HHS Public Access

Author manuscript

Am J Otolaryngol. Author manuscript; available in PMC 2025 November 01.

Published in final edited form as:

Am J Otolaryngol. 2024 ; 45(6): 104448. doi:10.1016/j.amjoto.2024.104448.

Tinnitus after COVID-19 Vaccination: Findings from the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink

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Abstract

Purpose: To assess the occurrence of tinnitus following COVID-19 vaccination using data mining and descriptive analyses in two U.S. vaccine safety surveillance systems.

Methods: Reports of tinnitus after COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) from 2020 through 2024 were examined using empirical Bayesian data mining and by calculating reporting rates. In the Vaccine Safety Datalink (VSD) population, ICD-10 coded post-vaccination medical visits were examined using tree-based data mining, and tinnitus visit incidence rates during post-vaccination days 1–140 were calculated by age group for COVID-19 vaccines and for comparison, influenza vaccine.

Disclaimer: The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Food and Drug Administration.

Ethics approval

This activity was reviewed by the CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy. See e.g., 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C.§3501 et seq.

Results: VAERS data mining did not find disproportionate reporting of tinnitus for any COVID-19 vaccine. VAERS received up to 84.82 tinnitus reports per million COVID-19 vaccine doses administered. VSD tree-based data mining found no signals for tinnitus. VSD tinnitus visit incidence rates after COVID-19 vaccines were similar to those after influenza vaccine except for the group aged ≥65 years (Moderna COVID-19 vaccine, 165 per 10,000 person-years; Pfizer-BioNTech COVID-19 vaccine, 154; influenza vaccine, 135).

Conclusions: Overall, these findings do not support an increased risk of tinnitus following COVID-19 vaccination but cannot definitively exclude the possibility. Descriptive comparisons between COVID-19 and influenza vaccines were limited by lack of adjustment for potential confounding factors.

Keywords

COVID-19 vaccination; tinnitus; vaccine safety

INTRODUCTION

Tinnitus is the perception of ringing or other noise in the ears that does not have an external source. It is a common condition; prevalence estimates vary, but a recent meta-analysis found that tinnitus affects 14% of adults and 24% of older adults globally [1]. Its causes are not fully understood, but there are multiple risk factors for tinnitus, including environmental, infectious, neurophysiological, age-related, and trauma-related factors [2–4]. Concerns have been raised about a possible association between COVID-19 vaccination and tinnitus. A randomized placebo-controlled clinical trial of the Janssen adenovirus-vectored COVID-19 vaccine with approximately 22,000 patients in each arm found 6 tinnitus cases within 28 days of vaccination in the vaccine group versus 0 in the placebo group [5]. Although a causal relationship with the Janssen COVID-19 vaccine could not be determined, tinnitus was listed as an adverse reaction in the Emergency Use Authorization fact sheet for vaccine recipients and caregivers [6]. Tinnitus after COVID-19 vaccination has been the subject of dozens of publications, many of which were case reports, case series, or other small studies, with limited ability to assess risk or evaluate causation [7–19]. The mechanism by which tinnitus might result from vaccination is unknown, but suggested modes of action include an immunological pathophysiology [11]; a hypersensitivity reaction with an abnormal autoimmune response or a vasculitic event [15]; damage to hearing organs via thrombotic complications (after receipt of adenovirus-vectored vaccines) [8]; and multisystem inflammation and organ dysfunction [12].

Two observational epidemiologic studies reached different conclusions. The first, using electronic health record data on more than 2.5 million mRNA COVID-19 vaccine recipients in the U.S., found that 0.038% (95% CI: 0.036%−0.041%) had a new diagnosis of tinnitus within 21 days of receipt of Dose 1 and that there was a lower risk of tinnitus after mRNA COVID-19 vaccine Dose 1 than after influenza, Tdap, or pneumococcal vaccinations [20]. More recently, a self-controlled case series analysis of data from general practices in Australia found an increase in presentations of patients with tinnitus in the 42 days after the AstraZeneca adenovirus-vectored vaccine and the Pfizer-BioNTech and Moderna mRNA vaccines compared with baseline periods [21].

Tinnitus has also been documented in patients infected with SARS-CoV-2 and commonly in those with long COVID [22, 23]. One small study of audiological and vestibular symptoms after SARS-CoV-2 infection and COVID-19 vaccination in children concluded that those recently infected with SARS-CoV-2 had a higher prevalence of tinnitus than the vaccinated [7].

To investigate tinnitus following COVID-19 vaccines, we examined data from two complementary U.S. vaccine safety surveillance systems: the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD).

METHODS

Vaccine Adverse Event Reporting System (VAERS)

VAERS is the U.S. passive vaccine safety monitoring system co-managed by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) and is used to detect potential safety concerns [24]. Empirical Bayesian data mining techniques [25] are routinely used to identify Medical Dictionary for Regulatory Activities (MedDRA) preferred terms [26] reported more often than expected for each vaccine compared with all other vaccines in VAERS. Data mining analysis examines relative reporting ratios by calculating a value called the Empirical Bayes Geometric Mean with a 90% confidence interval (EB05, EB95). An EB05 ≥2 indicates a vaccine-event pair occurs at least twice as often as expected, which was prespecified as a threshold for further evaluation of an adverse event [27]. For COVID-19 vaccines, data mining was performed periodically since 2020. Here we report the results for tinnitus using data accumulated from December 14, 2020 through January 26, 2024.

We also descriptively analyzed reports of tinnitus following COVID-19 vaccination received by VAERS from December 14, 2020 to May 4, 2023, by searching for reports assigned the MedDRA Preferred Term “tinnitus.” Reports were analyzed similarly to VAERS analyses of other outcomes after COVID-19 vaccination [28]. Reporting rates were calculated using vaccine doses administered as the denominator [29].

Vaccine Safety Datalink (VSD)

The VSD is a collaboration between the CDC and several integrated health care organizations (sites) that uses health care encounter data to evaluate vaccine adverse events [30]. The analyses described here used data from eight participating sites, including data on more than 7 million people aged ≥5 years who received at least one COVID-19 vaccine from December 1, 2020, through November 30, 2022. The VSD conducted data mining for medically attended outcomes following COVID-19 vaccines using tree-based scan statistics.

a. Tree-based scan data mining—The VSD tree-based scan statistics (here after referred to as “TreeScan” for short) methods and results for COVID-19 vaccines have been published previously [31–33]. In brief, data from the vaccinated population’s medical encounters during post-vaccine exposure follow-up are scanned to detect statistically unusual clustering of diagnoses within the ICD-10-CM “tree” of diagnoses. Our signal detection work on COVID-19 vaccines used the conditional version of the tree-temporal

variant, conditioning on the number of events observed in each node of the tree as well as on the total number of events occurring during the scanning risk window across the entire tree. This model adjusts for the type of temporal confounding that can occur when there are differences in the volume of general healthcare-seeking behavior over the course of follow-up, e.g., more follow-up visits to specialists shortly after compared with longer after vaccination.

We evaluated the Pfizer-BioNTech, Moderna, and Janssen primary series (during 2020–2021); monovalent boosters (2021–2022); and bivalent Pfizer-BioNTech and Moderna vaccines (2022–2023). Novavax vaccine was not assessed in the VSD due to the relatively small number of doses administered. Our primary analyses were restricted to incident diagnoses (first-in-400-days, considering all settings in the look-back) in either the emergency department or inpatient setting. Outpatient settings were included in supplemental analyses of primary series and bivalent vaccination. To look for temporal clusters of cases in the branches of the ICD-10-CM tree, the scan interval was set to a minimum of 2 days and a maximum of half the follow-up period in length (e.g., 35 days), and clusters could occur anytime during follow-up. The vaccination day (Day 0) was not included in the follow-up period in any analysis. The threshold for statistical significance was pre-specified as a one-sided P value of 0.01. TreeScan software was used for these analyses [34].

In addition to the pre-specified data mining analyses, we did the following two *ad hoc* analyses of tinnitus after COVID-19 vaccination and also after influenza vaccination, which served as a negative control exposure.

b. Temporal scan analyses—We examined the possibility of a statistical association between COVID-19 vaccination and medically attended tinnitus in any visit setting out to 140 days after Dose 1 of the primary series. We defined incident tinnitus as the first visit with ICD-10 code H93.1* without any H93.1* code appearing in the previous 400 days. The date range for eligible vaccines was January 1, 2019, through August 31, 2022. Although COVID-19 vaccines were not widely available until 2021, pre-pandemic time was included to obtain a robust sample size for influenza vaccination. For the COVID-19 vaccines, we anchored these scans on Dose 1 of primary series vaccination only. For influenza vaccines, we anchored on any dose not preceded by another dose in the previous 6 months. Each vaccine was identified irrespective of other vaccine types received concomitantly. Day 0 was not included in the scans.

We conducted a temporal scan analysis for each vaccine using TreeScan software, looking for the most likely cluster of any length between 2 and 70 days at any time during the 140 days. The statistical model in the temporal scan analysis of a single outcome is different from the one used in the conditional tree-temporal scan. There is no overall pattern of healthcare-seeking behavior to check against. Rather, it checks against a uniform risk of the outcome over time. If it detects anything other than a uniform pattern (equal contribution for every day in the follow-up period), then a signal can result.

c. Incidence comparisons—Using the same data on incident medically attended tinnitus in the 140 days after vaccination that were used for the temporal scan analyses, we calculated tinnitus incidence per 10,000 person-years by age group (<18, 18–39, 40–64, and 65+ years of age) after Dose 1 of each COVID-19 vaccine and after influenza vaccine. We used the exact binomial distribution to calculate 95% confidence intervals for incidence estimates. To allow crude comparisons with tinnitus incidences reported in the literature, we converted the values from 140-day follow-up periods to person-years.

RESULTS

VAERS

As of January 12, 2024, data mining did not reveal an elevated EB05 (≥2.0) for the MedDRA Preferred Term “tinnitus” for any COVID-19 vaccine (Table 1).

During December 14, 2020–May 4, 2023, VAERS received 17,859 reports of tinnitus after COVID-19 vaccination. Median patient age was between 51 to 59 years of age for the different vaccines. Median time to symptom onset after vaccination ranged from 1 to 3 days for different vaccines. Table 2 shows additional characteristics of reports of tinnitus following COVID-19 vaccination. The tinnitus reporting rate was greatest after Janssen vaccine (84.82 cases per one million doses administered). Reporting rates for bivalent mRNA COVID-19 vaccines were lower than rates for original monovalent vaccines (Table 2).

VSD

a. Tree-based scan data mining—Among medical visits with tinnitus diagnosis codes following a COVID-19 vaccination, 96% were outpatient visits, therefore the supplemental analyses, which included all settings and were conducted for the primary series and the bivalent vaccines but not for original monovalent boosters, are the most relevant. No statistically significant temporal clusters of tinnitus were found in any analysis (Table 3).

b. Temporal scan analyses—Frequency graphs and temporal scan results for tinnitus medical visits after Dose 1 vaccination are shown in Figure 1. For Pfizer-BioNTech, with 4,353,720 vaccinated and 12,277 incident tinnitus visits, the strongest (i.e., lowest P-value) temporal cluster was in Days 33–84 (compared to the risk in Days 1–32 and 85–140) with a relative risk (RR) of 1.14 (P=0.001). For Moderna, there were 2,572,408 vaccinated and 10,232 visits; the strongest cluster was in Days 41–105, with a relative risk of 1.09 (P=0.01). For Janssen, with 427,895 vaccinated and 1,352 subsequent tinnitus visits there were no statistically significant clusters identified. For Influenza vaccine, there were 8,104,373 vaccinated and 25,083 visits; the strongest cluster was in Days 5–36 with RR of 1.19 (P=0.0001).

Among mRNA COVID-19 vaccinees, 97% received Dose 2 during the 70 days after Dose 1, and approximately three-quarters of Dose 2s were received within 1 day of the recommended spacing after Dose 1, which was 21 days for Pfizer-BioNTech and 28 days for Moderna. In view of this information, the strongest clusters, which started on Day 33

for Pfizer-BioNTech and on Day 41 for Moderna, included tinnitus visits occurring around 12–13 days after Dose 2 for both mRNA vaccines.

c. Incidence comparisons—The incidence of post-vaccination tinnitus medical visits increased with age (Figure 2). Incidence rates in each age group were similar among the three different COVID-19 vaccines evaluated. The incidences following COVID-19 and influenza vaccines were similar in all age groups except among persons aged ≥65 years, where the incidence was lower after the influenza vaccine than after the mRNA COVID-19 vaccines.

DISCUSSION

Data mining using prespecified methods in VAERS and VSD did not signal an increased occurrence of tinnitus for any brand of COVID-19 vaccine in the United States. Because of the interest in this outcome from the public and in the literature, we did additional descriptive analyses for both systems, which also did not show a consistent pattern of increased risk.

VAERS is a system used primarily for signal detection. Since COVID-19 vaccines became available, the majority of VAERS reports have been for COVID-19 vaccines, which is unprecedented compared to pre-pandemic reporting. This might limit signal detection capability for COVID-19 vaccines using Empirical Bayesian data mining because disproportionality scores may be driven towards the null [35].

Comparing VAERS reporting rates to background rates from other sources is an alternative approach to signal detection. The VAERS tinnitus reporting rate was highest for the Janssen vaccine, followed by Novavax, and then the two mRNA COVID-19 vaccines. These differences in reporting rates between products might have been influenced by confounding factors. The higher reporting rate after Janssen might have been stimulated by the information about tinnitus in the Janssen fact sheets [5, 6]. The higher reporting rate after Novavax might reflect more complete reporting for this vaccine which had a relatively smaller number of doses administered nationally. The VAERS tinnitus reporting rate after the Janssen vaccine was 85 reports per million doses, which is lower than the rate observed in the Janssen phase 3 clinical trial of 274 events per million doses (based on 6 events within 28 days of vaccination among 21,895 Janssen COVID-19 vaccine recipients) [5]. The population background rate of tinnitus among adults was estimated to be 11,640 cases per million person-years in a systematic review and meta-analysis [1], which means that on average, 32 new cases of tinnitus would occur each day among 1 million people. In VAERS, half of tinnitus reports after the Janssen vaccine stated symptom onset was on the day of vaccination or the day after, which equates to 42 events per million doses over a two-day period, which is less than the expected average background rate of 64 cases per million people over a two-day period. The VAERS reporting rates of tinnitus following COVID-19 vaccination for all manufacturers and doses are lower than the expected background rate. However, VAERS data are subject to the general limitations of passive surveillance in which underreporting is typical (particularly for outcomes not involving hospitalization or ED

visits), and adverse events soon after vaccination are more likely to be reported than events that occur later.

In the VSD tree-based data-mining analyses, there was no statistical signal for tinnitus. Applying the conditional self-controlled tree-temporal TreeScan variant to post-vaccination ICD-10-CM diagnosis data, we found no temporal clusters of medically attended tinnitus diagnoses in the respective pre-specified follow-up period after any of the authorized COVID-19 vaccines studied (70 days after mRNA COVID-19 vaccine Dose 1; 56 days after Janssen, monovalent mRNA boosters, and bivalent mRNA doses). The *ad hoc* temporal scans of cases in 140 days of follow-up, which involve no adjustment for overall patterns in post-vaccination healthcare-seeking behavior, found statistically significant 7–9-week-long clusters of tinnitus after Dose 1 of the mRNA COVID-19 vaccines, but the relative risks were minimally elevated (~1.1) compared with the risk during the time periods outside of the clusters and within the 140-day follow-up period. These clusters started on Days 33 and 41 after Pfizer-BioNTech and Moderna COVID-19 vaccines, respectively, approximately 12–13 days after Dose 2 would have been received by many vaccinees. This pattern was not seen with the Janssen vaccine, where the sample size was smaller and there was no Dose 2 as part of the primary vaccination series.

The seasonal influenza vaccine was examined as a negative control exposure to assess for the presence of potential residual confounding in the temporal scan analysis. The presence of a cluster after influenza vaccine (RR=1.19) for which no association is expected suggests residual confounding in this analysis, therefore the lower relative risk estimates for the clusters after Pfizer-BioNTech (RR=1.14) and Moderna (RR=1.09) vaccines may also be due to residual confounding.

Among the different analyses presented in this paper, the VSD age-specific incidence rate analysis may provide the most valid comparison among the different COVID-19 vaccine brands and influenza vaccines (which have not been generally suspected to cause tinnitus). In the 18–39-year age group, the 95% confidence intervals of the four vaccine groups all overlapped with each other. In the 40–64 and ≥65-year-old age groups, tinnitus incidence after Moderna (with point estimates for the two age groups of 102.7 and 165.2 per 10,000 person-years, respectively) was found to be somewhat higher than after Pfizer-BioNTech (with point estimates of 95.4 and 154.0 per 10,000 person-years, respectively); incidences after both Moderna and Pfizer-BioNTech were higher than after influenza vaccination for the ≥65-year group (Figure 2). However, the three COVID-19 and influenza vaccines had different dosing schedules, were given during different time periods, and possibly given to people with different risk factors, which limit the interpretation of small differences in this descriptive analysis which were stratified by age but were not adjusted for other possible confounding variables. The population background rate of tinnitus meta-analysis mentioned above estimated an incidence of 116 cases per 10,000 person-years (95% CI: 48–283), the 95% confidence interval of which encompasses those of the VSD post-vaccination incidences [1]. In contrast, a single study of first-time general practitioner-recorded tinnitus in the United Kingdom during 2000–2016 found an age-standardized incidence of 25.0 cases per 10,000 person-years (95% CI: 24.6–25.5) [36], which was lower than what we observed. However, it is difficult to usefully compare the results of studies that use different

outcome definitions and are based on populations with different age structures. The VAERS reporting rates and the VSD incidence rates are also not directly comparable due to several factors, including (1) that VAERS can capture any event while VSD captures only medically attended events, (2) that VAERS relies on events reported by patients and clinicians while VSD captures only medically attended events in a specified follow-up period, and (3) the lack of a uniform risk interval.

Limitations of the VSD TreeScan, temporal scan, and incidence analyses include the following: (1) events occurring after vaccination on the day of the index vaccination (Day 0) were not included due to the inability to distinguish whether they had occurred before or after vaccination, (2) the analyses included only medically attended events, (3) the putative cases of incident tinnitus were not chart-confirmed, (4) the time between symptom onset and the medical encounter where the tinnitus diagnosis code was recorded could not be determined from available data, and (5) the analyses using data from the primary series were anchored on Dose 1, meaning that the timing of tinnitus diagnoses after Dose 2 was merely inferred from aggregate data on compliance with the recommended spacing between Doses 1 and 2 rather than being determined precisely.

CONCLUSIONS

Taken together, these findings do not support an increased risk of tinnitus following COVID-19 vaccination. The data mining methods used here previously identified an increased risk of myopericarditis following the Pfizer-BioNTech COVID-19 vaccine primary series [33], which is a less common condition than tinnitus. However, the lack of a signal for tinnitus does not definitively exclude the possibility of an association. Although our temporal scans found elevated RRs, temporal association alone is insufficient evidence of a causal association. Tinnitus is a common condition, and many cases would be expected to occur by chance alone following vaccination of a large population, which complicates its study as a potential vaccine-associated adverse event.

ACKNOWLEDGMENTS

The authors wish to thank Dr. Conrad A. Fung for calculating the exact binomial confidence intervals around the VSD post-vaccination tinnitus incidence estimates.

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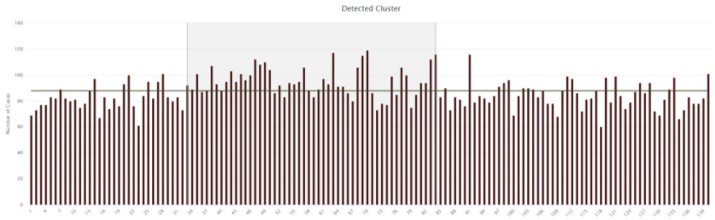
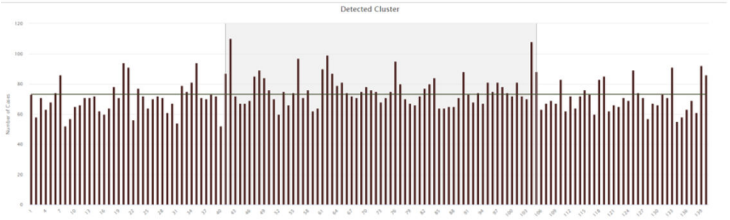
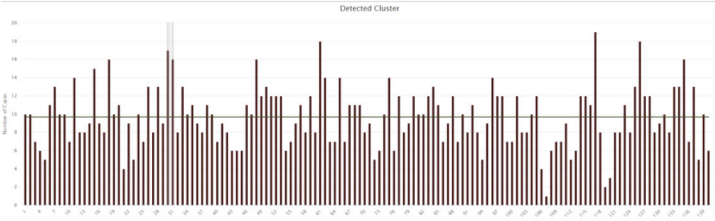
A. Pfizer-BioNTech COVID-19 vaccine: 4,353,720 doses; 12,277 cases; most likely cluster post-vaccination Days 33-84, RR=1.14, p=0.0001



B. Moderna COVID-19 vaccine: 2,572,408 doses; 10,232 cases; most likely cluster post-vaccination Days 41-105, RR=1.09, p=0.0099



C. Janssen COVID-19 vaccine: 427,895 doses; 1,352 cases; no statistically significant clusters



D. Influenza vaccine, 2019-2022: 8,104,373 doses; 25,083 cases; most likely cluster post-vaccination Days 5-36, RR=1.19, p=0.0001

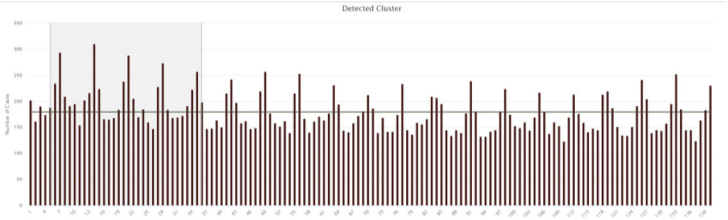


Figure 1.

Temporal scan cluster detection based on frequency of tinnitus coded medical visits (ICD-10-CM code H93.1) after Dose 1 of Pfizer-BioNTech, Moderna, or Janssen COVID-19 primary vaccination, or after influenza vaccination in the Vaccine Safety Datalink, January 1, 2019 through August 31, 2022.

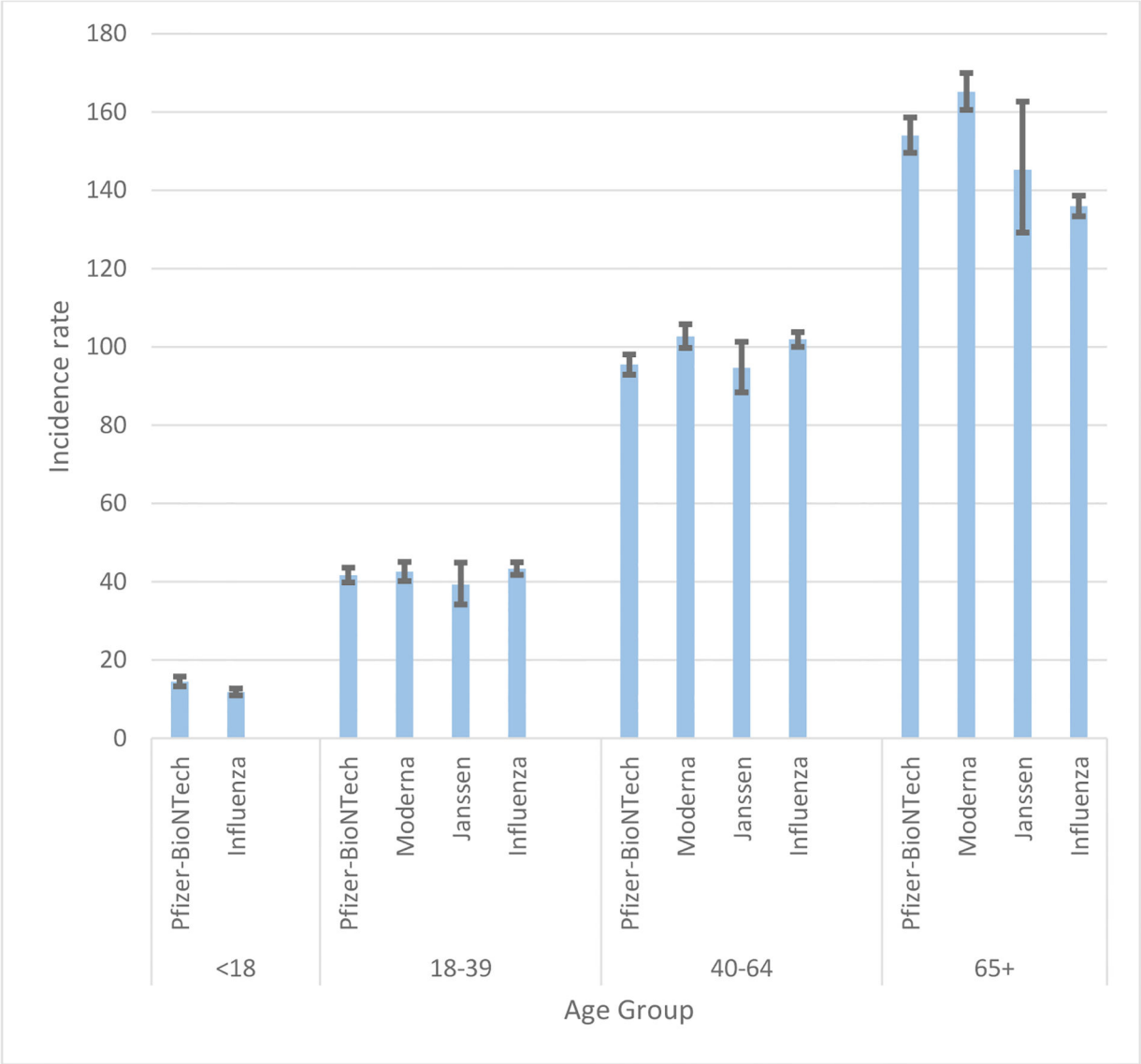


Figure 2.

Vaccine Safety Datalink. Incidence per 10,000 person-years of tinnitus coded medical visits (ICD-10-CM code H93.1) during the 140 days following Dose 1 of COVID-19 vaccine or influenza vaccine by age group and vaccine type with exact binomial 95% confidence intervals. The date range for eligible doses was January 1, 2019, through August 31, 2022.

Table 1.

Vaccine Adverse Event Reporting System (VAERS) data mining assessment for disproportionate reporting of tinnitus with COVID-19 vaccines.*

Vaccine	VAERS reports, n	EBGM	EB05	EB95	Signal
COVID-19 Pfizer-BioNTech	9024	1.225	1.204	1.246	no
COVID-19 Moderna	6753	0.869	0.852	0.887	no
COVID-19 Janssen	1577	1.158	1.111	1.207	no
COVID-19 Novavax	12	1.383	0.916	2.023	no
COVID-19 Pfizer-BioNTech bivalent	278	0.721	0.653	0.794	no
COVID-19 Moderna bivalent	194	0.771	0.685	0.864	no

Abbreviations: EBGM, Empirical Bayes Geometric Mean; EB05, the lower 90% confidence interval limit of the EBGM; EB95, the upper 90% confidence interval limit of the EBGM.

*Data mining used the Multi-Item Gamma Poisson Shrinker method. Analysis was stratified by sex, age group, and year report received. VAERS data included cumulative U.S.-only reports received from December 14, 2020 through January 26, 2024. A signal was defined as an EB05 ≥2, which indicates that the reporting rate for a vaccine and adverse event pair-wise combination is mathematically higher-than-expected.

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Table 2.

Characteristics of Vaccine Adverse Event Reporting System (VAERS) reports that include tinnitus following COVID-19 vaccination, by vaccine manufacturer* and formulation, December 14, 2020–May 4, 2023.

	Original monovalent COVID-19 vaccines				Bivalent COVID-19 vaccines (2022–2023)	
Characteristic	**Pfizer-BioNTech (N=9062)**	**Moderna (N=6744)**	**Janssen (N=1592)**	**Novavax (N=6)**	**Pfizer-BioNTech (N=255)**	**Moderna (N=178)**
Age, median (interquartile range)	52 (41–62)	55 (45–64)	51 (41–59)	53.5 (39–58)	59 (46–66)	56.5 (43–66.5)
Sex						
Female	5357 (59.1%)	4064 (60.3%)	864 (54.3%)	5 (83.3%)	160 (62.7%)	103 (57.9%)
Male	3560 (39.3%)	2607 (38.7%)	679 (42.7%)	1 (16.7%)	90 (35.3%)	69 (38.8%)
Sex not reported	145 (1.6%)	73 (1.1%)	49 (3.1%)	0 (0.0%)	5 (2.0%)	6 (3.4%)
COVID-19 vaccine given alone without other vaccines on the same day	8927 (98.5%)	6655 (98.7%)	1586 (99.6%)	6 (100.0%)	216 (84.7%)	150 (84.3%)
Median time to symptom onset, days (interquartile range)	2 (0–8)	2 (0–12)	1 (0–7)	1 (1–2)	2 (1–19)	3 (1–25)
Classified as serious†	1343 (14.8%)	871 (12.9%)	219 (13.7%)	3 (50.0%)	36 (14.1%)	24 (13.4%)
Disability or permanent damage	1170 (12.9%)	719 (10.7%)	163 (10.2%)	3 (50.0%)	29 (11.4%)	19 (10.7%)
Medical care ǂ						
Hospitalization	221 (2.4%)	166 (2.5%)	62 (3.9%)	0 (0%)	6 (2.4%)	5 (2.8%)
ED or urgent care	993 (11.0%)	623 (9.2%)	235 (14.7%)	0 (0%)	20 (7.8%)	24 (13.5%)
Office/clinic visit	4346 (48.0%)	2954 (43.8%)	647 (40.6%)	6 (100%)	122 (47.8%)	98 (55.1%)
Reporting rate **						
Doses administered	363,525,233	229,197,530	18,770,063	89,195	36,200,660	20,546,586
Reports per million doses administered	24.93	29.42	84.82	67.27	7.04	8.66

*Twenty-two reports had no information on manufacturer of COVID-19 vaccine

†"Serious" reports are defined by the Code of Federal Regulations to include reports of hospitalization, prolongation of existing hospitalization, life-threatening illness, death, permanent disability, and congenital deformity [32]. A report can contain more than one adverse event, so tinnitus was not necessarily the reason a report was classified as serious.

ǂCategories are not mutually exclusive.

**Any apparent quantitative differences in reporting rates between vaccine types should be interpreted with caution because the rates do not adjust for potential differences in the vaccinated groups such as age, sex, medical comorbidities, or other factors which may influence reporting.

Table 3.

Vaccine Safety Datalink TreeScan data mining analyses results for tinnitus coded medical visits (ICD-10-CM code H93.1), by vaccine manufacturer and formulation.

Vaccine	Formulation / dose	Time period	Number of doses	Follow-up period	Primary analysis: Potential cases ascertained in ED and inpatient settings only	Supplemental analysis: Potential cases ascertained in ED, inpatient, and outpatient settings
Pfizer-BioNTech	Primary series, follow-up anchored on Dose 1	12/2020 to 12/2021	4,068,513 (Dose 1)	70 days	240 cases. No clusters of tinnitus found (P=1) *	3779 cases. No clusters of tinnitus found (P=0.9999)
Pfizer-BioNTech	Monovalent booster after mRNA COVID-19 vaccination	9/24/2021 to 4/2/2022	2,467,865	56 days	121 cases. No clusters of tinnitus found (P=1)	This supplemental analysis not done
Pfizer-BioNTech	Bivalent vaccine	8/2022 to 11/2022	979,189	56 days	32 cases. No clusters of tinnitus found (P=0.6921)	1220 cases. No clusters of tinnitus found (P=1)
Moderna	Primary series, follow-up anchored on Dose 1	12/2020 to 12/2021	2,559,563 (Dose 1)	70 days	104 cases. No clusters of tinnitus found (P=1)	3053 cases. No clusters of tinnitus found (P=1)
Moderna	Monovalent booster after mRNA COVID-19 vaccination	9/24/2021 to 4/2/2022	1,873,849	56 days	97 cases. No clusters of tinnitus found (P=1)	This supplemental analysis not done
Moderna	Bivalent vaccine	8/2022 to 11/2022	352,509	56 days	15 cases. No clusters of tinnitus found (P=1)	454 cases. No clusters of tinnitus found (P=1)
Janssen	Primary dose	12/2020 to 12/2021	417,854	56 days	19 cases. No clusters of tinnitus found (P=1)	334 cases. No clusters of tinnitus found (P=1)
Janssen	Monovalent booster after initial Janssen vaccination	10/21/2021 to 4/2/2022	65,238	56 days	1 case. No clusters of tinnitus found (P=1)	This supplemental analysis not done

* P = 0.01 was pre-specified as the cut-off for statistical significance of clusters.