Science, Public Health Policy, and The Law
Volume 2:59–80
May, 2021
Clinical and Translational Research

An Institute for Pure and Applied Knowledge (IPAK)

Public Health Policy Initiative (PHPI)

A Report on the U.S. Vaccine Adverse Events Reporting System (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals

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Abstract

Following the global roll-out and administration of the Pfizer/BioNTech (BNT162b2) and Moderna (mRNA-1273) COVID-19 vaccines[1] on December 17, 2020 in the United States, and of the Janssen COVID-19 Vaccine PF (produced by Johnson & Johnson) on April 1st, 2021, tens of thousands of individuals have reported adverse events (AEs) using the Vaccine Adverse Events Reports System (VAERS). This work summarizes this data to date and serves as information for the public and a reminder of the relevance of any adverse events, including deaths, that occur as a direct result of biologicals as prophylactic treatments. This is especially relevant in the context of technologically novel treatments in the experimental phase of development. Analysis suggests that the vaccines are likely the cause of reported deaths, spontaneous abortions, anaphylactic reactions and cardiovascular, neurological and immunological AEs. The precautionary principle promotes transparency and the adoption of preventative measures to address potential risks to the public in the arena of vaccination programs, and it is vital that individuals are informed of these potential risks before agreeing to participate in any medically involved treatment program. VAERS reporting and recording is essential to the proper functioning of this system. It cannot be over-emphasized that the public should know how to use this system such that they actually do use it, and that once reports are made, responsible individuals enter each report into the database accordingly.

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Keywords

VAERS (Vaccine Adverse Event Reporting System), AE (Adverse Event), SAE (Severe Adverse Event), COVID-19 (Corona Virus Disease 2019)

[1.] mRNA biologicals are not true vaccines. True vaccines are a preparation of a weakened or killed pathogen, such as a bacterium or virus, or of a portion of the pathogen's structure that, upon administration to an individual, stimulates antibody production or cellular immunity against the pathogen but is incapable of causing severe infection. Vaccines undergo an extremely rigorous time-dependent testing protocol to ensure safety and efficacy, typically enduring between 10 and 15 years. The mRNA biologicals do not satisfy either of these requirements and are thus more akin to experimental treatments.

Contents

1. Background

The Vaccine Adverse Event Reporting System (VAERS) was created and implemented in 1990 by the Food & Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to receive reports about adverse events that may be associated with vaccines. Most vaccine adverse event reports concern relatively minor events, such as injection site pain. Other reports describe serious events, such as hospitalizations, life-threatening illnesses, or deaths.[1] The reports of serious events are of greatest concern and are meant to receive the most careful scrutiny by VAERS staff and healthcare professionals. The primary purpose of maintaining the database is to serve as an early warning or signaling system for adverse events not detected during pre-market testing. In addition, the National Childhood Vaccine Injury Act of 1986 (NCVIA) requires healthcare providers and vaccine manufacturers to report to the DHHS specific adverse events following the administration of those vaccines outlined in the Act.[1] It must be noted that the adverse events reported to VAERS represent a fraction of the actual number of incidents. Studies have shown that the percentage of incidents reported can be quite low (1–10%) but, for the purposes of this report, in order to do the necessary calculations, VAERS numbers were used and the results should be considered to reveal trends.[1,2]

An Adverse Event (AE) is defined as any untoward or unfavorable medical occurrence in a human study participant, including any abnormal physical exam or laboratory finding, symptom, or disease, temporally associated with the participants' involvement in the research, whether or not it is considered related to participation in the research. A Serious or Severe Adverse Event (SAE) is defined as any adverse event that results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects, or is another condition which investigators judge to represent significant hazards.[2,3] The VAERS handbook states that

[2.] National Institute on Aging. Adverse Event and Serious Adverse Event Guidelines. https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf [40]
[3.] FDA. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?frexternal%20icon

approximately 15% of reported AEs are classified as severe.[1]

Ongoing collection of data in systems such as VAERS in the United States, the Coronavirus Yellow Card reporting site for the United Kingdom, as well as independent reports of AEs, merits further examination into both the safety and efficacy of the mRNA vaccines currently being rolled-out globally in response to COVID-19, in particular those designed by Pfizer/BioNTech (BNT162b2, now known as the Pfizer-BioNTech COVID-19 Vaccine) and Moderna (mRNA-1273), which have been the most widely administered.[4] mRNA platforms are new in medical microbiology and have never before been implemented for use in human subjects on a global scale in the context of viruses. Safety is always a point of relevance with regards to new biological agents. As stated, the primary purpose for maintaining the VAERS database is to serve as an early warning system and one should be cautious in drawing conclusions regarding safety in its context. But since the number and range of side effects is vast and no long-term data of potential damaging effects such as autoimmune reactions exists, AE collection systems such as these are of utmost importance, not only to flag potential severe AEs not detected during pre-market testing but also for weighing in on the potential safety of the biologicals themselves. The efficacy of a conventional vaccine is measured via explicit demonstration of broad-spectrum potent immune responses in the forms of both cellular and humoral responses as well as the establishment of enduring immunity.[3–7]

Although there are some studies claiming efficacy for these mRNA biologicals in humans, [4,5] that efficacy is not based on immunological assessment but rather on clinical assessment based on primary and secondary endpoints including confirmed or severe COVID-19. In these same studies, safety is assessed based on a *maximum* observation period of six months. This is not adequate to assess long-term safety outcomes. In this context, it is worth noting that the Pfizer/BioNTech, Moderna, and Janssen COVID-19 vaccines have **not** been approved or licensed by the FDA, having been authorized instead for emergency use by the FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19), for use in individuals 16 years of age and older.[8–10] Ultimately, the roll-out of COVID-19 vaccines is actively being monitored, but all of the risks are not yet known.[9,10] In spite of this, real-world trials and administration of these biologicals into pregnant women and children are being pursued in countries around the world, such as Israel.[11] The VAERS dataset is currently the best (if not the only, albeit imperfect) way the public can monitor and be informed of the risks associated with administration of the COVID-19 injectables.

It is vital for the public to be aware of this reporting system and the valuable information therein so that informed decisions can be made and a risk/benefit analysis done. One of the ways that risk is assessed using findings from this study is by comparing the death rate reported in VAERS with the Infection Fatality Rate (IFR), which is a measure of the chance of dying from

4. Messenger ribonucleic acid, first discovered in 1961 at Caltech, has been called the "software of life." Conventional vaccine types primarily use live-attenuated whole viruses or killed viruses as a means to elicit potent immune responses in the forms of both cellular and humoral responses and life-long immunity. Periodically, boosts are required in order to maintain longevity of immune responses, especially in the form of neutralizing antibodies.[42] mRNA treatment types use specific mRNA that encodes a particular protein, which is meant to be mass-produced by host cells as a means to trigger an appropriate immune response, primarily in the form of neutralizing antibodies, in order to provide a degree of protection upon challenge with the wild-type coronavirus. Although studies show cellular and humoral responses upon injection, it is not known how long immunity might last, and thus it has been suggested that many boosts will be required. It has also been detailed that these particular vaccines do not prevent transmission, and thus the effectiveness of these vaccines is very questionable.[8,9,10] Perhaps even more important is that it is unknown what the impact of non-neutralizing antibodies will be in the long term.

the nCoV-2019 pathogen. All infected individuals, both symptomatic and asymptomatic, are accounted for in the IFR calculation, and data therein is based on serology. It is important for anyone analyzing or comparing death statistics to use the IFR and not the Case Fatality Rate (CFR) — the ratio between confirmed deaths and confirmed cases [12,13] — because the CFR is based on potentially unreliable death and confirmed case accounts.[5] There is also a lag in time between when people are infected and when they die, and, most importantly, it does not capture the population with innate immunity. The major difference in the numbers, 1.8% (CFR) versus 0.15% (IFR), is due to a significantly larger denominator whereby infected individuals with an effective innate immune response represent asymptomatic cases. The latter metric highlights the true risk of succumbing to the virus in the general population. It is more compelling to use the IFR as a metric for comparison for this and future studies.[12]

2. Methods

1. General methodology and descriptive statistics

To analyse the VAERS data set, R was used (a language and environment for statistical computing). The VAERS data set is available for download (https://vaers.hhs.gov/data/datasets) in three separate comma-separated values (csv) files representing i) general data for each report; ii) the reported AEs or 'symptoms'; and iii) vaccine data including vaccine manufacturer and lot number, as per report. The VAERS dataset is updated approximately once a week and the uploaded set is approximately one week behind the reports. Upon individual reporting of vaccine side effects or adverse events, a VAERS ID number is provided to the individual to preserve confidentiality, and a detailed description of the side effects are transcribed along with the individual's age, residence by state, past medical history, allergies and gender and many other details. In addition, the vaccine lot number, place of vaccination and manufacturer details are included in the report. In order to maximize the input variables for my analysis, the three files were merged by VAERS ID that is included as a linking variable in all three files. The merged data set comprises data collected pertaining to all reported AEs associated with the Pfizer/BioNtech and the Moderna COVID-19 products. Data was sorted according to vaccine type (data reported for COVID-19) and relevant variables were sorted including VAERS ID, AEs, age, gender, state, vaccination date, date of death, incident of death, dose series, treatment lot number, treatment manufacturer, hospitalizations, emergency department visits and onset date of AEs. To determine the total number of AEs, multiple individually reported AEs were aggregated into a single column vector. An additional column vector called AGE_GROUPS was created to group the individuals who made reports according to age by decade. The grouped AE categories were created by selecting "Y" in the case of the death, hospitalizations and emergency doctor visits while the cardiovascular, neurological and immunological groups were created by selecting key words indicative of an immunological medical issue such as 'lymphadenopathy', in the case of the immunological AE group, for example.

There are two primary vaccine manufacturers responsible for nCoV-2019 vaccines currently being administered, Pfizer/BioNTech and Moderna. Recently, a third, the Janssen COVID-19 Vaccine PF (produced by Johnson & Johnson), has begun to be administered. All three are included in this analysis, except where discrepancies were found by comparison between manufacturers.

5. The CFR is the fraction of reported deaths from nCoV-2019 to the reported confirmed cases of nCoV-2019. This gives an unreliable metric in that both the numerator and denominator may not be accurate (and have been reported not to be).[12,13]

Descriptive statistics on the incidence rates of relevant AEs were calculated as a percentage of the number of unique VAERS IDs and the fully vaccinated population in the United States.[6] Also calculated are the death rates by nCoV-2019 for each respective VAERS update date as reported by the Our World in Data collection. [14] It should be noted the death rate was reported from the nCoV-2019 virus report CFR, not IFR. Although a confirmed positive serological test should be conducted, according to the World Health Organization (WHO), the US Department of Health and Human Services, the CDC, the National Center for Health Statistics, and the National Vital Statistics System, it is acceptable to report COVID-19 on a death certificate without this confirmation.[7]

2. Statistical testing and causation

Statistical analysis was done using the Student's t-Test to determine statistically significant differences between age groups in the context of grouped data, such as individuals who died versus individuals who did not die, for example. Causation implies that a change in one variable necessarily leads to a change in another variable. The three criteria for establishing causation are association, time ordering and non-spuriousness. Association is shown in the incidence rate data and using heatmaps and are corroborated using Chi-Square Tests. Heatmaps can be found in the Supplementary material. Time ordering is presented in temporal relationship between vaccination date and the following onset of AE date or the date of death.

Non-spuriousness is more difficult to prove in real-world settings since it is not truly possible to rule out external influences as contributing factors for the associations. For example, it is possible that the individuals who died within 24 hours of getting vaccinated did so not due to the vaccine but due to underlying conditions such as heart defects. This challenge is met by looking at data available on potential third variable causes such as medications taken at the time of vaccination and existing medical conditions. Skewing in distribution of data is tested using Pearson's Skewness Index, I, which is defined as I = (mean-mode)/standard deviation. The data set is considered to be significantly skewed if $|I| \geq 1$.

3. Results

1. General information

To date, approximately 15% of the total US population has been 'fully vaccinated' against COVID-19, with 183,467,709 million doses administered as of April 10, 2021; ~0.5% of the total US population have been vaccinated against the flu, with 1,300,000 million doses administered as of March 26, 2021.[8] Based on the fact that the ratio of COVID-19 to flu vaccinations at the end of March was ~100:1, then it is not surprising that 380 times more reports have been made in the context of the COVID-19 injections. 99% of all AEs reported in 2021 have been in the context of COVID-19 reports, while only 0.3% of all AEs reported to date have been in the context of the influenza vaccines. Of all vaccines administered in 2021, 0.7% have been influenza vaccines,[9] meaning that the higher percentage of reports made in the context of COVID-19 are due to more frequent reporting subsequent to more frequent administration of the COVID-19 products.

Figure 1.1 illustrates the total number of adverse events reported and uploaded to the VAERS database per year. There is an increase in the number of reports being made each year

6. Our World in Data. https://ourworldindata.org/covid-vaccinations [14]
7. CDC. Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID–19). Vital Statistics Reporting Guidance, Report No. 3, April 2020. https://www.cdc.gov/nchs/data/nvss/vsrg/vsrg03-508.pdf
8. CDC. Seasonal Influenza Vaccine Supply & Distribution. https://www.cdc.gov/flu/prevent/vaccine-supply-distribution.htm
9. Ibid.

Figure 1.1 Time series plot – VAERS reporting rate normalized to US population by year

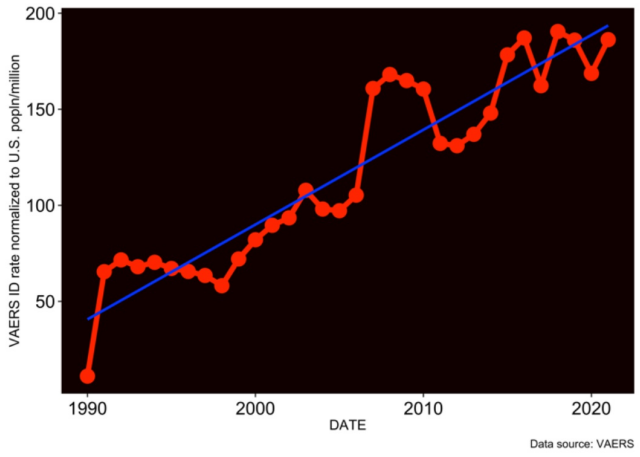
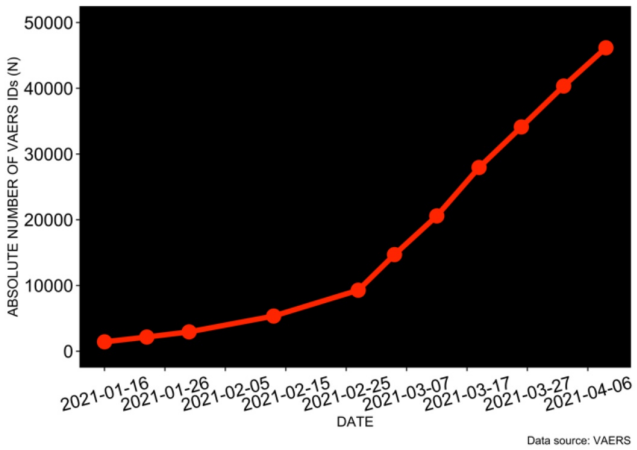


Figure 1.2 Time series plot – Absolute number of VAERS reports for the COVID-19 products for 2021



over the past 30 years (possibly due to increasing awareness and adoption of the reporting system). 20% of all reports were COVID-19 vaccine-related in 2020 and this was due to only 14 days of the year since administration began on December 17th, 2020. Figure 1.2 shows reports for 2021 by week. The most recent updated data files have almost surpassed the sum total reports for the entire year in 2020 (and this includes reports for all vaccines, not just ones related to COVID-19). This is because reports relating to COVID-19 vaccines in 2021 to date are in the order of all vaccines in 2020.

SAEs comprise 26% of all AEs, which is almost twice the estimate of SAEs documented in the VAERS handbook. Of all individuals having received the first dose who reported an SAE, 74% did so after receiving the first dose. Similarly, of the individuals who reported mild AEs, 81% did so after receiving the first dose. Of the total population of VAERS reports, 79% were made after receiving the first dose.

1.1 Incidence rates of AE groups by VAERS ID

As of mid-April 2021, a total of 4507 types of AEs have been reported and 46163 VAERS IDs have been assigned. Interestingly, of the reports, 74% came from females. This is likely due to a higher proportion of females reporting AEs but could stem from females succumbing to AEs more often than males. 5%, 12% and 16% of all AE reports involved death, hospitalization or an emergency doctor visit, respectively, as shown in Table 1. 18%, 12% and 35% of all AE reports involved cardiovascular, neurological or immunological events, respectively, also shown in Table 1.

Table 1. Summary table showing percentages of categories and COVID-19 cases by VAERS ID[10]

date	fully vaxxed/US popln (N (%))	nCoV deaths/US popln (N (%))	VAERS deaths (N (%))	IDs (N (%))	Hospital (N (%))	ER (N (%))	VAERS COVID-19 cases (N (%))	CV (N (%))	Neuro (N (%))	Immuno (N (%))	SAEs (N (%))
1/16/21	4582089 (1.39)	87431 (0.027)	137 (0.0030)	1431 (0.031)	338 (0.007)	338 (0.007)	194 (0.004)	271 (0.006)	157 (0.003)	310 (0.007)	625 (0.01)
1/23/21	7664179 (2.32)	109214 (0.033)	281 (0.0037)	2160 (0.028)	607 (0.008)	576 (0.008)	254 (0.003)	417 (0.005)	223 (0.003)	425 (0.006)	1101 (0.01)
1/30/21	11037313 (3.34)	151382 (0.046)	456 (0.0041)	2946 (0.027)	953 (0.009)	847 (0.008)	326 (0.003)	586 (0.005)	307 (0.003)	523 (0.005)	1668 (0.02)
2/13/21	18895522 (5.72)	170073 (0.052)	810 (0.0043)	5351 (0.028)	1747 (0.009)	1493 (0.008)	619 (0.003)	1088 (0.006)	538 (0.003)	930 (0.005)	2977 (0.02)
2/27/21	27167910 (8.23)	196899 (0.060)	984 (0.0036)	9286 (0.034)	2195 (0.008)	2187 (0.008)	717 (0.003)	1794 (0.007)	963 (0.004)	2360 (0.009)	4017 (0.01)
3/5/21	31720149 (9.61)	207524 (0.063)	1162 (0.0037)	14701 (0.046)	2676 (0.008)	2980 (0.009)	776 (0.002)	2707 (0.009)	1583 (0.005)	4533 (0.014)	5193 (0.02)
3/12/21	37735074 (11.43)	215468 (0.065)	1419 (0.0038)	20586 (0.055)	3412 (0.009)	3855 (0.010)	943 (0.002)	3768 (0.010)	2347 (0.006)	6406 (0.017)	6648 (0.02)
3/19/21	44145522 (13.37)	229869 (0.070)	1561 (0.0035)	27955 (0.063)	3913 (0.009)	4763 (0.011)	1057 (0.002)	5049 (0.011)	3370 (0.008)	9150 (0.021)	8000 (0.02)
3/26/21	49740782 (15.06)	231427 (0.070)	1957 (0.0039)	34121 (0.069)	4387 (0.009)	5529 (0.011)	1169 (0.002)	6079 (0.012)	4024 (0.008)	11663 (0.023)	9268 (0.02)
4/2/21	57325150 (17.36)	237741 (0.072)	2149 (0.0041)	40348 (0.077)	4758 (0.009)	6329 (0.012)	1267 (0.002)	7200 (0.013)	4706 (0.008)	14041 (0.024)	10350 (0.02)
4/7/21	66203123 (20.50)	241151 (0.073)	2240 (0.0034)	46163 (0.070)	4906 (0.007)	6983 (0.011)	1404 (0.002)	8194 (0.012)	5303 (0.008)	16480 (0.025)	10484 (0.02)

10. The SAEs total represents all emergency room visits, hospitalizations and deaths.

Table 2. Summary table showing percentages of categories and COVID-19 cases according to the fully vaccinated population in the US

date	fully vaxxed/US popln (N (%))	nCoV deaths/US popln (N (%))	VAERS deaths (N (%))	IDs (N (%))	Hospital (N (%))	ER (N (%))	VAERS COVID-19 cases (N (%))	CV (N (%))	Neuro (N (%))	Immuno (N (%))	SAEs (N (%))
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1.2 Incidence rates of AE groups per fully vaccinated population

As shown in Table 2, presuming that the deaths are related to the injections, the incidence rate of VAERS-reported deaths with respect to the fully vaccinated population is quite low with 34 individuals dying per million. The fully vaccinated population comprises 20.5% of individuals as reported by Our World in Data statistical group as of April 11, 2021.[11] This is comparable to the incidence rate of nCoV-2019-reported deaths which is 730 out of every million individuals as of April 11th, 2021.5 74% of all individuals who reported death using VAERS did so before receiving the second dose.

In the context of the fully vaccinated population, hospitalization and ER visit reports are at 70 and 110 per million, respectively, but as shown in Figures 2.1 and 2.2, the numbers of these reports are steadily increasing as the weeks pass. 68% of all individuals who reported being hospitalized and 77% of individuals who reported visiting an emergency room physician did so after the first dose.

With regards to AEs such as cardiovascular, neurological and immunological events, the number of reports when compared to the fully vaccinated population are currently at 120, 80 and 250 individuals per million, respectively. It is important to remember that these reports

Figure 2.1 Time series plot — Increase in VAERS deaths, ER visits, hospitalizations, cardiovascular, neurological and immunological reports

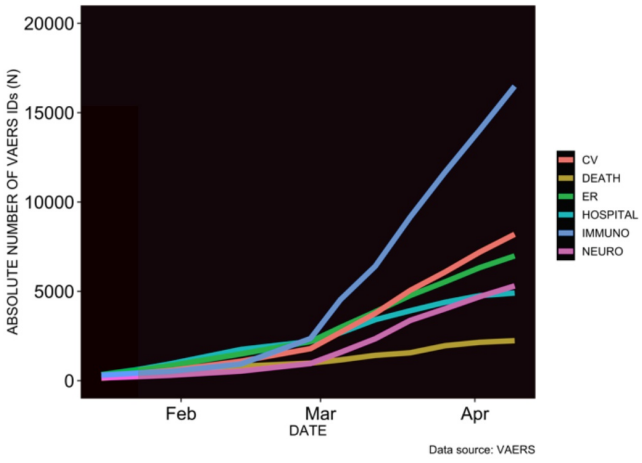
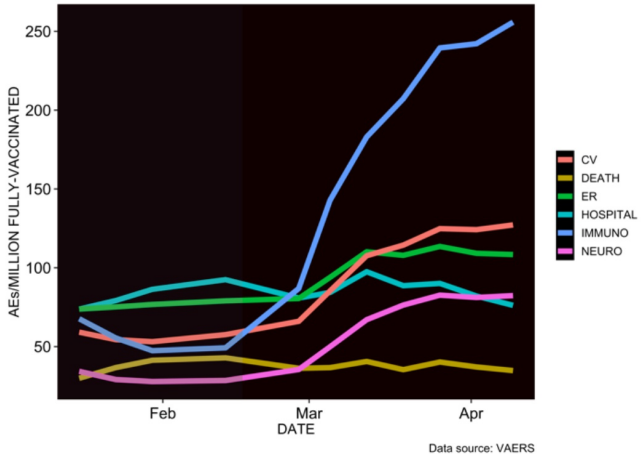


Figure 2.2 Time series plot — Relative change in deaths, ER visits, hospitalizations, cardiovascular, neurological and immunological reports with respect to the fully vaccinated population



11. This is the death rate calculated by dividing the number of people who were reported to have died in the US

Figure 3. Distribution of age groups across all AEs

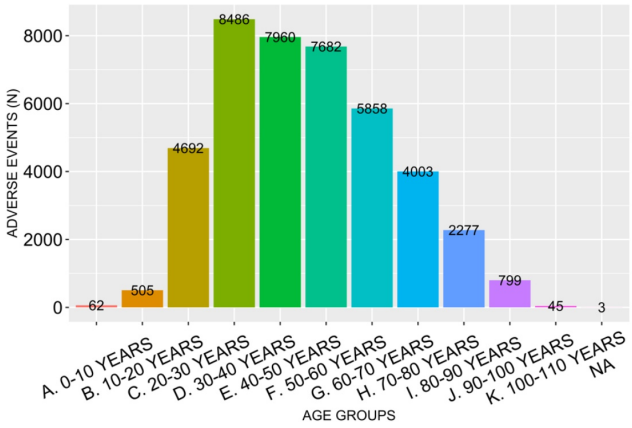
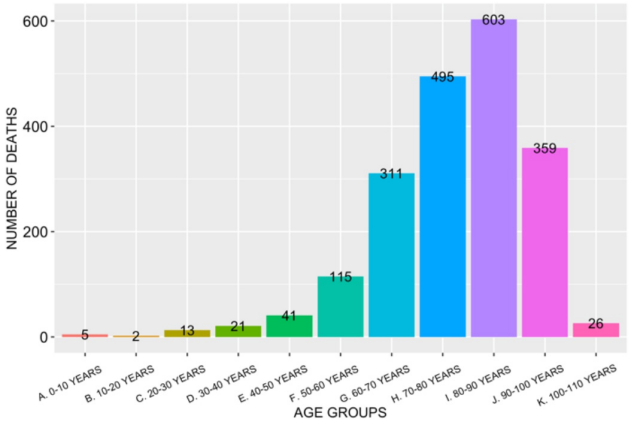


Figure 4.1 Distribution by VAERS ID according to age in individuals who died



likely under-estimate the true values by 10–100 times. Of the individuals who reported cardiovascular AEs, 81% did so after the first dose. Likewise, 79% of the individuals who suffered neurological AEs did so after receiving the first dose, and 80% of the individuals who reported suffering an immunological AE did so after receiving the first dose as well.

Relative to the total number of reports, most of the trajectories of the AEs remain stable relative to the total number of IDs reported (Figure 2.2), with the exception of the immunological AE trajectory, which continues to rise (relative to other AE categories). Interestingly, immunological AEs appear to dominate the AE cases, and this warrants investigation from the scientific community. Again, it is important to recall that we are very early on in the analysis: only four months' worth of data has been collected to date. For more details on statistics regarding the most frequently reported AEs by group according to dose/injection number, refer to Supplementary materials Table S1.

2. Distribution of data: Age association with vaccine-associated AEs

The distribution of all VAERS reports according to age group is symmetric, unimodal and bell-shaped across all age groups with no significant skewing whereby |I|=0.34. (Figure 3).

The highest absolute number of events reported are for individuals between the ages of

Figure 4.2 Distribution according to age in individuals who were hospitalized

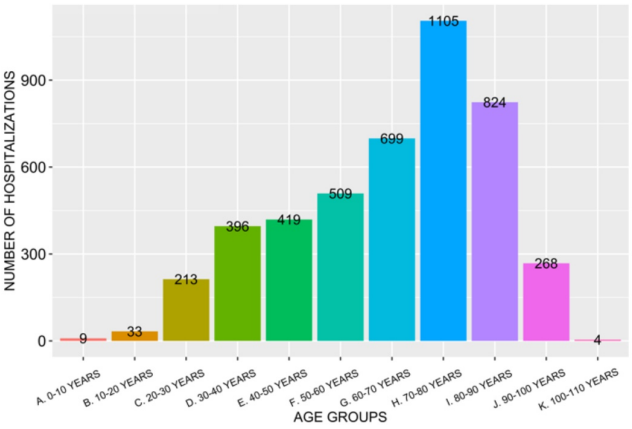
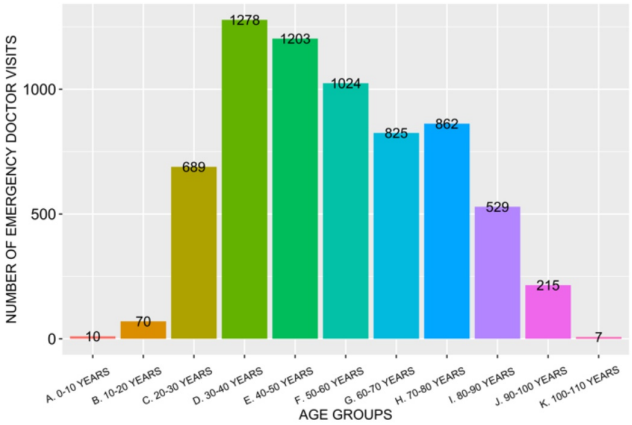


Figure 4.3 Distribution according to age in individuals who visited an emergency doctor



30 and 40 years of age (which account for 18% of all IDs), followed closely by individuals between the ages of 40 and 60 years of age (accounting for 17% in each age group, respectively). In general, the spread of data is normal and symmetric with low absolute numbers of individuals between the ages of 0 and 10 and 100 and 110.

2.1 Deaths, hospitalizations and ER visits

Higher absolute numbers of VAERS deaths and hospitalization reports are associated with the elderly where the cut-off for the elderly is 65 years of age, and this is not surprising (Student's T-Test: $p<0.05$; $p<0.05$, respectively). However, emergency doctor visits are not associated with age (Student's T-Test: $p>0.05$).

Absolute numbers of VAERS-reported deaths grouped according to age group reveal that 84% of individuals who were the subject of death reports were 70–90 years of age, as is shown in Figure 4.1. The death data is in fact left-skewed toward the elderly in a statistically significant way whereby the absolute value of I is 1.15 (abs(I)=1.15). The hospitalization spread is uniform over the age range, with 50% of reports made by individuals between the ages of 20 and 70. 43% of hospitalization reports were made by individuals between the ages of 70 and 90. Emergency doctor visit reports are even more uniform across middle-aged age groups, with more than half of the reports (61%) made by individuals aged 20–60 years. Neither are the distributions for the hospitalizations nor the ER visits skewed by age in a statistically significant way (abs(I)=0.59 and abs(I)=0.27, respectively).

2.2 Cardiovascular, neurological and immunological events

A substantial proportion of individuals reported having cardiovascular, neurological and/or immunological events at 18%, 11% and 37%, respectively, of the total number of reports. In spite of the fact that individuals between the ages of 30 and 40 years comprise the largest subset of reports overall in the context of age grouping by decade, the highest frequency of cardiovascular reports were made by individuals between the ages of 20 and 30 years of age.

The highest frequencies of events occur in young and middle-aged people in all three categories, and this might be because they are the most vaccinated in absolute number. Neurological events were reported at the highest frequency in individuals between the ages of 40 and 50 years old. All histograms are unimodal and bell-shaped, with cardiovascular data appearing more uniform and neurological and immunological data being more symmetric. None of the cardiovascular, neurological or immunological

Figure 5.1 Distribution by VAERS ID according to age in individuals who reported cardiovascular adverse events

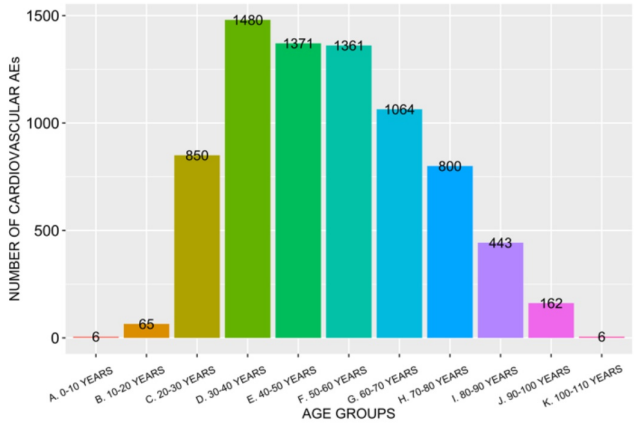


Figure 5.2 Distribution by VAERS ID according to age in individuals who reported neurological adverse events

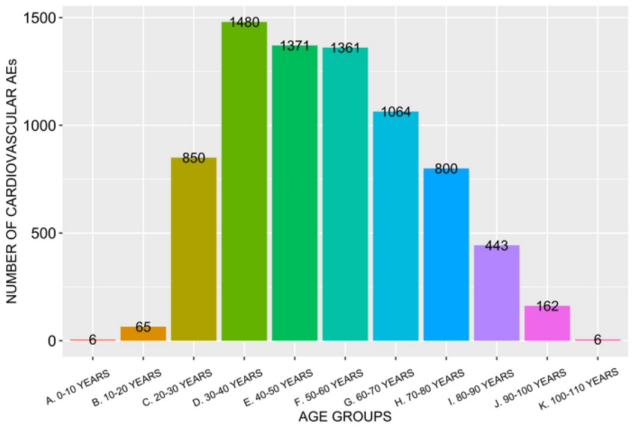


Figure 5.3 Distribution by VAERS ID according to age in individuals who reported immunological adverse events

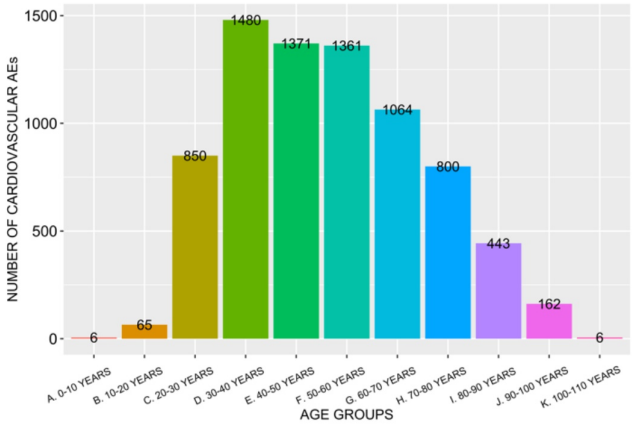
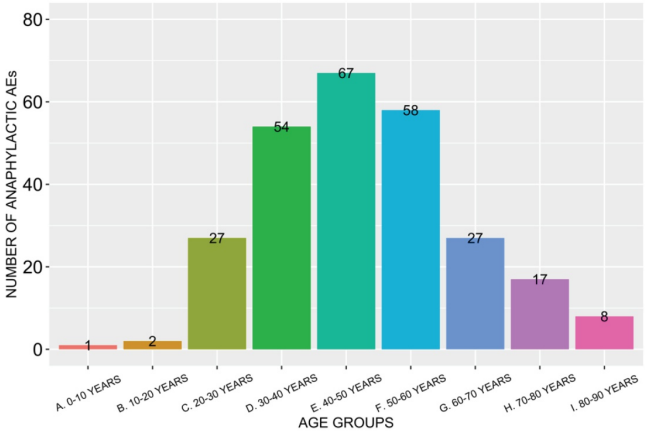


Figure 6. Distribution according to age in individuals who reported anaphylactic reactions



data are skewed toward a specific age group in a statistically significant way (abs(I)=0.34, abs(I)= 0.36, abs(I)=0.40, respectively).

2.3 Anaphylactic reactions

Anaphylactic reactions are reported in the VAERS database at a rate of 1%. Anaphylaxis was reported in individuals primarily between the ages of 30 and 60 years of age, yet distribution of the data symmetric, unimodal and bell-shaped over the age range, as shown in Figure 6. This particular AE is interesting to examine from a causation point of view since most reactions of this nature are known to be caused by specific triggers. It has been reported that one such trigger, poly-ethylene glycol (PEG), is an ingredient in the Moderna and Pfizer/BioNTech products.[15] It is also documented that polysorbate is an ingredient in the Janssen COVID-19 Vaccine PF product, and individuals are advised against using it if a known allergy exists for polysorbate. In many cases, individuals are unaware of the potential for an acute allergic response. In the following section, it will become clearer from time-series plots and heatmaps that causation is not only likely but probable.

Anaphylactic events are reported with highest frequency in individuals between the ages of 40 and 50 years old. The distribution of data is not skewed toward a specific age group in a statistically significant way (abs(I)=0.29). Of the individuals who reported an anaphylactic reaction, 76% did so after receiving the first dose.

2.4 Spontaneous abortions

Spontaneous abortions are not technically included as deaths as part of the VAERS data, but miscarriages involve foetal death. Since the number of these reports is increasing on average by six per week, it is included in this analysis as a stand-alone AE and classified as a severe adverse event. Spontaneous abortions were reported in females between the ages of 20 and 45 and were more frequent in women in their early 30s. This is likely due to more women in their early 30s being pregnant more frequently.

Figure 7. Distribution by age in individuals who reported spontaneous abortions

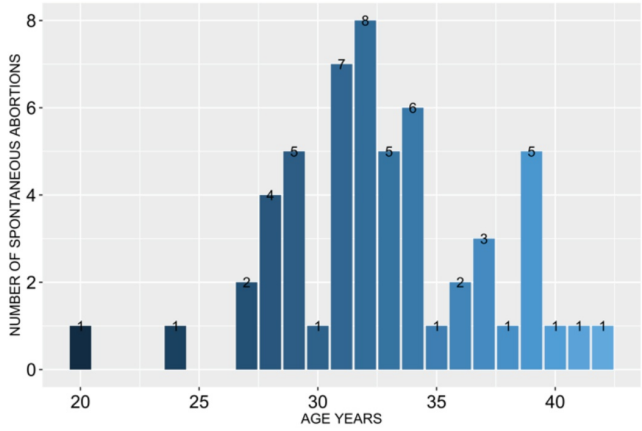


Table 3. Percentages of individuals reporting AEs following 24- and 48-hour periods

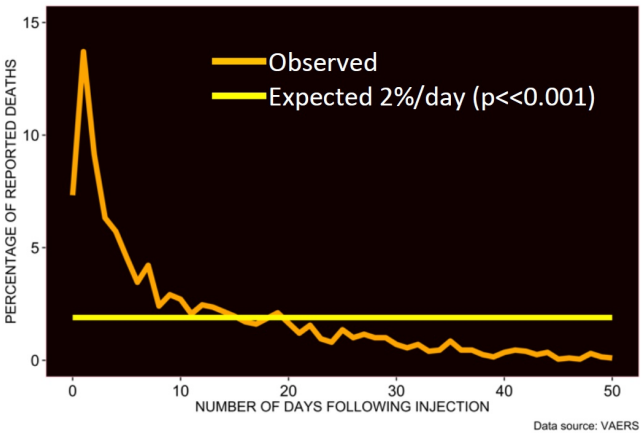
	AE within 24 hrs (% of cases)	AE within 48 hrs (% of cases)
Death	13	44
Hospital	15	47
ER	18	47

The distribution of data is not skewed toward a specific age in a statistically significant way (abs(I)=0.1). Of the women who reported having a spontaneous abortion, 65% did so after receiving the first dose. In the following section, the likelihood of causation is investigated since it is absolutely necessary to elucidate the conditions that induced miscarriage in these women, since plans for large-scale roll-out of these products into pregnant women are looming or currently active.

3. Evidence to support causation

A causal effect means that a change in one variable leads to change in another variable. In the context of all the AEs, 70% of all individuals had onset of symptoms within 48 hours following first or second doses. Table 3 shows the percentages of individuals succumbing to particular AEs following a 24-hour or 48-hour period.

Figure 8.1 Time series plot — Percentage of reported deaths by time elapsed between the injection date and the reported adverse event



Figures 8.1–3 shows the number of days following injection as a percentage of the reported AEs with regards to deaths, hospitalizations and emergency doctor visits. The percentages of reported deaths, hospitalizations and emergency doctor visits are highest in the first two days post-injection.

If deaths, for example, following COVID-19 injections are not causally linked, then the reported percentages of deaths should be equally distributed across days following injection: there should not be an excess of reports on days 0, 1 and 2, yet there are. Chi-square tests confirm association for each AE group with p-values less than 0.001 in each case. If risk is not accentuated

Figure 8.2 Time series plot — Percentage of reported hospitalizations by time elapsed between injection date and adverse event

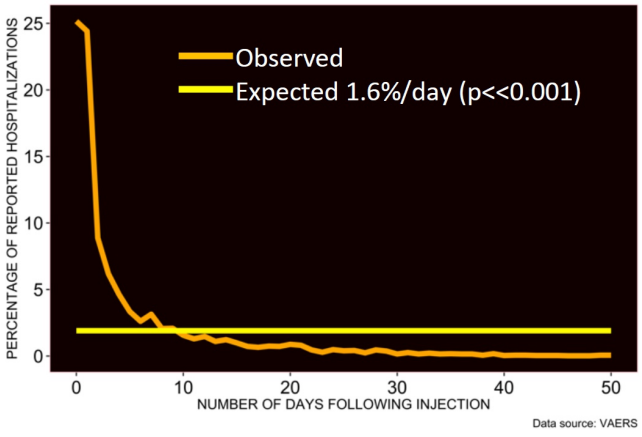


Figure 8.3 Time series plot — Percentage of reported emergency doctor visits by time elapsed between injection and adverse event

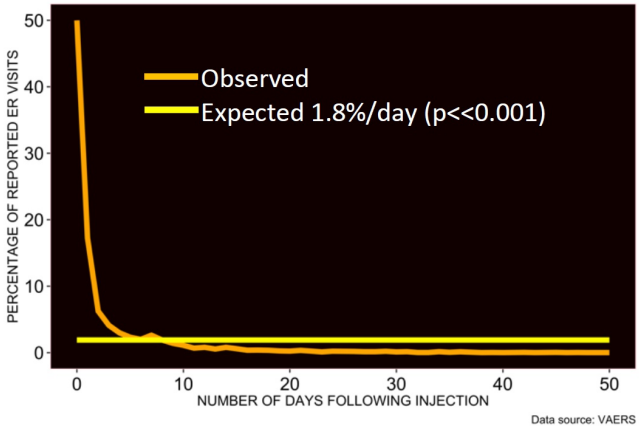


Figure 9.1 Time series plot — Percentage of reported cardiovascular AEs by time elapsed between injection date and adverse event

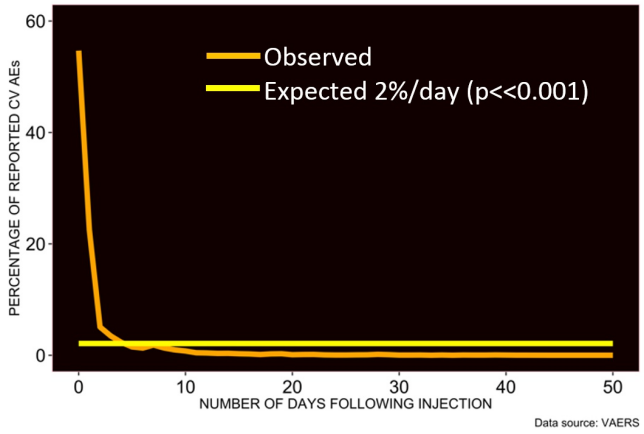
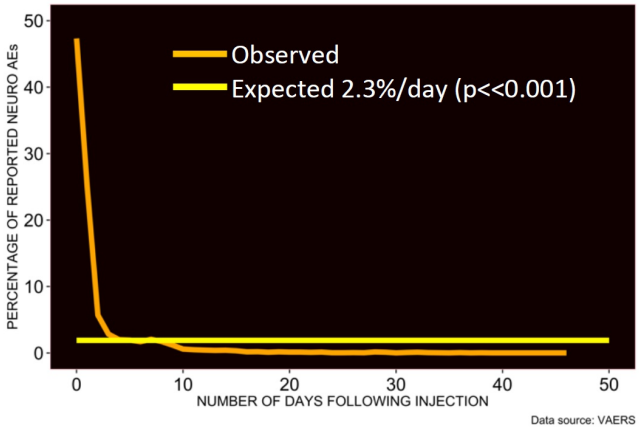


Figure 9.2 Time series plot — Percentage of reported neurological AEs by time elapsed between injection date and adverse event



by some immediate factor temporally, then that risk should necessarily plateau or diminish each day (see Supplementary Figures 1.1–1.3). This logic applies to each of the grouped AEs and each follows the same pattern: the percentages of Day 0 and 1 (time periods representing 0–24 hours and 24–48 hours) are much higher than the percentages of other time periods post-injection.

This same reasoning applies to the grouped AEs representing cardiovascular, neurological and immunological events as shown in Figures 9.1–3. The percentages of cardiovascular, neurological and immunological events are highest in the first two days post-injection. Again, if causation was absent, there should not be an excess of reports on days 0, 1 and 2. Chi-square tests confirm association for each AE group with p-values less than 0.001 in each case. Table 4 shows the percentages of individuals succumbing to particular AEs following a 24-hour or 48-hour period.

There is a higher percentage (7%) of individuals who reported immunological events on the seventh day following injection, as shown in Figure 9.3. From an immunological point of view, this could be worth investigating in further studies.

Figures 10.1 and 10.2 show the same trend toward the highest percentages of anaphylactic reactions and spontaneous abortions occurring in the first two days post-injection. A staggering 87% of all anaphylactic reactions were reported within 48 hours and 76% were reported within 24 hours. This is not surprising, considering the nature of this stand-alone AE. One would expect

Figure 9.3 Time series plot — Percentage of reported immunological AEs by time elapsed between injection date and adverse event

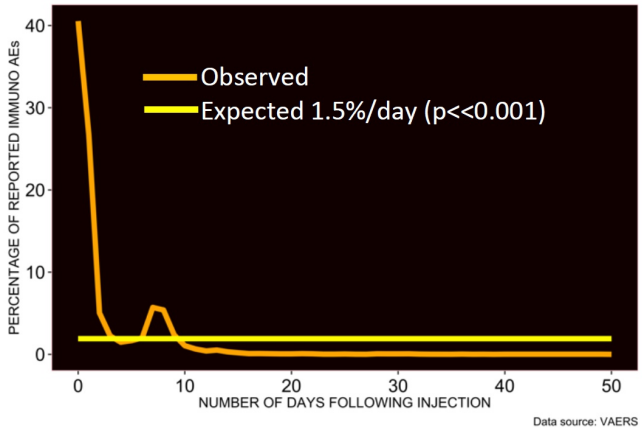


Table 4. Percentages of individuals experiencing AEs within 24- and 48-hour periods

	AE within 24 hrs (% of cases)	AE within 48 hrs (% of cases)
Cardiovascular	13	44
Neurological	15	47
Immunological	18	47

Figure 10.1 Time series plot — Percentage of reported anaphylaxis with respect to time elapsed between date of injection and AE

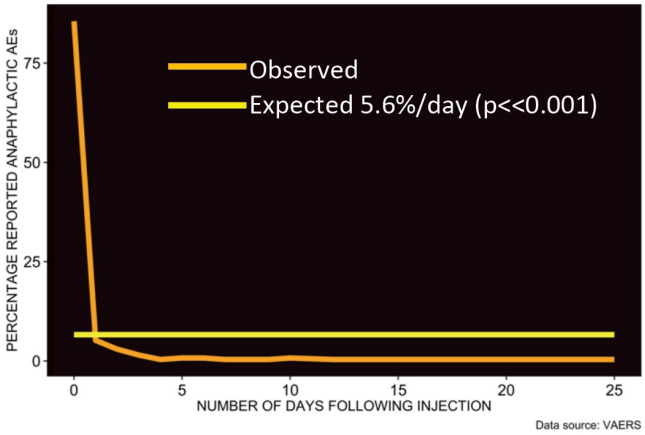
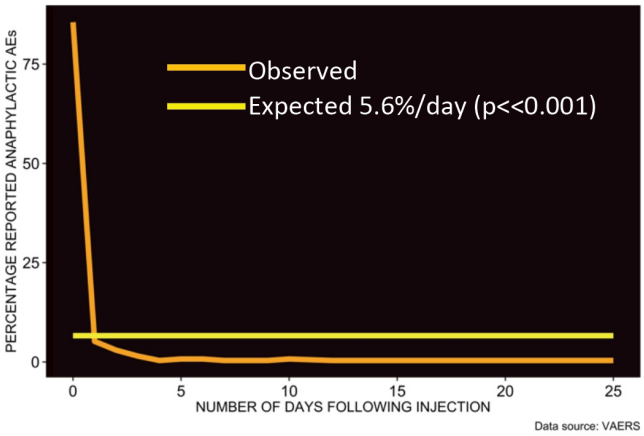


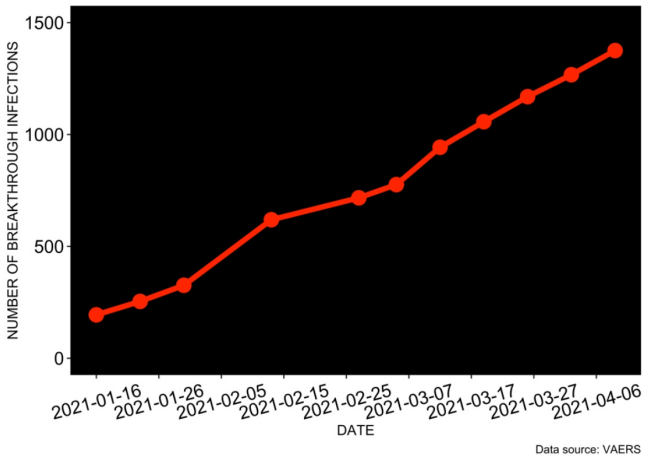
Figure 10.2 Time series plot — Percentage of reported spontaneous abortions by time elapsed between date of injection and AE



an anaphylactic reaction to occur quite immediately. More than half (61%) of all spontaneous abortions were reported within 48 hours of injection, and 42% within 24 hours. See Supplementary Figures S1.1–S3.2 for corroborative heatmaps.

These descriptive statistics give merit to association and time ordering post-injection in the contexts of these categorized AEs. In order to rule out spuriousness, the potential contribution of additional variables, including pre-existing conditions and medications, that could have contributed to death were examined. Of the medications, the most frequently reported occurred in ~6% of the individuals, and on the facet of prior conditions which may have led to death, only 8.5% of the individuals had some heart-related incident reported in their prior history. This was the highest percentage of conditions reported in the medical histories. It should be acknowledged that the VAERS-reported medical history is bound to be incomplete, and therefore it is possible that the AEs in question could be due to conditions not reported in VAERS data. Based on the data available, the three conditions of causation are satisfied, in general, but I leave it up to the reader to extrapolate beyond the data.

Figure 11. Time series plot — Increase in absolute number of COVID-19 confirmed cases from VAERS data



4. Confirmed COVID-19 cases post-vaccination

A total of 1267 COVID-19 cases have been reported to date with the Pfizer/BioNTech product representing a 3% rate and the Moderna product representing a 0.5% rate. Since the Janssen product first appeared in the VAERS system as of two weeks ago, a low 0.007% rate is not surprising. The latter, included in Table 2, is data on the change in COVID-19 confirmed cases, which relative to the fully vaccinated population is decreasing, but increasing absolutely. Figure 11 illustrates this increase over time, which appears to be a linear trajectory.

Distribution of COVID-19 cases in vaccinated individuals across age groups is

Figure 12. Distribution of COVID-19 confirmed cases from VAERS data by age

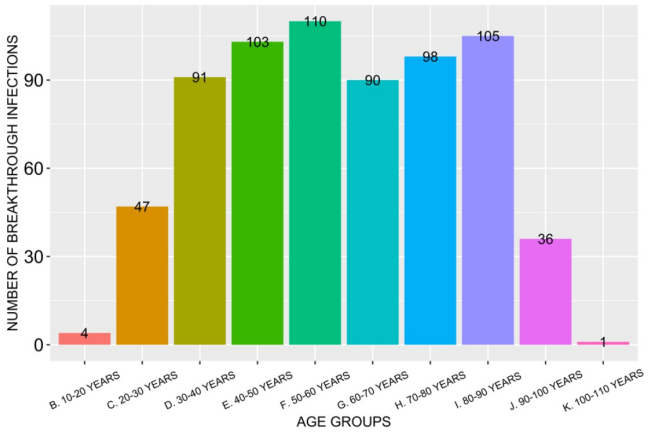
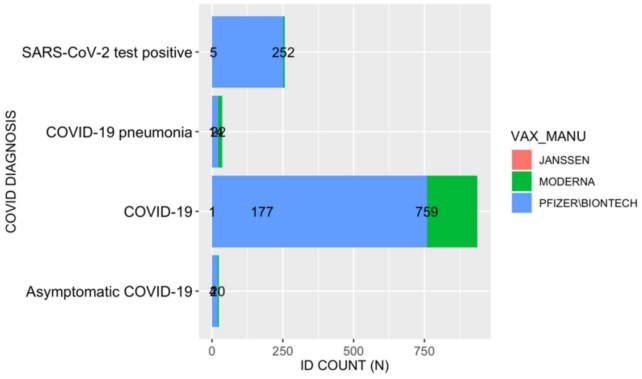


Figure 13. Distribution of COVID-19 cases according to vaccine manufacturer



uniform across the age groups between 30 and 90 years, as shown in Figure 12. No skewing was found relating a specific age group to COVID-19 case that was statistically significant. The skewness should be compared versus the vaccinated/reporting population and not within the data subset itself, but this is for a future study.

When the COVID-19 data is examined by manufacturer, it stands out that 81% of all confirmed COVID-19 cases are associated with the Pfizer/BioNTech product. Without knowing the distribution proportions of the manufacturers in the population base, it is not possible to make claims about this sample with regards to any potential higher probability of getting COVID-19 in the context of the Pfizer/BioNTech product. If this data can be acquired, this question can be answered. This is reserved for a future study. Figure 13 shows the distribution of confirmed COVID-19 cases in VAERS reports across vaccine manufacturer.

4. Discussion

Safety and efficacy are the two requirements of any true vaccine. Based on this study, the risk of suffering an SAE following injection is minimal, with an average of 200 individuals succumbing to an SAE per million. By comparison, 1,500 individuals in every million die from to the virus. Of the SAEs in the data reported so far, while taking the reported numbers at face value, the most undesirable reported is death. According to current VAERS data, 34 individuals per million will succumb to death. The rates are slightly higher at 120, 80 and 250 per million pertaining to specific AEs involving cardiovascular, neurological or immunological events. The risk overall, according to analysis of this data set, appears to be quite low. However, again, this data is very early and, in the context of a rushed, non-FDA-approved, ongoing experimental roll-out, conclusions about long-term outcomes cannot be made yet. The VAERS data is very dynamic and new patterns may emerge at any time, depending on new reports.

The infection fatality rate (IFR), which is the number of individuals who died from COVID-19 among all infected individuals (both symptomatic and asymptomatic) is estimated to be 0.15% or 1500 individuals per million.[12,13] Thus, if compared to the death rate reported in the VAERS database in the context of the COVID-19 injections, which is 0.0034% or 34 individuals per million, the chance of dying from nCoV-2019 is greater than from the injections, based on data collected from the past four months. It is vital to remember here that the actual number of adverse events ongoing are likely being under-reported, and there are likely to be thousands more backlogged due to under-recording. If the estimated death rate is two

orders of magnitude greater in reality, which it very well could be, this puts the death rate closer to 3,400 individuals per million, which is higher than the IFR estimate. Despite the fact that 20.5% of the US population is fully vaccinated, the death count is still rising at a constant rate according to Our World in Data statistics. If one looks to Israel, the country with the most fully vaccinated individuals at 57.26%, it is clear to see that the death count remains on a steady upward trajectory (Supplementary Figures S4.1 and S4.2).[14,16]

In a recent CDC report titled 'Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19 Vaccine',[18,19] only the severity of the most frequently reported AEs in the VAERS database are reported in tabular form and not the SAEs themselves. They report that occurrence of severe adverse events involving system organ classes and specific preferred terms were balanced between vaccine and placebo groups and presented at a mere 0.5%. Although SAEs (grade ≥3, defined as interfering with daily activity) occurred more commonly in vaccine recipients than in placebo recipients, their claim is that no specific safety concerns were identified with regards to SAEs.[18,19] Supplementary Table S1 provides details of the frequencies of SAEs divided by deaths, hospitalizations and emergency doctor visits. It provides a more complete picture of the SAE occurrences and frequencies in specific contexts.

Effective antiviral responses against the nCoV-2019 virus in the form of both cellular and humoral immune responses have been reported in peer-reviewed studies.[20,21,22,23,24,25] Because of the combination of a low IFR indicating effective and robust immune responses, it remains unclear why multiple experimental mRNA vaccines have been fast-tracked through conventional testing protocols and are also being fast-tracked through production and administration into the public. With repurposed drugs like Chloroquine and Ivermectin showing extremely positive results in patients [26,27,28,29,30,31,32,33,34,35,36], it is also unclear why these drugs are not being more extensively promoted as effective tools in the fight against this virus. One looming possibility is that EUA is not permissible if FDA-recognized, effective treatments exist.

5. Conclusion

This work summarizes VAERS data to date (April 9th, 2021) and serves as information for the public and a reminder of the relevance of any adverse events, including deaths, that likely occurred as a direct result of vaccine administration. Based on analysis of the VAERS numbers, it may appear that AEs are not currently imposing a significant burden on the fully vaccinated population; however, the weekly releases of VAERS data do not include all of the reports made to date — they are all the reports the CDC has processed to date — and the backlog is likely to be staggering. Thus, due to both the problems of under-reporting and the lag in report processing, this analysis reveals a strong signal from the VAERS data that the risk of suffering an SAE following injection is significant and that the overall risk signal is high.

Analysis suggests that the vaccines are likely the cause of reported deaths, spontaneous abortions and anaphylactic reactions in addition to cardiovascular, neurological and immunological AEs. Based on the precautionary principle, since there is currently no precedent for predictability with regards to long-term effects from mRNA injections, extreme care should be taken when making a decision to participate in this experiment. mRNA platforms are new to humans with regard to mass injection programs in the context of viruses. There is currently no way to predict potential detrimental outcomes with regards to SAE occurrences in the long-term. Also, with regards to short-term analysis, this data is limited based on reporting that likely significantly underestimates actual events.

It cannot be emphasized enough that this is very early data and that, based on the dynamic nature of the data, these conclusions may not be the same in a month's time. The efficacy of these products needs to be assessed by immunological assays, and long-term studies are required, while safety needs to be evaluated by rigorous clinical, laboratory and imaging assessments of severe reported adverse events. Autopsies should be done in cases of deaths temporally associated with COVID-19 injectables.

Overall, it is vital not to be hasty and to make a proper risk assessment by being informed prior to making a decision as to whether or not to participate in experimental trials.

Treatments against nCoV-2019 and subsequent COVID-19 symptom formation are meant to minimize harm from the latter. It appears from this analysis that these treatments are, in fact, doing more harm than good when considering the points made herein, especially in the context of specific risk groups which are the very people we are claiming to want to protect.

Future work may include an investigation into potential correlations between SAE occurrences and frequencies and vaccine lot number, and of course updates should be made in accordance with the VAERS weekly update. In addition, investigation and focus on immunological issues MUST be a priority in future studies with regards to adverse events reports related to COVID-19 biologicals.

Funding and Conflict of Interest Information

This article received no specific funding.
No conflicts of interest are declared.

Editor-in-Chief and Reviewing Editor:
James Lyons-Weiler, PhD

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7. Supplementary Figures

These findings are illustrated using heatmaps. Heatmaps cross-classify the distributions of two continuous variables (i.e. vaccination date and onset of symptoms or date of death) by reporting a frequency count, n, against a condition. The condition imposed is the count of n with n=0, 1, … , m where m is the number of days with the assigned number 'n'. They are incredibly informative in that many data points can be cross-correlated and 'mapped' at once.

For this study, each tile is shaded according to the number of intersections, with blue representing the lowest number of event inter-sections and red representing the highest.

Figure S1.1 Intersection of vaccination dates and date of death with respect to ID count

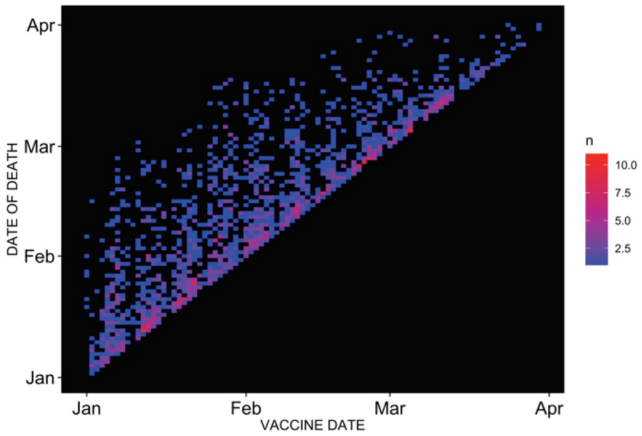
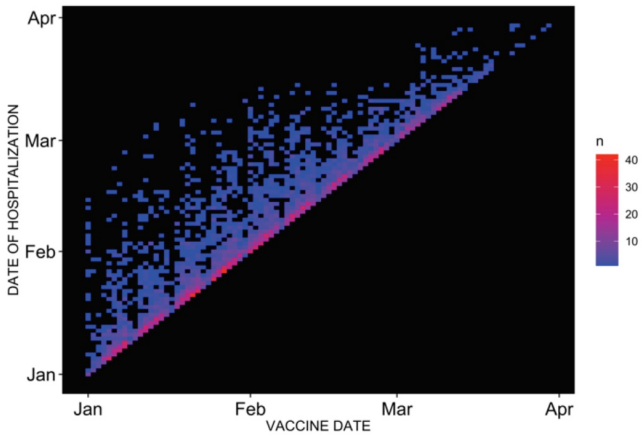


Figure S1.2 Intersection of dates of vaccination and hospitalization



Any value on the diagonal has an R-value of 1, meaning a perfect correlation.

Figure S1.3 Intersection of vaccination dates and date of emergency doctor visit

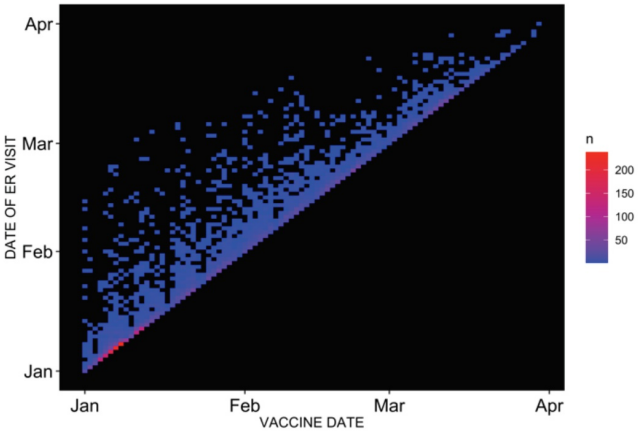


Figure S2.1 Intersection of dates of vaccination and cardiovascular AE with respect to ID count for symptom group

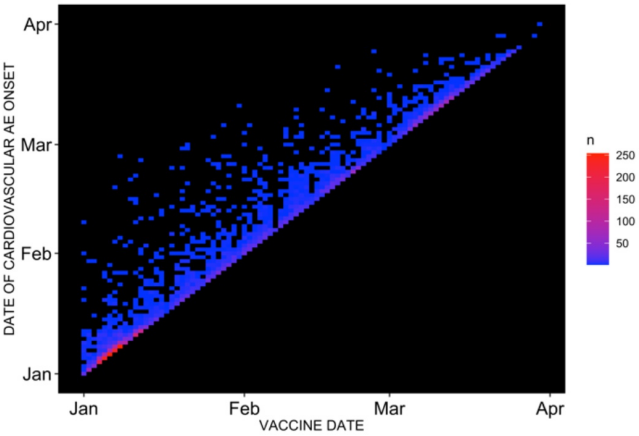


Figure S2.2 Intersection of dates of vaccination and neurological AE with respect to ID count for symptom group

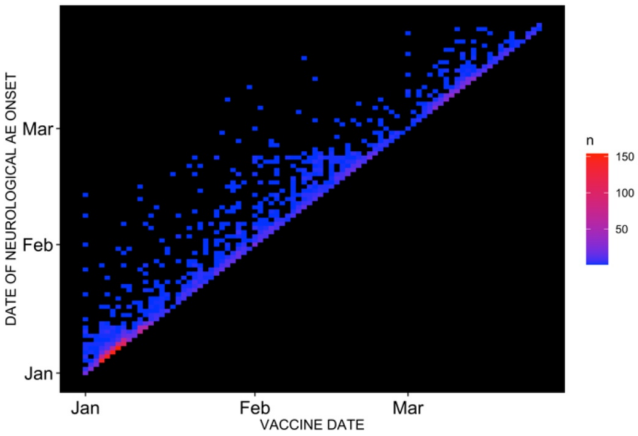


Figure S2.3 Intersection of dates of vaccination and immunological AE with respect to ID count for symptom group

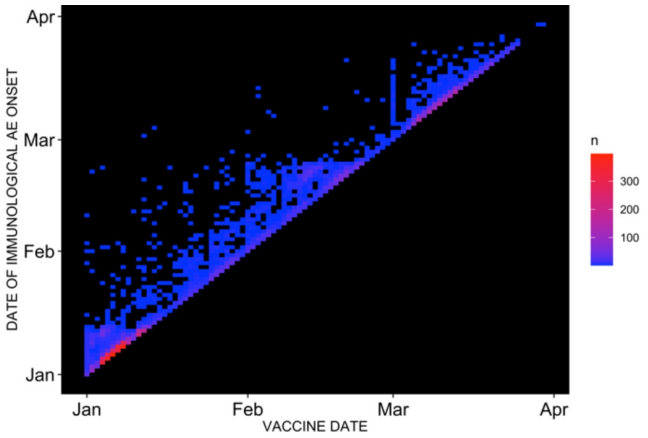


Figure S3.1 Intersection of dates of vaccination and anaphylaxis with respect to ID count for the symptom group

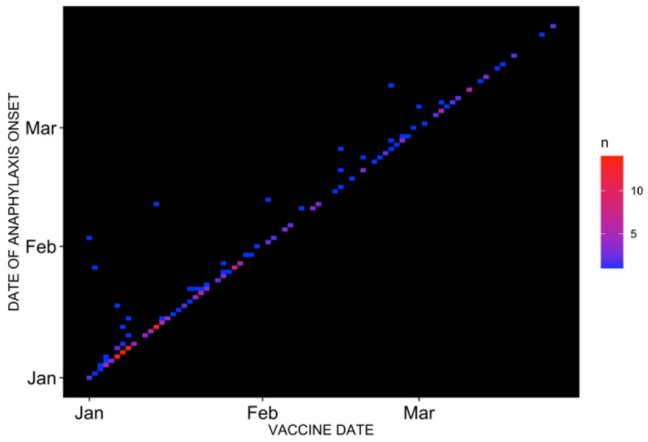


Figure S3.2 Intersection of dates of vaccination and spontaneous abortion with respect to ID count for the symptom group

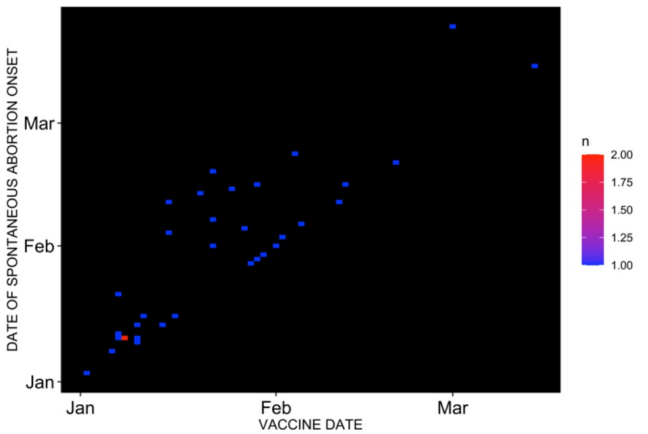


Figure S4.1 Time series plot — Fully vaccinated population in Israel

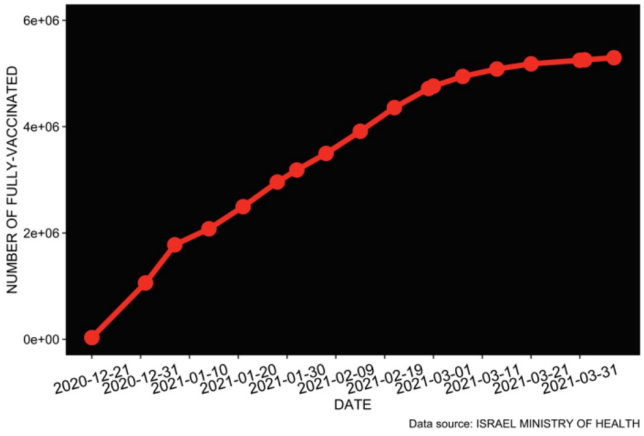
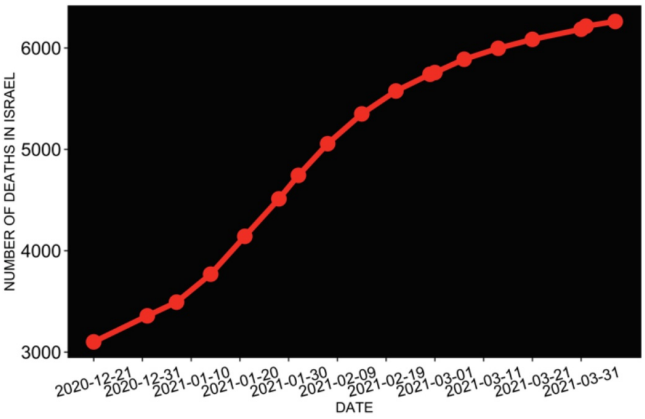


Figure S4.2 Time series plot — nCoV-2019



Chi-Square Test Calculations in R

Death

Chi-squared test for given probabilities
data:
MERGED_SYM_DAT_VAX_23_04_2021_8300kb_VD_DD$OBSERVED
X-squared = 3909.5, df = 50, p-value < 2.2e-16

Hospitalizations

Chi-squared test for given probabilities
data:
MERGED_SYM_DAT_VAX_23_04_2021_8300kb_H_VD_OD$OBSERVED
X-squared = 31658, df = 50, p-value < 2.2e-16

Table S1. Most frequently reported AEs by group according to dose/injection number

AE group	Dose 1 (N(%))	Dose 2 (N (%))	Total AE Dose 1 (N (%))	Total AE Dose 2 (N (%))
Death	602 (48)	206 (48)	1252 (74)	430 (26)
Hospital	178 (7)	95 (8)	2525 (68)	1193 (32)
ER	225 (5.5)	74 (6)	4069 (77)	1238 (23)
Cardiovascular	1458 (28)	259 (21)	5,289 (81)	1214 (19)
Neurological	978 (30)	252 (37)	3268 (82)	697 (18)
Immunological	2878 (27)	1187 (44)	10640 (80)	2705 (20)
ALL AEs	2273 (9.2)	1016 (16)	24544 (79)	6495 (21)

Emergency doctor visits
Chi-squared test for given probabilities
data:
MERGED_SYM_DAT_VAX_23_04_2021_830
0kb_ER_VD_OD$OBSERVED
X-squared = 144097, df = 50, p-value < 2.2e-16

Cardiovascular AEs
Chi-squared test for given probabilities
data:
MERGED_SYM_DAT_VAX_23_04_2021_830
0kb_CV_VD_OD$OBSERVED
X-squared = 204191, df = 47, p-value < 2.2e-16

Neurological AEs
Chi-squared test for given probabilities
data:
MERGED_SYM_DAT_VAX_23_04_2021_830
0kb_NEURO_VD_OD$OBSERVED
X-squared = 93039, df = 42, p-value < 2.2e-16

Immunological AEs
Chi-squared test for given probabilities
data:
MERGED_SYM_DAT_VAX_23_04_2021_830
0kb_IMMUNO_VD_OD$OBSERVED
X-squared = 275292, df = 44, p-value < 2.2e-16

Spontaneous Abortions
Chi-squared test for given probabilities
data:
MERGED_SYM_DAT_VAX_23_04_2021_830
0kb_SA_VD_OD$OBSERVED
X-squared = 90.783, df = 24, p-value = 1.069e-09

Anaphylactic AEs
Chi-squared test for given probabilities
data:
MERGED_SYM_DAT_VAX_23_04_2021_830
0kb_ANAP_VD_OD$OBSERVED
X-squared = 3497.3, df = 13, p-value < 2.2e-16