September 22, 2021
Dr. Jessica Rose

To whom it may concern,

The Vaccine Adverse Event Reporting System (VAERS) was created and implemented in 1990 by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to receive reports about adverse events that may be associated with vaccines. The primary purpose for maintaining the database is to serve as an early warning or signaling system for adverse events not detected during pre-market testing. In addition, the National Childhood Vaccine Injury Act of 1986 (NCVIA) requires health care providers and vaccine manufacturers to report to the DHHS specific adverse events following the administration of those vaccines outlined in the Act. Under-reporting is a known and serious disadvantage of the VAERS system.

My name is Dr. Jessica Rose and I am a viral immunologist and computational biologist. I have taken it upon myself to become a Vaccine Adverse Event Reporting System (VAERS) analyst to organize the data into comprehensive figures to convey information to the public in both published work, and video mediums.

Credentials

I pursued a Bachelor of Science in Applied Mathematics at Memorial University of Newfoundland (MUN) immediately after high school and subsequently, a Master of Science in Medicine in Immunology at MUN. I was one of five esteemed graduates of a newly established interdisciplinary degree program pursing a master's degree in Medicine with a focus on Immunology. 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)) at Bar 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 pursuing the task of teaching myself 'R' using the VAERS data from the United States as an exploratory database. I have published my findings in the journal 'Science, Public Health Policy and the Law' and have two other publications in peer review soon to be published - both pertaining to VAERS data. One of the manuscripts is a critical appraisal of VAERS pharmacovigilance and the other is a review of Myocarditis adverse events.

Some of the Points of Interest herein are FACTS as presented at the 167th meeting for the Vaccines and Related Biological Products Advisory Committee (September 17, 2021)

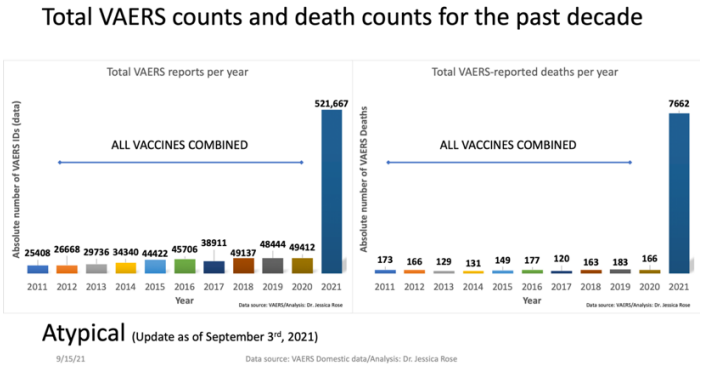
Safety and Efficacy are the cornerstones of the development and administration of biological products meant for human use.

Risk is a measure of the probability of an adverse event occurring and the severity of the resultant harm to health of individuals in a defined population.

Safety: A judgement of the acceptability of this **risk** in a specified situation.

Efficacy: **The probability of benefit** to individuals in a defined population from a medical technology.

Point of Interest #1:



The cumulative adverse event count has seen a >1000% increase in 2021.

Figure 1: Bar plot that shows the past 10 years of VAERS data plotted against the total number of adverse event reports for all vaccines for the years 2011 through 2020 and for COVID-associated products ONLY for 2021.
As shown in Figure 1, the left bar plot represents ALL adverse event reports and the right bar plot represents all DEATH adverse event reports. There is over a 1000% percent increase in the number of total AEs for 2021 and

we are not done with 2021. This is highly anomalous on both fronts. These increased reporting rates are NOT due to increased rates in injection and NOT due to simulated reporting. This has been shown using a comparative analysis of influenza data. The onus is on public health officials, the FDA, the CDC and policy makers, to answer to these anomalies, to acknowledge the clear risk signals emerging from VAERS data and to confront the issue of COVID-injectable product use risks that, in my opinion, outweigh any potential benefit associated with these products, especially for children.

Point of Interest #2:

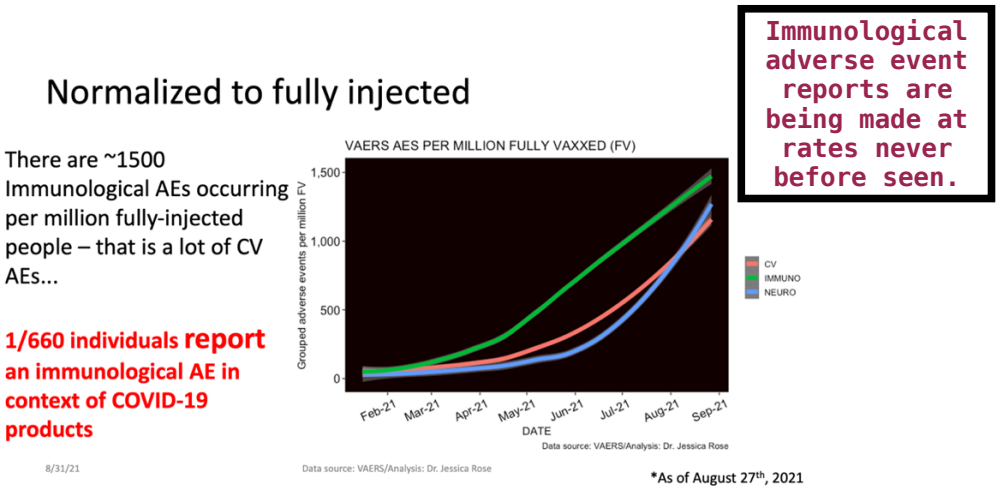


Figure 2: Time series plot that shows the total cumulative number of Cardiovascular, Immunological and Neurological AEs for 2021 associated with COVID-products.

These products include Moderna, Pfizer/BioNTech and Janssen. When the cumulative absolute counts are normalized to the total number of fully injected individuals in the US, we can see that 1/660 individuals are succumbing to and REPORTING immunological AEs associated with the COVID-19 products. The under-reporting factor is not considered here.

Point of Interest #3:

Injection-associated myocarditis reporting rates in VAERS are above background, especially in young males.

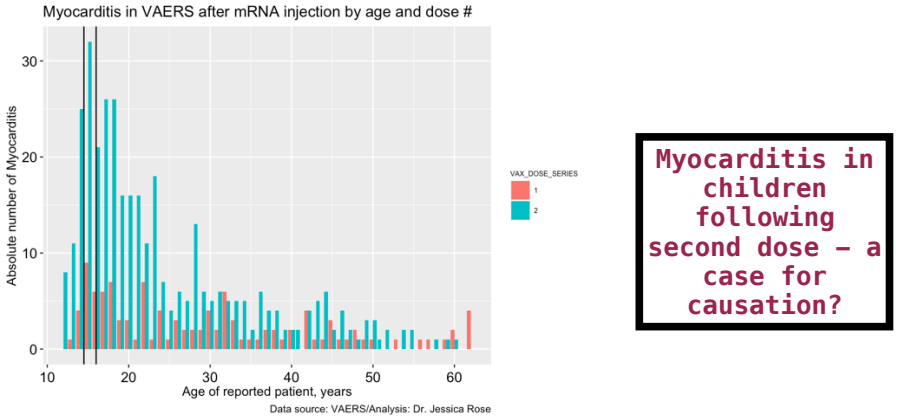


Figure 3: Histogram showing Myocarditis cases reported in VAERS following injection with COVID-19 products according to age and dose.

As of May 18th, 2021, 600,000 children aged 12-15 had been injected with COVID-19 products.[1] The CDC estimated that 3,430,741 children aged 12-15 have received at least one dose of the COVID-19 products as of

[1] Myocarditis in children: incidence, clinical characteristics and outcomes. Jul 29, 2020. Myocarditis Foundation.

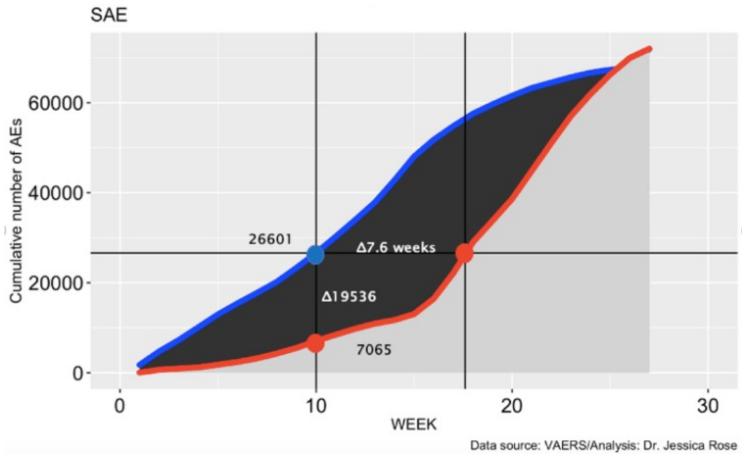
June 7th, 2021. Since 1 per 100,000 children per year are affected by myocarditis then, statistically, we would expect ~5 myocarditis cases if we calculate the expected number of cases using the June 7th CDC sample. To date (up to and including July 2nd, 2021), 97 children aged 12-15 have had reports submitted to VAERS representing 17.4% of all myocarditis reports – and these are merely the cases that we are aware of. Thus, after 8 weeks of roll-out into the 12-15 years-old age group, we are at ~19 times the expected number of cases within this sample. Thus, the number of VAERS-reported cases far outnumber what would typically be expected to date. It is important to note that of the 559 myocarditis VAERS reports, 6 died (1.1%) and 33% of these deaths were in individuals under 20 years of age: 1 individual was 13 and one was 19 years of age.

The prevalence of myocarditis reports in the VAERS system is much higher in the context of dose 2 when comparing by age (t-test: p-value = 0.00092) and more highly associated with BNT162b2 (74% of all dose 2 reports are in the context of BNT162b2. It is also much higher in males when comparing by age (t-test: p-value = 0.000009). Dose 2 is generally administered 3 weeks following the first dose assuming the individual survives dose 1 without any major complications, including death. The BNT162b2 maintains a 21-day interval between dose 1 and 2 while the mRNA-1273 maintains a 28-day interval. Figure 5 reveals that myocarditis reports peak in frequency at 6X for dose 2 in 15-year-old males. It also reveals that regardless of age, myocarditis cases are more frequently reported following dose 2.

Since the high-risk age population for myocarditis is from puberty through early 30s, myocarditis should be considered diagnostically in any young adult who experiences shortness of breath, palpitations or chest pain following injection with dose 1 of any COVID-19 injectable product. It is notable that chest pain is a prevalent tandem AE (25% of individuals who filed myocarditis reports into VAERS also experienced chest pain following dose 1) and this may not be acknowledged by a teenager, or even a medical professional, as a warning sign of cardiac insult.[2]

Point of Interest #4:

There is a lag-phase between reporting and recording of data and thus the safety signals generated from VAERS are being lost. 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 4 shows the difference in data with respect to the data as per weekly update and to the updated data as of August 7th, 2021, for all SAEs.



Safety signals being lost due to backlog of VAERS data.

Figure 4: Shaded plot showing the SAE data as it was input per respective update (grey shaded region) compared with these data as they are reported in each individual updated file (black).

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

[2] Jessica Rose, PhD, MSc, BSc* and 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. Submitted to Reviews in Cardiovascular Medicine.

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.

Conclusions and comments

1. VAERS is functioning as the pharmacovigilance tool that it is by providing safety signals in the context of the COVID-injectable products.

2. The FDA and the CDC are obligated to acknowledge the safety signals emanating from VAERS and to act accordingly to enable transparency and informed consent for the people being subjugated. The safety signals include:

- highly anomalous 1000% increase in the number of total adverse events
- 1/400 individuals have reported an AE (not shown) in the context of COVID-19 products and 1/660 persons have reported an immunological adverse event in this context
- in eight weeks, 19 times the expected rate of myocarditis (heart inflammation) in children ages 12-15 was observed
- the lag time in reporting is resulting in lost safety signals and waning pharmacovigilance

3. Early treatment options exist and should be deployed without restriction.

I continue to disseminate analyzed data as published by the FDA and the CDC in VAERS to the public in a comprehensive way with the goals of **transparency** and **informed consent** in mind.

https://i-do-not-consent.netlify.app
https://ipaknowledge.org/joshua-kuntz-research-fellowship.php

Sincerely, Dr. Jessica Rose