media dismissed true reports of the efficacy of hydroxychloroquine and ivermectin as “misinformation” in order to fuel the mainstream narrative about the supposedly “safe and effective” COVID-19 remedies being promoted by the vested interests.

The suppression of effective early treatments greatly hindered efforts to mitigate the pandemic, with most estimates indicating that there would have been a substantial reduction in mortality if hydroxychloroquine and ivermectin had been used (Kory & McCarthy, 2023). Notable reductions in COVID-19 fatalities resulting from the use of these medications, with a mean 31% relative risk of mortality vs. controls, were documented based on careful review of the evidence (Santin et al., 2021). Early ambulatory (not hospitalized, treated at home), multidrug therapy was shown to be “safe, feasible, and associated with low rates of hospitalization and death” (Procter et al., 2020). Subsequent investigations revealed that the dismissal of ivermectin and other inexpensive yet effective treatment options stemmed from a deliberate campaign to withhold efficacious therapies, which would have invalidated the Emergency Use Authorization granted for the mass distribution of COVID-19 modmRNA injectables. It has been estimated that if these initial treatments had been endorsed and made readily available to the public, approximately 85% of COVID-19 deaths in 2020 could have been prevented (Kory & McCarthy, 2023).

The increasingly frequent removal of these counter-establishment papers regarding early treatment and other public health mitigation measures underscores concerns about the suppression of dissenting scientific viewpoints. Given the colossal revenues generated by the COVID-19 modmRNA products (netting over \$200 billion per year, by recent estimates), Pfizer and Moderna have a clear vested interest in censoring scientists who oppose the use of these products. These weaponized retractions benefit the vaccine enterprise by (a) concealing crucial information on COVID-19 vaccine risks, (b) undermining the credibility of the research presented in the retracted papers, and (c) damaging the reputations of the co-authors, potentially weakening their future research and publication prospects. In short, such retractions constitute a highly effective tactic for suppressing contrarian views stemming from scientific findings and analyses that the Bio-Pharmaceutical Complex believes will threaten the beliefs, perceptions, and policies it strives to promote for ongoing distribution of the modmRNA products.

In 2023, Haslam and Prasad conducted a comprehensive analysis of articles submitted to preprint servers, intended as platforms for the dissemination of research pending peer review. A substantial proportion of submissions to these servers were either rejected or removed, despite later acceptance and widespread dissemination through traditional journals. One striking example of a preprint retraction involved the *Lancet* preprint by Hulscher et al., a systematic review of 325 autopsy cases in which 74% of deaths ( $n = 240$ ) were independently adjudicated as “directly due to or significantly contributed to by COVID-19 vaccination” (Hulscher et al., 2023a, 2023b, 2024). In the Haslam-Prasad analysis, most of the retracted preprints related to critiques of the CDC and policy missteps by the Biden administration. Prasad speculates that the servers may be selectively filtering out critiques of the CDC and policy missteps by the Democratic administration (Prasad, 2023). He notes that the criteria for denying or rejecting submissions that commend the public health agencies are different from those that are critical. The ones in agreement with the mainstream and praising the CDC, etc., tend to be accepted, while the ones challenging the stated principles and guidelines of the experimental genetic platform are summarily rejected. However, if preprint servers only accept papers that commend the public health agencies, they undermine the fundamental role of science for oversight and for the correction of



policy errors (Prasad, 2023; Rose & McCullough, 2021). They must, in the long run, also undermine public trust in the medical profession and the pharmaceutical industry in general.

A dramatic example of scientific censorship involved retraction of this very narrative review, which was originally published under a shorter title on 24 January 2024 in the peer-reviewed journal *Cureus* (Mead et al., 2024a). Four weeks after its publication, our paper was retracted by the publisher, Springer-Nature. During that brief period, the article was viewed more than 350,000 times (by contrast, the average *Cureus* paper has only approximately 2,700 views in an entire year) and received a scholarship impact quotient rating of 9.3 out of 10. The journal's editors could have rejected the paper at any point during the intensive 2.5-month review process, which involved 8 reviewers and multiple editors. The retraction lacked sufficient justification and thus constituted a violation of the Committee on Publication Ethics Guidelines (McCullough, 2024). The points raised in the retraction letter strongly suggested that the *Cureus* editors and the publisher Springer-Nature had been pressured by the BioPharmaceutical Complex. Four of the retraction points seemed as though they were position statements issued by the COVID-19 injectable promoters. We will address those below in our **Discussion**. They asserted the following claims all of which were empirically and theoretically refuted in our paper: (1) the modmRNA “vaccines” are not genetic therapy products; (2) these products are not contaminated with high levels of plasmid DNA; (3) the spike proteins generated by the modmRNA injections do not persist in the body and cause adverse events; and finally (4) the modmRNA products underwent adequate safety and efficacy testing — a critical point shown to be false in our paper; Kirsch, 2024). In our rebuttal to the retraction letter issued by Springer, all of the points were controverted with evidence cited directly in our paper. We believe the retraction was gratuitous, essentially issued under false pretenses (McCullough, 2024).

In a recent *JAMA* editorial, Stanford epidemiologist John Ioannidis and colleagues stated that peer review and scientific publishing are at a crossroads (Ioannidis et al., 2023). They noted that the scientific publishing sector, characterized by its immense profitability and foundational role in the broader scientific and biomedical economies, is influenced by a multitude of stakeholders. These stakeholders might seek to leverage the scientific literature for profit or influence, potentially at the expense of scientific integrity and societal benefit. In pressuring journals to retract articles on sensitive topics, the stakeholders typically allege that the article in question violated scientific standards or was published without sufficient peer review. Despite these practices being publicly exposed (as documented above for our “Lessons Learned” retraction by *Cureus* and Springer-Nature), no corrective actions have been reported, highlighting a troubling trend towards the erosion of scientific standards and ethics (Thacker, 2022).

In general, retractions tend to have a chilling effect, compelling scientists and academics to engage in self-censorship when publishing out of fear of backlash, reprisal, or social stigma (Finley, 2023). This results in widespread reluctance to discuss certain topics — even in contexts where free expression should, in principle, be allowed — and to share dissenting perspectives that would otherwise enrich the scientific discourse. This concerning pattern jeopardizes the open exchange of scientific ideas, viewpoints, findings and discoveries, an exchange that is crucial to the public good and to the flourishing of any free society.



Finally, scientific censorship can also manifest in the form of omissions of crucial information from published reports by authoritative sources. A notable example is the April 2024 report by the National Academies of Sciences, Engineering, and Medicine, whose 15-member committee reviewed evidence of potential injuries related to COVID-19 modmRNA injections for which people had submitted compensation claims (National Academies of Sciences, Engineering, and Medicine, 2024). The report identified a causal connection between COVID-19 modmRNA injections and myocarditis but dismissed links to other serious adverse events such as female infertility, Guillain-Barré syndrome, Bell's palsy, thrombosis with thrombocytopenia syndrome, ischemic stroke, and heart attacks. The report said the association with myocarditis was "mild" despite evidence of permanent heart damage in many cases. Additionally, the National Academies of Sciences, Engineering, and Medicine report ignored many comprehensive reviews and key studies addressing serious adverse events related to cardiovascular, neurological, hematological, reproductive, and autoimmune issues associated with mRNA injections. We will come back to those in our Part 2 of this response to the unwarranted retraction of our *Cureus* paper. Critically, the report overlooked findings from the Fraiman et al. re-analyses of the original Pfizer and Moderna trial data, such as the conservative estimate of approximately 1 serious adverse event for every 800 modmRNA injections (Fraiman et al., 2022). The basis for the conclusions of the National Academies of Sciences, Engineering, and Medicine raises further concerns about bias, primarily selecting literature sources that seem to favor the modmRNA products while almost uniformly sidelining studies that indicate substantial risks of modmRNA-induced injury and mortality. The biographies of National Academies of Sciences, Engineering, and Medicine committee members revealed that the majority had received grants or contracts from the U.S. Department of Health and Human Services, the Department of Defense, or the pharmaceutical industry.

Another example of how seemingly authoritative publications can distort the adverse impacts of the modmRNA products is a recent multinational Global Vaccine Data Network cohort study by Faksova et al. (2024), published in the journal *Vaccine*. Setting aside Kyle Beattie's work with all the reporting entities in Our World in Data, the Faksova study, is the largest safety study of the COVID-19 injectable products to date, examining adverse events among approximately 99 million individuals ( $n = 99,068,901$ ). The authors used electronic health records to investigate the association between COVID-19 injections and 13 adverse events of special interest comprising cardiovascular, neurological, and haematological conditions across 10 sites in eight countries. For the modmRNA products, the analysis identified prioritized warning signals for myocarditis/pericarditis and acute disseminated encephalomyelitis. Signals were also identified for pulmonary embolism, thrombocytopenia, supraventricular tachycardia, febrile seizures, and Bell's palsy; however, these signals did not meet the threshold for "prioritized" warning signals. Guillain-Barré syndrome was a signal, but only for the adenoviral vector-based injections, a major discrepancy with data from the Vaccine Adverse Events Reporting System, which shows a strong signal for Guillain-Barré syndrome associated with the modmRNA injections (Rose 2021a, 2021b).

The cohort study by Faksova et al. (2024) faces two major limitations. First, it does not stratify by age and gender, thus masking the true magnitude of injuries that are known to disproportionately affect certain subpopulations, such as myocarditis in younger populations under age 40. Bardosh et al. (2024) estimated that mandating boosters for younger adults

would likely result in net harms, projecting at least 18.5 serious adverse events from the modmRNA injections for every COVID-19 hospitalization prevented. The analysis included about 1.5 to 4.6 cases of myopericarditis associated with the booster in males, which generally requires hospitalization (Bardosh et al., 2024). Second, the use of electronic health records leads to under-reporting of adverse effects, introducing biases such as selection bias, detection (or ascertainment) bias, and incomplete documentation. In terms of detection bias, for example, approximately half of all cases of myocarditis are initially asymptomatic, resulting in under-detection and under-reporting of the condition (Cheng et al., 2022). A large proportion of modmRNA-induced myocarditis and other adverse events may manifest initially in a mild form so that the individual does not seek medical attention and therefore delays entering into the electronic health records. Taken together, these kinds of limitations likely result in substantial underestimation of adverse events. The authors' caveat that "potential underreporting across countries may have led to an underestimation of the significance of potential safety [warning] signals" is an understatement. Many of the adverse event signals were grossly underestimated; many others were missed entirely because the researchers cast a narrow net.

For the general public and much of the medical community as well, the impressive size and statistical power of the Faksova et al. (2024) study could easily engender the impression that this is a rigorous, comprehensive study with trustworthy conclusions. In the end, however, as with the National Academies of Sciences, Engineering, and Medicine report, such flawed studies only serve to manufacture the illusion of a narrowly defined set of potential harms, the bulk of which are presented as relatively mild or non-threatening. By disclosing only partial or selective information, the full truth about the serious adverse event profile of the modmRNA products is concealed. Known as the "limited hangout" strategy in media circles, this tactic can be employed to divert and manage public perception, to protect specific interests, and to mitigate the potential fallout from full disclosure. Selective disclosures, in revealing merely a portion of the facts and omitting alternate perspectives, can distort the harm done by the modmRNAs while promulgating the deceitful agenda of the BioPharmaceutical Complex. As a result, the general public is presented with a skewed and incomplete picture that seems to be intended to allow the pharmaceutical companies and government agencies to remain unaccountable.

The narrative may be collapsing as direct human experience clashes with previously misinformed beliefs and assumptions. A recent *New York Times* article titled "Thousands Believe COVID Vaccines Harmed Them" featured a number of high-profile anecdotes of modmRNA-injured individuals within the scientific community (Mandavilli, 2024). The article highlighted the experience of *Vaccine* editor-in-chief Gregory Poland, PhD, who spoke of how his peers seemed to dismiss his own modmRNA injury, and Yale University vaccine researcher Akiko Iwasaki, PhD, who described the gaslighting of those with post-modmRNA injuries. Also featured was the ordeal of neuroscientist Michelle Zimmerman, PhD, who suffered brain damage following the modmRNA injection. Janet Woodcock, MD, former director of the FDA Center for Drug Evaluation and Research, acknowledged that some individuals suffered severe and life-altering effects from the modmRNA injections, most of which are not being recognized by federal agencies (Mandavilli, 2024).

As the reality of modmRNA-related injuries and deaths becomes personal and more widely known, it is hoped that the mainstream media will no longer be able to ignore these events,

and that the scientific publishing world may be compelled to shift accordingly. Medical journals such as *IJVT*, free from the constraints of biopharmaceutical industry bias and influence, may emerge as the torchbearers of integrity-based scientific discourse. Valid ideas that were once considered radical, or that were disingenuously labelled as “conspiracy theories”, such as the power of the modmRNA injectables to cause psychosis (Lazareva et al., 2024), can hardly be regarded as mere theories. Real conspiracies abound and they are being exposed by thanks to courageous scientific reporting and publishing. A shift is taking place in what is considered acceptable discourse concerning COVID-19 modmRNA product injuries. An evolutionary leap seems to be taking place in public sentiment and scientific understanding. Initially, skepticism was marginalized, with the modmRNA “vaccines” widely portrayed and propagandized as overwhelmingly beneficial. As more data has emerged, however, including analyses suggesting rising risks that are all too real being compared to hypothetical benefits that keep vanishing, the window of acceptable discussion has widened. “Vaccine hesitancy” is being replaced by “modmRNA skepticism”. Conspiracy theorists and “misinformation spreaders” are being recast as rational theorists and truth tellers, respectively. Surveys show that vaccine hesitancy (or skepticism) is highly correlated with perceiving oneself as being at lower risk of developing severe COVID-19 disease (Gomes et al., 2022), and by implication, trusting one’s immune system. Concerns regarding the modmRNA safety and potential “side effects” are consistently among the main reasons found in the literature for refusing the injections (Soares et al., 2021). This is not conspiracy theorizing but rational thinking.

The questioning of modmRNA product safety, once taboo, now occupies a central position in public discourse and has become increasingly nuanced, influencing policy debates, and public opinion. This shift has the potential to reshape public health strategies and messaging to address legitimate concerns not only regarding public health but also the scientific enterprise itself. Science cannot flourish without the free exchange of discourse in the sharing of ideas, and findings through diverse channels as we pursue knowledge and understanding. We must always protect our fundamental right to open scientific inquiry and discourse, particularly when such activities impact public health safety on a global scale.

## Discussion

In Part 1 of this review, we have considered alternative narratives based on a direct assessment of available data and published studies, and we will continue to do that in Part 2 as well. In doing so, our intention is to foster transparency, trust, and informed decision-making, ensuring that legitimate questions concerning COVID-19 modmRNA products are addressed. This approach not only contributes to the ongoing discourse about “safety” but also paves the way for improving public health strategies going forward. The ethical implications of our inquiry relate to epidemiological inequities: whereas COVID-19 has primarily afflicted the immunosuppressed, elderly, and those with multiple comorbidities, the COVID-19 modmRNA injectables have the potential to adversely impact people of all ages, not only frail elderly individuals — the most vulnerable sub-group — but also young and relatively healthy individuals, most of whom have a near-zero risk of serious consequences from COVID-19 (Pezzullo et al., 2023). When we consider the likelihood of more frequent serious adverse events resulting from interactions between COVID-19 modmRNA inoculations and subsequent SARS-CoV-2 infections, it is important to bear in mind that the

Omicron subvariant infections that have been dominant since early 2022 follow a mild course and are almost always non-lethal (Dhama et al., 2023). Moreover, whereas infections by their very nature are involuntary and accidental, the modmRNA injections are a choice with potentially life-threatening repercussions.

The pivotal role of randomized placebo-controlled clinical trials in assessing the efficacy of drugs, vaccines, and other interventions has long been recognized within the medical and public health communities. The value of well-designed controlled trials was highlighted in a report by the WHO Ad Hoc Expert Group on the Next Steps for COVID-19 Vaccine Evaluation published in January 2021 (WHO Ad Hoc Expert Group, 2021). Ensuring the credibility of observed outcomes, particularly in the context of novel experimental drugs such as modified RNA-LNP products, entails a meticulous process of randomly assigning subjects meeting various criteria to either intervention or placebo groups. Randomization not only establishes a baseline for comparison but also facilitates the attribution of any differences in outcomes to the intervention itself. The placebo control minimizes the chances of erroneous conclusions about the effects of any intervention. Although invaluable as tools for detecting warning signals, national health surveillance databases such as Vaccine Adverse Events Reporting System and Yellow Card do not meet the rigorous standards set by controlled trials, further underscoring the necessity of this approach for the assessment of medical and public health interventions.

In retrospect, the most concerning revelation from the registrational trials that led to the Emergency Use Authorization was not the apparent overstatement of 95% efficacy, but rather the indication within those trials that the modmRNA products carried a significant risk of serious adverse events and premature death, even among a relatively healthy group of participants. Based on the extended Pfizer trial findings, our person-years estimate yielded a 31% increase in overall mortality among modmRNA recipients, a clear trend in the wrong direction. Moreover, the Fraiman et al. (2022) analysis showed a significant 36% higher risk of serious adverse events (including deaths and many life-threatening conditions) in the modmRNA group for the Pfizer trial. The Michels et al. (2023) analysis found a nearly four-fold increase in cardiovascular serious adverse events among subjects in the Pfizer trial who received the BNT162b2 injection compared to placebo, a fact never reported to the public at the time of the rollouts in December 2020. Notwithstanding these grave concerns, the Moderna product has shown even more frequent adverse events when compared to its Pfizer counterpart (Beatty et al., 2021; Chapin-Bardales et al., 2021a, 2021b; Kitagawa et al., 2022; Valera-Rubio et al., 2022; Sultana et al., 2023). Both modmRNA products were linked with increased risks of ischemic stroke, brain hemorrhage, acute coronary syndrome, and other conditions known to reduce life expectancy.

Against this backdrop, and, in particular, given the high number needed to vaccinate — ~52,000 modmRNA injections hypothetically needed to prevent 1 COVID-19 death — the rationale behind the FDA's decision to declare the COVID-19 modmRNA products “safe and effective” for worldwide distribution after only 20 weeks of observation seems dubious at best. Indeed, one might have expected the COVID-19 modmRNA products to have been withdrawn from the market following the Fraiman study revelation of 1 serious adverse event in 800 injections. The 1976 swine flu vaccine was pulled after being associated with Guillain-Barré Syndrome at a rate of approximately 1 in 100,000 (Centers for Disease Control and Prevention, 2020). The rotavirus vaccine, Rotashield, was withdrawn following

reports of intussusception in 1 or 2 in 10,000 vaccinees (Centers for Disease Control and Prevention, 1999). And on May 8, 2024, the Astrazeneca Vaxzevria COVID-19 injectable product was recalled (European Medicines Agency, 2024). The COVID-19 products contain genetically-modified organisms (European Medicines Agency, 2021) and have been notoriously linked to thrombotic thrombocytopenic purpura (European Medicines Agency, 2021b). In the case of the modmRNA products, Fraiman's team reported their preliminary findings to both the FDA and the European Medicines Agency. Leaders from both agencies met with the team and provided feedback that resulted in a revised analysis (Fraiman et al., 2022). Nonetheless, the regulators took no action afterward to warn the public and restrict access to the injections.

Along similar lines, the forensic analysis by Michels et al. (2023) exposed serious flaws in the methods used by the FDA, CDC, and NIH in the development and safety/efficacy evaluation of new pharmaceutical products. The authors concluded that “the decision to approve the BNT162b2 mRNA vaccine by the US FDA and other international regulatory agencies was not an informed decision based on an unbiased, thorough, and transparent evaluation of the evidence intended to demonstrate that this vaccine met the criteria that it was a ‘safe and effective’ means of controlling the COVID-19 pandemic” (Michels et al., 2023). Pfizer had an ethical responsibility to proactively disclose any new information that could impact the FDA decision-making process, and it should have taken account of the recently discovered SV40 promoter/enhancer in the plasmid used to produce the modmRNA (Speicher et al., 2023). Failure to do so was factually misleading. Conversely, it is reasonable to expect that all participants in the Vaccines and Related Biological Products Advisory Committee meeting should have been aware that the mortality data from the November 14, 2020 trial, had become outdated.

Remarkably, no Vaccines and Related Biological Products Advisory Committee members inquired about updates on adverse events that transpired between the Emergency Use Authorization data cut-off date (November 14, 2020) and the date of the meeting (December 10, 2020; Michels et al., 2023). According to a 393-page confidential document requested by the EMA and released in August 2022, Pfizer had documented approximately 1.6 million adverse events covering nearly every organ system in the human body (Pfizer, 2022a, 2022b; Horowitz, 2023). One-third of the adverse events were classified as serious. Among the many findings were 3,711 tumors, 264 categories of vascular disorders (73,542 cases total), over 100,000 blood and lymphatic disorders, 127,000 cardiac disorders (including 270 categories of heart damage in addition to myocarditis and pericarditis), 77,000 psychiatric disorders (including psychoses, depression, suicide and suicidal behaviors), and hundreds of categories of neurological disorders (696,508 cases total), many of which are supposed to be “very rare” thus comprising a clear indication of grave hazards in the use of these products. These estimates offer a striking contrast with the official FDA document titled “Summary Basis for Regulatory Action” dated November 8, 2021, in which the review committee voted to approve the Pfizer-BioNTech product (US Food and Drug Administration, 2021b). When neurological injuries that are supposed to be “very rare” exceed all of the other serious and life-threatening injuries associated with the injections exceed all of them combined, the future of the impacted minds and spirits of injected human beings is appalling.

The entire “Risk-Benefit Assessment” section in the report consists of a single sentence:



Considering the data submitted to support the safety and effectiveness of COMIRNATY that have been presented and discussed in this document, as well as the seriousness of COVID-19, the Review Committee is in agreement that the risk/benefit balance for COMIRNATY is favorable and supports approval for use in individuals 16 years of age and older (US Food and Drug Administration, 2021b).

International analyses of excess mortality indicate that COVID-19 modmRNA injections have had serious largescale consequences. In a careful study of mass administration of the modmRNA injectables throughout Europe in 2021-2022, Aarstad & Kvitastein (2022) analyzed the potential interplay between COVID-19 gene-based vaccination (both modmRNA and adenovirus vector injections) coverage in 2021 across Europe and subsequent monthly excess mortality through 2022. Using a well-curated dataset encompassing 31 nations, the authors applied population-weighted analyses and found the following: (a) increases in all-cause mortality during the initial nine-month period of 2022 were positively correlated with increases in 2021 vaccination patterns; and (b) each percentage point increase in 2021 gene-based vaccination coverage was associated with a 0.105% increase (95% CI 0.075-0.134) in monthly mortality during 2022. An extensive, multi-country ecological analysis by Rancourt and colleagues estimated that COVID-19 genetic injections resulted in 17 million excess deaths, with a global vaccine-dose fatality rate ( $vDFR$ ) of  $0.1257 \pm 0.0035\%$ , or approximately 0.1% (Centers for Disease Control and Prevention, 1999). Rancourt's 180-page report showed that the COVID-19 genetic injectable rollouts were synchronously followed by peaks in all-cause mortality in many countries, stratified by age (Rancourt et al., 2023a, 2023b).

Before concluding Part 1 of this narrative review, we wish to address the main criticisms that followed our original publication in the journal *Cureus* (Mead et al., 2024a). It included nearly all of the material that has been presented here in Part 1 though some of that material will be addressed more intensively in Part 2.

#### ***CRITICS SAID OUR RISK-BENEFIT CALCULATIONS WERE COUNTERINTUITIVE***

First, many readers of (or possibly bots programmed to comment on) the original version of this paper, as published in *Cureus*, claimed that our risk-benefit calculations were counterintuitive and must have been incorrect, given that CDC, Google, Chat GPT, and mainstream media had repeatedly claimed the majority of COVID-19 deaths in 2021 were among the “unvaccinated”, not those who had been injected with modmRNA. This claim was rooted in propaganda stemming from flawed studies, improper reporting protocols, and basic misconceptions regarding the epidemiology of COVID-19. Initially, for instance, the global rollout in 2021 meant that many individuals had not yet achieved “full vaccination status” during the first half of the year. The result, logically, was that a disproportionate number of people were classified as “unvaccinated” simply because the modmRNA injectables had not yet been distributed to large segments of the population. The mainstream media reported high COVID-19 case rates among the “unvaccinated” without properly contextualizing the base rate issue, thereby misleading the public about the relative risk of infection for modmRNA-injected versus non-injected individuals. This base-rate-neglect resulted in erroneous interpretations of the CDC's statistics concerning the impact of COVID-19 disease on “vaccinated” versus “unvaccinated” segments of the population.

On a fundamental note, it is important to recall that the pivotal criterion for designating COVID-19 as cause-of-death involved testing positive for SARS-CoV-2 at any point prior to the death. One could die from one or multiple *other* causes — including gunshot wounds and car accidents — yet still be counted as a “COVID death”. This again helped create the illusion of a tsunami of COVID-19 deaths. Another large contributing factor was the many ways the CDC’s definition of “unvaccinated deaths” could add up. In the following paragraph, we list some of the well-documented miscategorization scenarios that have applied. As a result, many deaths among “unvaccinated” persons were falsely attributed to COVID-19. The number of cases of infection was similarly distorted beyond reason. In U.S. hospitals, the practice of reporting COVID-19 cases, based simply on either a past PCR test result, or on some clinician’s judgment, was heavily incentivized by the US Coronavirus Aid, Relief and Economic Security Act. Under this Act, hospitals nationwide received 20% extra compensation for each hospitalized Medicare patient who was counted as a “COVID case”, as well as additional payments averaging \$76,975 per patient admission if the “COVID case” either died or was placed on a ventilator (Held, 2020). Such pecuniary incentives led to dramatic inflation of case counts and false media reports of hospitals being “overrun” by COVID-19 patients, along with the attendant overestimates of “COVID deaths”, all of which helped shape the myth of “the pandemic of the unvaccinated” (McLeod et al., 2021).

Many complex factors can bias and distort the assessment of COVID-19 vaccine efficacy. At the top of the list are three classes of miscategorizing errors: those concerned with (1) infections by COVID-19, (2) deaths from COVID-19, and (3) whether a person is “fully vaccinated” against COVID-19 or not. As pointed out by Ioannidis (2022; also see Neil et al., 2024) variations in ways of determining vaccination status, testing practices, and confounding due to disease risk factors can lead to huge biases. Fung et al. (2024) carefully analyzed the foregoing and other sources of bias in the vaccine trials, notably focusing on what they termed “the case-counting window bias” — showing that counting biases which pertain to diagnosis and placement in “vaccinated” versus “unvaccinated” groups — can inflate estimates of vaccine efficacy by 50% to 70%. Lataster (2024) contends that various methodological issues within the studies were not accounted for in the Fung et al., analysis, and thus that the true magnitude of the distortion associated with the counting window bias may be even larger. Lataster shows that the well-documented under-counting of adverse effects can only have contributed to exaggerated claims of COVID-19 product safety. Careful re-analyses have exposed numerous misclassification problems inherent in large scale studies evaluating the safety and effectiveness of the modmRNA products (Fenton et al., 2021). A systematic review of the literature by Neil et al. (2024) identified 39 studies with miscategorization bias in which vaccinated individuals were incorrectly classified as unvaccinated for an arbitrarily determined time after they received an injection. Almost a third (31%) of the studies had one or more of the identified types of bias. In the process of writing this paper, we reviewed 77 observational studies from 2021-2022 that involved comparisons of vaccinated to unvaccinated individuals in the context of COVID-19 vaccinations. All contained methodological flaws that could only artificially inflate estimates of vaccine efficacy, thereby upholding the false claim that modmRNA-injected individuals had lower COVID-19 infection rates and were less likely to die of COVID-19 than the unvaccinated (Neil et al., 2024).

Among the scenarios whereby a COVID-19 death could be miscategorized with respect to vaccination status are the following:

#### *Delays in Reporting Vaccination Status*

In clinics and hospitals nationwide, many individuals have been incorrectly classified as “unvaccinated” because of delays in recording or reporting the vaccination status at the time of death. Deaths that occurred at home have often been misclassified in this way, as have deaths while hospitalized. Financial incentives created by the Coronavirus Aid, Relief and Economic Security Act have surely encouraged the inflation of COVID-19 diagnoses and deaths especially in people regarded incorrectly as unvaccinated.

#### *CDC Definition of Vaccination Status*

The CDC’s official definition of vaccination status is 14 days after the second modmRNA injection, i.e., the individual is not considered “fully vaccinated” until this point in time. If someone gets hospitalized or dies following a positive PCR test result anytime between the 1<sup>st</sup> injection and 14 days after the 2<sup>nd</sup> injection, that hospitalization or death was likely to be counted as of an “unvaccinated” person (Neil et al., 2023). This has resulted in hundreds of reports of deaths and hospitalizations being falsely attributed to unvaccinated persons.

#### *Injection Shortly Before Death*

Similar to the above scenario, if an individual receives the modmRNA injection very shortly before contracting COVID-19, or before dying, they may still be recorded as “unvaccinated”, or only “partially vaccinated”. This is because, according to the prevailing theory, the injectable has not had sufficient time to exert its full immunological impact, estimated at around 14 days.

#### *Incomplete Records*

In some cases, individuals might receive their modmRNA injection in a different jurisdiction from where they receive medical care, or where they may actually die. If the records are not shared across different health systems (or states), or if distinct jurisdictions are not properly linked, the deceased’s vaccination status might not be accurately captured. Many injections may have occurred, say at a Walgreens or CVS pharmacy, without being documented or reported to the central database promptly, or at all. In such cases, individuals would end up being misclassified as “unvaccinated”. Some states are known to be more prone to underreporting than others.

#### *Assumptions in Data Collection*

Assumptions made during data collection, reporting, or the framing of questions regarding vaccination status can result in misclassification. For example, a vaccinated person could be classified as “unvaccinated” because they simply were not carrying their vaccine card. Many hospitals did not require definitive proof of modmRNA injections. They may have relied on mere verbal affirmations by persons being admitted, or the healthcare provider may have merely assumed that certain persons were or were not vaccinated.

### *Data Entry Errors*

Human error in data entry can lead to incorrect recording of vaccination status. For example, individuals who had received only 1 dose were often misclassified as “unvaccinated” in hospital records rather than “partially vaccinated”. Whenever such data are entered incorrectly into a health record, or any reporting system, it can mislead the analysis of the impact of the modmRNA injectables on serious adverse events and mortality.

Each of these factors can compromise the accuracy of mortality data, with the potential to greatly inflate estimates of modmRNA product safety and effectiveness. To use a specific example, consider the CDC’s large cohort study of approximately 11 million persons enrolled in seven Vaccine Safety Datalink sites during the first half of 2021 (Xu et al., 2021). The study found large reductions in *non-COVID* mortality (66% and 69% for Pfizer and Moderna modmRNA products, respectively, after dose 2) when comparing “vaccinated” to “unvaccinated” groups. Such findings have no rational basis and could only have resulted from the CDC’s definition of COVID-19 vaccination status, along with miscategorization due to the 14-day rule described above. Whereas deaths within the 14-day “unvaccinated”-by-definition-window are supposed to be recorded as “unvaccinated” fatalities according to the CDC definition of “fully vaccinated” persons, autopsies of individuals who have died from one or more of the modmRNA injections show that the majority of them occur within the 14-day “unvaccinated” window (Hulscher et al., 2024).

### ***THEY SAID WE FOCUSED TOO MUCH ON HARM FROM THE INJECTIONS***

The second and perhaps most common criticism of our *Cureus* paper was that the initial iteration was too heavily focused on harms associated with COVID-19 modmRNA vaccines, without presenting a balanced discussion of benefits. The common perception of “imbalance” was based, we believe, on the widely held assumption that these products confer substantial benefits for public health. We have shown that the presumed benefits have been vastly overstated (see section, **Shifting Narratives, Illusions of Protection**) and are based exclusively on (a) low-level evidence from nonrandomized studies, most of which are fundamentally flawed, and (b) clinical trials that suffered from underreporting of critical data and numerous other problems addressed in the first three sections of this paper. Moreover, reliable data from the Cleveland Clinic (Shrestha et al., 2023a, 2023b) supports the findings from real-world population studies indicating that natural immunity confers superior protection, and that multiple modmRNA injections produce immune dysfunction, resulting in increased autoimmune disease risks and other poor health outcomes when compared to minimal or no injections (Irrgang et al., 2023; Chevairsakul et al., 2023; Kyriakopoulos et al., 2024).

Related to this second criticism is the common belief among well-educated individuals who lack training in epidemiology that a scientific consensus exists in favor of the safety and efficacy of the COVID-19 modmRNA injections. This presumed consensus mainly stems from the assumption that, since the original trials demonstrated efficacy in reducing COVID-19 symptoms, this would naturally lead to a decrease in severe COVID-19 cases, hospitalizations, and fatalities. As we documented earlier in this paper, however, the trials themselves were riddled with methodological problems leading to overestimating any reduction in COVID-19 symptoms. Moreover, any such reduction could only be at best an

indirect and superficial measure of efficacy. It could only indirectly relate to disease severity or the likelihood of hospitalization. Four years after the rushed authorization, not a single large, controlled trial has demonstrated any positive impact on transmission, infection, or hospitalization, not to mention death. While subsequent observational studies suggested that the modmRNA injectables may reduce transmission and disease severity, these claims were based on substandard inferences, and flawed methodologies. Given the colossal profits reaped by the pharmaceutical industry during the pandemic — e.g., well over \$100 billion dollars in cumulative revenue generated for Pfizer and Moderna at the time of this writing — it is reasonable to expect that the vaccine companies would have reinvested some of their proceeds into well-designed randomized trials to evaluate the critical outcomes of reducing hospitalizations and deaths. The absence of any trials addressing these key issues constitutes a crucial omission in the assessment of the product efficacy, if not a tacit admission of the inability to demonstrate any such efficacy.

In short, the paucity of gold standard evidence seriously undermines any claims of a scientific consensus. Moreover, it should be emphasized that science itself is a process, a perpetual quest for truth, which often stands independent of any consensus. Indeed, major scientific progress invariably arises from challenges to the prevailing consensus. Those who fixate on “scientific consensus” in lieu of sound theory and replicable empirical outcomes are not champions of science. They are proponents of partisanship. Besides, it is easy to create the illusion of consensus when dissenting voices are constantly suppressed, or censored, as has been happening throughout the pandemic via retractions, de-platforming, and other strategies (Malhotra 2022a, 2022b). In fact, we can show that this has been going on with respect to protecting vaccine dogma for much longer (see Shaw, 2020, 2021). Thus, what is often conveyed as a scientific consensus is in fact commonly an ideological dogma masquerading as a consensus and repeatedly being promulgated by the Bio-Pharmaceutical Complex.

#### ***ACCUSED US OF PREDETERMINED BIAS AGAINST THE MODMRNA PRODUCTS***

A third criticism is that we, the authors, appear to have a predetermined or biased viewpoint against these modmRNA products. After all, scientific papers should aim to be objective, presenting data and conclusions without an apparent agenda. Admittedly, all of the authors of this paper have known people who contracted serious illnesses and/or disabilities following injection with the genetic therapy products. Some of us have personally known people who lost their lives as a consequence of receiving them. The emotional impact of such anecdotes could be presumed to (a) compromise our objectivity in assessing modmRNA products, and (b) influence our interpretation of data, leading to confirmation bias whereby we prioritize information confirming our experience. The main criticism is that such personal biases might result in overemphasizing potential risks and harms, possibly impacting the accuracy of our conclusions or causing us to use language that is emotive or suggestive to influence reader perceptions of whatever the research shows. For example, we said that the presumed disease-averting benefits of these injections are “profoundly outweighed by their potentially disabling and life-threatening harms”. This phrasing suggests a significant and unambiguous risk-benefit imbalance, and indeed we presented a great deal of evidence substantiating that conclusion. We stand by the rigor, logic, validity and accuracy of our research and analyses. Before publication in *Cureus* our writing was vetted by no fewer



than eight independent expert reviewers during the 2.5-month processing of the paper prior to its publication and subsequent retraction. Now we have submitted this amplified and re-examined review in two parts to a different distinguished board of reviewers of whom we have been assured that at least six members of the editorial board made one or more passes through all of our material. As for our use of straight talk and plain language, it is essential and required in view of the scope and magnitude of the injuries, juxtaposed to government agency censorship efforts and the pharmaceutical industry's ongoing propaganda campaign that is evident, and which, we believe, can only serve to mislead the public.

### ***WE REACHED CONTROVERSIAL SCIENTIFIC CONCLUSIONS***

A fourth criticism is that our paper makes claims that may be considered controversial within the scientific community. Scientific advances worthy of note are generally controversial when they are first brought to light and critical back-and-forth argumentation is the essence of scientific investigation. Our conclusions are drawn from credible empirical evidence and sound theory critically examined by many competent peer-reviewers before publication. We have relied on epidemiologically valid analyses. In some cases, we have cited Substack articles that we believe provide meaningful commentaries and invited immediate response that might otherwise be delayed or prevented from taking place in the mainstream medical journals. Several of the co-authors of this paper have used Substack to express controversial ideas because it offers a direct line to their audience without the impedance owed to the inevitable back-and-forth of academic peer-review that is nonetheless taking place as the Substacks are also being produced and examined. Freedom to express and examine ideas with other scientists and thinking persons is essential to discovery, creativity, critical thinking, analysis, and the formation and testing of hypotheses. Preprint servers, like Substack articles, afford the advantage of immediacy while postponing the necessary tedium of peer-review and can accelerate the dissemination of important scientific discourse.

In the context of preprints and Substack articles, how do we reconcile the need for open scientific discourse with the potential for compromising scientific rigor and integrity? Simply put, we take the next step and seek out competent peer-reviewed publication. That being said, the Substack community is very broad and highly educated, and it typically involves many of the same people we are apt to engage with in peer-reviewed settings. Citing either preprints or Substack articles in a scientific paper can be valid if treated cautiously and clearly identified as unreviewed content, contributing valuable, albeit preliminary, perspectives to scholarly discussions. In a true democracy, we believe it is essential to safeguard venues that enable research scientists to freely share dissenting or unorthodox perspectives, thereby enriching the scientific discourse and ensuring a rational dialogue within and beyond any particular scientific community.

Based on the research presented in this review and given the high level of harm that it has caused, the global COVID-19 injection campaign should be regarded as a grave medical error, or something worse. Medical errors have always represented a substantial threat to personal and public safety and have long constituted a leading cause of death (Starfield, 2000; Kohn et al., 2000; Oyebode, 2013; Rodziewicz et al., 2023). Misguided political and regulatory decisions were made at the highest levels and seem to have been heavily influenced by financial incentives — outcomes in the hospitals certainly were. Government agencies should have considered all reasonable treatment alternatives. The government

agencies should not have joined with the medical-pharmaceutical industry in rushing to promote, and especially in mandating, population-wide distribution of the experimental gene therapy products we have examined critically in this paper and its predecessor in *Cureus*. Had the FDA acknowledged the warning signals all along instead of covering them up, take as an example the nearly four-fold increase in cardiac serious adverse events (including deaths) in the Pfizer trial (Michels et al., 2023), it is doubtful that the Emergency Use Authorization would have been granted in December 2020.

## Conclusions

Going forward, careful and objective evaluation of the COVID-19 modmRNA products is crucial. Our narrative review concerning the registrational trials and the aftermath of the Emergency Use Authorization offers evidence-informed insights into how the experimental gene therapy products were marketed. In the context of the pivotal trials by Pfizer and Moderna, safety was never assessed in a manner commensurate with previously established standards, not even for vaccines, much less for gene therapy products. To be accurate, the modmRNA products would need to be evaluated and regulated as gene therapy products, with long-term follow-up to properly assess the potential risks of cancers and autoimmune diseases. Many key trial findings were either misreported or omitted entirely from published reports. The usual safety testing protocols and toxicology requirements were bypassed by the FDA and vaccine manufacturers, and the premature termination of the only trials undertaken obviated any unbiased assessment of potential serious adverse events due to an insufficient timeframe for proper trial evaluation. It was only after the Emergency Use Authorization that the serious biological consequences of rushing the trials became evident, with numerous cardiovascular, neurological, reproductive, haematological, malignant, and autoimmune serious adverse events identified and published in the peer-reviewed medical literature. We return to six categories of such adverse events in greater detail in Part 2 of this review.

Here in Part 1, we have re-examined and expanded the evidence-informed rationale we put forward in our *Cureus* article. We are questioning the government policy of recommending a continuous series of repeated boosters. We have shown the serious biological consequences associated with the modmRNA injections. Broadly speaking, the consequences may be divided into two categories: (1) diminishing returns following the injections due to various immune-suppressive effects along with extrinsic selective pressures that ultimately accelerate viral evolution and resistance; and (2) serious adverse events, notably the profound suffering and premature death resulting primarily from autoimmune, neurological, malignant and cardiovascular disorders. Consideration of both the potential immunological impacts of repeated booster doses on viral evolution and resistance alongside the risks of premature death and other serious adverse events is crucial for a comprehensive risk-benefit assessment of the modmRNA COVID-19 vaccinations.

Inconsistencies in recording and reporting vaccination status have complicated the accurate categorization of COVID-19 deaths and can only have contributed to overestimation of deaths among the “unvaccinated”. The collective result is a spurious portrayal of the pandemic as predominantly impacting the unvaccinated. These issues underscore the importance of reliable data collection and analyses to understand the true impact of the modmRNA injections on COVID-19 mortality rates. Mainstream publications of “real-

world observational studies” that used certain popular methodologies of 2021 and 2022 overstated COVID-19 vaccine efficacy while greatly underestimating the numerous cardiovascular, neurological, haematological, and immunologic harms associated with the modmRNA products.

Here in Part 1 of this review, we have shown that natural immunity after a coronavirus infection confers protection superior to the modmRNA injections. By now, the vast majority of Americans have been exposed to the coronavirus. There is currently no reliable evidence showing that a single modmRNA dose, or that any number of multiple doses, will confer any additional protection for individuals previously infected with any of the coronavirus variants. Moreover, despite ongoing efforts by government agencies to get US children injected with these gene-based prodrugs, there is not a single reliable study showing a protective benefit in children. There is mounting evidence, however, of harm being done. Finally, the three Cleveland Clinic studies and multiple real-world observational studies have shown, collectively, that the more injections one receives, the greater the risk of being diagnosed with a COVID-19 infection, and the greater the likelihood of adverse impacts downstream from any gene-therapy injection.

Based on the Pfizer trial data, for every case of severe COVID-19 prevented, we estimated that there were at least 16 serious adverse events caused by the modmRNA products within a six-week period — a disparity that logically must increase over time; furthermore, for every life that was theoretically saved by these genetic vaccines, there were nearly 14 times more deaths caused by the injections. These must be considered conservative estimates. In short, the widely proclaimed theoretical benefits of the COVID-19 injectables — based largely on faulty simulations and computer models proclaiming “millions of lives saved” and so forth — are now known to have been illusory. The predicted results were never forthcoming. The truth is that any presumed benefit of the modmRNA boosters has been profoundly outweighed by their actual disabling and life-threatening harms.

An in-depth investigation of the long-term impact of COVID-19 modmRNA products is urgently needed. In Part 2 of this narrative review, we provide a concise explanation of how and why these products failed, along with an evidence-informed overview of the six major domains of modmRNA injury: cardiovascular, immunological, neurological, hematological, reproductive, and oncological. We also propose next steps for government agencies. Initially, to ban these experimental agents — with a caution concerning the further development of cancer “vaccines” based on the modmRNA platform. In the meantime, and over the coming weeks, months and years, the modmRNA-injured segment of the population is going to need treatments that are informed by the critical lessons learned from what increasingly appears to have been a “pandemic” promoted, if not caused, by the Bio-Pharmaceutical Complex.

Despite the many striking revelations discussed in this review, most developed countries continue to advocate the ongoing adoption of COVID-19 modmRNA boosters for the entire “eligible” population — now being extended to cover almost all living persons including very young children. US federal agencies still claim “safety and effectiveness” of these products to reduce severe illness and prevent deaths by the coronavirus in its many mutant forms. All these boasts are made despite the absence of any randomized, double-blind, placebo-controlled trials to support them. There is a bewildering disconnect between

the sort of evidence-based scientific research we are doing and advocating — the kind that is not promoting some marketing scheme or slanting data analyses to benefit particular vested interests — and the public health policy that advocates, even mandates, products that are harming the very people they are supposed to help. Given the unacceptably high risk of death and other well-documented serious adverse events — such as heart damage, clotting and autoimmune disorders, and disabling neurological injuries (see our Part 2) — we urge governments to endorse and enforce a global moratorium on these modmRNA products and the lipid nanoparticle delivery platform, unless and until all relevant questions pertaining to causality, residual DNA, and aberrant protein production are resolved.

## Appendix 1

The projected three-year mortality for the Pfizer registrational trial is depicted in Figure 6. If the six-month trial had continued, the relative risk difference would reach statistical significance at 34 months, with a 31% higher mortality risk in the modmRNA group compared to the placebo group. Figure 6 offers a transparent, quantifiable, and simple illustration of how a small death rate at the start would become statistically significant over the three-year span

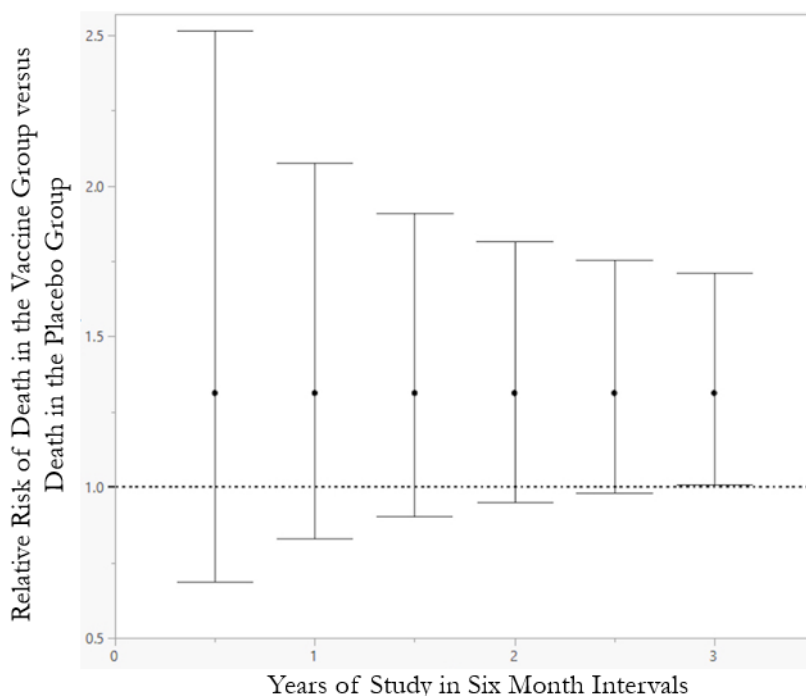


Figure 6. Registrational trial for Pfizer, projected relative risk of mortality over three years. If the six-month Pfizer trial had continued, the risk difference would reach statistical significance at 34 months, with a 31% higher mortality risk in the vaccine group compared to the placebo group. Chart generated by biostatistician Russ Wolfinger.

originally planned for the COVID-19 injectable trials. If the six-month Pfizer trial had continued, assuming the relative risk of 1.31 were to remain constant and deaths continued to accrue at the same rate as during the trial, then the lower limit of the 95% confidence interval would exceed 1.0 at 34 months. In other words, the relative risk would exhibit statistical significance ( $p < 0.05$ ) at this time, with a 31% increased mortality risk in the mRNA vaccine group versus the placebo group. The time series calculation assumes death rates are held constant in each group and mortality is measured at six-month intervals, with  $p$ -values monotonically declining over time. Thus, assuming the mortality rates should continue unchanged in both groups as observed in the initial six months, the all-cause mortality difference would have become statistically significant ( $p < 0.05$ ) in about 2.8 years (34 months). Reading forwards across the timeline, at 2.5 years, the  $p$ -value was at 0.065, decreasing to 0.053 by 2.75 years, and 0.05 at 3.0 years. The bottom-line is, to have made sense, the Pfizer registrational study should have been pursued for at least three years and not cut short as it was within a total period of only 6 months. The time frame and the design lacked the statistical power to accomplish its stated purposes.



## Appendix 2

Regarding potential harms, assuming 30% false-positive reports and a moderate under-reporting factor of 21, we calculate a risk of 27 deaths per 100,000 doses of BNT162b2. Thus, applying these reasonable assumptions, the estimated harms of the COVID-19 mRNA injectables outweigh the rewards by nearly 14-fold.

This mortality analysis combines two groupings of data, the first reflects hoped for benefits, and the second reveals undesirable adverse events to be kept to a minimum. The first data grouping assumes one is saving lives by using the injectable to prevent severe COVID-19 symptoms and hospitalization, based on the Pfizer and Moderna founding Randomized Control Trials. The second grouping uses data from an injury-reporting database, specifically the UK Yellow Card data as obtained by Norman Fenton and colleagues (Fenton, 2023). The Fenton data is “per dose” so is effectively doubled to a “course” consisting of 2 injections. The Excel (Microsoft Corporation, Redmond, Washington, United States) formula is based on the rules of joint probability:

$P(A \& B) = P(A) + P(B) - P(A)*P(B)$  (assuming the 2 events are independent).

It turns out that:

$P(A)*P(B)$  is small, so in effect, it is  $P(A) + P(B)$ , which if  $A=B$  is  $2*P(A)$ .

### Benefits/Rewards

Calculations for the number of lives saved per 100K vaccinations, based on most generous assumptions are as follows:

Assuming the number-needed-to-vaccinate at 119 and an infection-fatality-ratio at 0.23%, about ~52,000 vaccinations would be needed to prevent 1 death.

By such reasoning, the upper limit of lives saved would be  $10,000*1/52,000 = 0.19$  or ~0.2 or  $1/5^{\text{th}}$  of a life saved for every 10,000 courses of the mRNA vaccine.

Thus, if the foregoing is correct, for Pfizer mRNA vaccination, ~2 lives would have been saved from COVID-19 for every 100,000 courses of the vaccine.

Sources informing the numbers used in this last estimate are: number-needed-to-vaccinate to prevent 1 case is set at 119, based on data from Olliaro et al. (2021), and the infection-fatality-ratio of COVID-19 is generously estimated at 0.23%, based on 2021 WHO data from Ioannidis at <https://apps.who.int/iris/handle/10665/340124>.

Estimates of the infection-fatality-ratio are based on meta-analyses and the estimated number-needed-to-treat was obtained from the Phase 3 Pfizer trial. Given evidence of Randomized Control Trial fraud, the estimated benefit of a full course of the Pfizer injectable should be viewed as an upper limit; the true value is almost certainly much lower (i.e., a much smaller estimate of lives saved).

## Risks/Harms

The estimates of lives lost per 100,000 vaccinations are based on extremely conservative assumptions with the Under Reporting Range set at 10% based on the research of the Harvard Pilgrim Group (Lazarus et al., 2010, 2021):

Fenton calculates 68 deaths/1,000,000 doses = 12.8 deaths per 100,000 per primary course of Pfizer, or just under 13 deaths from serious adverse events per 100,000 for each primary course of the Pfizer vaccine.

Comparing adverse events to potential benefits, we calculate an excess death risk of  $12.8 - 2 = \sim 11$  deaths per 100,000 doses.

Thus, comparing the benefits to harms, at least 5 times more lives are lost than saved by the full course of Pfizer mRNA vaccinations.

**Notes on the estimate:** The Fenton estimate of 12.8 indicates an excess death risk of  $12.8 - 2 = \sim 11/100,000$  comparing the adverse effects to potential benefits. Our estimate predicts about 1 excess death per 9,000 Pfizer courses, which seems quite plausible. This is also in line with officially reported all-cause deaths in the Pfizer trial at 15 for vaccinated persons and 14 for unvaccinated, which is a  $\sim 7\%$  increase, although not statistically significant. If there is 1 excess death per 9,000 injections, a difference of  $\sim 2$  deaths in the 20,000 subjects/arm of the Phase-3 trial would be expected. Finally, a higher Under Reporting Range (e.g., 21% as suggested by the Rancourt data) would yield a higher estimate of deaths.

Pfizer trial data, applying the same Fenton calculation sequence and 30% false-positive reports, with a moderately conservative under-reporting estimate of 21%: (i) Lives saved per 100,000 vaccinated (by preventing 1 COVID-19 death): the number-needed-to-vaccinate to prevent 1 COVID-19 case = 59,574 (95% CI 51,118-71,381). Lives saved per 100,000 vaccinated = 1.7 (95% CI 1.4-2.0); (ii) Lives lost per million: Net excess deaths per primary Pfizer course: 3,705 (95% CI 3,667-3,744). Excess death risk of 27 deaths (95% CI 26.7-27.3) per 100,000 doses of Pfizer's COVID-19 mRNA vaccine.

Moderna trial data, applying the same Fenton calculation sequence and 30% false-positive reports, but with a moderately conservative Under Reporting Range of 21%: (i) Lives saved per 100,000 vaccinations (by preventing 1 COVID-19 death): number-needed-to-vaccinate to prevent 1 COVID-19 case = 25,394 (95% CI 22,434-29,254). Lives saved per 100,000 vaccinated (by preventing 1 COVID-19 death) = 3.9 (95% CI 3.4-4.5); (ii) Lives lost per 100,000 vaccinations (by preventing 1 COVID-19 death): Net excess deaths per primary Moderna course = 9,292 (95% CI 8,864-9,764). Excess death risk of 10.8 deaths (95% CI 10.2-11.3) per 100,000 Moderna vaccine courses.

## Commentary

There are three important numbers to consider in these calculations: net mortality, number-needed-to-vaccinate, and net excess deaths per primary course. Net mortality is the overall mortality, including deaths caused by the vaccines as well as other causes of death that could be biologically plausible given the population. In this case, however, the population is relatively healthy and at "low risk" in terms of COVID-19-related mortality being a relatively healthy population with no comorbid diseases at the baseline, and thus any disproportionate increase in overall mortality must logically be linked with the injections.

The epidemiological meaning of “net excess deaths per primary Pfizer, or Moderna, course” is the net cumulative incidence of increased deaths expected after vaccination, within about 3 months of an injection. In our calculation, the net excess deaths per primary course is the reciprocal of the net mortality.

Based on the founding clinical trial timeframes, we assume that 3 months is the period of time in which the vaccine would either incur benefit in terms of lives saved (related to the duration of trial and/or immunity), or incur harm, as in serious adverse events caused by the injection. In real-world observational studies, longer timeframes would likely reveal other serious adverse effects that could result in premature death.

We also assume a 30% false positive rate (very conservative) and Under Reporting Ranges, respectively, of 10% and 21%. The actual Under Reporting Range is somewhere between 10% and 100%, with the upper end based on Harvard data of Lazarus et al. (2010, 2021). Thus, the Under Reporting Range of 10% may be deemed excessively conservative, and the Under Reporting Range of 21% is only modestly less so.

Calculation of the number-needed-to-vaccinate is dependent on COVID-19 prevalence, and for this, we rely on the WHO seroprevalence study by Ioannidis (2021). Due to our use of the injury database data, the hierarchy of evidence would be considered lower (even more conservative) than those of Fraiman et al. (2022) and Classen (2021), which relied only on Randomized Control Trial evidence.

All of our “injury” or “harm” data is from the UK’s Yellow Card data set, which is stratified by vaccine in Fenton’s analysis (2024). While this information comes from the UK population, the trials were principally conducted in North America; nevertheless, it is unlikely that the adverse event rates would be different between the two populations.

## **Additional Information**

### ***AUTHOR CONTRIBUTIONS***

All authors have reviewed the final version to be published and have agreed to be accountable for all aspects of the work.

Concept and design: M. Nathaniel Mead, Stephanie Seneff, Russ Wolfinger, Peter A. McCullough

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### ***DISCLOSURES***

Conflicts of interest: In compliance with the ICMJE [International Committee of Medical Journal Editors] uniform disclosure form, all authors declare the following: Payment/services info: All

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