**Prepared for:**
**J D Vogel**
**Vogel Incorporated for Free State for Choice, University of the Free State**

**Prepared by: Dr. Jessica Rose**
**March 18, 2022**

I, Jessica Rose, PhD, state upon personal knowledge that:

1. I am an adult of sound mind, and make this statement of my own volition, based on my personal knowledge, education, facts or date, and experience, and under penalty of perjury.
2. I am competent to testify as an Applied Mathematician, Immunologist, Computational Biologist, Molecular Biologist and Biochemist to the facts and matters set forth herein. The facts and matters set forth herein are the types of facts and matters medical experts rely upon to reach expert conclusions. A true and accurate copy of my Curriculum Vitae is attached as Exhibit A.
3. I pursued a Bachelor of Science in Applied Mathematics at Memorial University of Newfoundland (MUN) and a Master of Science in Medicine in Immunology at MUN. I continued with my studies in Israel, having been invited to pursue a PhD in Computational Biology (Viral Kinetic studies on Cytomegalovirus (CMV) and Hepatitis B Virus (HBV)) atBar Ilan University. Since its completion, I have successfully completed two Post-Doctoral degrees in Molecular Biology, with a focus on Rickettsiology at the Hebrew University of Jerusalem, and Biochemistry, with a focus on Anisotropic Network modeling of ATP-Cassette-Binding Transporter molecule mechanisms at the Technion Institute of Technology. Since completion of the second Post Doc in December 2019 and the declaration of the global 'pandemic', I have been analyzing the Vaccine Adverse Event Reporting System (VAERS) data from the United States. I have published my findings twice in the journal "Science, Public Health Policy and the Law" and have another publication co-authored with Dr. Peter McCullough. The first publication is a general analysis, the second

is a critical appraisal of VAERS pharmacovigilance and the third is an analysis of myocarditis adverse events reported to VAERS in the context of the Moderna, Pfizer and Janssen COVID-19 injectable products.

4. VAERS is a pharmacovigilance tool launched by the U.S. Government in 1990 to provide safety signals not detected in pre-market testing in the context of pharmaceuticals and biologicals such as the COVID-injectable products. I consistently present updates of my VAERS data analyses to the Canadian COVID Care Alliance (CCCA), Vaccine Choice Canada (VCC), the World Council for Health (WCH) and many other organizations in the form of live/recorded video presentations.[1] I also gave 2 three minute live video presentations at the 167th and 170th VRBPAC meetings to discuss the administration of vaccine booster shots and giving shots to children aged 5-11, respectively.[2,3] The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 16 to 2 against rolling out boosters into individuals under 65 years of age due to my testimony, and others' testimonies.[4]

5. A typical timeframe for a newly-designed biological product meant for human use is between 5 and 15 years – from design, animal testing, Phase I-III trials to post-trial Phase IV monitoring to FDA approval and human use. Exclusion criteria lists are long for each of the clinical pre-market trial phases (I-III) and exclude pregnant women, lactating women, children less than 12 years old (NCT04368728)[5], and people with co-morbidities and autoimmune diseases, for example. The accelerated timeline of the COVID-19 products and the 6-9-month duration of the Phase III clinical trial (NCT04368728), precludes the generation of safety data for these groups. To my knowledge, prior to the EUA

[1] https://www.youtube.com/watch?v=Y4MViwU3XOo
[2] https://www.bitchute.com/video/RlvApxXqKGdZ/
[3] https://m.youtube.com/watch?t=17213&v=laaL0_xKmmA&feature=youtu.be
[4] https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products- advisory-committee-september-17-2021-meeting-announcement
[5] A phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-CoV-2 RNA vaccine candidates against covid-19 in healthy individuals. https://clinicaltrials.gov/ct2/show/NCT04368728

authorization of these vaccines, there was no safety data generated for pregnant women, lactating women, children less than 12 and people with co-morbidities or autoimmune conditions.

6. In 2021 and continuing into 2022, there has been an unprecedented increase in adverse event reports to VAERS in the context of the COVID-19 products compared with all other vaccine reports made for the past 30 years. In 2021, there was an over **7,000% increase** in adverse event reports of death (see Figure 1 in attached ppt document); and this increase in reporting is not due to an increase in the number of injections administered or due to simulated reporting.[6,7] A true and correct copy of my paper on a descriptive analysis of VAERS data as of May 2021 is attached as Exhibit B. As of March 11, 2022, there is an over 10,000% increase in reports of deaths.
7. According to the New York Times, distribution of the swine flu (H1N1) vaccine was halted in the 1970's after an estimated 450 people developed the paralyzing syndrome Guillain-Barré and more than 30 deaths occurred.[8] A true and correct copy of this New York Times Article is attached as Exhibit C. Death reports being made to VAERS in the context of COVID-19 products have far exceeded the number of deaths deemed unacceptable to tip the balance of the risk/benefit calculation to risk > benefit.
8. As of March 11, 2022, approximately 1 in 290 people are reporting adverse events in the context of COVID-19 products in the U.S. following a double dose regimen (considered 'fully vaccinated according to Our World in Data[9]), and 1 in 1529 are reporting severe adverse events[10] and this is not age-specific – there is a unimodal distribution of data when the

[6] Rose, J., Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System? Science, Public Health Policy, and the Law. Volume 3:100-129 October 2021. Clinical and Translational Research. (Exhibit B.)

[7] Montano Diego, Frequency and Associations of Adverse Reactions of COVID-19 Vaccines Reported to Pharmacovigilance Systems in the European Union and the United. Frontiers in Public Health. Volume=9, 2022. doi=10.3389/fpubh.2021.756633.

[8] Perlstein, Rick, "Gerald Ford Rushed Out a Vaccine. It was a Fiasco." New York Times, Sept. 2, 2020 (https://www.nytimes.com/2020/09/02/opinion/coronavirus-vaccine-trump.html).

[9] Hannah Ritchie, Edouard Mathieu, Lucas Rodés-Guirao, Cameron Appel, Charlie Giattino, Esteban Ortiz-Ospina, Joe Hasell, Bobbie Macdonald, Diana Beltekian and Max Roser (2020) - "Coronavirus Pandemic (COVID-19)". *Published online at OurWorldInData.org.* Retrieved from: 'https://ourworldindata.org/coronavirus' [Online Resource].

[10] A phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity,

adverse event data is grouped by age.

9. Over 10,000 different adverse event types have been reported to VAERS in the context of COVID-19 products to date (March 11th, 2022) and the adverse event counts for immunological, neurological and cardiovascular reports are in the hundreds of thousands (see Figure 2 in attached ppt document) – this is not accounting for the under-reporting factor[11]. Other adverse events increasingly being reported include those in the category of female reproductive issues which includes spontaneous abortions and dysmenorrhea (see Figure 3 in attached ppt document). Also of great concern, are myocarditis reports being made to VAERS in the context of the COVID-19 products for young males: my most recent study indicates that reports being made for children between the ages of 12-15 were 19 times above background rates (see Figure 4 in attached ppt document).[12]
10. Cancer reports being made to VAERS are increasing as weekly data is updated; the most prevalent type to date being breast cancer (see Figure 5 in attached ppt document).[13]
11. The COVID-19 products were primarily designed to merely reduce symptoms of COVID-19 (if disease ensues) and not to prevent COVID-19 (breakthrough infection) and are proving ineffective at reducing infection and transmission rates and appear to be bringing more harm than good in many cases according to persuasive research by J.Bart Classen.[14] A true and correct copy of Dr. Classen's study is attached as Exhibit D. It is vitalto assess risk versus benefit in the context of COVID-19 and associated products as per ***risk group*** and to first ask the question: Who is at risk? prior to rolling out en-masse blanket injection programs. VAERS data confirms increasing rates of COVID-19 breakthrough

and efficacy of sars-cov-2 RNA vaccine candidates against covid-19 in healthy individuals. PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines). Protocol C4591001. Pages. 126-127.

[11] Lazarus, Ross et al. Grant Final Report. Grant ID: R18 HS 017045. Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS). Submitted to The Agency for Healthcare Research and Quality (AHRQ).

[12] WITHDRAWN without explanation by Editor. Rose, Jessica, McCullough, Peter A., A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products, Current Problems in Cardiology, Oct 2021, doi:10.1016/j.cpcardiol.2021.101011.

[13] VAERS database.

[14] Classen B., US COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, "All Cause Severe Morbidity". Trends Int Med. 2021; 1(1): 1-6 (Exhibit D).

infections in people who have received COVID-19 injections and these rates are more highly associated with the Pfizer/BioNTech products.[15]

12. The majority of people in Israel have received 3 doses of the Pfizer/BioNTech products yet the cohort represents the majority of breakthrough cases and hospitalized individuals in the population according to Our World in Data analytics and the Israel Ministry of Health data dashboard.[10.] It is also clear from recent data on a pro-active study on safety in 'boosted' Israelis, that these products are associated with high rates of adverse events ranging from female reproductive disorders to neurological disorders.[16]
13. In collaboration with Steve Kirsch and Mathew Crawford, I contributed to a document where we estimated the under-reporting factor (URF) for Severe Adverse Events. Attached as Exhibit B is a true and correct copy of this document. The under-reporting factor estimated from this study used base data originating from a peer-reviewed study of acute allergic reactions in the context of the mRNA COVID-19 products,[17] to generate an estimate of ~150,000 deaths at the time of calculation.[18] A true and correct copy of the analysis by Steve Kirsch, Mathew Crawford and myself is attached as Exhibit E. My individual estimate of the URF used base data originating from the Phase III clinical trial data of the Pfizer-BioNTech product[19] generating an estimate of ~200,000 deaths at the time of calculation. Both estimates were calculated based on assessments of the Severe Adverse Event reporting rates.[20]
14. Bioaccumulation and biodistribution have been proven *in vivo* in the case of the Pfizer

[15] Our World in Data/Israel Ministry of Health Dashboard.
[16] https://jackanapes.substack.com/p/the-israeli-ministry-of-health-actually-db7?s=r
[17] Our World in Data/Israel Ministry of Health Dashboard.
[18] Blumenthal KG, Robinson LB, Camargo CA, et al. Acute Allergic Reactions to mRNA COVID-19 Vaccines. JAMA. 2021;325(15):1562–1565. doi:10.1001/jama.2021.3976
[19] Steve Kirsch et al, Estimating the Number of COVID vaccine deaths in America (Exhibit E).
[20] Vaccines and Related Biological Products Advisory Committee Meeting, December 10, 2020. FDA Briefing document Pfizer-BioNTech COVID-19 Vaccine.

COVID-19 injectable products.[21,22,23]

15. Reverse transcription of Pfizer mRNA BNT162b2 to DNA has been demonstrated *in vitro*.[24]
16. Dysregulation of immune mediators has been demonstrated in the context of the COVID-19 injections.[25]
17. The spike protein has been shown to be demonstrably dangerous to human physiology and to be hard to clear.[26,27]
18. The mRNA from the COVID-19 injections has been shown to be present in germinal center lymph nodes for up to 60 days following injection.[28]

I declare that the above is true and correct,

Sincerely Dr. Jessica Rose

_____

[21] https://jessicar.substack.com/p/the-pfizer-document-dump-pertaining?s=w
[22] A Tissue Distribution Study of a [3H]-Labelled Lipid NanoParticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats" in Test Facility Study No. 185350 [FDA-CBER-2021-5683-0013962].
[23] https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_26_pharmkin-written-summary.pdf
[24] Alden Markus, Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. Curr. Issues Mol. Biol. 2022, 44(3), 1115-1126; https://doi.org/10.3390/cimb44030073.
[25] Liu J, Wang J, Xu J, Xia H, Wang Y, Zhang C, Chen W, Zhang H, Liu Q, Zhu R, Shi Y, Shen Z, Xing Z, Gao W, Zhou L, Shao J, Shi J, Yang X, Deng Y, Wu L, Lin Q, Zheng C, Zhu W, Wang C, Sun YE, Liu Z. Comprehensive investigations revealed consistent pathophysiological alterations after vaccination with COVID-19 vaccines. Cell Discov. 2021 Oct 26;7(1):99. doi: 10.1038/s41421-021-00329-3. PMID: 34697287; PMCID: PMC8546144.
[26] Jiang H, Mei YF. SARS-CoV-2 Spike Impairs DNA Damage Repair and Inhibits V(D)J Recombination In Vitro. Viruses. 2021;13(10):2056. Published 2021 Oct 13. doi:10.3390/v13102056
[27] Patterson BK, Francisco EB, Yogendra R, Long E, Pise A, Rodrigues H, Hall E, Herrera M, Parikh P, Guevara-Coto J, Triche TJ, Scott P, Hekmati S, Maglinte D, Chang X, Mora-Rodríguez RA, Mora J. Persistence of SARS CoV-2 S1 Protein in CD16+ Monocytes in Post-Acute Sequelae of COVID-19 (PASC) up to 15 Months Post-Infection. Front Immunol. 2022 Jan 10;12:746021. doi: 10.3389/fimmu.2021.746021. PMID: 35082777; PMCID: PMC8784688.
[28] Röltgen, Katharina et al. "Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination." Cell, S0092-8674(22)00076-9. 25 Jan. 2022, doi:10.1016/j.cell.2022.01.018.

# Corresponding Figures for Report to J D Vogel

- Dr. Jessica Rose
- March 2022

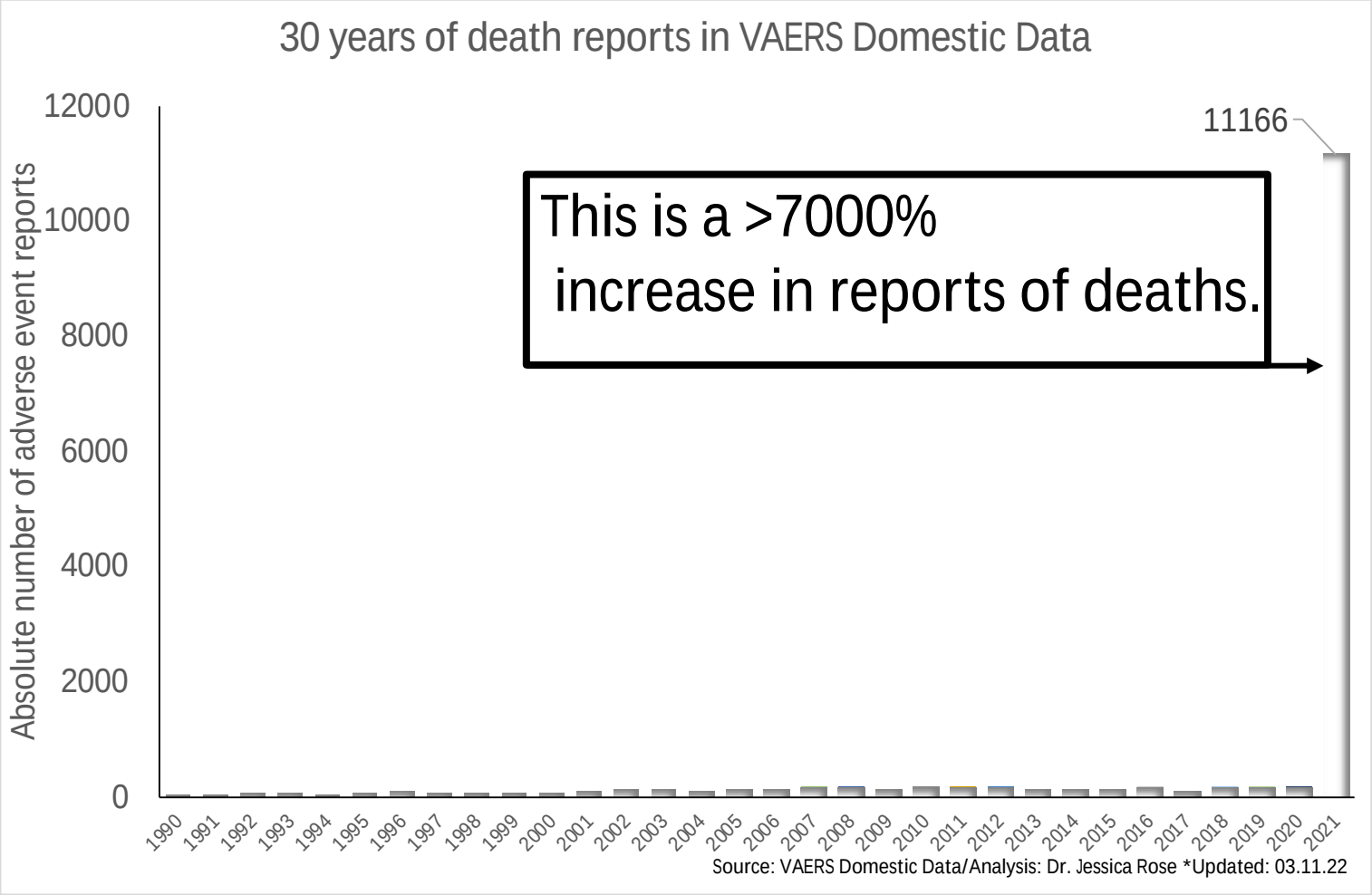
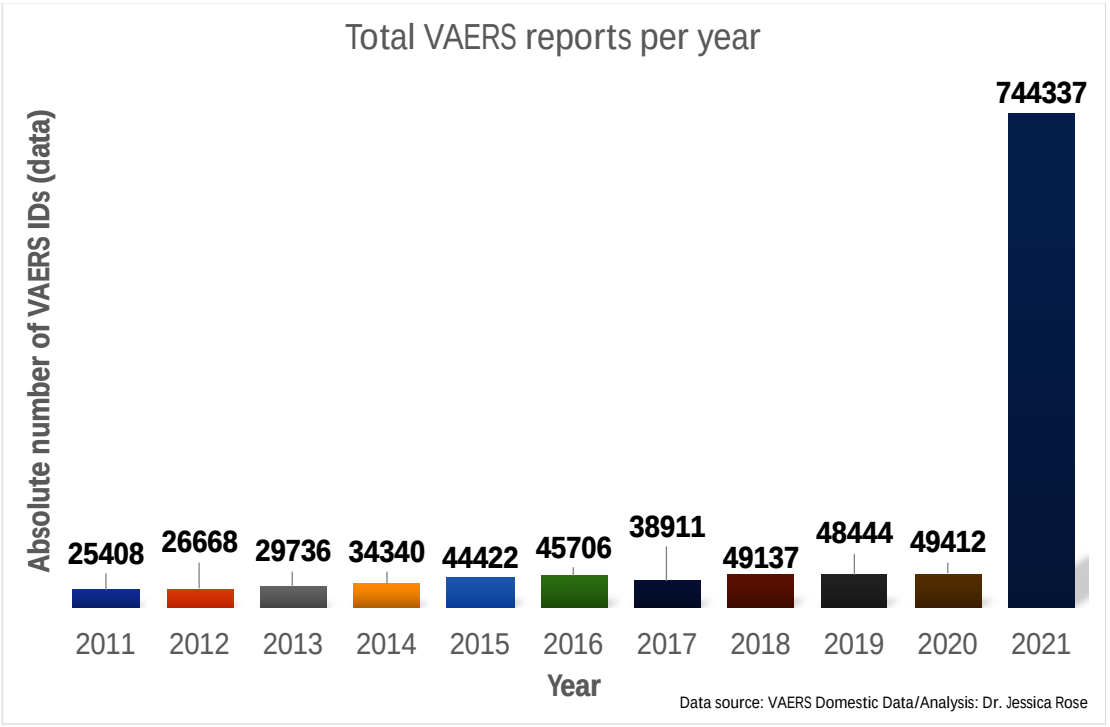
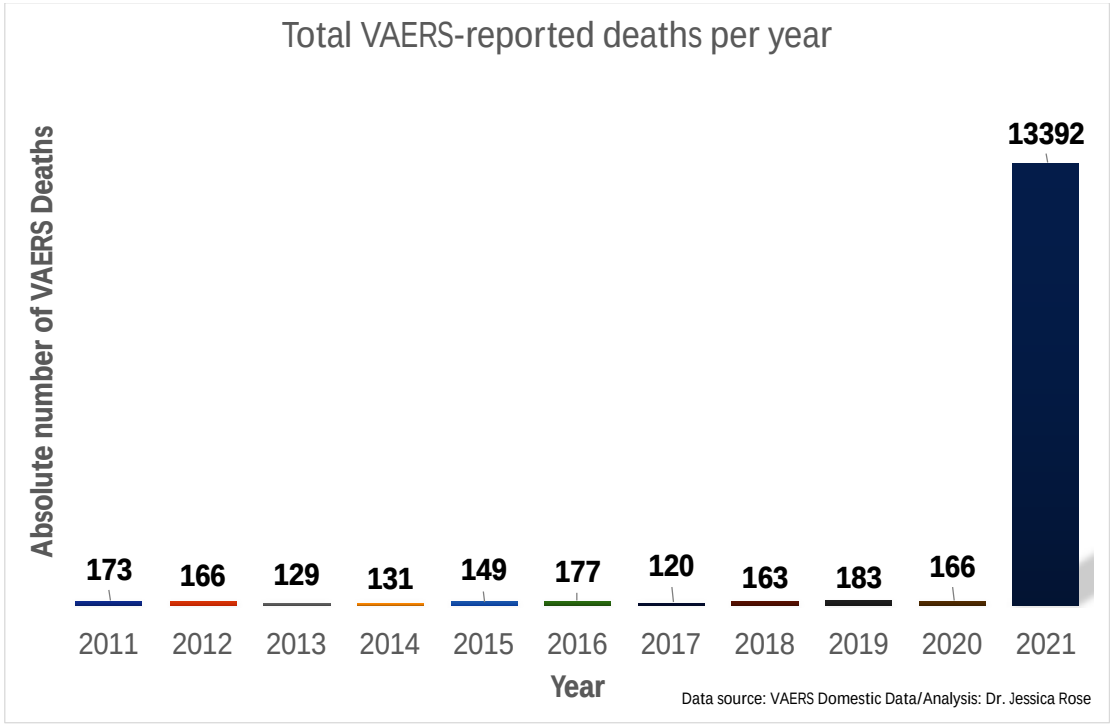



Figure 1a: Unexplained increase in reporting of deaths in the context of COVID-19 products in 2021




# Figure 1b: Unexplained increase in reporting in the context of COVID-19 products in 2021

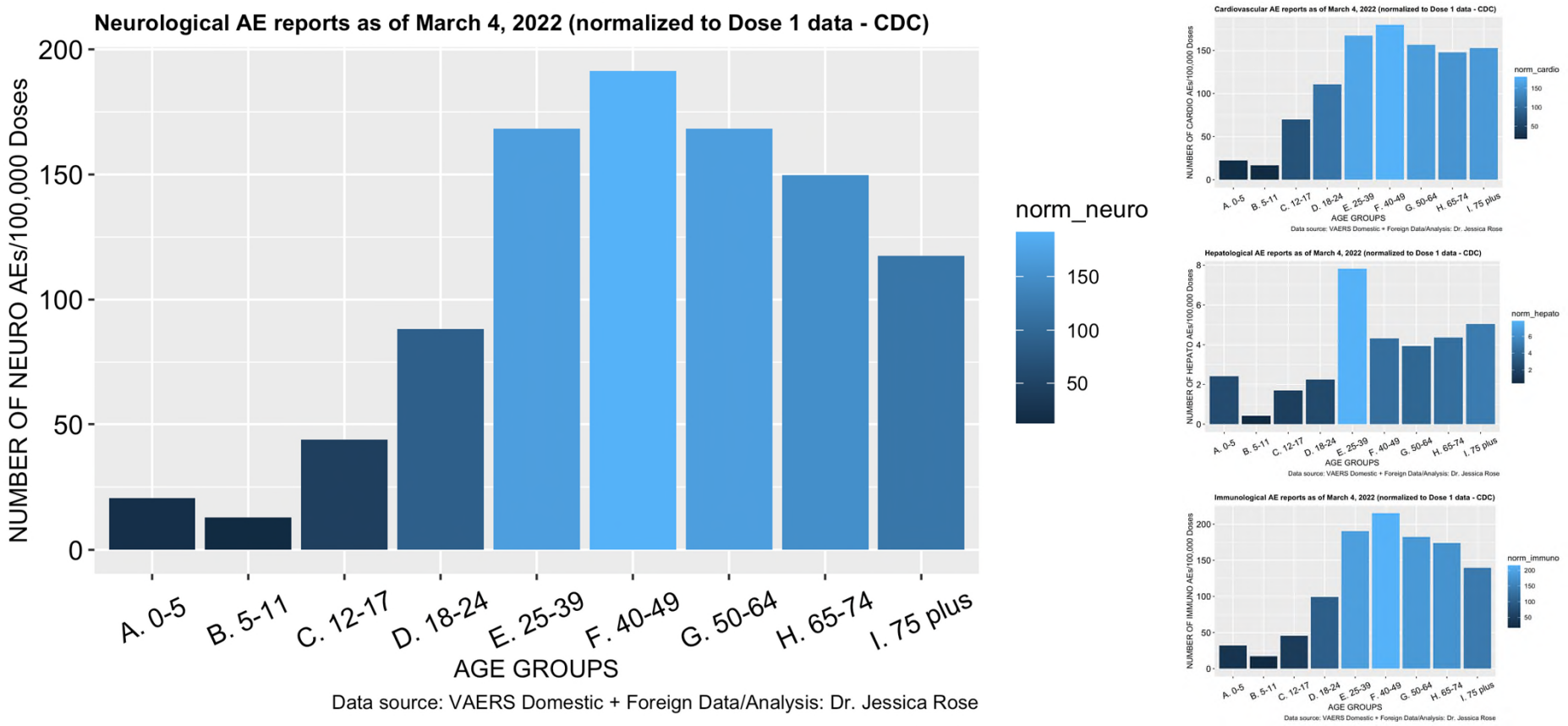
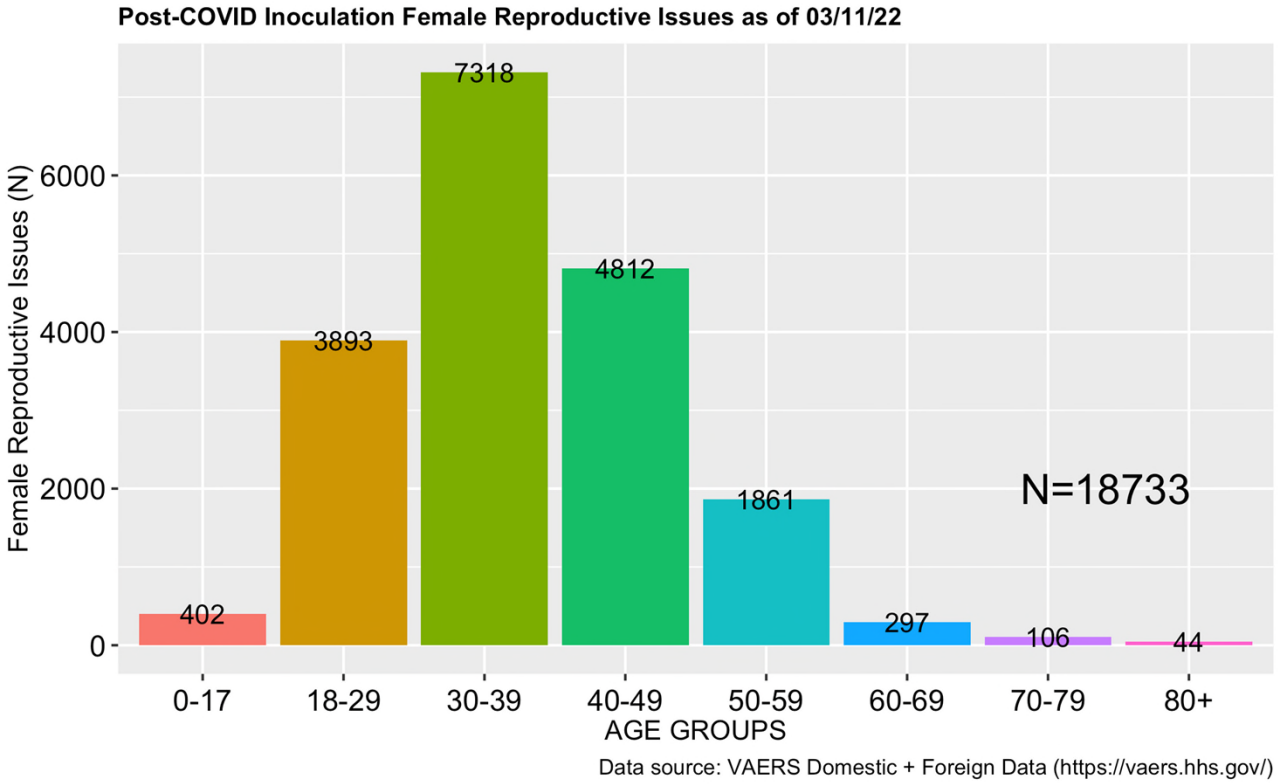



Figure 2: Grouped adverse event reports normalized to injection data (at least 1 dose)*



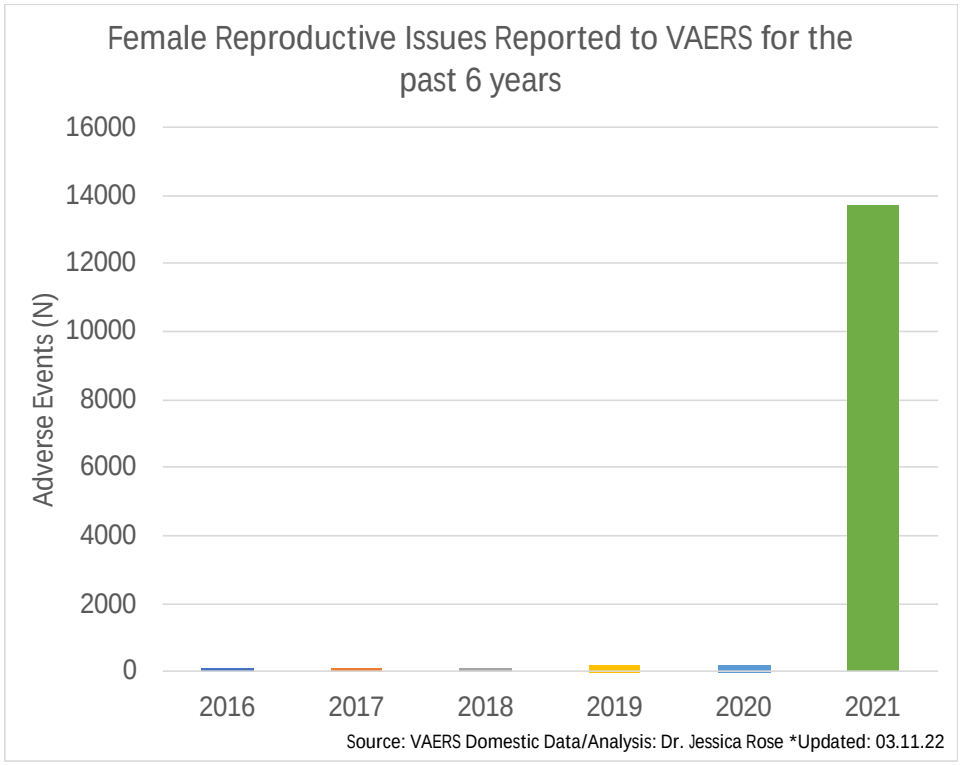
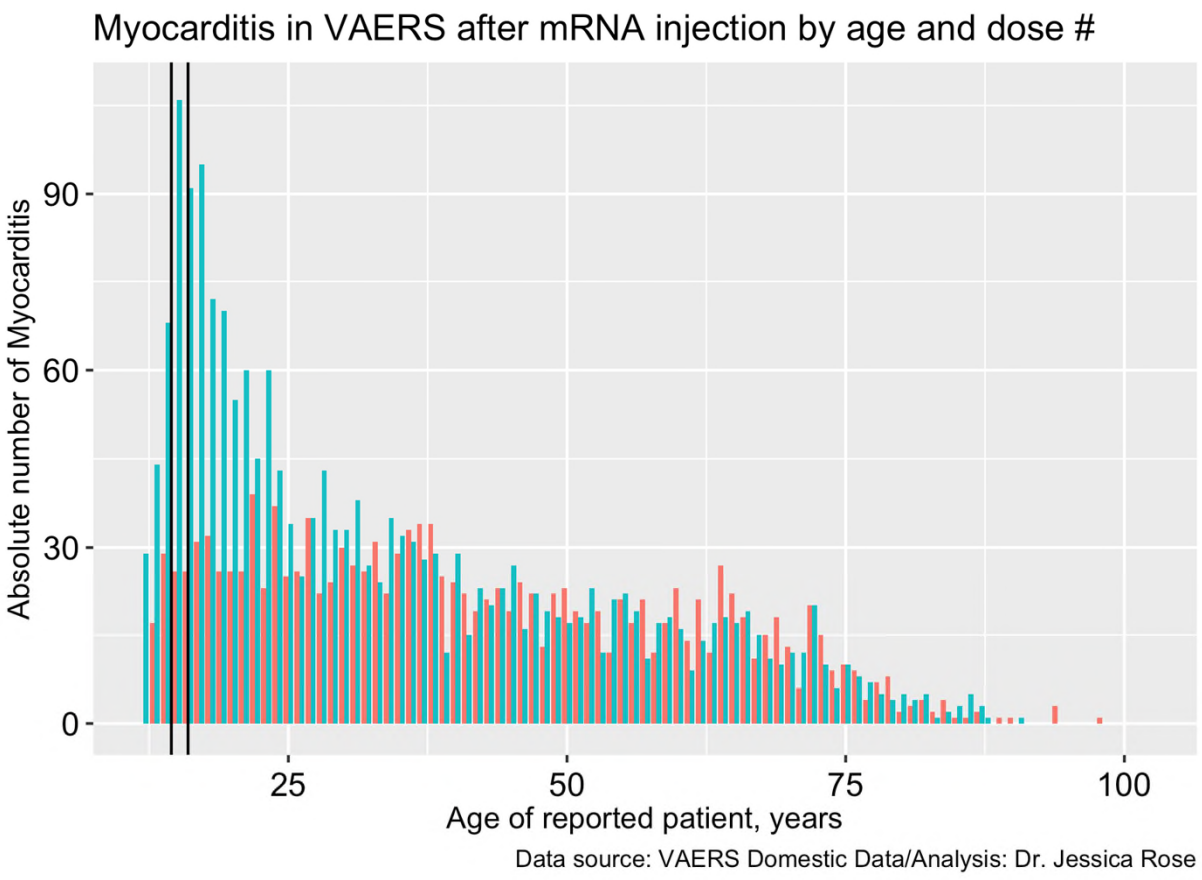




Figure 3: Female Reproductive Issues are being reported in great numbers – thousands of spontaneous abortion reports



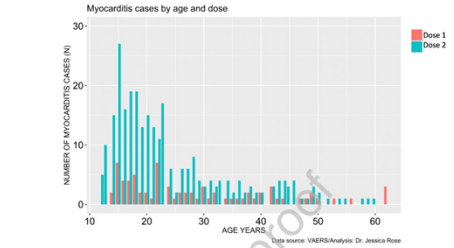




Figure 5. Histogram showing Myocarditis cases reported in VAERS following injection with COVID-19 products according to age and dose.



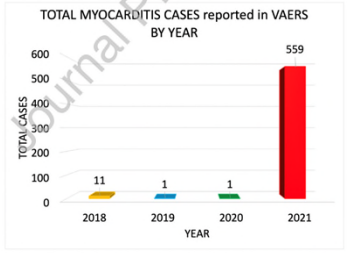



Figure 6. Bar plot showing Myocarditis cases reported in VAERS by year. *2021: up to and including July 9th, 2021.

**Expected vs. Observed reports after mRNA vaccination dose 2, 7-day risk period (N=765)***

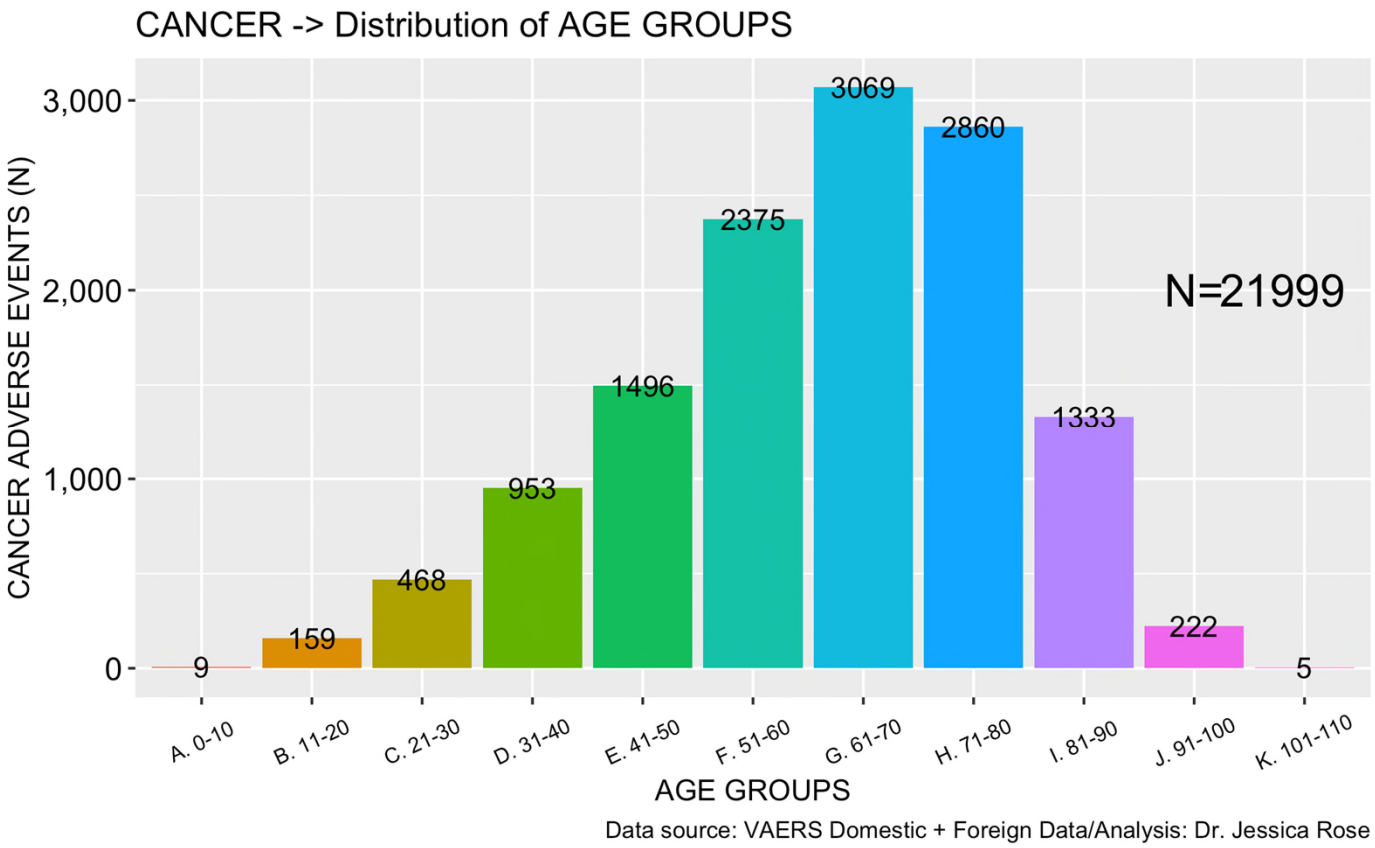
| Age group, years | Females | | Males | |
|---|---|---|---|---|
| | Cases of myopericarditis, expected | Cases of myopericarditis, observed | Cases of myopericarditis, expected | Cases of myopericarditis, observed |
| 12–15* | 0–3 | 12 | 1–5 | 117 |
| 16–17* | 0–2 | 15 | 0–3 | 121 |
| 18–24* | 1–8 | 24 | 1–11 | 213 |
| 25–29* | 1–6 | 16 | 1–9 | 56 |
| 30–39 | 2–21 | 10 | 2–19 | 72 |
| 40–49 | 2–22 | 22 | 2–19 | 45 |
| 50–64 | 4–40 | 15 | 4–35 | 13 |
| 65+ | 4–44 | 6 | 4–36 | 8 |

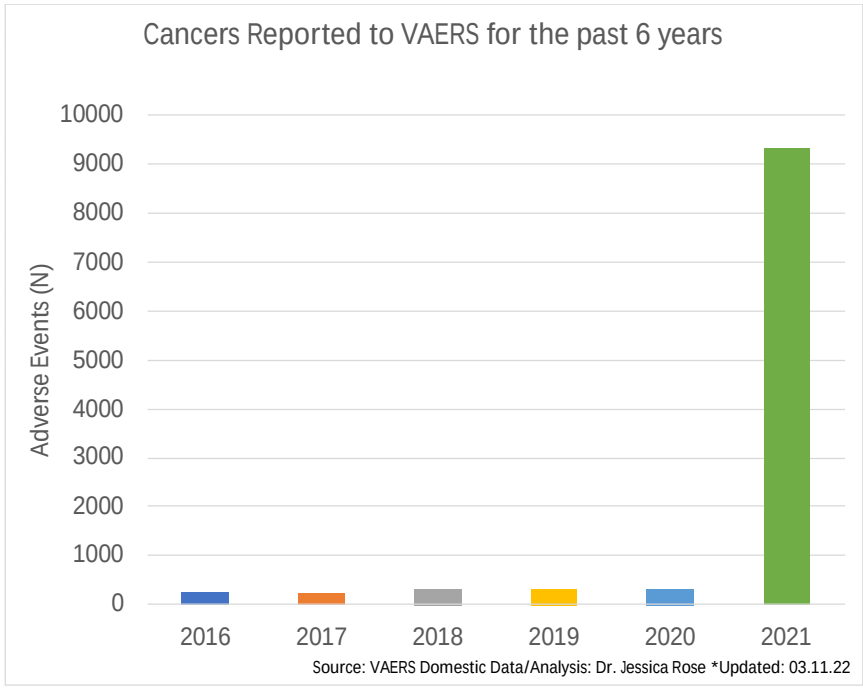
* As of Aug 18, 2021; assumes a 7-day observation window, with 765 of 897 reports after mRNA vaccines occurring during Days 0–6 after vaccination; counts among 12–29 years from reports meeting case definition for myopericarditis; expected estimates for females 12–29 years adjusted to reflect reduced incidence in this age group

7

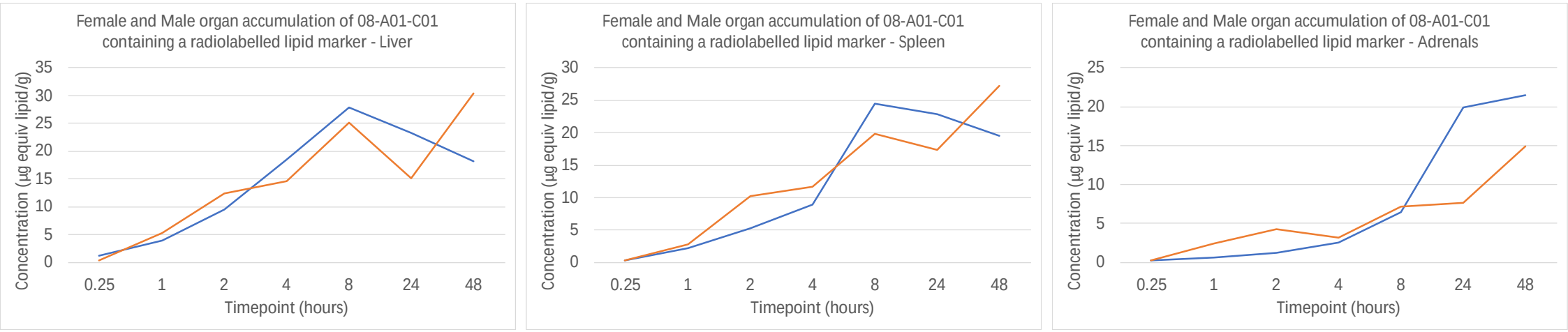
# Figure 4: Reports of Myocarditis in children are 4 times higher following dose 2 than for adults

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-30/03-COVID-Su-508.pdf



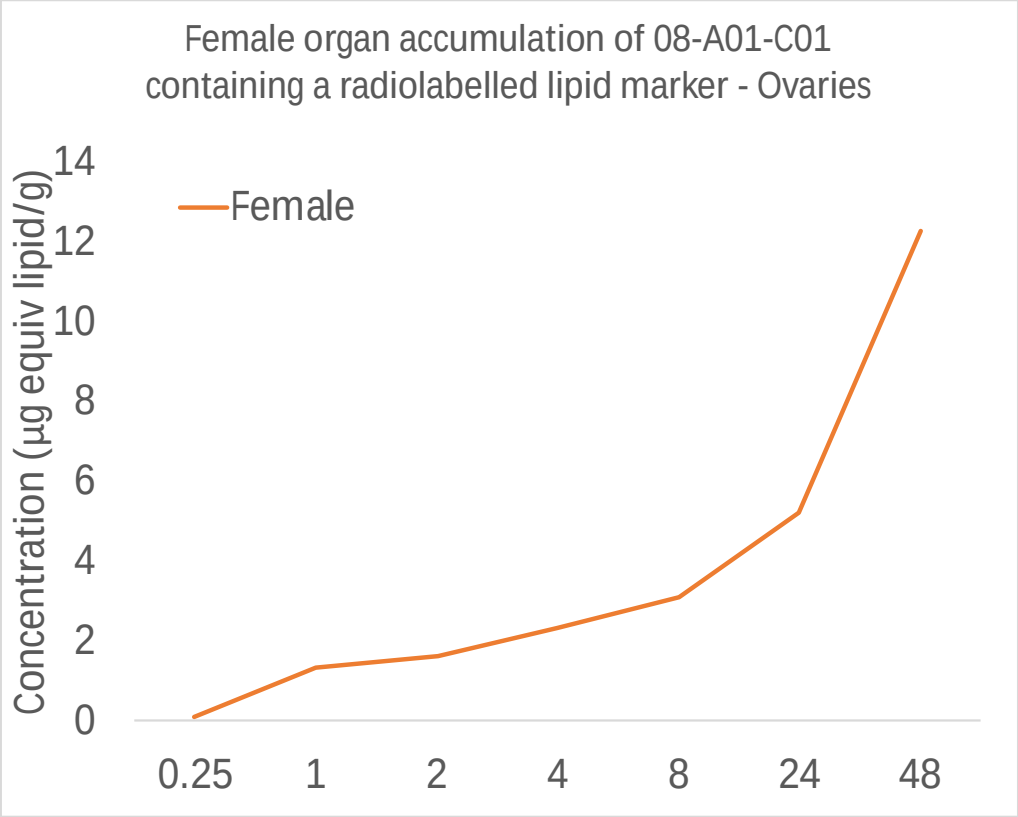




# Figure 5: Cancer reports are prolific in VAERS in the context of the COVID-19 injections




# Figure 6a: Accumulation of radiolabeled lipid marker in organs by gender

Is it possible that the rate accumulation is exponential?



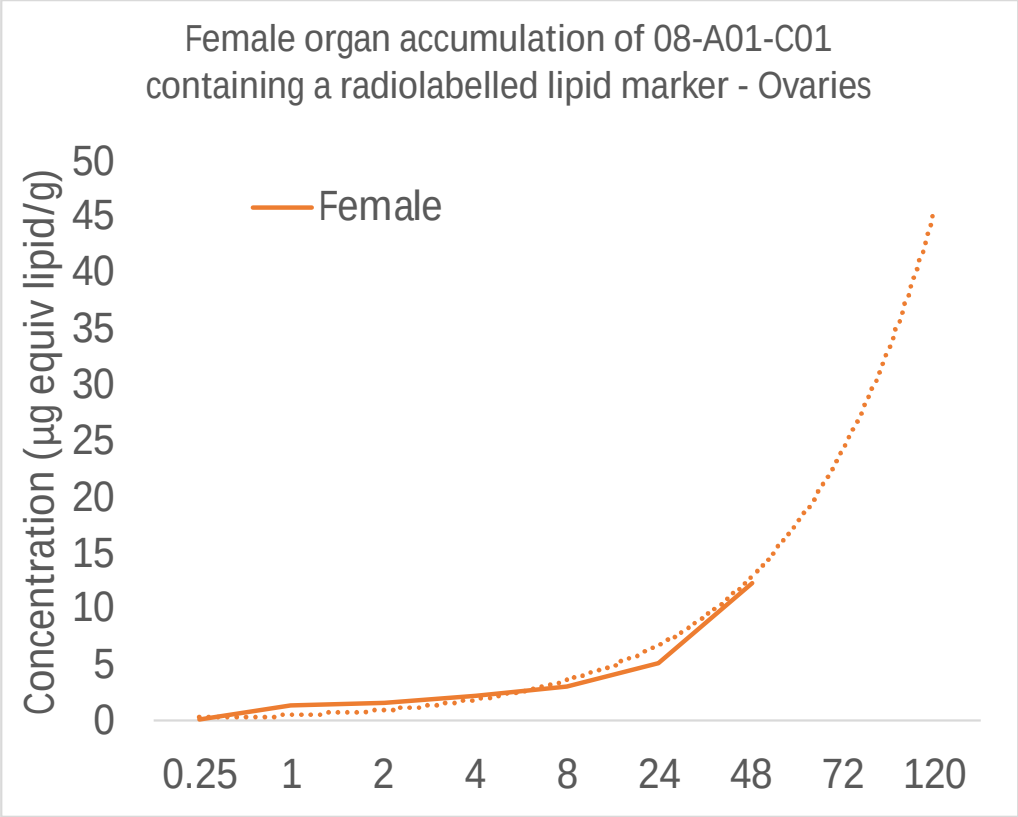
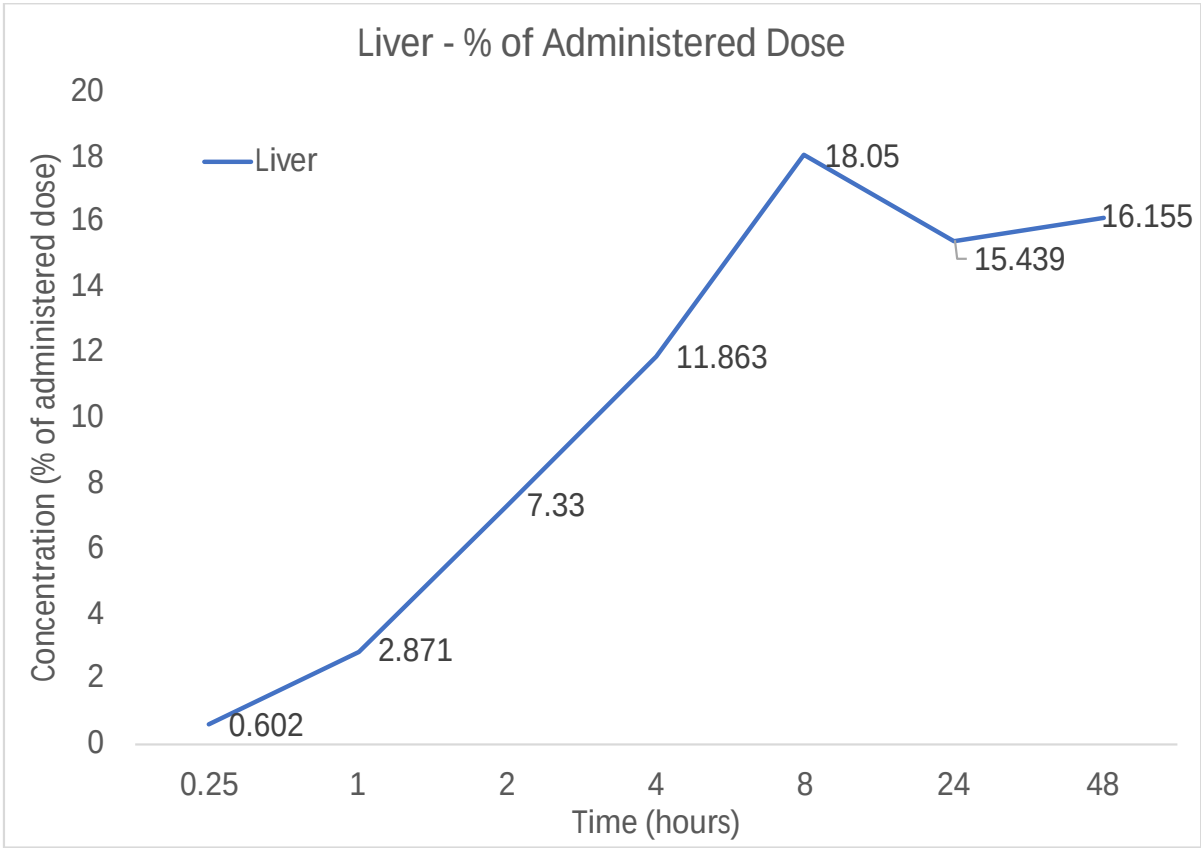



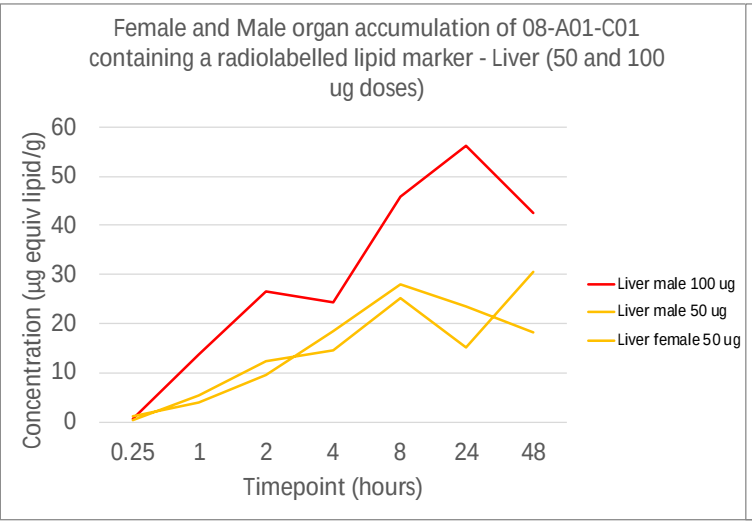

Figure 6b: Accumulation of radiolabeled lipid marker in ovaries

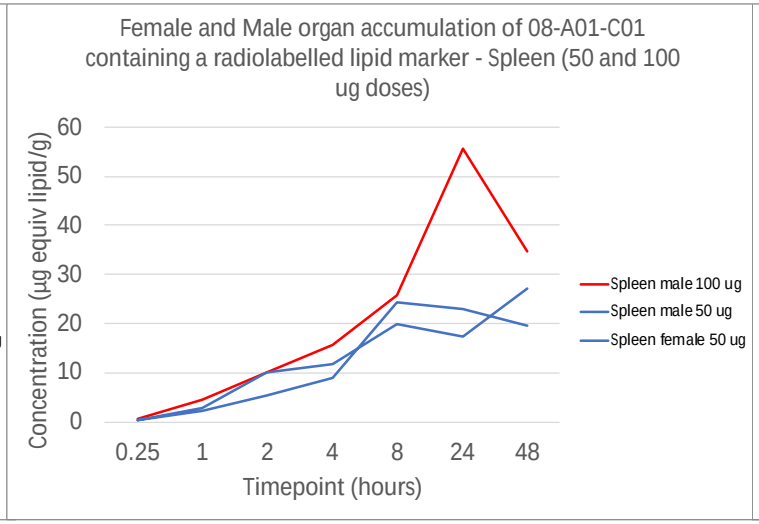


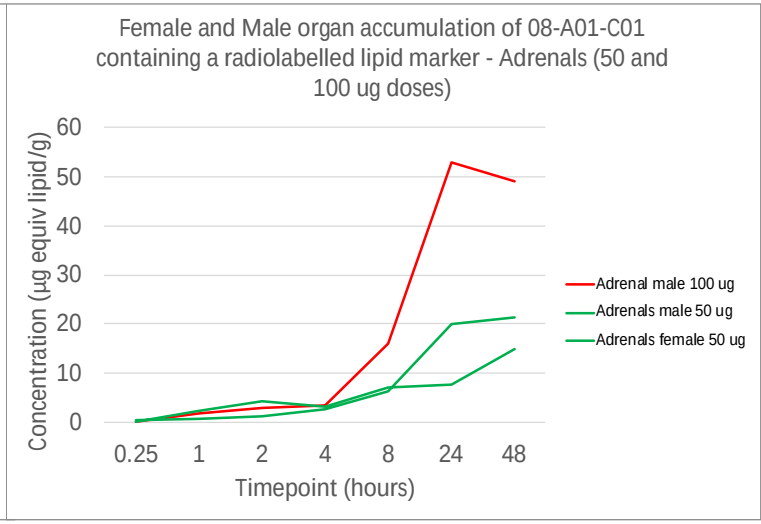

Target Dose Level: 50 µg mRNA/Animal; 1.29 mg Total Lipid/Animal
Results expressed as % of administered dose

# Figure 6c: Percentage of injected product in liver over time

Is it possible in the cases of the higher doses (red) that the downward trend in concentration following hour 24 occurs only in males?




# Figure 6d: Higher dose (100 ug) results faster accumulation to higher peak in liver, spleen and adrenals of males

## Dr. Jessica Rose

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**Positions and Degrees**

Post-Doctoral Fellow
*Technion Institute of Technology, Israel*
2016-2019
Biochemistry/Protein Biology
Research Topic: Molecular Dynamics and Experimental Studies on Type II ABC Importers and copper binding proteins

Visiting Senior Scientist
*Weizmann Institute of Science, Israel*
2016 Spring
Immunology
Subject: Intravital two-photon microscopy for visualization of the affinity maturation process in living mice

Post-Doctoral Fellow
*Hebrew University of Jerusalem, Israel*
2013-2015
Molecular Biology
Research topic: Epidemiological study of Rickettsia spp. transmitted by Ixodid ticks in Israel

Doctor of Philosophy (PhD)
*Bar Ilan University, Israel*
2008-2013
Computational Biology
Dissertation title: Kinetics of Chronic Human Viruses - Comparative Analysis of Bio-Mathematical Models and their Clinical Implications

Master of Science in Medicine (MSc)
*Memorial University of Newfoundland and Labrador, Canada*
2003-2006
Medicine (Immunology)
Thesis title: Dynamical Systems Analysis of HIV Immunopathogenesis and the Effects of Antiretroviral Treatment Interruption

Bachelor of Science (BSc)
*Memorial University of Newfoundland and Labrador, Canada*
1992-2002
Applied Mathematics

**Publications**


Hadley RC, Zhitnitsky D, Livnat-Levanon N, Masrati G, Vigonsky E, **Rose J**, Ben-Tal N, Rosenzweig AC, Lewinson O, The copper-linked E. coli AZY operon: Structure, metal binding, and a possible physiological role in copper delivery, Journal of Biological Chemistry (2021), doi: https://doi.org/10.1016/j.jbc.2021.101445.

**Jessica Rose** PhD, MSc, BSc , Peter A. McCullough MD, MPH, A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products, Current Problems in Cardiology (2021), doi: https://doi.org/10.1016/j.cpcardiol.2021.1010.

**Rose J**. 2021. Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System? Science, Public Health Policy and the Law (2021).

**Rose J**. 2021. A report on the US Vaccine Adverse Events Reporting System (VAERS) of the COVID-19 messenger ribonucleic acid (mRNA) biologicals. Sci Publ Health Pol & Law 2:59-80.

Kuznetsova A, Masrati G, Vigonsky E, Livnat-Levanon N, **Rose J**, Grupper M, Baloum A, Yang JG, Rees DC, Ben-Tal N, Lewinson O, Titratable transmembrane residues and a hydrophobic plug are essential for manganese import via the Bacillus anthracis ABC transporter MntBC-A, Journal of Biological Chemistry (2021), doi: https://doi.org/10.1016/j.jbc.2021.101087.

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# Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System?

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*"Patterns of adverse events, or an unusually high number of adverse events reported after a particular vaccine, are called 'signals.' If a signal is identified through VAERS, scientist[s] may conduct further studies to find out if the signal represents an actual risk."*

CDC on Vaccine Safety

## Abstract

Following the initiation of the global rollout and administration of the COVID-19 vaccines[1,2] on December 17, 2020, in the United States, hundreds of thousands of individuals have reported Adverse Events (AEs) using the Vaccine Adverse Events Reports System (VAERS). To date, approximately 50% of the population of the United States have received 2 doses of the COVID-19 products with 427,831 AEs reported into VAERS as of August 6th, 2021.

Pharmacovigilance (PV) is the process of collecting, monitoring, and evaluating AEs for safety signals to reduce harm to the public in the context of pharmaceutical and biological agents. Many of the issues with VAERS are becoming well known – especially with regards to reporting and recording of data – in light of the extensive use of this system this year, challenging its functionality as a pharmacovigilance system.

This appraisal assesses three issues that respond to the question of VAERS pharmacovigilance by analyzing VAERS data: 1. deleted reports, 2. delayed entry of reports and 3. recoding of Medical Dictionary for Regulatory Activities (MedDRA) terms from severe to mild. The most recently updated publicly available VAERS dataset was found to have N=1516 (0.4%) VAERS IDs removed ("missing").

1 The Brand Name: Pfizer-BioNTech COVID-19 Vaccine, the Previous Name: BNT162b2 or the Company Name: Pfizer Inc. and BioNTech SE. can be used in the case of the Pfizer/BioNTech COVID-19 products. The Brand Name: mRNA-1273 and/or Company Name: Moderna, Inc. can be used in the case of the Moderna COVID-19 products.

2 mRNA biologicals are not true vaccines. True vaccines undergo time-dependent testing protocols to ensure safety and efficacy, typically enduring between 10 and 15 years. 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. The mRNA biologicals do not satisfy either these requirements and as such are more akin to experimental treatments than vaccines.

Of this missing data, 13% represented death, 11% represented COVID-19 and 63% represented Severe Adverse Events (SAEs). Of these missing death data, only 59% represented redundancies – re-assigned new VAERS IDs – the remainder were unaccounted for.

A lag time between onset of AEs and entry of AEs into the VAERS public database was discovered, and it appears to depend on the AE type. For example, in the case of COVID-19 breakthrough cases, approximately mid-May, 4100 (38% of total) reports were retroactively added approximately 8.5 weeks following the original onset date. SAEs were not found to be downgraded to mild AEs (MAEs) for a tested cohort within 10 selected updates.

VAERS is designed to reveal potential early-warning risk signals from data, but if these signals are not detectable as they are received, then they are not useful as warnings. Considering the relevance of safety concerns in the face of the large numbers of AEs being reported into the VAERS system in the context of COVID-19 products, it is essential that the VAERS system be carefully and meticulously maintained. Despite the emergence of the Standard Operating Procedures (SOP) for COVID-19, VAERS is lacking in transparency and efficiency as a PV system, and it requires amendment or replacement.



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**Keywords**
COVID-19; Vaccine Adverse Events Reports System (VAERS); Adverse Events (AEs); Severe Adverse Events (SAEs); Mild Adverse Events (MAEs); VAERS Wayback Machine; Standard Operating Procedures (SOP); Medical Dictionary for Regulatory Activities (MedDRA); Pharmacovigilance (PV)

## Contents



## 1 Background

Pharmacovigilance is the process of collecting, monitoring, and evaluating AEs for safety signals to reduce harm and promote safety to the public in the context of pharmaceutical and biological agents [1,2]. There are a number of organizations and agencies that exist to ensure pharmacovigilance as part of regulation of biological products from conception to administration into humans for use. The Center for Biologics Evaluation and Research (CBER), as an example, actively participates in international pharmacovigilance efforts under the umbrella of the Food and Drug Administration (FDA) and the Department of Human Health Services (DHHS) [3]. International regulatory organizations such as the World Health Organization (WHO), the Pan American Health Organization (PAHO) and the World Intellectual Property Organization (WIPO) also function to ensure pharmacovigilance in biologicals and serve as sources of guidance pertaining to pharmacovigilance efforts. In addition, individual countries have their own regulatory authorities, such as the Medicines & Healthcare products Regulatory Agency (MHRA) of the United Kingdom (U.K.), responsible for rule and regulation enforcement and the issuance of guidelines to ensure pharmacovigilance in the development and administration of biological products. The U.K. 'Coronavirus Yellow

Card' reporting site allows collection of AE data monitored by the MHRA.

The U.S. FDA and Centers for Disease Control and Prevention (CDC) created and implemented the Vaccine Adverse Event Reporting System (VAERS) in 1990 to receive reports about AEs that may be associated with biological products such as vaccines.[3] Most vaccine AE reports in VAERS concern relatively minor events, such as injection site pain. Other reports describe serious events, such as hospitalizations, life-threatening illnesses, or deaths [4,5,6,7,8]. The reports of serious events are of greatest concern and are meant to receive the most scrutiny by VAERS staff and healthcare professionals. The primary purpose of the database is as a pharmacovigilance tool – to serve as an early warning or signaling system for AEs not detected during pre-market testing. The National Childhood Vaccine Injury Act of 1986 (NCVIA) requires health care providers and vaccine manufacturers to report AEs to the DHHS following the administration of vaccines outlined in the Act [4,5,6,7]. Reported AEs, as part of the VAERS system, represent a fraction of the actual number of AE incidents, so the numbers reported herein are likely far lower than actual numbers [6,7,9]. VAERS reports can be made by nurse practitioners, general practitioners, or family members, which can result in duplicate reports being made. As part of the VAERS Standard Operating Procedures for COVID-19 (SOP)[4] published on January 29th, 2021, the CDC and the FDA are meant to perform routine VAERS surveillance to identify potential emergent safety concerns in the context of COVID-19 injectable products [5,6,7,10,11,12]. Accordingly, VAERS reports are received, processed, and managed by trained CDC contractors. The VAERS reports are received online for subsequent review, and symptoms and diagnoses are assigned MedDRA standard codes. Additional information, including hospital records and autopsy reports, will be requested by these trained staff when appropriate, as outlined in the SOP. Reports are often changed or deleted. For example, in the case where a person successfully files a report using the VAERS system and subsequently dies, they are, in some cases, assigned a new VAERS ID number, unlinking their reported AEs and death records. In addition, as the AEs may become more enumerable in an individual, multiple changes can be made to their VAERS report under the same VAERS ID number or, as indicated, under a different VAERS ID number if they die.

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 considered related to participation in the research. Based on the Code of Federal Regulations, a Serious or Severe Adverse Event (SAE)[5] 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

3 VAERS has benefits of the PREP Act – while vaccine manufacturers are shielded from liability, and vaccine proponents tout VAERS as an example of active PV, VAERS users must acknowledge the data cannot be used to establish causality.

4 Vaccine Adverse Event Reporting System (VAERS), Standard Operating Procedures for COVID-19 (as of 29 January 2021), VAERS Team: Immunization Safety Office, Division of Healthcare Quality Promotion National Center for Emerging and Zoonotic Infectious Diseases and Centers for Disease Control and Prevention.

5 NIA Adverse Event and Serious Adverse Event Guidelines (2018). https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf

condition which investigators judge to represent significant hazards.[6] The VAERS handbook states that approximately 15% of reported AEs are classified as severe [4]. Nowhere in the VAERS handbook or on the website published by the CDC/FDA is there mention of deleted data or transparent description of the processes and criteria used for record deletion. The only reference I could find to legitimate removal of data, from WONDER's 'Reporting Issues' section, claims that 'Duplicate event reports and/or reports determined to be false are removed from VAERS'.[7]

A Wayback Machine[8] is an initiative of the Internet Archive, a 501(c)(3) non-profit, building a digital library of Internet sites and other cultural artifacts in digital form. The VAERS Wayback Machine[9] therefore allows an examination of the VAERS government data input each week. The U.S. Government publishes a new version of its VAERS database weekly and VAERS IDs can be changed or even deleted without documentation of edits. The VAERS Wayback Machine provides a way to trace and track deleted files based on matches in field entries between VAERS ID versions.[10]

## 2 Methods

### General methodology and descriptive statistics

To analyze the VAERS data sets, R was used. (R: a language and environment for statistical computing.) VAERS data are accessed through the CDC Wide-ranging Online Data for Epidemiologic Research (WONDER) system. The VAERS data are available for download[11] 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 for each report, including vaccine manufacturer and lot number. The VAERS dataset is updated weekly. Upon individual reporting of vaccine side effects or AEs, a VAERS ID number is provided to the individual to preserve confidentiality, and a detailed description of the AEs 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.

The VAERS ID was used as a linking variable to merge the three csv files. Data was filtered according to vaccine type (reports made only for COVID-19), and all variables were retained, 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, disabilities, life threatening AEs, birth defects and onset date of AEs. Deaths are categorized according to whether or not the individual had been marked as 'DIED'. Erroneous labelling is an issue in VAERS, for example, when 'Death' is an AE and yet the 'DIED' column is marked 'NA' or 'not applicable', thus the dataframe was checked and corrected for inconsistencies in the 'DIED' column vector. For the purposes of this analysis, deaths according to VAERS classification by 'DIED' plus these corrected cases of misclassification are reported here and used in the analysis. The grouped AE categories hospitalizations and emergency doctor visits were created by

6 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?
7 VAERS data can be accessed through the CDC Wide-ranging Online Data for Epidemiologic Research (WONDER) system. https://wonder.cdc.gov/vaers.html
8 https://web.archive.org/
9 https://medalerts.org/vaersdb/wayback/
10 https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html
11 https://vaers.hhs.gov/data/datasets

selecting 'Y' in the respective column vectors, while the cardiovascular, neurological and immunological groups were created by selecting keywords indicative of a respective medical issue. The SAEs were classified according to whether the individual succumbed to death, was hospitalized, was admitted to the ER, experienced a disability or a life-threatening AE, or if a birth defect ensued.

It should be noted at this point that anyone using the VAERS WONDER system will not see the same counts that are described in this analysis, since hospitalizations, ER visits and all SAEs counts were calculated by counting the 'Y' entries in the respective fields in the merged file. The difference between the counts in this analysis and counts from a WONDER query are simply due to the effect of losing field entries by merging the files. If one uses the files available for download from the VAERS website with the aim of comprehensive analysis of the full range of data, the 3 csv files must be merged. In order to know what 'SYMPTOMS' an individual succumbed to prior to death, for example, or to know what injectable product they were given, it is necessary to merge the DATA file with the SYMPTOM file and the VAX file. It is also vital to omit redundancies in VAERS IDs – if not done, this could lead to excess numbers in absolute counts. The downside to the merge is loss of data due to incomplete field entries; however, it is important to note that the merge counts are under-approximations, yet still prove the points made herein.

Deleted data were isolated and aggregated by using anti-join iterations in R on sequential dataframes. Anti-join returns the rows of the first dataframe that are not matched in a second dataframe. This was done iteratively for all sequential dataframes, and the unmatched data were aggregated and put into a new file entitled 'missing data'. The collective missing data file was subsequently filtered for duplicates to ensure that redundancies were omitted.

A missing VAERS ID can be missing due to having been removed because it is redundant, or for reasons yet unknown. The former entries are re-assigned a new VAERS ID and are traceable by matching fields in column vectors of dataframes. The latter are missing due to unknown reasons. To discern between redundant and deleted VAERS IDs, deleted data were cross-referenced by matching fields for relevant selected variables in the most recently updated publicly available dataset. This was done only for the deleted death data, since it is a time-consuming exercise. The matching algorithm was as follows: match age, state, and gender followed by vaccine lot if available, onset, vaccine and death dates followed by allergies, medications, and any other unique identifiers of the individual. If a match was found, the newly assigned VAERS ID was recorded alongside the old VAERS ID in a new file. If a match was not found, then the VAERS ID was deemed to have been deleted from the database.

Two methods were used to investigate temporal lags in data entry. The first method involved using only the most recently updated publicly available dataset. Assessment of temporal differences in data entry was done by calculating the difference in the number of days between the onset date (ONSET_DATE)[12] and the date that the AE was entered into the VAERS database (TODAY'S_ DATE).[13] The second method involved comparing the data from the weekly updates to the most recently updated file. Each week, a new set of data is available for download from the VAERS website, as mentioned previously. As an example of how the data sets were compared, consider the first and the last VAERS datasets available for download in

12 Onset Date (ONSET_DATE): The date of the onset of adverse event symptoms associated with the vaccination as recorded in the specified field of the form.

13 Today's date (TODAYS_DATE): Date Form Completed.

2021. According to a reference variable, such as the ONSET_DATE, these two datasets should both and equally capture all AEs submitted to VAERS from January 1st through January 7th, 2021, since the first available dataset would comprise the first week of data. If any two datasets do not equally capture all AEs, then this discrepancy would warrant explanation. A feasible explanation for a non-match in the number of VAERS IDs per ONSET_DATE entries reported would be retroactive addition of reports to the system due to a backlog.

The incidence of SAE downgrade to MAE was assessed by choosing 10 update files, calculating the SAE and MAEs, and subsequently comparing them to original counts for SAE and MAE in the original files. This was done using the semi-join function in R.

**Statistical Testing**

Statistical analysis was done using the Student's t-Test to determine statistically significant differences between AE types in the deleted data file. Skewing in distribution of data was 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

## 3.1 Historical pharmacovigilance of VAERS and other safety monitoring systems

VAERS and other safety monitoring systems have been useful for pharmacovigilance in the past. In 2010, rotavirus vaccines licensed in the U.S were found to contain Porcine circovirus (PCV) type 1 and were subsequently suspended. On 22 March, 2010, the FDA issued a statement recommending that clinicians and public health professionals in the United States temporarily suspend the use of Rotarix [13,14,15]. In 2009, an increased risk of narcolepsy was found following vaccination with a monovalent H1N1 influenza vaccine that was used in several European countries during the H1N1 influenza pandemic [15,16,17]. Between 2005 and 2008, a meningococcal vaccine was suspected to cause Guillain-Barré Syndrome (GBS) [15,18]. In 1998, a vaccine designed to prevent rotavirus gastroenteritis was associated with childhood intussusception after being vaccinated [15,19–29]. Also in 1998, a hepatitis B vaccine product was linked to multiple sclerosis (MS) [15,30]. Pharmacovigilance has functioned in the context of COVID-19 VAERS data with regards to myocarditis, resulting in a COVID-19 vaccine safety update by the Advisory Committee on Immunization Practices (ACIP, June 23rd, 2021) by Tom Shimabukuro. The report did not result in any changes to the rollout despite the danger signal having arisen [31].

To date, 50% of the total US population has received 2 doses of COVID-19 products,[14] with 427,831 AEs reported as of August 6th, 2021. These numbers are off the scale with regards to numbers associated with vaccine rollouts when compared to previous years. Even more atypical are the numbers of deaths reported in the context of the COVID-19 products. Figure 1 shows the total VAERS reports from data and total VAERS-reported death counts per year for the past 10 years up to and including the VAERS update on August 6th, 2021. Both the absolute numbers of total AEs and those of deaths per year dramatically outnumber the absolute numbers recorded in previous years. To date, there are 6639 (1.6% of all AEs) deaths in the VAERS database. Normalization to fully injected populations were done and compared with INFLUENZA vaccine data for past years and it was

14 https://usafacts.org/visualizations/covid-vaccine-tracker-states/

Figure 1: Bar plots showing the number of VAERS reports (left) and reported deaths (right) per year for the past decade. (2021 is partial data set.)

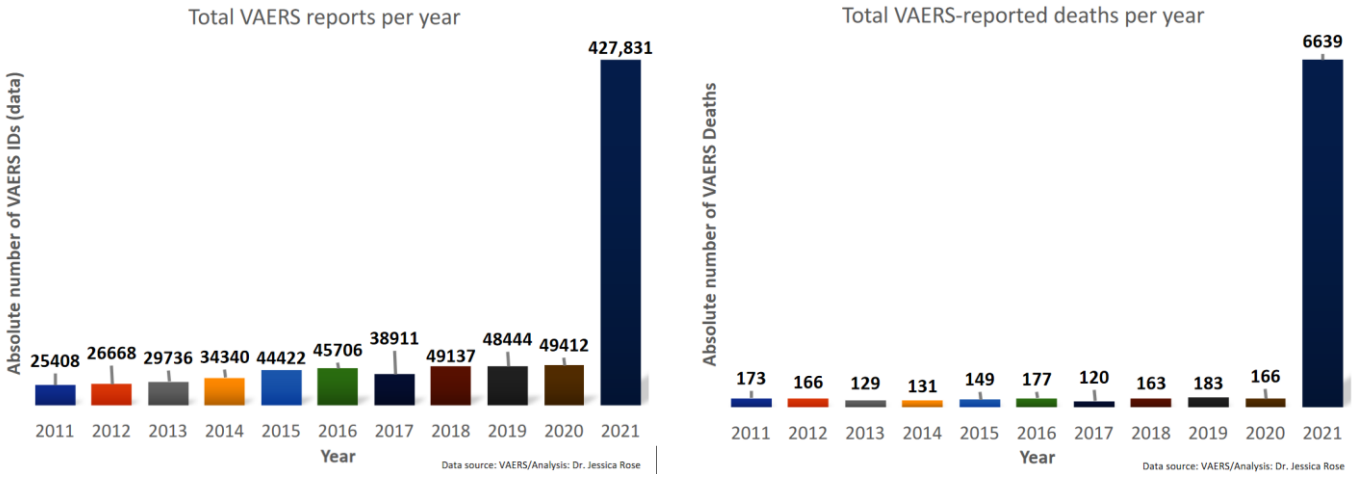
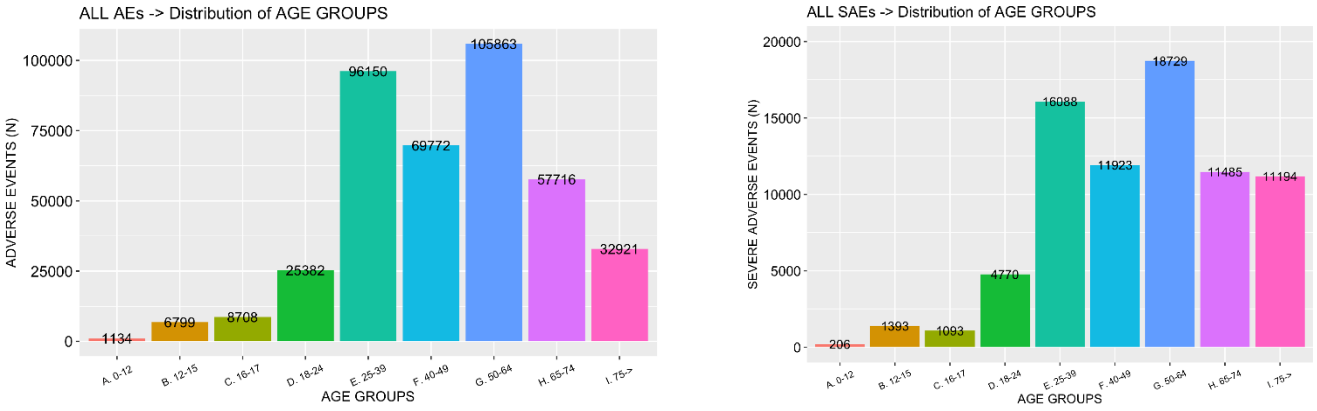



Figure 2: Histogram plots showing distributions of the AEs of the total VAERS ID count (left) and for SAEs (right).




found that the increase in AEs is not due simply due to an increase in injections [32].

As part of an ongoing analysis [8], VAERS data are being monitored according to weekly updates. Figure 2 shows the total AE count (up to and including the August 6th, 2021, VAERS update) by age group alongside the SAE data by age group (according to CDC age group classifications). The distribution in both cases is symmetric and unimodal, not skewed toward any particular age group, potentially meaning that there is no particular age group with lesser chance of succumbing to an AE or, more importantly, an SAE. Of the SAEs, there are 6,639 deaths, 26,402 hospitalizations, 59,061 ER visits, 7,423 life-threatening events, 6,861 disabled and 258 birth defects reported.

Female reproductive issues (FRIs) and AEs in children aged 12–18 years are on the rise. There are currently 6,398 total FRIs and 18,021 AEs reported in young children aged 12 through 18. These children represent 4.2% of the total VAERS data and 12.9% of all cardiovascular AEs. It should be highlighted that the rollout has only just begun recently for children in these young demographics. Figure 3 shows histograms for the FRIs (left) and

Figure 3: Histogram plots showing the distributions of female reproductive issue AEs and AEs in children aged 12–18 years old from the VAERS dataset according to age group (left) and age in years (right).

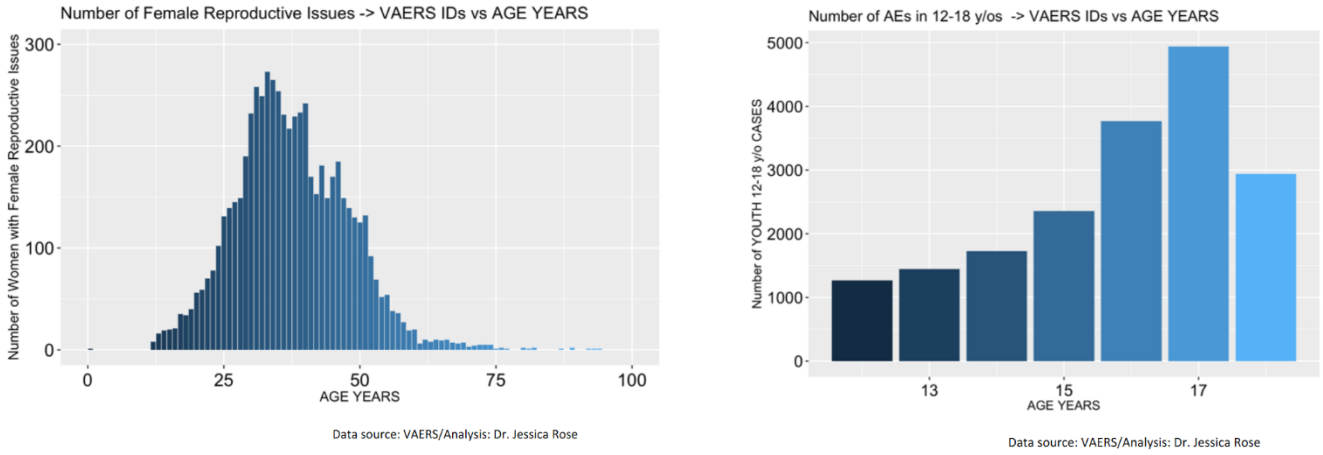
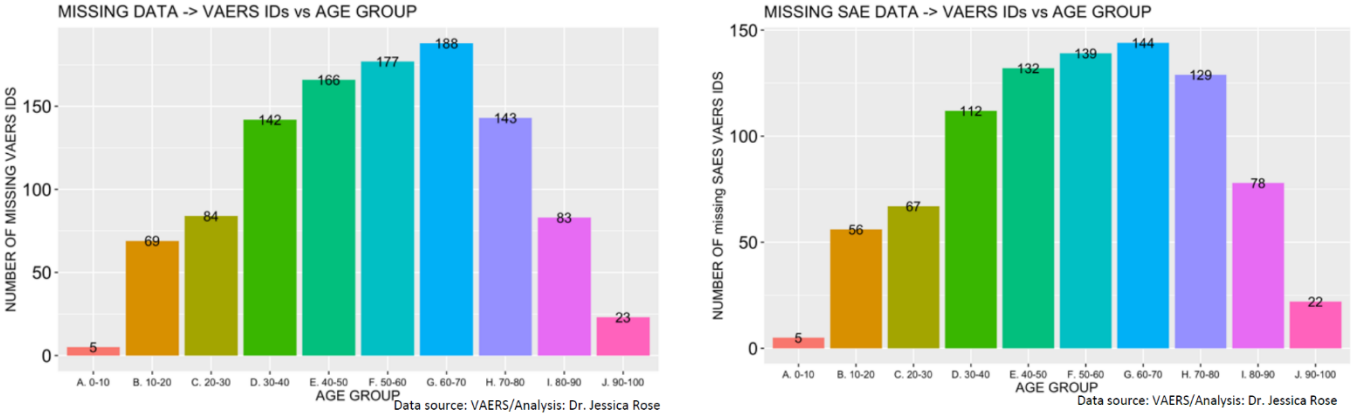



Figure 4: Histogram plots showing the distributions of the missing data of the total AE counts (left) and for SAEs (right) from the VAERS dataset according to age group.




for the children (right) with respect to age in years. Most reports within the children aged 12–18 were made for 17-year-olds.

### 3.2 Missing data

To date (August 6th, 2021), 1,516 VAERS IDs are missing from the most recently updated publicly available VAERS database. This represents 0.4% of the total VAERS IDs. For each of the 28 updates, one anti-join iteration was performed between sequential updates. For each anti-join iteration, of which there are currently 27, the extracted missing data counts are as follows: 10, 13, 20, 20, 4, 12, 30, 18, 41, 14, 25, 24, 45, 72, 89, 77, 69, 102, 53, 115, 89, 167, 95, 63, 62, 87 and 101. That is, between the first update and the second, 10 VAERS IDs are missing; between the second and third, 13 VAERS IDs are missing, and so on up to the second-last and the most recent update where 101 VAERS IDs are missing. Figure 4 shows the distribution of the missing data according to age groups for the entire missing data set (left) and for the SAEs within the set (right). The missing data are distributed in a symmetric and unimodal way with regards to age groups and are not skewed toward any group in a statistically significant way (I=-0.2) when compared to the dataset without removals.

Interestingly, when the data are not filtered by age group, 63% of all missing data reports qualify

as Severe AEs, and this represents 1.2% of the total SAEs reported to VAERS. When the data are filtered by age group, this percentage becomes 81%, as shown in Figure 4. The missing SAE data are distributed in a symmetric and unimodal way with regards to age groups and are not skewed toward any group in a statistically significant way (I=-0.4).

Of the total missing VAERS ID data set, 41% of the missing IDs involved hospitalizations and 37% involved emergency room visits (data not shown). Histograms of these two categories do not show any statistically significant skewing toward any particular age group (I=0.1 and I=-0.1, respectively; not shown).

Individuals who succumb to and are diagnosed with COVID-19 post-injection, also known as breakthrough events, comprise 11% of the total missing data (1.4% of total VAERS IDs). It is very strange to report that 70% of the age data contains an "NA" entry in the "AGE_YRS" field and thus age-grouped data analysis is not tenable here. FRIs comprise 0.8% of the missing VAERS IDs (0.2% of total FRIs reported to VAERS).

### 3.2.1 Death data comprises 13% of missing data

Although the absolute number of missing VAERS IDs may not be high, of this small subset of deleted data, 13% of total missing AEs are deaths. The total number of deaths is 199 and in each sequential iteration of the anti-joining of the datasets, death remained at the highest or near highest frequency for missing AEs in each "SYMPTOM" list for the extracted missing data set, save for SYMPTOM column 5, which rarely contains the primary or most prevalent AE reported per individual. For example, of the 5 SYMPTOM column variables representative of the reported AEs, SYMPTOM column 1 primarily contains the most prevalent AE listed and has 'COVID-19' as the #1 most frequently occurring missing report (22%) with 'Death' at #2 (15%). This missing death data comprises 3% of the total VAERS death reports.

Figure 5: A histogram plot showing distribution of missing death data according to age group

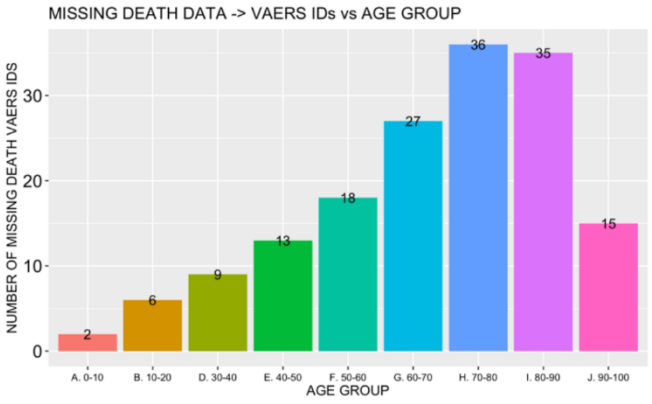
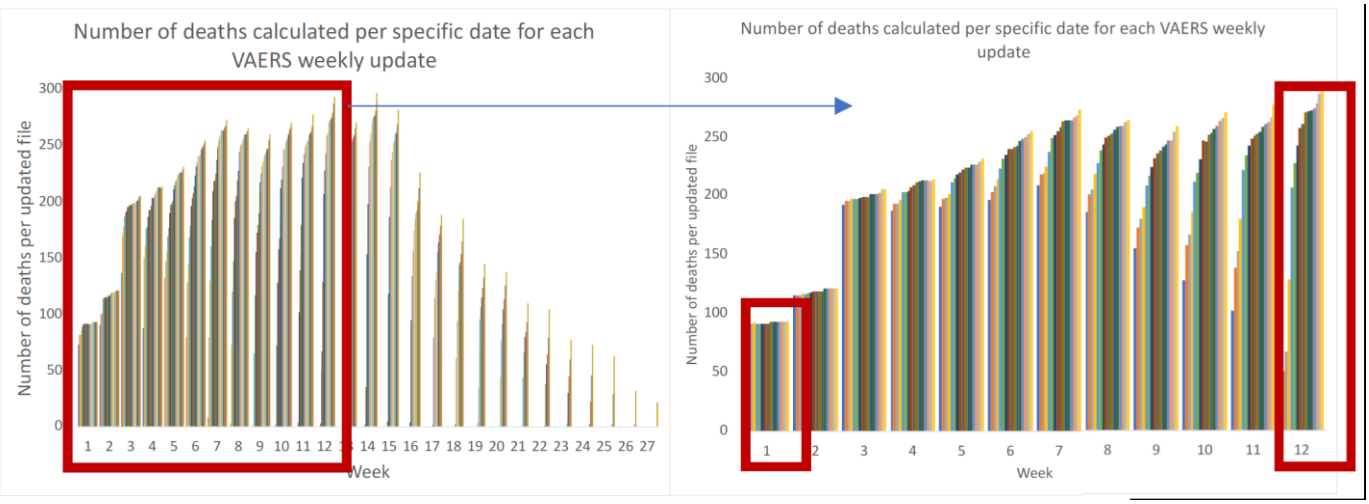



Figure 5 shows that the distribution of deleted death data is asymmetric, unimodal and not skewed in a statistically significantly way toward any specific age group in this data set (Figure 7 (I)=0.7). Of the missing death data, 15% of reports were made within 24 hours and 28% of reports were made within 48 hours indicating a clustering of reports in very close temporal proximity to the injection.

### 3.3 Redundancy deletions versus deletions for unknown reasons in death reports

There are 199 deleted death entries to date from the VAERS database and 214 deleted death entries to date collected from the VAERS Wayback Machine. The discrepancy of 15 deleted deaths, which accounts for 3% of all reported deaths, arises from deletions of individuals in a 'foreign location' that are not included on the publicly available Domestic dataset. The deleted death data list can be found in the Supplementary materials. Deletions of redundant entries are marked by NA in the 'True deletions' column and the accompanying new VAERS IDs are listed. Deletions due to unknown reasons are marked by TRUE value in the 'True deletions' column. Of the total list, 59% were found to be redundant entries and 41% of the entries were true deletions. For the remaining 1317 non-death-related AEs, a cross-reference search would need to

Figure 6: Bar plots showing the discrepancies in cumulative data by slope of increase at the beginning of the data versus slope of decrease at the end (current update)




be completed in future work to discover what percentage of total missing AEs are true deletions.

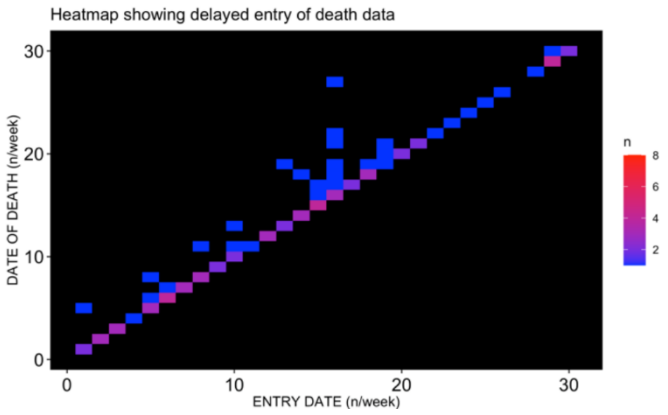
### 3.4 Unexplained lag in data input

An anomaly in the data pertaining to data entry times when compared to onset of AE dates can be seen when total AE counts reported in the most recently updated publicly-available VAERS dataset (updated August 6th, 2021) are compared with total AE counts as per VAERS weekly updates. To date, there are 28 sets of data, and discrepancies can be found between the files from update to update. This would not necessarily be perceived by a data analyst if they were simply looking at the data from the most recently uploaded data to the VAERS system. One would only notice this discrepancy if simultaneously analyzing the individual sets as compared with the most recently updated set by update date. If the VAERS system was functioning as a pharmacovigilance system and in fact passive, these data sets would be expected to follow the same trajectory. Evidently, there are two trajectories, and they are not similar quantitatively or qualitatively.

Figure 6 (left) shows the number of deaths for each specific update date per week. For example, the first row of bars with x-axis marker '1' shows the number of deaths for each of the updates according to weeks 1–27 (01/30/21–07/30/21). A closer look (examining only weeks 1–12 for clarity) at Figure 6 (right) reveals that the number of deaths were essentially equal for the first 12 updates for week 1. By week 12, this number started to change with respect to week-by-week calculations of death counts. If we observe the slope of the difference in absolute number in the data per update date, it is increasing quite consistently as the week number increases. This is precisely what we would expect to see if data were being retroactively added. The inconsistency is the increasing slope that emerges. It should not be increasing – not even remotely. The only increase we would expect to see is a grouped increase over a week. Absolute numbers should not change per week with respect to weekly data already entered. Thus, if data are being retroactively added, then we would see changes reflected per week as shown in the red rectangle on the right in Figure 6 (right).

Another way to visualize this phenomenon is using a heatmap. Figure 7 is a correlation plot illustrating the number of deaths per week for death week versus the week of entry into the VAERS

Figure 7: Heatmap showing the delayed death data entries where n is the number of deaths per intersection tile




database. Any entry that is not on the diagonal is an entry that was not entered on the week that the person died. 21 tiles (42%) representing n>1 deaths indicates that many entries were entered well after the death date. In one case, the AE was entered 77 days post death. This is clear evidence of death data being retroactively added. Considering that death certificates can take time to be processed, it is to be expected that some death entries to VAERS would occur quite temporally distal to the date of death, but this is a phenomenon that was observed for any AE checked.

### 3.4.1 Why does this matter?

This corroborates the hypothesis that there is a lag-phase between reporting and recording of data. The duration between reporting following onset of an AE reaction and recording into the VAERS publicly available data varies from a few days to many months. Figure 8 shows the difference in data with respect to the data as per weekly update and to the updated data as of August 6th, 2021, for all SAEs. The black shaded area represents data that is in excess with regards to the data originally presented to the public. The data under the blue line is the most recently update data and the data under the red line is the weekly updated data. The most alarming observation from this figure, however, is the amount of data that was present early on that simply was not publicly available at the time that they were generated. For example, the Δ cumulative AEs between the individual updated data for week 10 is 19,536. The Δ time in weeks is 7.6. This means that almost 20,000 SAEs that should be observable in the publicly available VAERS Domestic dataset were not present at the time they occurred and were originally reported. This means that only 7,065 (red)/26601 (blue) = ~20% of the actual SAEs as of that date (week 1) were entered into the database.

Only after a lag time of almost 2 months did this data become visible. If week 5 is examined, this lag-time becomes 10 weeks (Figure 8 - right). It is only recently that these data were made visible and this is most likely due to a huge backlog being tended to. The fact that the data sets have converged is due to the backlog being sufficiently dealt with. This phenomenon was found to exist to varying degrees in all AEs checked. Figure 9 shows 3 representative plots for Chills, Death and Breakthrough COVID-19 AEs. It is fortunate (in a way) that the death data does not seem to have been a victim of the lag like some others. This phenomenon was also not dependent on an AE being mild or severe but the degree to which the phenomenon occurred in each AE is yet to be ascertained. This can be checked.

Another way to assess temporal differences in data entry is to calculate the number of days between the onset date (ONSET_DATE)[15] and the date that the AE was input into the VAERS database (TODAY'S_DATE)[16] using only the most recent updated file. For example, the difference between the completed form entry date and the onset of the AE date should be the same for any two

15 Onset Date: The date of the onset of adverse event symptoms associated with the vaccination as recorded in the specified field of the form.
16 Today's date: The date the form was completed.

Figure 8: Shaded plots showing the SAE data as they were input per respective update (grey shaded region) compared with these data as they are reported in each individual updated file (black)

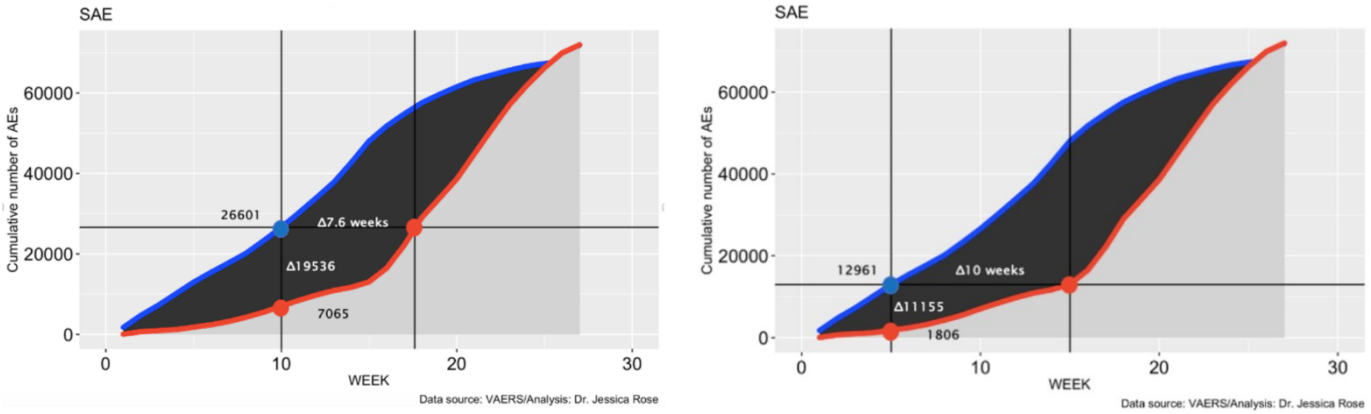
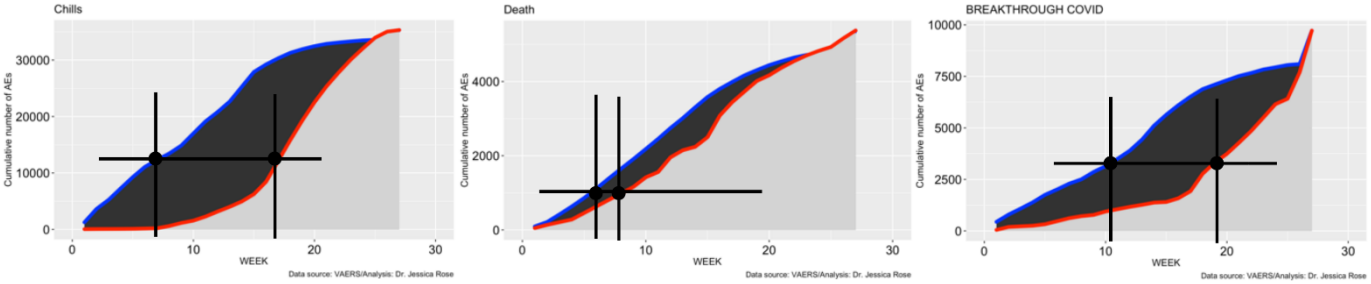


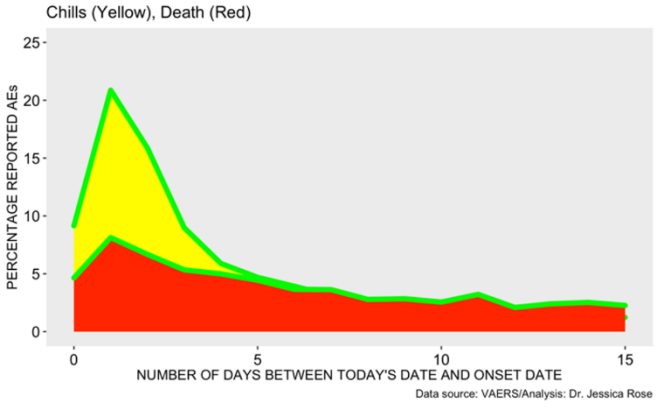

Figure 9: Shaded plots showing the Chills, Death and Breakthrough COVID AE data as they were input per respective update (grey shaded region) compared with these data as they are reported in each individual updated file (black)




randomly selected AEs. If there was a difference between the percentages of reports made for any two AEs, based on the difference between entry date and onset of AE date, then this would require explanation, especially if the difference was statistically significant. The most frequently reported AE in the VAERS system in the context of COVID-19 products is "Chills". I chose this AE as a positive control against deaths in the context of whether or not these two AE types were being added to the publicly available VAERS database in the same way, temporally.

Figure 10 shows the percentages of reported Deaths and Chills as a starting point for the comparison. The T-test confirms a statistically significant difference between the respective means of the Death and Chills AEs with regards to differences

Figure 10: Time series plot showing percentages of Chills (green/yellow) and Death (green/red) of the total VAERS dataset (as of update July 30th, 2021) against the number of days calculated in between the entry date of the report into the database and the onset date of AE for up to 15 days' difference

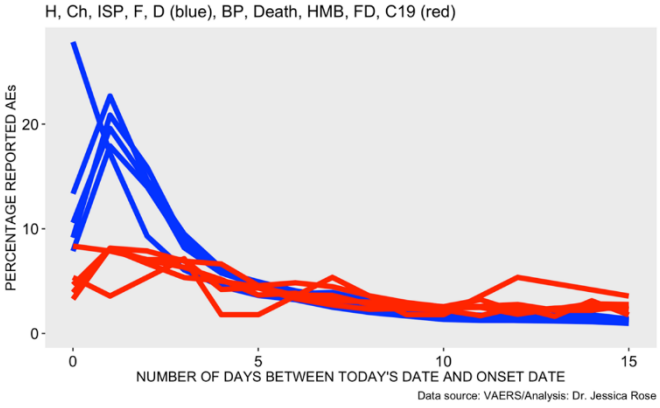


in reporting times following onset of AE with a p-value = 0.005. The figures show areas under the curves generated to demonstrate how many more entries were made in the case of Chills than for Death within the first 5 days following onset of AE.

### 3.4.2 Lag time dependency on AE type?

Figure 11 shows the percentages of reported Deaths, Bell's palsy, Heavy menstrual bleeding, Myocarditis, Injection site pruritis, Chills, Headache, and Fatigue data against the differences in days between their onset dates and the entry dates into the Domestic front-end VAERS system that is available for download. These 10 were selected since 5 are classified as severe and 5 are classified as mild.

Figure 11: Time series plot showing percentages of reported Headache (H), Chills (Ch), Injection site pruritis (ISP), Fatigue (F), Dizziness (D) (blue), Bell's palsy (BP), Death (D), Heavy menstrual bleeding (HMB), Foetal death (FD), COVID-19 (C19) (red) of the total VAERS dataset (as of update July 30th, 2021) against the number of days calculated in between the entry date of the report and the onset date of AE




There is a clear difference in the percentages of reports made between the mild AEs: Headache (H), Chills (Ch), Injection site pruritis (ISP), Fatigue (F) and Dizziness (D) and severe AEs: Bell's palsy (BP), Death (D), Heavy menstrual bleeding (HMB), Foetal death (FD), COVID-19 (C19). In the case of the mild AEs listed, the area under the curves (AUCs) are greater than the AUCs in the first few days following the onset of the AE. In the cases of the more severe AEs, <10% of reports were entered within the first few days. It is yet unclear whether or not this is a coincidence.

### 3.5 Are SAEs being downgraded to MAEs each week?

The rate of SAE occurrence according to VAERS data is 19% (nSAE/N reports to VAERS (%)). If we use only Pfizer data, this rate increases to 21%. If we normalize to dose number, we get 0.02% rate of SAE (nSAE/N doses) so this translates to ~1/5000 individuals succumbing to a SAE. There is variation between the criteria that the CDC uses to determine SAEs in VAERS and the medical definition of SAEs [4,5,6,7]. This raises the question of whether specific SAE reports in VAERS are downgraded over time to MAEs. The short answer is no. To determine whether or not SAEs were being downgraded to mild AEs, I semi-joined the datasets for a selected update date

Table 1: Calculated SAE and MAE differences between reference file and original file for 10 sample update files downloaded from VAERS

| | | | | | | | | | | | Reference Update (RU) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Δ (date-RU) | 03_05_21 | 03_12_21 | 03_19_21 | 03_26_21 | 04_02_21 | 04_09_21 | 04_16_21 | 04_23_21 | 04_30_21 | 05_07_21 | 05_14_21 | **21_05_21** |
| Δtotal AE count | 86 | 118 | 105 | 124 | 94 | 94 | 93 | 120 | 162 | 149 | 77 | 0 |
| ΔSAE count | 14 | 38 | 35 | 49 | 23 | 28 | 28 | 53 | 107 | 98 | 49 | 0 |
| ΔMAE count | 72 | 80 | 70 | 75 | 71 | 66 | 65 | 67 | 55 | 51 | 28 | 0 |
| Δ% SAE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Δ% MAE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(03/05/21) with 10 sequential updates to maintain the same smaller cohort within the data frames. This allowed the comparison of the original SAE and MAE counts to the original counts for the individual dataframes to check if the counts were changing as updates were being added. None of the SAE counts were different when compared to semi-joined dataframes which means that SAEs are not being downgraded to mild AEs as the updates come in (Table 1). The discrepancies in deltas seen in adverse events (and thus both SAEs and MAEs) are most likely due to variations in data reporting and recording that are known.

## 4 Discussion

Functioning pharmacovigilance in VAERS was examined in this study. It appears from this short appraisal that although VAERS could be a functioning pharmacovigilance system, it is not being used as such. The only reference to legitimate deletion of data from the VAERS system was in the VAERS/WONDER 'Reporting Issues' section, which claims that 'Duplicate event reports and/or reports determined to be false are removed from VAERS'. Despite this 'disclaimer', there is no way to check or validate 'falseness' of data that may have been removed. This means that, in the case of deleted deaths, which represent 3% of all death data, their removal needs to be explained. These deaths were reported to VAERS and recorded by hired CDC contractors. They represent people who died in temporal proximity to having been given an as-yet non-FDA-approved, experimental transfective biological product by intramuscular injection. They cannot simply be deleted. Something worth noting was the commonality in deleted entries where a causality relationship between the injections and the AE was not only implied but also suggested by the sender, which is typically the physician or emergency-room physician who attended to the individual's case. Refer to Supplementary Table 1 for deleted death entries in the VAERS Wayback machine.

Trained contractor staff are required to enter each VAERS report into the database, and if it should be deemed necessary to delete a VAERS ID from this database once entered, then it must be documented with a valid reason for the deletion. In addition, when a VAERS ID number is changed to a new number, this should also be documented by contractor staff. It has been suggested that vaccine-induced deaths have been classified as COVID-19 deaths. If this is the case, then deaths are being skewed away from the elusive vaccine-induced death count toward the COVID-19 death count [33,34]. It is unscientific to deny any possibility that the injections are the possible cause of the injuries, particularly in some cases where the clear temporal proximity makes this possibility a high probability [8,35]. If this denial was implemented into a system of denial, it would most likely manifest in this way.

VAERS was designed to reveal potential risk signals from data, but if these signals are not detectable as they are received, then they are not useful as timely warnings. There is evidence that the VAERS data are being entered into the publicly available dataset much later than one would expect, considering that this is a passive system. It is conceivable that death AEs have extended processing times for the issuance of death certificates, but there would be no reason for other AEs, severe or mild, to have delays with regards to data entry, especially not delays greater than 4 weeks. Public health policy decisions on expanding the vaccination program might have been made differently if the true rates of reported SAEs and deaths had been known in real time. Similarly, if individuals knew of SAEs and deaths occurring so early on in the rollout, and also that the percentage of SAEs is atypically high, then perhaps they would have exercised their rights to informed consent, declined these injections or simply waited for safety data to come in. This is precisely what the VAERS

system is designed for in its pharmacovigilance task: to warn policy makers and individuals of potential risks not detected during clinical trials. If there is a large backlog of data, then more trained staff need to be hired to expedite data entry to ensure that the VAERS system is able to deliver safety signals as they are reported. In the case where late entry of data occurs due to another reason, then this needs to be acknowledged, investigated and remedied. The evidence provided herein lends to the hypothesis that data is being entered according to AE severity. This alone requires investigation.

As a point of concern with regards to CDC safety signal metrics, as defined in section 2.3.1 in the SOP, the proportional reporting ratio (PRR) is used to define safety signals originating from VAERS. The PRR is a metric that compares the ratio of specific AEs to total AEs for vaccine products. It is defined as:

$$PRR = \frac{\left[\frac{a}{(a+b)}\right]}{\left[\frac{c}{(c+d)}\right]}$$

where a = specific AE for specific vaccine; b = all other AEs for specific vaccine; c = specific AE for all other vaccines; d = all other AEs for all other vaccines [36,37]. However, this technique is inherently flawed in that the PRR does not change when the specific vaccine-related AE event counts are very large or very small [34,36,37,38]. Therefore, the scaling factor that arises due to the excess of specific AEs is normalized to the total number of AEs, and this ratio is then again normalized to the total for all other vaccines. This is a problem in the context of the COVID-19 injectable products since both the specific AEs and the total number of AEs are atypically high. This means that no matter how many times higher the death rate, for example, the PRR will be the same as it would be for a product that was not killing people at all. The PRR, therefore, on its own, cannot be used as reliable a safety signal detection metric – it does not work.

To be clear, the absolute number of AEs reported in the context of the COVID-19 products is approximately 11x higher than for all the reported AEs for 2020 combined. The absolute number of deaths reported is approximately 42x higher than for all deaths reported for 2020. However, the PRR does not emit a safety signal even though the number of deaths is 266 times higher in the context of the COVID-19 products when compared to INFLUENZA products [32]. In spite of peer-reviewed studies noting significant association of COVID-19 injectable products with Bell's palsy, thrombocytopenia and myocarditis [39,40,41,42], the CDC maintains the position that no specific safety concerns have been identified with regards to SAEs [8,31,43,44,45]. In a recent CDC report titled 'Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19 Vaccine' [44], 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 SAEs involving system organ classes and specific preferred terms were balanced between vaccine and placebo groups and presented at a mere 0.5%, and 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, which is false [43,44,45].

One more discussion point that is worth its own publication but will be added as a point of interest in this study is the Under-Reporting Factor (URF) of AEs. Under-reporting is a problem in pharmacovigilance systems, VAERS included. VAERS is a passive reporting system, and it has been suggested as part of a Harvard study that a mere 1% of AEs are reported to VAERS [46]. However, this is not necessarily the case, nor is it

universally applicable for all products; certainly not for distinct AEs. For example, under-reporting of mild AEs such as rashes or low-grade fever would most likely be far greater than for SAEs, such as death. To calculate the URF, the expected number of SAEs ($E_{SAE}$) is divided by the observed number of SAEs ($O_{SAE}$). The $E_{SAE}$ is calculated by multiplying the total number of doses administered in the U.S. (assuming a single dose can result in an AE) by the number of SAEs recorded in COVID-19 product safety trials. According to the FDA Safety Overview of the Pfizer/BioNTech COVID-19 product (Study C4591001 – refer to section 5.2.6 page 33) [47,48]. 0.7% of Pfizer/BioNTech COVID-19 product recipients suffered SAEs. As of August 10th, 2021, 197,399,471 million Pfizer/ BioNTech COVID-19 product doses had been administered in the U.S. [49,50] and therefore the number of expected SAE occurrences in the U.S. volunteer recipients of the Pfizer/BioNTech products should be ~1.4 million SAEs, if we use this reported rate. Thus, the ratio of $E_{SAE}$ to $O_{SAE}$ is 31 to 1, suggesting a URF of 31 ($N_{SAE\_Pfizer\_trial}/N_{SAE\_Pfizer\_VAERS}$ = ~1.4M/43,948). Using this URF for all VAERS-classified SAEs, estimates to date are as follows: 205,809 dead, 818,462 hospitalizations, 1,830,891 ER visits, 230,113 life-threatening events, 212,691 disabled and 7,998 birth defects to date [38]. Since the URF for MAEs is very likely larger than for SAEs, it is satisfactory to assume that 31 is a humble estimate URF for all AEs (refer to Supplementary Table 2). Relative reporting rates are also shown in Supplementary Table 2 to demonstrate that that AE reports associated with COVID-19 products are much higher than for previous years. For all symptoms listed in red, we limited the search to 20–60-year-olds since these people are less noisy with respect to symptoms and younger people aren't yet vaccinated. All fields color-coded yellow contain observed/expected incidence rates >100, and these only occur in the non-control AEs, such as reported AEs that are presumably unrelated to the vaccines, like 'Lyme disease', seen in blue and green in Supplementary Table 2.

## 5 Conclusion

It cannot be stressed enough when referring to VAERS data collected in the context of the COVID-19 injectable products that 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 [51–56]. Because of the low Infection Fatality Rate, 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 hydroxychloroquine and Ivermectin showing extremely positive results in patients [57–68], it is also unclear why these drugs are not being more extensively promoted as effective tools in the fight against this virus. What is clear is that the injectable products are proving unsafe for many individuals and inefficacious in others (see Israeli data in Supplementary Material). As part of the WHO's own minimum requirements for a functioning pharmacovigilance system, sub-standard products need to be removed from circulation to ensure patient safety. Since VAERS is capable as a functioning pharmacovigilance system as it reveals safety issues with the COVID-19 biologicals, it should be used as such, but it is not.

Despite the low frequency of missing VAERS IDs, data have been deleted from the VAERS database, and this requires explanation, not only ethically but also because it lends to the possibility of inexact measurements of death counts and therefore can potentially lead to missed signals. Statistical power is primarily influenced by sample size (also effect size and significance level), and the

bigger the sample size, the higher the statistical power. The deleted data from the total VAERS ID count are individuals enrolled in post-market surveillance human-subject studies: the whereabouts of their VAERS reports of death need to be accounted for. There is absolutely no reason for these data to be missing, from what can be ascertained. If the data were false, as was suggested as the only reason to delete an entry, then there needs to be a record of this edited data made available with the publicly available VAERS data.

Data are being retroactively added to the VAERS database far later than would be expected for the system to be considered a timely, functioning pharmacovigilance system. This could be explained by manual curation of a large backlog of data. However, if AEs are being entered differentially, with respect to time, based on severity, then we all must ask the difficult question: "Why?" Again, VAERS was designed to reveal potential risk signals from data, but if these signals are not detectable as they are received, then they are not useful as warnings and pharmacovigilance becomes moot. The duration between reporting following onset of an adverse event reaction and recording into the VAERS publicly available data varies from a few days to many months. If earlier information was available to public health policy-makers and to the public, including the off-the-charts prevalence of SAEs (19%) and deaths, then perhaps the decision to volunteer to have these products injected would have been more prevalently declined or simply put on hold until more safety data had accumulated. This, again, is part of pharmacovigilance that has failed with regards to assessment of risk/benefit management.

According to this analysis, VAERS IDs are not being downgraded from SAEs to mild AEs. In fact, the percentage of SAEs continue to increase from month to month. Even without considering the URF, the ratio of fully vaccinated individuals succumbing to an adverse event is high. With approximately 1 in every 400 individuals experiencing an adverse event (~1 in every 25,000 for death) in the context of the COVID-19 fully vaccinated population in the United States, it is therefore unclear why these injections are continuing to be used in the human population, especially since no long-term effects are known and no long-term data exists, to date. It was important to contextualize death counts since a disproportionate number of all the missing data AEs are deaths.

It may appear that the number of missing VAERS IDs is nothing to be concerned about from an analytical point of view, but I remind the reader that these are not just data: they are people. This report addressed three issues that respond to the question of VAERS pharmacovigilance by analyzing VAERS data in relation to: 1. deleted reports, 2. delayed entry of reports, and 3. recoding of MedDRA terms from severe to mild.

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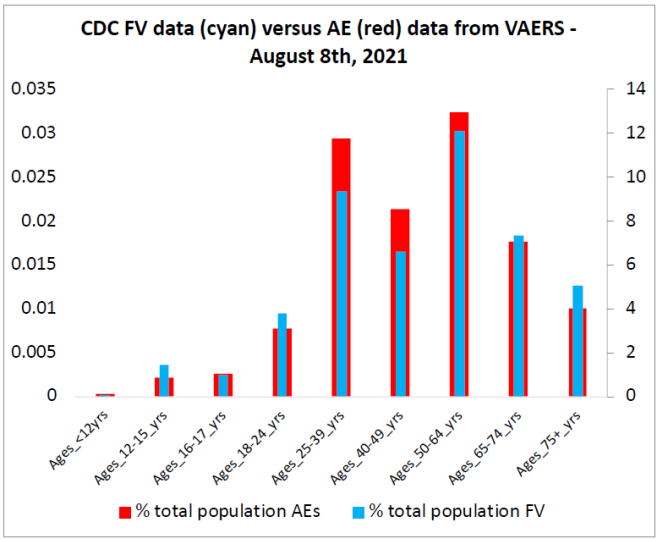
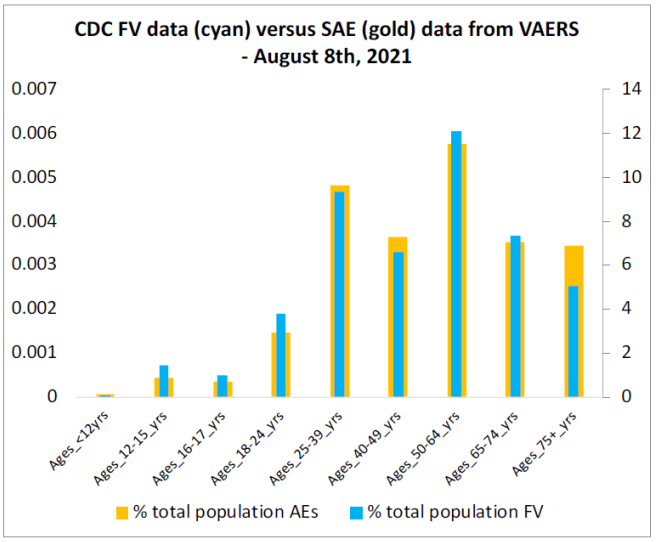
## 7 Supplementary Materials

Supplementary Figure 1: Injection rates in each age group in the general population compared to the total AE VAERS reports (above) and total SAE VAERS reports (below)



Supplementary Table 1: The true deletions shown in the context of all missing data. The new VAERS IDs assigned to the redundant entries are also shown.

| Count | VAERS ID missing | New VAERS ID | True deletions | DIED classification (B&A) | Adverse Event | Deleted from date |
|---|---|---|---|---|---|---|
| 1 | 918723 | N | TRUE | Y(Location: foreign) | Death | 1/7/21 |
| 2 | 923149 | N | TRUE | Y(Location: foreign) | Death | 1/7/21 |
| 3 | 930386 | N | TRUE | Y | Death | 1/15/21 |
| 4 | 930418 | N | TRUE | Y | Death | 1/15/21 |
| 5 | 934963 | N | TRUE | Y | Death | 1/15/21 |
| 6 | 937985 | N | TRUE | Y(Location: foreign) | Death | 1/15/21 |
| 7 | 940950 | N | TRUE | Y | Death | 1/15/21 |
| 8 | 940954 | 930466 | NA | Y/Y | Death | 1/15/21 |
| 9 | 944273 | N | TRUE | Y | Death | 1/15/21 |
| 10 | 944385 | N | TRUE | Y | Death | 1/22/21 |
| 11 | 944659 | 944641 | TRUE | Y/Y | Death | 1/15/21 |
| 12 | 946097 | 935767 | NA | Y/Y | Death | 1/15/21 |
| 13 | 947974 | 940955 | NA | Y/Y | Death | 1/22/21 |
| 14 | 949547 | 945253 | NA | Y/Y | Death | 1/22/21 |
| 15 | 951960 | 985715 | NA | Y/Y | Death | 1/29/21 |
| 16 | 955878 | N | TRUE | Y | Death | 1/22/21 |
| 17 | 957321 | N | TRUE | Y(Location: foreign) | Death | 6/11/21 |
| 18 | 960437 | N | TRUE | Y | Death | 1/22/21 |
| 19 | 964729 | 1329449 | NA | Y/NA | Death | 1/29/21 |
| 20 | 964956 | 962940 | NA | Y/Y | Death | 1/29/21 |
| 21 | 966236 | Dead in 30 mins | TRUE | Y | Death | 1/29/21 |
| 22 | 970044 | 950533 | NA | Y/NA | Death | 1/29/21 |
| 23 | 970139 | 950441 | NA | Y/Y | Death | 1/29/21 |
| 24 | 970161 | ITP? | TRUE | Y | Death | 1/29/21 |
| 25 | 971561 | 962325 | NA | Y/Y | Death | 1/29/21 |
| 26 | 971800 | 921768 | NA | Y/Y | Death | 1/29/21 |
| 27 | 978872 | 971969 | NA | Y/Y | Death | 2/4/21 |
| 28 | 982778 | 935815 | NA | Y/Y | Death | 1/29/21 |
| 29 | 983482 | 978959 | NA | Y | Death | 2/4/21 |
| 30 | 999818 | N | TRUE | Y(Location: foreign) | Death | 2/12/21 |
| 31 | 1000669 | 986901 | NA | Y/Y | Death | 2/4/21 |
| 32 | 1000910 | 977186 | NA | Error: Wrong Patient (documentation in EMR) | Unevaluable | 2/4/21 |
| 33 | 1004651 | N | TRUE | Y | Death | 2/18/21 |
| 34 | 1011588 | 985527 | NA | Y/NA | Death | 2/18/21 |
| 35 | 1017127 | 989006 | NA | Y/Y | Death | 2/12/21 |
| 36 | 1020144 | 994544 | NA | Y/Y | Death | 2/12/21 |
| 37 | 1024103 | N | TRUE | Y | No death | 2/12/21 |
| 38 | 1024731 | 1024592 | NA | Y/Y | Death | 2/12/21 |
| 39 | 1045540 | 939050 | NA | Y/Y | Death | 4/1/21 |
| 40 | 1048687 | N | TRUE | Y | Cerebrovascular Accident | 3/5/21 |
| 41 | 1051447 | Litigation request | TRUE | Y | Death | 3/11/21 |
| 42 | 1064933 | | TRUE | Y(Location: foreign) | Death | 8/6/21 |
| 43 | 1074247 | N | TRUE | Y | Death (2 y/o) | 4/1/21 |
| 44 | 1076914 | N | TRUE | Y | Death | 3/19/21 |
| 45 | 1102077 | 1090801 | NA | Y/Y | Death | 3/19/21 |
| 46 | 1108447 | 1145662? (JJ?P?) | NA | Y/Y | Death | 4/1/21 |
| 47 | 1108969 | 1096497 | NA | Y/Y | Death | 3/19/21 |
| 48 | 1113963 | 1084036 | NA | Y/Y | SARS-CoV-2 | 3/19/21 |
| 49 | 1122171 | 1084419/1126060 | NA | Y/Y | Death | 4/1/21 |
| 50 | 1131199 | 1037207 | NA | Y/Y | Death | 4/1/21 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 51 | 1131598 | N | TRUE | Y | Death | 4/16/21 |
| 52 | 1131608 | 1123165 | NA | Y/Y | Death | 4/16/21 |
| 53 | 1133045 | 1059857 | NA | Y/NA | Death | 4/8/21 |
| 54 | 1137741 | N | TRUE | Y | ARDS | 4/1/21 |
| 55 | 1153083 | 1134651 | NA | Y/Y | Cerebrovascular accident | 4/1/21 |
| 56 | 1153539 | 1120952 | NA | Y/Y | Death | 4/8/21 |
| 57 | 1155507 | N | TRUE | Y | Death | 4/1/21 |
| 58 | 1157502 | 1098028 | NA | Y/Y | Death | 4/1/21 |
| 59 | 1161844 | | TRUE | Y(Location: foreign) | Death | 7/30/21 |
| 60 | 1162016 | N | TRUE | Y | Death | 4/16/21 |
| 61 | 1176029 | 940955 | NA | Y/Y | Death | 4/8/21 |
| 62 | 1179211 | N | TRUE | Y | Death | 4/8/21 |
| 63 | 1182768 | 1145183 | NA | Y/Y | Death | 4/8/21 |
| 64 | 1203204 | 1191979 | NA | Y/Y | Death | 4/16/21 |
| 65 | 1203633 | 1169518 | NA | Y/Y | Death | 4/16/21 |
| 66 | 1205852 | 1145526 | NA | Y/Y | Death | 4/16/21 |
| 67 | 1205973 | 1120315 | NA | Y/NA | Death | 4/16/21 |
| 68 | 1207253 | 1281778 | NA | Y/Y | Death | 4/16/21 |
| 69 | 1207999 | 1147303 | NA | Y/Y | Death (Changed 2x) | 6/11/21 |
| 70 | 1208299 | N | TRUE | Y | Death | 4/16/21 |
| 71 | 1209810 | N | TRUE | Y | Death | 4/23/21 |
| 72 | 1209975 | 1027051 | NA | Y/Y | Death | 4/23/21 |
| 73 | 1210750 | 1207989 | NA | Y/Y | Death | 4/16/21 |
| 74 | 1212517 | 1205423 | NA | Y/Y | Death | 4/23/21 |
| 75 | 1212701 | 230404 | NA | Y/Y | Death | 4/23/21 |
| 76 | 1213488 | 1122080 | NA | Y/Y | Death | 4/16/21 |
| 77 | 1215091 | N | TRUE | Y | Death | 4/16/21 |
| 78 | 1216074 | ? | TRUE | Y | Death | 4/23/21 |
| 79 | 1218081 | 1199455 | NA | Y/Y | Death | 4/23/21 |
| 80 | 1218343 | ? | TRUE | Y | Death | 4/30/21 |
| 81 | 1218740 | N | TRUE | Y | Death | 4/23/21 |
| 82 | 1219137 | 1171204 | NA | Y/Y | Death | 4/23/21 |
| 83 | 1219153 | N | TRUE | Y | Death | 4/23/21 |
| 84 | 1219898 | N | TRUE | Y | Death | 4/23/21 |
| 85 | 1220310 | 1033682 | NA | Y/Y | Death | 4/23/21 |
| 86 | 1221164 | 1221163 | NA | Y/Y | Death | 4/23/21 |
| 87 | 1223602 | 1039271 | NA | Y/Y | Death | 4/23/21 |
| 88 | 1223603 | 1044825 | NA | Y/NA | Death | 4/23/21 |
| 89 | 1223695 | 1104671 | NA | Y/Y | Death | 4/23/21 |
| 90 | 1227272 | 1202320? | NA | Y/Y | Death | 5/21/21 |
| 91 | 1227283 | 1160365 | NA | Y/Y | Death | 4/23/21 |
| 92 | 1228634 | 1101703 | NA | Y/NA | Death | 4/23/21 |
| 93 | 1229325 | N | TRUE | Y | Death | 4/23/21 |
| 94 | 1229793 | N | TRUE | Y | Death | 4/23/21 |
| 95 | 1230023 | 1214079 | NA | Y/NA | Death | 4/23/21 |
| 96 | 1231377 | ? | TRUE | Y | Death | 4/23/21 |
| 97 | 1232040 | 1116557 | NA | unk | Not Death | 4/23/21 |
| 98 | 1233431 | 1126563 | NA | Y/Y | Death (Changed 2x) | 6/11/21 |
| 99 | 1235812 | N | TRUE | Y | Death | 4/23/21 |
| 100 | 1235826 | 1199575 | NA | Y/Y | Death | 4/23/21 |

*Supplementary Table 1 continued*

| | | | | | | |
|---|---|---|---|---|---|---|
| 101 | 1237250 | N | TRUE | Y | Death | 4/23/21 |
| 102 | 1237773 | 1224121 | NA | Y/Y | Death | 4/23/21 |
| 103 | 1241174 | N | TRUE | Y | Death (Changed 2x) | 6/11/21 |
| 104 | 1242693 | 1198211 | NA | Y/Y | Death | 4/23/21 |
| 105 | 1242935 | 1137886 | NA | Y/NA | Death | 4/23/21 |
| 106 | 1243057 | 1230389 | NA | Y/Y | Death | 4/23/21 |
| 107 | 1243311 | 1230587 | NA | Y/NA | Death | 6/25/21 |
| 108 | 1243516 | 1225942 | NA | Y/Y | Death(16y/o) | 4/23/21 |
| 109 | 1244328 | 1199143/1363773? | NA | Y/Y | Death | 4/23/21 |
| 110 | 1246186 | N | TRUE | Y | Death | 4/30/21 |
| 111 | 1246844 | 1203534? | NA | Y/Y | Death | 4/30/21 |
| 112 | 1247482 | 1203475 | NA | Y/Y | Death | 4/30/21 |
| 113 | 1248103 | N | TRUE | Y | Death | 4/30/21 |
| 114 | 1249552 | 1000968 | NA | Y/NA | Death | 6/25/21 |
| 115 | 1250965 | N | TRUE | Y | Death | 4/30/21 |
| 116 | 1255689 | N | NA | Y | Death | 6/25/21 |
| 117 | 1255745 | N | TRUE | Y | Death (2 y/o) | 4/30/21 |
| 118 | 1261822 | 1155002? | NA | unk | Diabetes mellitus | 4/30/21 |
| 119 | 1262644 | 1168198 | NA | Y/Y | Death | 4/30/21 |
| 120 | 1263917 | ? | TRUE | Y | Death | 4/30/21 |
| 121 | 1266028 | N | TRUE | Y | Death (Changed 2X) | 6/25/21 |
| 122 | 1266783 | 1196113 | NA | Y/NA | Death | 4/30/21 |
| 123 | 1270090 | 1217275 | NA | Y/NA | Death | 4/30/21 |
| 124 | 1270235 | 1270229 | NA | Y/NA | Death | 4/30/21 |
| 125 | 1270697 | 1112773 | NA | Y/Y | Death | 4/30/21 |
| 126 | 1271195 | 1176003 | NA | Y/Y | Death | 4/30/21 |
| 127 | 1271332 | 1123229 | NA | Y/Y | Death | 4/30/21 |
| 128 | 1271352 | 1208360 | NA | Y/Y | Death | 4/30/21 |
| 129 | 1271604 | N | TRUE | Y | Death | 4/30/21 |
| 130 | 1271889 | 1025171 | NA | Y/NA | Death | 4/30/21 |
| 131 | 1276250 | N | TRUE | Y | Death (Changed 1x) | 5/21/21 |
| 132 | 1279436 | | TRUE | Y | Death (Changed 1X) | 7/16/21 |
| 133 | 1282687 | N | TRUE | Y | Death (Changed 1x) | 6/25/21 |
| 134 | 1284326 | | TRUE | Y(Location: foreign) | Death | 7/16/21 |
| 135 | 1284667 | 1401679 | NA | unk/Y | Adverse event | 5/7/21 |
| 136 | 1288451 | N | TRUE | Y | Death | 5/21/21 |
| 137 | 1292382 | 1230371 | NA | Y/Y | Death | 5/7/21 |
| 138 | 1292417 | 1124195 | NA | Y/Y | Death | 5/7/21 |
| 139 | 1293310 | 1291385 | NA | Y/Y | Death | 5/7/21 |
| 140 | 1293571 | N | TRUE | Y | Death (Changed 1x) | 7/2/21 |
| 141 | 1293685 | N | TRUE | Y | Death | 5/7/21 |
| 142 | 1313571 | 1311248 | NA | Y/NA | Death | 5/14/21 |
| 143 | 1323317 | 1286108 | NA | Y/Y | Death | 7/2/21 |
| 144 | 1327681 | 1327666 | NA | Y/Y | Death | 5/21/21 |
| 145 | 1329956 | 1291811 | NA | Y/Y | Death | 5/21/21 |
| 146 | 1330375 | 1213047 | NA | Y/Y | Death | 5/21/21 |
| 147 | 1330653 | N | TRUE | Y | Death | 5/21/21 |
| 148 | 1331099 | N | TRUE | Y | Death | 5/21/21 |
| 149 | 1332457 | N | TRUE | Y | Death | 5/21/21 |
| 150 | 1334003 | 1297262 | NA | Y/Y | Death | 5/21/21 |

*Supplementary Table 1 continued*

| | | | | | | |
|---|---|---|---|---|---|---|
| 151 | 1334181 | 1282119 | NA | unk/NA | Adenovirus test | 5/21/21 |
| 152 | 1334269 | 1334263 | NA | Y/NA | Death | 5/21/21 |
| 153 | 1334696 | N | TRUE | Y | Death | 5/21/21 |
| 154 | 1334875 | 1175722 | NA | Y/Y | Death | 5/21/21 |
| 155 | 1336138 | 1302428 | NA | Y/Y | Death | 5/21/21 |
| 156 | 1338402 | N | TRUE | Y | Death | 6/4/21 |
| 157 | 1338586 | N | TRUE | Y | Death | 6/25/21 |
| 158 | 1345049 | military | TRUE | Y | Death | 7/23/21 |
| 159 | 1345689 | 1161963 | NA | Y/Y | Death | 6/4/21 |
| 160 | 1349013 | | TRUE | Y | Death | 7/30/21 |
| 161 | 1349598 | 1307657 | NA | Y/Y | Death/Suicide (17 y/o) | 6/4/21 |
| 162 | 1351033 | N | TRUE | Y | Death | 6/11/21 |
| 163 | 1353097 | N | TRUE | Y | Death (15 y/o botch job) | 6/11/21 |
| 164 | 1355181 | 951678 | NA | Y/Y | Death | 6/4/21 |
| 165 | 1357031 | 1311693 | NA | Unk/Y | Bone biopsy | 6/4/21 |
| 166 | 1357033 | 12922137 | NA | Y/Y | Death | 6/4/21 |
| 167 | 1363909 | 1326951 | NA | Y/Y | Death | 6/4/21 |
| 168 | 1367961 | 1271213 | NA | Y/Y | Death | 6/4/21 |
| 169 | 1369944 | N | TRUE | Y | Death | 6/4/21 |
| 170 | 1371376 | 1356045 | NA | Y/Y | Death | 6/4/21 |
| 171 | 1371898 | N | TRUE | Y | Death | 6/4/21 |
| 172 | 1372095 | N | TRUE | Y | Death | 6/4/21 |
| 173 | 1372291 | 1371905 | NA | Y/Y | Death | 6/4/21 |
| 174 | 1373818 | 1355806 | NA | Y/Y | Death | 6/4/21 |
| 175 | 1374141 | | TRUE | Y | Death | 8/6/21 |
| 176 | 1383620 | 1382906 | NA | Y/Y | Death (15 y/o) | 6/11/21 |
| 177 | 1384697 | | TRUE | Y(Location: foreign) | Death | 7/16/21 |
| 178 | 1391003 | | TRUE | Y(Location: foreign) | Death | 7/16/21 |
| 179 | 1396407 | 1394314 | NA | Y | Death | 7/30/21 |
| 180 | 1409720 | 1385038 | NA | Y/Y | Death | 6/25/21 |
| 181 | 1412023 | | TRUE | Y(Location: foreign) | Death | 7/16/21 |
| 182 | 1412025 | | TRUE | Y(Location: foreign) | Death | 7/30/21 |
| 183 | 1412027 | | TRUE | Y(Location: foreign) | Death | 7/30/21 |
| 184 | 1412492 | 1209873 | NA | Y/Y | Death | 7/16/21 |
| 185 | 1414996 | | TRUE | Y | Death | 7/23/21 |
| 186 | 1416375 | N | TRUE | Y(Location: foreign) | Death | 7/9/21 |
| 187 | 1419174 | N | TRUE | Y(Location: foreign) | Death (foetus – no data) | 7/2/21 |
| 188 | 1420738 | 1154465 | NA | Y/Y | Death (MS) | 7/2/21 |
| 189 | 1423098 | 1381906 | NA | Y/Y | Death | 7/16/21 |
| 190 | 1425803 | 1108312 | NA | Y/Y | Death (JJ) | 7/2/21 |
| 191 | 1425809 | 1296197 | NA | Y/Y | Death (JJ:1805018) | 7/2/21 |
| 192 | 1425810 | 1396485 | NA | Y/Y | Death (JJ:1805018) | 7/2/21 |
| 193 | 1425811 | 1396378 | NA | Y/Y | Death (JJ:1805018) | 7/2/21 |
| 194 | 1426491 | 1437355 | NA | Y/Y | Death (JJ:1805018) | 7/2/21 |
| 195 | 1426828 | 1386841 | NA | Y/Y | Death (JJ:1805018) | 7/2/21 |
| 196 | 1426983 | 1355185 | NA | Y/Y | Death (JJ:1805018) | 7/2/21 |
| 197 | 1427916 | | TRUE | Y | Death | 7/16/21 |
| 198 | 1428844 | N | TRUE | Y(Location: foreign) | Death | 7/9/21 |
| 199 | 1428951 | | TRUE | Y(Location: foreign) | Death | 8/6/21 |
| 200 | 1429457 | 1406840 | NA | Y | Death (13y/o/myo/2nd shot) | 7/23/21 |
| 201 | 1432771 | | TRUE | Y | Death | 7/16/21 |
| 202 | 1435280 | N | TRUE | Y(Location: foreign) | Death | 7/9/21 |
| 203 | 1435440 | | TRUE | Y(Location: foreign) | Death | 7/30/21 |
| 204 | 1435941 | Causation susp | NA | Y | Death/Myo | 7/23/21 |
| 205 | 1437520 | 1338618? | NA | Y | Death | 7/23/21 |
| 206 | 1437660 | | NA | Y | Death | 7/16/21 |
| 207 | 1440209 | 1285387 | NA | Y/Y | Death | 7/16/21 |
| 208 | 1440557 | | TRUE | Y | Death | 7/23/21 |
| 209 | 1442083 | | TRUE | Y(Location: foreign) | Death | 7/30/21 |
| 210 | 1442096 | | TRUE | Y(Location: foreign) | Death | 7/30/21 |
| 211 | 1445472 | | TRUE | Y(Location: foreign) | Death | 7/30/21 |
| 212 | 1445472 | | TRUE | Y(Location: foreign) | Death | 7/30/21 |
| 213 | 1450091 | 1381906 | NA | Y/Y | Death | 7/16/21 |
| 214 | 1450342 | | TRUE | Y | Death | 7/30/21 |

*Supplementary Table 1 continued*

Supplementary Table 2: Table using Under-Reporting Factor (URF) conversion (30x) to demonstrate suggested actual numbers of AEs rather than simply reported values in VAERS.
Data source: VAERS/Analysis: Steve Kirsch, Dr. Jessica Rose

| Adverse Event (AE) | Observed AE 2021 (N) | Number AE (2015-2019) | Expected (Average/year) | Incidence Rate (AE) (N/Average per year) | URF adjusted (OBS*31) |
|---|---|---|---|---|---|
| Metal poisoning | 2.0 | 47.0 | 9.4 | 0.2 | 62.0 |
| Otitis media | 48.0 | 255.0 | 51.0 | 0.9 | 1,488.0 |
| Hepatitis | 331.0 | 1,457.0 | 291.4 | 1.1 | 10,261.0 |
| Bursitis | 189.0 | 395.0 | 79.0 | 2.4 | 5,859.0 |
| Conjunctivitis | 172.0 | 278.0 | 55.6 | 3.1 | 5,332.0 |
| Caesarean section | 38.0 | 97.0 | 19.4 | 2.0 | 1,178.0 |
| Wart | 1.0 | 7.0 | 1.4 | 0.7 | 31.0 |
| Rotator cuff syndrome | 55.0 | 148.0 | 29.6 | 1.9 | 1,705.0 |
| Breech delivery | 0.0 | 3.0 | 0.6 | 0.0 | 0.0 |
| Cancer | 31.0 | 132.0 | 26.4 | 1.2 | 961.0 |
| Diabetes | 155.0 | 284.0 | 56.8 | 2.7 | 4,805.0 |
| Obesity | 14.0 | 9.0 | 1.8 | 7.8 | 434.0 |
| Lyme disease | 42.0 | 53.0 | 10.6 | 4.0 | 1,302.0 |
| Abortion Spontaneous | 707.0 | 90.0 | 18.0 | 39.3 | 21,917.0 |
| Anaphylactic Reaction | 1,503.0 | 204.0 | 40.8 | 36.8 | 46,593.0 |
| Aphasia (inability to talk) | 1,184.0 | 55.0 | 11.0 | 107.6 | 36,704.0 |
| Appendicitis | 433.0 | 11.0 | 2.2 | 196.8 | 13,423.0 |
| Bell's Palsy | 2,637.0 | 133.0 | 26.6 | 99.1 | 81,747.0 |
| Blindness | 723.0 | 86.0 | 17.2 | 42.0 | 22,413.0 |
| Cardiac arrest | 719.0 | 14.0 | 2.8 | 256.8 | 22,289.0 |
| Chills | 61,972.0 | 4,725.0 | 945.0 | 65.6 | 1,921,132.0 |
| Cough | 9,637.0 | 1,002.0 | 200.4 | 48.1 | 298,747.0 |
| Deafness | 1,022.0 | 117.0 | 23.4 | 43.7 | 31,682.0 |
| Death | 6,639.0 | 90.0 | 18.0 | 368.8 | 205,809.0 |
| Deep vein thrombosis | 1,473.0 | 14.0 | 2.8 | 526.1 | 45,663.0 |
| Depression | 503.0 | 488.0 | 97.6 | 5.2 | 15,593.0 |
| Diarrhoea | 13,495.0 | 6,262.0 | 1,252.4 | 10.8 | 418,345.0 |
| Dyspnoea (difficulty breathing) | 20,674.0 | 194.0 | 38.8 | 532.8 | 640,894.0 |
| Dysstasia (difficulty standing) | 1,349.0 | 133.0 | 26.6 | 50.7 | 41,819.0 |
| Fatigue | 61,900.0 | 4,575.0 | 915.0 | 67.7 | 1,918,900.0 |
| Guillain-Barre syndrome (GBS) | 448.0 | 378.0 | 75.6 | 5.9 | 13,888.0 |
| Headache | 73,565.0 | 6,231.0 | 1,246.2 | 59.0 | 2,280,515.0 |
| Herpes zoster | 4,807.0 | 700.0 | 140.0 | 34.3 | 149,017.0 |
| Insulin resistance | 6.0 | 6.0 | 1.2 | 5.0 | 186.0 |
| Multiple organ dysfunction syndrome | 26.0 | 37.0 | 7.4 | 3.5 | 806.0 |
| Myalgia | 17,047.0 | 3,208.0 | 641.6 | 26.6 | 528,457.0 |
| Myocarditis | 671.0 | 73.0 | 14.6 | 46.0 | 20,801.0 |
| Neuropathy | 133.0 | 195.0 | 39.0 | 3.4 | 4,123.0 |
| Paraesthesia | 9,860.0 | 2,440.0 | 488.0 | 20.2 | 305,660.0 |
| Paralysis | 179.0 | 411.0 | 82.2 | 2.2 | 5,549.0 |
| Parkinson's disease | 26.0 | 5.0 | 1.0 | 26.0 | 806.0 |
| Pericarditis | 447.0 | 49.0 | 9.8 | 45.6 | 13,857.0 |
| Pruritus | 18,103.0 | 11,250.0 | 2,250.0 | 8.0 | 561,193.0 |
| Pulmonary embolism | 1,191.0 | 10.0 | 2.0 | 595.5 | 36,921.0 |
| Seizure | 2,362.0 | 431.0 | 86.2 | 27.4 | 73,222.0 |
| Completed suicide | 19.0 | 3.0 | 0.6 | 31.7 | 589.0 |
| Thrombosis | 1,588.0 | 45.0 | 9.0 | 176.4 | 49,228.0 |
| Tinnitus | 6,523.0 | 282.0 | 56.4 | 115.7 | 202,213.0 |
| **Total** | **324,649.0** | **47,112.0** | **9,422.4** | **3,758.3** | **10,064,119.0** |

Unrelated events (blue): The goal for symptoms like metal poisoning, hepatitis, and otitis media (shown in blue) is to look for the propensity to over-report this year. If this was just over reporting we'd see a rate increase for these symptoms that are unrelated to the vaccines and are not comorbidities.
Pre-existing comorbidities (green): These conditions like diabetes and cancer in the table above increase simply because of the increased number of people filing reports in 2021.
Symptoms: For all symptoms (Deaths and others), we limited the search to 20-60-year-olds since these people are less noisy with respect to symptoms and younger people aren't yet vaccinated [21].

Supplementary Table 3: Table showing injected versus un-injected individuals in the context of hospitalizations in Israel. Chart courtesy of Dr. Rafael Zioni. Data source: Israel Ministry of Health.

| Israel Confirmed Cases, July 4th – July 10th, Vaccinated* vs. Unvaccinated** | | | | |
|---|---|---|---|---|
| Age Group | Cases, Vaccinated | Cases, Unvaccinated | Percent of Cases Vaccinated | Percent of Population*** Vaccinated |
| 20-29 | 217 | 61 | 78% | 77% |
| 30-39 | 248 | 84 | 75% | 82% |
| 40-49 | 356 | 54 | 87% | 85% |
| 50-59 | 237 | 26 | 90% | 89% |
| 60-69 | 227 | 14 | 94% | 91% |
| 70-79 | 143 | 12 | 92% | 95% |
| 80-89 | 42 | 6 | 88% | 91% |
| קבוצת גיל | נדבקים מחוסנים | נדבקים לא מחוסנים | אחוז נדבקים מחוסנים | אחוז מחוסנים באוכלוסיה |
| ישראל, מקרי קורונה מאומתים, 4 ביולי עד 10 ביולי, מחוסנים לעומת לא מחוסנים | | | | |

*Source: Israel Ministry of Health Dashboard*
*https://datadashboard.health.gov.il/COVID-19/general*
** Vaccinated – 2 shots.*
*** Unvaccinated – No shots.*
**** Excluding population with 1 shot.*

## 8 Author statement

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https://www.nytimes.com/2020/09/02/opinion/coronavirus-

# Gerald Ford Rushed Out a Vaccine. It Was a Fiasco.

Trump should keep that in mind as he pushes for a coronavirus shot.

Sept. 2, 2020

**By Rick Perlstein**

Mr. Perlstein is the author of "Reaganland: America's Right Turn, 1976-1980."

Last week, news arrived that President Trump had lurched into what may be his most reckless obsession yet: His administration would probably seek an "emergency use authorization" for a Covid- 19 vaccine long before some scientists believe it would be safe to do so.

A spokesman for the Department of Health and Human Services immediately addressed the obvioussuspicion: "Talk of an 'October surprise'"— an attempt to manufacture good news just before the November election — "is a lurid Resistance fantasy."

As he does often, however, the president proudly admitted to the exact thing his underling insisted was inconceivable.

"The deep state, or whoever, over at the F.D.A.," he tweeted recently at Stephen Hahn, the commissioner of the Food and Drug Administration, "is making it very difficult for drug companies toget people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after Nov. 3. Must focus on speed and saving lives!"

To that end, the Centers for Disease Control and Prevention has notified public health officials across the country to prepare to distribute a coronavirus vaccine to health care workers and other high-riskgroups as soon as late October.

The president's desperate words betray a gamble: Yes, rushing out a vaccine in an emergency may save lives, but it can also jeopardize safety, further erode public confidence in vaccines — and possibly kill.

History offers Mr. Trump a cautionary tale. In February 1976, hundreds of soldiers at Fort Dix, N.J., contracted a new strain of the H1N1 virus that seemed to be a descendant of the one responsible for the1918 flu pandemic, which killed at least 50 million people worldwide and possibly as many as 100 million.

OPINION CONVERSATION

*Questions surrounding the Covid-19 vaccine and its rollout.*

- **As more vaccine mandates arrive, how will we handle verification?**
  Tom Frieden, a former director of the C.D.C., describes how a safe and securesystem could work.
- **What are the next steps for the U.S. in fighting the pandemic?**
  Two academics who have studied the disease make a case for tying specificgoals to every new Covid-19 policy.
- **Are vaccine mandates a problem for civil liberties?**
  Two writers from the A.C.L.U. argue that actually, it's quite the opposite.
- **How many people have died because of undervaccination?** Comparing different areas of the U.S. suggests there have been manypreventable deaths.

Back in those days, the World Health Organization twice a year convened a panel of experts to determine which strains of influenza should be included in that year's flu shots, then provided the necessary "seed virus" to manufacturers. President Gerald Ford, however, decided to leapfrog the protocol in the face of the news out of Fort Dix.

It was, after all, an election year, and Mr. Ford, who had risen to the presidency upon Richard Nixon's resignation 19 months earlier, was seeking his first full term.

On March 22, Mr. Ford met with senior administration officials, who recommended a mass vaccination program. A memo marked "the president has seen" warned of "the ingredients for a pandemic" though also noted that "an argument can be made for taking no extraordinary action."

But Mr. Ford was advised that Congress would likely act anyway — which meant they, not he, would get the credit for a potentially heroic decision — and that the government "can tolerate unnecessary health expenditures better than unnecessary death and illness." He was also reminded of a significant political consideration: "Congress, the media and the American people will expect some action."

Two days later, he met with a so-called blue ribbon panel of experts and then appeared before televisioncameras. Telling reporters that "we cannot afford to take a chance with the health of our nation," he announced that he was requesting an immediate $135 million congressional appropriation "for the production of sufficient vaccine to inoculate every man, woman and child in the United States."

He went on to say that he was directing what was then known as the Department of Health, Educationand Welfare "to develop plans that would make this vaccine available to all Americans" in the fall.

An unnamed official at the W.H.O., which had not been consulted, expressed his organization's surprise in widely quoted comments, and noted that "no other countries have plans for mass inoculations" against what was popularly known simply as swine flu.

U.S. officials immediately pressured the W.H.O. to endorse Mr. Ford's decision. And, as the historian George Dehner noted, "The pressure worked: by the next day W.H.O. officials were quoted in the news media as stating, 'W.H.O. endorses President Ford's plan for massive inoculation against swine flu virus.'"

That fall, celebrities lined up to get jabbed with the vaccine before cameras to set an example — including the president, sleeve rolled up, in the Oval Office. On "Saturday Night Live," Chevy Chase did his famous Ford impression sporting a syringe in his arm during a debate against Dan Aykroyd's Jimmy Carter.

As it turned out, the H1N1 strain never made it out of Fort Dix, where only one Army recruit died. And,as it also turned out, this swine flu was not nearly as virulent as the 1918 influenza.

But fast-tracking the vaccine for broad distribution among the public carried risks. Of the 45 million vaccinated against the swine flu, an estimated 450 people developed the paralyzing syndrome Guillain-Barré and of those, more than 30 died. The National Academy of Medicine subsequently concluded thatpeople who received the 1976 swine flu vaccine had an increased risk for developing Guillain-Barré.

The emergence of Guillain-Barré led the government to suspend and effectively end its massvaccination effort in December.

In all, it's a complicated tale. Were the motivations behind the crash vaccination program political, or a sincere but perhaps misguided sense of urgency about the public health, or a little of both? Philip M. Boffey, a science writer at The New York Times, summed it up this way in an article headlined "Soft Evidence and Hard Sell."

> Has the government acted wisely in launching the swine flu inoculation campaign? Reasonable peoplemay reach conflicting answers. Critics consider the program a waste of money, and a potentially dangerous one at that, while proponents call it sound preventive medicine.
>
> It's clear that the scare tactics used to promote the campaign are unwarranted. Many participants in the drama have implied that another 1918 disaster is imminent. Health officials used that fear to help sell the program to their political superiors; President Ford used it to pry funding from Congress and to goad the American public to participate, and the media, ever on the lookout for a compelling news angle, repeatedly stressed the 1918 analogy. The result has been confusion and exaggerated fears that interfere with sound judgment.

That said, the very reason Gerald Ford had his job in the first place was that, when Vice President Spiro Agnew resigned in scandal just as the first inklings of the possible impeachment of Richard Nixonwere being raised, senators said they would confirm only a vice-presidential appointee who would provide a steady, mature hand on the tiller should he rise to the Oval Office. And that was precisely Gerald Ford's reputation.

If steady, mature Gerald Ford succumbed to haste when his presidency was on the line, imagine what Donald Trump will do. But maybe, just maybe, Mr. Trump can finally learn a lesson from history and move prudently, not impetuously, in rolling out new vaccines for Covid-19. And if that means they comeout after the election, so be it.

Jerry Ford's Hail Mary didn't work, after all: He lost to Jimmy Carter anyway. That's a history lesson even Donald Trump can understand.

Rick Perlstein is a journalist and historian.

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Research Article

Trends in Internal Medicine

# US COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, "All Cause Severe Morbidity"

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## ABSTRACT

*Three COVID-19 vaccines in the US have been released for sale by the FDA under Emergency Use Authorization (EUA) based on a clinical trial design employing a surrogate primary endpoint for health, severe infections with COVID-19. This clinical trial design has been proven dangerously misleading. Many fields of medicine, oncology for example, have abandoned the use of disease specific endpoints for the primary endpoint of pivotal clinical trials (cancer deaths for example) and have adopted "all cause mortality or morbidity" as the proper scientific endpoint of a clinical trial. Pivotal clinical trial data from the 3 marketed COVID-19 vaccines was reanalyzed using "all cause severe morbidity", a scientific measure of health, as the primary endpoint. "All cause severe morbidity" in the treatment group and control group was calculated by adding all severe events reported in the clinical trials. Severe events included both severe infections with COVID-19 and all other severe adverse events in the treatment arm and control arm respectively. This analysis gives reduction in severe COVID-19 infections the same weight as adverse events of equivalent severity. Results prove that none of the vaccines provide a health benefit and all pivotal trials show a statically significant increase in "all cause severe morbidity" in the vaccinated group compared to the placebo group. The Moderna immunized group suffered 3,042 more severe events than the control group (p=0.00001). The Pfizer data was grossly incomplete but data provided showed the vaccination group suffered 90 more severe events than the control group (p=0.000014), when only including "unsolicited" adverse events. The Janssen immunized group suffered 264 more severe events than the control group (p=0.00001). These findings contrast the manufacturers' inappropriate surrogate endpoints: Janssen claims that their vaccine prevents 6 cases of severe COVD-19 requiring medical attention out of 19,630 immunized; Pfizer claims their vaccine prevents 8 cases of severe COVID-19 out of 21,720 immunized; Moderna claims its vaccine prevents 30 cases of severe COVID-19 out of 15,210 immunized. Based on this data it is all but a certainty that mass COVID-19 immunization is hurting the health of the population in general. Scientific principles dictate that the mass immunization with COVID-19 vaccines must be halted immediately because we face a looming vaccine induced public health catastrophe.*

## Keywords

Clinical trial, Vaccines, COVID-19.

## Introduction

For decades, true scientists have warned that pivotal clinical trial designs for vaccines are dangerously flawed and outdated [1]. Vaccines have been promoted and widely utilized under the false claim they have been shown to improve health. However, this claim is only a philosophical argument and not science based. In a true scientific fashion to show a health benefit one would need to show fewer overall deaths during an extended period in the vaccinated group compared to a control group. Less stringent

indicators of a health benefit would include fewer severe events of all kinds, fewer days hospitalized for any reason, lower heath care expenses of all types, fewer missed days from work for any health reason. No pivotal clinical trial for a vaccine preventing an infectious disease has ever demonstrated an improvement in health using these scientific measurements of health as a primary endpoint. Instead, vaccine clinical trials have relied on misleading surrogate endpoints of health such as infection rates with a specific infectious agent. Manufactures and government agents have made the scientifically disproved and dangerous philosophical argument that these surrogate endpoints equate to a health benefit.

True medical scientists, outside the vaccine fields, have embraced the use of true health measurements as the proven proper scientific endpoint of clinical trials. Decades ago, a pharmaceutical manufacturer would only need to show that a chemotherapeutic agent shrank a tumor or reduce cancer deaths to obtain FDA approval. Manufacturers would market their products under the fraudulent philosophical argument that shrinking tumors or reducing cancer deaths equates to improved survival. However, many of the toxic chemotherapeutic agents would destroy vital organs and actually reduce survival while decreasing cancer deaths at the same time. The FDA and comparable agencies around the world switched to "all cause mortality" as the primary endpoint for pivotal cancer drug trails. The gold standard for marketing approval is to show that those receiving a cancer drug actually live longer than those who do not. Typically, new "miracle" anticancer drugs only prolong survival about 2 months but this added time may be spent severely ill suffering from adverse events caused by the chemotherapy. Application of true scientific principles often severely deflates the hype promoting pharmaceutical products.

All previous vaccine trials have suffered not only from lacking a proper primary clinical endpoint put also from insufficient perspective follow up of adverse events. The trials have failed to account for the well-established toxicity data and epidemiology data that vaccines are associated with chronic immune mediated disorders that may not develop for years after immunization. These adverse events, for example type 1 diabetes, are quite common, develop 3 or more years after immunization, and can exceed the reduction in infectious complications induced by the vaccine as was shown with a hemophilus vaccine [1]. Pivotal trials for the recombinant hepatitis B vaccine prospectively recorded adverse events for about 7 days after immunization and newer vaccines typically prospectively follow patients 6 months for adverse events.

Use of "all cause morbidity or mortality" as the primary endpoint is warranted in vaccine trials for several reasons. First, the recipients are generally healthy (relative to patients with terminal cancer for example) and the risk of severe morbidity from the target infection is low so even rare adverse events can result in an unfavorable risk benefit. Second, stimulating the immune system with a vaccine can lead to almost any type of adverse event including increasing the incidence or severity of diseases already present in the population. One needs a trial design with a primary endpoint that captures both a decline in infectious complications as well as small rises in hundreds of different immune modified disorders of similar or worse severity as the infectious complications.

Three COVID-19 vaccines are approved by the US FDA under Emergency Use Authorization (EUA). These vaccines have been developed by Pfizer-BioNTech, Moderna, and Janssen. Since marketing has begun multiple reports of potential, adverse events have been recorded. These reports include prion disease [2,3] , clotting disorders [4], myocarditis, reproductive issues, death and many more. A clear difference in frequency of adverse events between different COVID-19 vaccines has been published [3]. The clinical trial designs of the pivotal trials and the resulting data was evaluated to determine if scientifically the results support mass immunization with the vaccines for COVID-19. The published data from the manufacturers' own clinical trials was re analyzed using the proper scientific endpoint "all cause severe morbidity".

## Method

Data from all three US COVID-19 vaccines was published in the New England Journal of Medicine [4-6]. Data from these three publications and the accompanying published appendixes provided the bulk of the information analyzed. On rare occasions supplemental data was found on the FDA's website (https://www.fda.gov/advisory-committees/advisory-committee-calendar) in briefing documents pertaining to FDA advisory panel committees for COVID-19 vaccines from Pfizer-BioNTech, Moderna, and Janssen. The scientific primary endpoint, "all severe events", in the treatment group and controls was calculated by adding all severe or life threatening events reported in the clinical trials by the manufacturers. Severe events included both severe cases of COVID-19 and all other severe events in the treatment arm and control arm respectively.

A Chi square analysis using a 2x2 table was used to calculate statistical p values. An online statistical chi square calculator (***https://www.socscistatistics.com/tests/chisquare***) was used. Statistical calculations ignored small differences in total subject number between efficacy and adverse event populations. The randomized number, shown in Table 1, was used as the study population for statistical calculations. In general, the population for adverse events was slightly higher than that for efficacy. Given the statistical significant p, values generated (see Table 1), these small differences do not appear to be material.

The FDA document entitled Guidance for Industry Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials, 2007, provided the following definitions for adverse events.

Grades 3, Severe: Prevents daily activity and requires medical intervention.
Grades 4, Potentially life threatening: ER visit or hospitalization.

## Results

### Moderna

The Moderna pivotal Phase III trial results and protocol are published in the New England Journal of Medicine (NEJM) [5]. The primary endpoint was COVID-19 illness starting 14 days after the second dose of vaccine however the trial had a secondary endpoint

which was patients developing severe COVID-19 symptoms. This later endpoint allowed for a direct comparison to severe adverse events. The study randomized 30,420 individuals, 15,210 were randomized to receive injections with Moderna's mRNA-1273 vaccine and 15,210 were randomized to receive injections with placebo. Two shots were administered 28 days apart. "Solicited" adverse events were collected 7 days after immunization and "unsolicited" adverse events were reported up to 28 days after administration of each vaccine or approximately 56 days after the first dose according to protocol. Because of dropouts, adverse events were recorded on 15,185 vaccinated patients and 15,166 placebo patients (reference 5, appendix table S8). The treatment group had 11 cases of symptomatic COVID-19 infections and 0 cases severe COVID-19 infections (reference 5, appendix table S13). There were 234 cases of severe "unsolicited" adverse events in the treatment group (reference 5, appendix table S8), and an additional 3,751 "solicited" severe or life threatening (Grade 3 or Grade 4) adverse events (reference 5, appendix table S3 and S4). By contrast, the control group had 185 cases of symptomatic COVID-19 infections and 30 cases of severe COVID-19 infections. However, only one of these case of COVID-19 out of 15,166 controls required admission to an intensive care unit (see reference 5, appendix table S13). There were 202 cases of severe "unsolicited" adverse events in the placebo group and an additional 711 "solicited" severe or life threatening (Grade 3 or Grade 4) adverse events. There were 3 deaths in the placebo group and 2 in the vaccinated group (reference 5, appendix table S8).

## Pfizer-BioNTech

The Pfizer-BioNTech (Pfizer) pivotal Phase III trial results are published in the New England Journal of Medicine [6]. The Pfizer trial was classified as a Phase 1/2/3 trial. Two shots were administered 21 days apart. The primary endpoint was confirmed COVID-19 infections 7 days after the second dose. A post hoc analysis of severe COVID-19 infections was included in the appendix published by the NEJM. The study randomized 43,548 individuals of which 100 did not receive injections, 21,720 received injections with the vaccine and 21,728 received injections with placebo. "Solicited" adverse events were collected 7 days after immunization and "unsolicited" severe adverse events were reported up to 14 weeks after administration of the second dose. However, median safety follow up for "unsolicited" events was only approximately 2 months after the second dose at the time of publication in the NEJM. In the treatment arm there was 1 case of severe Covid-19 (reference 6, appendix table S5), 240 "unsolicited" severe adverse events and 21 "unsolicited" life threatening adverse events (reference 6, appendix table S3). In the placebo arm, there were 9 cases of severe COVID-19, 139 "unsolicited" severe adverse events and 24 "unsolicited" life threatening adverse events. Pfizer used a safety subset of approximately 8,183 (both vaccinated and unvaccinated) to record "solicited" adverse events at 7 days. These data that are not shown in Table 1 in part because the data was depicted graphically in the NEJM manuscript. However, graphical data in the NEJM strongly

**Table 1:** All Cause Severe Morbidity

| | **Moderna** | | **Control** | | **Difference** | **P value** |
|---|---|---|---|---|---|---|
| Randomized | 15,210 | | 15,210 | | | |
| Days of Safety Follow Up | 56 | | 56 | | | |
| # Severe COVID-19 Cases | 0 | | 30 | | | |
| # Unsolicited Severe Adverse Events | 234 | | 202 | | | |
| # Solicited Grade 3 AE, Shot 1 | 848 | | 361 | | | |
| # Solicited Grade 4 AE, Shot 1 | 5 | | 6 | | | |
| # Solicited Grade 3 AE, Shot 2 | 2884 | | 341 | | | |
| # Solicited Grade 4 AE, Shot 2 | 14 | | 3 | | | |
| # Total Severe Events | 3985 | | 943 | | 3042 | p=0.00001 |
| #Deaths | 2 | | 3 | | | |
| | **Pfizer** | | **Control** | | **Difference** | **P value** |
| Randomized | 21,720 | | 21,728 | | | |
| Days of Safety Follow Up | 81 | | 81 | | | |
| # Severe COVID-19 Cases | 1 | | 9 | | | |
| # Unsolicited Severe Adverse Events | 240 | | 139 | | | |
| # Unsolicited Life Threatening Adverse Events | 21 | | 24 | | | |
| # Total Severe Events | 262 | | 172 | | 90 | p=0.000014 |
| #Deaths | 2 | | 4 | | | |
| | **Jansen** | **Jansen** | **Control** | **Control** | **Difference** | **P value** |
| Randomized | 19,630 | | 19,691 | | | |
| Safety Subset | | 3,356 | | 3,386 | | |
| Days of Safety Follow Up | 28 | | 28 | | | |
| # Severe COVID-19 Cases | 21 | | 78 | | | |
| # Solicited Grade 3 Adverse Events | | | | | | |
| Local (**extrapolated**) | **135** | 23 | **35** | 6 | | |
| Systemic (**extrapolated**) | **357** | 61 | **122** | 21 | | |
| # Unsolicited Grade 3-4 Adverse Events | 83 | | 96 | | | |
| # Total Severe Events | 595 | | 331 | | 264 | p=0.00001 |
| # Deaths | 3 | | 16 | | | |

indicates the vaccinated group has more "solicited" adverse events of all grade levels than the control group.

### Janssen

The Janssen pivotal Phase III trial design and trial results are published in the New England Journal of Medicine [4]. The primary endpoint was prevention of molecularly confirmed, moderate to severe–critical COVID-19 14 days post vaccination however a secondary endpoint was prevention of molecularly confirmed, severe–critical COVID-19 14 days post vaccination. This later endpoint allowed for a direct comparison to severe adverse events. The study randomized 19,630 to receive a single injection with Janssen's adenovirus COVID-19 vaccine and randomized 19,691 to receive a single injection with placebo. "Solicited" adverse events were collected 7 days after immunization and "unsolicited" adverse events were reported up to 28 days after administration of the single dose of vaccine. The treatment group had 21 cases of severe or critical COVID-19 infections while the placebo control group had 78 (reference 4, appendix table S9). Further analysis shows that only 2 of 19,514 immunized patients needed medical intervention for COVID-19 infections starting 14 days after immunization, while only 8 of 19,544 controls needed medical intervention for COVID-19 infections starting 14 days after placebo injection where the COVID-19 infection was confirmed by a central lab (reference 4, appendix table S10). There were 83 "unsolicited" and approximately 492 "solicited" serious adverse events in the vaccinated group compared to 96 "unsolicited" and approximately 157 "solicited" serious adverse events in the control group (reference 4, appendix table S7). There were 3 deaths in the treatment group and 16 in the control group (reference 4, appendix table S7).

Janssen did not collect "solicited" adverse events from the whole group at day 7 but instead collected these adverse events from a safety group comprising 3,356 vaccinated and 3,380 control patients. FDA briefing document Table 23, page 39 [7] provided the number of "solicited" Grade 3 adverse events in each group. These figures as well as the number of patients randomized were used to extrapolate the number of solicited severe adverse events in the full vaccinated and placebo group as recorded in Table 1.

## Discussion

Scientific analysis of the data from pivotal clinical trials for US COVID-19 vaccines indicates the vaccines fail to show any health benefit and in fact, all the vaccines cause a decline in health in the immunized groups. Health is the sum of all medical events or lack there of. COVID-19 vaccines are promoted as improving health while in fact there is no evidence that these vaccines actual improve health in the individual or population as a whole. The current analysis used the proper scientific endpoint of "all cause severe morbidity", a true measure of health. By contrast, manufactures and government officials promote the vaccines using a surrogate measure of health, severe infections with COVID-19, and the disproved philosophical argument that this surrogate endpoint equates to health. This substitution of philosophy for science is extremely dangerous and is certainly leading to a catastrophic public health event.

Review of data from the three COVID-19 vaccines marketed in the US shows complete lack of a health benefit and even an increase in severe events among vaccine recipients. The proper scientific clinical trial endpoint, "all cause severe morbidity" was created by combing all severe and or life threatening events, both infectious and non-infectious, occurring in the vaccinated and placebo control groups respectively. The data (Table 1) shows there are clearly more severe events in the vaccinated groups. The results are highly statistically significant. The use of a true scientific measure of health as an endpoint for a vaccine trial gives a contrasting result compared to the use of a non-scientific surrogate endpoint of heath, severe infections with COVID-19.

Clinical trial data show there were actually few very "severe" cases of COVID-19 in either the vaccinated or the placebo group. Moderna data shows that only one of 15,166 unvaccinated patients required admission to an intensive care unit for COVID-19. Data provided by Janssen shows that only a few of the "severe" COVID-19 infections required medical intervention. Table S10 in the appendix published in the New England Journal of Medicine [4] , shows only 2 of 19,514 patients immunized with the Janssen vaccine needed medical intervention for severe COVID-19 infections starting 14 days after immunization, while only 8 of 19,544 controls needed medical intervention for severe COVID-19 infections starting 14 days after placebo, where the infection was confirmed by a central lab. This benefit, reduction in 6 case of COVID-19 requiring medical intervention, in 19,630 vaccinated patients is simply statistically insignificant in a population that has a hundred fold more severe events of any cause. The Janssen vaccinated group had 595 severe Grade 3 or 4 events in the first 28 days post immunization. Science thus does not support a health benefit with COVID-19 vaccines. All arguments for immunization are purely philosophical and based on false, discredited, assumptions.

Reductions in infection rates, hospitalization rates and even death with COVID-19 are poor surrogate markers for health and are not proper primary endpoints for a vaccine clinical trial. As discussed earlier with cancer treatments, a trial endpoint showing reduced cancer deaths is not equivalent to enhanced survival. One could apply enough radiation (or cytotoxic chemotherapy) to cancer patients to kill all their cancer cells and prevent cancer deaths but these cancer patients would die of radiation sickness (or chemotherapy induced organ failure) faster than if they died naturally of cancer. In the same manner, reducing severe COVID-19 infections does not equate to enhanced survival especially when the vaccine can cause clotting, heart disease and many other severe adverse events. Potential vaccine recipients need to know if the vaccine improves their survival in order for them to make an informed consent to be immunized. Unfortunately, the current studies with COVID-19 vaccines in fact show they cause a decline in health.

The actual health decline caused by the vaccines is probably much worse than what is depicted in Table 1 for many reasons. First manufactures took a haphazardly approach to recording adverse events in contrast to recording a reduction in COVID-19 events. At

the time of publication, patients were only followed prospectively for approximately 7 days after immunization for "solicited" adverse events, and then relied on "unsolicited" reports of adverse events for approximately 30-60 days after immunization. Serious non-infectious events occurring after this 30-60 day period were not part of the published data. By contrast, infections with COVID-19 were followed indefinitely since the time of immunization. Both Janssen and Pfizer were specifically lax recording adverse events and only recorded "solicited" adverse events at day 7 in a safety cohort representing less than 20% of the study population. Given that some of the vaccine clinical trials recruited patients in the third world, patients with low education, and potentially even elderly with dementia the patients can not be expected to understand when they may be having an serious event that needs reporting or how to report it. For these and others reason only 5% of adverse events are generally ever reported [8].

COVID-19 vaccines were released for marketing under a EUA. Use of such a protocol should be reserved for outbreaks of life threatening epidemics. If this were, actually the case with COVID-19 then reduction in "all cause mortality" should be the primary outcome for the vaccine trials and "all cause severe morbidity" should be the secondary endpoint. However, the manufacturers show no evidence of a survival benefit. Deaths in the trials were extremely rare and of 30 deaths, out of roughly 110,000 trial participants, only about 6 deaths were confirmed to have COVID-19 at the time of death. Regrettably, the vaccines did not reduce morbidity but caused an increase in severe events. Worse, the pivotal clinical trials were never designed to show a benefit in "all-cause mortality" or reduction "in all cause severe morbidity". The fact that the trials were never designed to show these health benefits is an admission that those developing the vaccines never expected the vaccines to result in measurable health benefits. Regrettably some manufacturers have published the false claim [6] that the vaccine have been proven to be "effective" and that its now "unethical" to withhold immunization from the control group. They advocate abolishing the control group by immunizing them. This unscientific act only further proves the pharmaceutical industry is unaccountable to any one and does not feel the need to adhere to principles of science, ethics, or public health.

The COVID-19 vaccine pivotal clinical trials were of very short duration and the question exists whether longer-term follow up will reverse the vaccine induced health decline and show a health benefit. The question is purely philosophical. Some manufactures have already threatened to destroy the randomization by immunizing the control group, as stated above, making further scientific study impossible. While it is possible that the vaccines will continue to prevent severe infectious disease long after the immunization, the reality is that immunity wanes with time and vaccine resistant variants keep developing. Another issue is that severe adverse events will continue to occur over time. Given evidence of prion genic activity by both established pathophysiology [2], animal toxicity data [9] and epidemiology data [3] one can expect an increase in adverse events in the vaccinated group for decades.

Yearly booster are unlikely to improve the health outcome with COVID-19 vaccines. A booster may provide a small incremental benefit in preventing severe COVID-19 infections however, the boosters are likely to cause many more severe adverse events. Looking at the data on secondary injections with the Moderna vaccine (Table 1) there are approximately 3 times as many Grade 3 or 4 adverse events after the second dose than after the first dose. However, this is not the case following the second dose of placebo in the Moderna placebo group. The net is that adding a booster shot is highly unlikely to induce a favorable health benefit that was missing with the first series of immunization.

Government officials are promoting COVID-19 vaccines as a way to stop the epidemic. There is however no scientific data that the COVID-19 vaccines can improve the health of the population. In fact, the data from the clinical trials seems to point in the opposite direction. Given that the population is the sum of the individuals, and the vaccines cause a decline in health in the individuals, then mass immunization is likely to erode the health of the general population, not improve it. Immunization may even cause a selection bias for new variants. Finally, if the COVID-19 outbreak is the result of a bioweapons attack and vaccine resistant variants represent the release of different prototypes then immunization is almost certain to fail [10].

There is an old saying, fool me once shame on you, fool me twice shame on me. This saying can be applied to the COVID-19 mass immunization program. The US anthrax attack of 2001, which originated at US army is Fort Detrick, has demonstrated that there are people in the US government who desire to attack US citizens with bioweapons [10]. According to the chief FBI agent leading the investigation of the US anthrax attack, conspirators were likely not apprehended in part because the investigation was prematurely ended and prior to stopping the investigation, people at the top of the FBI deliberately tried to sabotage the investigation [11]. In the US anthrax attack of 2001, people high in the US government publicly anticipated the anthrax attack as early as 1999 [10]. Similarly with the COVID-19 attack, people high in government anticipated the COVID-19 attack [12,13] several years before the attack took place [10]. There is even data that an effort was made in 2018 to protect certain populations against COVID-19 by immunizing them with MMR vaccine [14].

In such a hostile government environment, the citizens need to individually evaluate the science of immunization with COVID-19 vaccines and not rely on philosophical arguments propagated by government officials. In this case there is no scientific evidence that the COVID-19 vaccines improve the health of the individual, much less of the population as a whole. Mass immunization with COVID-19 vaccines is certainly leading to a catastrophic public health event.

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# Estimating the number of COVID injection-related deaths in America

By Steve Kirsch, Jessica Rose, Mathew Crawford

*Abstract: Analysis of the Vaccine Adverse Event Reporting System (VAERS) database can beused to estimate the number of excess deaths caused by the COVID vaccines. A simple analysis shows that it is likely that over 150,000 Americans have been killed by the current COVID vaccines as of Aug 28, 2021.*

Note: Twitter banned me for posting a link to this article. I'm offering a $1M academic grant to anyone who can show the analysis is flawed by a factor of 4 or more in either direction and provide a more accurate analysis to the correct number. We'll have a panel of 3 judges decide ifwe disagree. Please send me an InMail on LinkedIn if you think you found I was off by a factor of 4 or more. First one to show the "correct" answer gets the $1M research grant.

The Vaccine Adverse Event Reporting System (VAERS) database is the only pharmacovigilancedatabase used by FDA and CDC that is accessible to the public. It is the only database to whichthe public can voluntarily report injuries or deaths following vaccinations. Medical professionals and pharmaceutical manufacturers are mandated to report serious injuries or deaths to VAERS following vaccinations when they are made aware of them. It is a "passive" system with uncertain reporting rates. VAERS is called the "early warning system" because it is intended to reveal early signals of problems, which can then be evaluated carefully by using an "active" surveillance system.

Those who believe the FDA mantra that you cannot use VAERS to determine causality, shouldstart by reading this editorial (If Vaccine Adverse Events Tracking Systems Do Not Support Causal Inference, then "Pharmacovigilance" Does Not Exist).

There are effectively two separate determinations:

1. What is the number of "excess deaths" which is the total # of deaths from this vax - # of deaths normally expected from the typical vaccine. Causality plays no role whatsoever indetermining this number.
2. Ascribing a cause of the excess deaths. This is where causality comes in. Were theseexcess deaths caused by the vaccine or something else?

The detailed steps are:

1. Determine the URF by using a known significant adverse event rate
2. Determine the number of US deaths reported into VAERS
3. Determine the propensity to report significant adverse events this year
4. Estimate the number of excess deaths using these numbers

5. Validate the result using independent methods

Determining the VAERS under-reporting factor(URF)

One method to discover the VAERS underreporting analysis can be done using a specificserious adverse event that should always be reported, data from the CDC, and a study published in JAMA.

Anaphylaxis after COVID-19 vaccination is rare and occurs in approximately 2 to 5 people permillion vaccinated in the United States based on events reported to VAERS according to the CDC report on Selected Adverse Events Reported after COVID-19 Vaccination.

Anaphylaxis is a well known side effect and doctors are required to report it (see FDA Fact Sheet at the top of page 10) because it is considered a "severe adverse reaction." It occurs rightafter the shot. You can't miss it. It should always be reported.

A study at Mass General Brigham (MGM) that assessed anaphylaxis in a clinical setting after the administration of COVID-19 vaccines published in JAMA on March 8, 2021, found "severereactions consistent with anaphylaxis occurred at a rate of 2.47 per 10,000" people fully vaccinated. This rate is based on reactions occurring within 2 hours of vaccination, the mean time was 17 minutes after vaccination. This study used "active" surveillance and tried not to miss any cases.

When asked about this, both the **CDC and FDA sidestepped answering the question.** Here'sthe proof at the CDC (see page 1 which incorporates the CDC response to the original letter onpages 2 and 3).

As noted in the letter, this implies that VAERS is underreporting anaphylaxis by 50X to 123X.
**The CDC chose not to respond to the letter.**

Is the anaphylaxis under reporting rate a good proxy for reporting fatalities? Since anaphylaxisis such an obvious association, one could argue that the rate would be a lower bound. Others would argue that deaths are more important and would be more reported than anaphylaxis.

We don't know, but it doesn't matter because this is just an estimate to get to a ballpark figure.Since there are 5 other estimates, if we are wrong, we'll know pretty quickly. Lacking a more definitive method, we go with this as our "best guess" in the meantime. We are working on a clever way to determine the fatality URF directly which will be a good "double check" on our estimate.

In general, most of us think It is therefore entirely reasonable to assert that deaths are reportedeven less frequently than anaphylaxis since deaths are not as proxmate to the injection event.

The MGH study used practically identical criteria as CDC used in its study to define a case of anaphylaxis.

We ran the numbers ourselves and confirmed this.Therefore, a conservative estimate (giving the government the greatest benefit of the doubt) would use 50X as the underreporting rate.

However, after the MGH study was published, one doctor pointed out that doctors were morecareful to avoid anaphylaxis; t**here was more careful screening of people likely to have anaphylaxis**, and they were advised to see their allergist and take more precautions prior to vaccination. This sort of thing would overstate the numbers above.

So we ran the numbers BEFORE the JAMA study appeared and got a more conservativeestimate (and AFTER the FDA had issued their [anaphylaxis warning letter]).

Here's the data from Google (which uses World In Data):

National Vaccine Information Center
Your Health. Your Family. Your Choice.

MedAlerts Home

## Search Results

**From the 7/30/2021 release of VAERS data:**

**Found 583 cases where Location is U.S. States or Unknown and Onset Interval is 0 and Vaccine is COVID19 and Vaccine Dose is '1' and Symptom is Anaphylactic reaction or Anaphylactic shock and Vaccination Date on/before '2021-03-31'**

### Table

| Event Outcome | Count | Percent |
|---|---|---|
| Death | 2 | 0.34% |
| Permanent Disability | 3 | 0.51% |
| Office Visit | 111 | 19.04% |
| Emergency Doctor/Room | 388 | 66.55% |
| Hospitalized | 71 | 12.18% |
| Recovered | 308 | 52.83% |
| Life Threatening | 112 | 19.21% |
| Not Serious | 51 | 8.75% |
| TOTAL | † 1,046 | † 179.42% |

† Because some cases have multiple vaccinations and symptoms, a single case can account for multiple entries in this table. This is the reason why the Total Count is greater than 583 (the number of cases found), and the Total Percentage is greater than 100.

We've vaccinated 97.5M people from the start thru March 2021 and there were 583 reports inVAERS who had an anaphylaxis reaction on their first dose. **This suggests that the under-reporting factor (URF) is 41X**.

Other estimates such as How Underreported Are Post-Vaccination Serious Injuries and Deaths in VAERS? suggests UFR=30 factor based on VAERS. However, this used a serious adverse event rate from the Pfizer Phase 3 study which we believe under-reported these events for threereasons: 1) the patients were much healthier than average with a 10X lower rate of cardiac

arrest than the general public (for example), 2) it was hard to report adverse events if you werein the trial (the evidence of this was unfortunately deleted when Facebook removed the vaccineside effect groups), and 3) there was known malfeasance in the reporting of adverse events in the 12-15 year old trial where the paralysis of 12-year-old Maddie de Garay was never includedin the trial results and the FDA and CDC refused to investigate and the mainstream media would not report on it.

Another estimate is to use myopericarditis. There are 2,888 reports in VAERS after 200M vaccinations. The rate of myopericarditis across all age groups is 1 in 1,000 people vaccinated(see mRNA COVID-19 Vaccination and Development of CMR-confirmed Myopericarditis).

This leads to an UFR=200/2.888=69. This makes total sense since myopericarditis isn't asserious as anaphylaxis, so the UFR would be much higher than for anaphylaxis.

The point of this paper is not to find the exact number of deaths, but merely to find the mostcredible estimate for deaths. We think that anaphylaxis is an excellent proxy for a serious adverse event that, like a death, should always be reported so we think 41X is the most accurate number.

Our hypothesis is that this number will be applicable to deaths as well. In order to confirm our hypothesis, we must derive the death count in different ways and see if we come up with the same answer.

When used for less serious events, such as a headache, it's likely that 41X is going to be lowsince such events are less likely to be reported.

So our hypothesis is that 41X is a safe, conservative factor useful for all types of event.

Determining the number of US deaths

As of August 27th, 2021, a search of the VAERS database shows that there are 7,149 domesticdeaths in the VAERS database (US/Territories/Unknown).

Estimate the propensity to report for 2021

Healthcare providers have been required by law to report serious adverse events in VAERS withpassage of the National Childhood Vaccine Injury Act (NCVIA) in 1986.

Therefore, nothing has changed this year vs. previous years:

1. no new legal requirements,
2. no noticeable promotion or incentives to report into VAERS.

Some people would still argue that more than 10 times as many doctors are reporting becauseof the huge visibility of the vaccination program. They never produce any evidence to back up their claim.

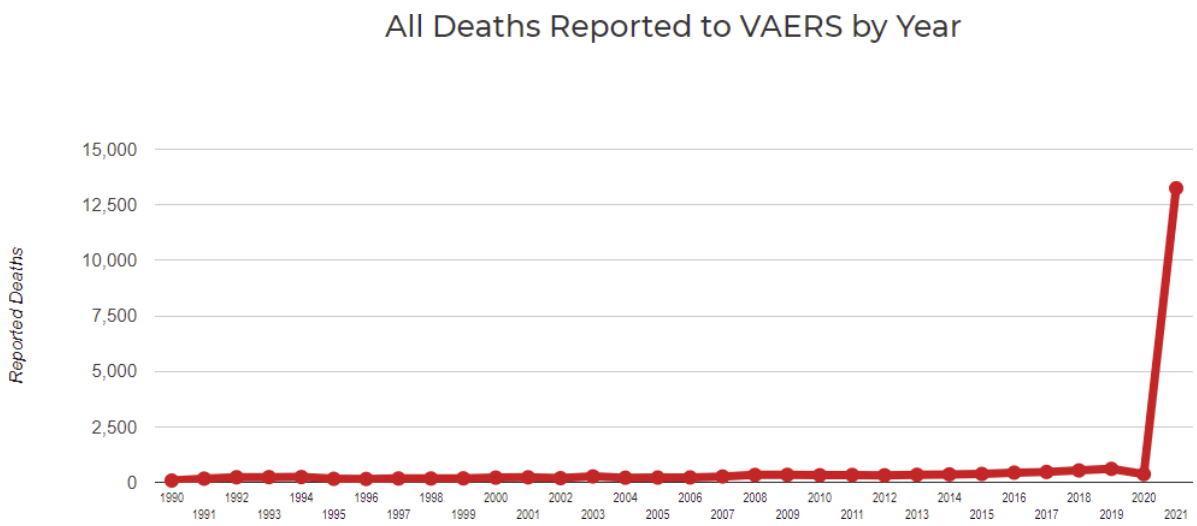
To make things simple, there are basically two hypotheses:

1. VAERS is over-reported this year for COVID19 events so all the deaths are simply background deaths. The vaccine has caused zero deaths. This is the FDA/CDC hypothesis.
2. VAERS is reported this year at the same rate as previous years. All the excess deathsrelative to previous years are due to the vaccine. This is our hypothesis.

Now, let's look at the evidence/arguments. You decide which hypothesis better fits the data.

Even when there are strong promotions to report adverse events as there was with H1N1 in 2009 where there were **serious campaigns** to raise the visibility of reporting, this didn't impactthe background fatality event reporting: **it didn't go up at all in 2009 and 2010** as can be seenfrom the graph below.

In short, it is extremely difficult to materially change the propensity to report serious adverse events into the VAERS system; it is remarkably consistent from year to year. This makes sense:old habits die hard… behaviors are hard to change. And there was nothing "new" this year to incentivize a massive change in behavior.




**Method #1**: Look at the weekly data below. The massive increase in reporting pretty much happened almost instantaneously as soon as the vaccines started rolling out. And it was proportional to the rollout. That is not how behavioral change works… behavioral change wouldhappen very slowly over time; especially if you are trying to get doctors to change their long term behaviors. The reporting basically followed the rollout of the vaccine. Doctors were more

likely to report to VAERS this year because there were simply more events to report. We haveverified that by talking directly to the doctors as the reason they are reporting more for these vaccines.

**Results**

**1.1 General information**

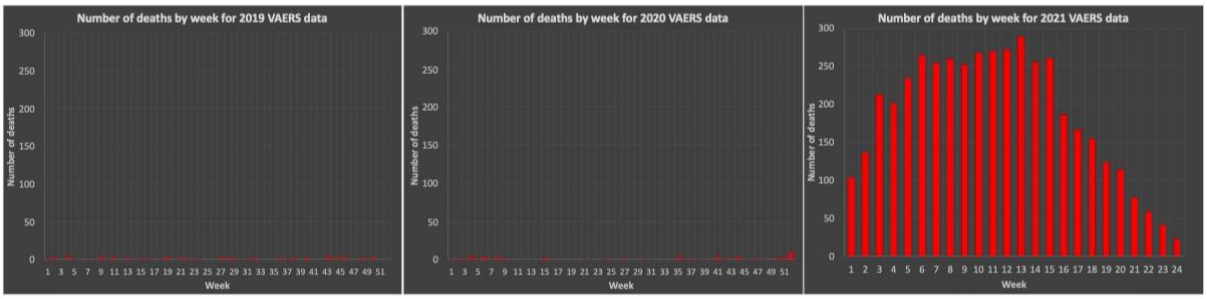



Figure 1: Bar plots showing the number of VAERS reported deaths per week for 2019, 2020 and 2021. Analysis: Dr. Jessica Rose

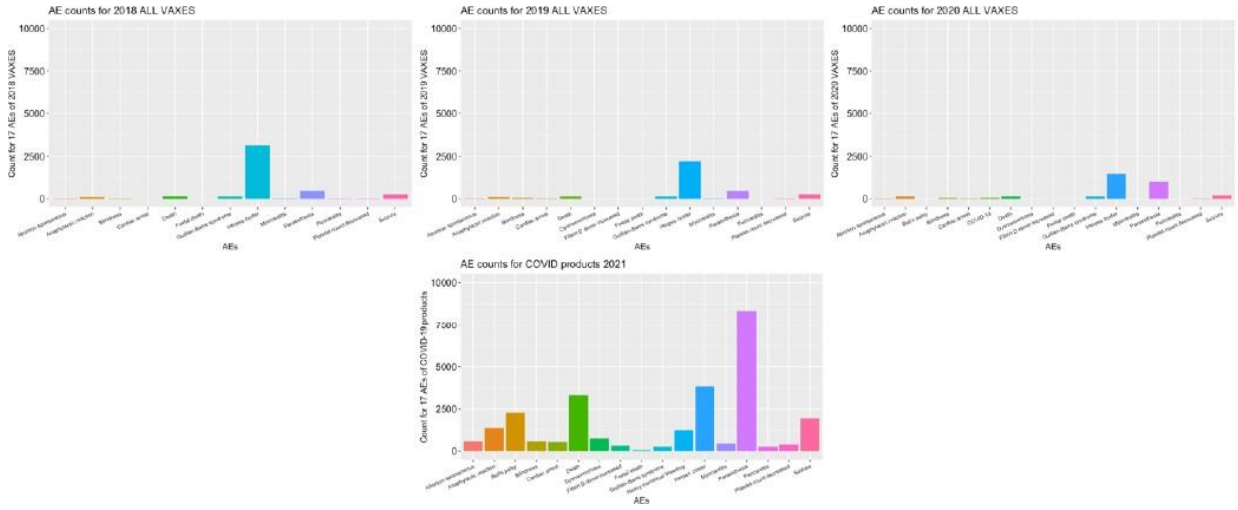
**Method #2:** To double check our hypothesis that the propensity to report is unchanged this year, we ran VAERS queries using symptoms unrelated to those impacted by the vaccines. We ruled out any known comorbidities like diabetes and obesity since these would likely be elevatedsince there are more adverse events.

We found that the reporting rates for these unrelated events (listed in the table below) are nodifferent this year than in previous years and for some of these events, the reporting rate is dramatically lower. Note that the number in the 2015-2019 column is the total for the 5 years,not an average annual amount. The Rate Increase is an X factor (i.e., A/B*5)

| Symptom | 2021 | 2015-2019 | Rate increase |
|---|---|---|---|
| Metal poisoning | 2 | 47 | 0.22 |
| Otitis media | 48 | 255 | 0.94 |
| Hepatitis | 331 | 1457 | 1.13 |
| Wart | 1 | 7 | 0.71 |
| Cancer | 31 | 132 | 1.17 |
| Breech delivery | 0 | 3 | 0 |

**Method #3**: Another way to see that 2021 isn't simply over-reporting normal background adverse events is to look at the "adverse event (AE) footprint" of the vaccine. You do that by

listing adverse events on the X-axis and AE counts on the Y-axis. If there is over-reporting thisyear, the overall outline of the boxes will be exactly the same as previous years, and they will just be higher due to the higher propensity to report the same types of events. As you can see,that is not the case here. This vaccine is definitely causing a completely different “shape” of severe adverse events. Here we show 2018, 2019, 2020, and 2021.




For a more detailed set of vaccine fingerprints (COVID vs. other vaccines), see [these charts](from Jessica Rose.

**Method #4**: Another way to confirm there wasn’t over-reporting is through informal physician surveys. In our informal physician surveys we saw a bias to under-report serious adverse eventsin order to make the vaccines look as safe as possible to the American public since most physicians believe they are hurting society if they do anything to create vaccine hesitancy.
Secondly, we’d estimate that at least 95% of physicians have completely bought into the “safe and effective” narrative and thus any event that they observe they deem as simply anecdotal and don’t bother to report it since it couldn’t have been caused by such a safe vaccine that appeared to do so well in the Phase 3 trials. The physicians who are clued into the danger of the vaccines say there is more reporting this year because there are more events. Our neurologist for example had 2,000 events to report this year, but had 0 in all 11 years she’s beenin practice.

**Method #5**: A fifth way is to simply look at the reporting curve relative to vaccination date. As you can see from the chart below, the curve is flat for a safe vaccine and peaks at Day 1 for thisvaccine with a very strong peak in the first few days:

**Method #6**: Scott Mclachlan paper determined that 86% of the deaths could have been causedby the vaccine

**Method #7**: CDC VAERS review of the 12-17 year old data shows these kids didn’t die fromnormal causes. More below.

**Method #8**: The German pathologist who determined that at least 30 to 40% of the deaths after vaccination were due to the vaccine.

We could keep going here but you get the idea. None of these is definitive proof. But all of themare consistent with the hypothesis that there are a significant number of excess deaths and thus the propensity to report hasn't changed much if at all. The FDA won't give us a single method tojustify their position that there are no deaths and this is just a higher propensity to report..

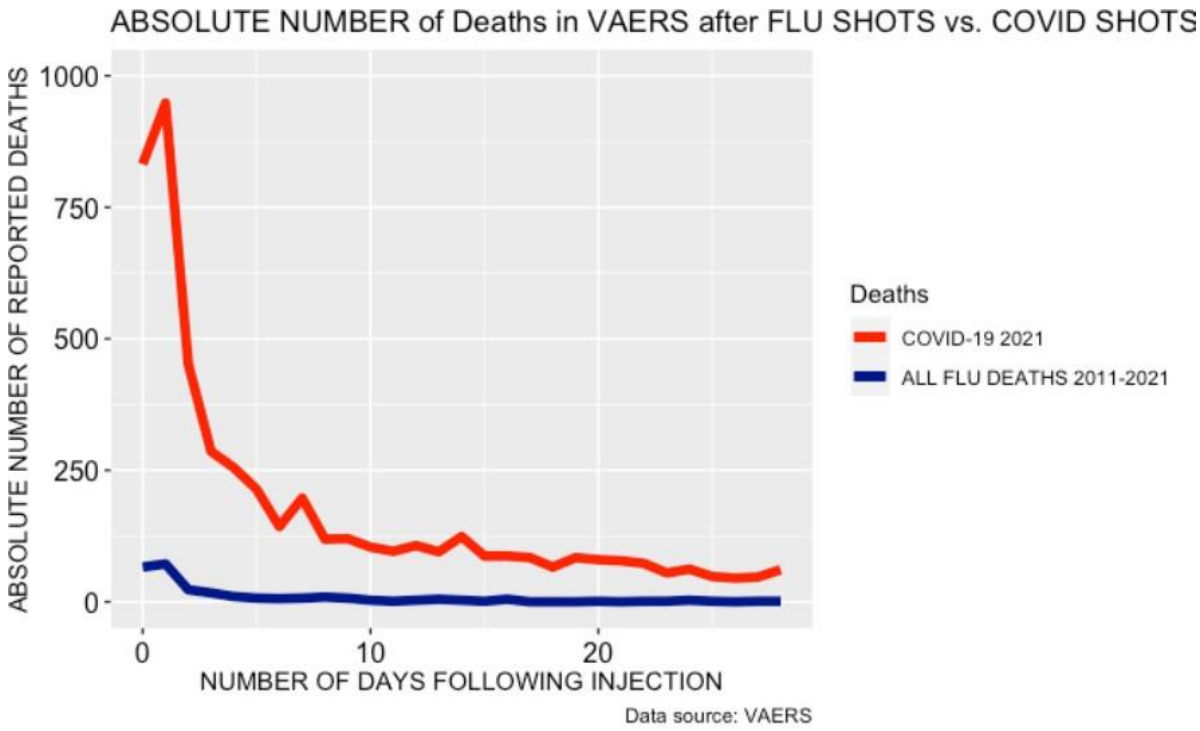



Figure 5: Absolute number of reported deaths for all COVID-19 deaths and all FLU deaths reported to VAERS with respect to time elapsed between injection date and AE onset.

Determining the number of excess deaths caused bythe COVID vaccines

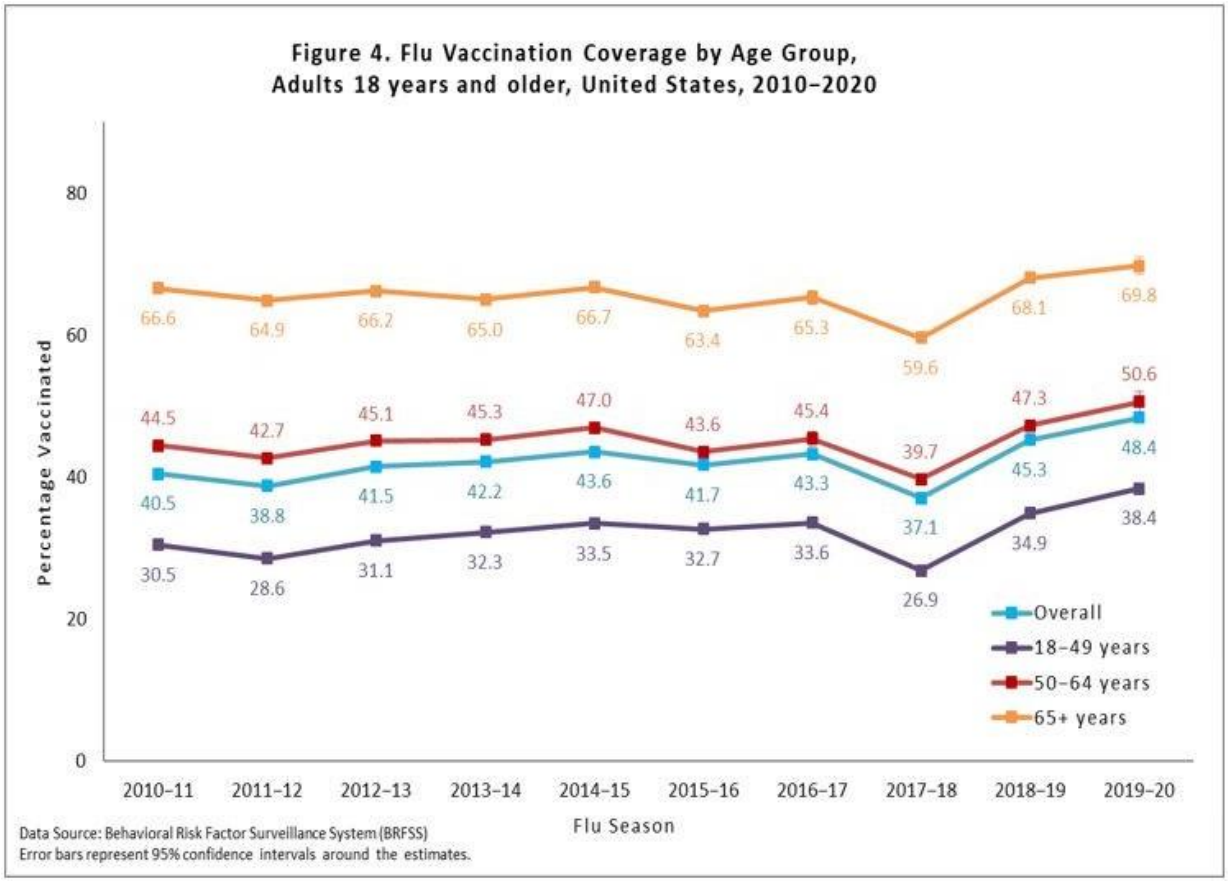
There are three ways to estimate the number of excess deaths caused by the vaccine. Using these three methods we can estimate the low and high likely bounds for the number of excessdeaths caused by the vaccine:

1. Subtract the average number of background deaths in previous years
2. Use 86% based on the analysis in the Mclachlan study
3. Use 40% based on the estimate of Dr. Peter Schirmacher one of the world's top pathologists

Here is the result we get from the three methods:

| **Method** | |
|---|---|
| Subtract average background deaths | (7149-1000)*41 = 252,109 |
| Mclachlan case analysis | .86 * 41* 7149= 252,073 |
| Pathologist estimate | .60 * 41* 7149= 175,865 |

In the first method, we used 500 background deaths as normal for a year since the propensity toreport is the same this year as in previous years as shown earlier. However, we should assume that the age cohort is older this year than previous years. For example, here are the vaccinationrates shown in a CDC report for influenza:




So a conservative estimate is to take the <500 deaths per year and increase it by 50% to morethan account for a shift to higher ages so subtract 750 background deaths.

In the second method, Mclachlan examined 250 VAERS reports in detail and concluded that upto 86% of the deaths were consistent with the vaccine being causal for the death. We use the higher number, because using a lower number makes no sense since it leads to a background

death rate that would be excessive compared to previous years (.14*7149 = 1,000 which isalready higher than the 500/yr background death rate).

The third method uses estimates made by Dr. Peter Schirmacher, one of the world's top pathologists, for the % of deaths examined by autopsy within 2 weeks of the vaccine that were clearly caused by the vaccine. The range was from 30% to 40% and we used the high end of the range since we believed that in making a potentially career-ending revelation such as this that Dr. Schirmacher was being extremely conservative and only estimating what he was 100%certain of proving. 40% is likely very conservative since Norway was under no such reputationalpressure and in the the first 13 bodies they assessed, 100% of the deaths were found to be caused by the vaccine (see Norwegian Medicines Agency links 13 deaths to vaccine side effects). Therefore using a 60% number seems relatively conservative (less than the 65% average of 30 and 100).

Therefore we have a range of death estimates from **148,000 to 216,000** deaths which averagesto 182,000 deaths.

Sanity check using seven other methods

In order to validate that our estimates are reasonable (or simply that the evidence was more likely consistent with the hypothesis that the vaccine does more harm than good), we looked atseven different quantitative methods from very small to very large and summarized their estimates in the table below.

The most credible analysis in the table are the two done by Crawford.

We didn't rely on ANY of these analyses. All can have flaws. But now we have 8 differentmethods that are disjoint and they all come to the same conclusion.

It is hard to explain that the CDC's analysis that there have been no excess deaths caused bythe vaccine is consistent with any of these methods.

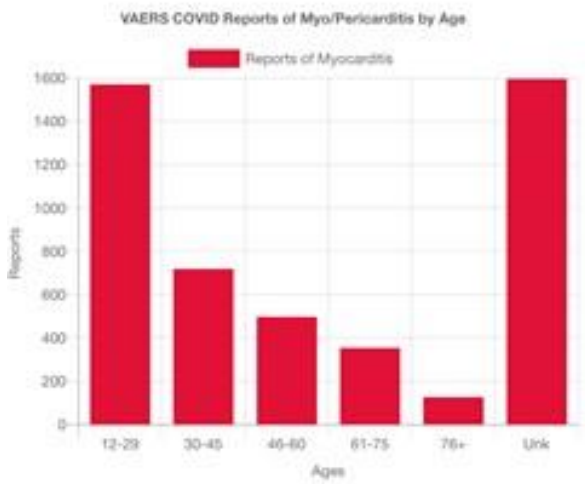
| **Method** | **Estimate of US excess vaccine deaths** |
|---|---|
| Excess CFR analysis done in Europe determines 200-500 D/M doses | 72,000 - 180,000 |
| Excess death analysis done in 23 nations (comprising 25% of world population) which includes 2 Europe nations in the CFR analysis which determined a 411 D/M doses.<br><br>Together, the two analyses cover 35% of the global population | 147,960 |

| | |
|---|---|
| Small island study done by Marc Girardot | 171,000 |
| By mid-January, Norway had vaccinated around 40,000 people. They had 23 reporteddeaths, so 1 in 1700 (maybe more because it's hard to know when such statements are formulated relative to a program that was vaccinating several thousand per day). That scales to 575/M, and assuming a 2:1 ratio for 1st:2nd dose puts the U.S. in the ballpark of 150k deaths. | 150,000 |
| Professional pollster analysis<br>Few people attribute death to the vaccine (including doctors); it just looks like "bad luck." So "death caused by the vaccines" is likely to be under-reported in the surveys. Even with that, the estimated death count isstaggering. | 174,000 |
| Asking my doctor friends who are "clued in" that the vaccines can cause death. Charles Hoffe found 1 death in 1,000. Ira Bernstein had two deaths in 700. George Fareed had 3 deaths in 3,000 patients. A lot of docs simply don't know the answer since they don't track it unfortunately, so it is hard to get good data points. I wish I had more data on this, but thiswas not cherry picked and this is the weakestitem on this list, but what we found was consistent. | ~ 200,000 |
| Pilot data<br>Pilot deaths are rare. British Airways lost 4 pilots in ~1 month after the jabs rolled out. The vaccination status of each pilot was officially "unknown." They each died from a different cause, but each cause was verified elevated by the vaccine. It is statistically unlikely this happened by chance (1 in 525,000). We'll assume one death was just bad luck. That leaves 3 deaths out of an estimated 3,000 jabbed pilots (75%) which is1 in 1,000 | ~ 200,000 |

There are additional qualitative methods that show a large number of deaths. The point of thesemethod is to show that the FDA assumption that “the vaccines are safe and all of the reports in VAERS are background events” is not even close to being true.

**Example 5:** The pericarditis data below shows that the number of events for these vaccines areanything but safe: they generate myocarditis/pericarditis at **860 times the rate of the typical fluvaccine in a year**.

Myo/Pericarditis




**Myo/Pericarditis Cases post COVID 19 Vaccine VS. All Flu Vaccines**

| AGE RANGE | FLU CASES IN 20 YRS. | COVID19 CASES IN 7 MOS. |
|---|---|---|
| 6-18 | 16 | 694 |
| 19-29 | 61 | 877 |
| 30-39 | 28 | 481 |

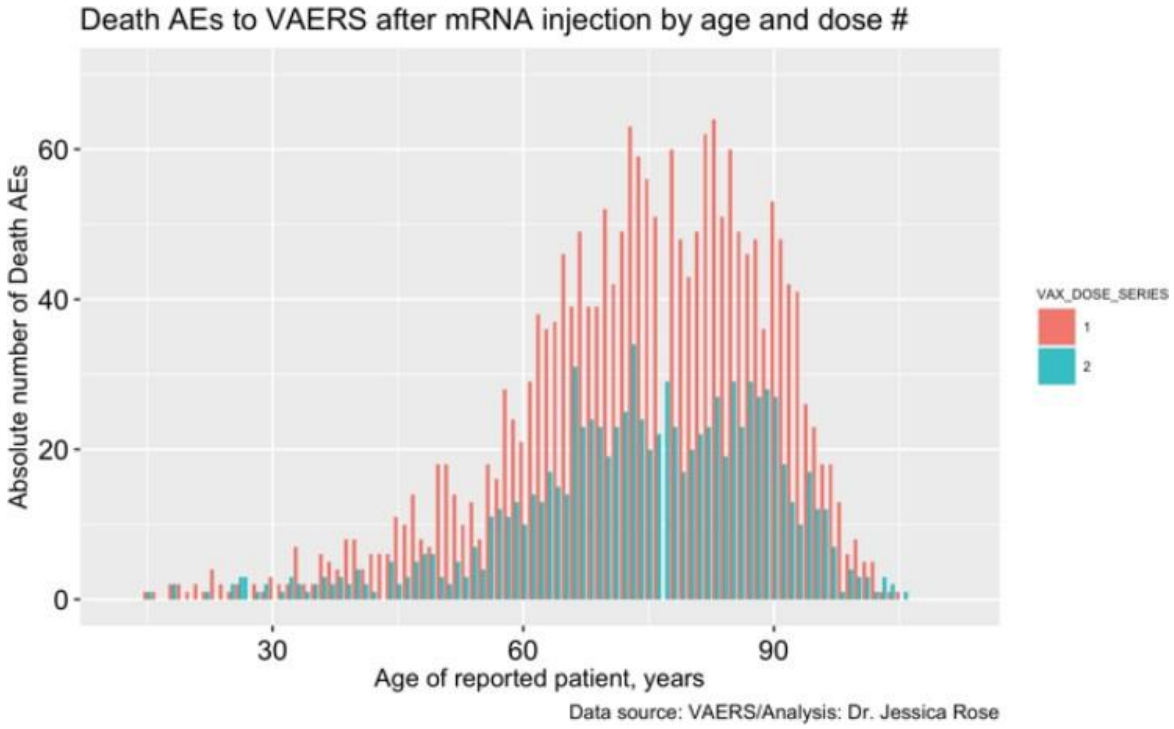
A friend of ours got pericarditis right after getting the influenza vaccine when she was 30 yearsold. It took her two years to recover. The heart muscle never really regenerates like other organs unfortunately.

**Example 6**: A total of 23 deaths have been reported in connection with the corona vaccination to the Norwegian Medicines Agency. Of those, 13 deaths were linked to the vaccine’s side effects. The other 10 haven’t been evaluated yet. Thus, 100% of the reported deaths have beendeemed to be caused by the vaccine. If the vaccine is perfectly safe and has killed no one, thenthis is statistically impossible. Someone is lying. The fact that there are no autopsies being donein the US in public view suggests that it is more likely that the CDC is lying than the Norwegian Medicines Agency.

**Example #7**: An analysis of excess deaths in Israel, especially among young people, that was done by Dr. Steven Ohana, clearly shows a huge rise in excess deaths that have no explanationother than the rollout of a mass vaccination program.

**Example #8**: A published analysis of VAERS data by Dr. Jessica Rose and a more recent analysis of VAERS data done by Christine Cotton show massive numbers of cardiovascular andneurological adverse events occurring within temporal proximity to the injection date.

**Example #9**: Causality of these adverse events is confirmed using Dose 1 and Dose 2 studiesdone by Dr. Jessica Rose.




**Example #10:** If the vaccine is perfectly safe, the number of deaths would be equally likely afterthe first dose vs. the second dose since both are effectively "non-events." Because there are 15% fewer people who get the second dose than the first dose, we should expect the blue bars to be uniformly 15% lower than the red bars. This is not the case here. If the vaccine kills 50% of the 1% most vulnerable people each time it is administered, this can explain the dramatic drop off in events.

Another explanation is that the vulnerable population experienced severe adverse events following Dose 1 and thus chose not to get a second Dose despite the societal pressure (vaccine mandates, peer pressure, etc) to do so. It is likely a combination of both effects. Here isan example of this from a comment posted to TrialSiteNews on A New Low For the FDA:

KatieZ2

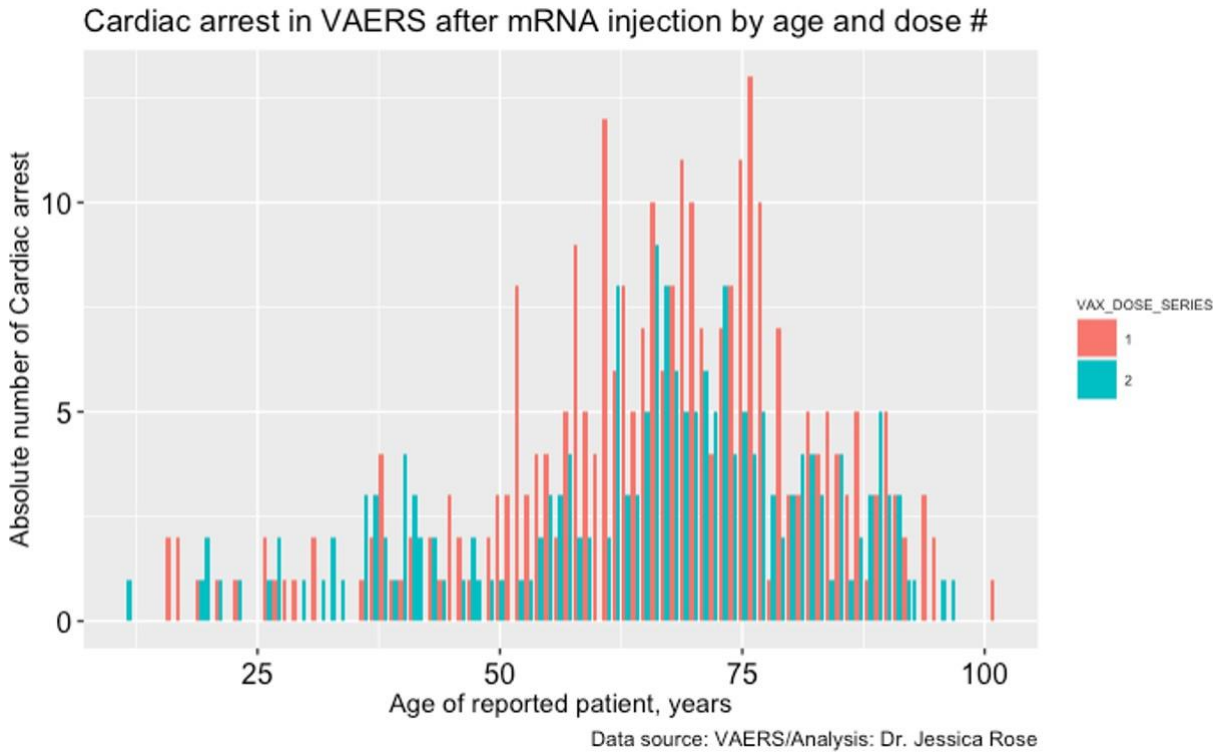
August 23, 2021

As someone who suffered one of these adverse effects, all I can say is shame on the FDA. I am on the Liberal side of the fence, and would not typically see myself on something like TrialSiteNews, but I am being shunned by my own camp any time I say anything about my story or the safety of these vaccines. I was very excited to get my vaccine but had so many symptoms post dose #1, including heart involvement, that I was unable to get dose #2. More than one VAERS report in – doctor completed a VAERS. Absolutely no follow-through by anyone. It's also correct that no one gets back to you – Senators or Congressmen. It has taken months to get better. The Ivy drug that shall not be named has helped me. There are docs using the Ivy med trying to help both long haul covid and post vax patients. Except for a few brave docs, all the injured are just being ignored. I can't believe it. I just can't fathom it.

Reply Edit

Whatever the cause, evidence to support the arisal and reporting of multiple severe adverseevents that are dose-related is a very strong safety signal that requires investigation.

**Example #11**: The same commentary as before applies for cardiac arrest; a safe vaccineshould have blue bars on average 15% below the red bars.



**Example 12:** Absolute numbers of VAERS reports plotted according to "time to death" is very revealing. We don't know what the exact distribution of timing looks like because this was never measured. But we speculate that maximum accumulation of spike protein is achieved around 24hours or so after injection and then it plateaus after that point as the mRNA disintegrates.
Therefore, we would expect to see a death peak more than 24 hours after injection, i.e., on Day1 and not on Day 0 This is exactly what happens in practice:

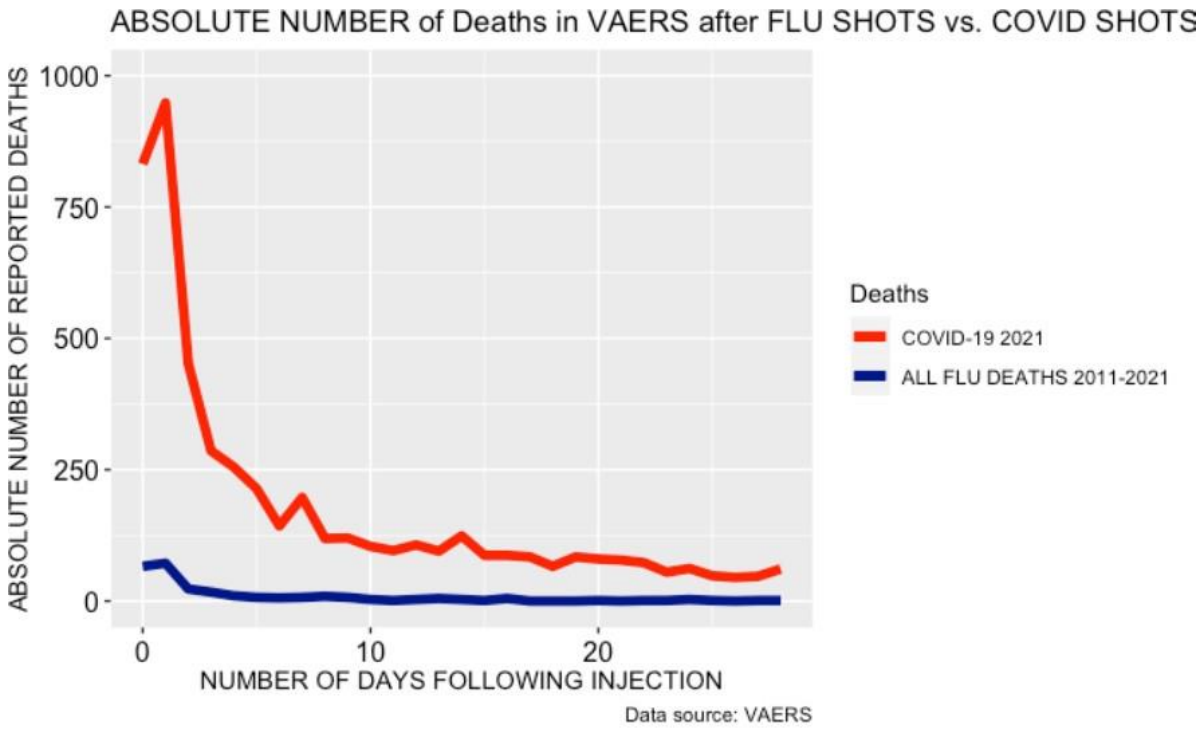


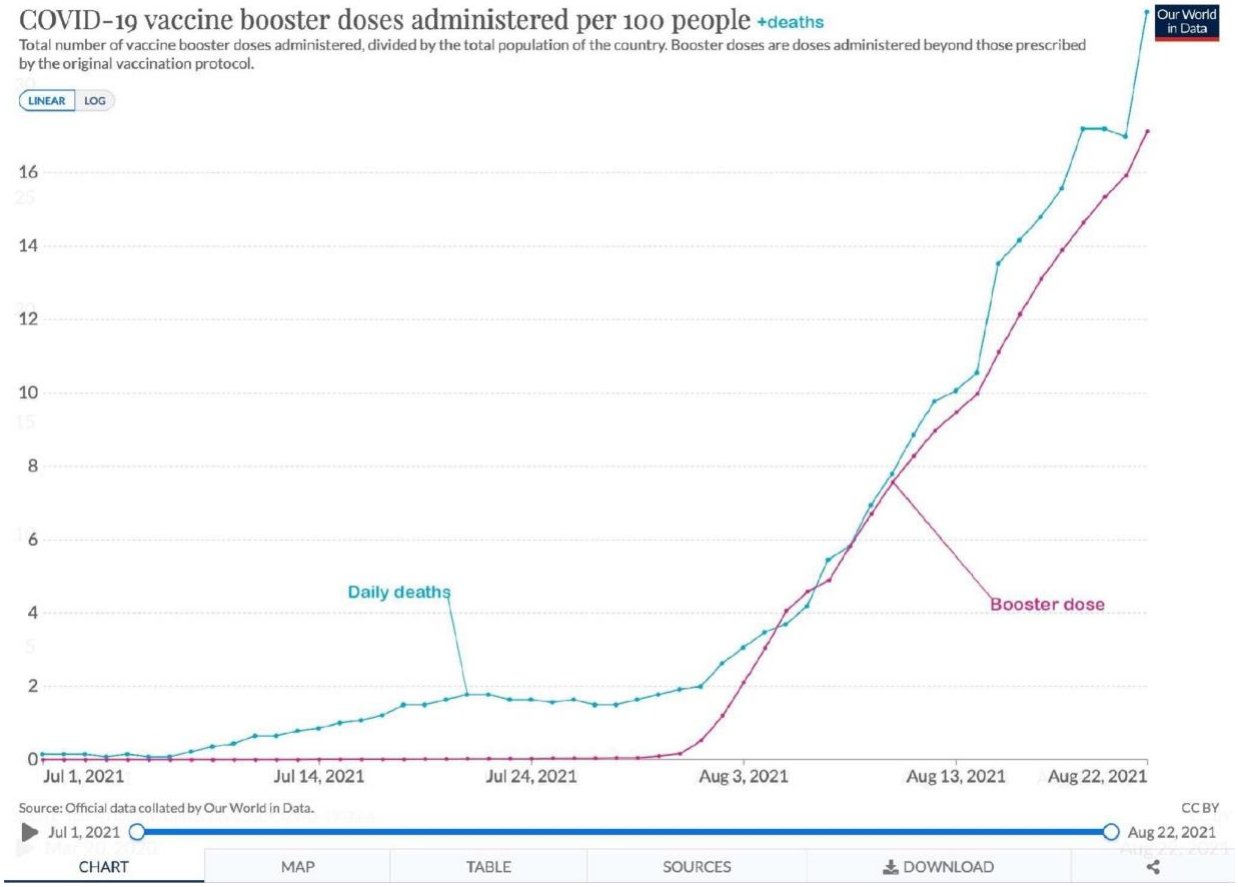

Figure 5: Absolute number of reported deaths for all COVID-19 deaths and all FLU deaths reported to VAERS with respect to time elapsed between injection date and AE onset.

If these were simply random background deaths, we would expect to see a peak on the first daysince that has the highest propensity to report, and it would drop from there; it would never peakon Day 1. In the graph above, we plot 8 months of the COVID19 vaccine reports compared to alldeath reports from all influenza vaccines for the past 10 years combined. So the blue line at 0 is20 years of death reports, it is **not** an annual average. In short, the killing power of this vaccine is at least 200X greater than the influenza vaccine and probably a lot more than that since background deaths are included in both red and blue bars.

Furthermore, the shape of the two curves is completely different. The combined flu deaths arerelatively flat with a slight rise in the first few days. The COVID vaccine generally kills people very quickly, and then gradually over time from there.

**Example 13**: A visual way to show that excess deaths are likely caused by the vaccine is to plotvaccinations and deaths on the same axis using data from the COVID-19 data explorer. For

Israel we get this chart which shows a correlation between vaccine booster doses given (cumulative booster doses per 100 people) and average daily deaths per million: they trackalmost in lock step. This is hard to explain any other way.




In summary, the qualitative and quantitative confirmation techniques we used were all independent of each other and of our main method, yet all were consistent with the hypothesisthat the vaccines cause large numbers of serious adverse events and excess deaths and are inconsistent with the null hypothesis that the vaccines have no effect on mortality and have a safety profile comparable to that of other vaccines.

We were not able to find a single piece of evidence that supported the FDA and CDC positionthat all the excess deaths were simply over-reporting of natural cause deaths.

Serious adverse events elevated by the COVIDvaccines

We made a table comparing the rate of adverse events this year relative to the annual VAERSincidence rate reported for all vaccines over the period from 2015-2019 for ages 20 to 60. We limited the age range to show that these events are affecting young people and not just the elderly. Also, the signal to noise ratio is much stronger in this younger age group since they areless likely to suffer "background" adverse events. A value of 473 means the rate reported in VAERS for the COVID19 vaccines in 2021 was 473 times higher than what is typical for all vaccines combined in the typical average year.

Nearly all serious adverse events we looked at were strongly elevated compared to the expected normal baseline event rate. This table is useful when assessing whether the vaccinemay have been involved in causing death in cases. The symptoms listed here are consistent with the presumed mechanism of action for how these vaccines kill people (producing spike protein throughout the body that cause inflammation, scarring, and blood clots).

Surprisingly, only a few of these symptoms appear in the labeling of the recently approved Pfizervaccine. Thus, this table is important and timely.

| **Symptom** | **Incidence rate elevation over normal(X factor)** |
|---|---|
| Pulmonary embolism | 473 |
| Stroke | 326 |
| Deep vein thrombosis | 264.3 |
| Thrombosis | 250.5 |
| Fibrin D dimer increased | 220.8 |
| Appendicitis | 145.5 |
| Tinnitus | 97.3 |
| Cardiac arrest | 75 |
| Death | 58.1 |
| Parkinson's disease | 55 |
| Slow speech | 54.3 |
| Aphasia (inability to talk) | 52.3 |

| | |
|---|---|
| Fatigue | 50.9 |
| Pericardial effusion | 50.5 |
| Headache | 46.4 |
| Chills | 45.6 |
| Pericarditis | 44.9 |
| Deafness | 44.7 |
| Myocarditis | 43.2 |
| Haemorrhage intracranial | 42.5 |
| Abortion Spontaneous | 41.3 |
| Cough | 38.5 |
| Bell's Palsy | 36.6 |
| Paraesthesia | 29.5 |
| Blindness | 29.1 |
| Dyspnea (difficulty breathing) | 28.4 |
| Myalgia | 28.4 |
| Dysstasia (difficulty standing) | 27.8 |
| Seizure | 27 |
| Thrombocytopenia | 25 |
| Anaphylactic Reaction | 21 |
| Suicide | 18.3 |
| Speech disorder | 17.2 |
| Convulsion | 16.3 |
| Thrombotic thrombocytopenic purpura (TTP) | 16.3 |
| Paralysis | 16 |
| Swelling | 14.3 |
| Diarrhoea | 11.9 |

| | |
|---|---|
| Neuropathy | 11.2 |
| Multiple organ dysfunction syndrome | 11.1 |
| Depression | 8.9 |

Child deaths are consistent with symptoms elevatedby the COVID vaccines

Perhaps most troubling of all is child deaths.

The CDC VAERS review of the 12-17 year old data released on July 30, 2021 showed there were 345 cases of myocarditis and 14 deaths. Unlike old people, kids don't spontaneously dieevery day at anywhere near the same rate.

Using the table above and investigating each death, all of these deaths where there was sufficient detail in the death report showed that it involved one or more of the symptoms listed inthe elevated adverse event table.

14*41 = 574 deaths

There are fewer total child deaths for 17 and under (which is a much wider age range thanabove) in the entire pandemic.

## PEDIATRIC MORTALITY

**Pediatric Deaths of Ages 17 and Under, COVID-19 vs. Recent Flu Outbreaks**

| H1N1 April 12, 2009 - April 10, 2010 (1) | COVID-19 Jan. 1, 2020 - Aug. 14, 2021 (3) |
|---|---|
| 1,282 | 361 |
| 2012-13 Flu Season (2) | 2010-11 Flu Season |
| 1,161 | 352 |
| 2014-15 Flu Season | 2015-16 Flu Season |
| 803 | 266 |
| 2017-18 Flu Season | 2016-17 Flu Season |
| 643 | 251 |
| 2018-19 Flu Season | 2013-14 Flu Season |
| 477 | 130 |
| 2019-20 Flu Season | (2011-12 estimate unavailable) |
| 434 | |

(1) Clinical Infectious Diseases journal, Vol. 52, published January 2011
https://academic.oup.com/cid/article/52/suppl_1/S75/499147
(2) CDC, Past Seasons Estimated Influenza Disease Burden for 2010-11 through 2019-20
https://www.cdc.gov/flu/about/burden/past-seasons.html
(3) CDC Provisional COVID-19 Deaths by Sex and Age
https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-by-Sex-and-Age/9bhg-hcku/data

Therefore, the cost benefit case for children isn't there.

Lack of a stopping condition

In 1976, they halted the H1N1 vaccine after 500 GBS cases and 32 people died.

However, there is no stopping mortality condition for these vaccines. We are likely at 150,000 deaths and counting and nobody in the mainstream medical establishment, mainstream media,or Congress is raising any concerns.

No member of the medical community is calling for any stopping condition nor autopsies. Wefind this troubling.

Negative efficacy

This paper shows that the vaccines we received may well shortly become **completely uselessto protect us** and, to make matters worse, might **enhance the ability of future variants to infect us** due to vaccine enhanced infectivity/replication, rather than "classical" ADE.

In short, even if the vaccine were perfectly safe and killed no one, it's rapidly becoming a netnegative based on efficacy alone.

We are starting to see evidence of this today. UK data destroys entire premise for vaccine push.August 21. 2021. "Again, 402 deaths out of 47,008 cases or 0.855% CFR in fully vaccinated, and; 253 deaths out of 151,054 cases or 0.17% CFR in unvaccinated. If you get Covid having been fully vaccinated, according to this UK data, **you are five (5) times more likely to die thanif you were not vaccinated!"**

All-cause mortality is the single most important thingto focus on and it's not there

Today, most people focus on the relative risk reduction of the vaccines against infection, hospitalization death from COVID. They pay less attention to the absolute risk reduction fromCOVID. And they pay no attention at all to the absolute all-cause mortality benefit.

The funny thing is that we should be paying attention to these in the opposite order that welisted them.

**All-cause mortality is key**. If there is no improvement in all-cause mortality, nothing elsematters.

In short, say our vaccine reduces the risk of dying from COVID by 2X. But it came at a cost, e.g., increasing your risk of dying from a heart attack by 4X. And let's say both events are equally likely (which they aren't). Then you've made a bad decision… you're more likely to die ifyou took the vaccine.

Here are the results from the Pfizer 6-month study:

| **Phase** | **Vaccine deaths** | **Placebo deaths** |
|---|---|---|
| Pre-unblinding | 15 | 14 |

| | | |
|---|---|---|
| Post-unblinding | 5 | 0 |

Discussion of these results is quite a bit more complex than we have space to go into here, butthese are the basic stats. For more information, see the 10-page discussion of the Pfizer 6 month trial at Why so many Americans are refusing to get vaccinated.

All the all cause mortality numbers are negative from the 6 month Pfizer study. This is not asurprise: it is caused by the high rates of adverse events we've already discussed.

**There is no evidence of statistically significant mortality improvement.**

If there was the CDC, FDA, and NIH would certainly let us know. But just the opposite happened: when the Pfizer 6 month study came out, the mainstream media and mainstream medical scientists were silent on the lack of all-cause mortality evidence. It didn't even make it into the abstract. The fact that 4 times as many people were killed by cardiac arrest wasn't evenmentioned.

When you combine (1) the negative efficacy of the vaccine with (2) the negative all-cause mortality benefit, it's impossible to justify vaccination. Either alone is sufficient to kill the benefit;both of them together makes things even more difficult for recommending vaccination.

The bottom line is clear: If you got the vaccine you were simply more likely to die. The youngeryou are, the greater the disparity.

Early treatment using repurposed drugs has alwaysbeen the safer and easier way to treat COVID infections

Early treatment protocols such as those used by Fareed and Tyson have been shown to providemore than a 99% relative risk reduction, work for all variants, and the drugs don't maim or harm the recipients. It is baffling that we are ignoring these treatments and waiting for more evidence when we have a vaccine which appears to kill more people than it saves, soon will be completely useless against future variants, and is likely going to make things worse for the recipient by enhancing replication and/or infectivity.

There are also a variety of prophylaxis techniques that are simple, safe, and highly effective including. The precautionary principle suggests that if there is evidence from a credible sourceof the benefits of these treatments (which there are), that doctors should discuss these treatments with patients in a shared decision-making process.

Because early treatments using repurposed drugs don't create a measurable risk of death, theall-cause mortality for early treatments is always positive.

Many people assume that vaccination is the only path forward. It isn't. Allowing people to be infected and develop recovered immunity leads to immunity which is broader against variantsand lasts longer. See "Recovered immunity is broader and longer lasting" in this document.

It is instructive to compare Israel with India.

Israel is one of the most vaccinated countries on Earth with 80 percent of citizens above the ageof 12 fully inoculated. As of Aug 24, 2021, Israel reported 9,831 new diagnosed cases on Tuesday, a hairbreadth away from the worst daily figure ever recorded in the country—10,000—at the peak of the third wave.

At the same time, India recorded 354 deaths in a day, Israel was reporting 26 deaths andrecord high cases. Here's how they stack up:

| **Country** | **Population (M)** | **Vaccination rate** | **Covid deaths permillion** |
|---|---|---|---|
| India | 1395 | 9.5% | 0.25 |
| Israel | 8.7 | 80% | 2.9 |

Obviously, India has 11.6X lower deaths per capita than Israel.

The conclusion is clear, vaccination is not the only solution nor the best solution.

What is the Bradford-Hill test for causality?

Our symptoms meet all five of the Bradford-Hill criteria for vaccines.

You cannot infer causality from data unless you satisfy all these conditions (known as theBradford-Hill criteria):

1. **Temporal relation:** the patient did not have the condition BEFORE the injection and thecondition is new AFTER the injection. Note the condition could be an exacerbation of anexisting condition, e.g., worsening of insulin resistance.
2. **Strength of association:** the rates should be higher than normal and the absolutenumbers are large enough that it wasn't just random small numbers chance

3. **Consistency**: The results are consistent (e.g., it isn't just from one region or reports allfrom the same doctor or one batch of drug or happened in the first week and not any other week)
4. **Specificity:** The event shouldn't occur on its own or as a result of just the action ofgetting an injection or visiting the doctor, e.g., anxiety could be associated with the vaccination itself and would thus be not specific to the injection. So it should be a reaction that is specific to getting vaccinated such as a severe headache that startswithin hours after the injection
5. **Biological plausibility:** The mechanism of action of the vaccine for how it harms patients should be able to explain the outcome. For example, mercury poisoning isn't caused by vaccines. However, a wide range of neurological and cardiovascular events are within scope as are organ failures including multiple organ failure. Dysfunction of thebrain, heart, and lungs, especially are suspect.

Summary

Using the VAERS database and independent rates of anaphylaxis events from a Mass Generalstudy, we computed a 41X under-reporting factor for serious adverse events in VAERS, leadingto an estimate of over 150,000 excess deaths caused by the vaccine.

The estimates were validated multiple independent ways.

There is no evidence that these vaccines save more lives than they cost. Pfizer's own study showed that adverse events consistent with the vaccine were greater than the lives saved by the vaccine to yield a net negative benefit. Without an overall statistically significant all-cause mortality benefit, and evidence of an optional medical intervention that has likely killed over 150,000 Americans so far, vaccination mandates are not justifiable and should be opposed by all members of the medical community.

Early treatments using a cocktail of repurposed drugs with proven safety profiles are a safer, more effective alternative which always improves all-cause mortality in the event of infection andthere are also safe, simple, and effective protocols for prophylaxis.