# **Analysis of Adverse Event Rates**

In this section we compare the rate of Global and US reports of post-vaccination adverse events (AE), for the COVID-19 vaccine and the Flu vaccine. For each of the AE, we compare three relevant rates of reporting: i) the rate of reported AE per unit time, ii) the rate of reported AE per dose given, and iii) the rate of reported AE per person vaccinated.

In Table 0 below, we report the period used for normalizing the data, Global values are reported on the top line, US value on the second line.

Vaccine	Time Tracked	Billion Doses Given	Billion People Vaccinated
COVID-19	18 Months	12.07 0.596	5.23 0.260
Flu	294 Months	66 (estimated) 3.3	9.23 (simulated) 0.389 (simulated)

#### Table 0

Counting the number of people vaccinated with the COVID-19 vaccine is straightforward because there has only been one worldwide attempt at vaccination and the data has been tracked from day one. The Flu vaccine is harder because individuals are not tracked and there are yearly seasons where an individual may choose to receive a subsequent vaccinations. We run a Monte Carlo simulation to estimate the number of people since 1998 that have received at least one Flu vaccine in the US.

We track a sample population where each year a fraction of the population is vaccinated,  $f_v$ , a fraction of the population dies (some of whom may be vaccinated),  $f_d$ , and a new fraction of the population is born (none of whom are vaccinated),  $f_b$ . By simulating the demographics change yearly, we can estimate the total number of people who have received at least one flu vaccine by 2022. We use the UN population data to estimate  $f_b$  and  $f_d$  each year (reference: <a href="https://population.un.org/">https://population.un.org/</a>) and the conditional probability of Flu vaccination from Kwong, et al. (reference: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6961264/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6961264/</a>). Kwong reports that roughly 57% (33,234 out of 58,021) of the population in their study who receives a flu shot in one year repeats it a subsequent year. The CDC reports that approximately 50% of the population receives the vaccine in any given year. From that, we estimate  $f_v = 0.57$  for previously vaccinated individuals and  $f_v = 0.43$  for previously unvaccinated individuals, which will result in the rough CDC approximation of 50% of the population being vaccinated any given year.

To allow simulation "burn in" for the stochastic nature of this experiment, we start in 1980 with a sample of the US population of 100,000,000 people with 50% of them "pre-vaccinated" from previous years. From 1980 to 1997 we grow the population by  $f_b$ , shrink it by  $f_d$ , and vaccinate individuals by the conditional  $f_v$  based on their current vaccination status, by 1997 we can see that the fraction of vaccinated population has stabalized. We continue the simulation until 2021 with the addition that in 1998 we start accumulating the number of people who were vaccinated and died. The results of that simulation are shown below in Table 00.

End of Year	Sample Population (Thousands)	Vaccinated Population (Thousands)	Total Vaccinated Since 1998 (Thousands)
1980	100685	70921 (70.4%)	

End of Year	Sample Population (Thousands)	Vaccinated Population (Thousands)	Total Vaccinated Since 1998 (Thousands)
1981	101328	82921 (81.8%)	
1982	101936	89923 (88.2%)	
1983	102629	94190 (91.8%)	
1984	103253	96842 (93.8%)	
1985	103924	98746 (95.0%)	
1986	104615	100133 (95.7%)	
1987	105344	101170 (96.0%)	
1988	106017	102026 (96.2%)	
1989	106742	102790 (96.3%)	
1990	107434	103590 (96.4%)	
1991	108187	104335 (96.4%)	
1992	108919	105104 (96.5%)	
1993	109637	105790 (96.5%)	
1994	110313	106507 (96.5%)	
1995	110959	107191 (96.6%)	
1996	111615	107893 (96.7%)	
1997	112289	108579 (96.7%)	
1998	112919	109203 (96.7%)	110157 (97.6%)
1999	113542	109799 (96.7%)	111722 (98.4%)
2000	114182	110390 (96.7%)	113264 (99.2%)
2001	114821	111055 (96.7%)	114889 (100.1%)
2002	115497	111745 (96.8%)	116497 (100.9%)
2003	116175	112461 (96.8%)	118139 (101.7%)
2004	116819	113102 (96.8%)	119745 (102.5%)
2005	117465	113757 (96.8%)	121371 (103.3%)
2006	118119	114412 (96.9%)	122989 (104.1%)
2007	118792	114997 (96.8%)	124521 (104.8%)
2008	119496	115736 (96.9%)	126181 (105.6%)

End of Year	Sample Population (Thousands)	Vaccinated Population (Thousands)	Total Vaccinated Since 1998 (Thousands)
2009	120074	116317 (96.9%)	127789 (106.4%)
2010	120665	116899 (96.9%)	129362 (107.2%)
2011	121265	117562 (96.9%)	130979 (108.0%)
2012	121819	118175 (97.0%)	132571 (108.8%)
2013	122308	118774 (97.1%)	134195 (109.7%)
2014	122830	119335 (97.2%)	135733 (110.5%)
2015	123360	119866 (97.2%)	137231 (111.2%)
2016	123855	120378 (97.2%)	138736 (112.0%)
2017	124287	120819 (97.2%)	140225 (112.8%)
2018	124730	121263 (97.2%)	141695 (113.6%)
2019	125123	121666 (97.2%)	143178 (114.4%)
2020	125570	122107 (97.2%)	144657 (115.2%)
2021	125981	122575 (97.3%)	146200 (116.0%)

#### Table 00

After running the simulation, in 2021 our 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 Flu vaccine since 1998 (116% of the current population). Now, we scale this estimate to the true 2022 the total population of 334,805,000 (reference: <a href="https://population.un.org/">https://population.un.org/</a>), we estimate the same fraction of 116% of the current population vaccinated since 1998, that results in roughly a total 389 million people in the US that have received at least one dose of flu vaccine. Using the same scaling factor for a world population of 7.95 billion, we get an estimate of 9.23 billion people worldwide who have received at least one dose of the flu vaccine since 1998. These are all rough estimates given the limited data available; however, even if these estimates are high by a factor of 10 (highly unlikely), the signals reported below are still significant.

In Table 1 below we show the count of AE reported post vaccine 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. Report count and rates for the COVID-19 Vaccine are on the top line with the counts and rates for the Flu vaccine below them for each AE. The same data for global counts and rates is 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)
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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)
Abnormal uterine bleeding (menstrual irregularity)	6352	353	10700	24400
	54	0.184	16.4	139
Miscarriage	1232	68.4	2070	4740
	259	0.881	78.5	666
Fetal chromosomal abnormalities	7	0.389	11.7	26.9
	0	0.00	0.00	0.00
Fetal malformation	2	0.111	3.35	7.69
	1	0.00340	0.303	2.57
Fetal cystic hygroma	5	0.278	8.39	19.2
	0	0.00	0.00	0.00
Fetal cardiac disorders	10	0.556	16.8	38.5
	2	0.00680	0.606	5.15
Fetal arrhythmia	3	0.167	5.03	11.5
	0	0.00	0.00	0.00
Fetal cardiac arrest	3	0.167	5.03	11.5
	0	0.00	0.00	0.00
Fetal vascular mal-	5	0.278	8.39	19.2
perfusion	0	0.00	0.00	0.00
Fetal growth abnormalities	59	3.28	99.0	227
	20	0.0680	6.06	51.5
Fetal abnormal surveillance	125	6.94	210	481
	36	0.122	10.9	92.6
Fetal placental	5	0.278	8.39	19.2
thrombosis	0	0.00	0.00	0.00
Fetal death (stillbirth)	168	9.33	282	646
	42	0.143	12.7	108

Table 1

Globa Adverse Event	al 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)
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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)
Abnormal uterine bleeding (menstrual irregularity)	12843	714	1060	2460
	65	0.221	0.985	7.04
Miscarriage	3338	185	277	638
	325	1.11	4.92	35.2
Fetal chromosomal abnormalities	10	0.556	0.829	1.91
	0	0.00	0.00	0.00
Fetal malformation	22	1.22	1.82	4.21
	2	0.00680	0.0303	0.217
Fetal cystic hygroma	8 0	0.444 0.00	0.663 0.00	1.53 0.00
Fetal cardiac disorders	18	1.00	1.49	3.44
	2	0.00680	0.0303	0.217
Fetal arrhythmia	5	0.278	0.414	0.956
	0	0.00	0.00	0.00
Fetal cardiac arrest	20	1.11	1.66	3.82
	0	0.00	0.00	0.00
Fetal vascular mal-	12	0.667	0.994	2.29
perfusion	0	0.00	0.00	0.00
Fetal growth abnormalities	188	10.4	15.6	35.9
	24	0.0816	0.364	2.60
Fetal abnormal surveillance	178	9.89	14.7	34.0
	45	0.153	0.682	4.88
Fetal placental	6	0.333	0.497	1.15
thrombosis	0	0.00	0.00	0.00
Fetal death (stillbirth)	402	22.3	33.3	76.9
	64	0.218	0.970	6.93

#### Table 2

For all AE, the rates of reports post COVID-19 vaccine are higher than the Flu vaccine across all three normalization methods: by unit time, by dose given, and by person vaccinated. We proceed with 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% CI of AE reports after the COVID-19 vaccine versus the Flu vaccine. That is, we answer the questions: 1) "Are the rate of AE reports post COVID-19 vaccine (statistically) different than the rates of report post

Flu vaccine?" and 2) "How much more frequently is an AE reported after the COVID-19 vaccine than after the Flu vaccine?"

#### Statistical Significance

We treat each AE report as discrete independent events occurring at the mean rate specified in Tables 1 and 2 which we model as a Poisson distribution. Given two rates  $r_1$  and  $r_2$  over a period, P, we perform a Poisson E-test [reference: <a href="https://userweb.ucs.louisiana.edu/~kxk4695/JSPI-04.pdf">https://userweb.ucs.louisiana.edu/~kxk4695/JSPI-04.pdf</a>] to compute the p-value. The E-test is used for Poisson statistics analogous to the traditional t-test used for Gaussian statistics. The p-value is interpreted in the same way: the probability that the observed events came from the same probability distribution. Or stated another way: the probability that the means (in this case rates) are same by random chance.

We use the rates in Tables 1 and 2 above and normalize the event counts over each period, P: the time-, dose-, or people-vaccinated-window 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 [reference: https://github.com/nolanbconaway/poisson-etest].

#### Estimating Relative Reporting Rates

For the rates that have non-zero counts in the reporting period, we compute ratio of rates of AE reports for each vaccine and the 95% confidence interval (We do not use the p-value as a metric here to avoid claims of p-hacking, the full confidence interval is shown and the reader can deduce significance from that). That is, we compute how much more often a post COVID-19 vaccination AE is reported compared to post Flu vaccination. Consider a case were Event A is reported at a rate of 100 per month and Event B is reported at a rate of 10 per month. The naïve approach is to simply state that Event A is reported  $\frac{100/month}{10/month} = 10$  times as often as Event B. However, events do not occur at uniform frequency, independent events occur at frequencies described by the Poisson distribution. We proceed by computing the ratio distribution, R, which is the distribution of the ratio of two different Poisson distributions. That is, given two Poisson distributions,  $Poisson(r_1)$  and  $Poisson(r_2)$ , we aim to compute the ratio distribution, R, which represents the probability distribution of the ratio of the distribution of events.

$$R(r_1, r_2) = rac{Poisson(r_1)}{Poisson(r_2)}$$

We estimate the shape of R for each AE and period, P, by performing Monte Carlo simulations. We draw 1,000,000 random samples from Poisson distributions with rates  $r_1$  and  $r_2$  resulting in a sample of paired event counts  $n_1$  and  $n_2$ , respectively, over the observation window P.

$$n_i \leftarrow Poisson(r_i)$$

That is, we create a set of 1,000,000 tuples of event counts  $\{(n_1,n_2)_1,(n_1,n_2)_2,\ldots,(n_1,n_2)_{1000000}\}$  drawn from the two Poisson distributions. The ratio distribution, R, is built up from the ratio of the draws of each pair of  $n_1$  and  $n_2$ 

$$R(r_1,r_2) = \left\{ \left(rac{n_1}{n_2}
ight)_1, \left(rac{n_1}{n_2}
ight)_2, \ldots, \left(rac{n_1}{n_2}
ight)_{1000000} 
ight\}$$

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 have converged to a precision of 1% or better. For AE that are reported infrequently post Flu vaccine there is finite probability that  $n_2$  is zero resulting in R being undefined. To mitigate this problem, we use the zero-truncated Poisson distribution [reference: <a href="https://www.jstor.org/stable/2527552">https://www.jstor.org/stable/2527552</a>] and only count instances of non-zero  $n_2$  draws. This approach skews the R distribution to the left [reference: <a href="https://epubs.siam.org/doi/10.1137/0134043">https://epubs.siam.org/doi/10.1137/0134043</a>] and makes the AE rates for the COVID-19 vaccine actually look better. That is, in these cases, the AE rate is actually a lower bound.

We did these analyses using a custom-written Python script, and will make it available upon request.

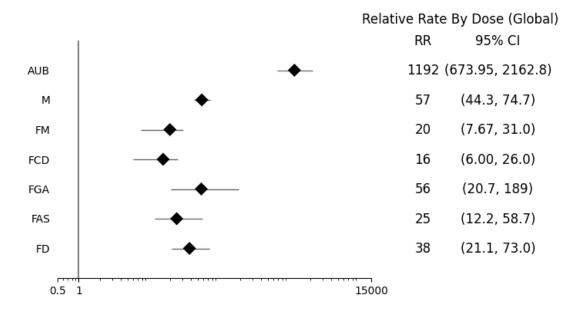
We report in Table 3 below the relative rate of post COVID-19 vaccine AE reports to post Flu vaccine AE report. Global values are the top line and US values are in the bottom line for each AE. A relative rate greater than 1 implies that there are more post COVID-19 vaccine AE reports than post Flu vaccine AE report. According to CDC's Standard Operating Procedures for COVID-19 [reference: <a href="https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf">https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf</a>] when doing a Proportional Reporting Ratio (PRR) analysis (which is analogous to the analysis presented here in this paper), a 2x increase in reporting is a sufficient signal to be concerned.

Adverse Event	Relative Rate (by time)	Relative Rate (by dose)	Relative Rate (by person vaccinated)
Abnormal uterine bleeding (menstrual irregularity)	4257 [1589.1-	1192 [673.95-	359 [261.1-506.8]
	12893] p=0.0	2162.8] p=0.0	p=0.0
	2524 [894.57-	738 [391.6-1584]	181 [131.2-255.5]
	6419.0] p=0.0	p=0.0	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	18 [15.7-21.2] p=0.0 7 [6.1-8.4] p=0.0
Fetal chromosomal abnormalities	p=0.00058	p=0.00058	p=0.00058
	p=0.0048	p=0.0048	p=0.0048
Fetal malformation	21 [10.0-32.0]	20 [7.67-31.0]	16 [5.00-30.0]
	p=1.9x10 <sup>-07</sup>	p=1.9x10 <sup>-07</sup>	p=2.1x10 <sup>-06</sup>
	p=0.20	p=0.20	p=0.20
Fetal cystic hygroma	p=0.0024	p=0.0024	p=0.0024
	p=0.020	p=0.020	p=0.020
Fetal cardiac disorders	17 [8.00-27.0]	16 [6.00-26.0]	13 [4.00-25.0]
	p=2.6x10 <sup>-06</sup>	p=2.6x10 <sup>-06</sup>	p=2.7x10 <sup>-05</sup>
	10 [4.00-17.0]	9 [3.0-16]	7 [1.7-15]
	p=0.00058	p=0.00058	p=0.0047
Fetal arrhythmia	p=0.020	p=0.020	p=0.020
	p=0.088	p=0.088	p=0.088
Fetal cardiac arrest	p=6.9x10 <sup>-07</sup>	p=6.9x10 <sup>-07</sup>	p=6.9x10 <sup>-07</sup>
	p=0.088	p=0.088	p=0.088
Fetal vascular mal-perfusion	p=0.00015	p=0.00015	p=0.00015
	p=0.020	p=0.020	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	15 [8.60-27.6] p=0.0 5 [2.6-9.1] p=1.7x10 <sup>-08</sup>

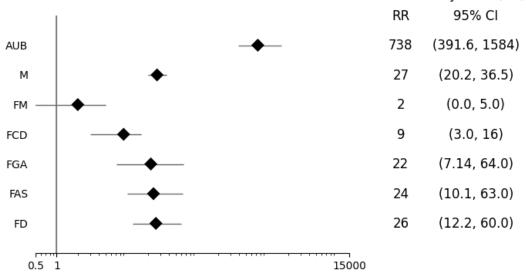
Adverse Event	Relative Rate (by time)	Relative Rate (by dose)	Relative Rate (by person vaccinated)
Fetal abnormal surveillance	83 [26.9-193] p=0.0 68 [21.6-140] p=0.0	25 [12.2-58.7] p=0.0 24 [10.1-63.0] p=0.0	7 [4.8-11] p=0.0 5 [3.5-8.6] p=0.0
Fetal placental thrombosis	p=0.0096 p=0.020	p=0.0096 p=0.020	p=0.0096 p=0.020
Fetal death (stillbirth)	135 [48.25-412.0] p=0.0 82 [26.5-184] p=0.0	38 [21.1-73.0] p=0.0 26 [12.2-60.0] p=0.0	11 [8.14-16.3] p=0.0 6 [4.2-9.4] p=0.0

Table 3

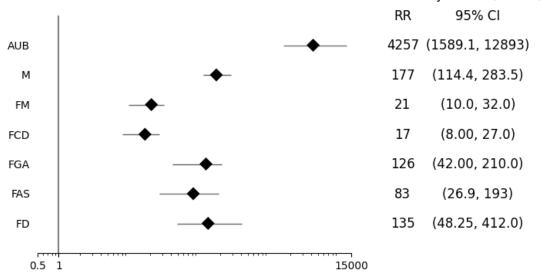
In the Figures below we show the Global and US relative rates of the reports of AE after the COVID-19 vaccine versus the Flu vaccine for the rates of AE by unit time, by dose given, and by person vaccinated. A value greater than 1 implies that the AE is reported more frequently after the COVID-19 vaccine than after the Flu vaccine. Note the log scale spanning multiple orders of magnitude indicating a large effect across many different AE - all (much) greater than 1.



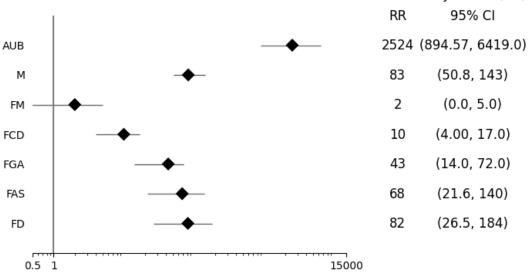
### Relative Rate By Dose (US)



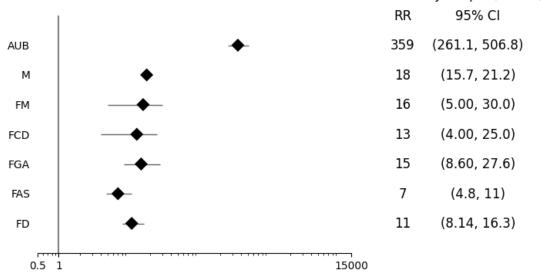
### Relative Rate By Month (Global)



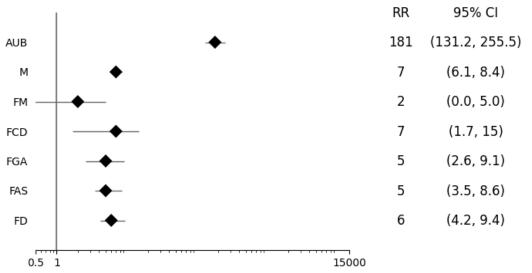
### Relative Rate By Month (US)



#### Relative Rate By People (Global)



### Relative Rate By People (US)



## Log

Output log from analysis code

*** RATES *** Abnormal uterine bleeding (menstrual irregularity)	6352	10653.60	068 54
16.3636			
Miscarriage	1232	2066.31	.67 259
78.4848			
Fetal chromosomal abnormalities 0.0000	7	11.74	04
Fetal malformation 0.3030	2	3.35	544 1
Fetal cystic hygroma	5	8.38	860 0
0.0000 Fetal cardiac disorders	10	16.77	21 2
0.6061 Fetal arrhythmia	3	5.03	316 0
0.0000			
Fetal cardiac arrest 0.0000	3	5.03	316 0
Fetal vascular mal-perfusion 0.0000	5	8.38	860 0
Fetal growth abnormalities	59	98.95	551 20
6.0606 Fetal abnormal surveillance	125	209.65	36
10.9091			
Fetal placental thrombosis 0.0000	5	8.38	360 0
Fetal death (stillbirth) 12.7273	168	281.77	705 42
***********			
*** P VALUES ***			
Abnormal uterine bleeding (menstrual irregularity)	0.000e+	00	
Miscarriage	0.000e+	00	
Fetal chromosomal abnormalities	4.759e-	03	
Fetal malformation	1.973e-	01	
Fetal cystic hygroma	1.976e-	02	
Fetal cardiac disorders	5.781e-	04	
Fetal arrhythmia	8.838e-	02	
Fetal cardiac arrest	8.838e-	02	
Fetal vascular mal-perfusion	1.976e-	02	
Fetal growth abnormalities	0.000e+	00	
Fetal abnormal surveillance	0.000e+	00	
Fetal placental thrombosis	1.976e-	02	
Fetal death (stillbirth)	0.000e+	00	
*************			
*** RELATIVE RATES ***	720 1	220 20	1 6250
Abnormal uterine bleeding (menstrual irregularity) 1583.5000	738.1	JJY 39	1.6250
Miscarriage	26.9	146 2	0.1833
36.5294			

Fetal chromosomal abnormalities 0.0000	0.00	0.0	000
Fetal malformation 5.0000	1.90	72 0.0	000
Fetal cystic hygroma 0.0000	0.00	0.0	000
Fetal cardiac disorders	9.11	87 3.0	000
16.0000 Fetal arrhythmia	0.00	0.0	000
0.0000 Fetal cardiac arrest	0.00	00 0.0	000
0.0000 Fetal vascular mal-perfusion	0.00	00 0.0	000
0.0000 Fetal growth abnormalities	21.57	57 7.1	429
64.0000 Fetal abnormal surveillance	23.57	55 10.1	111
63.0000 Fetal placental thrombosis	0.00	00 0.0	000
0.0000 Fetal death (stillbirth)	26.28	01 12.2	000
60.0000			
**************************************			
[('Abnormal uterine bleeding (menstrual irregularity)', ('Miscarriage', 'M', 1232, 259), ('Fetal chromosomal abn ('Fetal malformation', 'FM', 2, 1), ('Fetal cystic hygrocardiac disorders', 'FCD', 10, 2), ('Fetal arrhythmia', cardiac arrest', 'FCA', 3, 0), ('Fetal vascular mal-perf ('Fetal growth abnormalities', 'FGA', 59, 20), ('Fetal a 'FAS', 125, 36), ('Fetal placental thrombosis', 'FPT', 5 (stillbirth)', 'FD', 168, 42)]	ormaliti ma', 'FC 'FA', 3, usion', bnormal	es', 'FCM' M', 5, 0), 0), ('Fet 'FVMP', 5, surveillan	('Fetal al 0), ce',
cperiod= 18 cperiod= 294			
**************************************			
*** RATES ***			
Abnormal uterine bleeding (menstrual irregularity) 0.1837	6352	352.8889	54
Miscarriage 0.8810	1232	68.4444	259
Fetal chromosomal abnormalities 0.0000	7	0.3889	0
Fetal malformation 0.0034	2	0.1111	1
Fetal cystic hygroma 0.0000	5	0.2778	0
Fetal cardiac disorders 0.0068	10	0.5556	2

Fetal arrhythmia 0.0000	3	0.1667	0
Fetal cardiac arrest	3	0.1667	0
Fetal vascular mal-perfusion 0.0000	5	0.2778	0
Fetal growth abnormalities	59	3.2778	20
Fetal abnormal surveillance	125	6.9444	36
0.1224 Fetal placental thrombosis	5	0.2778	0
0.0000 Fetal death (stillbirth)	168	9.3333	42
0.1429 ******************			
*** P VALUES ***			
Abnormal uterine bleeding (menstrual irregularity)	0.000e+00		
Miscarriage	0.000e+00		
Fetal chromosomal abnormalities	4.759e-03		
Fetal malformation	1.973e-01		
Fetal cystic hygroma	1.976e-02		
Fetal cardiac disorders	5.781e-04		
Fetal arrhythmia	8.838e-02		
Fetal cardiac arrest	8.838e-02		
Fetal vascular mal-perfusion	1.976e-02		
Fetal growth abnormalities	0.000e+00		
Fetal abnormal surveillance	0.000e+00		
Fetal placental thrombosis	1.976e-02		
Fetal death (stillbirth)	0.000e+00		
**********			
*** RELATIVE RATES ***			
Abnormal uterine bleeding (menstrual irregularity) 6419.0000	2523.5285	894.57	14
Miscarriage 143.2222	83.4301	50.83	333
Fetal chromosomal abnormalities 0.0000	0.0000	0.00	000
Fetal malformation 5.0000	1.9811	0.00	000
Fetal cystic hygroma 0.0000	0.0000	0.00	000
Fetal cardiac disorders	9.6984	4.00	000
Fetal arrhythmia	0.0000	0.00	000
0.0000 Fetal cardiac arrest	0.0000	0.00	000
0.0000  Fetal vascular mal-perfusion 0.0000	0.0000	0.00	000
0.000			

Fetal growth abnormalities 72.0000	42.50	020 14.00	000
Fetal abnormal surveillance	67.98	390 21.60	000
Fetal placental thrombosis	0.00	0.00	000
Fetal death (stillbirth) 184.0000	82.15	521 26.50	000
**********			
******			
**** People (US) ****			
[('Abnormal uterine bleeding (menstrual irregularity)'			7 0)
('Miscarriage', 'M', 1232, 259), ('Fetal chromosomal a ('Fetal malformation', 'FM', 2, 1), ('Fetal cystic hyg			
cardiac disorders', 'FCD', 10, 2), ('Fetal arrhythmia'			
cardiac arrest', 'FCA', 3, 0), ('Fetal vascular mal-pe			
('Fetal growth abnormalities', 'FGA', 59, 20), ('Fetal			
'FAS', 125, 36), ('Fetal placental thrombosis', 'FPT',	5, 0), (	Fetal death	1
(stillbirth)', 'FD', 168, 42)]			
cperiod= 0.25996			
cperiod= 0.38861			
^^^^^			
*** RATES ***			
Abnormal uterine bleeding (menstrual irregularity)	6352 2	24434.5284	54
138.9568			
Miscarriage	1232	4739.1906	259
666.4780			
Fetal chromosomal abnormalities	7	26.9272	0
0.0000	2	7 6025	1
Fetal malformation 2.5733	2	7.6935	1
Fetal cystic hygroma	5	19.2337	0
0.0000	J	17.2007	
Fetal cardiac disorders	10	38.4675	2
5.1465			
Fetal arrhythmia	3	11.5402	0
0.0000			
Fetal cardiac arrest	3	11.5402	0
0.0000	_	10 2227	0
Fetal vascular mal-perfusion 0.0000	5	19.2337	0
Fetal growth abnormalities	59	226.9580	20
51.4655	37	220.7300	20
Fetal abnormal surveillance	125	480.8432	36
92.6379			
Fetal placental thrombosis	5	19.2337	0
0.0000			
Fetal death (stillbirth)	168	646.2533	42
108.0775			
***********			

*** P VALUES ***		
Abnormal uterine bleeding (menstrual irregularity)	0.000e+00	
Miscarriage	0.000e+00	
Fetal chromosomal abnormalities	4.759e-03	
Fetal malformation	1.973e-01	
Fetal cystic hygroma	1.976e-02	
Fetal cardiac disorders	4.682e-03	
Fetal arrhythmia	8.838e-02	
Fetal cardiac arrest	8.838e-02	
Fetal vascular mal-perfusion	1.976e-02	
Fetal growth abnormalities	1.675e-08	
Fetal abnormal surveillance	0.000e+00	
Fetal placental thrombosis	1.976e-02	
Fetal death (stillbirth)	0.000e+00	
*****		
*** RELATIVE RATES ***		
Abnormal uterine bleeding (menstrual irregularity)	180.9633	131.2245
255.4800		
Miscarriage	7.1526	6.1040
8.4052		
Fetal chromosomal abnormalities	0.0000	0.0000
0.0000		
Fetal malformation	1.6813	0.0000
5.0000		
Fetal cystic hygroma	0.0000	0.0000
0.0000		
Fetal cardiac disorders	6.9717	1.6667
15.0000		
Fetal arrhythmia	0.0000	0.0000
0.0000		
Fetal cardiac arrest	0.0000	0.0000
0.0000		
Fetal vascular mal-perfusion	0.0000	0.0000
0.0000		
Fetal growth abnormalities	4.8033	2.5789
9.1111		
Fetal abnormal surveillance	5.4263	3.4857
8.5714		
Fetal placental thrombosis	0.0000	0.0000
0.0000		
Fetal death (stillbirth)	6.2095	4.1538
9.4375		
******		
******		
**** Dose (Global) ****		

```
[('Abnormal uterine bleeding (menstrual irregularity)', 'AUB', 12843, 65),
('Miscarriage', 'M', 3338, 325), ('Fetal chromosomal abnormalities', 'FCM', 10,
0), ('Fetal malformation', 'FM', 22, 2), ('Fetal cystic hygroma', 'FCM', 8, 0),
('Fetal cardiac disorders', 'FCD', 18, 2), ('Fetal arrhythmia', 'FA', 5, 0),
('Fetal cardiac arrest', 'FCA', 20, 0), ('Fetal vascular mal-perfusion', 'FVMP',
12, 0), ('Fetal growth abnormalities', 'FGA', 188, 24), ('Fetal abnormal
surveillance', 'FAS', 178, 45), ('Fetal placental thrombosis', 'FPT', 6, 0),
('Fetal death (stillbirth)', 'FD', 402, 64)]
cperiod= 12.07
cperiod= 66
*********
*** RATES ***
Abnormal uterine bleeding (menstrual irregularity) 12843 1064.0431
                                                                           65
  0.9848
Miscarriage
                                                        3338 276.5534
                                                                        325
  4.9242
Fetal chromosomal abnormalities
                                                          10
                                                                 0.8285
                                                                             0
  0.0000
Fetal malformation
                                                          22
                                                                 1.8227
 0.0303
                                                           8
Fetal cystic hygroma
                                                                 0.6628
                                                                             0
  0.0000
Fetal cardiac disorders
                                                                 1.4913
                                                                             2
                                                          18
  0.0303
Fetal arrhythmia
                                                                 0.4143
 0.0000
Fetal cardiac arrest
                                                          20
                                                                 1.6570
                                                                             0
  0.0000
Fetal vascular mal-perfusion
                                                          12
                                                                 0.9942
                                                                             0
  0.0000
Fetal growth abnormalities
                                                         188
                                                                            24
                                                                15.5758
Fetal abnormal surveillance
                                                         178
                                                                14.7473
                                                                            45
 0.6818
Fetal placental thrombosis
                                                                0.4971
  0.0000
Fetal death (stillbirth)
                                                         402
                                                                33.3057
                                                                           64
  0.9697
*******
*** P VALUES ***
Abnormal uterine bleeding (menstrual irregularity)
                                                      0.000e+00
Miscarriage
                                                      0.000e+00
Fetal chromosomal abnormalities
                                                      5.781e-04
Fetal malformation
                                                      1.855e-07
Fetal cystic hygroma
                                                      2.378e-03
Fetal cardiac disorders
                                                      2.618e-06
Fetal arrhythmia
                                                      1.976e-02
Fetal cardiac arrest
                                                      6.949e-07
Fetal vascular mal-perfusion
                                                      1.473e-04
Fetal growth abnormalities
                                                      0.000e+00
```

Fetal abnormal surveillance	0.000e+00	
Fetal placental thrombosis	9.631e-03	
Fetal death (stillbirth)	0.000e+00	
*********		
*** RELATIVE RATES ***		
Abnormal uterine bleeding (menstrual irregularity)	1191.8561	673.9474
2162.8333		
Miscarriage	57.1421	44.3421
74.6591		
Fetal chromosomal abnormalities	0.0000	0.0000
0.0000		
Fetal malformation	20.0241	7.6667
31.0000		
Fetal cystic hygroma	0.0000	0.0000
0.0000		
Fetal cardiac disorders	16.3892	6.0000
26.0000	0.000	
Fetal arrhythmia	0.0000	0.0000
0.0000 Fetal cardiac arrest	0 0000	0 0000
0.0000	0.0000	0.0000
Fetal vascular mal-perfusion	0.0000	0.0000
0.0000	0.0000	0.0000
Fetal growth abnormalities	56.1703	20.6667
189.0000	0012700	
Fetal abnormal surveillance	25.2665	12.1538
58.6667		
Fetal placental thrombosis	0.0000	0.0000
0.0000		
Fetal death (stillbirth)	37.9790	21.0526
73.0000		
**********		
**************************************		
**** Month (Global) **** [('Abnormal uterine bleeding (menstrual irregularity)'	ALID   120/:	0 65)
('Miscarriage', 'M', 3338, 325), ('Fetal chromosomal a		
0), ('Fetal malformation', 'FM', 22, 2), ('Fetal cysti		
('Fetal cardiac disorders', 'FCD', 18, 2), ('Fetal arm		
('Fetal cardiac arrest', 'FCA', 20, 0), ('Fetal vascul		
12, 0), ('Fetal growth abnormalities', 'FGA', 188, 24)		
surveillance', 'FAS', 178, 45), ('Fetal placental thro		
('Fetal death (stillbirth)', 'FD', 402, 64)]		
cperiod= 18		
cperiod= 294		
*******		
ulu DATEC ulu		
*** RATES ***	120/2	2 5000
Abnormal uterine bleeding (menstrual irregularity) 0.2211	12843 713	3.5000 65
V • Z Z I I		

Miscarriage	3338	185.4444	325
1.1054 Fetal chromosomal abnormalities	10	0.5556	0
0.0000			
Fetal malformation	22	1.2222	2
0.0068			
Fetal cystic hygroma	8	0.4444	0
0.0000	4.0	4 0000	
Fetal cardiac disorders 0.0068	18	1.0000	2
Fetal arrhythmia	5	0.2778	0
0.0000		0.2770	
Fetal cardiac arrest	20	1.1111	0
0.0000			
Fetal vascular mal-perfusion 0.0000	12	0.6667	0
Fetal growth abnormalities	188	10.4444	24
0.0816			
Fetal abnormal surveillance	178	9.8889	45
0.1531			
Fetal placental thrombosis	6	0.3333	0
0.0000 Fetal death (stillbirth)	402	22.3333	64
0.2177	402	22.3333	04
*************			
*** P VALUES ***			
Abnormal uterine bleeding (menstrual irregularity)	0.000e+00		
Miscarriage	0.000e+00		
Fetal chromosomal abnormalities	5.781e-04		
Fetal malformation	1.855e-07		
Fetal cystic hygroma	2.378e-03		
Fetal cardiac disorders	2.618e-06		
Fetal arrhythmia	1.976e-02		
Fetal cardiac arrest	6.949e-07		
Fetal vascular mal-perfusion	1.473e-04		
Fetal growth abnormalities	0.000e+00		
Fetal abnormal surveillance	0.000e+00		
Fetal placental thrombosis	9.631e-03		
Fetal death (stillbirth)	0.000e+00		
*******			
*** RELATIVE RATES ***			
Abnormal uterine bleeding (menstrual irregularity)	4256.614	2 1589.12	250
12893.0000			
Miscarriage	177.145	2 114.41	L38
283.5000			
Fetal chromosomal abnormalities	0.000	0.00	000
0.0000	24 222	E 10 01	0.00
Fetal malformation 32.0000	21.326	5 10.00	OUU
02.000			

Fetal cystic hygroma	0.0	0.0	000
0.0000	47 /	F20 0 0	0.00
Fetal cardiac disorders 27.0000	1/.4	539 8.0	000
Fetal arrhythmia	0.0	000 0.0	000
0.0000			
Fetal cardiac arrest	0.0	000 0.0	000
0.0000			
Fetal vascular mal-perfusion	0.0	0.0	000
0.0000			
Fetal growth abnormalities	126.2	765 42.0	000
210.0000 Fetal abnormal surveillance	92.6	192 26.8	E 7 1
193.0000	02.0	192 20.0	3 / I
Fetal placental thrombosis	0 0	000 0.0	000
0.0000	0.0	0.0	000
Fetal death (stillbirth)	135.3	308 48.2	500
412.0000	20010		
******			
******			
***** People (Global) *****			
[('Abnormal uterine bleeding (menstrual irregularity)'	, 'AUB',	12843, 65),	
('Miscarriage', 'M', 3338, 325), ('Fetal chromosomal a	bnormalit	ies', 'FCM'	, 10,
0), ('Fetal malformation', 'FM', 22, 2), ('Fetal cysti	c hygroma	', 'FCM', 8	, 0),
('Fetal cardiac disorders', 'FCD', 18, 2), ('Fetal arr			
('Fetal cardiac arrest', 'FCA', 20, 0), ('Fetal vascul	ar mal-pe	rfusion', '	FVMP',
12, 0), ('Fetal growth abnormalities', 'FGA', 188, 24)	, ('Fetal	abnormal	
surveillance', 'FAS', 178, 45), ('Fetal placental thro	mbosis',	'FPT', 6, 0	),
('Fetal death (stillbirth)', 'FD', 402, 64)]			
cperiod= 5.23			
cperiod= 9.23			
************			
*** RATES ***			
Abnormal uterine bleeding (menstrual irregularity)	12843	2455.6405	65
7.0423			
Miscarriage	3338	638.2409	
35.2113			325
Fetal chromosomal abnormalities			325
	10	1.9120	325
0.0000	10	1.9120	
0.0000 Fetal malformation	10	1.9120 4.2065	
			0
Fetal malformation			0
Fetal malformation 0.2167	22	4.2065	0
Fetal malformation 0.2167 Fetal cystic hygroma	22	4.2065	0
Fetal malformation 0.2167 Fetal cystic hygroma 0.0000	22	4.2065 1.5296	0 2
Fetal malformation 0.2167 Fetal cystic hygroma 0.0000 Fetal cardiac disorders	22	4.2065 1.5296	0 2
Fetal malformation 0.2167  Fetal cystic hygroma 0.0000  Fetal cardiac disorders 0.2167  Fetal arrhythmia 0.0000	22 8 18	4.2065 1.5296 3.4417	0 2 0 2
Fetal malformation 0.2167  Fetal cystic hygroma 0.0000  Fetal cardiac disorders 0.2167  Fetal arrhythmia 0.0000  Fetal cardiac arrest	22 8 18	4.2065 1.5296 3.4417	0 2 0 2
Fetal malformation 0.2167  Fetal cystic hygroma 0.0000  Fetal cardiac disorders 0.2167  Fetal arrhythmia 0.0000	22 8 18 5	4.2065 1.5296 3.4417 0.9560	0 2 0

Fetal vascular mal-perfusion	12	2.2945	0
0.0000			
Fetal growth abnormalities	188	35.9465	24
2.6002 Fetal abnormal surveillance	170	2/ 02//	/. E
4.8754	178	34.0344	45
Fetal placental thrombosis	6	1.1472	0
0.0000	Ŭ	1.1.7	
Fetal death (stillbirth)	402	76.8642	64
6.9339			
******			
*** P VALUES ***			
Abnormal uterine bleeding (menstrual irregularity)	0.000e+00		
Miscarriage	0.000e+00		
Fetal chromosomal abnormalities Fetal malformation	5.781e-04		
	2.096e-06		
Fetal cystic hygroma Fetal cardiac disorders	2.378e-03 2.707e-05		
Fetal arrhythmia	1.976e-02		
Fetal cardiac arrest	6.949e-07		
Fetal vascular mal-perfusion	1.473e-04		
Fetal growth abnormalities	0.000e+00		
Fetal abnormal surveillance	0.000e+00		
Fetal placental thrombosis	9.631e-03		
Fetal death (stillbirth)	0.000e+00		
***********			
*** RELATIVE RATES ***			
Abnormal uterine bleeding (menstrual irregularity)	358.6413	261.0816	
506.7602			
Miscarriage	18.2268	3 15.7302	
21.1975			
Fetal chromosomal abnormalities	0.0000	0.0000	
0.0000	46.0506		
Fetal malformation	16.2592	5.0000	
30.0000 Fetal cystic hygroma	0.0000	0 0000	
0.0000	0.0000	0.0000	
Fetal cardiac disorders	13.2949	4.0000	
25.0000	13.277	7.0000	
Fetal arrhythmia	0.0000	0.0000	
0.0000			
Fetal cardiac arrest	0.0000	0.0000	
0.0000			
Fetal vascular mal-perfusion	0.0000	0.0000	
0.0000			
Fetal growth abnormalities	15.0360	8.6000	
27.6250			
Fetal abnormal surveillance	7.2770	4.7895	
11.2667			

Fetal placental thrombosis	0.0000	0.0000
0.0000		
Fetal death (stillbirth)	11.4116	8.1364
16.2917		
*******		

### **Extra**

![Abnormal uterine bleeding (menstrual irregularity)-Dose (Global)

