# Adverse Events Reported Following COVID-19 Vaccinations

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There has been a dramatic increase in the number of reports submitted to the US Vaccine Adverse Events Reporting System (VAERS) following the rollout of COVID-19 vaccines. For example, as of Aug. 6, 2021, reports of serious events and deaths following COVID-19 vaccines represented 39% of serious events and 51% of deaths ever reported to VAERS since 1990.<sup>2</sup> In this report, I present data and analysis to respond to two questions about this increase:

- 1. Is the increase in reports due to the increase in the number of vaccinations?
- Is the increase in reports due to what public health officials refer to as "stimulated reporting," meaning that people are reporting more due to increased awareness of the existence of VAERS and/or increased fear surrounding the COVID-19 vaccines due to media exposure of adverse events, awareness of the reporting system, mobilization by vaccine critics, etc.

### IS THE INCREASE IN REPORTS DUE TO AN INCREASED NUMBER OF VACCINATIONS?

Figure 1 below shows the number of reports, serious events, and deaths reported to VAERS, comparing reports for all other vaccines submitted from 2010-2020 to reports for COVID-19 vaccines. Panels a, c, and d show totals and panels e, f, and g show the rate per million vaccine doses.<sup>3</sup> The number of all reports per million vaccination doses is 9 times the annual average from 2010-2020, serious reports are 17 times the average, and deaths are 42 times the average. The average reporting rate for all three types of reports per million doses are about 31% lower than unadjusted figures, suggesting that about 31% of the increase has been due to the increase in the number of vaccinations. Therefore, we can conclude that the number of vaccinations does not explain most of the increase in reporting to VAERS following COVID-19 vaccinations.<sup>4</sup>

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<sup>&</sup>lt;sup>2</sup> VAERS reports analyzed here include \*only\* reports from U.S. states and D.C.

<sup>&</sup>lt;sup>3</sup> Methodological notes for all tables and figures are in the appendix.

<sup>&</sup>lt;sup>4</sup> Note this comparison is based on reports for COVID-19 vaccines appearing in VAERS as of Aug. 6 so it does not yet include adverse event reports yet to be submitted.



# Figure 1. Reports to the U.S. Vaccine Adverse Events Reporting System (VAERS) (for Non-Covid-19 Vaccines 2010-2020 and for COVID-19 Vaccines)

#### IS THE INCREASE DUE "STIMULATED REPORTING"?

The CDC uses VAERS as a way of detecting potential safety signal with vaccines. If they detect a signal, they can follow up with more appropriate data and methods to investigate its connection to the vaccine. As described in a paper written by senior researchers at the CDC, the main way they detect safety signals using VAERS is to compare "the proportion of reports involving a specific adverse event and a specific vaccine can be compared to the proportion of reports involving the same adverse event and other vaccines" (Shimabukuro et al. 2015:4401). The authors further note that such an analysis "also includes evaluation of reporting rates of adverse events in the context of vaccine doses distributed for use in the U.S. marketplace" (Ibid.:4401) This is the logic behind the statistical methods the CDC uses to determine if an increase in adverse events is due to stimulated reporting.

A paper by researchers at the CDC (Velozzi et al. 2010) investigated stimulated reporting in the context of the H1N1 Swine Flu vaccine introduced in 2009, following which there was an increase in reporting to VAERS that was 2 to 3 times greater than for seasonal influenza vaccines per million vaccinations. However, they concluded that this was due to stimulated reporting since the overall proportion of adverse events reported in different categories for the H1N1 vaccine was—for the most part—similar to the proportion reported for seasonal influenza vaccines.

I adopted the approach described in Shimabukuro et al. (2015) and used by Velozzi et al. (2010) to compare reporting rates for categories of adverse events between COVID-19 vaccines and seasonal influenza vaccines. I selected several categories of adverse events taken from the CDC's "VAERS Standard Operating Procedures" <u>internal planning document</u> dated January 29, 2021. That document outlines the CDC's plans to continuously monitor VAERS for safety signals. The adverse events from that document included in this report are: serious events, deaths, Guillan-Barré Syndrome (GBS), coagulopathy, and acute myocardial infarction.<sup>5</sup> Serious adverse events include events that involved at least one of the following: death; hospitalization; life-threatening illness; "permanent disability" (defined as a persistent or significant incapacity or substantial disruption of ability to function normally); or a congenital anomaly/birth defect. I also included all adverse events reported and all reports received. Adverse events are not the same as reports. Reports refers to reports

<sup>&</sup>lt;sup>5</sup> Reports to VAERS are coded according to the Medical Dictionary for Regulatory Activities (MedDRA). Each specific code is called a "preferred term" (PT). In the CDC's on-line system (<u>WONDER</u>) for analyzing VAERS data, "symptoms" correspond to preferred terms. The "coagulopathy" category created by the CDC includes a set of 26 preferred terms for thromboembolic events (although the category does not include coagulopathy PT. The full list of PT's for GBS, coagulopathy and acute myocardial infarctions can be found in Table 3 of the CDC's SOP document.

submitted by individuals to VAERS, whereas events refer to all of the adverse event codes contained in those reports. For COVID-19 vaccines there is an average of 4.5 events per report and 3.8 per report for influenza vaccines over this period.

#### Comparison of adverse event reports per 100,00 vaccination doses: COVID-19 vs. Flu

The tables below respond to the second question regarding stimulated reporting. Table 1 shows the reporting rate for different adverse events per million doses of vaccine administered, comparing reports for COVID-19 vaccines to the total number of reports for flu vaccines from July-June in five recent influenza seasons: 2015/16, 2016/17, 2017/18, 2018/19 and 2019/20 influenza seasons. (The 2020-21 flu season was excluded to avoid conflation with the SARS Cov-2 pandemic and vaccination drive). The comparison is made for 4 different age groups and for the total of those age groups. Note that all reports with an indication of SARS-CoV-2 infection or COVID-19 were not included in counts for COVID-19 vaccines. (Further methodological details can be found in the appendix.)

## Table 1. COVID-19 vs Flu Vaccines: Adverse Event Reporting Rate per Million Vaccine Doses

	All Events		Α	ll Repo	rts	Seri	ous Rep	oorts		Deaths	;		GBS		Coa	agulopa	thy	Муоса	rdial Inf	arction	
	COVID	Flu		COVID	Flu		COVID	Flu		COVID	Flu		COVID	Flu		COVID	Flu		COVID	Flu	
Ages	Rate	Rate	Ratio	Rate	Rate	Ratio	Rate	Rate	Ratio	Rate	Rate	Ratio	Rate	Rate	Ratio	Rate	Rate	Ratio	Rate	Rate	Ratio
10-17	2535	122	21	831	33	25	47	1.4	34	0.8	0.02	32	0.6	0.08	7	2.65	0.04	74	0.27	0	n.e.
18-49	5575	192	29	1210	47	26	57	2.3	25	2.5	0.04	64	1.0	0.39	3	12.80	0.06	226	1.76	0.004	403
50-64	5101	239	21	1103	61	18	80	3.1	26	7.8	0.09	85	1.7	0.66	3	18.35	0.08	239	3.38	0.028	121
65+	3856	306	13	883	83	11	123	4.2	30	29.5	0.30	98	1.5	0.55	3	21.40	0.06	370	5.32	0.060	88
TOTAL	4837	224	22	1076	58	19	80	2.8	28	10.9	0.12	91	1.3	0.46	3	15.95	0.06	276	3.04	0.024	126

Notes: The COVID:Flu ratio is the ratio of COVID-19 reporting rate to the flu reporting rate (per million vaccines). All differences between COVID-19 and flu reporting rates are statistically significant. "n.e." is not-estimable because dividing by zero is undefined. Flu reporting rates represent the total reports to VAERS across the 2015/16 to 2019/20 flu seasons for each age group. Covid-19 reporting rates include all reports to VAERS for COVID-19 vaccines for each age group through Aug. 6, 2021. Vaccine doses estimated using data from the CDC and the US Census Bureau. COVID-19 vaccination totals are from Aug. 5, 2021. All reports with SARS-COV-2 infection or COVID-19 are excluded from counts.

The first set of columns marked "All Events" shows the reporting rate for all adverse events reported to VAERS per million doses for COVID-19 and influenza vaccinations, as well as the ratio between these reporting rates. The other columns report the comparative reporting rates and ratios for all reports, serious reports, deaths, GBS, coagulopathy, and myocardial infarction.

The results indicate that, compared to influenza vaccines, the reporting rate per vaccine dose is much higher for all types of events and reports compared to number of

reports for influenza vaccines from 2015-2020.<sup>6</sup> If the increase was due to stimulated reporting, we would expect the difference between COVID-19 vaccines to be fairly similar across different types of events and age categories. But the table shows exactly the opposite: The overall COVID:Flu reporting ratio for all age groups for all reports is 19, for serious reports 28, for deaths 91, for GBS 3, for coagulopathy 276 and for myocardial infarctions it is 126. The rate varies significantly across ages as well. For example, the death reporting rate for 18-49 year olds is 64 while the reporting rate for 65 and up is 91. It is worth underscoring that among 10-17 year olds, there were zero myocardial infarctions reported for influenza vaccines from 2015-2020, whereas there have been 5 reported so far for that age group following COVID-19 vaccination.

Taken together, the greater rate of serious events, deaths, GBS, coagulopathy and myocardial infarction reported and the variation across age groups constitute a strong *prima facie* signal of disproportionately serious harm from COVID-19 vaccines.

#### Comparison of adverse events as percentage of reports: COVID-19 vs. Flu

Velozzi et al. (2010) examined the number of serious events and reports of GBS as a proportion of all reports to VAERS without taking into account number of vaccine doses distributed. Table 2 below reports a similar comparison for the adverse events examined in this paper. They show a "proportional reporting ratio" (PRR) that is based on the calculating the proportion of all reports (or events) that are for a specific type of report (or event). For example, the PRR for deaths takes the proportion of all reports for COVID-19 vaccines that included death as an outcome (.01012) divided by the proportion of deaths out of all flu reports (.00205). The CDC's SOP document states that a PRR greater than 2 with a chi-square statistic greater than 4 and with more than 3 events constitutes a safety signal (see page 16). (Further methodological details can be found in the appendix.)

The results reported in Table 2 provide another way of examining whether the overall pattern of reporting for COVID-19 vaccines is different from the pattern of reporting for influenza vaccines. Although they paint a slightly different picture than the tables of reports per vaccine dose, they still provide strong indication that the increase in reporting is not simply due to stimulated reporting but instead constitutes a very clear safety signal.

<sup>&</sup>lt;sup>6</sup> All differences in the reporting rate per vaccine dose between COVID-19 and influenza vaccines are statistically significant using a 2-sample, 2-tailed test of proportion. Although a ratio could not be calculated for years when no deaths were reported for the flu vaccine for a given age group (since dividing by zero is undefined), tests of statistical significance could still be calculated.

	REPORTS		SER	IOUS EVE	NTS		DEATHS			GBS		COA	GULOPA	ТНҮ		M.I.	
-			Proprtion			Proportion			Proportion			Proportion			Proportion		
Ages	COVID	Flu	COVID	Flu	PRR	COVID	Flu	PRR	COVID	Flu	PRR	COVID	Flu	PRR	COVID	Flu	PRR
Age 10-17	15,378	2,717	0.057	0.042	1.35*	0.001	0.001	1.24	0.001	0.003	0.28*	0.003	0.001	2.89*	0.0003	0	n.e.
Age 18-49	178,687	10,844	0.047	0.048	0.99	0.002	0.001	2.52*	0.001	0.008	0.10*	0.011	0.001	8.82*	0.001	0.0001	15.78*
Age 50-64	98,397	8,743	0.073	0.050	1.45*	0.007	0.001	4.74*	0.002	0.011	0.14*	0.017	0.001	13.22*	0.003	0.0005	6.71*
Age 65+	80,855	13,733	0.140	0.051	2.76*	0.033	0.004	9.16*	0.002	0.007	0.26*	0.024	0.001	36.97*	0.006	0.0007	8.27*
Age 10+	373,317	36,037	0.074	0.049	1.52*	0.010	0.002	4.93*	0.001	0.008	0.15*	0.015	0.001	14.84*	0.003	0.0004	6.78*

Note: The PRR is the ratio of the proportion of a specific event type out of all reports for COVID-19 divided by its proportion out of all reports for the combined 2015-2019 flu seasons. PRR's in bold consitute a safety signal according CDC criteria. A \* inidicates a tatistically significant difference between the proportion of COVID-19 and flu reports for each age group and event type. Numbers for flu reports to to VAERS across the 2015/16-2019/20 flu seasons for each age group. Covid-19 reporting rates include all reports to VAERS for COVID-19 vaccines for each age group as of Aug. 6, 2021.

The results reported in Table 2 provide another way of examining whether the overall pattern of reporting for COVID-19 vaccines is different from the pattern of reporting for influenza vaccines. All of the PRR's in bold in Table 2 exceed the CDC's threshold for signal detection. This includes all PRR's for death except for the youngest age group, all PRR's for coagulopathy and all PRR's for myocardial infarction, except for the youngest age group because there were no myocardial infarctions reported for influenza vaccines.

The only event outcome for which the COVID-Flu reporting ratio is less than one and statistically significant is for GBS. What this means is that a greater proportion of reports for flu are for GBS compared to COVID-19 vaccines. However, as shown in Table 1, the GBS reporting rate per million doses for flu vaccines is three times the reporting rate for COVID-19. What this means is that, per vaccine dose you are three times more likely to report GBS following a COVID-19 vaccination than an influenza vaccination (Table 1). However, because the reporting rate for other adverse events is so much higher for COVID-19 vaccines than for flu, the overall proportion of reports for GBS out of all reports is lower for COVID-19 than for flu (Table 2).

With regards to the question of stimulated reporting, the pattern of reporting as measured by the PRR is different across different types of events and different ages. If the increase was simply due to stimulate reporting, we would expect similar proportions of reports from COVID-19 and influenza vaccines across different type of events and ages. For example, the reporting ratio for deaths is nearly 5, for GBS it is 0.15, for coagulopathy it is 15 and for myocardial infarction nearly 7. Furthermore, there is substantial variation across age groups. For example, while the COVID:Flu ratio for deaths for the 18-49 age group is 2.5, for 50-64 years olds it is 4.7, and 9.2 for 65 plus.

#### CONCLUSION

There has been a dramatic increase in the number of serious adverse events and deaths reported to VAERS. This report has provided strong evidence that the increase is not due mainly to an increase in the number of vaccinations given, nor to stimulated reporting. After taking the number of vaccine doses into account, the reporting rate for deaths following COVID-19 vaccines is 30 times higher than the reporting rate for all vaccines combined from 2010-2020. Furthermore, the reporting rate for serious events and deaths per vaccine dose is significantly higher for COVID-19 vaccines than for influenza vaccines since 2015, reaching as high as 98 times the reporting rate of deaths and 370 times the reporting rate for coagulopathy for ages 65 and older. If the increase in the reporting rate was due to stimulated reporting, we would expect to see a similar reporting ratio across different adverse event types and age groups. But there are substantial differences, and these differences are evident in all tables for all age groups.

Of course it is possible, even likely, that some of the difference between COVID-19 and influenza vaccination reporting is due to stimulated reporting. In their 2010 study on stimulated reporting for the H1N1 vaccination, Velozzi et al. (2010) found that per vaccine dose, reports for H1N1 were about three times higher than for other influenza vaccines. The average reporting rate per million COVID-19 vaccinations for all events and reports is 20 times the average reporting rate for influenza. One could take that as an upper-bound for the increase in reporting due to stimulated reporting. But even if stimulated reporting accounts for a difference of 20 fold, the reporting rate for serious events, deaths coagulopathy and myocardial infarction are still well above that number, and so the overall conclusions remain unchanged.

Taken together, the greater rate of serious events and even greater rate of deaths, coagulopathy and myocardial infarction reported following COVID-19 vaccines and the variation across age groups constitute a robust signal of disproportionately serious harms from COVID-19 vaccines that cannot be attributed to stimulated reporting.

#### **METHODOLOGICAL APPENDIX**

All data used to prepare this report can be found in a zipped folder at this URL: https://tinyurl.com/AEReportDataFiles

#### Population Estimates

- Data on the population in each age group and year was calculated from the US Census Bureau's American Community Survey in <u>Census Table S0101</u> based on 1year estimates for each year.
  - Due to incompatibility across all the datasets in age categories—in particular the population data from the census—I was not able to restrict the teen population categories to ages 12-17, which is the youngest age group for which COVID-19 vaccinations are currently recommended. Therefore, the adverse events data, population and flu vaccine doses include 10-17 year-olds, but the COVID-19 vaccination doses represents 12-17 year-olds. Note that some VAERS data include reports for 10-11 year olds, as vaccinations are given mistakenly to younger children and also given to children in certain high risk groups. As of August 6, there were 450 adverse events for 10-11 year olds for COVID-19, 1 serious event and no additional deaths or cases of GBS, coagulopathy or myocardial infarction. So in practice the reporting rate for COVID-19 vaccines is for 12-17 year olds although it is labeled 10-17.
  - Adverse event reports for flu include reports during each flu season from July 1 to June 30 in the following year. These reports were compared to vaccination totals calculated using population estimates from the calendar year at the beginning of the flu season (so for example, the calculation of adverse events per vaccination for the 2015/16 flu season are based on vaccination data that is calculate based on the 2015 population. In any event, the vast majority of flu inoculations occur from August December.
  - The census provides an estimate of the proportion of the total population in each age group. I multiplied the total population by these percentages to calculate estimates of the total population in each age group. For 2017-2019, the census also provides totals for different age categories, but for 2015 and 2016, they only provide the proportion. Multiplying the proportion by the total population does not yield the same number as the population size estimates in the table for 2017-2019, so I used the same method of multiplying the proportion by the total population also for 2017-2019 for consistency. Using the census's population size totals for each age group for those years would produce slightly different results. Below is a table of population estimates by year and age used in the analysis.

POPULATION BY AGE GROUP									
YEAR	10-17 years	18 to 49	50-64	65+					
2015	33,106,139	136,924,418	62,998,089	47,891,404					
2016	33,282,134	137,006,066	63,332,993	49,115,382					
2017	33,874,795	138,104,931	63,515,240	50,812,192					
2018	33,698,246	138,064,659	63,143,316	52,346,790					
2019	33,808,671	138,188,839	62,693,749	54,159,521					

#### Vaccine Doses

 Covid-19 vaccination doses by age group were taken from USA Facts, which receives its data directly from the CDC (according to e-mail correspondence with a company representative). I use the figures from USA Facts, because CDC does not provide information to the public on COVID-19 vaccinations broken down by as many age categories. USA Facts does not provide total dosage numbers by age. Instead they provide figures for fully vaccinated and for fully or partially vaccinated. I calculated the total number of doses by subtracting the number of fully vaccinated from the partially or fully to estimate the number that had received one dose. I multiplied the total number of fully vaccinated by two and added that number to the estimated number of people who had received one dose. Comparing the estimated number of doses from USA Facts to data directly available from the CDC for comparable age groups, the USA Facts numbers were about 5% lower on average. So I inflated estimates of COVID-19 vaccine doses administered for different age groups by 5% in order to provide more conservative estimates when calculating reporting rates per million doses. The number of doses is so high relative to the number of adverse events that changes of many million in any direction have a negligible effect on the outcome and interpretation of results. (For example, subtracting 10 million vaccine doses when calculating the reporting rate for serious events raises the estimated COVID-19 rate for all age groups from 80.2 to 82.5 and for flu from 2.85 to 2.89.) The number of COVID-19 vaccine doses for each age group used in this report are given in the table below:

AGE	DOSES
Age 12-17	18,513,063
Age 18-49	147,661,016
Age 50-64	89,232,851
Age 65 +	91,542,644
TOTAL	346,949,574

- Non-Covid Vaccination doses for Figure 1 were calculated as follows:
  - For non-influenza vaccinations, I estimated the total number of immunizations administered to children six years and younger in the US. To do this, I first gathered information on the number of live births in every year from 2005-2020 from the CDC's National Center for Health Statistics. I then adjusted the number of births downward using the annual infant mortality rate in the US from the World Bank's World Development Indicators.<sup>7</sup> From the CDC's childhood vaccination schedule, I took the number of vaccine doses recommended in the first, second and 4-6<sup>th</sup> years of life. Those numbers are 14, 9 and 4, respectively. For each year, I multiplied the number of recommended vaccines in the first year by the adjusted birth cohort size for that year; I multiplied the number of recommended vaccines in the second year by the adjusted birth cohort size for the previous year; and I multiplied the number of recommended vaccines in 4-6 years by the cohort size from five years earlier. I then summed these together to arrive at an estimated number of vaccine doses. However, that number assumes a 100% coverage rate, which is higher than the actual coverage rate. The CDC has estimated the national coverage rate for childhood vaccines at greater than or equal to 90% so I adjusted the estimated number of vaccines downwards by multiplying it by 0.9. The numbers are so large relative to the number of adverse events that an error of several million in either direction makes a negligible difference.
  - For influenza vaccinations, flu coverage rates for adults and for children greater than 6 months old and younger than nineteen were taken from the CDC's Flu Vax View for the 2010/11 to 2018/19 seasons and from the CDC's Influenza Season Summary for the 2019/20 and 2020/21 seasons. I multiplied coverage rates by the total population of adults and children for each year from the census bureau (see data sources for population above). Since the coverage rates only apply to children greater than six months old, I subtracted the estimated number of 6-month olds using the adjusted birth cohort figures discussed above (*viz.*, I multiplied the adjusted number of live births by 0.5 and subtracted that from the total childhood population for that year).
  - The estimated annual number of non-covid vaccination doses used in Figure 1 are shown in the table below. Note that the number of total non-covid vaccinations is likely to be significantly larger, because the numbers below do not include routine (and in some states mandatory) teenage vaccinations

<sup>&</sup>lt;sup>7</sup> I did not adjust the numbers for subsequent child mortality after one year of life.

(such as DTaP boosters for middle school students and HPV vaccinations), varicella vaccinations for adults and children, as well as all other noninfluenza vaccines received by adults, for example when travelling to foreign countries. Also, due to the adjustment for infant mortality, the figures below assume that children who died before their first birthday received zero vaccinations. For these reasons, the estimates of reports per million doses of non-COVID vaccines is almost certainly lower than those shown in Figure 1, which makes the comparison to COVID-19 vaccines very conservative.

Estimated Number of Non-COVID											
Vaccinations, 2010-2020											
Adjusted Childhood											
	Childhood	Total Flu	Influenza								
Year	Doses	Vaccinations	(Estimated)								
2010	105,285,924	129,752,184	235,038,108								
2011	104,001,160	129,265,349	233,266,509								
2012	103,787,907	140,302,423	244,090,331								
2013	103,256,028	144,556,819	247,812,847								
2014	103,531,856	149,409,610	252,941,467								
2015	103,418,628	145,812,887	249,231,515								
2016	102,734,374	150,042,567	252,776,940								
2017	101,211,280	135,049,641	236,260,921								
2018	99,421,270	159,717,161	259,138,431								
2019	98,503,938	168,915,417	267,419,355								
2020	74,777,646	183,596,487	258,374,132								

Influenza Vaccination Doses for Tables 1 and 2 were calculated as follows: The coverage rate for each age group was multiplied by the population in that age group in that year. Data on proportion in each age group vaccinated against influenza in each year comes from <u>CDC's FluVaxView data</u> compiled <u>here</u>. For population figures see section above on population. The table below shows estimates of the number of influenza vaccinations administered to each age group in each year:

NUMBER OF FLU VACCINATIONS IN EACH AGE GROUP										
FLU SEASON	10-17	18-49	50-64	65+	TOTAL					
2015-16	15,493,673	44,774,285	27,467,167	30,363,150	118,098,275					
2016-17	16,241,681	46,142,609	28,753,179	32,072,345	123,209,814					
2017-18	16,056,653	37,062,608	25,215,550	30,284,066	108,618,877					
2018-19	17,590,485	48,184,566	29,866,788	35,648,164	131,290,003					
2019-20	18,020,022	52,938,470	31,723,037	37,803,346	140,484,875					
TOTAL	83,402,513	229,102,538	143,025,721	166,171,071	621,701,843					

Note that the CDC only provides flu coverage estimates for 5-12 and 13-17 year olds. The number of vaccinations for 10-17 year olds was calculated by multiplying the proportion of 13-17 year olds vaccinated by the number of 10-17 year olds in the population. This assumes a similar rate of vaccination for 10-12 year olds as 13-17. However, the rate of vaccination for 5-12 year olds is 20-30% higher than 13-17 year olds, and so the rate for 10-12 year olds is likely to be somewhat higher than for 13-17 year olds. The estimate was calculated using the lower coverage rate for 13-17 year olds in order to err on the side that would tend to provide a larger estimate of influenza vaccines administered in order to make a more conservative comparison with COVID-19 vaccines; therefore the true rate of AE's per flu vaccination is likely slightly higher than the estimate here.

#### Adverse Events

- Total adverse events for COVID-19 were calculated as follows: I used the CDC's online database analysis tool, <u>WONDER</u> to extract data from the VAERS database that was updated on Aug. 13, 2021 and included all reports by age from U.S. states and D.C. that were submitted to VAERS as of Aug. 6. Reports from foreign countries, US territories and unknown origin were excluded. This was done to ensure that only AE's reported from the US were used when calculating rates based on vaccination coverage in the US. I extracted reports on the following adverse events, stratified by age: all events, all reports, reports marked as serious, deaths, GBS, coagulopathy, and myocardial infarction. For the last three categories, I limited the search to reports that had at least one of the preferred terms listed for each outcome, as detailed in the CDC's <u>Standard Operating Procedures</u> internal planning document, Table 3. [Reports to VAERS are coded according to the Medical Dictionary for Regulatory Activities (MedDRA). Each specific code is called a "preferred term" (PT)]. Reports where age was unknown were not included.
  - GBS, coagulopathy and myocardial infarction are each indicated by more than one PT according to the SOP document. For each of these outcomes, the number of total events is greater than the total number of reports with at least one of the corresponding PT's. This is because some reports were coded for more than one PT for each corresponding type of event. For example, there are multiple PTs corresponding to coagulopathy coded for some reports. Adding up all the different PT's and treating them as separate events would produce a significantly higher estimate of the number of these types of events. The method adopted here of only counting reports with at least one of the corresponding PT's is a more conservative approach.

- The category "coagulopathy" includes the following adverse event PT's: cavernous sinus thrombosis, cerebral venous thrombosis, deep vein thrombosis, disseminated intravascular coagulation, embolism venous, hepatic vein thrombosis, immune thrombocytopenia, intracranial venous sinus thrombosis, mesenteric vein thrombosis, portal vein thrombosis, pulmonary embolism, pulmonary thrombosis, pulmonary venous thrombosis, subclavian vein thrombosis, thrombocytopenia, thrombocytopenic purpura, thrombosis, thrombotic thrombocytopenic purpura, transverse sinus thrombosis, vena cava embolism, vena cava thrombosis, and venous thrombosis.
- To avoid conflating adverse events following vaccination with adverse events as a result of SARS-CoV-2 infection, I produced counts by age group for all events and reports where the report also contained at least one of 13 PT's for SARS-CoV-2 infection or COVID-19.<sup>8</sup> (These were the only PT's that might indicate an infection that I was able to identify.) These counts were subtracted from the total counts for each age group. The percentage of events/reports that included a COVID-19 PT ranged from 0.3% for all events for 10-17 year olds to 15.5% for deaths among 50-64 year olds. Although one cannot know whether the adverse event was due to infection, removing them from the counts provides a more conservative estimate of adverse events, which is warranted in light of the ongoing pandemic. It is also possible that there were additional reports from people with SARS-CoV-2 infections where this was not known, mentioned or coded.
- WONDER only displays adverse event counts for ages 6-17 year-olds, and it is not possible to specify specific age ranges. I used another <u>VAERS data</u> <u>analysis tool</u> at MedAlerts.org to produce AE counts for 10-17 year olds. I compared the output for other age ranges from MedAlerts to WONDER and they were identical, including results for 6-17 year olds. Additionally, it is impossible in WONDER to produce counts of total events where the report that the event appears in also had one of the COVID-19 PT's (the same is not true of reports containing different types of events or outcomes). Therefore, I also used MedAlerts to produce counts of all events that were taken from reports with a COVID-19 PT, in order to subtract out these events from the total number of events produced with WONDER. Here again I cross-validated

<sup>&</sup>lt;sup>8</sup> These PT's are: asymptomatic covid-19, corona virus infection, coronavirus infection, coronavirus test positive, covid-19, covid-19 pneumonia, covid-19 treatment, post-acute covid-19 syndrome, suspected covid-19, sars-cov-2 sepsis, sars-cov-2 test false negative, sars-cov-2 test positive, and vaccine breakthrough infection.

the count of different types of reports with COVID-19 PT's between WONDER and MedAlerts to ensure that they produced the same results.

- Adverse events for influenza vaccinations were calculated as follows: I used CDC's WONDER to extract reports from VAERS for all 11 seasonal flu vaccines listed in WONDER<sup>9</sup> across 5 different flu seasons: 2015/16, 2016/18, 2017/18, 2018/19 and 2019/20. The 2020/21 flu season was not included in the analysis due to avoid confounding with the pandemic and its potential effects on flu vaccine coverage and VAERS reporting. However, the total number of events submitted for the 2020/21 flu season appears in line with the other years, although there were fewer serious events reported, which means that including 2020/21 would only make flu vaccines appear safer in comparison to COVID-19 vaccine.
  - As with COVID-19 vaccines, reports not from U.S. states and D.C. were excluded as were reports where age was unknown.
  - Events for each flu season were included in the analysis if they were received by VAERS from July 1 through June 30 of the following year and if the vaccination date was listed as occurring in that same period. Note that the inclusion criteria used here are wider than those used by Velozzi et al. (2010), because they restricted their comparison to vaccinations received from July 1 through January 30 and reports received from July 1 through March 15. There were 909 reports received during this period with vaccination dates prior to the July 1, 2015 and 2,050 reports received during the period included in the analysis where the vaccination date was unknown (of which 137 were serious and 21 included deaths. Reports with unknown vaccination were not included to avoid including reports from previous flu seasons. In addition, the majority of serious reports (n=95) did not include information on age, so they would not have been included in the analysis. Including the remaining reports in the analysis would make a negligible difference due to the very large number of inoculations, which renders small differences in reports virtually meaningless.

<sup>&</sup>lt;sup>9</sup> H1N1 vaccines were not included, however there were only H1n1 3 reports during the period under study from H1N1 vaccines that had also been administered during the years included here. The influenza vaccine types included in the analysis are listed in WONDER as follows: influenza virus vaccine, no brand name (FLUX); influenza virus vaccine, quadrivalent (injected) (FLU4); influenza virus vaccine, quadrivalent (injected) (FLU4); influenza virus vaccine, quadrivalent (intranasal spray) (FLUN4); influenza virus vaccine, quadrivalent, adjuvant (injected) (FLUA4); influenza virus vaccine, quadrivalent, recombinant (injected) (FLUR4); influenza virus vaccine, trivalent (injected) (FLU3); influenza virus vaccine, trivalent (injected) (FLU3); influenza virus vaccine, trivalent (injected) (FLUA3); influenza virus vaccine, trivalent, adjuvant (injected) (FLUA3); influenza virus vaccine, trivalent) (FLUC3); influenza virus vaccine, trivalent, recombinant (injected) (FLUR3).