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Safety of mRNA Injectables Administered During the First Twenty-Four Months of the International COVID-19 Injection Program

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ABSTRACT

Two mRNA-based COVID injectables were granted emergency use authorization in both children and adults in 2021 after an accelerated approval process that allowed the manufacturers to fast-track their products. We analyzed data from regulatory surveillance and self-reporting systems such as Defense Medical Epidemiology Database (DMED); EudraVigilance; Eurostat; German health insurers; the Israeli Ministry of Health; the Natural Cycles App; Public Health Scotland; the United Kingdom's (UK) Office for National Statistics (ONS); UK's yellow card reporting system; the Vaccine Adverse Event Reporting System (VAERS); and V-Safe After Vaccination Health Checker entries to find long-term adverse events of the COVID products that cannot be captured during the expedited safety analyses. In this observational study, we analyzed non-foreign VAERS data for selected symptoms reported after COVID, influenza, and pertussis vaccines and calculated rates per dose administered as well as proportion of total reports received. We also looked at DMED data and compared annual incidence rates of selected conditions by taking into account the total number of military personnel for each study-year. Our data show, among other trends, increases in adverse event reports if we compare COVID products to influenza and pertussis vaccines and statistically significant higher numbers of hospital encounters in military personnel, as well as increases in incidences of thromboembolic conditions, such as menstrual abnormalities, myocarditis, and cerebrovascular events after the implementation of COVID injection mandates, compared to the preceding five years. We verified these observations using data from EudraVigilance; the UK's ONS; German health providers; and Eurostat. Our meta-analysis of both national and international vaccine adverse events emphasizes the importance of re-evaluating public health policies that promote universal mass injection and multiple boosters for all demographic groups. In combination with informal reports from reliable witnesses, limitations of the safety trials, and the decreased lethality of new strains, our research demonstrates that the cost (both monetary and humanitarian) of injecting healthy people, and especially children, outweighs any claimed though unvalidated benefits.

Keywords: *all-cause mortality, cerebrovascular events, COVID-19 mRNA vaccines, COVID-19 injections, COVID-19 injectables, Defense Medical Epidemiology Database (DMED), EudraVigilance, menstrual abnormalities, myocarditis, Vaccine Adverse Event Reporting System (VAERS), vaccines*

INTRODUCTION

In December 2020, two mRNA-based COVID-19 injectables were awarded an Emergency Use Authorization (EUA) in the United States (US). By the end of 2021, one of these injectable products had been approved for use in any person above the age of five (*Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age*, 2022). The normal timeline for the development and approval of a vaccine would require four years, but the mRNA-based COVID-19 injectables were granted EUA in less than one year (Ball, 2021). The "authority" to issue EUAs was supposed to permit "the FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats, including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies" (*Emergency Use Authorization*, 2022). A combination of previous research on vaccines targeting related viruses; unprecedented funding that allowed companies to run parallel trials; and the speed at which regulatory agencies issued approvals was unprecedented (Ball, 2021).

In the aftermath, post-authorization monitoring is a useful tool that can help characterize the empirical risks of these intended prophylactics instead of classifying specific adverse events as "rare". The major sources for investigating vaccine safety data in the US are the Vaccine Adverse Event Reporting System (VAERS) and, more recently, the V-Safe After Vaccination Health Checker. In addition, due to the large number of COVID-19 mRNA doses that have been administered to date, we can review data collected by sources such as the Centers for Disease Control and Prevention (CDC) and DMED in the US; yellow card submissions in the United Kingdom; and EudraVigilance in Europe.

Since initial approval of the Moderna and Pfizer mRNA injectables against COVID, over 2.5 million adverse events have been reported (*Search the VAERS Database*, 2022). As a reference point, as of the end of November, 2022 there had been just over 600,000 adverse events and just under 500,000 adverse events reported for all the influenza and pertussis vaccines, respectively (*Search the VAERS Database*, 2022).

With the US Food and Drug Administration (FDA) recently authorizing emergency use of both the Moderna and the Pfizer-BioNTech COVID-19 injectables in children as young as six months of age, it is imperative that a comprehensive analysis of the safety of both the BNT162b2 (Pfizer) and mRNA1273 (Moderna) injectables be carried out retrospectively, using currently available data (*Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age*, 2022).

METHODS

VAERS

VAERS is a national voluntary reporting system for adverse events related to the administration of vaccines authorized or licensed in the US that is co-administered by the CDC and the FDA. It accepts mostly online submissions from health-care providers and members of the public; electronic transmissions from vaccine manufacturers; and a few reports by mail, fax, and telephone. Reports are updated weekly and include demographic information about the person vaccinated, the type of vaccine they received, and the adverse event experienced. Reports were searched online on December 1, 2022 and filtered by symptom(s) experienced (see Adverse Events of Interest, below), vaccine(s) administered, and/or whether the patient died (*The Vaccine Adverse Event Reporting System (VAERS) Request*, 2022) Only reports from the US were counted and for both influenza and pertussis, only data from 1990 onward was used. The number of vaccine doses administered as of December 1, 2022 was obtained from Our World in Data (Mathieu et al., 2022).

DMED

On December 7, 2020, the Department of Defense (DoD) issued their "Coronavirus Disease 2019 Vaccine Guidance", which authorized the DoD to "provide vaccines to Service members and other eligible DoD healthcare beneficiaries, as well as selected other-than-U.S. forces (OTUSF) populations, such as DoD civilian employees and specified contractor employees" (Smith, 2020). By November 22 of the following year, the same employees were required to be "fully vaccinated" (Hicks, 2021). Health.mil, the official website of the Military Health System provides "large, linked electronic health records (AHLTA/MHS GENESIS) and administrative data systems for near real-time safety monitoring and research", which allowed us to query diagnoses of interest (*V-Safe After Vaccination Health Checker for COVID-19 Vaccine*, 2022). Comparing data for 2021 (when COVID injectables would have been administered to the entire personnel) to previous years provides an insight into potential health hazards that may be attributed to the effects of those injectables.

On February 1, 2022, Senator Ron Johnson wrote a letter to Secretary of Defense, Lloyd J. Austin III addressing data from DMED, which was since uploaded in a Google Sheet (available here), that showed dramatic increases in a wide array of medical conditions for the first ten to eleven months of 2021, when compared to the previous five years (Johnson, 2022). After accessing and downloading this data, we used it to calculate cases per month per person for the conditions of interest for every year from 2016 to 2021 and an average for 2016-2020. For the data from 2021, we erred on the side of caution and performed calculations using the assumption that it was eleven, rather than ten, months of data. Therefore, any effects of the vaccination were, if anything, underestimated.

The number of female military personnel per year was obtained by searching the Military One Source demographic profiles for data regarding the percentage of male and female military personnel for the years in question (*Military Community Demographics*, 2022). The 2021 data was not available yet, so we used an average of the percentages for the available years and extrapolated the number of service women using the total number of military personnel for 2021.

Adverse Events of Interest

Events related to menstrual abnormalities in females were drawn from VAERS, DMED, and V-Safe. In VAERS, the following conditions were selected: "amenorrhoea"; "delayed menarche"; "dysmenorrhoea"; "heavy menstrual bleeding"; "hypomenorrhoea"; "menarche"; "menometrorrhagia"; "menopause"; "menopause delayed"; "menorrhagia"; "menstruation delayed"; "menstruation irregular"; "oligomenorrhoea"; "polymenorrhagia"; "polymenorrhoea"; "postmenopausal haemorrhage"; "premature menarche"; "premature menopause"; and "retrograde menstruation". DMED data was obtained from the February 1, 2022 download and we analyzed "dysmenorrhea". V-Safe data was obtained from an August, 2021 CDC data release and the rate of "spontaneous abortions" before twenty weeks was compared between vaccine recipients and the general US female population.[1]

Events related to myocarditis were drawn from both VAERS and DMED. In VAERS, the following conditions were selected: "acute myocardial infarction"; "autoimmune myocarditis"; "cardiomyopathy"; "ecg [electrocardiogram] signs of myocardial infarction"; "ecg signs of myocardial ischaemia"; "enterovirus myocarditis"; "eosinophilic myocarditis"; "giant cell myocarditis"; "hypersensitivity myocarditis"; "immune-mediated myocarditis"; "myocardial haemorrhage"; "myocardial infarction"; "myocardial injury"; "myocardial ischaemia"; "myocardial rupture"; "myocarditis"; "myocarditis infectious"; "myocarditis post infection"; "myocarditis septic"; "myopericarditis"; "restrictive cardiomyopathy"; "silent myocardial infarction"; and "viral myocarditis". DMED data was obtained from the February 1, 2022 download and we analyzed "acute myocarditis" events.

Events related to cerebral infarctions were drawn from both VAERS and DMED. In VAERS, the following conditions were selected: "cerebral infarction"; "cerebral ischaemia"; "cerebral vasoconstriction"; "hypertensive cerebrovascular disease"; and "intracranial hypotension". DMED data was obtained from the February 1, 2022 download and we analyzed "cerebral infarction" events.

Maternal Outcomes

Eudravigilance is a system operated by the European Medicines Agency (EMA) that manages adverse event reactions to medicines involved in clinical trials in the European Economic Area (EEA). We used data collected in 2021 by Mascolo et al. to determine rates of spontaneous abortion, fetal death, stillbirths, and fetal disorders associated with administration of different COVID-19 injectables during pregnancy (Mascolo et al., 2022).

England and Wales Heart Attack Data

The Office of National Statistics holds mortality data or England and Wales collected at death registration. This information contains an underlying cause of death coded using the International Classification of Diseases, Tenth Revision. The ICD-10 codes associated with myocardial infarction are: "I21 – Acute myocardial infarction"; "I22 – Subsequent myocardial infarction", and "I23 – Complications following acute myocardial infarction" (*Heart attack deaths in 2019, 2020, 2021, and 2022*, 2022).

German Sudden Death

A December 2022 German report highlighting data from health insurance showed an increase in sudden deaths following widespread COVID-19 injection (Renner, 2022). We used the quarterly death totals for "sudden cardiac death"; "cardiac arrest, unspecified"; "sudden death"; "death occurring within less than 24 hours after onset of symptoms, not otherwise specified"; "death without presence of other persons"; and "other causes of death, vague or unspecified" combined.

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[1] It is noteworthy that what are called "spontaneous" abortions are probably most frequently caused by medications, medical procedures, or in the cases of interest here, by COVID-19 injectables. The definition of "spontaneous abortion" according to is Dugas, C., & Slane, V. H. (2022). Miscarriage. In *StatPearls*. https://www.ncbi.nlm.nih.gov/pubmed/30422585 is merely one that involves "the loss of a pregnancy at twenty weeks or less of gestation".

International Mortality Data

Excess mortality data for countries in the European Union is available through EuroStat (*Excess mortality - statistics*, 2022). January and February 2020 were used as pre-pandemic data and August and September 2022 were used as post-vaccination campaign numbers).

Statistical Analysis

We calculated averages, standard errors, and correlation coefficients using Microsoft Excel. Probabilities reported as *p*-values were calculated using the free online tool, Statistics Kingdom (95% confidence interval, one-tailed distribution) (*Statistics Kingdom*, 2022).

Ethical Considerations

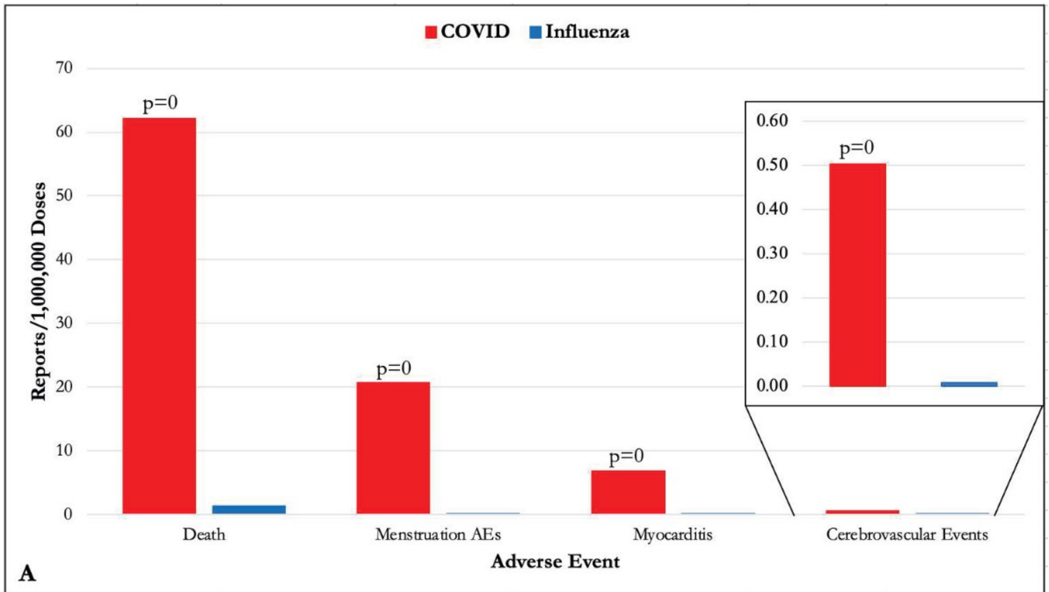
Institutional Review Board approval was not obtained for this study because no live participants were involved. All data presented is aggregated and readily available. Written informed consent was not necessary for this research as all our calculations were performed on previously published or presented data. We trust that any individual data presented in other peer-reviewed journals was obtained with the subjects' informed consent.

RESULTS

From December 14, 2020, to the writing of this article in December, 2022, over 650 million doses of mRNA COVID-19 injectables were administered in the US, alone (Mathieu et al., 2022). During that time, VAERS received and processed over 2.5 million reports (*Search the VAERS Database*, 2022). The reporting rate was approximately 42 per 10,000 doses. During that same time, 3.4 million mRNA COVID-19 injectable recipients enrolled in V-Safe, after one of their injectable doses and completed at least one health survey within the first week. The enrollment rate was approximately 52 per 10,000 doses. In addition, nearly two million military personnel received two COVID injectable doses between December 14, 2020, and November 22, 2021 (Hicks, 2021).

VAERS

VAERS processed 40,883 reports of death related to an mRNA COVID-19 injection, which is equivalent to ~6 deaths per 100,000 injectable doses administered (Figure 1A). That is over 45 times as many deaths per vaccine dose as have been reported for all the influenza vaccines since 1990 combined. Among VAERS reports filed for the COVID-19 injections, over 13,000 (0.50%) were reports of menstrual irregularities ("amenorrhoea"; "delayed menarche"; "dysmenorrhoea"; "heavy menstrual bleeding"; "hypomenorrhoea"; "menarche"; "menometrorrhagia"; "menopause"; "menopause delayed"; "menorrhagia"; "menstruation delayed"; "menstruation irregular"; "oligomenorrhoea"; "polymenorrhagia"; "polymenorrhoea"; "postmenopausal haemorrhage"; "premature menarche"; "premature menopause"; or "retrograde menstruation") (Figure 1A). There were over 1,000 times as many menstrual irregularities per vaccine dose reported for COVID-19 than for influenza. Of the VAERS reports filed for COVID-19 injections, over 4,000 (~0.16%) were reports of myocarditis ("acute myocardial infarction"; "autoimmune myocarditis"; "cardiomyopathy"; "ecg signs of myocardial infarction"; "ecg signs of myocardial ischaemia"; "enterovirus myocarditis"; "eosinophilic myocarditis"; "giant cell myocarditis"; "hypersensitivity myocarditis"; "immune-



Vaccine Type	Death	Menstruation AEs	Myocarditis	Cerebrovascular Events	Total Reports	Doses Given
COVID	40,883	13,634	4,503	331	2,748,860	657,925,531
Influenza	4,498	68	215	25	615,932	3,283,000,000
Pertussis	6,774	30	60	35	473,266	

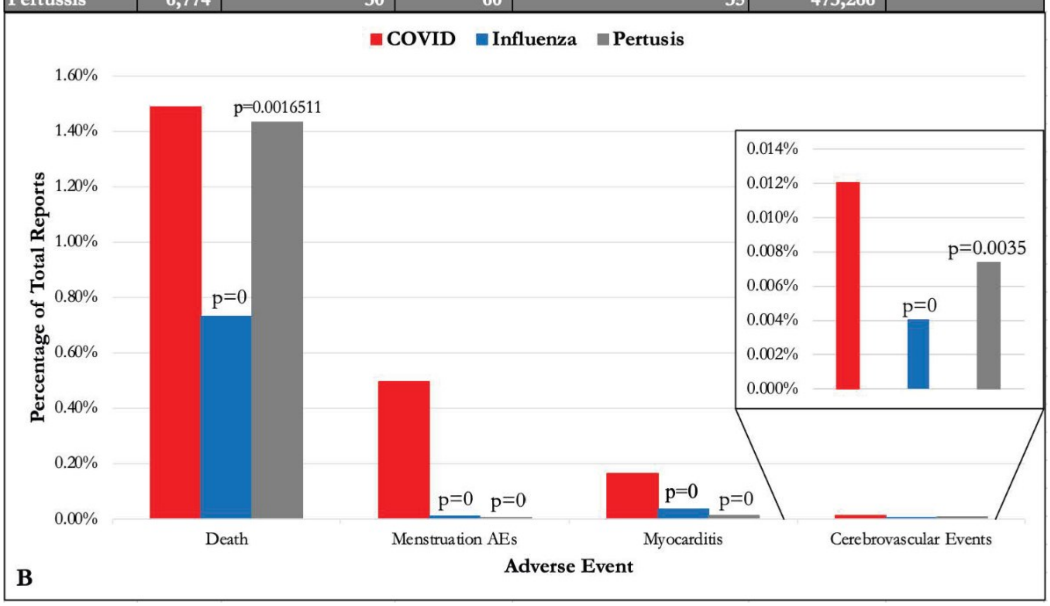


Figure 1. Results obtained from querying the CDC's VAERS reporting tool. Differences in normalized reporting rates of adverse events related to administration of the COVID-19 vaccine versus the influenza (A and B) and pertussis (B) vaccines. Figure 1A shows the reports of death, myocarditis, menstrual abnormalities and cerebrovascular events as a function of total COVID-19 vaccine doses administered (red bars) and total influenza vaccine doses administered since 1990 (blue bars) (insert is a magnification of the data for cerebrovascular events). Figure 1B shows the percentage of total reports attributed to death, myocarditis, menstrual abnormalities, and cerebrovascular events for COVID-19 (red bars), influenza (blue bars), and pertussis (grey bars) vaccinations (insert is a magnification of the data for cerebrovascular events). The *p*-values here were calculated using a two-sample proportion *z*-test.

mediated myocarditis"; "myocardial haemorrhage"; "myocardial infarction"; "myocardial injury"; "myocardial ischaemia"; "myocardial rupture"; "myocarditis"; "myocarditis infectious"; "myocarditis post infection"; "myocarditis septic"; "myopericarditis"; "restrictive cardiomyopathy"; "silent myocardial infarction"; or "viral myocarditis") (Figure 1A). This is equivalent to 100 times as many myocarditis events per vaccine dose reported for COVID-19 than for influenza. In addition, although cerebrovascular events ("cerebral infarction"; "cerebral ischaemia"; "cerebral vasoconstriction"; "hypertensive cerebrovascular disease"; or "intracranial hypotension) made up a small percentage of the COVID-19 injection VAERS reports (<0.1%), there were over 60 times as many cerebrovascular events per dose reported for a COVID-19 injection than for influenza vaccine (Figure 1A).

To account for differences in access to reporting across both time and geographic region, we normalized the VAERS data to represent percentage of total VAERS reports. This allowed us to include another widely administered vaccine, that against pertussis. As a percentage of VAERS reports, the number of deaths associated with COVID-19 injection was over twice that with influenza and slightly higher than that with pertussis (Figure 1B). The number of menstrual irregularities (see above) associated with COVID-19 injection was over 40 times that with influenza and nearly eighty times that with pertussis (Figure 1B). The number of myocarditis diagnoses (see above) associated with COVID-19 injections was four times that with influenza and nearly 13 times that with pertussis (Figure 1B). The number of cerebrovascular events (see above) associated with COVID-19 injection was nearly three times that with influenza and nearly two times that with pertussis (Figure 1B).

MILITARY HEALTH SYSTEMS

The results obtained by analyzing VAERS are mirrored when evaluating Military Health Systems data. In 2021, there were nearly two million reports of diseases and injuries among military personnel, which is significantly higher than the number of diseases and injuries reported in the five years prior when normalized for number of months with the available data and total number of service members (99.41 vs. 89.31+2.44 cases per month per 100 people; p-value = 0.0000174; Figure 2A). Among the injuries and diseases reported, three were of particular interest for this study: dysmenorrhea, acute myocarditis and cerebral infarction.

From 2016 to 2020 an average of less than one of every 1,000 service women experienced dysmenorrhea (0.78+0.05) every month. In 2021, those numbers rose by a factor larger than four (3.22 cases per 1,000 service women per month; Figure 2B; $p = 0$). From 2016 to 2020, the average number of acute myocarditis among military personnel was less than one for every 100,000 service members (0.65+0.21) per month. In 2021, however, that number more than doubled (1.42 cases per 100,000 service members per month; Figure 2C; $p = 0.0001331$). From 2016 to 2020, less than one service member out of every 10,000 had a cerebral infarction every month (0.35+0.02). In 2021, there were nearly five times as many incidences (1.58 cases per 10,000 service members; Figure 2D; $p = 0.02174$).

EUROPEAN DATA

Results observed in US data sets are reproducible in international data sets. Mascolo et al. reviewed 3,592 Case Safety Reports related to COVID-19 injection filed by pregnant women in EudraVigilance during 2021 (Mascolo et al., 2022). When the reports from pregnant women who received mRNA injectables were

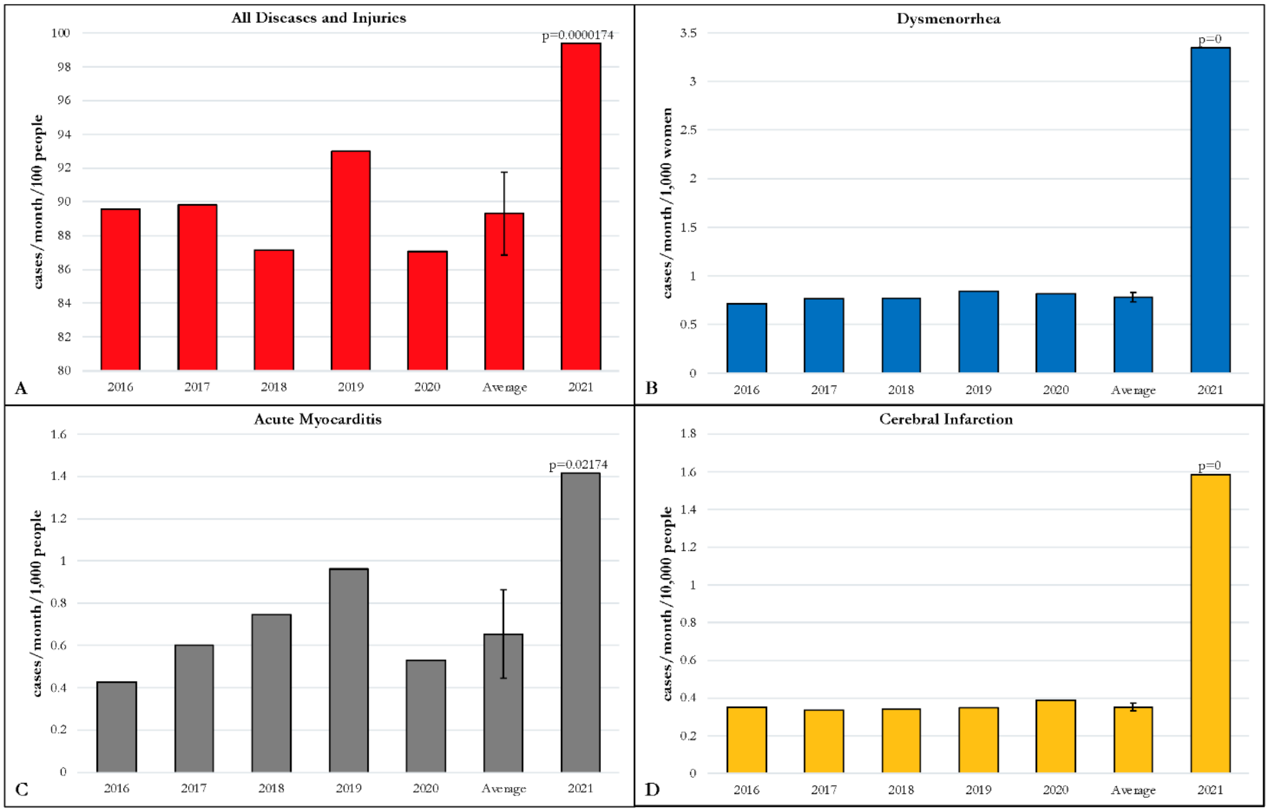


Figure 2. Results obtained from analyzing the Military Health Systems data. Figure 2(A) shows the number of diseases and injuries reported by Department of Defense personnel per month, per 100 people for the years 2016-2021, including the average for 2016-2020. Figure 2(B) shows the number of cases of dysmenorrhea per month per 1,000 service women for the years 2016-2021, including the average for 2016-2020. Figure 2(C) shows the number of reports of acute myocarditis per month per 1,000 service members for the years 2016-2021, including the average for 2016-2020. Figure 2(D) shows the number of incidences of cerebral infarctions per month per 10,000 service members for the years 2016-2021, including the average for 2016-2020. Error bars are equivalent to one standard deviation and *p*-values were calculated using a one-tailed distribution and 95% confidence interval for a normal confidence interval.

compared to those of pregnant women who received non-mRNA injectables, the former experienced nearly ctwelve times as many fetal deaths (0.81% vs. 0.07%); higher rates of stillbirths (0.22% vs. 0.17%); almost nine times as many hemorrhages during pregnancy (0.62% vs. 0.07%); over three times as many fetal disorders (2.5% vs. 0.71%) and congenital anomalies (0.11% vs. 0.03%); almost four times as many premature babies (0.64% vs. 0.17%); and twice as many neonatal deaths (0.06% vs. 0.03%) (Figure 3; (Mascolo et al., 2022).

The ONS collects, analyzes, and disseminates statistics about the UK's population. In response to a freedom of information request, the ONS published statistics on heart attack deaths in England and Wales in 2019, 2020, 2021, and 2022. The 2022 data showed significantly higher monthly deaths in 30–34-year-olds (4 vs. 3+0.34); 35-39-year-olds (11 vs. 7+0.65); 40-44-year-olds (20 vs. 15+1.75); 50-54-year-olds (80 vs. 56+3.79); 55-59-year-olds (110 vs. 88+7.27); 60-64-year-olds (137 vs. 116+11.01); and 65-69-year-olds (175 vs. 142+4.25) when compared to 2019 through 2021 data (Figure 4) (*Heart attack deaths in 2019, 2020, 2021, and 2022*, 2022).

Furthermore, as recently as December 2022, a German press conference showed a noticeable increase in deaths classified as occurring due to: "sudden cardiac death"; "cardiac arrest, unspecified"; "sudden death";

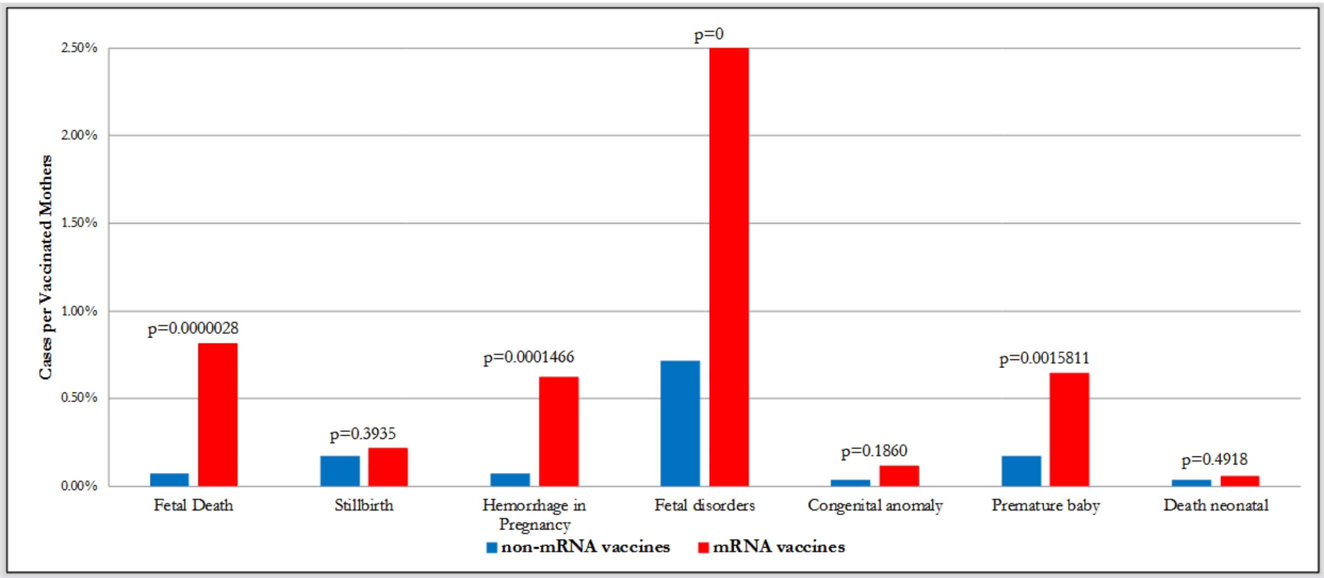


Figure 3. Maternal, fetal and neonatal outcomes among pregnant women receiving COVID-19 injection. Individual Case Safety Reports related to the use of COVID-19 injectables during pregnancy in the year 2021 were retrieved from EudraVigilance by Mascolo et al. (2022), and results were compared for women receiving the mRNA injectables (Moderna and Pfizer, red bars) and women receiving non-mRNA injectables (AstraZeneca and Janssen, blue bars). The *p*-values here were calculated using a two-sample proportion *z*-test.

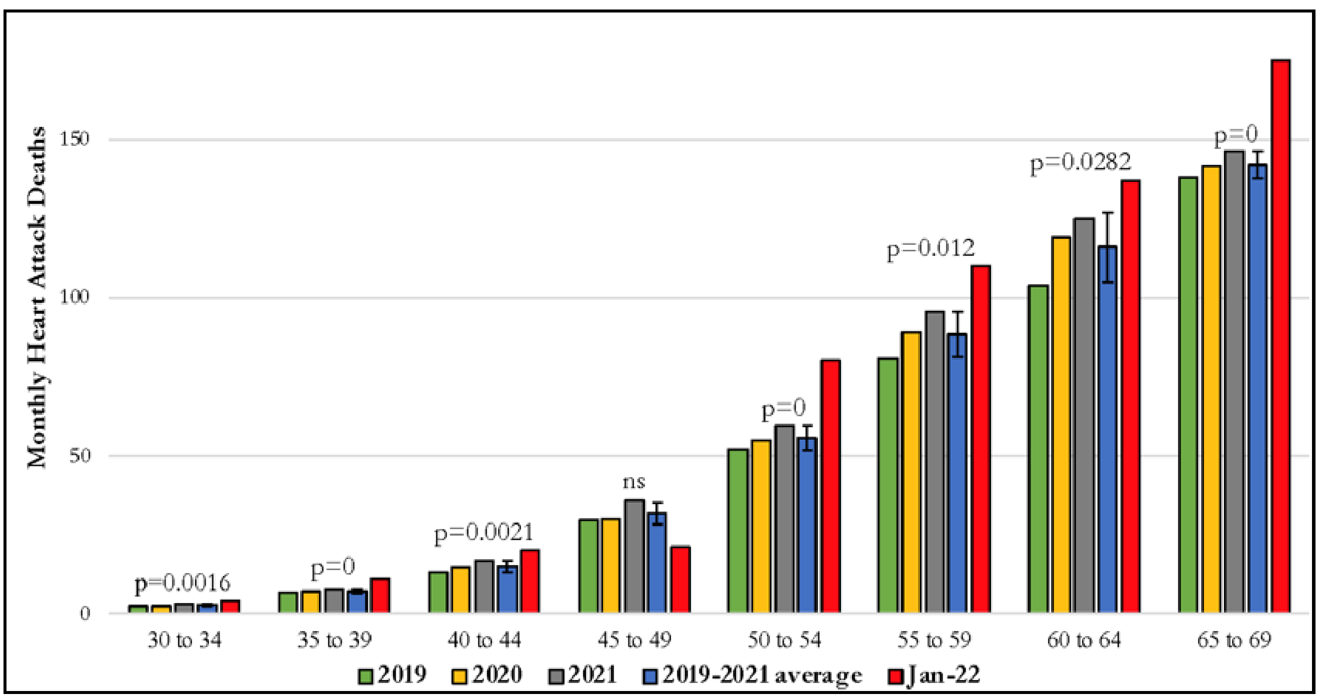


Figure 4. Heart attack deaths in England and Wales from 2019 to 2022. The average number of annual deaths due to heart attacks in England and Wales. (separated by five-year age brackets) were obtained from the ONS (*Heart attack deaths in 2019, 2020, 2021, and 2022*, 2022) and converted to monthly data. The numbers for 2019 (green bars), 2020 (yellow bars), 2021 (grey bars), and the average for the three years (blue) were compared to the deaths due to heart attacks for the first month of 2022 (red bars). Error bars are equivalent to one standard deviation and *p*-values were calculated using a one-tailed distribution and 95% confidence interval for a normal confidence interval.

“death occurring within less than 24 hours after onset of symptoms, not otherwise specified”; “death without presence of other persons”; or “other causes of death, vague or unspecified” (Renner, 2022). We standardized this data and compared the quarterly deaths per 100,000 people for 2016-2020 and to the deaths per 100,000 people for the first quarter of 2022. There were more than twice as many deaths in these categories in 2022 as any of the prior years (17.43 vs. 6.26+0.85; 2021 was not used in the comparison to avoid any increases attributable, at least in part, by pre-injection pandemic effects; Figure 5). We also performed the calculations looking specifically at the first quarter of the years in question in order to account for any skewing toward higher numbers at the beginning of the year. Our results were almost identical and equally significant (Figure 5; *p*-value = 0).

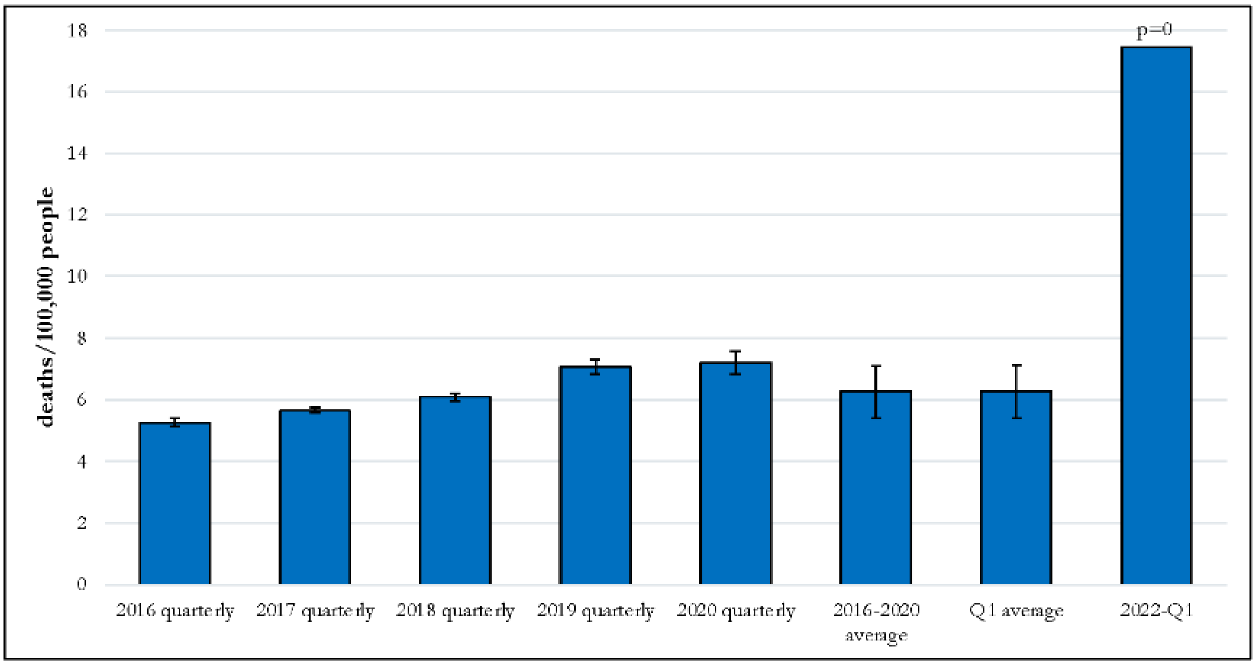


Figure 5. Quarterly unexplained and cardiac deaths in Germany from 2016 to 2022. The average number of quarterly unexplained and cardiac deaths per 100,000 people in Germany was obtained by Renner (Renner, 2022). We compared the quarterly unexplained and cardiac deaths from 2016-2020 (total and first quarter only) to the deaths in the first quarter of 2022. Error bars are equivalent to one standard deviation and p-values were calculated using a one-tailed distribution and 95% confidence interval for a normal confidence interval.

Finally, when excess mortality after the injection campaign in the European Union (August and September 2022), was compared to excess mortality during the pre-pandemic period in the European Union (January and February 2020), there was an overall increase (with the exception of Cyprus), with many countries showing a significant increase (Figure 6; *Excess mortality - statistics*, 2022).

DISCUSSION

From December 2020 to the time of publication, nearly 13 billion doses of mRNA COVID-19 injectables have been administered worldwide (Mathieu et al., 2022). We found definite indications of negative health consequences correlated to injection with one or more doses of mRNA COVID-19 injectables. Hospital encounters (both ambulatory and in-patient) for Department of Defense personnel were significantly

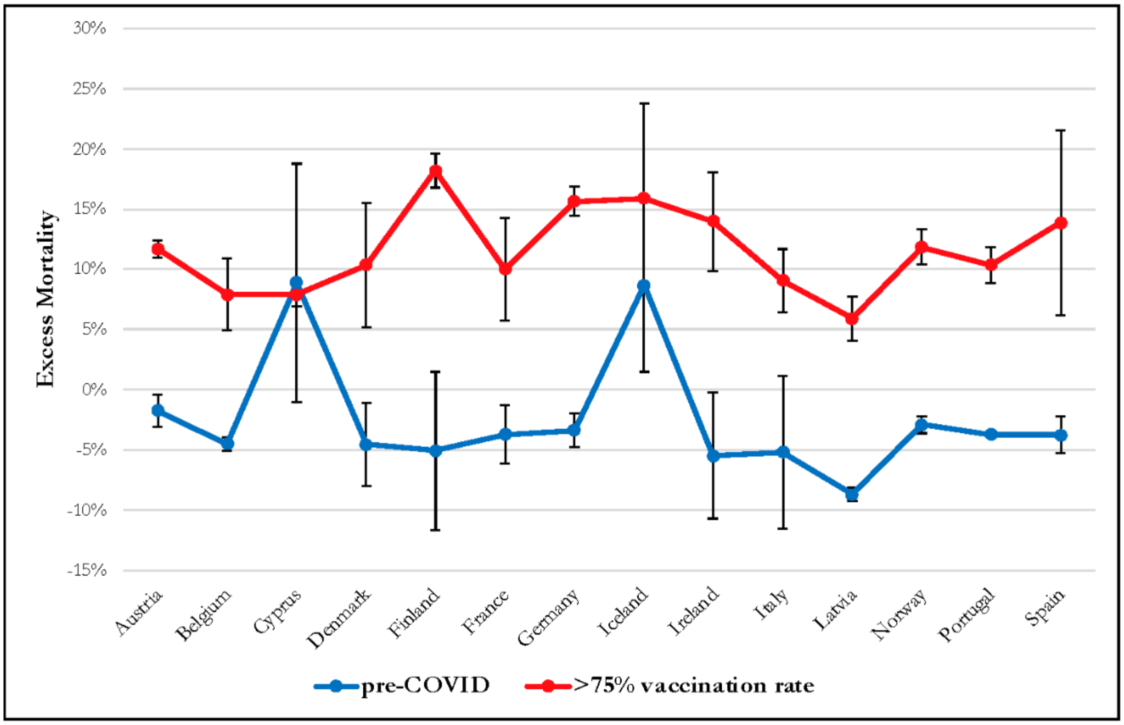


Figure 6. Results obtained from analyzing international excess mortality data. Excess mortality for countries in the European Union the first two months of 2020 (pre-pandemic, blue line) compared to August and September 2022 (75% average vaccination rate, red line). Error bars are equivalent to one standard deviation and *p*-values were calculated using a one-tailed distribution and 95% confidence interval for a normal confidence interval.

increased in 2021 (the year injectable administration began), when compared to similarly normalized data for the five previous years. When we compare VAERS reports per COVID-19 injectable dose to VAERS reports per influenza vaccine dose, the former is over twenty-fold higher (Figure 1A). Because these are total reports and one individual can file more than one VAERS report, the significance of this data cannot be determined, although there is a noticeable effect. Internationally, these observations were reproducible in Scotland, where there was an increase in hospital admissions for 5-14-year-olds of 15% when comparing the last four weeks of 2022 (post-injection campaigns) to the same weeks in 2015 to 2019 (*COVID-19 wider impact on the health care system*, 2023).

Indications that mRNA COVID-19 injectables may have negative health consequences were present as early as preclinical trials, which showed that mRNA injectables were not as immunogenic in humans as in animals and that there were serious "side effects" (actually, adverse events) associated with the COVID-19 injectables (Alberer et al., 2017; Bahl et al., 2022). Further, in the Fall of 2020, a whistleblower from Ventavia, a company that was managing three sites for Pfizer's mRNA injectable clinical trials, disclosed that the sites were not keeping up with reports of severe symptoms or reactions in response to vaccine administration and hence, these were not getting reported to the FDA (Thacker, 2021).

For the purposes of this article, we chose to focus, specifically, on thromboembolic events — those relating to female fertility, cardiovascular health, and cerebrovascular injury. In December 2020, a since-removed blog post claimed that a senior Pfizer employee had concerns about the possibility that antibodies evoked by their COVID-19 mRNA injectable could attack synctin-1, a protein in the placenta that shares a small segment of genetic code with the spike protein ("Does the COVID-19 Vaccine Affect Fertility? Here's What the Experts Say," 2021). Although the employee's claims were removed and could not subsequently be checked, documents concerning COVID-19 mRNA injectables confirm a concentration of the nanolipid particles and the mRNA cargo in the ovaries. Also, our results show that women of child-bearing age have reasons to be concerned that inoculation with mRNA injectables are likely to have lasting negative effects on their fertility (Thorp et al., 2022).

Menstrual cyclicity is a quantifiable measure of fertility. As of November 23, 2022, there had been 224,960 Yellow Card Reports filed in the UK related to the Moderna and Pfizer-BioNTech COVID-19 mRNA injectables combined, of which 23% (51,695) were of menstrual abnormalities (menopausal effects NEC [necrotizing enterocolitis], abnormal uterine bleeding, dysmenorrhea, intermenstrual bleeding, menstruation irregular, withdrawal bleed, menstruation with decreased bleeding, menstruation with increased bleeding) (*Coronavirus vaccine - summary of Yellow Card reporting*, 2022).

Natural Cycles App is an FDA-approved birth control application. In a study of prospectively tracked data from this software program, 3,959 women aged 18-45 who received both injectable doses within one menstrual cycle experienced a 2.32+0.73 day (98.75% CI) increase in cycle length compared to uninjected individuals (Edelman et al., 2022). In a 2021 study of women living in the Middle East and North Africa (MENA) region, 66.3% of respondents had post-injectable menstrual symptoms (Muhaidat et al., 2022). Similarly, roughly half of Norwegian women that responded to an online survey questionnaire experienced menstrual irregularities after even a single dose of an mRNA-based COVID injectable (Trogstad, 2022).

In VAERS, the rate of menstrual abnormalities (see above) after one or more COVID-19 injectables was over 40 times and almost 80 times the rate after influenza and pertussis vaccines, respectively (Figure 1B). DMED showed over four times as many cases of dysmenorrhea per month per 1,000 service women in 2021 than in each of the previous five years (averaged; Figure 2B). Changes in menstrual cycles have been reported during COVID-19 infection, leading to the suggestion that the spike protein could cause this pathogenesis (Costeira et al., 2021).

Menstrual patterns are a marker of ovarian and hormonal health and may be an indicator of overall fertility (Wesselink et al., 2016). Bentov et al. attempted to quantify fertility issues more directly by measuring Atrial Follicle Count (AFC) in women undergoing oocyte retrieval in Jerusalem, Israel (Bentov et al., 2021). Such a procedure involves a physician counting the number of egg-containing follicles developing in the ovaries in with a view to trying to assess the patient's potential fertility. In their study, the AFC was lower for COVID-19 injected females (13.3+4.7) compared to the control group (15.6+6.70) (Bentov et al., 2021). Presumably, because of the small sample size (n = 32) and the consequent variability measures within it, the contrasts are not statistically significant at an α-level of 0.05. However, the median for the injected females (14) was indicative of a left-skewed (lower AFC) distribution and that for the uninjected females (17.4) was indicative of a right-skewed (higher AFC) distribution.

V-Safe surveys are another method to directly estimate and possibly measure the effects of COVID-19 injectables on fertility. They include questions to identify women who are or become pregnant after receiving a COVID-19 injectable. There were 3,958 participants enrolled in the pregnancy registry. Registrants included 827 completed pregnancies, 104 of which (12.6%) resulted in what is euphemistically called "spontaneous" abortion (Shimabukuro et al., 2021) — more probably a medically induced event caused by the injections. Earlier this year, the American College of Obstetrics and Gynecology estimated the incidence of so-called "spontaneous" abortion to be 10% (*Early Pregnancy Loss*, 2022). It is important to note, that in pre-clinical trials, COVID-19 injected rats had a lower pregnancy index than non-injected rats (84.1% vs. 93.2%; (CHMP, 2021).

Adverse pregnancy results were not limited to the US, but were also seen in Europe. Mascolo et al. reviewed 3,592 Case Safety Reports related to COVID-19 injections filed by pregnant women in EudraVigilance during 2021. When the reports related to mRNA injectables were compared to those related to non-mRNA vaccines, the former group showed significantly higher numbers of several unfavorable maternal outcomes (Figure 3; Mascolo et al., 2022).

Although birth defects have traditionally been attributed to genetics, or to environmental agents — especially, alcohol, legal and illegal drugs, medicinal procedures such as amalgam placement, oxygen deprivation (in cerebral palsy), and so forth — it is believed that some viruses can also cause abnormal developments manifested as pre- or post-natal defects (Ferrer-Vaquer & Hadjantonakis, 2013). Because normal growth and development is a process that is just beginning with conception and continuing through childhood, adolescence, and adulthood, the detrimental effects of toxins and genetic corrupting factors can manifest over a lifetime. The fertility problems, menstrual irregularities, and birth abnormalities that have manifested themselves over the last two years, are indicators that we can expect to continue to see long-term negative outcomes owed to COVID-19 injectables into the foreseeable future.

To take just one example, there is the phenomenon known as "vaccine-associated myocarditis", that pre-dates mRNA injectables. In 2003, Halsell et al. showed a causal relationship between smallpox vaccination and myopericarditis in 21-33-year-old white men (Halsell et al., 2003). As early as preliminary clinical trials, Moderna documented that their COVID-19 injected individuals, but not placebo recipients, suffered from embolic stroke, ischemic heart attack, and deep vein thrombosis ((CHMP), 2021).

In Israel, nearly 150 cases of myocarditis and pericarditis were documented within the first thirty days of mass nationwide COVID-19 injections — (*Surveillance of Myocarditis (Inflammation of the Heart Muscle) Cases Between December 2020 and May 2021 (Including)*, 2021). In June of 2021, the Israeli Ministry of Health (by a time when over half of the Israeli population was "fully vaccinated" — i.e., with multiple doses) reported a huge spike in myocarditis cases, and, later that year, data from Clalit Health Services showed that COVID-19 injections tripled (3.24) the 42-day risk of myocarditis when compared to uninjected persons (Barda et al., 2021; Witberg et al., 2021).

Perhaps the most concerning data regarding vaccine-associated myocarditis in males comes from Mevorach et al., (2021). They compared ratios of myocarditis rates in COVID-19 injected individuals to myocarditis rates prior to COVID (2017-2019) and to myocarditis rates in uninjected individuals. They found marked increases, especially in males ages 16-19 who had received two doses of the Pfizer mRNA COVID product (see Table 1 here, using data from Mevorach et al. (Mevorach et al., 2021). In conjunction with this finding, there were 25% more emergency calls for cardiac arrests/acute coronary symptoms involving 16-19 year-olds in Israel from January to May 2021 than for the same time period in either 2019 or 2020, yet not more COVID-19 cases (Sun et al., 2022).

Simone et al. (2021) found similar results when they looked at the incidence of myocarditis in members of Kaiser Permanente Southern California aged 18 years or older who received at least one dose of the Pfizer or Moderna mRNA injectable between December 14, 2020, and July 20, 2021. They found nearly a six-fold increase in the incidence rate over a ten-day observation period in members who had received their second dose of the injectable.

DMED data was an ideal source to evaluate the correlation between administration of COVID-19 mRNA injectables and increased risk of myocarditis. Roughly 80% of the Department of Defense is male; about three-fourths of this population is aged 35 and under, and, in 2021, the entirety of the US military was mandated to receive two doses of an mRNA COVID-19 injectable (Hicks, 2021; Military Community Demographics, 2022). When we normalized data to cases per month per 1,000 people, there were more than twice as many cases of myocarditis in 2021 than in each of the previous five years (Figure 2C). This observation was validated in VAERS where there were over four times and nearly thirteen times as many reports of myocarditis as a percentage of total reports for COVID-19 injectables than for influenza and pertussis vaccines, respectively (Figure 1B).

Table 1.
Comparison of rate ratios for diagnosis of myocarditis after the first and second vaccine dose. Using data obtained by Mevorach et al, we compared the rates of myocarditis after the first and second vaccine dose to rates of myocarditis from 2017-2019 (prior to the pandemic; second and third columns, respectively). We also compared myocarditis rates among the vaccinated to myocarditis rates among the unvaccinated during the same time frame (fourth column) (Mevorach et al. 2021). There is a drastic increase in the incidence rate of myocarditis among fully vaccinated 16–19-year-old males regardless of the controls used.

Age and Sex	One Vaccine Dose/ 2017-2019 Cases	Two Vaccine Doses/ 2017-2019 Cases	Two Vaccine Doses/ Unvaccinated Cohorts
All Recipients	1.42	5.34	2.35
Males 16-19	1.62	13.6	8.96
Males 20-24	2.14	8.53	6.13
Males 25-29	1.39	6.96	3.58

Many cases of myocarditis go undiagnosed but clinically verified myocarditis has over a 50% mortality by five years (Fung et al., 2016; Mason et al., 1995). In addition, children who suffer from acute myocarditis (whether it is diagnosed at the time or not) have a 40% probability of needing a transplant within ten years (Towbin et al., 2006). These trends would indicate that in the next five to ten years, we will see spikes in death rates attributed to the increase in myocarditis documented above, as well as in the number of otherwise healthy young adults needing transplants to survive, and all the complications associated with such a transplant.

In fact, in response to a freedom of information request, the ONS published statistics on heart attack deaths in England and Wales in 2019, 2020, 2021, and 2022. The 2022 data showed significantly higher monthly deaths when compared to 2019 through 2021 (Figure 5; *Heart attack deaths in 2019, 2020, 2021, and 2022*, 2022). In addition, as recently as December 2022, a German press conference showed a noticeable increase in deaths classified as occurring due to: "sudden cardiac death"; "cardiac arrest, unspecified"; "sudden death"; "death occurring within less than 24 hours after onset of symptoms, not otherwise specified"; "death without presence of other persons"; or "other causes of death, vague or unspecified" (Renner, 2022). We took this data and normalized it so that we could compare the quarterly deaths per 100,000 people for 2016-2020 and compare to deaths per 100,000 people for the first quarter of 2022. The 2022 were more than twice as high as any of the prior years (Figure 5).

In order to cause cerebrovascular pathology, a substance must first be able to cross the blood-brain barrier. The mRNA from Moderna's mRNA-lipid nanoparticles, specifically, has been seen in the brain of injected rats, showing its ability to cross the blood-brain barrier (CHMP, 2021).

Within the US Department of Defense, there were nearly five times as many hospital encounters for cerebral infarctions in 2021 (after the injectable mandates) than in the five prior years (Figure 2D). When VAERS data was analyzed to corroborate these findings, we saw the same pattern. There were over sixty times more reports of cerebrovascular events per mRNA COVID injectable dose administered than per influenza vaccine dose administered (Figure 1A). When normalized to total reports received, there were three times as many and nearly two times as many cerebrovascular events reported as a percentage of total reports for mRNA COVID injectables than for influenza vaccines or pertussis vaccines, respectively (Figure 1B).

Altogether, the pathologies we've outlined above, along with others which are outside the scope of this investigation, would be expected to cause overall increases in mortality rates. This should not be surprising, considering that the lipid nanoparticles used to deliver mRNA injectables caused high mortality in mice that were injected with them (Ndeupen et al., 2021). Indeed, we have already witnessed increases in excess mortality in Europe. Eurostat numbers showed an increase in excess mortality in all participating European countries except Cyprus (Figure 6) and data downloaded from Public Health Scotland showed an excess mortality over 10% when comparing 2022 numbers to 2020 numbers, the latter of which, presumably, include large numbers of pandemic deaths (*COVID-19 wider impact on the health care system*, 2023).

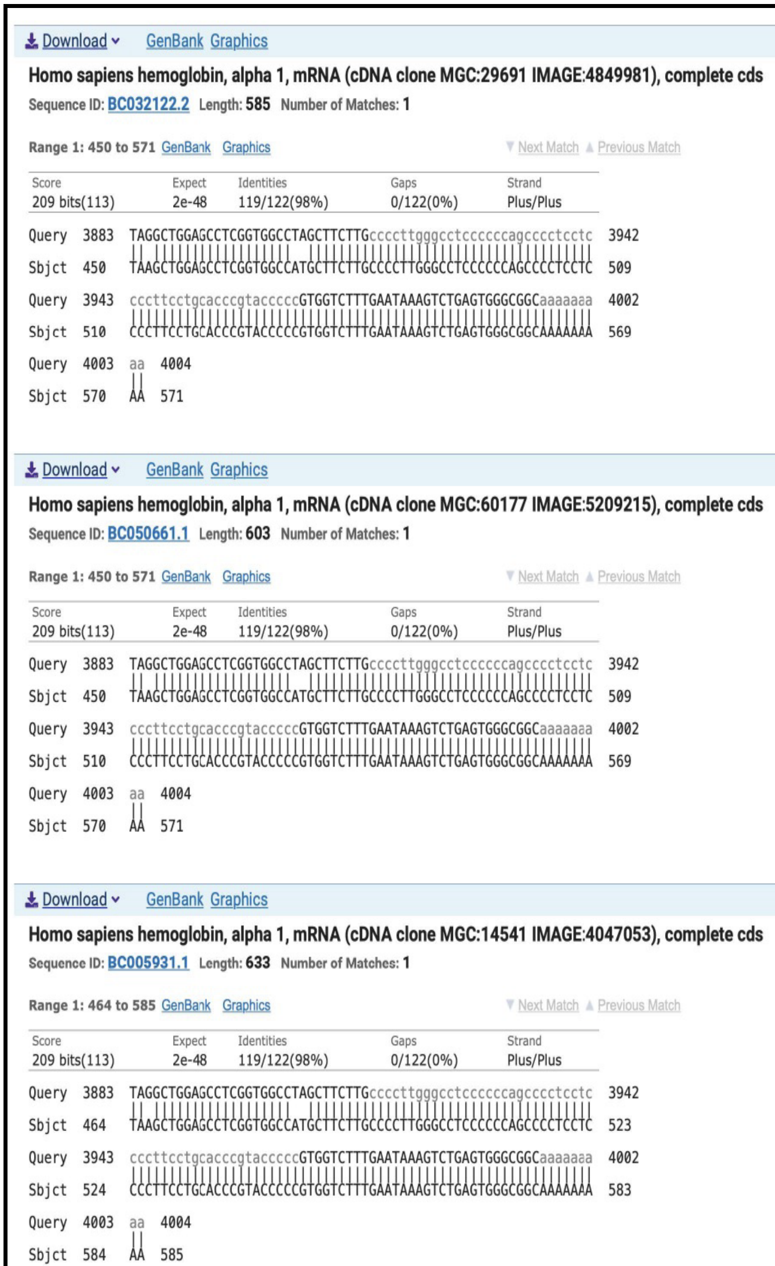


Figure 7. BLAST sequence alignment of the Moderna mRNA vaccine reverse sequence against human libraries. The reverse transcribed sequence of the Moderna mRNA vaccine obtained from a group at Stanford University (Winter, 2021) was pasted into the BLAST sequence alignment tool where it was screened against human libraries to identify small regions of homology with human haemoglobin.

CONCLUSIONS

During mRNA injection, extracellular RNA can evidently promote blood coagulation and pathological thrombus (Kell & Pretorius, 2017; Pardi et al., 2018; Kell et al., 2022; Nyström & Hammarström, 2022). The most potent amyloidogenic spike components (spike 192 and spike 258) identified *in vitro* by Nyström & Hammarström, also shown to be in BNT162b2 (Santiago & Oller, 2023), could be causing some of the thromboembolic events we are seeing after injection with a COVID-19 mRNA injectable. Alternatively, the vascular consequences of mRNA COVID-19 injection mentioned above could be directly related to the spike protein (which the injectables encode mRNA for). It binds to a protein called ACE2, that is ubiquitously expressed, but overexpressed in blood vessels and heart tissue, among others (Shirbhate et al., 2021). When the protein enters the blood vessels, it damages the cells that line them, causing the production of clots as part of the repair process (Shirbhate et al., 2021). Blood clots can clog blood vessels, leading to downstream effects. When spike protein was given to rodents, it caused inflammation and microvascular damage similar to the abnormal clotting that is currently being found in humans (Avolio et al., 2021). Finally, Moderna never published the sequence of their mRNA injectable, but a group of scientists out of Stanford University sequenced it from injectable residue in a vial (Winter, 2021). It shares some homology with human hemoglobin (Figure 7), a protein found in human red blood cells. We need further investigation into the cause of the increases in all these vascular conditions and whether or not it is due to mass injectable administration (Sun et al., 2022).

Given the vascular events outlined in this paper, along with some not addressed, such as pulmonary embolism and subarachnoid hemorrhage, it should be anticipated that many of the unexpected deaths being recorded, may eventually be traced back to injectable-mediated vascular pathogenesis. For example, when standardized autopsies were performed on 25 individuals in Europe who had died unexpectedly within 20 days of an anti-SARS-CoV-2 injection, five of them had acute (epi-)myocarditis without any other significant disease or health condition that could have caused their unexpected deaths (Schwab et al., 2022).

In hematopoietic stem/progenitor cells exposed to spike protein, 311 out of 441 proteins were expressed at either higher (142) or lower (169) levels (Kucia et al., 2021). This is equivalent to over 70% of the proteins crucial to normal development being misregulated. With the normal homeostasis of so many proteins being disrupted, multisystemic pathologies such as cancers, fertility issues, and birth defects can be expected to reach never-before seen levels. Early evidence of this is now manifesting in the US and elsewhere, as can be seen in data from the Department of Defense, and EudraVigilance.

The fatality rates from COVID-19 infection supposedly range from 0.4% to 14% (Levin et al., 2020) — but are known to be inflated by influenza, other viruses, and many stress factors including lockdowns, shut-in isolation, masks, business failures, loss of employment, and so forth. Since there is a low morbidity associated with COVID-19 infection in the populations focused on in this study, (also see (Abbasi, 2020), we suggest that, for many young men and women, the risk of injuries from the injectables leading to serious adverse events and known mortalities outweighs the risk of potential symptoms from COVID-19 infection and should be considered when making recommendations about the COVID-19 injectables, or similar experimental products now in the background but known to be under development. It is important to raise awareness of the potential early symptoms of the adverse events discussed here, and others that were outside the scope of this investigation, in order to inform public policy and hopefully minimize or even prevent further avoidable harm (Sun et al., 2022).

Conflicts of Interest

The authors declare no conflicts of interest.

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