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An analysis of vaccinated populations: Mortality rates and adverse event episodes

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Abstract: The purpose of the present study is to determine the mortality rate for COVID-19 vaccines in the United States, using the Vaccine Adverse Event Reporting System (VAERS) as the primary data source. In addition, regression analysis was used to estimate the factors that may affect the reported number of days from vaccination to onset of symptoms due to vaccine complications and the reported number of days from vaccination until death. It was estimated that the crude mortality rate for all COVID-19 vaccines was 6.3 deaths per 100,000 vaccinated persons for the period December 14, 2020 to December 31, 2023. If one examines only those deaths that occurred with 60 days of vaccination, the crude mortality rate was 3.24 deaths per 100,000 persons for the period in question. This mortality rate is substantially lower than the crude mortality rate for non-COVID-19 vaccines estimated in McCarthy et al. (2013) which was 608 deaths per 100,000 persons. In addition, the mean number of days from vaccination to onset of symptoms and from vaccination to death increased dramatically once the COVID-19 vaccines became available. This includes the means for non-COVID vaccines as well.

Keywords: *COVID-19, Mortality rates, Statistics.*

1. Introduction

On January 9, 2020, the World Health Organization (WHO) announced the discovery of a novel coronavirus-related pneumonia (COVID-19) in Wuhan, China. Within weeks, the entire world was affected by this new pathogen. On January 21, 2020, the first confirmed case of COVID-19 was found in the United States. By February 2, 2020, global air travel restrictions were imposed. On March 11, 2020, WHO declared COVID-19 a pandemic.

Even before COVID-19 was declared a pandemic, governments and private pharmaceutical companies raced to create vaccines. In August of 2020, Russia announced it had fast-tracked the creation of a vaccine, named Sputnik V. Between April and July of 2020, Sinovac Biotech Ltd., a Chinese biotech company, launched clinical trials of an inactivated virus vaccine, Coronavac. Around the same time, clinical trials of two novel vaccines (made by Moderna and Pfizer-BioNTech) began in the United States. Those vaccines were based on decades-old technology, where messenger RNA (mRNA) would be used to deliver a message to immune cells to create their own version of a protein that looks like the proteins on the surface of the virus. This would allow vaccines to be created without the need to grow the virus in a laboratory. All that would be needed to develop the vaccine is the genetic code for the virus' proteins.

In December of 2020, the Food and Drug Administration (FDA) authorized two mRNA vaccines for emergency use. In February of 2021, a viral vector vaccine made by Johnson & Johnson Janssen was also authorized for emergency use. The Janssen vaccine delivers mRNA to immune cells inside an inactivated adenovirus, triggering the recipient immune cells to create proteins. As of April 15, 2022, nineteen vaccines were authorized for emergency use, and twelve were given full approval for use. Although the currently approved COVID-19 vaccines were deemed safe in clinical trials, adverse

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reactions such as fever, headache, fatigue, injection site pain, and nausea were reported as is typical with many vaccines. Cardiac arrest and death were also reported.

Even before the COVID-19 pandemic, vaccines were sometimes viewed suspiciously, especially with respect to their adverse side effects and their potential ineffectiveness. The alleged link between childhood vaccines and autism is probably the most noteworthy of these concerns. Although it is generally accepted that vaccines have saved millions of lives, there is still rather significant hesitancy to vaccines primarily due to anecdotal information regarding the safety of vaccines and the publication of studies in academic journals that note statistically significant relationships between vaccines and severe adverse events (Lamptey, 2021; Saeed, Al-Shahrabi, Alhaj, Alkokhardi, & Adrees, 2021).

Vaccine hesitancy was amplified during the COVID-19 pandemic, due primarily to the speed with which the mRNA vaccines were developed and the mandatory vaccination policies that were adopted by both public and private sector organizations. Many believed that COVID-19 vaccines were developed too quickly and could not be safe or effective due to the lack of lengthy clinical trials. In addition, many schools and employers required students and employees to get vaccinated, which many felt was unnecessary or potentially life-threatening, given the lack of clinical trials and significant safety and efficacy testing.

In order to address the concerns of the safety of COVID-19 vaccines, the purpose of the present study is to determine the mortality rate for COVID-19 vaccines in the United States using the Vaccine Adverse Event Reporting System (VAERS) as the primary data source. The estimated COVID-19 vaccine mortality rate will be compared to the mortality rate for non-COVID-19 vaccines, such as MMR, TDAP, and VARCEL. Finally, regression analysis will be used to estimate the factors that may affect the reported number of days from vaccination to onset of symptoms due to vaccine complications and the reported number of days from vaccination until death. A review of the relevant literature follows.

2. Literature Review

An early study regarding the mortality rates of non-COVID-19 vaccines was McCarthy et al. (2013). Using data obtained from the Vaccine Safety Datalink (VSD) for the years 2005-2008, the authors calculated mortality rates for a variety of vaccines. In addition, the study examined cause of death patterns and mortality rates by age, gender, and number of days following vaccination. The VSD is a collaborative project between the Centers for Disease Control and Prevention (CDC) and ten Managed Care Organizations (MCO) throughout the United States. The VSD collects vaccination and medical data on ten million people annually. The VSD mortality data are updated annually and report cause and date of death. For the period examined, 13 million people received at least one vaccine, with a total of 24.8 million vaccines administered between 2005-2008. During this period, there were 116,043 deaths due to vaccines that occurred within 60 days of the vaccination. For all observations, the mean number of days between vaccination and death was 269. The authors estimated the overall age-adjusted death rate to be 442.5 deaths per 100,000 persons for 2005-2008 (deaths within 60 days of vaccination). The crude rate was estimated to be 608 deaths per 100,000 persons. The authors also noted that mortality rates were highest in the oldest age group. This estimated mortality rate will be used as a comparison group for the present study.

Most of the studies examining side effects and mortality rates of COVID-19 vaccines were published in 2021, the first full year COVID-19 vaccines were first available. Most of this research did not discuss mortality rates (Cai et al., 2021; Ganesan et al., 2022; Menni et al., 2021; Riad et al., 2021; Saeed et al., 2021). One of the few studies that examined the mortality rates of COVID-19 vaccines was Lv, Yuan, Xiong, and Li (2021). Data for this study was obtained from the Vaccine Adverse Event Reporting System (VAERS) for the period December 14, 2020 to January 8, 2021. During this period, 6.7 million people were vaccinated, and 55 deaths were reported, indicating a COVID-19 vaccination mortality rate of 8.2 per million population. Regarding vaccinations in long term care facilities, 693,246 vaccines were administered, and 37 deaths were reported, indicating a mortality rate of 53.4 per million population.

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Another study that utilized the VAERS dataset is Day et al. (2023). This study examined data for the period December 14, 2020 to November 17, 2021. During this period, there were 9,201 deaths reported for all COVID-19 vaccines, which indicates a mortality rate of 43.6 per million persons vaccinated with at least one dose. The mean number of days from vaccination to death was eleven days. According to this study, the COVID-19 vaccine mortality rate is ten times lower than the expected all-cause death rate within seven days of vaccination and 36 times lower than the expected all-cause death rate within 42 days of vaccination.

Finally, Rosenblum et al. (2022) also used VAERS data. Their period of study was December 14, 2020 to June 14, 2021. During this period, 4,496 deaths due to COVID-19 vaccines were reported. The estimated mortality rate was 15 per million doses administered. All of the reviewed studies indicated that the COVID-19 vaccine mortality rates were much lower than the non-COVID-19 vaccine mortality rates estimated by McCarthy et al. (2013). Unfortunately, all prior studies only examined data from 2021, the first full year that COVID vaccines were available. To determine if the mortality rate for COVID-19 vaccines has increased since this initial period, the present study will examine VAERS data for a much longer period than examined by any previous study. In addition, the present study will also determine the mean number of days between vaccination and onset of adverse event symptoms and between vaccination and death. A discussion of the empirical technique employed in the present study follows.

3. Methods and Results

The present study expands on this prior research by examining VAERS data for the period January 1, 2018 to December 31, 2023. Mortality rates were estimated for COVID-19 vaccines, and the mean number of days from vaccination to onset of symptoms and from vaccination to death were estimated for both COVID-19 vaccines and non-COVID-19 vaccines. Finally, an ordinary least squares regression model was estimated to ascertain the determinants of the number of days from vaccination to death and from vaccination to onset of symptoms.

All data used in the present study were obtained from VAERS. VAERS is jointly managed by the CDC and the Food and Drug Administration (FDA). It is part of the vaccine safety system in the United States. VAERS accepts reports from anyone regarding adverse events after vaccination. It is important to note that VAERS is not designed to determine if a vaccine was a causal factor in an adverse event. While healthcare providers and vaccine manufacturers are required by law to report certain types of adverse events, private parties are not under any such obligation. Hence, the data may under-report the actual number of adverse events due to a vaccine. In addition, VAERS data cannot be used to determine if a vaccine was a contributing factor in causing the reported adverse event. This characteristic of the data may result in an over-reporting of the number of adverse events due to a vaccine. Therefore, the VAERS data may under-report or over-report the number of adverse events reported for a particular vaccine. Given the limitations of the data employed in the present study, care must be taken in interpreting the results reported in this study.

To simplify the analysis, reported deaths were the only adverse events examined in the present study. The reason for excluding other types of adverse events is because of the difficulty in categorizing non-fatal events and the potential inability of lay persons to accurately describe non-fatal adverse events. All questionable and erroneous observations were eliminated from the dataset. Examples of questionable data include responses that list a COVID-19 vaccination date prior to December 14, 2020, or the respondent lists the vaccination date as coming after the date of death. In addition, many observations were missing important data, such as date of vaccination, date of death, and sex. Observations with missing data were not excluded from the dataset.

During the period in question, there were 17,006 deaths due to the COVID-19 vaccines as reported to VAERS. Given that at least 270 million Americans had received at least one dose of a COVID-19 vaccine by December 31, 2023, the crude mortality rate was estimated to be 6.3 deaths per 100,000 vaccinated persons for the period December 14, 2020 to December 31, 2023. If one examines only those

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deaths that occurred within 60 days of vaccination, the crude mortality rate was 3.24 deaths per 100,000 persons for the period in question. This mortality rate is significantly lower than the mortality rate for non-COVID-19 vaccines estimated in McCarthy et al. (2013) which was 608 deaths per 100,000 persons. However, the COVID-19 vaccine mortality rate reported in the present study is higher than the mortality rates reported in prior research, but this was not unexpected, given that all prior research on COVID-19 vaccine-related deaths examined data only from the year 2021. Descriptive statistics by year are presented on Tables 1-6, and Figures illustrating the annual changes in total number of deaths attributable to vaccines are presented on Figures 1-3.

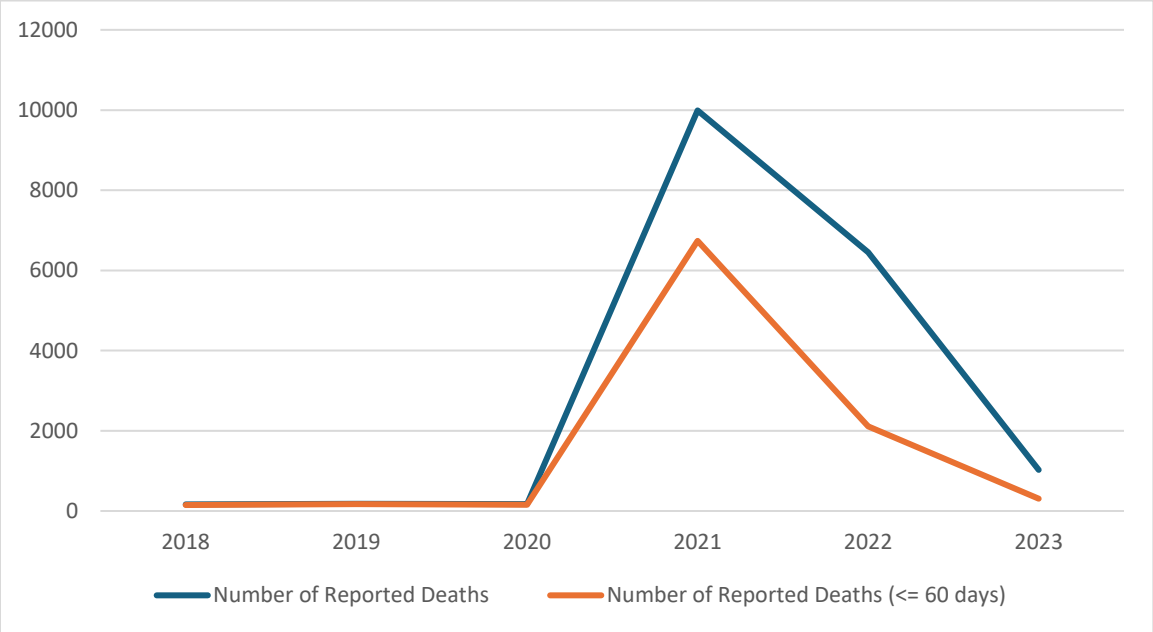

Figure 1.
Number of Reported Deaths: All Vaccines.

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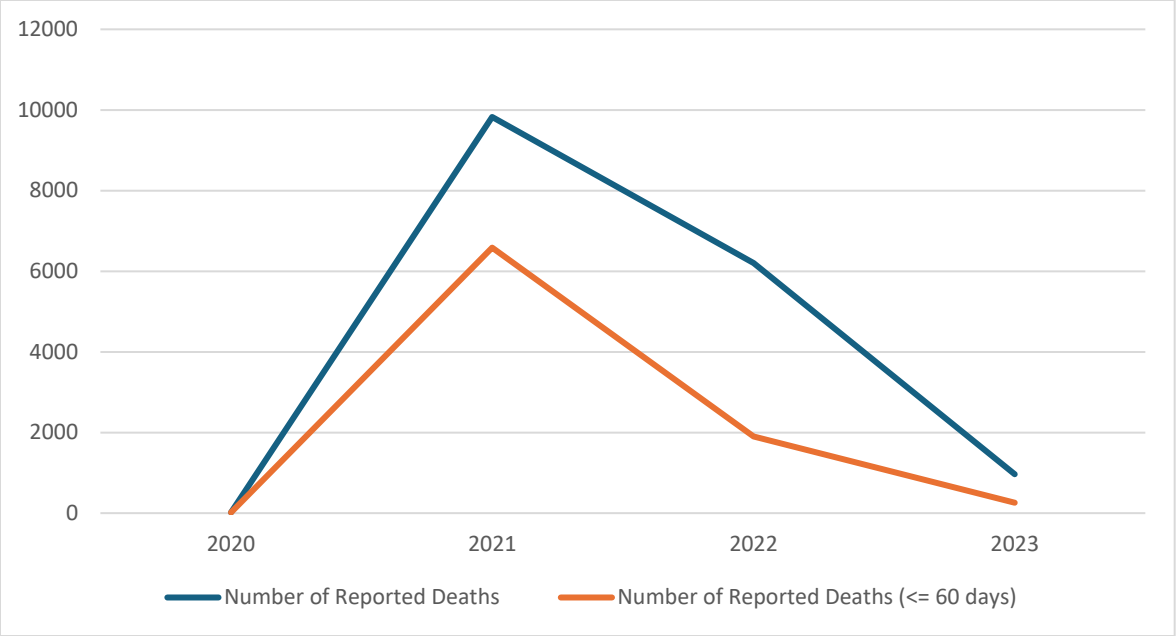

Figure 2.
Number of Reported Deaths: Covid-19 Vaccines.

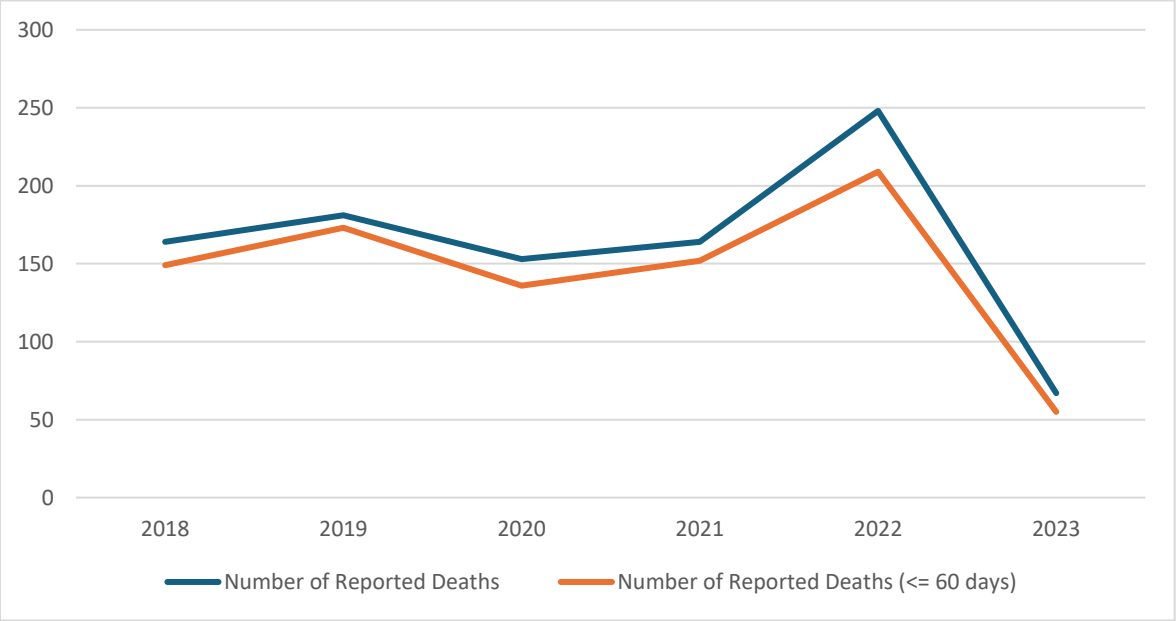

Figure 3.
Number of Reported Deaths: Non-Covid-19 Vaccines.

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Table 1.
Descriptive Statistics 2018 VAERS Data.

Variable	Mean	Standard Deviation
Days from Vaccination to Onset of Symptoms	46	223
Days from Vaccination to Death	86	305
Multiple vaccines	0.287	0.453
Dose administered	1.48	0.73
Age of patient	33.8	36.5
Male patient	0.514	0.502
Hospitalized patient	0.231	0.423
N=164		

Table 2.
Descriptive Statistics 2019 VAERS Data.

Variable	Mean	Standard Deviation
Days from Vaccination to Onset of Symptoms	11	38
Days from Vaccination to Death	64	361
Multiple vaccines	0.243	0.43
Dose administered	1.43	0.74
Age of patient	36.9	35.2
Male patient	0.572	0.496
Hospitalized patient	0.248	0.433
N=181		

Table 3
Descriptive Statistics 2020 VAERS Data.

Variable	Mean	Standard Deviation
Days from Vaccination to Onset of Symptoms	26	124
Days from Vaccination to Death	77	297
COVID-19 vaccine	0.095	0.293
Multiple vaccines	0.237	0.426
Dose administered	1.30	0.66
Age of patient	42.8	37.7
Male patient	0.452	0.499
Hospitalized patient	0.142	0.35
N=169		

Table 4.
Descriptive Statistics 2021 VAERS Data.

Variable	Mean	Standard Deviation
Days from Vaccination to Onset of Symptoms	69	378
Days from Vaccination to Death	73	367
COVID-19 vaccine	0.985	0.127
Multiple vaccines	0.003	0.057
Dose administered	1.62	0.607
Age of patient	72.8	16.2
Male patient	0.593	0.491
Hospitalized patient	0.327	0.469
N=9990		

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Table 5.
Descriptive Statistics 2022 VAERS Data.

Variable	Mean	Standard Deviation
Days from Vaccination to Onset of Symptoms	187	150
Days from Vaccination to Death	204	155
COVID-19 vaccine	0.962	0.192
Multiple vaccines	0.004	0.065
Dose administered	2.08	0.782
Age of patient	73.8	15.3
Male patient	0.606	0.488
Hospitalized patient	0.46	0.498
N=6450		

Table 6.
Descriptive Statistics 2023 VAERS Data.

Variable	Mean	Standard Deviation
Days from Vaccination to Onset of Symptoms	351	282
Days from Vaccination to Death	350	309
COVID-19 vaccine	0.935	0.247
Multiple vaccines	0.031	0.173
Dose administered	2.38	1.088
Age of patient	73.2	17.6
Male patient	0.537	0.498
Hospitalized patient	0.599	0.49
N=1029		

According to the VAERS data, the total number of deaths attributed to the COVID-19 vaccine are significantly greater than the total number of deaths attributed to non-COVID-19 vaccines. It is important to note, however, that the total number of persons receiving COVID-19 vaccines was much greater in the early years of the pandemic than were the total number of persons receiving non-COVID-19 vaccines. Hence, the estimates reported by McCarthy et al. (2013) should still be applicable during the COVID-19 pandemic. Given that many persons delayed preventive care, including vaccines, during the early years of the pandemic, it is quite likely that the total number of non-COVID-19 vaccines administered and the total number of non-COVID-19 vaccine adverse events reported were much lower than pre-pandemic levels. Finally, given that COVID-19 is now endemic, one would expect that the total number of COVID-19 vaccines administered in a given year, and, by extension, the total number of adverse events reported, would decline quite significantly in the future.

Another interesting observation regards the mean number of days from vaccination to onset of symptoms and from vaccination to death. In 2018, the first year of data examined, the mean number of days from vaccination to onset of symptoms was 46 [95% Confidence Interval:

(-1.59) – 94.51] and the mean number of days from vaccination to death was 86 [95% Confidence Interval: 22.33 – 149.88]. It is important to note that, in 2018, there were no COVID-19 vaccines, and the standard deviations of these variables were large. The range for the number of days from vaccination to onset of symptoms was 0 to 1818, and the range for the number of days from vaccination to death was 0 to 2585. If one limits the variables to no more than 60 days, then the mean number of days from vaccination to onset of symptoms was 6.47 [95% Confidence Interval: 3.7 – 9.24], and the mean number of days from vaccination to death was 10.13 [95% Confidence Interval: 6.83 – 13.43]. It is generally accepted that most adverse events manifest themselves within 60 days of being vaccinated (McCarthy et al., 2013).

For the year 2023, however, the results are significantly different. For non-COVID-19 vaccines, the mean number of days from vaccination to onset of symptoms was 189 [95% Confidence Interval: (-43.37) – 421.37], and the number of days from vaccination to death was 182.75 [95% Confidence Interval: (-31.37) – 396.12]. Once again, the ranges of these variables were large, with the range of the

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number of days from vaccination to onset of symptoms being 0 to 4170, and the range of the number of days from vaccination to death being 0 to 5457. Limiting the variables to at most 60 days, the mean number of days from vaccination to onset of symptoms was 5.35 [95% Confidence Interval: 1.86 – 8.84] and the mean number of days from vaccination to death was 4.82 [95% Confidence Interval: 2.27 – 7.72].

Regarding COVID-19 vaccines, for the year 2023 and limiting the variables to at most 60 days, the mean number of days from vaccination to onset of symptoms was 13.57 [95% Confidence Interval: 10.87 – 16.27] and the mean number of days from vaccination to death was 10.47 [95% Confidence Interval: 8.24 – 12.7]. These results indicate the mean number of days from vaccination to onset of symptoms and the mean number of days from vaccination to death for COVID-19 vaccines are significantly greater than are those means for non-COVID-19 vaccines. Data for both variables are presented on Figures 4-6. In examining these Figures, it is worthwhile to note the significant increases since 2018 in the number of days from vaccination to onset of symptoms and in the number of days from vaccination to death.

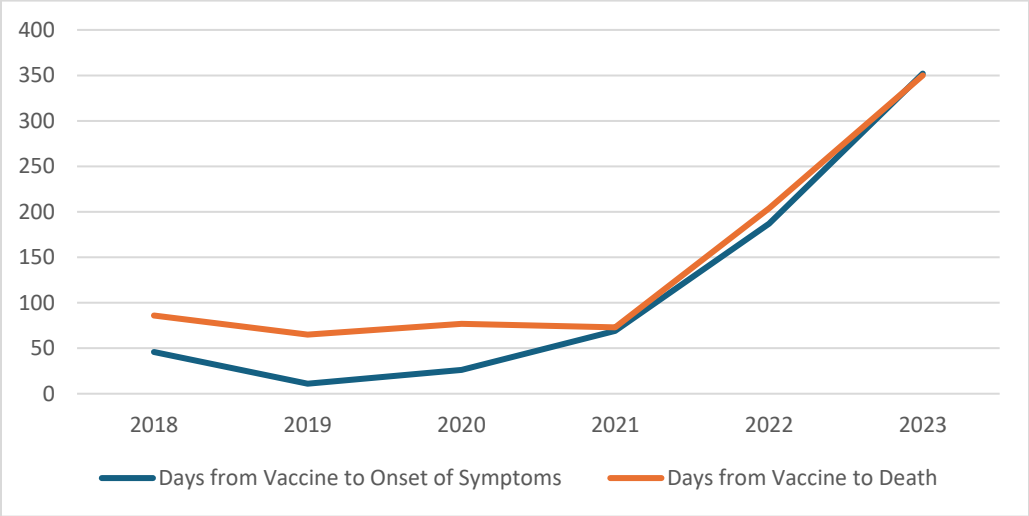

Figure 4.
Days from Vaccine to Symptom Onset and Death: All Vaccines.

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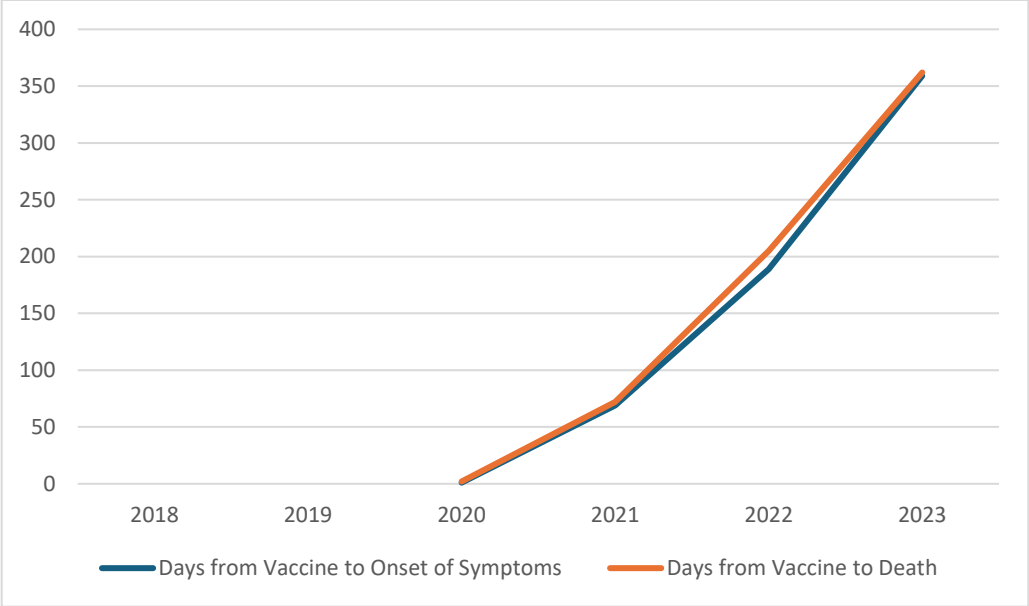

Figure 5.
Days from Vaccine to Symptom Onset and Death: Covid-19 Vaccines.

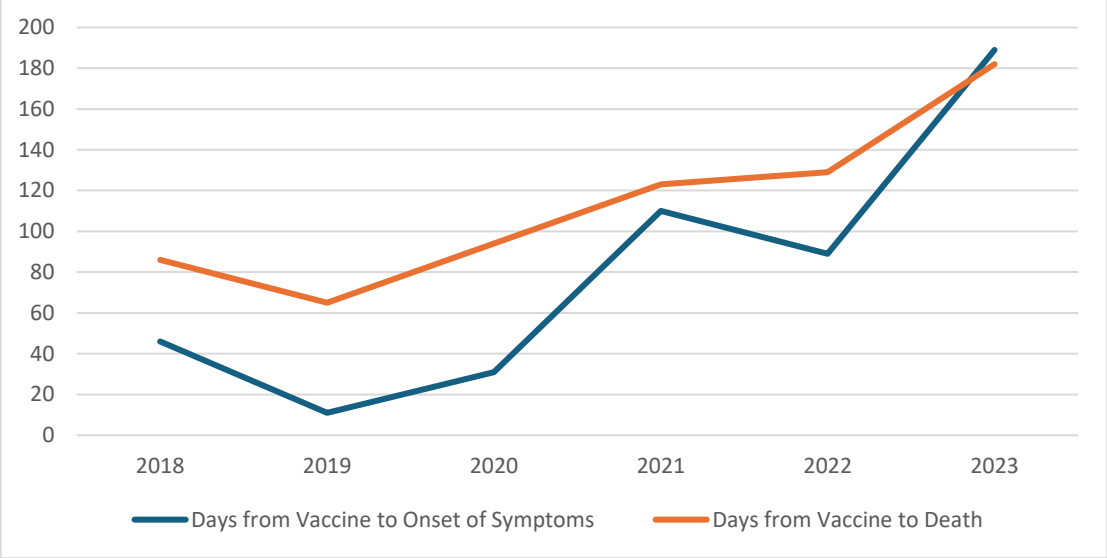

Figure 6.
Days from Vaccine to Symptom Onset and Death: Non-Covid-19 Vaccines.

To get a greater understanding of the determinants of the number of days from vaccination to onset of symptoms and the number of days from vaccination to death, an ordinary least squares regression was estimated for the years 2018 to 2023. The equation that was estimated is as follows:

$$Y_i = \beta_0 + \beta_1 \text{ MULTIPLE} + \beta_2 \text{ COVID} + \beta_3 \text{ DOSE} + \beta_4 \text{ AGE} + \beta_5 \text{ MALE} + \beta_6 \text{ HOSPITAL} + \beta_7 \text{ YEAR} + € \quad (1)$$

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Equation (1) is estimated for two dependent variables: the numbers of days from vaccination to onset of symptoms and the number of days from vaccination to death. Explanatory variables are as follows:

(1) MULTIPLE: dummy variable that equals one if multiple vaccines were administered at the same time and zero otherwise;
(2) COVID: dummy variable that equals one if COVID-19 vaccine was administered and zero otherwise;
(3) DOSE: the number of the dose of vaccine administered;
(4) AGE: age of patient;
(5) MALE: dummy variable that equals one if patient was male and zero otherwise;
(6) HOSPITAL: dummy variable that equals one if patient was admitted to hospital due to adverse event and zero otherwise;
(7) YEAR.

The error term is assumed to be normally distributed. Regression model was estimated for the entire sample and for a subset of only those patients who experienced onset of symptoms or death within 60 days of vaccination. Results are presented on Tables 7-10.

Table 7.
OLS Results Days Until Onset of Symptoms Entire Sample.

Variable	Coefficient	Test Statistic
Constant	-147292	-18.57***
COVID-19 vaccine	-17.03	-1.16
Multiple vaccines	47.80	1.76*
Dose administered	0.099	12.86***
Age of patient	0.778	75.83***
Male patient	0.14	9.17***
Hospitalized patient	70.41	12.32***
Year	72.88	18.57***
N=17983		
R^2 = 0.425		
F = 1898.81		
10% Significance = *; 1% Significance = ***		

Table 8.
OLS Results Days Until Death Entire Sample.

Variable	Coefficient	Test Statistic
Constant	-95337	-11.16***
COVID-19 vaccine	153.48	9.72***
Multiple vaccines	97.37	3.33***
Dose administered	0.041	4.95***
Age of patient	0.42	38.02***
Male patient	0.07	4.28***
Hospitalized patient	60.60	9.85***
Year	47.12	11.15***
N=17983		
R^2 = 0.184		
F = 578.44		
1% Significance = ***		

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Table 9.
OLS Results Days Until Onset of Symptoms Days <= 60.

Variable	Coefficient	Test Statistic
Constant	55911	7.68***
COVID-19 vaccine	73.90	6.93***
Multiple vaccines	99.32	5.22***
Dose administered	0.095	15.36***
Age of patient	0.734	101.22***
Male patient	0.108	10.19***
Hospitalized patient	4.62	0.76
Year	-27.74	-7.70***

N=9635
R^2 = 0.687
F = 3028
1% Significance = ***

Table 10.
OLS Results Days Until Death Days <= 60.

Variable	Coefficient	Test Statistic
Constant	136886	15.96***
COVID-19 vaccine	317.50	25.29***
Multiple vaccines	192.36	8.59***
Dose administered	0.014	1.97**
Age of patient	0.368	43.02***
Male patient	0.037	2.94***
Hospitalized patient	-12.66	-1.77*
Year	-67.90	-16.00***

N=9635
R^2 = 0.339
F = 705.82
10% Significance = *; 5% Significance; 1% Significance = ***

For the full sample, results indicate that patients who had multiple vaccines, had a booster dose, were older, were male, and were hospitalized reported a significantly greater number of days from vaccination to onset of symptoms and from vaccination to death. In addition, the positive coefficient on YEAR indicates that the dependent variables were increasing during the period in question, holding all other factors constant. Interestingly, COVID-19 had a significant and positive effect on the number of days from vaccination to death but was insignificant for the number of days from vaccination to onset of symptoms.

For the regressions limiting the dependent variables to no more than 60 days, the results indicate that patients who received multiple doses, had the COVID-19 vaccine, had a booster dose, were older, and were male reported greater number of days from vaccination to onset of symptoms and from vaccination to death. However, YEAR was significant and negative, indicating the dependent variables were declining during the period in question, and HOSPITAL was only significant and positive for days from vaccination to death.

4. Discussion

The purpose of the present study was to determine the mortality rate for COVID-19 vaccines in the United States, using the Vaccine Adverse Event Reporting System (VAERS) as the primary data source. In addition, regression analysis was used to estimate the factors that may affect the reported number of days from vaccination to onset of symptoms due to vaccine complications and the reported number of days from vaccination until death.

It appears that the estimated mortality rate of COVID-19 vaccines is significantly lower than the mortality rate for non-COVID-19 vaccines. It was estimated that the crude mortality rate for all

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COVID-19 vaccines was 6.3 deaths per 100,000 vaccinated persons for the period December 14, 2020 to December 31, 2023. If one examines only those deaths that occurred with 60 days of vaccination, the crude mortality rate was 3.24 deaths per 100,000 persons for the period in question. This mortality rate is substantially lower than the crude mortality rate for non-COVID-19 vaccines estimated in McCarthy et al. (2013) which was 608 deaths per 100,000 persons. There is no a priori reason why the mortality rate for non-COVID-19 vaccines in 2023 would be statistically significantly different from the mortality rate for non-COVID-19 vaccines in 2013. It is important to note that the COVID-19 vaccine mortality rate estimated in the present study is significantly higher than the mortality rates reported in prior research. This was not unexpected, given that all prior research on COVID-19 vaccine-related deaths only examined data from the year 2021.

In addition, the mean number of days from vaccination to onset of symptoms and from vaccination to death increased dramatically once the COVID-19 vaccines became available. This includes the means for non-COVID-19 vaccines as well. It is unclear why this increase would occur. One potential reason may be an increase in skepticism regarding all vaccines, even vaccines that had been publicly available for years. Patients may have been mistakenly interpreting adverse events that occurred months after inoculation as being related to the vaccine. Although the results of the present study do not provide evidence in support of this theory, the only exogenous event that occurred that may explain this increase was the pandemic and the introduction of COVID-19 vaccines, especially vaccines created using novel technologies. More research is warranted in this area.

Transparency:

The authors confirm that the manuscript is an honest, accurate, and transparent account of the study; that no vital features of the study have been omitted; and that any discrepancies from the study as planned have been explained. This study followed all ethical practices during writing.

Copyright:

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