

# Letters

## RESEARCH LETTER

### Preliminary Analysis of Association Between COVID-19 Vaccination and Sudden Hearing Loss Using US Centers for Disease Control and Prevention Vaccine Adverse Events Reporting System Data

Many vaccine-related adverse events are associated with otolaryngologic manifestations. In particular, the incidence of sudden sensorineural hearing loss (SSNHL) was examined after influenza vaccination in a large-scale study that demonstrated no association between vaccination and the rate of SSNHL.<sup>1</sup> Anecdotal reports are rapidly emerging from the otolaryngology community of SSNHL occurring after inoculation by SARS-CoV-2 vaccines that are currently in use in the US under US Food and Drug Administration Emergency Use Authorizations. Recognizing the important public health implications of any association between COVID-19 vaccination and SSNHL, and motivated by patients who presented to our practice (Johns Hopkins University; Baltimore, Maryland) with audiometrically confirmed unilateral SSNHL that occurred within 24 hours of COVID-19 vaccination, we sought to (1) estimate the national incidence of SSNHL after COVID-19 vaccination using data from the Vaccine Adverse Events Reporting System (VAERS) maintained by the US Centers for Disease Control and Prevention (CDC) and (2) compare this with the expected incidence of SSNHL in the wider population.<sup>2</sup>

**Methods** | This study was determined to be exempt from institutional review board approval by Johns Hopkins University because it used publicly available, deidentified data. The CDC VAERS is a national repository of incident reports associated with adverse reactions that occur after any vaccination.<sup>3</sup> Any individual may submit a report, and all

reports are publicly available. This database was queried for adverse events in which sudden hearing loss, deafness, deafness unilateral, deafness neurosensory, and hypoacusis were listed as an adverse event from vaccinations administered between December 14, 2020, and March 2, 2021, which yielded 147 reports after deduplication. The narrative and laboratory results section of each report were reviewed. A subset of all incidents found to have a temporal association (onset of hearing loss occurred within 3 weeks of vaccination) and high credibility of reporting (eg, reported by a health care clinician with documentation of audiologic findings or steroid treatment) were classified as *most likely* (n = 40; 25 women [63%]). We then estimated the incidence of SSNHL that occurred after vaccination on an annualized

**Table. Demographic and Clinical Characteristics of Hearing Loss Incidents for 40 Individuals<sup>a</sup> After Receipt of COVID-19 Vaccine Dose As Reported in the Vaccine Adverse Events Reporting System Between December 14, 2020, and March 2, 2021<sup>b</sup>**

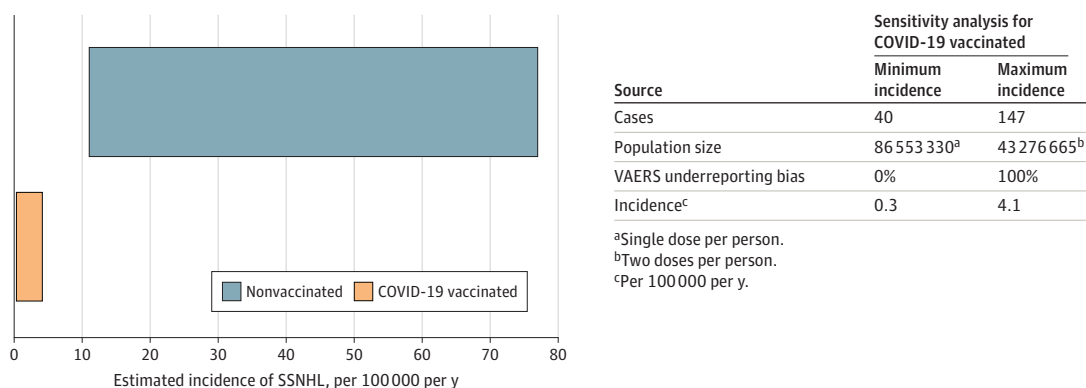
Characteristic	No. (%)
Mean age (range), y	56 (25-88)
Sex	
Women	25 (63)
Men	15 (37)
Manufacturer	
Pfizer	28 (70)
Moderna	12 (30)
Mean SSNHL onset after vaccine dose (range), d	4 (0-21)
Steroid treatment	30 (75)

Abbreviation: SSNHL, sudden sensorineural hearing loss.

<sup>a</sup> Incidents classified as *most likely* based on temporal association and high credibility of reporting.

<sup>b</sup> A total of 86 553 330 vaccine doses were administered.

**Figure. Comparison of Estimated Incidence Range of Sudden Sensorineural Hearing Loss (SSNHL) That Occurred After COVID-19 Vaccination**



Based on Vaccine Adverse Events Reporting System (VAERS) reports of known SSNHL incidence, with an associated sensitivity analysis underlying determination of incidence estimates for the COVID-19 vaccine cohort.

basis, performed a sensitivity analysis of this estimate, and compared our findings with known incidence of SSNHL in the wider population.<sup>2</sup>

**Results** | Between December 14, 2020, and March 2, 2021, 86 553 330 SARS-CoV-2 vaccine doses were administered in the US.<sup>4</sup> Demographic and clinical characteristics of reported “most likely” cases of SSNHL are shown in the **Table**. Because VAERS reports are unverified, susceptible to under-reporting bias,<sup>5</sup> and the number of unique individuals within the vaccine cohort is not known exactly, we performed a sensitivity analysis and estimated a minimum and maximum incidence by tuning these assumptions. The results of these incidence estimates compared with the known population incidence of SSNHL are presented in the **Figure** and demonstrate that the incidence of SSNHL occurring after COVID-19 vaccination does not exceed that of the general population, and may be lower.

**Discussion** | The CDC VAERS is a unique and important tool for postmarket surveillance, which has allowed systematic research in vaccine safety on a national scale.<sup>6</sup> These preliminary findings of VAERS data in the early phase of societal COVID-19 vaccination using 2 messenger RNA vaccines suggest that no association exists between inoculation with a SARS-CoV-2 messenger RNA vaccine and incident sudden hearing loss. While the reporting period did not include other vaccines that are currently in use, we hope these findings will reassure health care clinicians and patients to receive all scheduled doses of the vaccination as recommended by current public health guidelines. We urge clinicians to rigorously report all possible adverse events to VAERS<sup>3</sup> to allow identification of sentinel trends and systematic vaccine safety studies. Timely and detailed reporting to VAERS will be critical in studying whether specific patient characteristics (eg, sex, comorbid autoimmune disease, and history of preexisting labyrinthine conditions [such as Ménière disease]) may be associated with an elevated risk of hearing loss or other otolaryngologic adverse events.

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