Review Article

Summary of COVID-19 Vaccine-Related Reports in the Vaccine Adverse Event Reporting System

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Abstract

Identification of the severe acute respiratory syndrome coronavirus 2 in humans toward the end of 2019 triggered a rapid, intensive effort to develop a vaccine. Among the first three COVID-19 vaccines granted emergency use authorization by the U. S. Food and Drug Administration (FDA) were two mRNA vaccines, never used on a large scale in humans, and one replication-incompetent human adenovirus vector vaccine. Since the beginning of the vaccination efforts in December 2020, almost 220,000 adverse events (AEs) have been reported through the Vaccine Adverse Event Reporting System, a reporting platform administered jointly by the FDA and the Centers for Disease Control to monitor vaccine-related AEs. We queried this database twice (04/23/21 and 05/14/21) and identified the AE reports with valid manufacturer-specific lot numbers (n = 76,336), a subset representing 33.54% of the total reported AEs. Using vaccine and demographic characteristics at the time of each query date, a model was generated to predict significant AEs, such as death. Our regression analysis revealed that the average age (IRR 1.08) and the number of doses administered in an assisted living facility (IRR 1.01) were significantly associated with the number of deaths observed in each lot, whereas the proportion of remaining vaccine shelf-life (IRR 1.30) and the vaccine manufacturer (IRR 1.09) were not. Studies such as this one are vital, as one of the best answers to vaccine hesitancy is reliable data confirming that the available COVID-19 vaccines are safe and not associated with a significantly higher risk of AEs than vaccines for other conditions.

Keywords: *COVID-19, mRNA, safety, vaccine, vaccine adverse event reporting system*

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Introduction

The Vaccine Adverse Event Reporting System (VAERS) is a national monitoring system in the U. S. that allows for the reporting of adverse events associated with vaccines approved by the U. S. Federal Drug Administration (FDA). The system is jointly managed by the Centers for Disease Control and Prevention (CDC) and the FDA; however, anyone can submit a report. Some specific adverse events, those listed in the VAERS Table of Reportable Events Following Vaccination, are required to be reported to VAERS when by health-care works or reported to vaccine manufacturers. In addition to these mandatory reporting events, any adverse event occurs within a specific time frame of vaccine administration, regardless of the likelihood to be a consequence of vaccine administration or felt to be related to a vaccine can be reported to VAERS.

In response to the COVID-19 pandemic, the FDA granted emergency use authorization (EUA) to several vaccines. Included among this group, at the time of writing, were two mRNA-based vaccines, which had never previously been used in a large-scale human vaccination effort. Importantly, when these vaccines were first made available under an EUA, they were administered to specific populations, namely high-risk

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individuals and frontline workers. Due to this, for the 1st weeks to months that vaccines were available, the majority of recipients were elderly, nursing home residents, and those with preexisting conditions. In just the first 5 months that a COVID-19 vaccine has been available in the U. S, the CDC reported that 163.9 million people, or 49.4% of the U. S. population, had received at least one dose of a COVID-19 vaccine.[1]

Recently, it has been pointed out that there is an unusually high number of deaths and significant adverse events associated with COVID-19 vaccines in VAERS. Since the vaccines have been disproportionately administered to high-risk individuals, a true estimate of the rate of adverse events in the general population remains elusive. Herein, we review the publicly available VAERS data to better understand if these reports of serious adverse events represent legitimate reasons for concern or unnecessarily contribute to vaccine hesitancy.

Given the prioritized populations, the expected mortality as a proportion of administrations is elevated in the early days of vaccine availability. This, coupled with the hypervigilance and reporting requirements, has resulted in an unprecedented number of reports in VAERS. In 2020, COVID-19 vaccines were responsible for 10,876 reports, or 22.58% of all 48,159 individuals with a report that year [Table 1].[2] Hence, far in 2021, there have been a total of 220,825 reports associated with a COVID-19 vaccine. This is out of 222,634 total reports across all vaccines and comes from 217,716 individuals [Table 2].[2] There are a greater number of reports associated with the COVID-19 vaccines than individuals due to the fact that two of the available vaccines require two doses, and thus, a single individual may have separate reports associated with each administration.

Table 1: Summary of all 2020 vaccine adverse event reporting system reports

Vaccine type	Reported events (*n*)	Percent of individuals (*n*=48,159)
Adenovirus Type 4 and 7, live oral	3	0.01
Anthrax	94	0.20
Bacillus Calmette–Guerin	5	0.01
Cholera	18	0.04
Comvax	1	0.00
COVID-19	10,876	22.58
Dengue tetravalent	1	0.00
DTP with/out polio, HEP B, and Haemophilus B	3498	7.26
Diphtheria and tetanus	140	0.29
Haemophilus B conjugate	933	1.94
HEP A and/or B	2091	4.34
HPV bivalent and recombinant (all types)	1727	3.59
Influenza virus (all types/brands)	12,379	25.70
Japanese encephalitis virus vaccine (all)	45	0.09
Measles, mumps, and rubella virus (all)	2172	4.51
Meningococcal (any) alone or combined	1777	3.69
Pneumococcal (any)	4338	9.00
Poliovirus inactivated	311	0.65
Rabies virus	135	0.28
Rotavirus (any)	1101	2.29
Rubella	1	0.00
Smallpox	30	0.06
Tetanus toxoid	28	0.06
Typhoid	803	1.67
Varivax-varicella virus live	1596	3.31
Yellow fever	28	0.06
Zoster	12,109	25.14
Unknown	1551	3.22
Total	57,792	120.00

DTP=Diphtheria tetanus pertussis, HEP=Hepatitis, HPV=Human papillomavirus

Methods

The raw report data were downloaded from VAERS at two distinct time points: the first time on May 6, 2021, and the second on May 21, 2021. The reason for the second query was the inadvertent observation of the sudden doubling of the VAERS reports on May 14, 2021. With the understanding that the newly available data had the potential to modify our first model, we proceeded to a second data query and analysis. Data presented here include the first query and analysis, as well as the second query and analysis. Each download consisted of three files, the data file, the symptoms file, and the vaccine file. The data file contains individual-level demographic, concurrent therapy, and comorbidity information. The symptom file lists the symptoms reported following vaccine administration and the vaccine file contains the list of vaccines, manufacturer, lot numbers, and relevant dates.

All VAERS reports associated with a COVID-19 vaccine were organized and the lot numbers were gathered.

The lot numbers were validated using publicly available lookup tools made available by Moderna and Janssen.[3,4] Since lookup tools only exist for the Janssen and Moderna vaccines, reports associated with the Pfizer-BioNTech vaccine were excluded from lot-specific analyses. Obvious look alike and sound alike entry errors or discrepancies were manually assessed using the scheme described in Table 3. Discrepancies encountered are presented in Table 3, including a list of discrepancies that were accepted in the validation process and a list of discrepancies that were not.

For all VAERS reports for which the lot number could be validated, the expiration date was recorded. In addition, several key pieces of patient-level data were abstracted from the VAERS reports including age, sex,

Table 2: Summary of 2021 vaccine adverse event reporting system reports, current through May 14, 2021

Vaccine type	Reported events (*n*)	Percent of individuals (*n*=217,716)
Adenovirus Type 4 and 7 live oral	4	0.00
Anthrax	1	0.00
Cholera	3	0.00
COVID-19	220,825	101.43
Dengue tetravalent	1	0.00
DTP with/out polio, HEP B, and Haemophilus B	63	0.03
Haemophilus B conjugate	15	0.01
Hepatitis A and/or B	37	0.01
HPV bivalent and recombinant (all types)	32	0.01
Influenza virus (all types/brands)	487	0.22
Measles, mumps, and rubella virus (all)	37	0.01
Meningococcal (any) alone or combined	33	0.02
Pneumococcal (any)	91	0.04
Poliovirus (any)	4	0.00
Rabies virus	3	0.00
Rotavirus (any)	11	0.00
Tetanus toxoid	3	0.00
Typhoid	4	0.00
Varivax-varicella virus live	15	0.01
Yellow fever	1	0.00
Zoster	298	0.14
Unknown	667	0.31
Total	222,634	102.26

DTP=Diphtheria tetanus pertussis, HEP=Hepatitis, HPV=Human papillomavirus

and administration facility. The total number of deaths associated with the given lot as well as the proportion of assumed 6-month shelf-life remaining was also recorded for each included lot.

A model to predict the number of deaths for a given lot was built using Poisson regression based on the data available through April 23, 2021. Potential confounders that were considered included number of males and females, average age, proportion of vaccine shelf-life remaining, the vaccine manufacturer, and the number of vaccines administered by facility type. Interactions between the number of administrations and proportions of vaccine administered according to facility type were also considered. When the updated data through May 14, 2021, became available, the expected number of deaths per lot was predicted using the Poisson model and compared to the actual deaths observed during the same time frame. For the final iteration of the model, the model coefficients were re-estimated using the updated data (thru May 14, 2021), and revised predictions were made. All analyses were performed using R version 4.0.5, R Foundation for Statistical Computing. Vienna, Austria. URL: https://www.R-project.org/.

Table 3: List of accepted and unaccepted discrepancies in lot number validation*

Accepted lot number mistakes	Unaccepted lot number mistakes
Extra or missing spaces	Non-terminal character omission
Extra or missing hyphen	Character inversions
Unnecessary periods	"//", for letter "J"
Leading zeros	Characters "1C" for letter "K"
Duplicated character	Letter "K" for letter "R"
Last character omission	Number 1 for letter "L"
The "@" symbol in place of number 2	Number 1 for letter "J"
")" for number 0	Number 3 for letter "E"
Letter "M" for letter "N"	Number 8 for letter "A"
Number 0 for letter "C"	Number 0 for number 6
Number 0 for letter "D"	Number 0 for number 9
Number 0 for letter "O"	Number 2 for number 7
Number 0 for letter "Q"	
Number 1 for letter "I"	
Number 4 for letter "A"	
Number 5 for letter "S"	
Number 6 for letter "G"	
Number 8 for letter "B"	

*A validated lot could only have one accepted discrepancy occurrence

Results

With respect to COVID-19 vaccines specifically, in 2020, there were 10,864 adverse events reported, between January 1, 2021, and April 23, 2021, an additional 107,882 events were reported, and in the following 3 weeks, there were 109,010 more adverse events reported in association with a COVID-19 vaccine, for a total of 216,752 reports associated with a COVID-19 vaccine by May 14, 2021 [Table 4]. With respect to vaccine-related deaths, by April 23, 2021, 3391 deaths had been reported in association with any COVID-19 vaccine, and an additional 719 deaths associated with a COVID-19 vaccine were reported in the following 3 weeks for a total of 4110 deaths reported in VAERS associated with a COVID-19 vaccine by May 14, 2021 [Table 5].

Analysis of the raw data exactly as reported in VAERS revealed several important summary measures. Out of all 227,616 reports associated with a COVID-19 vaccine in 2020 and 2021, 166,271 (73.05%) were reports concerning female vaccine recipients [Table 5]. Of the 4126 reported deaths associated with a COVID-19 vaccine, 2,233 (54.12%) were male. Private facilities were associated with the highest frequency for adverse events related to a COVID-19 vaccine. The manufacturer most frequently associated with a COVID-19 vaccine-related

Table 4: Demographics and individual characteristics for the vaccine adverse event reporting system reports associated with COVID-19 vaccine administrations

	2020		2021			
	Alive	Deceased	January 1-April 23		April 24-May 14	
			Alive	Deceased	Alive	Deceased
Age						
Years, mean (SD)	43.1 (13.1)	82.2 (10.8)	48.5 (17.3)	75.2 (14.9)	53.2 (17.8)	71.1 (16.1)
Sex						
Female	8653	9	75,798	1478	80,025	308
Male	2022	7	24,211	1842	26,252	384
Unknown	173	0	4342	71	2014	27
Administration facility type						
Military	116	0	1572	37	1708	11
Pharmacy or store	91	0	9039	296	15,153	83
Public	532	1	10,332	298	15,761	58
Private	6320	0	33,625	857	27,200	173
School	30	0	1766	13	2214	3
Assisted living facility	359	12	3484	712	2261	41
Work	1366	1	7378	25	4668	7
Other	773	2	18,053	596	21,037	192
Unknown	173	0	19,102	557	18,289	151
Vaccine manufacturer*						
Janssen	_†	_†	24,841	212	8160	111
Moderna	3121	5	43,294	1702	57,825	308
Pfizer-BioNTech	7706‡	11‡	36,090‡	1459‡	41,738‡	296‡
Unknown	21	0	126	18	568	4

*Manual review of the lot numbers corrected any mismatched vaccine lots and manufacturers. ‡Pfizer-BioNTech lots were not available in a public repository for lot report accuracy validation. Reports involving Pfizer-BioNTech vaccines were thus excluded from the analysis. †The Janssen COVID-19 vaccine was not yet available in 2020. SD=Standard deviation

report in VAERS was Moderna (106,255), followed by Pfizer-BioNTech (87,300), and finally Janssen (33,324). There were 737 reports with an unknown manufacturer. As a percentage of reports, deaths were 0.16% of reports associated with a Moderna vaccine in 2020, 3.93% between January 1, 2021, and April 23, 2021, and 0.53% of reports between April 24, 2021, and May 14, 2021. For the Pfizer-BioNTech vaccine, the deaths as a percentage of reports were 0.14%, 4.04%, and 0.71% for the same timeframes, respectively. Similarly, for the Janssen vaccine, the deaths as a percentage of reports were 0.86% for January 1, 2021, to April 23, 2021, and 1.36% between April 24, 2021, and May 14, 2021.

Validated lots are those which could be looked up using publicly available lookup tools made available by Moderna and Janssen[3,4] and matched to an existing lot based on the criteria in Table 3. No public lookup tool or lot number repository was available for Pfizer-BioNTech vaccines, thus no Pfizer-BioNTech lots could be validated for inclusion in this study. This is emphasized here because the Pfizer-BioNTech is the most widely distributed COVID-19 vaccine in the U. S. and was associated with 7717 out of the 10,864 reports in 2020 and 79,583 out of 216,752 reports between January 1, 2021, and May 14, 2021. Of these reports, 4,772 and 42,341, respectively, were associated with a lot number that followed the general structure of the Pfizer-BioNTech lot number schema (i.e., two letters followed by four digits).

Of the 227,616 total reports associated with a COVID-19 vaccine in VAERS in 2020 and up to May 14, 2021, only 76,336 (33.54%) were associated with a lot that could be validated using the publicly available tools for checking expiration dates [Table 3]. This is still greater than the total 48,159 reports for all vaccines, including COVID-19, in 2020. Females represented 56,741 (74.33%) of the reports associated with a validated lot number, while males accounted for 823 (60.34%) of the 1364 deaths associated with a validated lot number. Again, private facilities were the most common facility for vaccine administration among the validated lot adverse event reports. As a percentage of reports, death represented 0.15%, 4.20%, and 0.49% for the Moderna vaccine in 2020, between January 1, 2021, and April 23, 2021, and between April 24, 2021, and May 14, 2021, respectively. For the latter two timeframes, once the Janssen vaccine was available, death represented 0.90% and 1.27% of reports associated with the Janssen COVID-19 vaccine.

Table 5: Demographics and characteristics of individuals with reports in vaccine adverse event reporting system associated with a COVID-19 vaccine and valid lot number

	2020		2021			
	Alive	Deceased	January 1-April 23		April 24-May 14	
			Alive	Deceased	Alive	Deceased
Age						
Years, mean (SD)	43.4 (13.6)	83 (16.5)	48.1 (17.1)	75.2 (14.3)	53.8 (17.7)	71.0 (15.7)
Sex						
Female	1620	0	28,851	466	25,734	70
Male	349	3	9236	696	7833	124
Unknown	10	0	1069	4	270	1
Administration facility type						
Military	25	0	698	18	633	4
Pharmacy or store	33	0	4894	137	5550	24
Public	231	1	5435	145	6189	26
Private	1079	0	10,863	857	8141	36
School	7	0	819	4	721	1
Assisted living facility	77	2	915	234	579	7
Work	263	0	2561	8	1501	2
Other	182	0	8331	253	6808	71
Unknown	82	0	4640	76	3715	24
Vaccine manufacturer*						
Janssen	_[†]	_[†]	14,532	131	3852	49
Moderna	1979	3	24,624	1035	29,985	146
Pfizer-BioNTech	_[‡]	_[‡]	_[‡]	_[‡]	_[‡]	_[‡]

*Manual review of the lot numbers corrected any mismatched vaccine lots and manufacturers. [‡]Pfizer-BioNTech lots were not available in a public repository for lot report accuracy validation. Reports involving Pfizer-BioNTech vaccines were thus excluded from the analysis. [†]The Janssen COVID-19 vaccine was not yet available in 2020, There is no "unknown" category as only validated lot numbers were included. SD=Standard deviation

Poisson regression was conducted to model the number of deaths observed in each lot [Figure 1]. The regression revealed that the average age of vaccine recipients, the proportion of the assumed 6-month shelf-life that was remaining, the number of doses reported as administered in a senior living or nursing facility, and the vaccine manufacturer were significantly associated with the number of deaths observed in each lot. In addition, there were significant interactions between the number of doses administered to females and the proportion of doses administered at a pharmacy. Specifically, the death incident rate ratio (IRR) was equal to 0.96 with a 95% confidence interval (95% CI) 0.92–0.99. The lower order effects were also significant: Females had an IRR of 0.99 (95% CI: 0.99–1.00) and the pharmacy IRR was 0.30 (95% CI 0.12–0.75).

In the final model, generated using the data from May 14, 2021, as the average age of recipients within a given lot increased, the expected number of deaths also increased. For every increase of 1 year in the average age of a lot's recipients, the death incidence rate increased by 7.50% (95% CI 4.54%–10.54%). Similarly, as the number of recipients residing in a senior living facility rose, so did the number of expected deaths. The IRR for the number of individuals in a senior living facility was 1.01 (95% CI 1.0–1.01). In addition, males were at an increased risk of death as compared to females. The death incident rate for males was 0.44% greater than females (95%CI 0.26-0.62). Moreover, Moderna vaccine administration also had an increased trend in the incidence rate of death per lot as compared to Janssen, IRR 1.09 (95% CI: 0.54–2.24). Pharmacies and stores were associated with a lower number of deaths compared to private facilities. The death incident rate for pharmacies was 27.68% lower than private facilities (95% CI: 5.56–89.15).

Discussion and Conclusion

Our review of the available VAERS data revealed that out of over 268 million administered doses of COVID-19 vaccine, only 227,616 total adverse events have been reported, yielding an adverse event rate of 0.08%. Furthermore, with a total of 4110 deaths potentially associated with COVID-19 vaccination, the overall mortality rate is an estimated 0.0015%. Poisson regression using externally validated lot-based adverse events reported in VAERS revealed that age of the recipient, proportion of shelf-life remaining, and receiving vaccination in a senior living or nursing

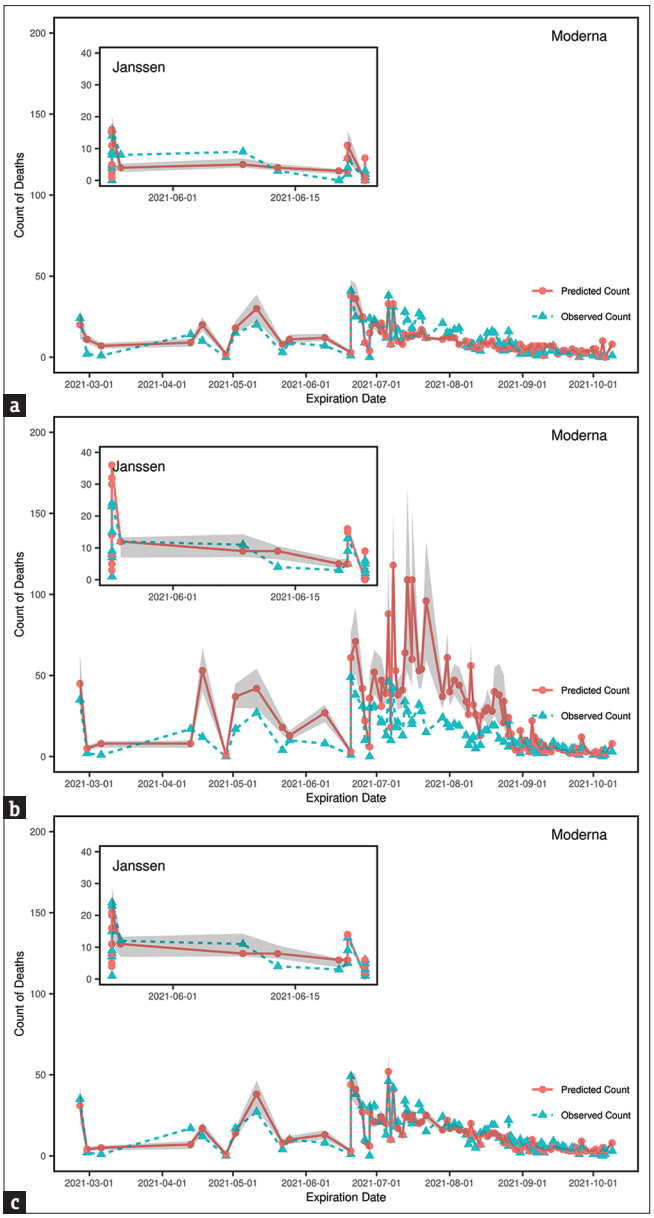

Figure 1: The original model was trained using VAERS COVID-19 vaccine adverse events data reported through April 23, 2021 (a). The model fit degraded significantly when applied to the second dataset, including the COVID-19 vaccine adverse events reported between April 24, 2021 and May 15, 2021 (b). The model fit improved after incorporating the second dataset into the training data (c).

facility were all associated with an increased potential for death.

To our knowledge, this is the first VAERS data analysis conducted using lot number validation against external publicly available manufacturer maintained repositories. Although this method resulted in the inclusion of only 33.54% of the total lots, it enabled more granular analysis, which included lot-based patient demographics, as well as lot-specific details, such as the proportion of shelf-life remaining. The proportion of shelf-life that had passed was used as a surrogate to estimate the proportion of a lot that had been administered. This assumes that the administration rate is constant. In the given time frame, this may be an acceptable assumption as the sites were administering the vaccines at the maximum possible rate. According to our assumption above, the administration of an entire vaccine lot was not significantly associated with IRR, 1.30 (95% CI: 0.63–2.68). It is possible that this lack of association is because all individual VAERS reports are from vaccine recipients and thus all have the protection from COVID-related death conferred by the vaccine. This also prevents us from being able to detect any difference in the incidence of death between vaccine recipients and nonrecipients. However, as described in Table 6, the low incidence of any reports as a percentage of administrations would imply a strong protective effect against death from COVID.

This type of analysis enables the assessment of a wider breadth of information than VAERS alone and reinforces that the handling of vaccines allows researchers to understand the potential influence that vaccine shelf-life may play on the occurrence of adverse events. The variability in expected deaths per lot, particularly those expiring between June and August 2021 that would have been administered among the first, may indicate that early handling errors led to a subpar pharmaceutical product being administered [Figure 1]. This could have been a consequence of a delay in the systematic implementation of the standard handling procedures at some immunization sites. Another possible explanation is that vulnerable and at-risk populations were prioritized to receive the vaccine in 2020 and early 2021. Thus, the early number of observed deaths may have been elevated due to the preexisting factors, such as the comorbidity level, advanced age, or requirement for institutionalized care, in the prioritized population. This is consistent with the fact that reports more than doubled between April 24 and May 14, 2021[1] [Table 6]; however, the number of deaths only increased by approximately 21% [Table 4]. Nonetheless, with mRNA vaccines requiring more controlled storage conditions, the inclusion of remaining shelf-life into the analysis of adverse event occurrence will be important in understanding how the risk of adverse events evolves over a vaccine lot's lifecycle.

One potential explanation for the difference in adverse event occurrence among manufacturers may be partially explained if the number of doses included in a given lot is substantially different. In other words, if a Janssen lot contains 1000 doses and a Moderna lot contains 1,000,000, it is unsurprising that there are more reports associated with each Moderna lot. However, if the lot sizes are comparable and we assume the voluntary reporting rate is also comparable, then there appears to be an increased risk of death associated with the Moderna vaccine as compared

Table 6: Number of administered doses and report proportions

	2020	2021		Total
		January 1-April 23	April 24-May 14	
Doses administered				
Janssen	–[†]	8,040,727	1,390,877	9,431,604
Moderna	1,107,143	96,246,591	17,774,050	115,127,784
Pfizer-BioNTech	2,630,115	114,124,516	26,926,260	143,680,891
Unknown	872	172,266	25,249	198,387
Total	3,738,130	218,584,100	46,116,436	268,438,666
Overall reports (*n*) (percentage of administrations)				
Janssen	–[†]	25,053 (0.31)	8271 (0.59)	33,324 (0.35)
Moderna	3126 (0.28)	44,996 (0.05)	58,133 (0.33)	106,255 (0.09)
Pfizer-BioNTech	7717 (0.29)	37,549 (0.03)	42,034 (0.16)	87,300 (0.06)
Unknown	21 (2.41)	144 (0.08)	572 (2.27)	737 (0.37)
Total	10,864 (0.29)	107,742 (0.05)	109,010 (0.24)	227,616 (0.08)

[†]The Janssen COVID-19 vaccine was not yet available in 2020

to Janssen. To account for the potential differences in lot size, the total number of reports associated with each lot is adjusted for in the model. An additional limitation of the present study is that the lot-validation information for Pfizer was not available. Since Pfizer is the most widely used vaccine within the United States, this could represent a potential source of sampling bias that might affect our model. The primary future direction to improve the predictive ability of our model is to include the Pfizer vaccine within the validated lot analysis. This would allow our model to be refined based on a truly representative cross-section of the COVID-19 vaccines which have been administered to people throughout the United States.

This novel methodology of cross-referencing VAERS adverse event data with manufacturer lot numbers enabled detailed modeling of adverse events related to COVID-19 vaccination. The initial disparity between model-predicted versus observed adverse events was likely due to the significant heterogeneity of the population that was originally vaccinated – frail, elderly patients in nursing homes and comparatively young, healthy, frontline health-care workers. The model was adjusted with data from further immunizations of progressively younger and likely healthier cohorts, and with this, the accuracy of the model increased significantly.

In many ways, this analysis is among the first of its kind, particularly due to the very high number of VAERS reports available for analysis and to the unprecedented lot lookup tools. Moreover, the drastically different demographic features between the population receiving a COVID-19 vaccine in 2020 and the population receiving one in 2021 led to the generation of two considerably different models. Yet, the observed differences were almost entirely explained by the demographics of the populations included in the analysis. Finally, while long-term safety data continue to be documented, it is important to note that, on a short-term safety assessment, this data review adds to the body of literature that supports that these vaccines are largely safe. Our model is an important step in providing the data that is needed to address vaccine hesitancy.

Authors' Contribution

Alice C. Ceacareanu, and Zachary A.P. Wintrob contributed equally to the study design, data interpretation, and manuscript writing. Alice C. Ceacareanu was responsible with identifying lot number discrepancies and validating lot numbers against public repositories. Zachary A.P. Wintrob was responsible for all data analysis.

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Conflicts of interest

There are no conflicts of interest.

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