Article

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

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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 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 abnormalities, miscarriage, fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal arrhythmias, fetal cardiac arrest, fetal vascular malperfusion, fetal growth abnormalities, fetal abnormal surveillance, fetal placental thrombosis, low amniotic fluid, preeclampsia, premature delivery, preterm premature rupture of membrane, fetal death/stillbirth, and premature baby death (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 complications and menstrual abnormalities are significantly more frequent following COVID-19 vaccinations than 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; stillbirth; miscarriage

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 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

 doi:10.20944/preprints202209.0430.v2

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 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 the CDC first approved Influenza vaccines for pregnant women in 1997. 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 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 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 abnormalities, 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, preeclampsia, premature rupture of membranes (PPROM), premature delivery/baby (PTD), fetal death (stillbirth) and premature baby death. 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 listed 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

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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 time (282 months Influenza vs 18 months COVID-19 vaccines), dose-administered, 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 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]

 doi:10.20944/preprints202209.0430.v2

Table 1. Depicted here are **US** adverse events (AE) counts in VAERS along with mean rate of AE over time tracked, mean rate per billion doses given, and mean rate 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 (AE)	US Count of AE post Vaccine - COVID-19 Influenza	US Rate of AE Count / Month	US Rate of AE Count / Billion Doses	US Rate of AE Count / Billion People Vaccinated
Menstrual Abnormalities	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 Malperfusion	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
	5	0.278	8.39	19.2

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Adverse Event (AE)	US Count of AE post Vaccine - COVID-19 Influenza	US Rate of AE Count / Month	US Rate of AE Count / Billion Doses	US Rate of AE Count / Billion People Vaccinated
Fetal Placental Thrombosis	0	0.00	0.00	0.00
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
Premature Delivery	141 168	7.83 0.571	236 50.9	542 537
Fetal stillbirth	168 42	0.167 0.00	282 12.7	646 134
Premature Baby Death	3 0	0.167 0.00	5.03 0.00	11.5 0.00

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Table 2. Depicted here are **global** post-vaccine adverse event (AE) counts in VAERS, along with the mean rate of AE over time tracked (18 months COVID-19, 282 months Influenza), mean rate per billion doses given, and mean rate 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 (AE)	US Count of AE post Vaccine - COVID-19 Influenza	US Rate of AE Count / Month	US Rate of AE Count / Billion Doses	US Rate of 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 Malperfusion	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 62	22.3 0.218	33.3 0.970	76.9 8.30

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Adverse Event (AE)	US Count of AE post Vaccine - COVID-19 Influenza	US Rate of AE Count / Month	US Rate of AE Count / Billion Doses	US Rate of AE Count / Billion People Vaccinated
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
Premature Delivery	384 212	21.3 0.721	31.8 3.21	73.4 27.5
Preterm Premature Rupture of Membranes	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

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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 adverse event (AE). A relative rate greater than 1 implies that there are more COVID-19 vaccine AE than Influenza vaccine AE. According to CDC's Standard Operating Procedures for COVID-19 a two-fold increase in PRR indicates a sufficient signal to be concerned.[11] Data are expressed as PRR mean (95% confidence interval).

Adverse Event (AE)	Relative Rate by Time	Relative Rate by Dose	Relative Rate by Person Vaccinated
Menstrual Abnormality	4257 (1589-12893) p=0.0 2524 (895-6420) p=0.0	1192 (674.0-2163) p=0.0 738 (392.0-1584) p=0.0	298 (223.0-406.0) p=0.0 145 (108.6-197.4) p=0.0
Miscarriage	177 (114-284) p=0.0 83 (50.8-143) p=0.0	57 (44-75) p=0.0 27 (20-37) p=0.0	15 (13-18) p=0.0 5.8 (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=1.9x10^{-07} 2 (0.0-5.0) p=0.20	20 (7.7-31) p=1.9x10^{-07} 2 (0-5) p=0.20	15 (4.5-30) p=2.1x10^{-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	18 (8.00-27.0) p=2.6x10^{-06} 10 (4.0-17) p=0.00058	16 (6.00-26.0) p=2.6x10^{-06} 9 (3.0-16) p=0.00058	12 (3.60-25.0) p=2.7x10^{-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=6.9x10^{-07} p=0.088	p=6.9x10^{-07} p=0.088	p=6.9x10^{-07} p=0.088
Fetal Vascular Malperfusion	p=0.00015 p=0.020	p=0.00015 p=0.020	p=0.00015 p=0.020
Fetal Growth Restriction	126 (42.00-210.0) p=0.0 43 (14.0-72.0) p=0.0	56 (21 - 190) p=0.0 22 (7.1 - 64) p=0.0	12 (7.4 - 21) p=0.0 4 (2.2-6.8) p=3.2x10^{-07}
Abnormal Fetal Testing	83 (27-190) p=0.0 68 (21.6-140) p=0.0	25 (12 - 59) p=0.010 24 (10 - 63) 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 F1uid	16.8 (8.00-25.0) p=5.1x10^{-06} 10.8 (4.50-18.0) p=0.00029	16.2 (7.00-25.0) p=5.1x10^{-06} 10.5 (4.00-18.0)	14.2 (4.67-25.0) p=5.1x10^{-06} 8.8 (2.5-17) p=0.00029

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Adverse Event (AE)	Relative Rate by Time	Relative Rate by Dose	Relative Rate by Person Vaccinated
		P=0	
Preeclampsia	83.2 (26.6-151) p=0.0 73.8 (24.3-123) p=0.0	33.4 (12.9-123) p=0.0 35.1 (12.3-110) p=0.0	7.4 (4.6-12) p=0.0 6.2 (3.7-10) p=0.0
Preterm Premature Rupture of Membranes	39.0 (14.7-58.0) p=0.0 15.2 (5.50-25.0) p=$5.1x10^{-06}$	28.8 (9.00-55.0) p=$7.7x10^{-14}$ 12.1 (3.50-24.0) p=$5.3x10^{-05}$	9.1 (3.6-25) p=$7.0x10^{-09}$ 3.7 (1.2-11) p=0.0095
Premature Delivery	32.3 (18.5-60.3) p=0.0 15.4 (8.00-31.6) p=0.0	10.2 (7.32-14.4) p=0.0 4.8 (3.2-7.2) p=0.0	2.7 (2.2-3.3) p=0.0 1.0 (0.80-1.3) p=0.91
Fetal stillbirth	135 (48.3-412) p=0.0 82.1 (26.5-183) p=0.0	38.0 (21.1-73.0) p=0.0 26.3 (12.2-60.0) p=0.0	9.5 (6.9-13) p=0.0 5.0 (3.4-7.2) p=0.0
Premature Baby Death	p=0.00058 p=0.088	p=0.00058 p=0.088	p=0.00058 p=0.088

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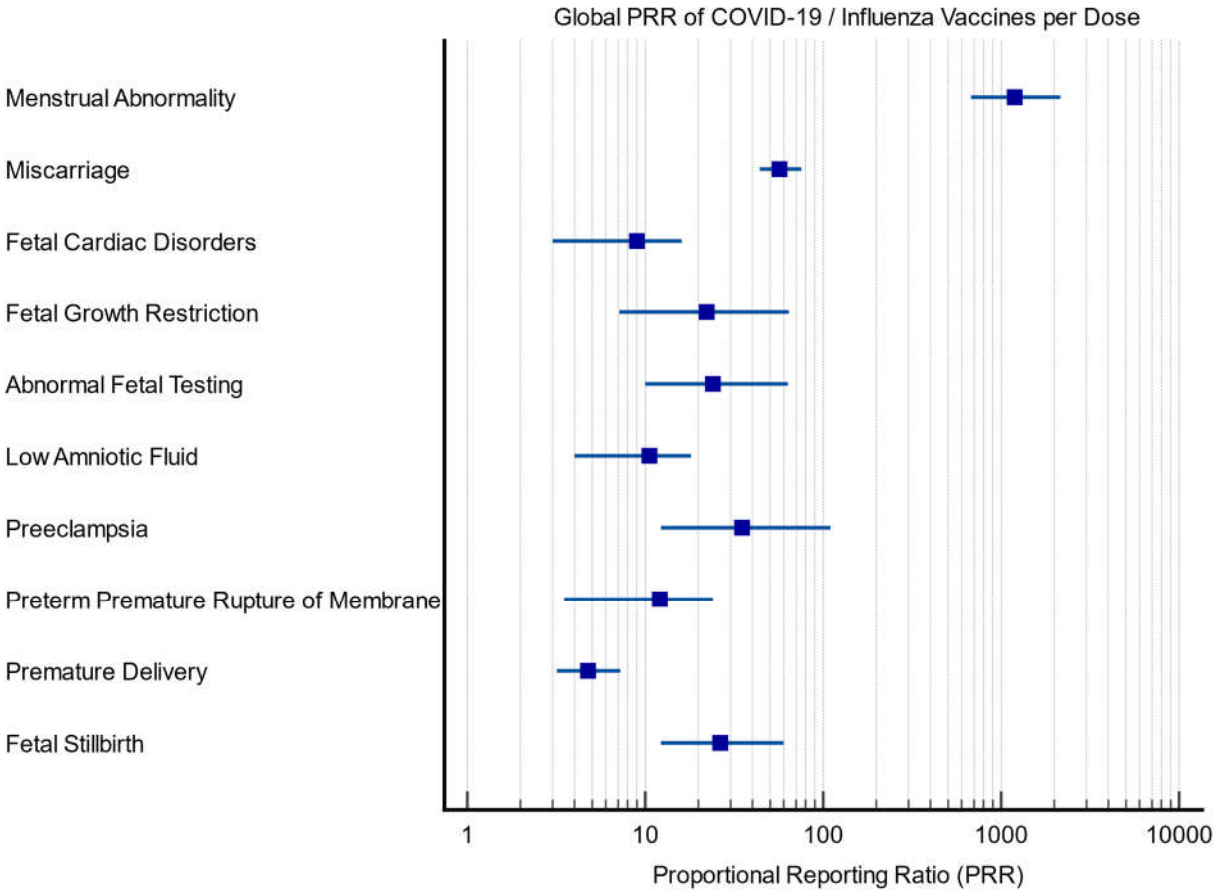

Figure 1. Global proportional reporting ratios of adverse event (AE). A value greater than 1 implies that AE are reported more frequently after COVID-19 vaccination compared to Influenza vaccinations. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. Data are reported as PRR with a 95% confidence interval. Abnormal Menses 1192, 674.0-2163; Miscarriage 57, 44-75, Fetal Malformation 20, 7.7-31; Fetal Cardiac Disorders 16, 6-26; Fetal Growth Restriction 56, 21-190; Abnormal Fetal Testing 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 a PRR.

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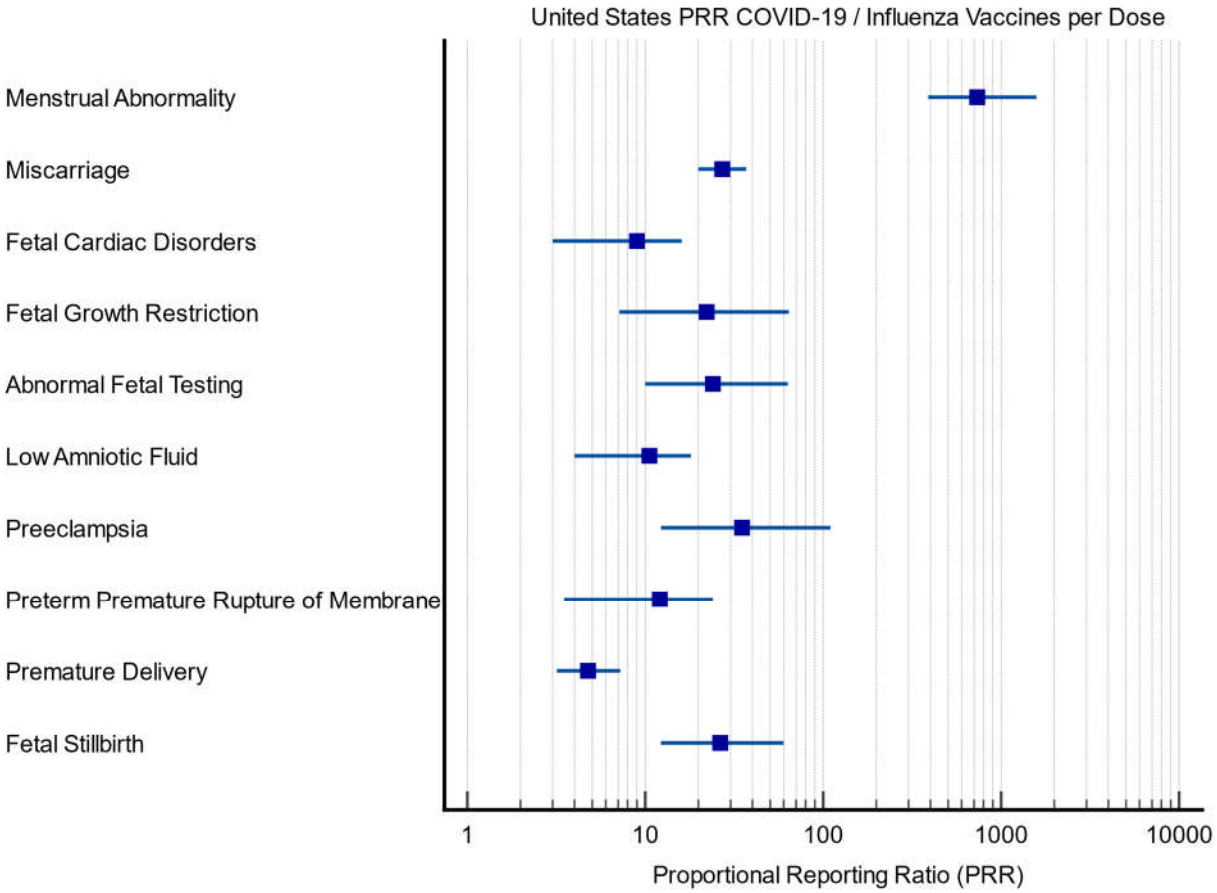

Figure 2. United States proportional reporting ratio (PRR) COVID-19 vaccination versus Influenza vaccination by dose given. A value greater than 1 implies that the AE is reported more frequently after the COVID-19 vaccines than after the Influenza vaccines. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. Data are reported as PRR with 95% confidence interval. 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 PRR with a zero in numerator or denominator cannot be calculated and are not depicted on this Forest Plot.

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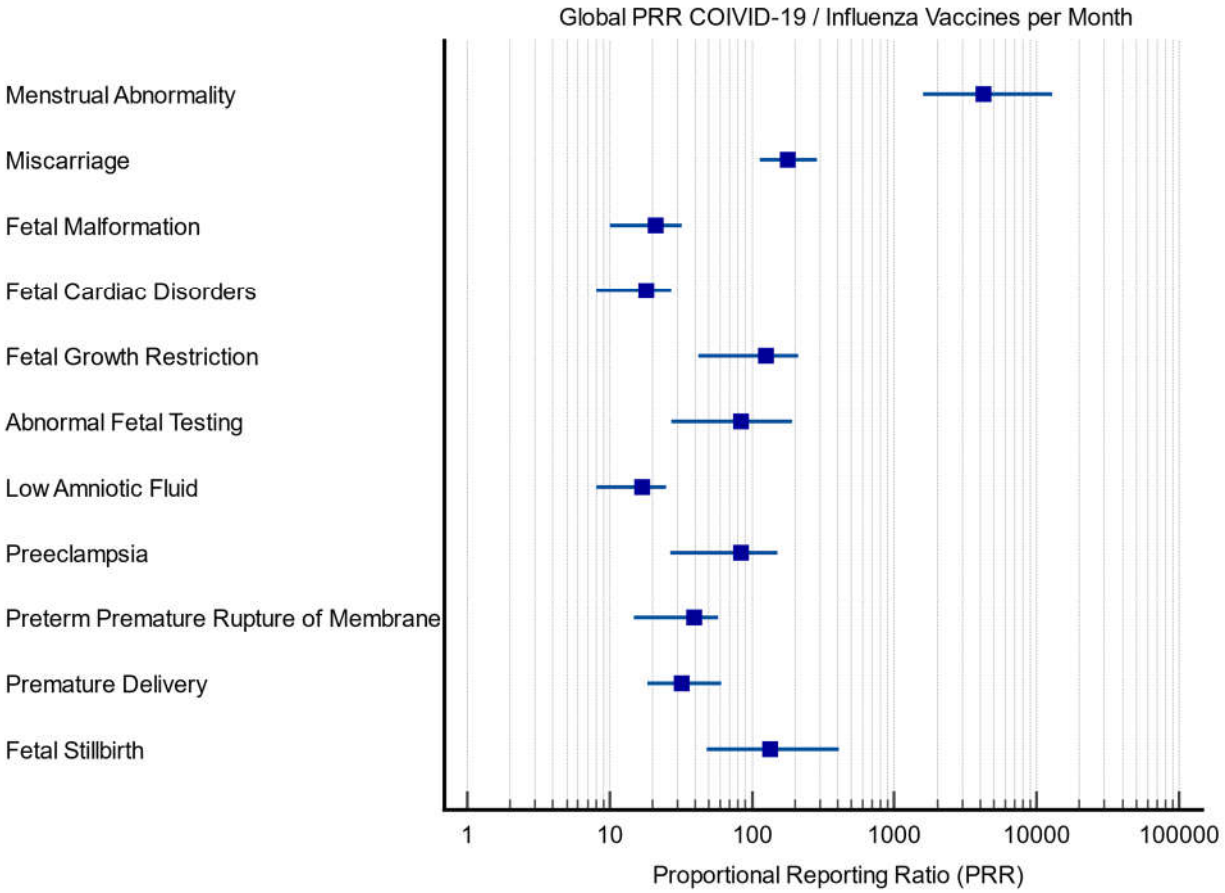

Figure 3. Global proportional reporting ratio (PRR) COVID-19 / Influenza per vaccination by month. A value greater than 1 implies that the AE is reported more frequently after the COVID-19 vaccines than after the Influenza vaccines. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different PRR - all substantially greater than 1. Data are reported as PRR with 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 83, 27-190; Low Amniotic Fluid Volume 17, 8-25; Preeclampsia 83.2, 26.6-151; Premature Rupture of Membrane 39, 14.7-58); Premature delivery 32.3, 18.5-60.3; and Stillbirth 135, 48.3-410).

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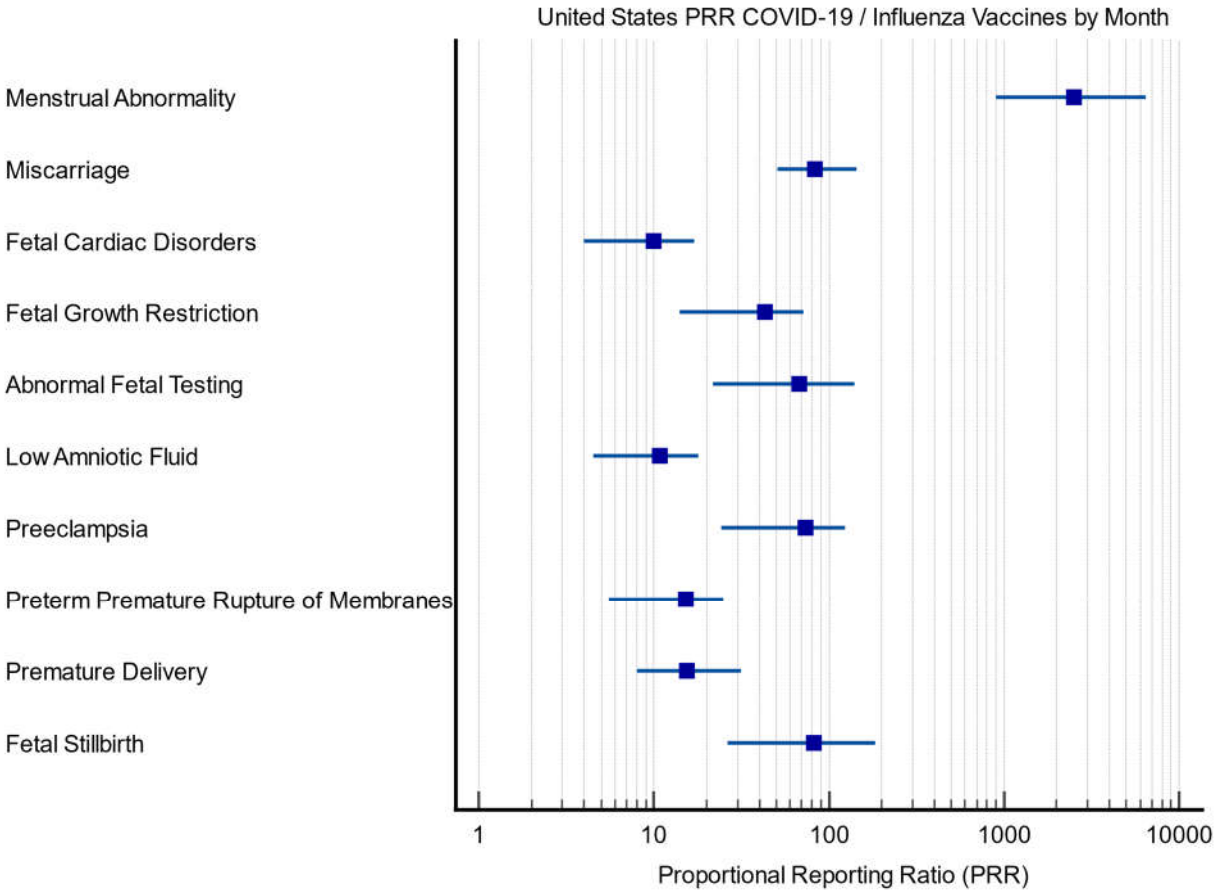

Figure 4. United States proportional reporting ratio (PRR) COVID-19 / Influenza vaccinations by month. A value greater than 1 implies that the AE is reported more frequently after the COVID-19 vaccines than after the Influenza vaccines. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. Data are reported as PRR with 95% confidence interval. 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, 4.5-18); Preeclampsia 73.8, 24.3-123; Premature Rupture of Membranes 15.2, 5.5-25; Premature Delivery 15.4, 8.0-31.6; and Stillbirth 82.1, 26.5-183).

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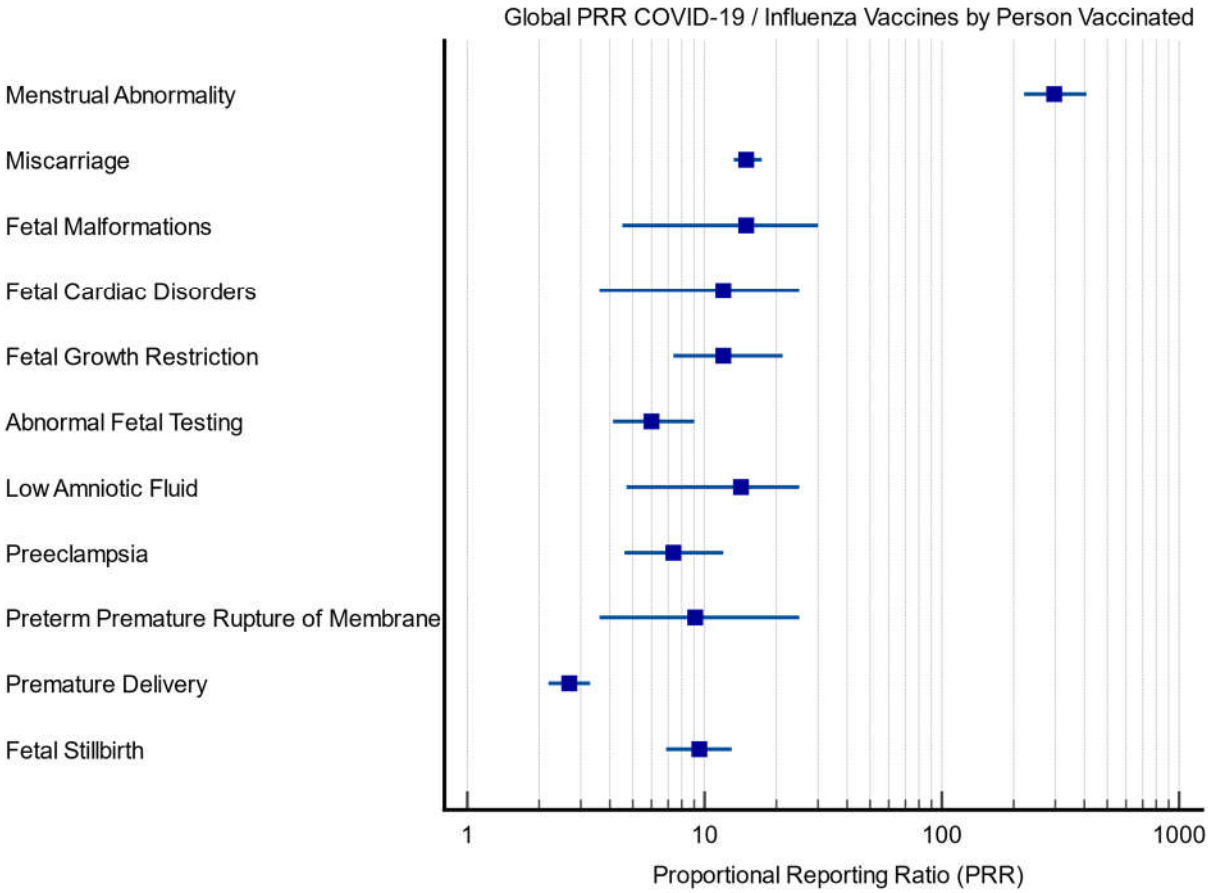

Figure 5. Global proportional reporting ratio (PRR) COVID-19 / Influenza vaccination by persons vaccinated. A value greater than 1 implies the PRR after the COVID-19 vaccines than after the Influenza vaccines. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. Data are reported as PRR with a 95% confidence interval. 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 Membrane 9.1, 3.6-25; Premature Delivery 2.7, 2.2-3.3; and Stillbirth 9.5, 6.9-13).

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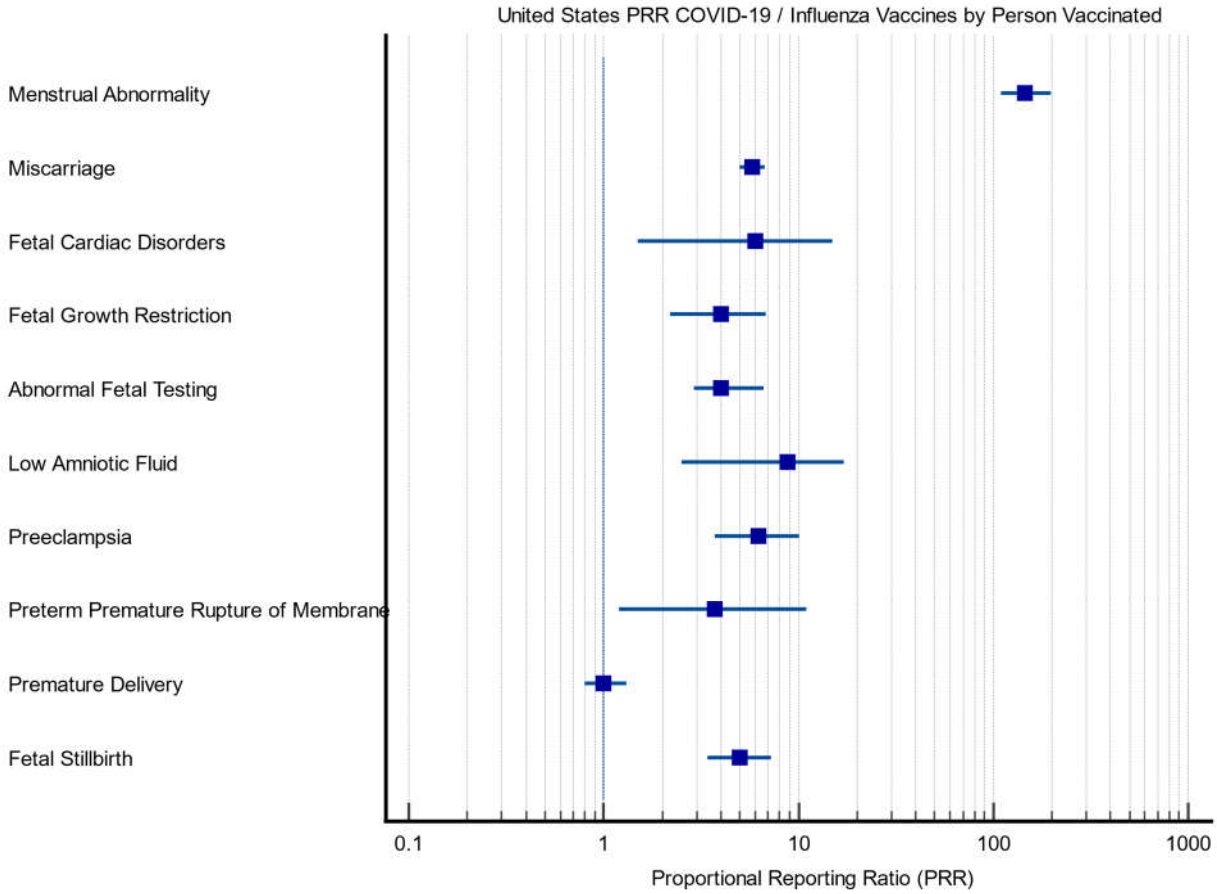

Figure 6. United States proportional reporting ratio (PRR) COVID-19 / Influenza vaccines by person vaccinated. A value greater than 1 implies that the AE is reported more frequently after the COVID-19 vaccines than after the Influenza vaccines. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. Data are reported as PRR with 95% confidence interval. Abnormal Menses 145, 109-197; Miscarriage 6, 5.0-6.7, Fetal Malformation 2, 0-5 (PRR 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).

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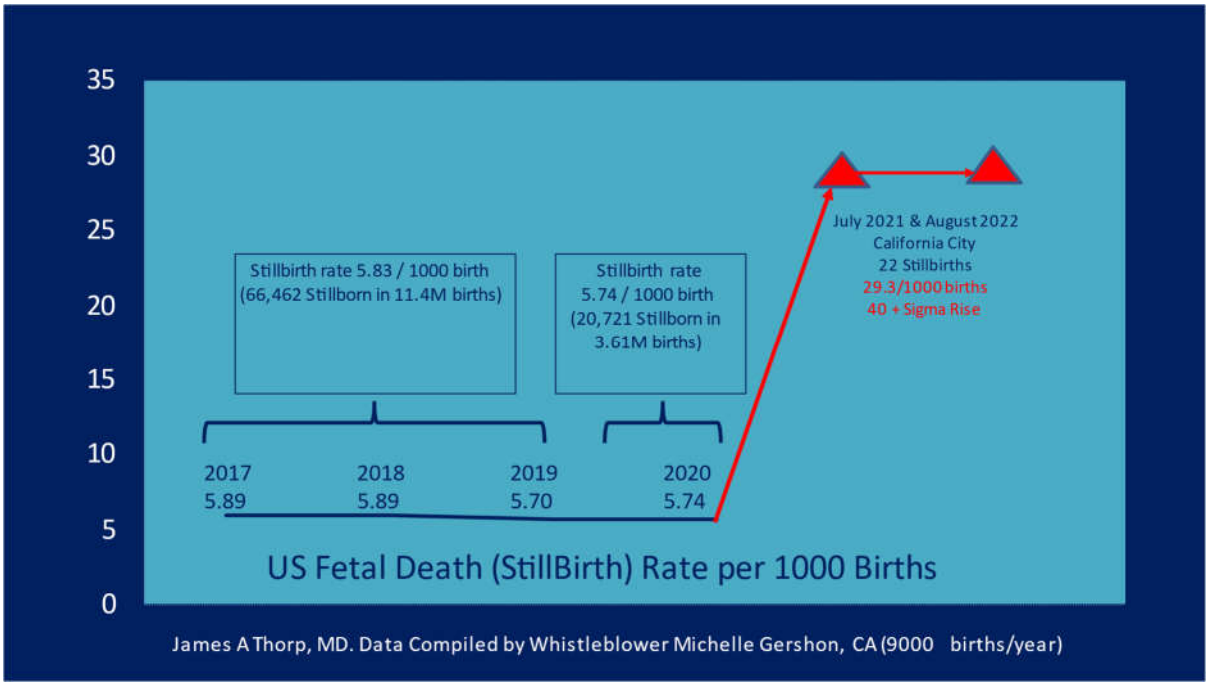

Figure 7. The US baseline rate of fetal death is 5.84 per 1000 births and has minimal variance. The US stillbirth rate dropped from the 2017-2019 aggregate of 5.83 to 5.74 in 2020 despite the COVID-19 caseload; COVID-19 infection clearly did not increase the rate of stillbirth in the US. Depicted here is the Whistleblower data taken directly from an administrative email to the postpartum nursing staff. The stillbirth rate shot up 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. While the rise in stillbirth from 5.8/1000 to 29.3/1000 at face value appears limited, the enormity of this massive rise cannot be overemphasized – it likely represents 40 standard deviations above the baseline (sigma ~ 0.5/1000 births).

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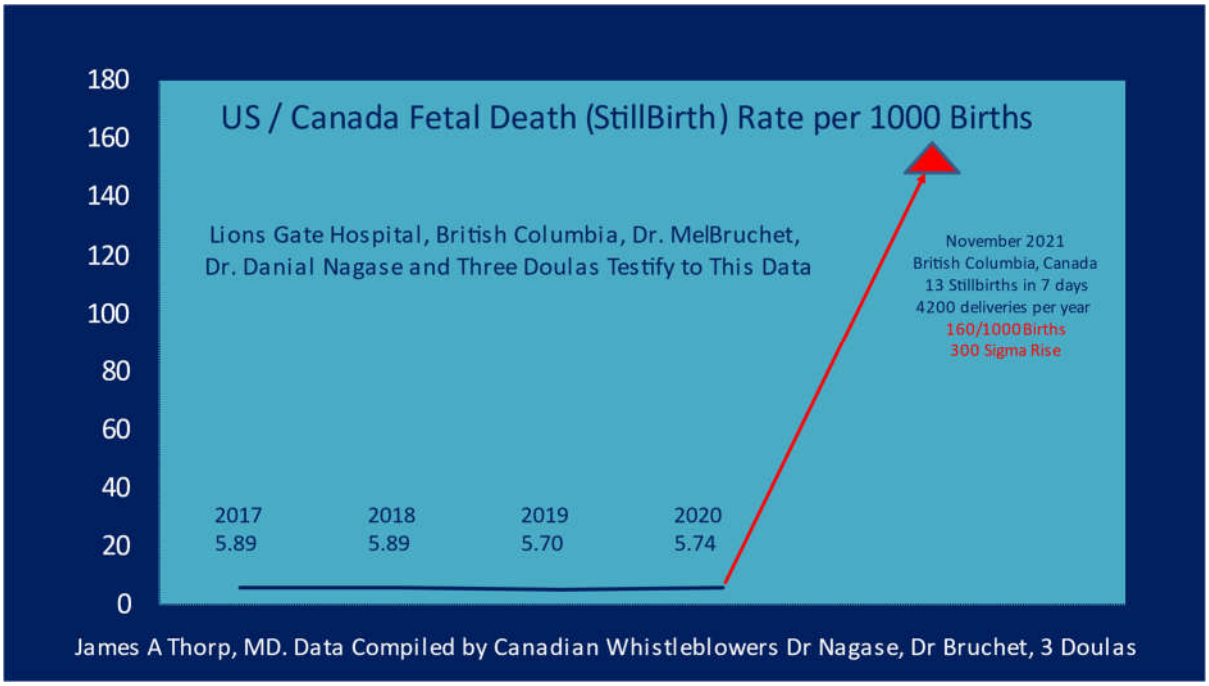

Figure 8. The US baseline rate of fetal death is 5.84 per 1000 births and has minimal variance. The US stillbirth rate dropped from the 2017-2019 aggregate of 5.83 to 5.74 in 2020 despite the COVID-19 caseload; COVID-19 infection clearly did not increase the rate of stillbirth in the US. Depicted here is the Whistleblower data taken directly from five healthcare workers (2 physicians and 3 doulas). Lions Gate Hospital in British Columbia, Canada experienced 13 stillbirths in just one 24 hour period. Because the rate was literally "off the charts" 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.

4. Discussion

An analysis of data from VAERS finds excessive adverse events (AE) for the COVID-19 vaccines as compared to the Influenza vaccines by more than a proportional reporting factor (PRR) 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]

The Vaccine Adverse Event Reporting System (VAERS) database is a passive vaccine surveillance tool administered by two agencies of the U.S. Department of Health and Human Services (HHS), the Centers for Disease Control (CDC), and the Food and Drug Administration (FDA). This database has tracked adverse reactions following the administration of vaccines since 1990. The FDA considers VAERS to be a valuable tool for post-marketing safety surveillance. The HHS advises that the VAERS database should be utilized 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 healthcare providers 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 the FDA and CDC before being published.[12,13] The FDA advises that any significant adverse event should be reported: "even if you are unsure whether a vaccine caused the event". It is considered a federal offense to falsify VAERS reports and is punishable by fine and imprisonment.

The FDA mandates that healthcare providers who administer COVID-19 vaccines are legally required to report to VAERS the following serious AE: 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

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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, multisystem inflammatory syndrome, as well as COVID-19 cases resulting in hospitalization or death are also required to be reported by the administering provider.

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. The 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 including: the UK Yellow Card System,[14] World Health Organization's VigiAccess,[15] and the European Economic Area's EudraVigilance data.[16]

The results of this study also align with recommendations from governments and non-governmental organizations. Recent documents from the UK government[17] 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 (page 7).[19] Specifically, 46% (124/270) of pregnant women in the first 90 days of rollout experienced AE and 81% (26/32) experienced miscarriage (page 12).[19]

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.[20] This data, along with Schädlich et al. from 2012,[21] 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.[22] Palmer and Bahdki documented 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 document severe adverse events 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: 20% drop in Hungary, 7% drop in Sweden, 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 in pregnancy increasing the risk of pregnancy complications, increased in premature deliveries, preeclampsia, preterm premature rupture of membranes, 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 jumps up three-fold to 17, dips again in the third quarter and then jumps again to 18 in the last quarter of 2021.[27]

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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. There are stunning examples both in California, and Canada. 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 corresponds to the national stillbirth rate of about 5.8/1000 births based upon that community of 9000 deliveries per year.

The email noted out that in July of 2021 and in August 2022 there were 22 fetal deaths and as the administrator pointed out, these were only the cases that showed up to labor & delivery - there were probably more that were not counted as some likely showed up to other locations including emergency rooms, the operating rooms, presented to other facilities or planned home births. **Figure 7** shows the baseline rate of fetal death to have minimal variance with a rate of fetal death to be 5.84 per 1000 births. It is obvious that the US aggregated 3-year stillbirth rate dropped from the 2017-2019 of 5.83 to 5.74 in 2020 despite the COVID-19 caseload; COVID-19 clearly did not increase the rate of US stillbirth. The stillbirth rate shot up 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. While the rise in stillbirth from 5.8/1000 to 29.3/1000 at face value appears limited, the enormity of this massive rise cannot be overemphasized – it likely represents 40 standard deviations (sigma ~ 0.5/1000 births) above the baseline.

While the highest stillbirth rate in the US 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 care providers (two physicians & 3 Doulas) noted an unprecedented 13 stillbirths in a 24-hour period at Lions Gate Hospital in British Columbia.[29] **Figure 8** documents this rate in comparison to the US 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.

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 one has 10% of their pregnant women vaccinated then one could expect a rise in the fetal death rates from 5.8/1000 to 8.3/100 (5.8 + 2.5). The senior author and maternal-fetal medicine physician while observing increased stillbirths in Florida, Missouri, and Illinois, that increment is much lower than that 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, even if they are off by a factor of five, the safety signal remains. Our methods estimating these denominators of vaccine doses and of people vaccinated all converge to a precision of 1% or better. Second, the relative under-reporting 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 Policy Makers

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,

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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 less than 30 deaths[30] and in the case of 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 government[17] 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]

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.[37-46] 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. For licensed vaccines, Title 21 of the Code of Regulations mandates that strict criteria for safety must be met.[47,48] 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 HHS describes VAERS as "a tool for identifying potential vaccine safety concerns that need further study using more robust data systems"[49] which is precisely why 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.

Acknowledgments: We are grateful to Theresa Long, MD, MPH, FS, Flight Aerospace Medicine, Fort Rucker, AL; to Amy B. Santamaria, PhD, Boulder, CO; and to Margery M. Thorp JD, MACP, Gulf Breeze, FL.

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