

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

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ABSTRACT

This population-based retrospective cohort study assesses 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 Vaccine Adverse Events Reporting System (VAERS) database from Jan 1, 1998, to Jun 30, 2022.

The proportional reporting ratio comparing AEs reported after COVID-19 vaccines with those reported after influenza vaccines is significantly increased (≥ 2.0) for COVID-19 vaccine for menstrual abnormality, miscarriage, fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal cardiac arrest, fetal arrhythmias, fetal vascular malperfusion, fetal growth abnormalities, fetal abnormal surveillance, placental thrombosis, fetal death/stillbirth, low amniotic fluid, preeclampsia, premature delivery, preterm premature rupture of membrane, and premature baby death.

When normalized by time-available, doses-given, or number of persons vaccinated, all COVID-19 vaccine AEs far exceed the safety signal on all recognized thresholds.

These results necessitate a worldwide moratorium on the use of COVID-19 vaccines in pregnancy.

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 (EUA), these vaccines were available to the public as early as 10 months after development. The sentiment at the onset of the pandemic was that early treatment strategies for COVID-19 were ineffective, 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. COVID-19 vaccines were immediately authorized for use in pregnant women, which is unprecedented in the history of medicine. The influenza vaccine underwent 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 data, and subsequent clinical observations prompt urgent inquiry into the safety of the COVID-19 vaccines in pregnancy.

Methods

A retrospective analysis was conducted of the adverse event (AE) reports post-COVID-19 vaccines and post-influenza vaccines in the U.S. Centers for Disease Control and Prevention (CDC) Vaccine Adverse Events Reporting System (VAERS) database between Jan 1, 1998, and Jun 30, 2022. Influenza

vaccines were chosen as the control group because the CDC first approved influenza vaccines for pregnant women in 1997. Reports in VAERS after Jan 1, 1998, would count AEs due to on-label use of the vaccines. The study period ending on Jun 30, 2022, provides 282 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 practice over 43 years, a board-certified obstetrician-gynecologist and maternal-fetal medicine physician (JAT) chose AEs of interest from the VAERS database that are 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 cardiac arrest, fetal arrhythmia, fetal vascular malperfusion, fetal growth abnormalities, fetal abnormal surveillance, placental thrombosis, fetal death (stillbirth), low amniotic fluid, preeclampsia, preterm premature rupture of membranes (PPROM), premature delivery/baby (PTD), and premature baby death. AE reports were counted globally and within the U.S. for both the COVID-19 and the influenza vaccines. The global counts for these events, which include U.S. counts, are listed in Table 1. U.S. counts only are in Table 1 Supplement, available at <https://japands.org/vol28no1/thorpsupplement.pdf>.

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 U.S.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 U.S. The influenza vaccines were administered to 7.71 billion people globally, including 313 million in the U.S. [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 in which an individual may or may not choose to receive subsequent vaccinations. To estimate the number of people who 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 U.S. population of 269.5 million (329.5 million minus 60 million who are too young)⁶ results in an approximate total of 313 million people in the U.S. who 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.

Results

For all AEs, the report rates post-COVID-19 vaccination are higher compared with influenza vaccination across all three normalization methods: by unit time, by dose given, and by persons vaccinated. We report two analyses below: 1) computing the p -value to determine whether the AE report rates are statistically different between the two vaccines, and 2) computing the proportional relative rate and 95% confidence interval (CI) of AE reports after the COVID-19 vaccine vs. the influenza vaccine (Table 2). Some cells contain only a p value because a CI cannot be calculated when there is a zero count in one of the categories.

Statistical Significance

Each AE report is treated as a discrete independent event occurring at the mean rates specified, which are modeled as a Poisson distribution. Given two rates, λ_1 and λ_2 , for COVID and influenza vaccine, respectively, we performed a Poisson E-test⁸ to compute the p -value. We use the rates in Table 1 and normalize the event counts over time (282 months for influenza vs. 18 months for COVID-19 vaccines), dose-administered, and people-vaccinated. 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

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.

$$R(\lambda_1, \lambda_2) = P(\lambda_1) / P(\lambda_2)$$

When 1,000,000 random samples are drawn from Poisson distributions with rates λ_1 and λ_2 , the result is a sample of paired event counts n_1 and n_2 , respectively, and R is the distribution of all n_1/n_2 ratios. The mean of R 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 AEs 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 distribution⁹ is used, and only instances of non-zero n_2 draws are counted. This approach skews the R distribution to the left¹⁰

and makes the AE rates for the COVID-19 vaccine appear safer. In these cases, the AE rate is a lower bound.

This is comparable to the method used by the CDC to give a proportional reporting ratio (PRR). According to CDC's Standard Operating Procedures for COVID-19, **a two-fold increase in reporting is a sufficient signal to be concerned.**¹¹ The CDC's PRR, however, does not take sample size or uncertainty into account, and is very easy to game. Our method is a ratio of two rates (RR: a reporting ratio or relative rate).

A simple example is that if 5 cars per minute go down street A and 10 cars per minute go down street B, the relative rate is 5/10 or 1/2. There are 1/2 as many cars on street A as on street B. Rather than simply doing that division, we do it with a Monte Carlo sampling drawn from the Poisson distribution. This correctly accounts for the sample size and uncertainty, as the CDC's PRR does not, and enables the calculation of our error bars.

The results of the statistical analyses of global data, with 95% confidence interval (CI) and p -values are tabulated in Table 2. The results for U.S. AEs only are in Table 2 Supplement, available at <https://jopands.org/vol28no1/thorpsupplement.pdf>.

See Figures 1-3 for a graphical representation (forest plots).

Table 1. Global Adverse Events (AEs): COVID Vaccines; Influenza Vaccines

Adverse Event (AE)	AE Count (COVID; influenza)	AE/month (COVID; influenza)	AE/billion doses (COVID; influenza)	AE/billion persons (COVID; influenza)
Menstrual abnormality	12,843; 65	714; 0.221	1,060; 0.985	2460; 8.43
Miscarriage	3,338; 325	185; 1.11	277; 4.92	638; 42.2
Chromosomal Abnormalities	10; 0	0.556; 0.00	0.829; 0.00	1.91; 0.00
Malformation	22; 2	1.22; 0.0068	1.82; 0.0303	4.21; 0.259
Cystic Hygroma	8; 0	0.444; 0.00	0.663; 0.00	1.53; 0.00
Fetal Cardiac Disorders	18; 2	1.00; 0.0068	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
Malperfusion	12; 0	0.667; 0.00	0.994; 0.00	2.29; 0.00
Growth Anomaly	188; 24	10.4; 0.0816	15.6; 0.364	35.9; 3.11
Abnormal Fetal Surveillance	178; 45	9.89; 0.153	14.7; 0.682	34.0; 5.84
Placental Thrombosis	6; 0	0.333; 0.00	0.497; 0.00	1.15; 0.00
Stillbirth	402; 62	22.3; 0.218	33.3; 0.970	76.9; 8.3
Low amniotic fluid	17; 1	0.944; 0.00340	1.41; 0.0152	3.25; 0.130
Preeclampsia	133; 28	7.39; 0.0952	11.0; 0.424	25.4; 3.63
Preterm Delivery	384; 212	21.3; 0.721	31.8; 3.21	73.4; 27.5
PPROM	45; 9	2.50; 0.0306	3.73; 0.136	8.60; 1.17
Premature Baby Death	10; 0	0.556; 0.00	0.829; 0.00	1.91; 0.00

Table 2. Statistical Analysis for Global Relative Rates (RR) of AEs for COVID Vaccines/Influenza Vaccines by Time, by Dose, and per Person [Mean (95% CI), *p*]

Adverse Event (AE)	RR by Time	RR by Dose	RR by Persons Vaccinated
Menstrual abnormality	4257 (1589-12893) <i>p</i> =0.0	1192 (674-2163) <i>p</i> =0.0	298 (223.0-406.0) <i>p</i> =0.0
Miscarriage	177 (114-284) <i>p</i> =0.0	57 (44-75) <i>p</i> =0.0	15 (13-18) <i>p</i> =0.0
Chromosomal Abnormalities	<i>p</i> =0.00058	<i>p</i> =0.00058	<i>p</i> =0.00058
Malformation	21 (10.0-32.0) <i>p</i> =1.9x10 ⁻⁰⁷	20 (7.7-31) <i>p</i> =2x10 ⁻⁰⁷	15 (4-30) <i>p</i> =2x10 ⁻⁰⁶
Cystic Hygroma	<i>p</i> =0.0024	<i>p</i> =0.0024	<i>p</i> =0.0024
Fetal Cardiac Disorders	18 (8.00-27.0) <i>p</i> =2.6x10 ⁻⁰⁶	16 (6.00-26.0) <i>p</i> =2.6x10 ⁻⁰⁶	12 (3.60-25.0) <i>p</i> =2.7x10 ⁻⁰⁵
Fetal Cardiac Arrest	<i>p</i> =6.9x10 ⁻⁰⁷	<i>p</i> =6.9x10 ⁻⁰⁷	<i>p</i> =6.9x10 ⁻⁰⁷
Fetal Arrhythmia	<i>p</i> =0.020	<i>p</i> =0.020	<i>p</i> =0.020
Malperfusion	<i>p</i> =0.00015	<i>p</i> =0.00015	<i>p</i> =0.00015
Growth Anomaly	126 (42.0-210) <i>p</i> =0.0	56 (21-190) <i>p</i> =0.0	12 (7.4 - 21) <i>p</i> =0.0
Abnormal Fetal Surveillance	83 (27-190) <i>p</i> =0.0	25 (12 - 59) <i>p</i> =0.010	6 (4.1-9.0) <i>p</i> =0.0
Placental Thrombosis	<i>p</i> =0.0096	<i>p</i> =0.0096	<i>p</i> =0.0096
Stillbirth	135 (48-412) <i>p</i> =0.0	38 (21-73) <i>p</i> =0.0	9.5 (6.9-13) <i>p</i> =0.0
Low amniotic fluid	17 (8.0-25) <i>p</i> =5.1x10 ⁻⁰⁶	16 (7.0-25) <i>p</i> =5x10 ⁻⁰⁶	14.2 (5-25) <i>p</i> =5x10 ⁻⁰⁶
Preeclampsia	83.2 (26.6-151) <i>p</i> =0.0	33.4 (13-123) <i>p</i> =0.0	7.4 (4.6-12) <i>p</i> =0.0
Preterm Delivery	32.3 (18.5-60.3) <i>p</i> =0.0	10 (7.32-14.4) <i>p</i> =0.0	2.7 (2.2-3.3) <i>p</i> =0.0
PPROM	39.0 (14.7-58.0) <i>p</i> =0.0	29 (9-55) <i>p</i> =7.7x10 ⁻¹⁴	9.1 (3.6-25) <i>p</i> =7x10 ⁻⁰⁹
Premature Baby Death	<i>p</i> =0.00058	<i>p</i> =0.00058	<i>p</i> =0.00058

Figure 1 displays global reporting ratios (RRs) of adverse events (AEs) for COVID-19 vaccines compared with influenza vaccines per dose. A value greater than 1 implies that an AE is reported more frequently after COVID-19 vaccination compared with influenza vaccinations. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AEs, all substantially greater than 1. Data are reported as RR with a 95% confidence interval: abnormal menses, 4257 (1589.1-12893); miscarriage, 177 (114.4-283.5); fetal malformation, 21 (10.0-32.0); fetal cardiac disorders, 17 (8.00-27.0); fetal growth restriction, 126 (42.00-210.0); abnormal fetal testing (surveillance), 25 (12.2-58.7); low amniotic fluid volume, 16 (7-25); preeclampsia, 33.4 (12.9-123); and stillbirth, 38 (21.1-73). Some variables are missing as a numerator or denominator of zero precludes calculation of an RR.

Figures 1-3 Supplement, available at <https://jpands.org/vol28no1/thorpsupplement.pdf>, displays the results for U.S. data only.

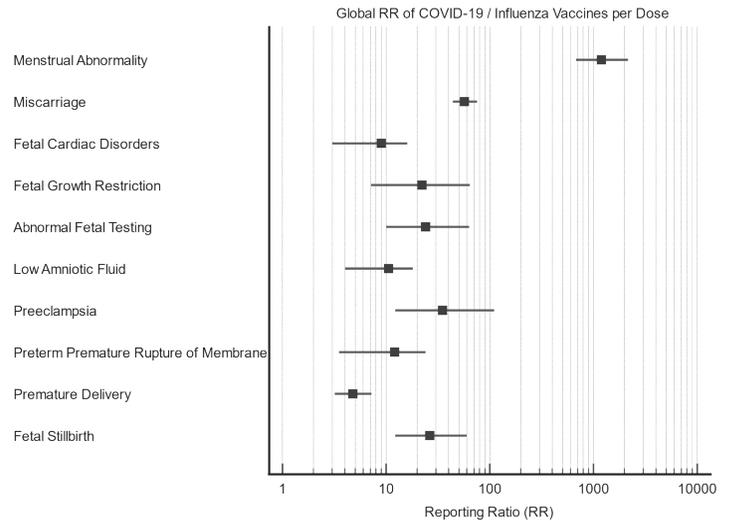


Figure 1. Global Reporting Ratios (RRs) of Adverse Events (AEs) for COVID-19 Vaccination vs. Influenza Vaccination by Dose Given

Figure 2 displays global RRs for COVID-19 vs. influenza vaccination per month. The RR (95% CI) values are: abnormal menses, 4257 (1589.1-12893); miscarriage, 177 (114.4-283.5); fetal malformation, 21 (10.0-32.0); fetal cardiac disorders, 17 (8.00-27.0); fetal growth restriction, 126 (42.00-210.0); abnormal fetal testing, 83 (27-190); low amniotic fluid volume, 17 (8-25); preeclampsia, 83.2 (26.6-151); preterm premature rupture of membranes (PPROM), 39 (14.7-58); premature delivery, 32.3 (18.5-60.3); and stillbirth, 135 (48.3-410).

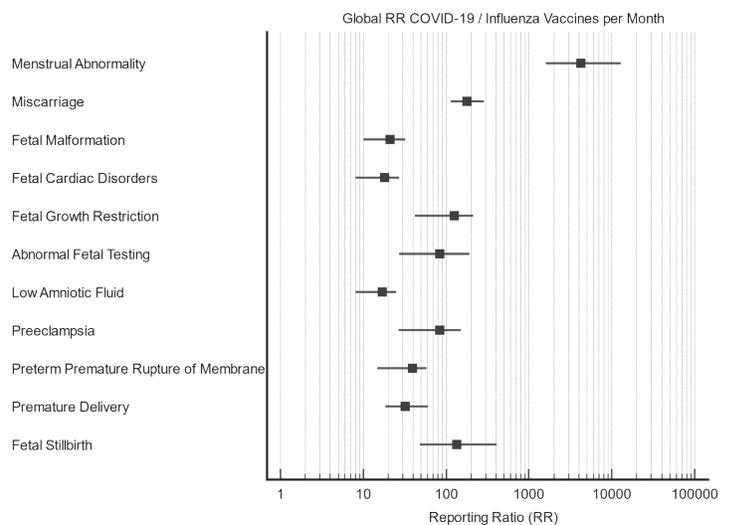


Figure 2. Global Reporting Ratios (RRs) for COVID-19 vs. Influenza Vaccination by Month.

Figure 3 displays global RRs for COVID-19 vs. influenza vaccination by number of persons vaccinated. The RR (95% CI) values are: abnormal menses, 298 (223.0-406.0); miscarriage, 15 (13.3-17.5); fetal malformation, 15 (4.5-30.0); fetal cardiac disorders, 12 (3.60-25.0); fetal growth restriction, 12 (7.42-21.4); abnormal fetal testing, 6 (4.1-9.0); low amniotic fluid volume, 14 (4.67-25); preeclampsia, 7.4 (4.6-12); preterm premature rupture of membranes, 9.1 (3.6-25); premature delivery, 2.7 (2.2-3.3); and stillbirth, 9.5 (6.9-13).

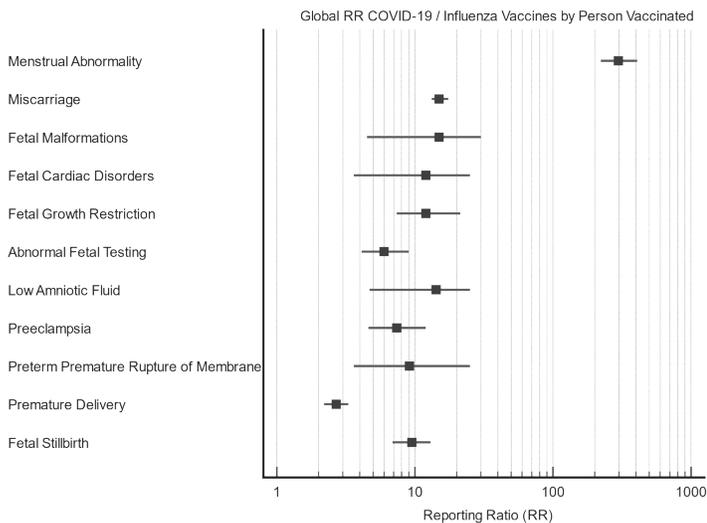


Figure 3. Global Reporting Ratios (RRs) for COVID-19 vs. Influenza Vaccination by Persons Vaccinated

Discussion

Analysis of VAERS data shows excessive AEs for the COVID-19 vaccines as compared with the influenza vaccines by more than a factor of two in almost all cases. According to the CDC, a PRR of two or greater is a safety signal that requires further study.¹¹

VAERS is a passive vaccine surveillance tool administered by two agencies of the U.S. Department of Health and Human Services (HHS), the CDC and the Food and Drug Administration (FDA). This database has tracked adverse reactions following the administration of vaccines since 1990. FDA considers VAERS to be a valuable tool for post-marketing safety surveillance. HHS advises that the VAERS database should be used to detect possible safety concerns with vaccines and stresses the importance of accurate, complete, and timely reporting to ensure vaccine safety monitoring.

Although vaccine manufacturers and medical professionals are historically the primary sources of VAERS reporting, consumers are also able to submit reports. Each VAERS submission must be reviewed by medical officers and vaccine safety experts with both FDA and CDC before being published.^{12,13} FDA advises that any significant AE should be reported “even if you are unsure whether a vaccine caused the event.” It is a federal offense to falsify VAERS reports and is punishable by fine and imprisonment.

FDA mandates that healthcare professionals who administer COVID-19 vaccines are legally required to report to VAERS the following serious AEs: death; a life-threatening AE; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; a congenital anomaly/birth defect; or an important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above. Additionally, with patients who received Pfizer, Moderna, or Novavax vaccines, cases of myocarditis, pericarditis, or multisystem inflammatory syndrome, as well as COVID-19 cases resulting in hospitalization or death, are also required to be reported by the administering professionals.

Strengths

This study went beyond clinical observation to analyze official U.S. 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 our selection of pregnant patients 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, including: the UK Yellow Card System,¹⁴ WHO’s VigiAccess,¹⁵ and the European Economic Area’s EudraVigilance data.¹⁶

The results of this study also align with recommendations from governments and nongovernmental organizations. Recent documents from the UK government¹⁷ 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. Women who are breastfeeding should also not be vaccinated.

The World Council of Health has also called for a ban on the COVID-19 vaccines in pregnancy and lactation.¹⁸ Producers of the COVID-19 vaccines themselves report significant AE post-COVID-19 vaccination including 1,223 deaths in the first 90 days of the COVID-19 vaccine rollout.^{19, p7} Specifically, 46% (124/270) of pregnant women in the first 90 days of rollout experienced an AE, and 81% (26/32) experienced miscarriage.^{19, p12}

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. There was a 118-fold concentration of the lipid nanoparticles in ovaries from injection to 48 hours when animals were sacrificed.²⁰ This data, along with Schädlich et al. from 2012,²¹ shows 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, with an age-related temporal pattern consistent with the U.S. vaccine rollout.²² Palmer and Bahdki demonstrated autopsy evidence of suspected vaccine-induced death and spike-mediated generalized endothelial inflammation (endothelitis) in many organ beds caused by spike protein.²³ In just 15 months after the vaccine rollout, 1,366 peer-reviewed articles documented severe AEs after the COVID-19 vaccinations,²⁴ a concerning safety signal not even rivaled by combining all other vaccines in the worldwide medical literature over the last century.

While birth rates have gradually fallen since the turn of the century, there has been an alarming drop since the rollout of the COVID-19 vaccines. Multiple researchers worldwide document reductions in birthrates following the rollout of COVID-19 vaccines: a 20% drop in Hungary, a 7% drop in Sweden, a 13% drop in Germany, and a 23% drop in Taiwan.^{25,26} Observational studies from around the world are consistent with declining fertility, and increased pregnancy complications including miscarriage, fetal death, and many more obstetrical

complications. Predictably, newborn death rates are increased, and this is explained by the deleterious effects of the COVID-19 vaccines on pregnancy with increased risk of pregnancy complications, premature deliveries, preeclampsia, PPROM, and increase in fetal growth restriction, as is noted in this study. The neonatal death rates (newborns dying in the first month of life) in Israel hovered between 4-8 per 1000 live births for 2019 and 2020. Then in the second quarter of 2021, it suddenly jumped three-fold to 17, dipped again in the third quarter, and then jumped again to 18 in the last quarter of 2021.²⁷

This study's results are supported by evidence that the most stunning rises in fetal death (stillbirth) rates are seen in those geographic areas whose cultures and governments aggressively push COVID-19 vaccines in pregnancy.

In a moderate-size community in central California, a postpartum nurse whistleblower brought to light a 1.5-page email from her Women's Healthcare administrator, who informed her that the staff was overwhelmed with an onslaught of fetal deaths.²⁸ According to the whistleblower, their usual frequency was 1-2 stillbirths every 2-3 months, which in that community of 9000 deliveries per year corresponds to the national stillbirth rate of about 5.8/1000 births.

The email noted that in July 2021 and in August 2022 there were all-time recorded highs of 22 fetal deaths, and as the administrator pointed out, these were only the cases that presented to labor and delivery. There were probably more that were not counted, from emergency rooms, operating rooms, other facilities, or planned home births. The massive increase from 5.8/1000 to 29.3/1000 constitutes an unprecedented catastrophic rise, which cannot be overemphasized. While the whistleblower stated that there was a sustained increase in fetal deaths in all months, these two months are the only ones for which the administrator provided numbers.

As Figure 4 shows, the U.S. baseline rate of fetal death is 5.84 per 1000 births and has minimal variance. The rate dropped from the 2017–2019 aggregate of 5.83 to 5.74 in 2020 despite the COVID-19 caseload; COVID-19 infection clearly did not increase the rate of stillbirth in the U.S. According to the data taken by the whistleblower data directly from the administrative email to the postpartum nursing staff, the stillbirth rate surged to 29.3/1000 (July 2021 and August 2022), the equivalent of 22 stillbirths in one month, based on 9000 births per year in this community. This rise in stillbirth from 5.8/1000 to 29.3/1000 represents 40 standard deviations above the baseline (sigma ~ 0.5/1000 births).

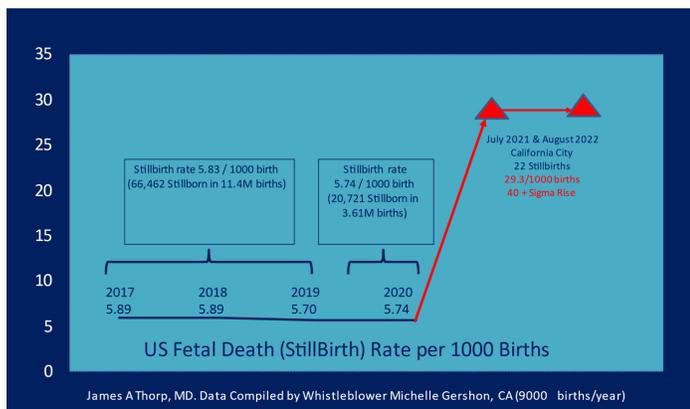


Figure 4. Stillbirth Rate in California City, Calif., U.S.

While the highest stillbirth rate in the U.S. appears to be present in the geographic locations that impose the greatest pressure on pregnant women to be vaccinated, the concerning rates (and vaccination rates) in Canada are even worse. Five professionals (two physicians and three doulas) noted an unprecedented 13 stillbirths in a 24-hour period at Lions Gate Hospital in British Columbia.²⁹ Figure 5 shows this rate in comparison to the U.S. fetal death rates. Because the rate was exponentially higher for one day, we used one week. Obviously, this underestimated the observed stillbirth rate at the Lions Gate Hospital at 160/1000 births. Assuming a similar standard deviation of about 0.5 stillbirth/1000 births, this observed surge is unfathomable at over 300 standard deviations (sigma) above baseline.

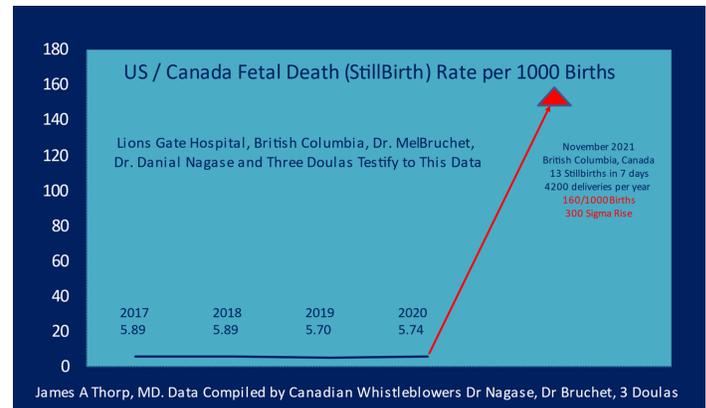


Figure 5. Stillbirths in Lions Gate Hospital, November 2021, vs. Baseline

A crude calculation of the stillbirth rate possibly attributed to the COVID-19 vaccines could simply add about 2.5 stillbirths/1000 births to the baseline rate (~ 5.8/1000 births) for every 10% increment in pregnant women vaccinated. Thus, if 10% of a population of pregnant women are vaccinated, one could expect a rise in the fetal death rates from 5.8/1000 to 8.3/1000 (5.8 + 2.5). The lead author (JAT) has observed increased stillbirths in Florida, Missouri, and Illinois, but the increment is much lower than that seen in California and Canada.

Limitations

There are several limitations to this study. First, estimates of influenza vaccine dose count and estimates of the number of people vaccinated are imprecise. Using available data and Monte Carlo simulation techniques, conservative good-faith estimates are calculated. While ideally these estimates would be more precise, the safety signal remains even if they are off by a factor of five. Our methods estimating these denominators of vaccine doses and of people vaccinated all converge to a precision of 1% or better. Second, the relative underreporting factors (URF) in VAERS for the 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 Policymakers

Given the safety signals observed with the COVID-19 vaccination in pregnancy, caution is necessary for our more vulnerable populations such as women of reproductive age,

pregnant women, preborn babies, and children. 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 the market after fewer than 30 deaths,³⁰ and the rotavirus vaccine was removed after only a few non-lethal cases of intussusception.³¹ The authors of this study concur with the recommendations previously made by the UK government¹⁷ and the World Council for Health.¹⁸ 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 non-pregnant patients for COVID-19 infections.³² 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.³³⁻³⁶

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.³⁷⁻⁴⁶ Yet, the US continues promoting COVID-19 vaccinations and boosters in all groups, including pregnant women, despite the fact that Title 21 of the Code of Regulations mandates that strict criteria for safety of licensed vaccines must be met^{47,48} and that HHS describes VAERS as “a tool for identifying potential vaccine safety concerns that need further study using more robust data systems.”⁴⁹

Future Work

Future research should verify these results to differentiate between vaccine-related AEs 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.

Conclusions

This study supports the recommendations of the UK’s Medicines & Healthcare products Regulatory Agency and the World Council of Health against COVID-19 vaccination and boosters for pregnant and lactating women. Because the COVID-19 vaccines are authorized under Emergency Use Authorization (EUA) without any rigorous safety trials prior to administration to the general public, it is imperative that special attention is paid to monitoring for any and all safety signals. The administration of COVID-19 vaccines in pregnancy and women of reproductive age should be halted immediately until these safety signals can be fully investigated.

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Table 1 Supplement. U.S. Adverse Events (AEs): COVID Vaccines; Influenza Vaccines

	AE Count (COVID; flu)	AE/month (COVID; flu)	AE/billion doses (COVID; flu)	AE/billion persons (COVID; flu)
Menstrual abnormality	6352; 54	353; 0.184	10700; 16.4	24400; 173
Miscarriage	1232; 259	68.4; 0.881	2070; 78.5	4740; 827
Chromosomal Abnormalities	7; 0	0.389; 0.00	11.7; 0.00	26.9; 0.00
Malformation	2; 1	0.111; 0.00340	3.35; 0.303	7.69; 3.19
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
Malperfusion	5; 0	0.278; 0.00	8.39; 0.00	19.2; 0.00
Growth Anomaly	59; 20	3.28; 0.0680	99.0; 6.06	227; 63.9
Abnormal Fetal Surveillance	125; 36	6.94; 0.122	210; 10.9	481; 115
Placental Thrombosis	5; 0	0.278; 0.00	8.39; 0.00	19.2; 0.00
Stillbirth	168; 42	9.33; 0.143	282; 12.7	646; 134
Low amniotic fluid	11; 1	0.611; 0.00340	18.4; 0.303	42.3; 3.19
Preeclampsia	106; 22	5.89; 0.0748	178; 6.67	408; 70.3
Preterm Delivery	141; 168	7.83; 0.57	236; 50.9	542; 537
PPROM	17; 7	0.944; 0.0238	28.5; 2.12	65.4; 22.4
Premature Baby Death	3; 0	0.167; 0.00	5.03; 0.00	11.5; 0.00

Table 2 Supplement. Statistical Analysis for U.S. Relative Rates (RRs) of AEs for COVID Vaccines/Influenza Vaccines by Time, by Dose, and per Person [Mean (95% CI), *p*]

Adverse Event (AE)	RR by Time	RR by Dose	RR by Persons Vaccinated
Menstrual abnormality	2524 (895-6420) <i>p</i> =0.0	738 (392-1584) <i>p</i> =0.0	145 (108.6-197.4) <i>p</i> =0.0
Miscarriage	83 (50.8-143) <i>p</i> =0.0	27 (20-37) <i>p</i> =0.0	5.8 (5.0-6.7) <i>p</i> =0.0
Chromosomal Abnormalities	<i>p</i> =0.0048	<i>p</i> =0.0048	<i>p</i> =0.0048
Malformation	2 (0.0-5.0) <i>p</i> =0.20	2 (0-5) <i>p</i> =0.20	2 (0.0-5.0) <i>p</i> =0.20
Cystic Hygroma	<i>p</i> =0.020	<i>p</i> =0.020	<i>p</i> =0.020
Fetal Cardiac Disorders	10 (4.0-17) <i>p</i> =0.00058	9 (3.0-16) <i>p</i> =0.00058	6 (1.5-15) <i>p</i> =0.0047
Fetal Cardiac Arrest	<i>p</i> =0.088	<i>p</i> =0.088	<i>p</i> =0.088
Fetal Arrhythmia	<i>p</i> =0.088	<i>p</i> =0.088	<i>p</i> =0.088
Malperfusion	<i>p</i> =0.020	<i>p</i> =0.020	<i>p</i> =0.020
Growth Anomaly	43 (14.0-72.0) <i>p</i> =0.0	22 (7.1-64) <i>p</i> =0.0	4(2-7) <i>p</i> =3x10 ⁻⁰⁷
Abnormal Fetal Surveillance	68 (21.6-140) <i>p</i> =0.0	24 (10 - 63) <i>p</i> =0.0	4 (2.9-6.6) <i>p</i> =0.0
Placental Thrombosis	<i>p</i> =0.020	<i>p</i> =0.020	<i>p</i> =0.020
Stillbirth	82.1 (26.5-183) <i>p</i> =0.0	26 (12.2-60.0) <i>p</i> =0.0	5.0 (3.4-7.2) <i>p</i> =0.0
Low amniotic fluid	10.8 (4.50-18.0) <i>p</i> =0.00029	10.5 (4.00-18.0) <i>P</i> =0	8.8 (2.5-17) <i>p</i> =0.00029
Preeclampsia	73.8 (24.3-123) <i>p</i> =0.0	35 (12.3-110) <i>p</i> =0.0	6.2 (3.7-10) <i>p</i> =0.0
Preterm Delivery	15.4 (8.00-31.6) <i>p</i> =0.0	4.8 (3.2-7.2) <i>p</i> =0.0	1.0 (0.80-1.3) <i>p</i> =0.91
PPROM	15.2 (5.50-25.0) <i>p</i> =5.1x10 ⁻⁰⁶	12.1 (3.50-24.0) <i>p</i> =5.3x10 ⁻⁰⁵	3.7 (1.2-11) <i>p</i> =0.0095
Premature Baby Death	<i>p</i> =0.088	<i>p</i> =0.088	<i>p</i> =0.088

Figure 1 Supplement shows U.S. reporting ratios (RRs) of adverse events (AEs) for COVID-19 vaccines compared with influenza vaccines per dose given. All RRs are substantially greater than 1. The RR (95% CI) values are: abnormal menses, 738 (391.6-1584); miscarriage, 27 (20-37), fetal malformation, 2 (0-5); fetal cardiac disorders, 9 (3-16); fetal growth restriction, 22 (7.1-64); abnormal fetal testing, 24 (10-63); low amniotic fluid volume, 11 (4.0-18); preeclampsia, 35.1 (12.3-110); and stillbirth, 26 (12-60). Note that RRs with a zero in numerator or denominator cannot be calculated and are not depicted on this forest plot.

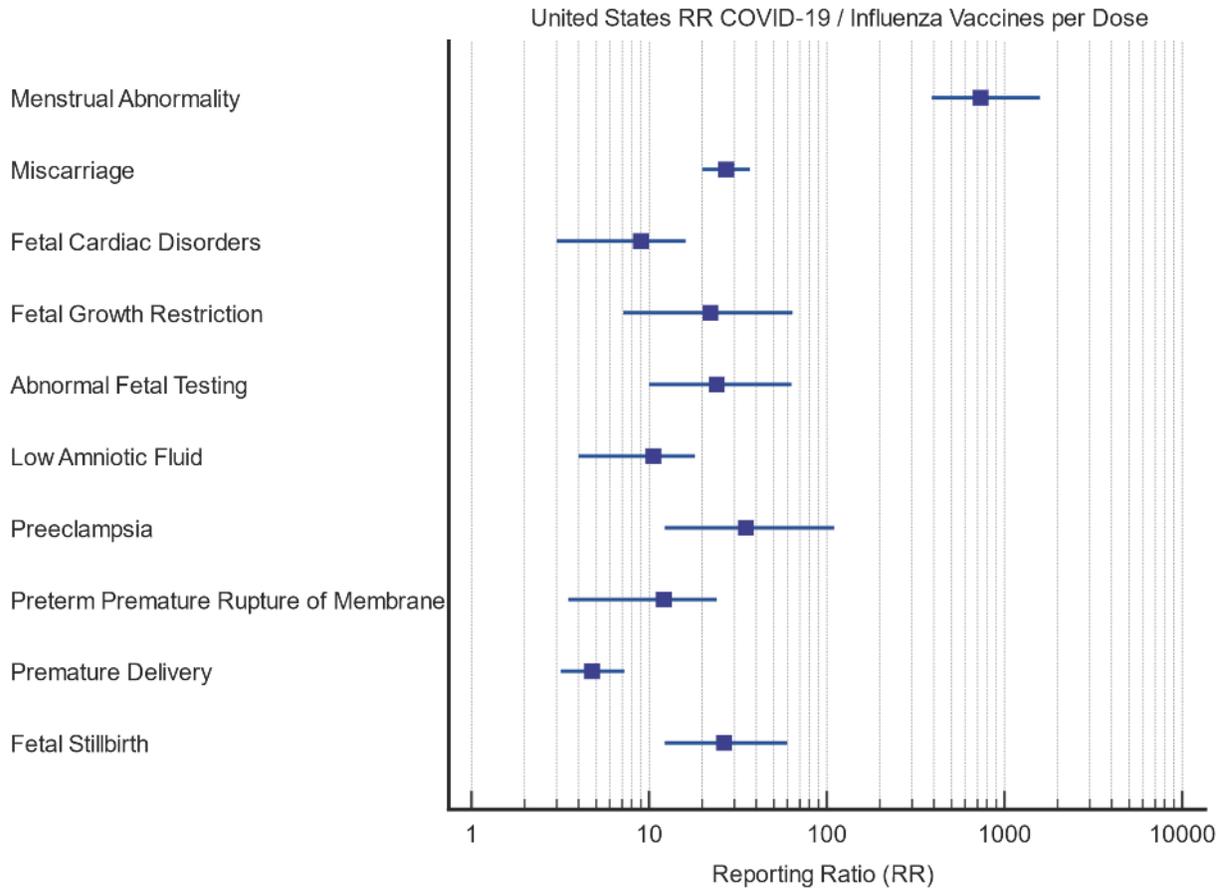


Figure 1 Supplement. U.S. Reporting Ratio (RR) for COVID-19 Vaccination vs. Influenza Vaccination by Dose Given.

Figure 2 Supplement shows U.S. RRs for COVID-19 vs. influenza vaccination by month. The RR (95% CI) values are: abnormal menses, 2524 (894.57-6420.0); miscarriage, 83 (50.8-143); fetal malformation, 2 (0-5); fetal cardiac disorders, 10 (4.00-17.0); fetal growth restriction, 43 (14.0-72.0); abnormal fetal testing, 68 (21.6-140); low amniotic fluid volume, 10.8 (14.5-18); preeclampsia, 73.8 (24.3-123); preterm premature rupture of membranes, 15.2 (5.5-25); premature delivery, 15.4 (8.0-31.6); and stillbirth, 82.1 (26.5-183).

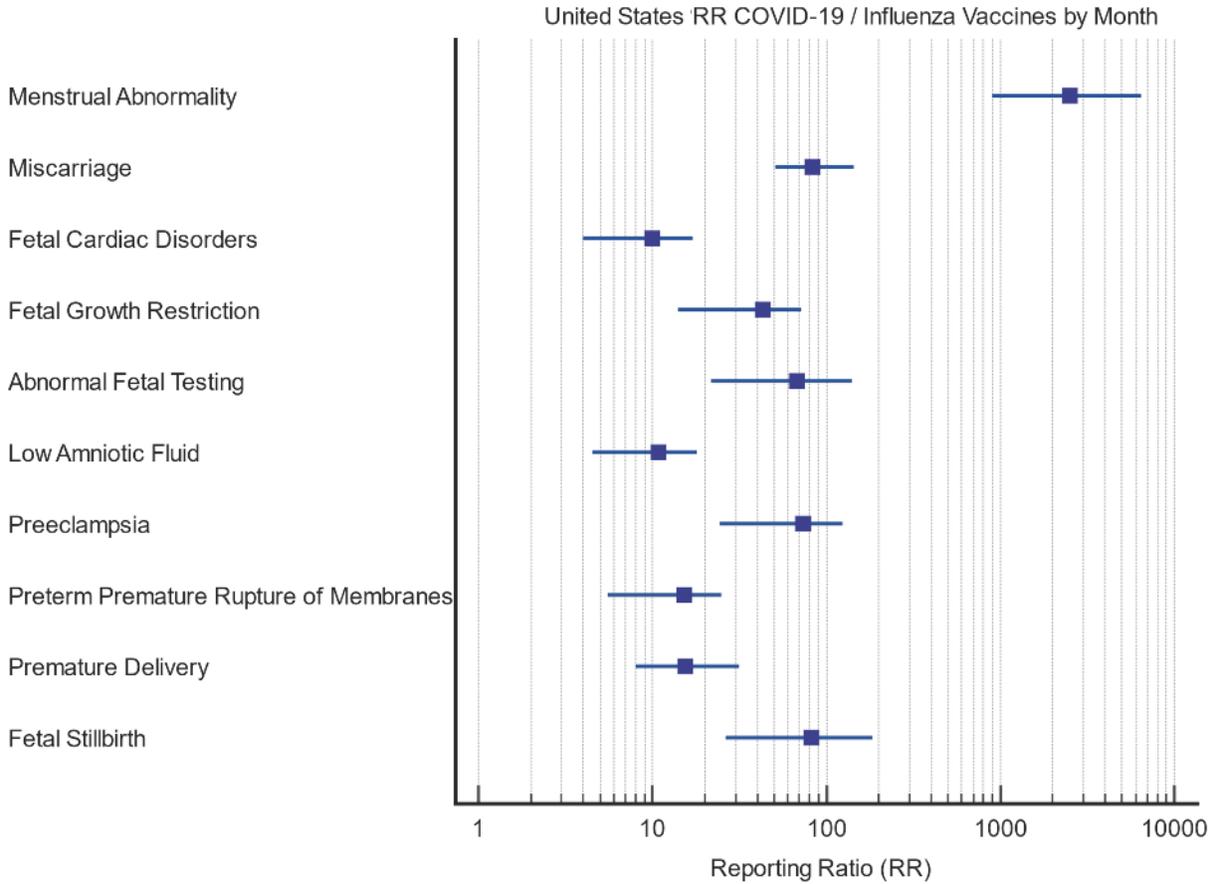


Figure 2 Supplement. U.S. Reporting Ratios (RRs) for COVID-19 vs. Influenza Vaccination by Month

Figure 3 Supplement displays U.S. RRs for COVID-19 vs. influenza vaccination by persons vaccinated. The RR (95% CI) values are: abnormal menses, 145 (109-197); miscarriage, 6 (5.0-6.7); fetal malformation, 2 (0-5) (RR cannot be calculated with zero); fetal cardiac disorders, 6 (1.5-15); fetal growth restriction, 4 (2.2-6.8); abnormal fetal testing, 4 (2.9-6.6); low amniotic fluid volume, 8.8 (2.5-17); preeclampsia, 6.2 (3.7-10); and stillbirth, 5 (3.4-7.2).

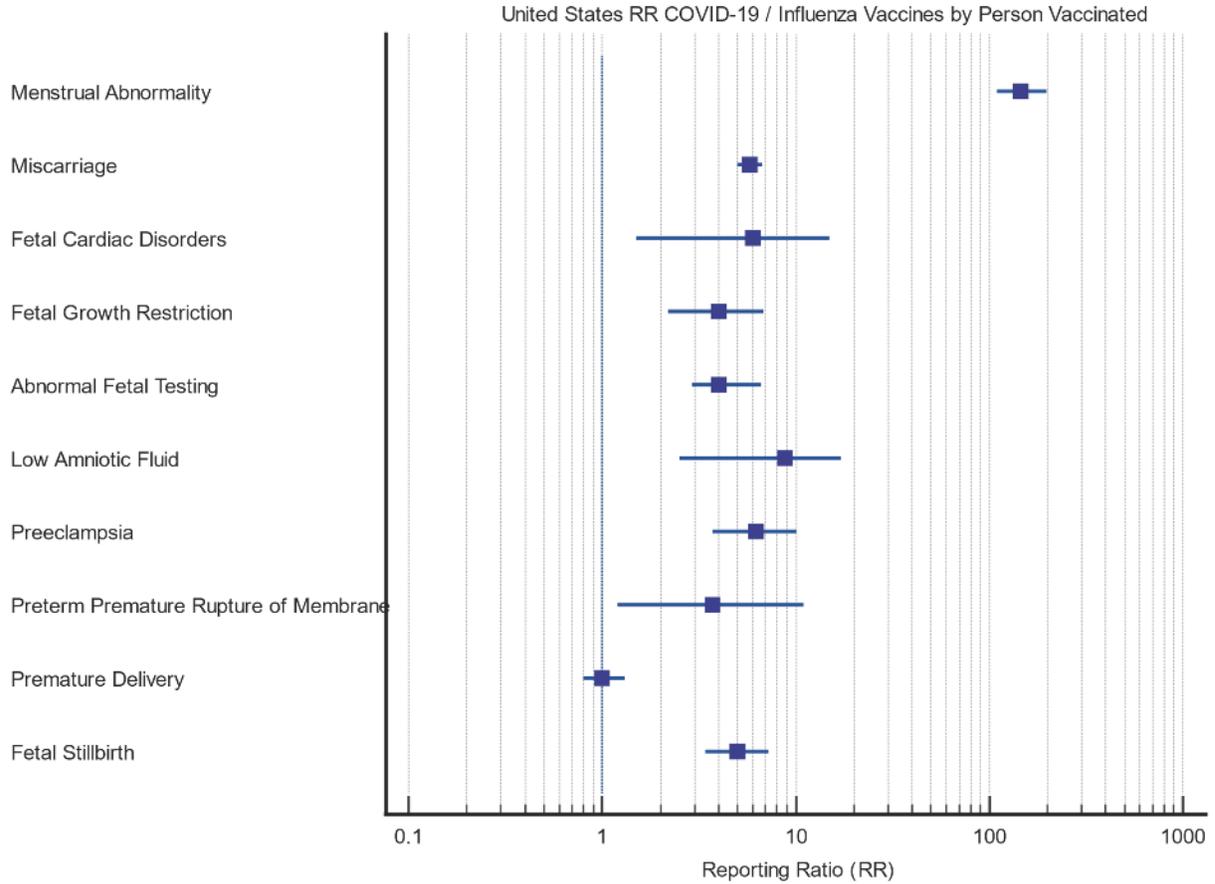


Figure 3 Supplement. U.S. Reporting Ratios (RRs) for COVID-19 vs. Influenza Vaccination by Persons Vaccinated