# Minimizing public susceptibility to misconceptions about the effects of vaccination: Vaccine Adverse Event Reporting System (VAERS)

A report of the Annenberg Public Policy Center in partnership with Critica

May 24, 2023





CRITICA



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# What is the Vaccine Adverse Event Reporting System (VAERS)?



#### What is VAERS?



- VAERS is "a national program managed by" the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) "to monitor the safety of all vaccines licensed in the United States."
- "VAERS collects and reviews reports of adverse events that occur after vaccination."

(CDC, n.d., VAERS Fact Sheet)

# Why VAERS matters

By facilitating work to identify and investigate patterns of unanticipated possible side effects, however unusual or rare, VAERS makes both early detection of complications and responsive action possible. Not only are healthcare providers required by law to report worrisome post-vaccination events, but the CDC encourages everyone, whether a health care provider or not, to report possible negative side effects from vaccination, even if it's unclear whether the vaccine caused them. In short, the bias in the system is toward disclosure.

Health experts mine the resulting avalanche of data for rare but medically significant vaccination complications not detected during clinical trials. The collection process also facilitates the tracking of anticipated ones. When investigation confirms a probable causal relationship between vaccination and the reported event, federal health experts advise health care providers to keep an eye out for that complication and offer them clinical guidance about ways to respond should such a case present itself. In addition, signals found in VAERS data have, on rare occasion, lead to withdrawal of a vaccine from the market in the United States. For example, in the late 1990s, the RotaShield vaccine against rotavirus – which causes severe diarrhea in infants and young children – was withdrawn after VAERS reports of "intussusception (a type of bowel obstruction that occurs when the bowel folds in on itself) among 15 infants" who had received that vaccine (CDC, 1999; see also Simonson et al, 2005).



# VAERS definitions and limitations



## What is an "adverse event"?

The CDC defines an adverse event as: "any health problem or 'side effect' that happens after a vaccination."

(CDC, n.d., VAERS Fact Sheet)



# Who can *submit* reports to VAERS?

VAERS reports can be submitted to the system by **anyone**, including:

- patients
- · family members
- healthcare providers
- · vaccine manufacturers
- · the general public

(CDC, n.d., VAERS Fact Sheet)









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# What are the *limitations* of VAERS?



- Reports "may contain information that is incomplete, inaccurate, coincidental, or unverifiable"
- Number of reports in VAERS alone cannot be interpreted as:
  - "evidence of a causal association between a vaccine and an adverse event"
  - "evidence about the existence, severity, frequency, or rates of problems associated with vaccines"
- Use of aggregated VAERS data has limitations and "should always be interpreted with these limitations in mind"

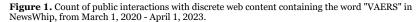
(CDC, n.d., VAERS Data)

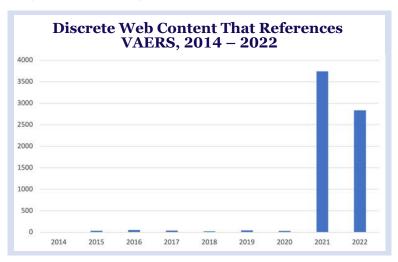


# VAERS became a fixture of the social media vaccination dialogue during the COVID-19 pandemic

The Vaccine Adverse Event Reporting System (VAERS) was not a routine part of the social media dialogue in the early months of the pandemic. A search of NewsWhip Analytics<sup>1</sup> for English language web items that contain the word "VAERS" yields no results with interactions before November 2020 (see Figure 3). As Figure 1 indicates, there were relatively few web references to VAERS at all before the onset of the COVID-19 pandemic. In November 2020, when the public learned that authorization of COVID-19 vaccinations was in the offing, VAERS references spiked (see Figures 1 and 2).

To determine whether mentions of VAERS contextualized the nature of its data, APPC researchers began by collecting social media data on the amount of content and level of engagement from March 1, 2020, to April 1, 2023, by searching NewsWhip Analytics for English-language articles and posts that contain the word "VAERS." 6,993 items were located, as were 1,256,701 interactions with 2,462 of them (4,531 had no interactions). The level of interaction elicited by these items is reflected in Figure 3. Although NewsWhip reported the existence of content prior to November 2020, it reported no interaction with those items.

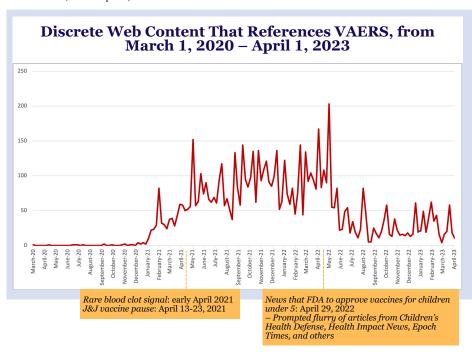




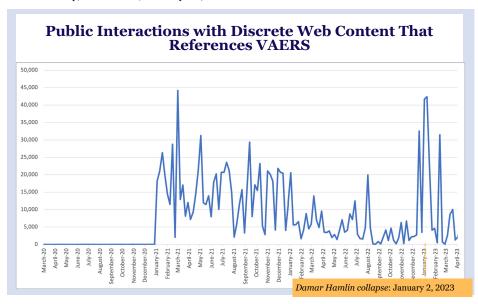
1. NewsWhip Analytics is an archive of public engagement measures on web and social data going back to 2014, which tracks discrete web content and public engagement with it. NewsWhip reports that it is "currently tracking content from over 500,000 websites [and that] [t]his database of websites is made up of online publications, and also blogs and websites..." It indicates as well that it tracks "content from certain blogs or websites that have a news or press releases section" (response to query made of NewsWhip support desk, April 26, 2023). Total interactions is the number of likes, shares, and comments an article receives on Facebook, Twitter influencer shares, and the number of Pinterest pins it receives.



**Figure 2.** Count of discrete web content in NewsWhip containing the word "VAERS" over time, from March 1, 2020 - April 1, 2023.



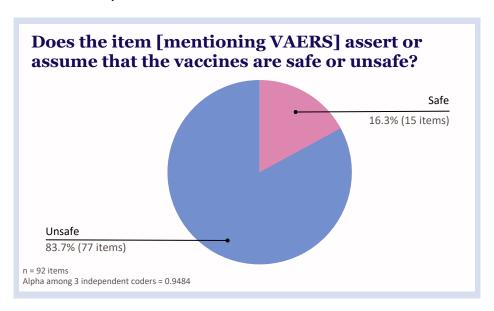
**Figure 3.** Count of public interactions with discrete web content containing the word "VAERS" in NewsWhip, from March 1, 2020 - April 1, 2023.





Three independent coders with a Krippendorff reliability alpha of 0.9484 (for content analysis in Figure 4) and 0.9828 (for content analysis in Figure 5) sampled 100 randomly-drawn items from the results of the NewsWhip search for web items containing the acronym "VAERS" published between March 1, 2020, and April 1, 2023.<sup>2</sup> Since eight of the 100 were no longer available, 92 items were coded. Just 16% (15 items) of the 92 items asserted or assumed that the vaccines are safe.

**Figure 4.** Content analysis of 92 items randomly drawn from a corpus of 6,993 items identified by NewsWhip as including the acronym "VAERS," March 1, 2020, to April 1, 2023. Items that simply listed incidents reported in VAERS were coded as "unsafe."



2. Methods. A sample of **100 items**, randomly drawn from the 6,993 identified by the NewsWhip analytics search as mentioning VAERS, was coded by three independent coders with a Krippendorff reliability alpha of 0.9484 (Figure 4) and 0.9828 (Figure 5). To draw this random sample, each row in the aggregated NewsWhip Analytics spreadsheet that had more than 0 interactions was given a cell with a RAND() function. The RAND() function uses a Mersenne Twister algorithm to generate a random number between 0 and 1 to the sixth decimal place. The sheet was sorted by this value (low to high), and the top 100 results were selected. 8 of the 100 items were no longer available, so 92 total items were coded. Coders confirmed that these 92 items did mention VAERS (Krippendorff alpha = 1.0000). Those items were then coded for type of mention. Mentions were coded as either containing one or more accurate descriptions of the nature of VAERS content, including those items that fact-checked claims that mischaracterized VAERS data, or as not containing an accurate description of the nature of VAERS data, including inaccurate descriptions and list data without a description. All items mentioning VAERS also were coded to indicate whether the article asserted or assumed that vaccines were safe or unsafe.



The content analysis revealed that just 26% (24 items) of the 92 items include an accurate description of the nature of VAERS content, regardless of tone. Of that 26%, half of the items (12) were fact-checks.

Some examples of accurate descriptions of the nature of VAERS content include:

- "Reports submitted to VAERS require further investigation before a causal relationship can be confirmed."
- "But instead, he questioned whether or not VAERS was actually reporting this, which led to a
  canned response by both Walensky and Fauci that VAERS is not reliable, because someone
  can get the vaccine and then walk outside and get hit by a car, and that is recorded as a
  vaccine death."

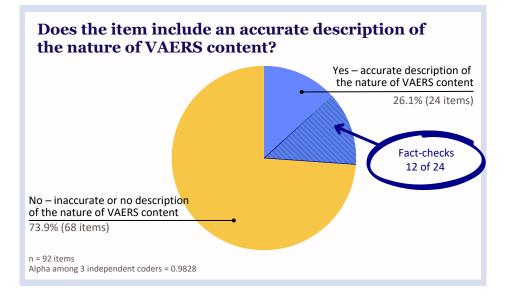
Examples of items not containing an accurate description of the nature of VAERS content include:

- o "The U.S. Government's Vaccine Adverse Events Reporting System (VAERS) database was updated this past Friday, March 11, 2022, and it is now reporting that there have been 1,168,894 cases of injuries and deaths following COVID-19 vaccines since December of 2020, when the FDA issued emergency use authorizations for the COVID-19 vaccines."
- "Halligan looked at data in the government's Vaccine Adverse Event Reporting System (VAERS) to come up with the 20 million dead and 2.2 billion injured figures. Since VAERS only captures a very small percentage of actual vaccine-related adverse events, Halligan extrapolated true figure estimates using multiplication."

The coding process located evidence that some who cite VAERS are aware of factcheckers' concerns, for example:

"Before going any further, as not to set off the 'fact checkers,' it is important to point out that
just because data is submitted to the CDC through VAERS, this does not in anyway mean that
these reactions are related to the COVID-19 vaccine.

**Figure 5.** Content analysis of 92 items randomly drawn from a corpus of 6,993 items identified by NewsWhip as including the acronym "VAERS," March 1, 2020, to April 1, 2023.





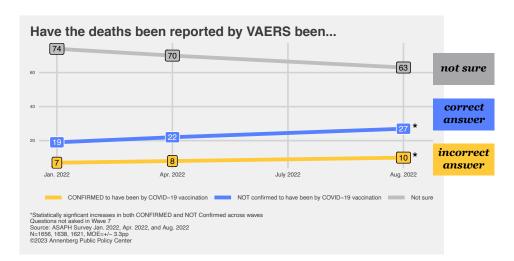
# Susceptibility to misconceptions about side effects that draw on VAERS data

Public susceptibility to misconceptions about vaccination is increased by confusion about the nature of the events reported to VAERS.

# Public confusion about whether events reported in VAERS are necessarily vaccine-caused

Figure 6 (below) shows that most Americans are not sure whether deaths reported in VAERS are confirmed to have been caused by COVID-19 vaccination. Notably, both the percentage incorrectly reporting that VAERS data register confirmed deaths and those correctly responding that the deaths registered in VAERS are not confirmed increased significantly between January 2022 and August of the same year. However, the percent that was unsure remained high, with 6 out of 10 indicating that that was the case.

**Figure 6.** Polling data showing public knowledge about whether deaths after vaccination against COVID-19 reported into VAERS have been confirmed to have been caused by the vaccine or not. Source: The Annenberg Public Policy Center's Annenberg Science and Public Health Knowledge Monitor (ASAPH). See Appendix for full methodology.



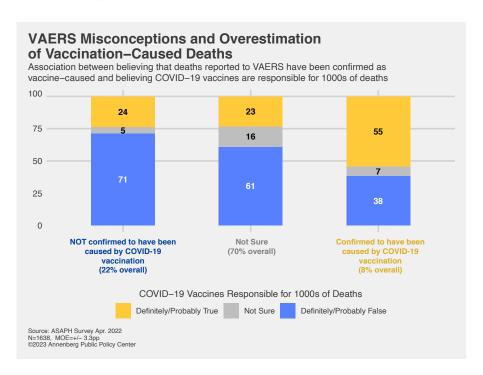


Belief that deaths reported in VAERS are confirmed is positively associated with the belief that "COVID-19 vaccines have been responsible for thousands of deaths in the U.S." It remains a positive predictor when we control for general vaccine misinformation items in Romer et al (2022).

In other words, according to our April 2022 survey data:

- Of the 22% of people in our overall sample who know that deaths reported in VAERS
  are not confirmed to have been caused by Covid-19 vaccination (the first bar in Figure
  7), most within this group (71%) also know it is false to say that Covid-19 vaccines are
  responsible for thousands of deaths.
- Among the 70% of our overall sample who are not sure whether deaths in VAERS are
  confirmed to have been caused by vaccines (second bar), a smaller majority (61%) also
  know it is false to claim that Covid-19 vaccines are responsible for thousands of deaths.
- But among the small group of people (8% overall) who believe that VAERS deaths are confirmed to have been caused by Covid-19 vaccines, more than half (55%) think it is true to say Covid-19 vaccines have caused thousands of deaths.

**Figure 7.** Polling data showing association between believing that deaths reported to VAERS are necessarily vaccine-caused and that COVID-19 vaccines are responsible for 1000s of deaths. Source: The Annenberg Public Policy Center's Annenberg Science and Public Health Knowledge Monitor (ASAPH). See Appendix for full methodology.





# <u>The difference between reported deaths in VAERS and CDC-confirmed, causally-associated deaths</u>

**Raw data: 3,362 reported deaths.** On Tucker Carlson Tonight on May 5, 2021, the then-Fox News host presented what he referred to as "the apparent death rate from the coronavirus vaccines," citing data from VAERS (AFP, 2021).

"Between late December of 2020 and last month, a total of 3,362 people apparently died after getting the COVID vaccine in the United States, 3,362. That's an average of roughly 30 people every day. So what does that add up to? By the way, that reporting period ended on April 23 and we don't have numbers past that. Not quite up to date. But we can assume that another 360 people at that rate have died in the 12 days since. You put it all together and that is a total of 3,722 deaths. **That's almost 4,000 people who died after getting the COVID vaccines.** The actual number is almost certainly higher than that, perhaps vastly higher than that. The data we just cited come from the Vaccine Adverse Events Reporting System, VAERS" (emphasis added).



Confirmed after investigation as of April 2021: zero causally-associated deaths. At the time Carlson made his claim, the CDC's most recent report from April 26, 2021, report indicated that its "review of available clinical information including death certificates, autopsy, and medical records revealed no evidence that vaccination contributed to patient deaths" (CDC, 2021, April 26).

# Raw data as of March 7, 2023: 19,476 reported deaths. Confirmed after investigation as of March 7, 2023: 9 causally-associated deaths.

The CDC continues to review reports of adverse events made to VAERS. As of March 7, 2023, the CDC updated their statement to reflect the fact that just "nine deaths causally associated with J&J/Janssen COVID-19 vaccination" had been identified as of that date (CDC, 2023, March 7).

• Reports of death after COVID-19 vaccination are rare. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. More than 672 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through March 1, 2023. During this time, VAERS received 19,476 preliminary reports of death (0.0029%) among people who received a COVID-19 vaccine. CDC and FDA clinicians review reports of death to VAERS including death certificates, autopsy, and medical records. Continued monitoring has identified nine deaths causally associated with J&J/Janssen COVID-19 vaccination. CDC and FDA continue to review reports of death following COVID-19 vaccination and update information as it becomes available.

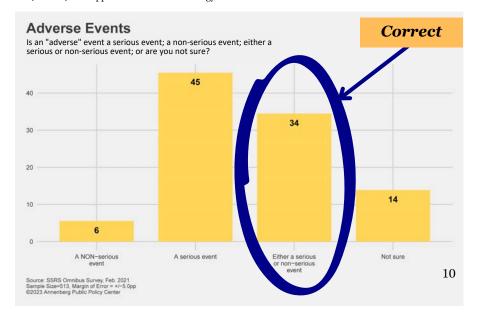


# Public confusion about whether adverse events are necessarily serious



# Only a third of the public (34%) knows that an "adverse event" as used in the named "VAERS" can be either a serious or non-serious event

**Figure 8.** Polling data showing public knowledge about the severity of "adverse events." Source: The Annenberg Public Policy Center's Annenberg Science and Public Health Knowledge Monitor (ASAPH). See Appendix for full methodology.





# Problems with the Vaccine Adverse Event Reporting System's name

There are three key problems with the name "Vaccine Adverse Event Reporting System" and public understanding of the data contained in the system:

- **Problem 1.** The name asserts a relationship between the vaccine and the event, when there is not necessarily any relationship at all.
- **Problem 2.** By drawing attention to adverse events, the name adopts a risk rather than a safety frame
- **Problem 3.** Adverse event makes the event sound serious. But both serious and non-serious events are included in the VAERS database.



# Misconceptions about VAERS fuel vaccine deceptions

In a video that elicited over 30,000 views before Instagram took it down in the spring of 2021, a female narrator invites a false inference about reports in the Vaccine Adverse Event Reporting System (VAERS), an alert system managed by the Centers for Disease Control and Prevention and the Food and Drug Administration to detect possible safety issues in vaccines (Jaramillo, 2021/2022). "Acute myocardial infarction," she says while pointing to a VAERS report. "That is a stroke, if you guys aren't aware of what that means."

Unmindful that a myocardial infarction is actually a heart attack, she scrolls through dozens of reported post-vaccination deaths: "Death. And here we are y'all — this is exactly what you guys wanted to see. Death. Patient passed away in her sleep. Look at all these deaths you guys," she notes (<u>Jaramillo</u>, 2021). The flawed implication is that the reported strokes and deaths were caused by a COVID-19 vaccine. Hers is not an isolated instance of VAERS abuse.

"[O]ver and over websites and social media posts improperly cite unverified raw data from the Vaccine Adverse Event Reporting System... as evidence that the approved COVID-19 vaccines cause deaths and serious events."

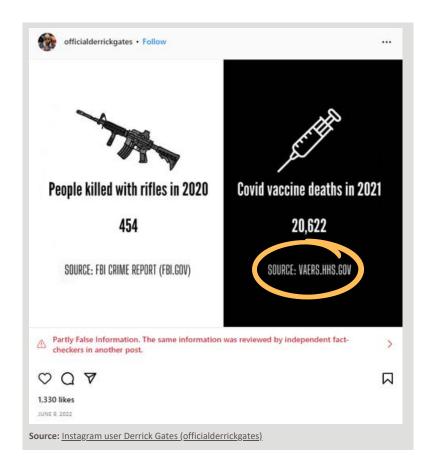
- FactCheck.org, a project of the Annenberg Public Policy Center (Jaramillo, 2021)



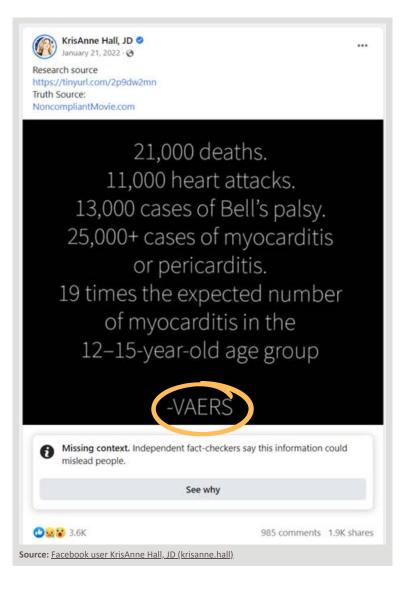
Since the inception of VAERS in 1990 (CDC, n.d., About VAERS), its data have been mistakenly cited to suggest that the recording of an event in VAERS confirms that it was vaccine-caused. Long before COVID-19 was added to our working vocabularies, people falsely alleging that the MMR vaccine causes autism were backing that bogus claim with mischaracterized VAERS event report data.

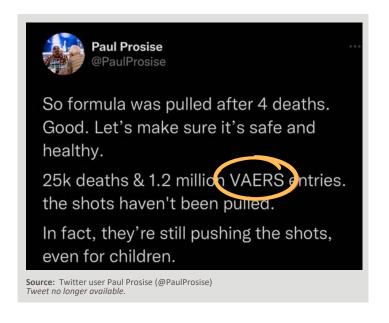
Such problematic uses persist. So, for example, on June 18, 2021, lawyer, author, and anti-vaccine activist Robert F. Kennedy, Jr., tweeted, "Latest numbers from CDC VAERS is in... Data for 12- to 17-year-olds include 7 deaths + 271 serious adverse events following COVID vaccine" (Kennedy, 2021). The mental representation invited by that text: COVID-19 vaccination is endangering teens.

# Examples of content citing VAERS











# References to VAERS by prominent individuals

Other prominent voices have also cited VAERS to argue that the Covid-19 vaccines are unsafe.

Tucker Carlson presented "the apparent death rate from the coronavirus vaccines" on his show on May 5, 2021, referencing data from VAERS (<u>Dunlop</u>, 2021. May 7). Carlson's then-Fox News program routinely drew the highest numbers of any primetime cable program, with some reports indicating that over 3 million viewers tuned in regularly (<u>Porter</u>, 2023, April 25).



Wisconsin Senator Ron Johnson referenced VAERS data in an October 5, 2022, appearance on The Vicki McKenna Show (emphasis added) (<u>The Vicki McKenna Show</u>, 2022).

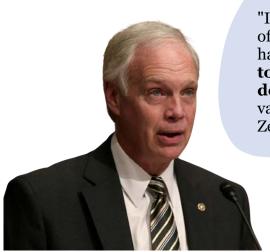
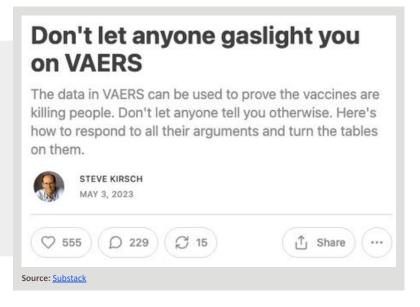


Photo of Johnson from 2016
Source: U.S. Customs and Border Protection, via Wikimedia Commons

"In general, the complaint is a very small percentage of adverse effects actually get reported, and so you have to take this with a grain of salt, but **according to the VAERS system, we are over 3,000 deaths** of, after, within 30 days of taking the vaccine. About 40 percent of those occur on Day Zero, One or Two."

Steve Kirsch, "a tech entrepreneur turned anti-vaccine activist" (<u>Hagen</u>, 2023, May 4), published a guide on Substack showing how to use (or misuse) VAERS data to argue against fact-checkers on May 3, 2022. His Substack newsletter has over 224,000 subscribers (<u>Kirsch</u>, n.d.).



As states debated the merits of requiring that school children be vaccinated against COVID-19, misleading and false VAERS-based claims migrated into legislative hearings as well. Pointing to a poster bearing the words "19,000 Deaths reported from COVID vaccines, more than from all other vaccines combined in 30 years" on December 6, 2021, Kennedy told an oversight meeting in the Louisiana statehouse that more people "have died in eight months from this vaccine than from 72 vaccines over the last 30 years," making the COVID-19 vaccine "the deadliest vaccine ever made" (Putterman, 2021, December 10). The citation on the poster attributed the data to VAERS. Kennedy was testifying against Governor John Bel Edwards' proposal to add Pfizer's Covid-19 vaccine to that state's childhood vaccine schedule.





# The problem: Confusing correlation with causation

Because we all are prone to confuse temporal association with causal connection, post-vaccination health problems are likely to be blamed on the vaccine when their actual cause (e.g., an underlying health condition) may lie elsewhere, and the association between the problem or event and vaccination may be coincidental (Jamieson, 2021). Roman philosophers tried to blunt the effects of this human disposition by terming its incarnation a "post hoc ergo propter hoc" ("after this therefore because of this") fallacy. Adopting today's parlance, we teach high school students that correlation is not causation.

# Minimizing public susceptibility to the correlation-equals-causation fallacy

To evaluate the accuracy of VAERS-related claims, the public needs to understand that VAERS includes valuable information that makes it possible for the CDC and FDA to monitor vaccine safety. But because these agencies want to know about any possible effects of vaccination and anyone can report any event they consider vaccine-related, a lot of coincidental events wind up being submitted. As a result, it is unsurprising that the CDC reports that "most health problems reported on VAERS soon after vaccination are not actually caused by the vaccine" (CDC, 2021, September 9).



# Protective knowledge about VAERS includes:



- It is an early warning system set up to detect any possible safety problems in vaccines.
- The VAERS database "contains information on unverified reports of adverse events (illnesses, health problems and/or symptoms) following immunization with US-licensed vaccines" (CDC, n.d., About The Vaccine Adverse Event Reporting System (VAERS)).
- "Anyone can report events to VAERS, even if it is not clear whether a vaccine caused the problem" (<u>CDC</u>, 2023).
- All reports of serious adverse events are reviewed (CDC, 2022).



# Communicating that because an event occurred after vaccination does not mean that vaccination caused it

#### Would the death have happened anyway?

Critica's Dr. Jack Gorman employed a real-life example to show why a post-vaccination death is not necessarily a death caused by the vaccine. "We know of a case in which a previously healthy elderly woman died hours before she was scheduled to receive a COVID-19 vaccine," he notes. "Had she died a few hours after the vaccine, a report could have been made to VAERS.... In fact, it would have been a coincidence."

#### Remember the Hulk!

To demonstrate that any kind of side effects can be reported to VAERS, one doctor evoked the Incredible Hulk. Dr. James R. Laidler, an anesthesiologist, reported to VAERS that after receiving an influenza vaccination "his skin turned green, his muscles grew and he started having rage problems," all signs that he may have been turning into the Marvel comic book character (Selby, 2017). Laidler's ability to do so highlights the fact that an adverse event reported in VAERS does not constitute either CDC confirmation that it actually happened or, if the event did occur, that it was vaccine-caused. A CDC spokesperson confirmed to PolitiFact that Laidler's report had been accepted and entered into the database (Selby, 2017). With his consent, the record was removed.



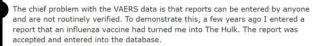
## neurodiversity weblog

Chelation & Autism - 2005-07-27 10:41

The following is a preview of an article by James R. Laidler, M.D., soon to be

Chelation & Autism by James R. Laidler, M.D.

Can chelation help autism?



Because the reported adverse event was so... unusual, a representative of VAERS contacted me. After a discussion of the VAERS database and its limitations, they asked for my permission to delete the record, which I granted. If I had not agreed, the record would be there still, showing that any claim can become part of the database, no matter how outrageous or improbable.



# **Protective knowledge**

When reading or citing VAERS data, remember the Hulk!



# Recommendations: Rename the system & change the description of its data

To paraphrase Coleridge, "language does our thinking for us." Tax increases are called "revenue enhancements" by those who favor them; the estate tax is called the "death tax" by those who oppose it (Schaffner & Sellers, 2010) for a reason. Because the two elicit opposite responses, language choice matters.

Language can affect behavior. An example from Japan provides dramatic evidence that what we hear and read affects what we think and how we behave. In 2002, the Japanese Society of Psychiatry and Neurology changed the communication of both doctors and the news media by altering the term for what in the West is called schizophrenia from "Seishin Bunretsu Byo" ("mind-split-disease"), to "Togo Shitcho Sho" ("integration disorder") (Aoki et al, 2016). Seven months after the change, a survey of all of the prefectures in Japan "found that the old term had been replaced by the new one in about 78% of cases. The renaming increased the percentage of cases in which patients were informed of the diagnosis from 36.7% to 69.7% in three years" (Sato, 2006).

# 1. Change "Vaccine Adverse Event Reporting System" to "Vaccine Safety Watch: Incident Reporting System"

Changing the name of this system from the "Vaccine Adverse Event Reporting System" could help to clear up some of the confusion surrounding the nature of the data.

Re-terming the system "Vaccine Safety Watch" and changing "Adverse Event" to "Incident" clarifies that the incidents of concern are unverified, relate to safety, and are part of a monitoring system. The moniker Vaccine Safety Watch parallels that of MedWatch (whose full name is MedWatch: The FDA Safety Information and Adverse Event Reporting Program). An alternative to "Vaccine Safety Watch" might be "Vaccine Safety Sentinel."

Adding "safety" to the title aligns the system with others in the CDC, v-safe notable among them, that include "safe" or "safety" in their name (CDC, n.d., CDC Monitors Health Reports Submitted After COVID-19 Vaccination to Ensure Continued Safety). Federal nuclear, aviation and automobile safety systems all foreground safety as well. "Safety" reinforces the monitoring system's goal: protecting those who have been vaccinated. At the same time, either "Watch" or "Sentinel" telegraphs that this is an early warning system, not a catalogue of confirmed cases. Like "Watch," use of "Sentinel" is precedented insofar as it is the name of the FDA's national electronic system that monitors the safety of FDA-regulated medical products.



To thwart the inference that the system records events that are confirmed side effects, replace "adverse event" with the less prejudicial "incident," making it an "Incident Reporting System."



#### Change the name of "VAERS"



#### Alternatives:

- "Vaccination Safety Monitor" (VSM)
- "Vaccination Safety Watch" (VSW)
- "Vaccination Safety Sentinel" (VSS)

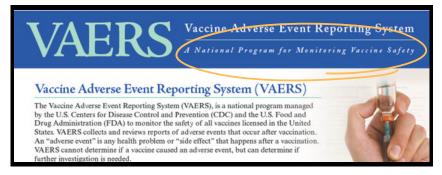
#### Advantages:

- Prime the positive "safety," not "adverse event"
- Disassociate "vaccine" from presumed, confirmed "adverse event"

# 2. Pending a name change, routinely point to VAERS' clarifying subtitle

Whenever mentioning the Vaccine Adverse Event Reporting System (VAERS), retain its descriptive subtitle – "A National Program for Monitoring Vaccine Safety."

**Figure 10.** Fact sheet on VAERS from the U.S. Department of Health & Human Services (HHS), CDC, & FDA (CDC, n.d., VAERS Fact Sheet).





## Protective knowledge

VAERS = A safety monitoring system



# 3. Describe data as raw & unconfirmed

The existence of fabricated accounts logged into VAERS is a vivid reminder that its reports are raw and unverified, as highlighted by Laidler's "Hulk" report.

Although Laidler's supposed Hulk-like transformation was deliberately fabricated to be caught, another fabricated account gained wide circulation in the height of the pandemic before it was detected and removed. "Two-year-old baby DIES during Pfizer's Covid-19 vaccine experiments on children," noted an article from Natural News (Huff, 2021), which Media Bias/Fact Check terms "one of the most discredited sources on the internet" (Van Zandt, 2016/2022). "As reported in the government's Vaccine Adverse Event Reporting System (VAERS), the two-year-old girl received her second dose of Pfizer's DNA-modifying mRNA injection on February 25. On March 1, she suffered some kind of serious adverse reaction. On March 3, she died" (Huff, 2021). As a CDC spokesperson told USA Today, that VAERS report was removed because it was "completely made up" (Sadeghi, 2021).

Because the CDC's guide to interpreting VAERS data has proven insufficient to protect statements from decontextualization, we urge the CDC to consider prefacing mentions of "death" or "adverse events" in the database with "unconfirmed" and the word "data" with "raw."

#### A test

To assess the utility of the changes we recommend, ask whether audiences would have been better able to explain the misleading implication in a Robert F. Kennedy, Jr., tweet had the vocabulary of the VAERS site made clear that the numbers were raw and the events "unconfirmed incidents."

- Original tweet: "Latest numbers from CDC VAERS is in... Data for 12- to 17-year-olds include 7 deaths + 271 serious adverse events following COVID vaccine" (Kennedy, 2021, June 18).
- Annotation: "Latest raw numbers from CDC Vaccine Safety Watch: Incident Report System are in... Raw data for 12- to 17-year-olds include 7 unconfirmed deaths + 271 unconfirmed incidents following COVID vaccine."

# 4. In all public statements, reiterate that VAERS data are unverified

Pronouncing the words "verified" and "VAERS" out loud makes one aware that, when spoken, VAERS sounds like a pluralized form of the first syllable of the word verified (ver-s). To break that association, we recommend associating the acronym VAERS with the characterization "unverified."



## **Protective knowledge**

VAERS = unverified

There is a silent 'U' in VAERS signaling that VAERS data are unverified.



# Recommendations

The confusion that VAERS has caused prompted noted vaccine expert Dr. Paul Offit to observe that:

"While it was created in order to enhance trust and openness in the vaccine system, it's often misunderstood, not only by parents, but by journalists, who think that the Vaccine Adverse Event Reporting System in any way gives important information about vaccine side effects, when it doesn't. I think that you could eliminate VAERS and just have the Vaccine Safety Datalink, because the Vaccine Safety Datalink looks at children who did or didn't receive a vaccine to see whether a vaccine caused a particular adverse event. VAERS, for the most part, is a lot of misleading noise" (Offit, 2016).

Assuming that, at least in the short run, VAERS will survive in its current form, we offer four recommendations to minimize public susceptibility to misuse of its data.

- **1.** Change "Vaccine Adverse Event Reporting System" to "Vaccination Safety Watch: Incident Reporting System"
- 2. Pending a name change, routinely point to VAERS' clarifying subtitle (i.e. "A National Program for Monitoring Vaccine Safety") whenever mentioning VAERS
- **3.** Within VAERS, describe data as raw & unconfirmed
- **4.** In all public statements, reiterate that VAERS data are unverified by indicating that there is a silent "u" in VAERS (uVAERS), standing for "unverified"



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# **Appendix**

These data come from the <u>Annenberg Science and Public Health (ASAPH)</u> survey. <u>As previously described</u>, these data were collected from a nationally representative probability panel survey drawn randomly from the SSRS Opinion Panel of U.S adults, 18 and older. SSRS Opinion Panel members are recruited randomly based on nationally representative address-based sample design (including Hawaii and Alaska). Additionally, hard-to-reach demographic groups were recruited via the SSRS Omnibus survey platform, a nationally representative (including Hawaii and Alaska) bilingual telephone survey designed to meet standards associated with custom research studies.

Both the phone and online surveys were available in Spanish with about 1.7% of the panel using this language. Panel members in our study were not selected for any other studies conducted by SSRS and are considered proprietary. Panelists were invited by email or telephone to participate in the panel and were compensated the equivalent of \$15 for their time at each survey wave. The median length of the surveys was 20 minutes. The survey was deemed exempt from review by the Institutional Review Board of the University of Pennsylvania.

Of the 3,476 U.S. adult panelists invited to participate in wave 1 of the survey, 1,941 completed that wave's survey in April 2021 (56% completion rate). The majority completed the survey online rather than by telephone (97% online and 3% by telephone). These 1,941 panelists were re-contacted at each subsequent wave unless they dropped from the panel. Postwave 1 panelist completion rates were high, averaging 84 percent between waves 2 and 10.

The most recent data in this report are drawn from wave 10 of the study, conducted from January 10-16, 2023, among a sample of 1,657 respondents, 1,611 from the web and 46 by telephone. A total of 1,625 surveys were conducted in English and 32 in Spanish. 2,048 panelists were invited to complete wave 10 of the survey. The response rate was 80.9%. The margin of sampling error for total respondents is +/-3.2 percentage points at the 95% confidence level. The design effect (DEFF) is 1.72. See Table A for waves 1-10.

Between waves 8 and 9, The Annenberg Public Policy Center of the University of Pennsylvania (APPC) engaged SSRS in recruiting additional panelists to the ASAPH panel to increase the sample size, account for attrition, improve the representativeness of the panel. Additional panelists were recruited again via address-based sampling in similar fashion to the initial recruitment as described above. From these recruits, ASAPH randomly selected 74 additional panelists with an educational attainment of a high school degree or less to participate to improve representativeness.

Between waves 9 and 10, APPC engaged SSRS to conduct an engagement survey with the purpose of recruiting additional panelists. The survey was conducted via the SSRS Opinion Panel and invited only newly recruited panelists with an educational attainment of a high school degree or less to participate to improve representativeness. Data collection was conducted from December 6 – December 12, 2022 by web in English only. The survey obtained 60 completes, among which 33 were recruited to the ASAPH Panel. In total, 107 new respondents were added. The reduction in design effect between waves 8 and 10 reflects the improved representativeness of the sample post-replenishment.



Table A. Summary of ASAPH survey waves.

Wave	Survey	N	MOE	Deff	Fielded	Closed
A-1	ASK 1	1941	2.9	1.76	3/30/21	4/19/21
B-2	ASK 2	1719	3.2	1.83	6/9/21	6/22/21
C-3	ASK 3	1669	3.2	1.83	8/16/21	9/5/21
D-4	ASK 4	1672	3.3	1.86	11/3/21	11/9/21
E-5	ASK 5	1656	3.3	1.86	1/11/22	1/17/22
F-6	ASK 6	1638	3.3	1.87	3/29/22	4/4/22
G-7	ASK 7	1580	3.3	1.82	7/12/22	7/18/22
H-8	MH/CH 1	1621	3.3	1.87	8/16/22	8/23/22
I-9	ASK 8	1646	3.2	1.80	10/11/22	10/18/22
J-10	ASK 9	1657	3.2	1.77	1/10/23	1/16/23

# **Weighting**

Data were weighted by SSRS to represent the adult (18+) population. The data were weighted by first applying a base weight then balancing the demographic profile of the sample to target population parameters.

The base weight for the SSRS Opinion Panel was the final weight from the first wave of the survey (April 2021). The base weights were then standardized and trimmed at the 2nd and 98th percentiles to prevent individual interviews from having too much influence. With the base weight applied, the probability panel was weighted to balance the demographic profile of the sample to the target population parameters.

SSRS employs a technique called hot decking for missing demographic data. Hot deck imputation replaces the missing values of a respondent randomly with another similar respondent without missing data. These are further determined by variables predictive of non-response that are present in the entire file.21 21This is conducted using an SPSS macro detailed in Myers, Teresa. 2011. "Goodbye, Listwise Deletion: Presenting Hot Deck Imputation as an Easy and Effective Tool for Handing Missing Data." Communication Methods and Measures 5 (4): 297–310.

Weighting was accomplished using SPSSINC RAKE, an SPSS extension module that simultaneously balances the distributions of all variables using the GENLOG procedure. Data were weighted to distributions of: sex by age, sex by education, age by education, race/ethnicity (for Hispanic include US born and foreign born), census region, civic engagement, frequency of internet usage, population density, religion, voter registration, and party identification.

The main demographic benchmarks were obtained from the 2021 Current Population Survey (CPS). The civic engagement benchmark was derived from September 2017 CPS Volunteering and Civic Life Supplement data. The population density came from Census Planning Database 2020. The internet usage benchmark was obtained from the 2019



American Community Survey (ACS) data. Voter registration parameters come from the 2021 Aristotle RV database. Both the religion and party identification benchmarks come from Pew's 2021 National Public Opinion Reference Survey (NPORS).

These weights reflect current recommendations and best practices from SSRS. In waves 1 through 7, weights did not adjust for religion, voter registration, or party identification. Prior benchmarks for race and internet usage were less granular. Both SSRS and APPC independently analyzed the revised practices and found the differences to be small and statistically insignificant for all our questions in Waves 7 and 8.