A brief analysis of VAERS-reported Adverse Events in the context of COVID-19 products in breast-feeding mothers, infants and pregnant women in the United States

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"Patient received second dose of Pfizer vaccine on March 17, 2020 while at work. March 18, 2020 her 5-month-old breastfed infant developed a rash and within 24 hours was inconsolable, refusing to eat, and developed a fever. Patient brought baby to local ER where assessments were performed, blood analysis revealed elevated liver enzymes. Infant was hospitalized but continued to decline and passed away. Diagnosis of TTP. No known allergies. No new exposures aside from the mother's vaccination the previous day."

Report for VAERS ID: 1166062

VAERS report for a male less than 1 year old who died.

Abstract

Following the initiation of the global roll-out and administration of the COVID-19 vaccines[1] on December 17, 2020 in the United States, tens of thousands of individuals have reported adverse events (AEs) using the Vaccine Adverse Events Reports System (VAERS).[2] In a previous study, I summarized this data to inform and remind the public of the relevance of any AEs that occur as a direct result of biologicals as prophylactic treatments, especially relevant in the context of technologically novel treatments in the experimental phase of development.[1] Since publishing this data, I have been maintaining up-to-date analyses of the weekly updated VAERS data. This short report focuses on the adverse events in the context of COVID-19 products reported for breast-feeding mothers, infants and pregnant women. Breast-feeding mothers, infants and pregnant women were in the exclusion criteria list for the phase III clinical trials of both Pfizer[3] and Moderna[4]. Therefore, there is no way to predict the effects on infants in these contexts. To claim safety in these contexts is malfeasance. Safety of these products in these groups must be proven in the context of clinical trials where informed consent is necessary, not merely sufficient, in order for a claim of safety with regards to these products to be made.

Background

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. Most vaccine adverse event reports concern relatively minor events, such as injection site pain. Other reports describe serious events, such as hospitalizations, life-threatening illnesses, or deaths.[1] The reports of serious events are of greatest concern and are meant to receive the most careful scrutiny by VAERS staff and healthcare professionals. The primary purpose 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.[5] It must be noted that the reported adverse events as part of the VAERS represent a fraction of the actual number of incidents. Studies have shown that the percentage of incidents reported can be quite low (1-10%) but, for the purposes of this analysis, in order to do the necessary calculations, VAERS numbers were used and the results should be considered to reveal trends.[2,3]

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

[3] https://clinicaltrials.gov/ct2/show/NCT04368728

[4] https://clinicaltrials.gov/ct2/show/NCT04470427

[5] https://vaers.hhs.gov/docs/VAERSDataUseGuide_November2020.pdf

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. A Serious or Severe Adverse Event (SAE) is defined as any adverse event that results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects or is another condition which investigators judge to represent significant hazards.[6,7]

The VAERS handbook states that approximately 15% of reported AEs are classified as severe.[2]

It is worth noting that the Pfizer Inc. and BioNTech SE COVID-19, Moderna, Inc. and the Janssen COVID-19 Vaccine PF products have ***not*** been approved or licensed by the U.S. Food and Drug Administration (FDA), having been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) originally designed for use in individuals 16 years of age and older.[4,5,6] Ultimately, roll-out of COVID-19 vaccines are actively being monitored but all of the risks are not yet known.[5,6] In spite of this, real world trials and administration of these biologicals into pregnant women and children are being pursued in countries around the world.[7] The VAERS dataset is currently the best (if not only and albeit imperfect) way the public can monitor and be informed of the risks associated with administration of the COVID-19 products.

Methods

To analyze the VAERS data set, R was used: A Language and Environment for Statistical Computing. The VAERS data set is available for download (https://vaers.hhs.gov/data/datasets) in three separate comma-separated values (csv) files representing i) general data for each report; ii) the reported AEs or 'symptoms', and; iii) vaccine data including vaccine manufacturer and lot number, for each report. The VAERS dataset is updated approximately once a week and the uploaded set is approximately one week behind the reports. Upon reporting of vaccine side effects or adverse events, a VAERS ID number is provided to the individual to preserve confidentiality, and a detailed description of the adverse events (ranging from 1-15 different types) 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.

To perform a comprehensive analysis pertaining to the adverse events associated with infants, pregnant and breast-feeding women, three groups were created. The first group (Group 1) includes children aged 0-10. The second (Group 2) includes women who were pregnant, got pregnant shortly after injection with a COVID-19 product or had a complication associated with their pregnancy following injection with a COVID-19 product. The third group (Group 3) includes women who were breast-feeding following injection with a COVID-19 product and provided maternal exposure. Groups 2 and 3 were created by selection of keywords that comprise the Medical Dictionary for Regulatory Activities (MedDRA) classification[8] name given in the VAERS database.

Results

Table 1 shows Groups 1, 2 and 3, respectively. As shown, the first Group was made by simply filtering by age and consists of a total of 312 AEs. Note that each VAERS ID is associated with up to 5 AEs. Groups 2 and 3 were created by running a function that seeks keywords over the AE fields. The keywords are listed in Table 1. Group 2 reveals 22 AEs related to pregnancy or loss of pregnancy, while Group 3 reveals 6 AEs related to breast-feeding.

[6] NIA Adverse Event and Serious Adverse Event Guidelines

[7] Based on the Code of Federal Regulations, classification of a serious adverse event includes a report of one of the following: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly, or birth defect. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?frexternal icon

[8] https://bioportal.bioontology.org/ontologies/MEDDRA?p=classes&conceptid=10055221

Children aged 0-10 (group 1)	Pregnancy (group 2)	Breastfeeding (group 3)
312 AEs	Complication of pregnancy	Breast milk discolouration
	Ectopic pregnancy	Lactation disorder
	Abortion of ectopic pregnancy	Poor milk ejection reflex
	Exposure during pregnancy	Maternal exposure during breast feeding
	Biochemical pregnancy	Maternal exposure during pregnancy
	Pregnancy	Suppressed lactation
	Anaphylactoid syndrome of pregnancy	
	Abortion spontaneous	
	Abortion of ectopic pregnancy	
	Abortion induced	
	Foetal non-stress test abnormal	
	Foetal hypokinesia	
	Foetal heart rate abnormal	
	Foetal growth restriction	
	Foetal death	
	Foetal cystic hygroma	
	Cerebral haemorrhage foetal	
	Bradycardia foetal	
	Pregnancy test positive	
	Maternal exposure before pregnancy	
	Haemorrhage in pregnancy	
	Foetal exposure during pregnancy	

Table 1: A list for Groups 1, 2 and 3, respectively, made by selection of keywords that comprise the MedDRA classification name given in the VAERS database.

Group 1: Children aged 0-11

To date (July 2, 2021), there are 166 AE reports in the VAERS database for children between 0 and 10 years of age. Most of the reports involve infants with 46% of the AE reports made for children 18 months and younger and 64% made for children 3 years and younger. The split between genders is 49.4% female, 45.8% male and 4.8% unknown. Figure 1 shows the distribution by age of AEs reported for the age demographic 0-10 years old for all data points and for SAEs.

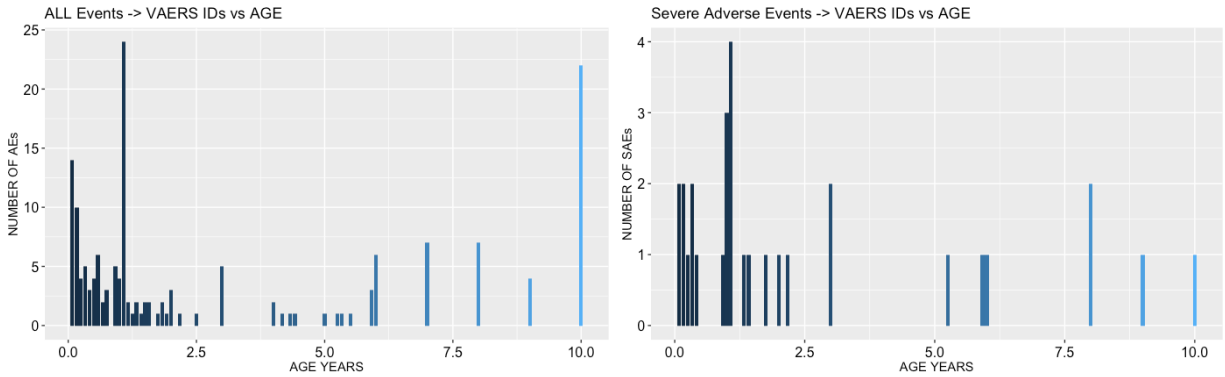

Figure 1: Histograms showing distribution of adverse events reported in the VAERS database for the age demographic 0-10 years old for all reports (left) and for SAE reports (right).

Of these children, 3 (1.8%) have died, 10 (6%) have been hospitalized and 22 (13%) were taken an emergency room doctor for care. Alarmingly, 18% of the AEs are considered Severe Adverse Events according to the VAERS classification system of what qualifies as an SAE. The standard maximal percentage of reports according to the VAERS handbook is 15% so the SAE percentage for children aged 0-10 in the context of the COVID-19 products is above the general standard. Of the AEs, there are 45 classified as cardiovascular, 69 as neurological and 61 as immunological. There is currently 1 breakthrough COVID-19 case.

The histograms in Figure 1 show the total number of AEs (left) and the SAEs (right). The distributions are asymmetric and multi-modal. What is notable here, is that the distributions are right-skewed meaning that children under 2 are associated with higher frequencies of these types of reports and this is statistically-significant (I=1.3, I=1.8, respectively).

As mentioned, there are a total of 312 types of AEs for Group 1 ranging from Rash to Death. Table 2 provides an example of some the AEs in this group for 13 randomly-selected VAERS IDs. This table is meant to demonstrate the types and range of AEs being reported and recorded in the VAERs in association with the COVID-19 products. Even though the data is sparse and potential warning signals not easily detectable yet, it is still vital to start the detection process so that if a signal reveals itself, it can be acknowledged.

VAERS_ID	SYMPTOM1	SYMPTOM2	SYMPTOM3	SYMPTOM4	SYMPTOM5	RECVDATE	STATE	AGE_YRS	VAX_MANU
918691	Paraesthesia	NA	NA	NA	NA	1/4/20	NA	0.58	Pfizer
921052	Allergy to vaccine	Exposure via breast milk	Infant irritability	Pyrexia	Rash	1/5/20	IL	1.17	Pfizer
940836	Myalgia	Pain	Pain in extremity	NA	NA	1/7/20	NA	1.08	Pfizer
940867	Respiratory depression	NA	NA	NA	NA	1/7/20	NA	1.08	Moderna
964521	Epistaxis	NA	NA	NA	NA	1/8/20	NA	1.08	Moderna
1166062	Death	Diet refusal	Emotional distress	Exposure via breast milk	Failure to thrive	4/4/20	NA	0.42	Pfizer
1182232	Crying	Discomfort	Pain	Pyrexia	Rash erythematous	4/8/20	AK	0.5	Pfizer
1313912	Diarrhoea	Fatigue	Injection site pain	Irritability	Nasal congestion	5/13/20	MD	1.83	Pfizer
1314377	Syncope	NA	NA	NA	NA	5/13/20	NY	0.25	Janssen
1353870	Myalgia	Oropharyngeal pain	NA	NA	NA	1/20/20	NA	1.08	Moderna
1407246	Myalgia	Pyrexia	NA	NA	NA	1/28/20	NA	0.67	Pfizer
1410084	Myalgia	NA	NA	NA	NA	3/18/20	NA	0.92	Janssen
1420695	Blindness	Dizziness	Feeling abnormal	NA	NA	6/23/20	MA	1	Janssen

Table 2: Table showing examples of AE types from 13 infants extracted from Group 1.

Group 2: Pregnancy

To date (July 2, 2021), there are 1950 AE reports in the VAERS database for pregnant women. Alarmingly, 28% of the AEs are considered Severe Adverse Events according to the VAERS classification system of what qualifies as a Severe Adverse Event (SAE). This is almost twice the standard according to the VAERS handbook. Figure 2 shows the distribution of AEs by age reported for pregnant women on the left and the distribution of SAEs by age on the right.

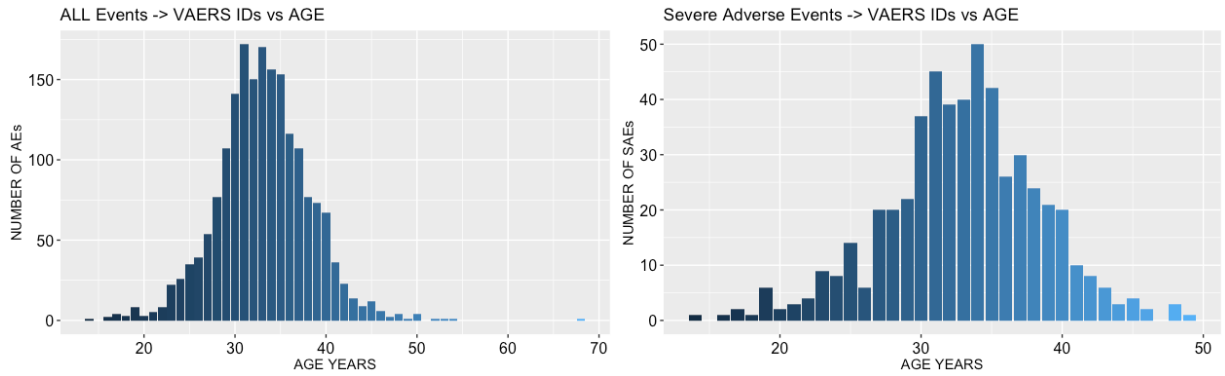

Figure 2: Histograms showing distribution of adverse events reported in the VAERS database for pregnant women for all reports (left) and for SAE reports (right).

Of these women, 11 (0.6%) have died, 209 (11%) have been hospitalized and 354 (18%) were taken an emergency room doctor for care. Of the AEs, there are 761 classified as cardiovascular, 565 as neurological and 606 as immunological. There are currently 29 (1.5%) breakthrough COVID-19 cases.

As shown in Figure 2, histograms show symmetric, unimodal distributions with the mean falling between 32 and 35 years of age. The distributions have no statistically-significant skewing.

Group 3: Breast-feeding women

To date (July 2, 2021), there are 177 AE reports in the VAERS database for breast-feeding women. Three of these reports were filed in the case where infants under 1 year of age had maternal exposure of COVID-19 by-products from the mother. These were reported by the mother and follow-up of infants are not known. They are omitted from the analysis here on in. 16% of the AEs are considered Severe Adverse Events. This is, again, higher than the standard according to the VAERS handbook. Figure 3 shows the distribution by age of AEs reported for pregnant women with the total number of AEs on the left and the SEAs on the right.

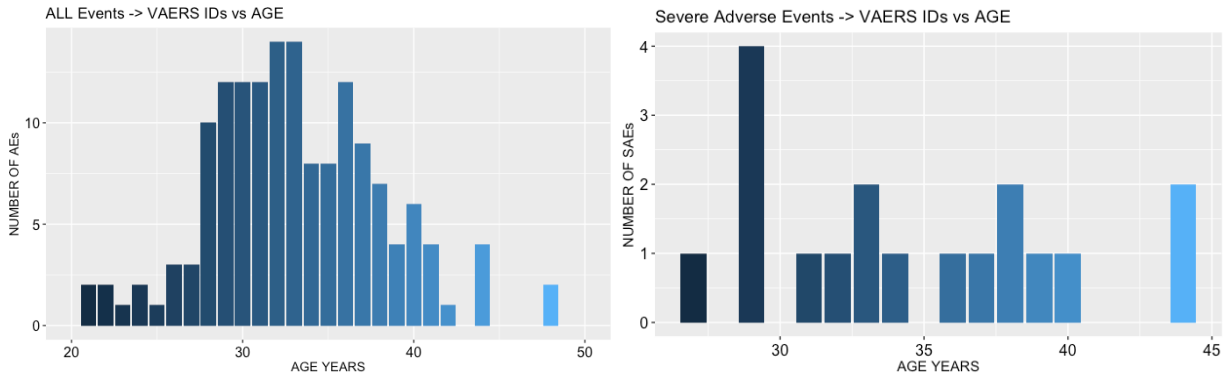

Figure 3: Histograms showing distribution of adverse events reported in the VAERS database for breast-feeding women for all reports (left) and for SAE reports (right).

Of these women, 5 (2.8%) have died, 11 (6.2%) have been hospitalized and 13 (7.3%) were taken an emergency room doctor for care. Of the AEs, there are 29 classified as cardiovascular, 47 as neurological and 47 as immunological. There is currently 1 breakthrough COVID-19 case.

Figure 3 left reveals a symmetric, unimodal distribution of all AEs and on the right in Figure 3 is the SAE data (28 data points in total; only 18 data points with AGE) and its 'distribution' appears bimodal but there is not sufficient data accrued to make any relevant observations due to lack of information in the AGE field in the VAERS database.

Discussion Points

1. The results from this very brief analysis clearly show that of the three Groups examined using descriptive statistics: children aged 0-11, breast-feeding women and pregnant women:
    a. the total number of VAERS reports is currently (as of July 2, 2021 VAERS update) 2,293 (0.6% of total reports to date)
    b. the total number of dead is 19 (0.4% of total death reports to date).

Although these percentages are low, it is important to note that the Group 1: 0-10-year-old demographic has only recently been added to the COVID-19 product roll-out so this data is still very early and likely to grow. It is also vital to recall that these data represent only a fraction of the actual AE occurrences due to known under-reporting and under-recording issues in VAERS.

2. Of the children, half fall under the age of 18 months. 64% of the AEs in this age demographic fall under 3 years old. This is interesting in the context of other childhood vaccines since the schedule includes many injections at age 3 years[9] and requires investigation in follow-up studies.

3. It is disturbing that children in infancy are suffering cardiovascular and neurological AEs and it is even more disturbing that this data are skewed toward the ages between 0 and 2 in a statistically-significant way. Of the breast-feeding Group, 3 infants under the age of 1 had maternal exposure during breast-feeding. It is very difficult to know if any AEs were subsequently reported for these infants since no follow-up in the VAERS database has not been found. Subsequent follow-up should be done.

4. It is also disturbing that 43% of all "Abortion spontaneous" reports were concomitantly reported with "Exposure during pregnancy".

Conclusions

Breast-feeding mothers, infants and pregnant women were in the exclusion criteria list for the phase III clinical trials of both Pfizer and Moderna. Therefore, there is no way to predict the effects on individuals in these contexts. Safety cannot be claimed for this reason and also based on the fact that the SAE reports in the VAERS database are atypically high for the groups examined.

The mRNA products ARE experimental: mRNA platforms are new in medical microbiology and have never before been implemented for use in human subjects on a global scale in the context of viruses. This is not refutable. Since it was not possible to perform a study on the effects of a full-term pregnancy in the timeframe lapsed for the clinical trials to have been deemed respectable and to subsequently issue EUAs for these products, it is not possible now to draw conclusions as to the effects on pregnant women or their infants who are breast-feeding.

The most effective way I can think of to answer questions pertaining to safety and efficacy in these contexts is to inject these products into pregnant women and collect the subsequent data of the effects.

"Patient was sitting down about 5 minutes after the shot. He said his vision was almost black and he felt faint. He requested EMS to be called so I called 911 and ambulance came down. His vision improved alot but he still didn't feel ok so EMS took him to hospital."

Report for VAERS ID: 1420695

VAERS report for 1 year old male who went blind.

[9] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

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