Article

COVID-19 Vaccines: The Impact on Pregnancy Outcomes and Menstrual Function

James A. Thorp[1]*, Claire Rogers[2], Michael P. Deskevich [3], Stewart Tankersley[4], Albert Benavides[5], Megan D. Redshaw [6] and Peter A. McCullough [7]

[1]   Maternal Fetal Medicine, Independent Researcher, Gulf Breeze, FL
[2]   Truth for Health Foundation, Rome, GA
[3]   Independent Researcher, Boulder, CO
[4]   Concerned Doctors, Montgomery, AL
[5]   Verity Medical Foundation, San Jose, CA
[6]   Independent Researcher, Palmyra, MO
[7]   Truth for Health Foundation, Dallas, TX
*Corresponding author: jathorp@bellsouth.net

Abstract: Objectives: Assess rates of adverse events (AE) after COVID-19 vaccines experienced by women of reproductive age, focusing on pregnancy and menstruation, using data collected by the US Centers for Disease Control and Prevention (CDC) Vaccine Adverse Events Reporting System (VAERS) database. **Design:** Population based retrospective cohort study. **Setting:** US and global entries in US Centers for Disease Control and Prevention (CDC) Vaccine Adverse Events Reporting System (VAERS). **Participants**   CDC VAERS entries from January 1, 1998 to June 30, 2022. **Interventions:** None. **Main Outcome and Measures:** A proportional reporting ratio analysis is performed using data in the VAERS system comparing adverse events (AE) reported post COVID-19 vaccines with that of post-Influenza vaccines. **Results:** COVID-19 vaccines, when compared to the Influenza vaccines are associated with a significant increase in AE with all proportional reporting ratios of   > 2.0: menstrual abnormality, miscarriage, fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal arrhythmia, fetal cardiac arrest, fetal vascular mal-perfusion, fetal growth abnormalities, fetal abnormal surveillance, fetal placental thrombosis, low amniotic fluid, and fetal death/stillbirth (all p values were much smaller than 0.05). When normalized by time-available, doses-given, or persons-received, all COVID-19 vaccine AE far exceed the safety signal on all recognized thresholds. **Conclusions:** Pregnancy and menstrual abnormalities are significantly more frequent following COVID-19 vaccinations than that of Influenza vaccinations. A worldwide moratorium on the use of COVID-19 vaccines in pregnancy is advised until randomized prospective trials document safety in pregnancy and long-term follow-up in offspring.

Keywords: COVID-19 vaccines; menstruation; pregnancy outcomes; Influenza vaccines; VAERS

1. Introduction

Historically, a vaccine is subjected to an average of 10-12 years in clinical trials before it is authorized to be administered to the general population. The response to the COVID-19 pandemic organized under Operation Warp Speed rolled out novel SARS-CoV-2 vaccines in record time. Under an Emergency Use Authorization these vaccines were available to the public as early as 10 months after development. The primary sentiment at the onset of the pandemic was that early treatment strategies for COVID-19 were ineffective and potentially unsafe, and these novel vaccines were promoted as the sole solution to the pandemic.

The rapid rollout of the COVID-19 vaccines meant that long-term safety studies had not been conducted by the time the vaccines were made available to the general population. In addition, COVID-19 vaccines were quickly authorized for use in pregnant women,

something never done in the history of medical regulation. For example, the Influenza vaccine was in continuous development and testing for nearly 60 years before being authorized in 1997 for use during pregnancy. The rapid development of COVID-19 vaccines, very limited safety studies, and subsequent clinical observations prompt inquiries into the safety of the COVID-19 vaccines in pregnancy. In this study, an evaluation of the safety of the COVID-19 vaccines is presented with a specific interest in pregnancy and in women of reproductive age.

2. Methods

A retrospective analysis of the AE reports post COVID-19 vaccines and post-Influenza vaccines in the VAERS database is performed for events reported between 1 January 1998 and 30 June 2022. Influenza vaccines were chosen as the control group because in 1997 the CDC's approval of the first Influenza vaccine for pregnant women. Reports in VAERS after 1 January   1998 would count AE due to on-label use of the vaccines. The end of the study period is 30 June 2022. This provides 294 months of data for the Influenza vaccine and 18 months of data for the COVID-19 vaccines.

AE Report Counts

Based on a high-volume obstetrical experience over 43 years, a board-certified obstetrician-gynecologist and maternal fetal medicine physician chose AE of interest from the VAERS database by those most relevant to fertility and reproductive physiology. A query of the VAERS database was made for each AE: menstrual abnormality, miscarriage (spontaneous abortion), fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal arrhythmia, fetal cardiac arrest, fetal vascular malperfusion, fetal growth abnormalities, fetal abnormal surveillance, fetal placental thrombosis, low amniotic fluid, and fetal death (stillbirth). AE reports were counted globally and within the US for both the COVID-19 vaccines and the Influenza vaccines. The counts for these events are in Tables 1 and 2.

Doses Given

The AE report count data is normalized by doses of each vaccine administered during the study period. Using Our World in Data,[1] we estimate that 12.07 billion doses of the COVID-19 vaccine were given globally. Using CDC data, we estimate that 66 billion doses of the Influenza vaccine were given globally and 3.3 billion doses were given in the US.[2-6]

Estimating the Number of People Vaccinated

Additionally, the AE report counts are normalized by the number of people vaccinated during the study period. CDC data estimates that 5.23 billion people received at least one dose of a COVID-19 vaccine globally, including 260 million in the US, and 7.71 billion people received at least one dose of the Influenza vaccine globally, including 313 million in the US.[2-6] Determining the number of people vaccinated with the COVID-19 vaccine is straightforward; however, the Influenza vaccine doses are difficult to count because there is no widespread tracking system and there are yearly seasons where an individual may or may not choose to receive subsequent vaccinations. To estimate the number of people that have received at least one dose of the Influenza vaccine since 1998, we used a Monte Carlo simulation.

The simulation started in 1980 with a sample of an eligible population of 100,000,000 people, with 50% of them pre-vaccinated from previous years. From 1980 to 1997 the population grows by f_e, shrinks by f_d, and individuals are vaccinated using a conditional f_v based on their current vaccination status. The simulation continues until 2021, accumulating the number of people who were vaccinated.[6] After running the simulation, in 2021 the sample population grew to 125,981,000, with a total of 146,200,000 (current vaccinated

living plus the accumulated vaccinated dead) receiving at least one dose of the Influenza vaccine since 1998 (116% of the current population).

Scaling this estimate to 2022, the total eligible US population of 269.5 million (329.5 million minus 60 million who are too young)[6] results in roughly a total of 313 million people in the US that have received at least one dose of Influenza vaccine.[7] Using the same scaling factor for an eligible global population of 6.65 (7.95 billion minus 1.3 billion), results in an estimate of 7.71 billion people worldwide who have received at least one dose of an Influenza vaccine since 1998.

3. Results

For all AE, the report rates post-COVID-19 vaccination are higher compared to Influenza vaccination across all three normalization methods: by unit time, by dose given, and by person vaccinated. We report two analyses below: 1) compute the p-value to determine if the AE report rates are statistically different between the two vaccines, and 2) compute the relative rate and 95% confidence interval (CI) of AE reports after the COVID-19 vaccine versus the Influenza vaccine.

Statistical Significance

Each AE report is treated as a discrete independent event occurring at the mean rate specified in Tables 1 and 2 which are modeled as a Poisson distribution. Given two rates λ_1 and λ_2 we perform a Poisson E-test[8] to compute the p-value. We use the rates in Tables 1 and 2 and normalize the event counts over the time-, dose-, and people-vaccinated-windows and report the p-values below in Table 3. Where there is sufficient data, the p-values are small, and where 0.0 is reported, it was too small to represent as a double precision floating point number in our E-test function.[8]

Proportional Reporting Ratio

For the rates that have non-zero counts in the reporting period, the ratio of rates of AE reports for each vaccine and the 95% CI is estimated. The ratio distribution, R, which is the distribution of the ratio of two different Poisson distributions, is computed. That is, given two Poisson distributions, $P(\lambda_1)$ and $P(\lambda_2)$, R, which represents the probability distribution of the ratio of the distribution of events is estimated with a Monte Carlo simulation.

$$R(\lambda_1, \lambda_2) = \frac{P(\lambda_1)}{P(\lambda_2)}$$

1,000,000 random samples are drawn from Poisson distributions with rates λ_1 and λ_2 resulting in a sample of paired event counts n_1 and n_2, respectively and R is the distribution of all $\frac{n_1}{n_2}$ ratios. The mean of R is is the expectation value for the ratio of the two Poisson distributions and the empirically derived quantile function of R is used to estimate the 95% CI of the mean.

All computed values converge to a precision of 1% or better. For AE that are reported infrequently post-Influenza vaccines there is a finite probability that n_2 is zero resulting in R being undefined. To mitigate this problem, the zero-truncated Poisson distribution[9] is used and only instances of non-zero n_2 draws are counted. This approach skews the R distribution to the left[10] and makes the AE rates for the COVID-19 vaccine appear safer. In these cases, the AE rate is a lower bound. According to CDC's Standard Operating Procedures for COVID-19 when doing a proportional reporting ratio (PRP) analysis, which is analogous to the analysis presented here, a 2-fold increase in reporting is a sufficient signal to be concerned.[11]

Table 1. Depicted here are the US AE report counts in VAERS along with the mean rate of report over the time tracked, the mean rate of report per billion doses given, and the mean rate of report per billion people vaccinated. Counts and rates are expressed as AE for COVID-19 vaccines / AE for Influenza vaccines. The same data for the global counts and rates are shown in Table 2.

Adverse Event	US Count of AE reports post Vaccine	US Rate of reported AE (count/Month)	US Rate of reported AE (count/billion doses)	US Rate of reported AE (count/billion people vaccinated)
Menstrual abnormality	6352 / 54	353 / 0.184	10700 / 16.4	24400 / 173
Miscarriage	1232 / 259	68.4 / 0.881	2070 / 78.5	4740 / 827
Fetal chromosomal abnormalities	7 / 0	0.389 / 0.00	11.7 / 0.00	26.9 / 0.00
Fetal malformation	2 / 1	0.111 / 0.00340	3.35 / 0.303	7.69 / 3.19
Fetal cystic hygroma	5 / 0	0.278 / 0.00	8.39 / 0.00	19.2 / 0.00
Fetal cardiac disorders	10 / 2	0.556 / 0.00680	16.8 / 0.606	38.5 / 6.39
Fetal arrhythmia	3 / 0	0.167 / 0.00	5.03 / 0.00	11.5 / 0.00
Fetal cardiac arrest	3 / 5	0.167 / 0.00	5.03 / 0.00	11.5 / 0.00
Fetal vascular mal-perfusion	5 / 0	0.278 / 0.00	8.39 / 0.00	19.2 / 0.00
Fetal growth abnormalities	59 / 20	3.28 / 0.0680	99.0 / 6.06	227 / 63.9
Fetal abnormal surveillance	125 / 36	6.94 / 0.122	210 / 10.9	481 / 115
Fetal placental thrombosis	5 / 0	0.278 / 0.00	8.39 / 0.00	19.2 / 0.00
Low amniotic fluid	11 / 1	0.611 / 0.00340	18.4 / 0.303	42.3 / 3.19
Fetal stillbirth	168 / 42	9.33 / 0.143	282 / 12.7	646 / 134

Table 2. Depicted here are the global post-vaccine AE report counts in VAERS, along with the mean rate of report over the time tracked, the mean rate of report per billion doses given, and the mean rate of report per billion people vaccinated. Counts and rates are expressed as AE for COVID-19 vaccines / AE for Influenza vaccines. The same data for the US counts and rates are shown in Table 1.

Adverse Event	Global Count of AE reports post Vaccine	Global Rate of reported AE (count/Month)	Global Rate of reported AE (count/billion doses)	Global Rate of reported AE (count/billion people vaccinated)
Menstrual abnormality	12843 / 65	714 / 0.221	1060 / 0.985	2460 / 8.43
Miscarriage	3338 / 325	185 / 1.11	277 / 4.92	638 / 42.2
Fetal chromosomal abnormalities	10 / 0	0.556 / 0.00	0.829 / 0.00	1.91 / 0.00
Fetal malformation	22 / 2	1.22 / 0.00680	1.82 / 0.0303	4.21 / 0.259
Fetal cystic hygroma	8 / 0	0.444 / 0.00	0.663 / 0.00	1.53 / 0.00
Fetal cardiac disorders	18 / 2	1.00 / 0.00680	1.49 / 0.0303	3.44 / 0.259
Fetal arrhythmia	5 / 0	0.278 / 0.00	0.414 / 0.00	0.956 / 0.00
Fetal cardiac arrest	20 / 0	1.11 / 0.00	1.66 / 0.00	3.82 / 0.00
Fetal vascular mal-perfusion	12 / 0	0.667 / 0.00	0.994 / 0.00	2.29 / 0.00
Fetal growth abnormalities	188 / 24	10.4 / 0.0816	15.6 / 0.364	35.9 / 3.11
Fetal abnormal surveillance	178 / 45	9.89 / 0.153	14.7 / 0.682	34.0 / 5.84
Fetal placental thrombosis	6 / 0	0.333 / 0.00	0.497 / 0.00	1.15 / 0.00
Fetal stillbirth	402 / 64	22.3 / 0.218	33.3 / 0.970	76.9 / 8.30

Table 3. Proportional Reporting Ratio (PRR) analysis is presented here for the relative rates by time, by dose, and per person. Global values are in the top line and US values are in the bottom line for each AE. A relative rate greater than 1 implies that there are more COVID-19 vaccine AE reports than Influenza vaccine AE reports. According to CDC's Standard Operating Procedures for COVID-19 a two-fold increase in PRR indicates a sufficient signal to be concerned.[11.]

Adverse Event	Relative Rate (by time)	Relative Rate (by dose)	Relative Rate (by person vaccinated)
Menstrual abnormality	4257 [1589.1-12893] p=0.0 2524 [894.57-6419.0] p=0.0	1192 [673.95-2162.8] p=0.0 738 [391.6-1584] p=0.0	298 [223.0-406.0] p=0.0 145 [108.6-197.4] p=0.0
Miscarriage	177 [114.4-283.5] p=0.0 83 [50.8-143] p=0.0	57 [44.3-74.7] p=0.0 27 [20.2-36.5] p=0.0	15 [13.3-17.5] p=0.0 6 [5.0-6.7] p=0.0
Fetal chromosomal abnormalities	p=0.00058 p=0.0048	p=0.00058 p=0.0048	p=0.00058 p=0.0048
Fetal malformation	21 [10.0-32.0] p=1.9×10^{-07} 2 [0.0-5.0] p=0.20	20 [7.67-31.0] p=1.9×10^{-07} 2 [0.0-5.0] p=0.20	15 [4.50-30.0] p=2.1×10^{-06} 2 [0.0-5.0] p=0.20
Fetal cystic hygroma	p=0.0024 p=0.020	p=0.0024 p=0.020	p=0.0024 p=0.020
Fetal cardiac disorders	17 [8.00-27.0] p=2.6×10^{-06} 10 [4.00-17.0] p=0.00058	16 [6.00-26.0] p=2.6×10^{-06} 9 [3.0-16] p=0.00058	12 [3.60-25.0] p=2.7×10^{-05} 6 [1.5-15] p=0.0047
Fetal arrhythmia	p=0.020 p=0.088	p=0.020 p=0.088	p=0.020 p=0.088
Fetal cardiac arrest	p=6.9×10^{-07} p=0.088	p=6.9×10^{-07} p=0.088	p=6.9×10^{-07} p=0.088
Fetal vascular mal-perfusion	p=0.00015 p=0.020	p=0.00015 p=0.020	p=0.00015 p=0.020
Fetal growth Abnormalities	126 [42.00-210.0] p=0.0 43 [14.0-72.0] p=0.0	56 [20.7-189] p=0.0 22 [7.14-64.0] p=0.0	12 [7.42-21.4] p=0.0 4 [2.2-6.8] p=3.2×10^{-07}
Fetal abnormal surveillance	83 [26.9-193] p=0.0 68 [21.6-140] p=0.0	25 [12.2-58.7] p=0.0 24 [10.1-63.0] p=0.0	6 [4.1-9.0] p=0.0 4 [2.9-6.6] p=0.0
Fetal placental thrombosis	p=0.0096 p=0.020	p=0.0096 p=0.020	p=0.0096 p=0.020
Low amniotic fluid	17 [8.00-25.0] p=5.1×10^{-06} 11 [5.00-18.0] p=0.00029	16 [7.00-25.0] p=5.1×10^{-06} 11 [4.00-18.0] p=0.00029	14 [4.67-25.0] p=5.1×10^{-06} 9 [2.5-17] p=0.00029

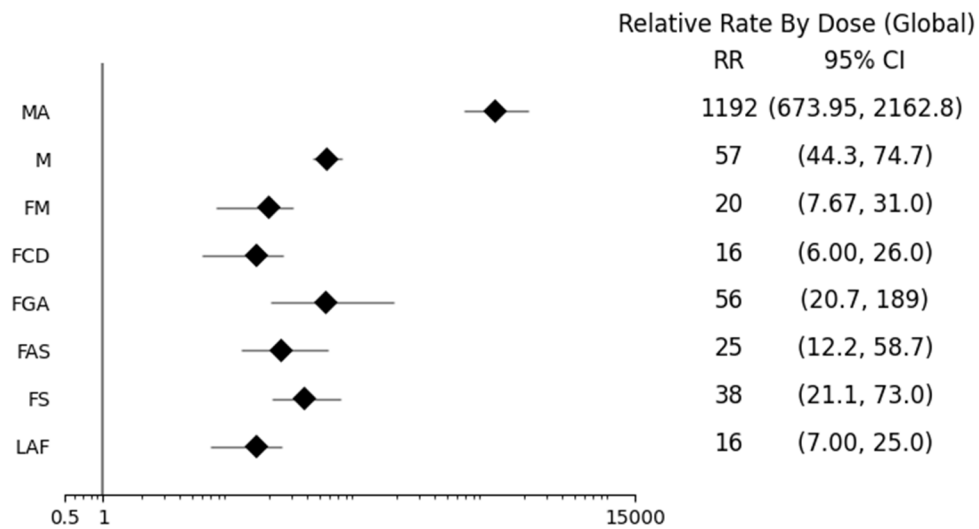| Adverse Event	Relative Rate (by time)	Relative Rate (by dose)	Relative Rate (by person vaccinated)
	82 [26.5-184] p=0.0 135 [48.25-412.0] p=0.0	38 [21.1-73.0] p=0.0 26 [12.2-60.0] p=0.0	5 [3.4-7.2] p=0.0 9 [6.9-13] p=0.0
Fetal stillbirth			

Figure 1. Global relative rates of AE reports after COVID-19 vaccines versus those after Influenza vaccines by dose given. A value greater than 1 implies that AE are reported more frequently after COVID-19 vaccination compared to Influenza vaccinations. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. MA=menstrual abnormality; M=miscarriage (spontaneous abortion); FM=fetal malformation; FCD=fetal cardiac disease; FGA=fetal growth abnormality; FAS=fetal abnormal surveillance; LAF=low amniotic fluid volume; FD=fetal death.
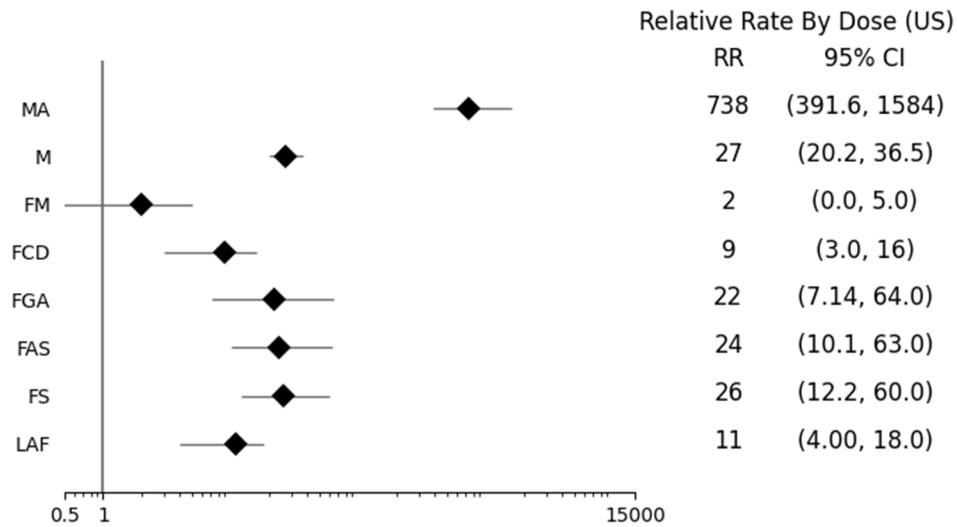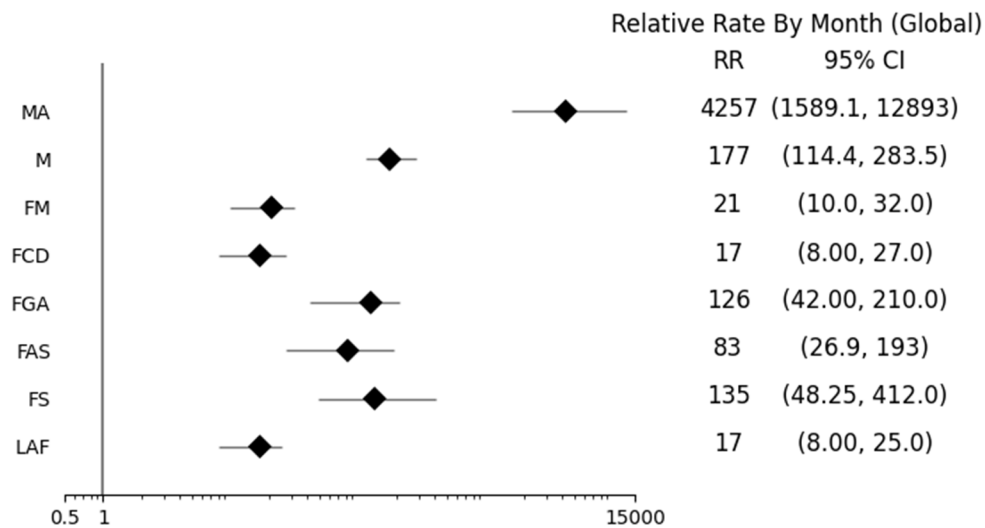
Figure 2. US relative rates of AE reports after COVID-19 vaccination versus those after Influenza vaccination by dose given. A value greater than 1 implies that the AE is reported more frequently after the COVID-19 vaccines than after the Influenza vaccines. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. MA=menstrual abnormality; M=miscarriage (spontaneous abortion); FM=fetal malformation; FCD=fetal cardiac disease; FGA=fetal growth abnormality; FAS=fetal abnormal surveillance; LAF=low amniotic fluid volume; FD=fetal death.
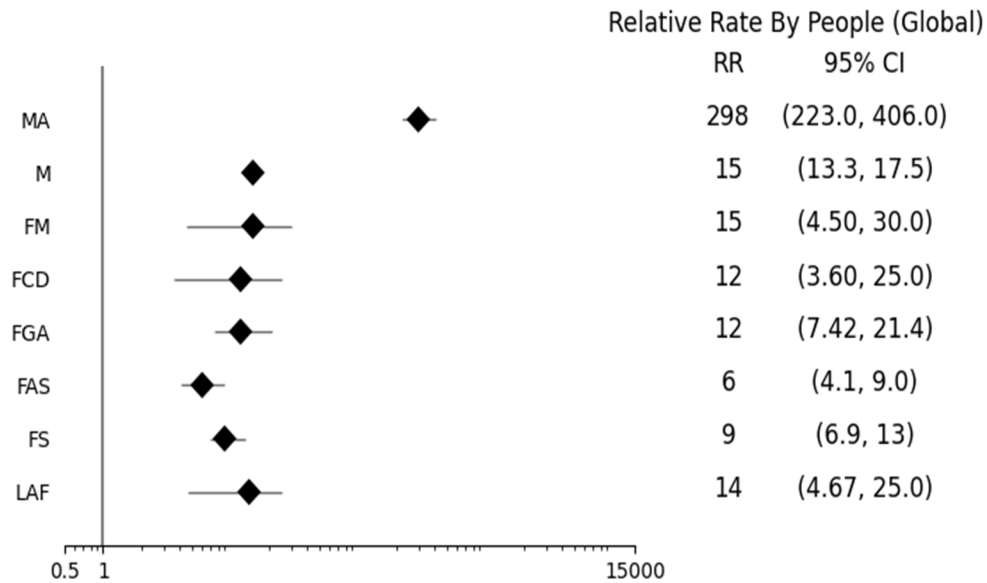

Figure 3. Global relative rates of AE events after COVID-19 vaccination versus those after Influenza vaccination by unit time (month). A value greater than 1 implies that the AE is reported more frequently after the COVID-19 vaccination than after the Influenza vaccination. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. MA=menstrual abnormality; M=miscarriage (spontaneous abortion); FM=fetal malformation; FCD=fetal cardiac disease; FGA=fetal growth abnormality; FAS=fetal abnormal surveillance; LAF=low amniotic fluid volume; FD=fetal death.

Figure 5. Global relative rates of AE events after COVID-19 vaccination versus those after Influenza vaccination by persons vaccinated. A value greater than 1 implies that the AE is reported more frequently after the COVID-19 vaccines than after the Influenza vaccines. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. MA=menstrual abnormality; M=miscarriage (spontaneous abortion); FM=fetal malformation; FCD=fetal cardiac disease; FGA=fetal growth abnormality; FAS=fetal abnormal surveillance; LAF=low amniotic fluid volume; FD=fetal death.
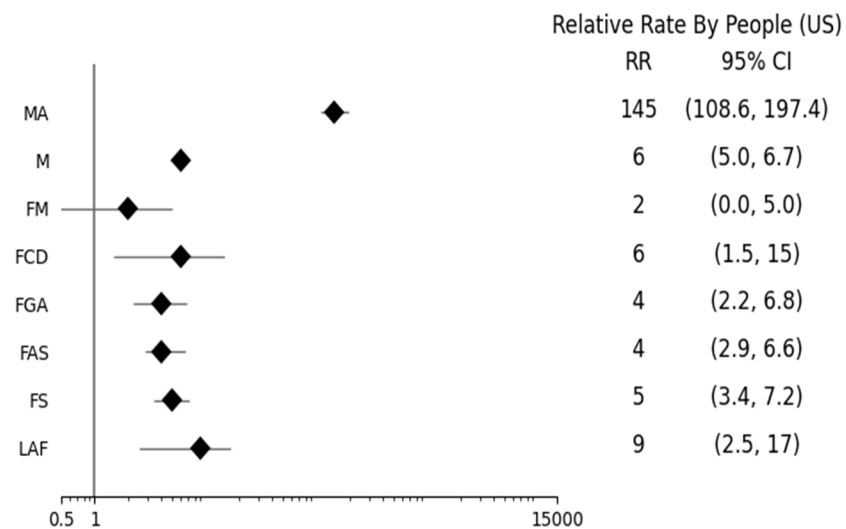

Figure 6. US relative rates of AE events after COVID-19 vaccination versus those after Influenza vaccination by persons vaccinated. A value greater than 1 implies that the AE is reported more frequently after the COVID-19 vaccines than after the Influenza vaccines. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. MA=menstrual abnormality; M=miscarriage (spontaneous abortion); FM=fetal malformation; FCD=fetal cardiac disease; FGA=fetal growth abnormality; FAS=fetal abnormal surveillance; LAF=low amniotic fluid volume; FD=fetal death.

4. Discussion

An analysis of data from VAERS finds excessive adverse event reports for the COVID-19 vaccines as compared to the Influenza vaccines by more than a factor of two in almost all cases. According to the CDC, a factor of two or greater is a safety signal that requires further study.[11]

Strengths

This study went beyond clinical observation to analyze official US government data on COVID-19 vaccine AE reports. The strengths of this study include the use of the VAERS database and leveraging of statistical modeling techniques. CDC and others have extensively researched the safety of Influenza vaccines in pregnancy supporting this selection as an ideal control group. Our findings align with a range of independent sources identifying similar safety concerns. In addition to VAERS, worldwide governmental vaccine pharmacovigilance databases also document safety signals with the COVID-19 vaccines include: the UK Yellow Card System,[12] World Health Organization's VigiAccess,[13] and the European Economic Area's EudraVigilance data.[14]

Results of this study also align with recommendations from governments and non-governmental organizations. Recent documents from the UK government[15] state "In the context of supply under Regulation 174, it is considered that sufficient reassurance of safe use of the vaccine in pregnant women cannot be provided at the present time; however, use in women of childbearing potential could be supported provided healthcare professionals are advised to rule out known or suspected pregnancy prior to vaccination." The World Council of Health has also called for a ban on the COVID-19 vaccines in pregnancy and lactation.[16] Producers of the COVID-19 vaccines themselves report significant AE post COVID-19 vaccination including 1,223 deaths in the first 90 days of COVID-19 vaccine rollout (page 7).[17] Specifically, 46% (124/270) of pregnant women in the first 90 days of rollout experienced AE and 81% (26/32) experienced miscarriage (page 12).[17]

Additional data from Pfizer also recorded biodistribution of the vaccine contents into the bloodstream within hours, crossing all physiologic barriers including the maternal-placental-fetal barrier and the blood brain barriers in both the mother and the fetus.[18] This data, along with Schädlich et al. from 2012,[19] documents a significant concentration of lipid nanoparticles in ovaries. Pantazatos et al. reported a significant rise in all-cause mortality 0-5 weeks post-injection in almost all age groups and with an age-related temporal pattern consistent with the US vaccine rollout.[20] Palmer and Bahdki documented autopsy evidence of suspected vaccine-induced death and spike-mediated generalized endothelitis in many organ beds caused by spike protein.[21] In just 15 months after vaccine rollout, 1,366 peer-reviewed articles document severe adverse events after the COVID-19 vaccinations,[22] a concerning safety signal not even rivaled by combining all other vaccines in the worldwide medical literature.

Limitations

There are several limitations to this study. First, estimates of Influenza vaccine dose count and estimates of the number of people vaccinated is imprecise. Using available data and Monte Carlo simulation techniques, conservative good-faith estimates are calculated. While ideally these estimates would be more precise, even if they are off by a factor of five, the safety signal remains. Second, the relative under-reporting factors (URF) in VAERS for Influenza vaccine versus COVID-19 vaccines are unknown. Without knowing the URF, it is assumed to be equal for the two vaccines.

Implications for Clinicians and Policy Makers

Given the safety signals with the COVID-19 vaccination in pregnancy, caution is necessary for our more vulnerable populations such as pregnant women, children and women of reproductive age. There is a precedent in medicine for halting vaccines with safety signals far less than what is observed with the COVID-19 vaccines. The swine flu

vaccine was removed from market after less than 30 deaths[23] and in the case of the rotavirus vaccine was removed after only a few non-lethal cases of intussusception.[24] The authors of this study concur with the recommendations previously made by the UK government[16] and the World Council for Health:[17] COVID-19 vaccines should not be used in pregnancy until long-term safety data are available.

Assumptions at the outset of the COVID-19 pandemic were made under the pressures of a worldwide health emergency and should be revisited. The assumption that pregnant women are at greater risk for infectious complications is not well established in current literature. A recent large-scale study indicates that pregnant patients are at lower risk for mortality and severe outcomes than are non-pregnant patients.[25] There is now even more evidence that early treatment of COVID-19 with vitamins, supplements and repurposed drugs are safe and effective especially when started early in the COVID-19 disease process.[26-29]

Future Work

Future research should verify these results to differentiate between vaccine-related AE and effects of COVID-19 illness. Additional research should focus on potential mechanisms of AE in pregnancy and lactation, including the vaccines' pro-inflammatory effects, the production and accumulation of spike protein, and the role of lipid nanoparticles, in addition to any other factors that may play a pathophysiologic role. Pathologic examinations of placental tissue and breast milk from vaccinated and non-vaccinated mothers should be undertaken and analyzed for various markers including spike protein.

5. Conclusion

Governments and public health agencies worldwide are stepping back from COVID-19 vaccine mandates and are beginning to recommend against or even prohibiting COVID-19 mandates and vaccinations for vulnerable groups such as children, pregnant women, and lactating women.[30-39] Yet, the US continues promoting COVID-19 vaccinations and boosters in all groups, including pregnant women. This study supports the recommendations of the UK's Medicines & Healthcare and The World Council of Health against COVID-19 vaccination and boosters for pregnant and lactating women.

References

1) Coronavirus (COVID-19) Vaccinations. https://ourworldindata.org/covid-vaccinations
US Census Bureau of Statistics with US Population by Year (accessed 14 September 2022).

2) US Population by year. https://www.multpl.com/united-states-population/table/by-year
(accessed 14 September 2022).

3) Flu Vaccination Coverage, United States, 2018-19 Influenza Season. https://www.cdc.gov/flu/fluvaxview/coverage-1819estimates.htm#table2 (accessed 14 September 2022).

4) Centers for Disease Control and Prevention (CDC). Historical Reference of Seasonal Influenza Vaccine Doses Distributed. https://www.cdc.gov/flu/prevent/vaccine-supply-historical.htm (accessed 14 September 2022).

5) Centers for Disease Control and Prevention (CDC). FLU vaccination dashboard. https://www.cdc.gov (accessed 14 September 2022).

6) UN Population Data. https://population.un.org/ (accessed 14 September 2022).

7) Kwong JC, Chung H, Jung JK, et al. On Behalf Of The Canadian Immunization Research Network Cirn Investigators. The impact of repeated vaccination using 10-year vaccination history on protection against influenza in older adults: a test-negative design study across the 2010/11 to 2015/16 influenza seasons in Ontario, Canada. Euro Surveill 2020 Jan;25(1):1900245. doi: 10.2807/1560-7917.ES.2020.25.1.1900245. PMID: 31937397; PMCID: PMC6961264.

8) Python Poisson E-Test. https://github.com/nolanbconaway/poisson-etest
(accessed 14 September 2022).

9) Estimating the Parameter in a Conditional Poisson Distribution. https://www.jstor.org/stable/2527552 (accessed 14 September 2022).

10) A Characterization of Positive Poisson Distribution and its Statistical Application. https://epubs.siam.org/doi/10.1137/0134043 (accessed 14 September 2022).

11) Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19. https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.PDF. (accessed 14 September 2022).

12) UK Yellow Card system. https://yellowcard.mhra.gov.uk/information (accessed 14 September 2022).

13) WHO VigiAccess. https://docs.google.com/document/d/1KuV9FMkdCZ1hr50J_tvaIwArZn-VuHNMUoVXQ1hhub68/edit#heading=h.jhdm6olc1r8a (accessed 14 September 2022).

14) EudraVigilance. https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance (accessed 14 September 2022).

15) UK.gov Medicines & Healthcare products Regulatory Agency. https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine (accessed 14 September 2022).

16) World Council For Health. https://www.worldcouncilforhealth.org (accessed 14 September 2022).

17) Pfizer 5.3.6 Post-Marketing Experience. Page 7, Table 1: 1,223 deaths in 90 days December 1, 2020 to February 28, 2021. Page 12 There was a 46% (124/270) rate of adverse reactions after COVID-19 vaccinations in pregnancy.
https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf (accessed 14 September 2022).

18) Pfizer 2.6.5.5B Pharmacokinetic: Organ Biodistribution data table Page 17 with 118-fold concentration of the lipid nanoparticles in ovaries from injection to 48 hours when animals were sacrificed. https://pandemictimeline.com/wp-content/uploads/2021/08/Pfizer-bio-distribution-confidential-document-translated-to-english.pdf

19) Schädlich A, Hoffmann S, Mueller T, Caysa H, Rose C, Göpferich A, Li J, Kuntsche J, Mäder K. Accumulation of nanocarriers in the ovary: a neglected toxicity risk? J Control Release. 2012 May 30;160(1):105-12. doi: 10.1016/j.jconrel.2012.02.012. Epub 2012 Feb 21. PMID: 22361117.

20) Pentazatos S, Seligmann H. COVID Vaccination and age-stratified all-cause mortality risk. October 2021. https://pa.childrenshealthdefense.org/video/the-vaccine-fatality-rate-a-conversation-with-dr-spiro-pantazatos-columbia-u/ (accessed 14 September 2022).

21) Palmer M, Bhakdi S. Vascular and organ damage induced by mRNA vaccines: Irrefutable Proof of Causality. https://palexander.substack.com/p/bhakdi-and-palmer-vascular-and-organ (accessed 14 September 2022).

22) Thorp KE, Thorp JA, Thorp EM. COVID-19 and the Unraveling of Experimental Medicine - Part III. G Med Sci. 2022; 3(1):118-158. https://www.doi.org/10.46766/thegms.pubheal.22042302

23) Swine Flu Program is Halted in 9 states as 3 die after shots. https://www.nytimes.com/1976/10/13/archives/swine-flu-programm-is-halted-in-9-states-as-3-die-after-shots.html. (accessed 14 September 2022).

24) Dennehy PH, Bresee JS. Rotavirus vaccine and intussusception. Where do we go from here? Infect Dis Clin North Am. 2001 Mar;15(1):189-207, x-xi. doi: 10.1016/s0891-5520(05)70275-0. PMID: 11301815.

25) Pineles BL, Harris AD. In-Hospital Mortality in a Cohort of Hospitalized Pregnant and Nonpregnant Patients With COVID-19. Ann Intern Med. 2021 Dec;174(12):1779-1780. doi: 10.7326/L21-0634. PMID: 34929121.

26) I-Care: Early COVID Treatment. Front Line COVID-19 Critical Care Alliance. Prevention & Treatment Protocols for COVID-19. September 6, 2022. https://covid19criticalcare.com/covid-19-protocols/i-care-early-covid-treatment/ (accessed 14 September 2022).

27) Kory P, Meduri GU, Varon J, Iglesias J, Marik PE. Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19. Am J Ther. 2021 Apr 22;28(3):e299-e318. doi: 10.1097/ MJT.0000000000001377. Erratum in: Am J Ther. 2021 Nov-Dec 01;28(6):e813. PMID: 34375047; PMCID: PMC8088823.

28) Marik PE, Kory P. Ivermectin, A Reanalysis of the Data. Am J Ther. 2021 Sep-Oct 01;28(5):e579- -e580. doi: 10.1097/MJT.0000000000001443. PMID: 34491955; PMCID: PMC8415512.arik

29) McCullough PA, Kelly RJ, Ruocco et al. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021 Jan;134(1):16-22. doi: 10.1016/j. amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805.

30) German government drops plan for Covid vaccine mandate. https://www.theguardian.com/world/2022/apr/08/german-government-drops-plan-for-covid-vaccine-mandate (accessed 14 September 2022).

31) Austria scraps compulsory COVID-19 vaccination, measure was suspended in March. https://www.foxnews.com/world/austria-scraps-covid-19-vaccination-measure-suspended-march (accessed 14 September 2022).

32) Uruguay suspends COVID vaccination for children under 13. https://abcnews.go.com/International/wireStory/uruguay-suspends-covid-vaccination-children-13-86409875 (accessed 14 September 2022).

33) Costa Rican president scraps COVID vaccine mandate, says forcing the clot shot on people "against the law". https://www.planet-today.com/2022/08/costa-rican-president-scraps-covid.html (accessed 14 September 2022).

34) Nordic countries are restricting the use of Moderna's Covid vaccine. Here's why. https://www.cnbc.com/2021/10/08/nordic-countries-are-restricting-the-use-of-modernas-covid-vaccine.html (accessed 14 September 2022).

35) Italy drops last COVID entry rules, ditches testing and vaccination restrictions. https://www.euronews.com/travel/2022/05/31/italy-travel-restrictions-what-are-the-new-testing-rules-for-eu-and-uk-passengers (accessed 14 September 2022).

36) Denmark becomes the first country to halt its Covid vaccination program.   https://www.cnbc.com/2022/04/28/denmark-the-first-country-to-halt-its-covid-vaccination-program.html (accessed 14 September 2022).

37) Sweden joins Germany, France and 15 other countries in suspending AstraZeneca's vaccine over possible side effects. https://www.businessinsider.com/astrazeneca-covid-vaccine-countries-suspend-denmark-thailand-batch-blood-clots-2021-3?op=1 (accessed 14 September 2022).

38) Romania and other Eastern European countries ask to stop buying COVID-19 vaccines they no longer need. https://www.ro-mania-insider.com/romania-eastern-europe-covid-vaccines   (accessed 14 September 2022).

39) 78 Countries That Don't Require Covid Vaccinations Or Testing For Travel https://www.travelinglifestyle.net/countries-with-out-covid-travel-restrictions-no-test-no-quarantine/ (accessed 14 September 2022).