

THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM

THE VAERS SYSTEM AND
REPORTING OF VACCINE
INJURIES AND
HOW TO PROVE CAUSATION

November 1, 2023

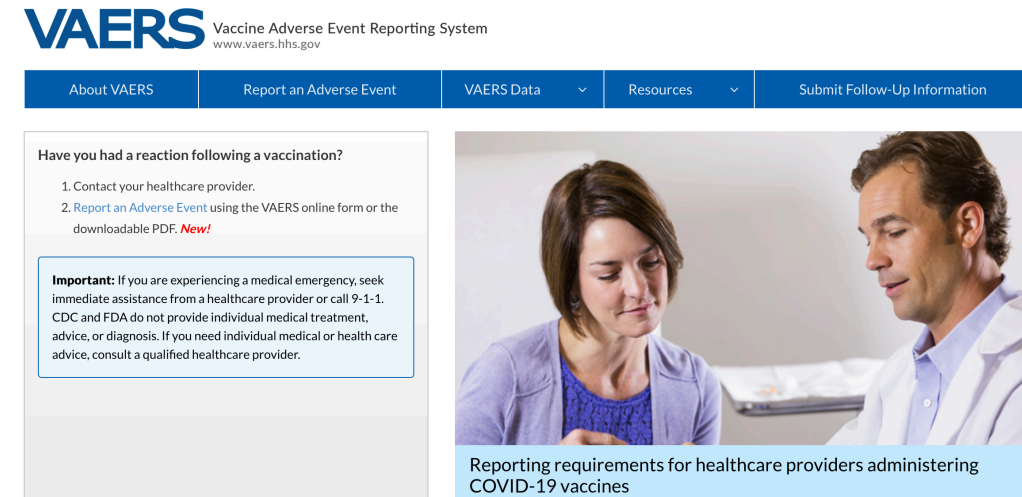
Jessica Rose, PhD



WHAT IS VAERS?

Vaccine Adverse Event Reporting System

- VAERS was created in 1990 by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to receive reports of AEs that may be associated with vaccines.
- The primary purpose for maintaining the database is to serve as an early warning or signaling system for adverse events not detected during pre-market testing and clinical trials.




VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

About VAERS | Report an Adverse Event | VAERS Data | Resources | Submit Follow-Up Information

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the downloadable PDF. *New!*

Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.



Reporting requirements for healthcare providers administering COVID-19 vaccines

WHAT IS VAERS?

Vaccine Adverse Event Reporting System

- In spite of the fact that the National Childhood Vaccine Injury Act of 1986 (NCVIA) requires health care providers and vaccine manufacturers to report to the DHHS specific AEs following the administration of vaccines outlined in the Act, **under-reporting is a known imperfection of the VAERS system.**

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

About VAERS Report an Adverse Event VAERS Data Resources Submit Follow-Up Information

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Reporting requirements for healthcare providers administering COVID-19 vaccines

REPORTING PROCEDURES

Two Ways to Submit an Online Report to VAERS



Option 1 - Report Online to VAERS

Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and returned to at a later time. Your information will be erased if you are inactive for 20 minutes; you will receive a warning after 15 minutes.



Option 2 - Report using a Writable PDF Form

Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.

If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967.

Checklist

What will I need to fill out the report?

- Patient information (age, date of birth, sex)
- Vaccine information (brand name, dosage)
- Date, time, and location administered
- Date and time when adverse event(s) started
- Symptoms and outcome of the adverse event(s)
- Medical tests and laboratory results (if applicable)
- Physician's contact information (if applicable)

[Full checklist](#)

28 items – 6 time-limited e-pages



About VAERS	Report an Adverse Event	VAERS Data	Resources	Submit Follow-Up Information
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Completion Status	Report an Adverse Event - Patient Information	Instructions en Español
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Patient Information

Reporter Information

Facility Information

Vaccine Information

Additional Information

Note: Fields marked with an * are essential and should be completed.

Item 1

Patient first name: Patient last name:

Street address:

City: State: County:

Zip code: Phone: Email:

Item 2

* Date of birth mm/dd/yyyy or mm/yyyy

Item 3

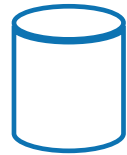
* Sex: Male Female Unknown

What happens after a report is submitted

Each VAERS report is assigned a VAERS identification number. This number can be used to provide additional information about the report to VAERS, if necessary. VAERS will send the identification number to the reporting individual in a confirmation letter (electronically or by mail, depending on communications preferences listed on the original report).

FRONT END DATA NOT THE FULL STORY

We Get a “Laundered” Set of Data

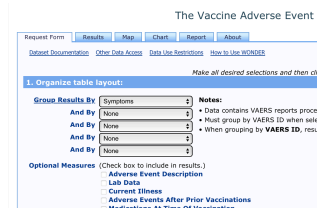


VAERS

The Original Database
Stores all Records and Updates



Filtered to remove extra fields, reports and updates
they don't want the public or researchers
to have access to



WONDER

Wide-ranging Online Data
for Epidemiological Research

A NOTE ON OPENVAERS

What is OpenVAERS.com?

- OpenVAERS was created to fill the gap in vaccine injury visibility left by the Wonder system.
- It draws the data directly from the Wonder system and presents it in an easily understandable format.
- It does not use adjustments or manipulate the data in any way.

Before

The Vaccine Adverse Event Reporting System (

Request Form | Results | Map | Chart | Report | About

Dataset Documentation | Other Data Access | Data Use Restrictions | How to Use WONDER

Make all desired selections and then click any **Send** button one time

1. Organize table layout:

Group Results By: Symptoms

And By: None

Optional Measures: (Check box to include in results.)

Adverse Event Description

Lab Data

Current Illness

Adverse Event

Medications A

History/Allerg

2. Select symptoms:

Click the Advanced Finder Options li

Browse or search to find items in the S
(The *Currently selected* box displays all <

[Finder Tool Help](#) | [Advanced F](#)

Browse | Search | Details

Symptoms

- + All* (All Symptoms)
- + 0-9 (0-9)
- + A (A)
- + B (B)
- + C (C)
- + D (D)
- + E (E)
- + F (F)
- + G (G)

Currently se

- + All* (All S

After

OpenVAERS

HOME | COVID VACCINE DATA | SEARCH ALL REPORTS | FAQ | f | t | @

VAERS COVID Vaccine Adverse Event Reports

Reports from the Vaccine Adverse Events Reporting System. Our default data reflects all VAERS data including the "nondomestic" reports.

As of 11-18-2022 VAERS has stopped putting free text field information in the public data for Europe/UK.

All VAERS COVID Reports US/Territories/Unknown

986,103 Reports Through September 15, 2023

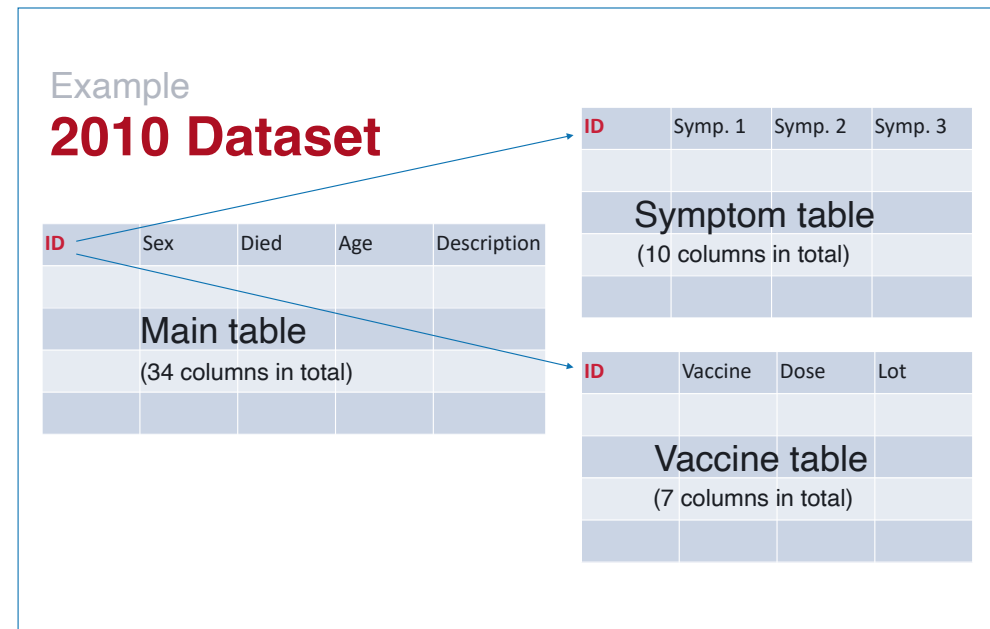
source: OpenVAERS.com

18,133 DEATHS	87,349 HOSPITALIZATIONS	117,149 URGENT CARE
196,016 DOCTOR OFFICE VISITS	2,460 ANAPHYLAXIS	6,259 BELL'S PALSY

VAERS DATA ITSELF IS A COMPOSITE OF 3 FILES – 'DATA', 'VAX' AND 'SYMPTOMS' (AVAILABLE MONTHLY AS OF OCTOBER 6, 2023)

A little background on the de-identified dataset

- Every week the dataset is brand new. Some reports are deleted, some added, and rarely, some are changed.
- The export is a set of three tables per year of VAERS data (currently 33 sets of tables).
- Each Symptom is a MedDRA term coded by a VAERS employee.
- The Description is the open textfield that the filer writes history, notes & the event in.



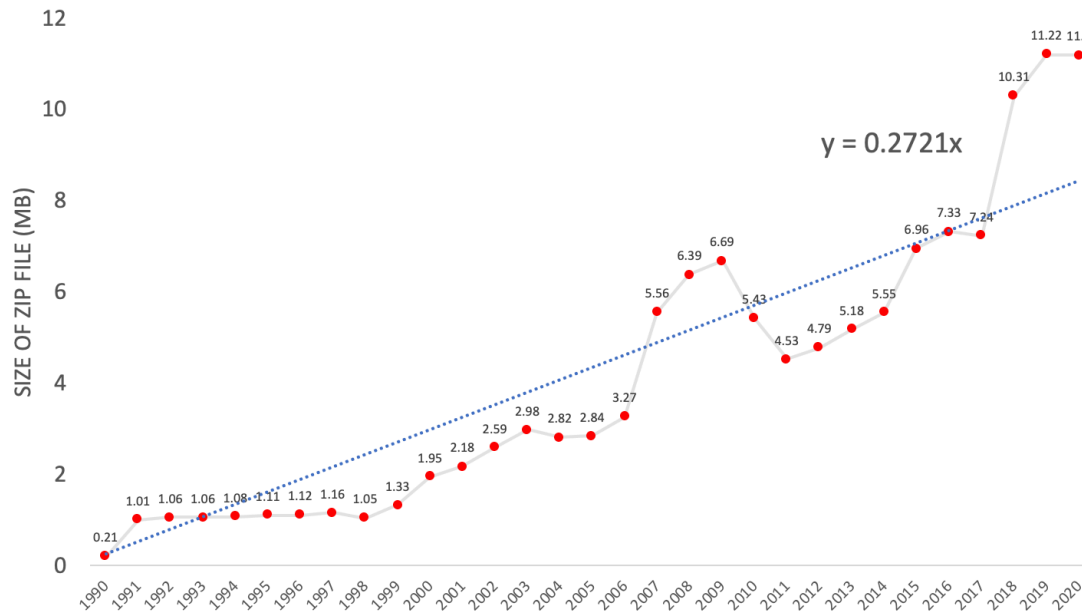
<https://en.wikipedia.org/wiki/MedDRA>; <https://www.meddra.org/>

WHAT'S GOING ON IN VAERS?

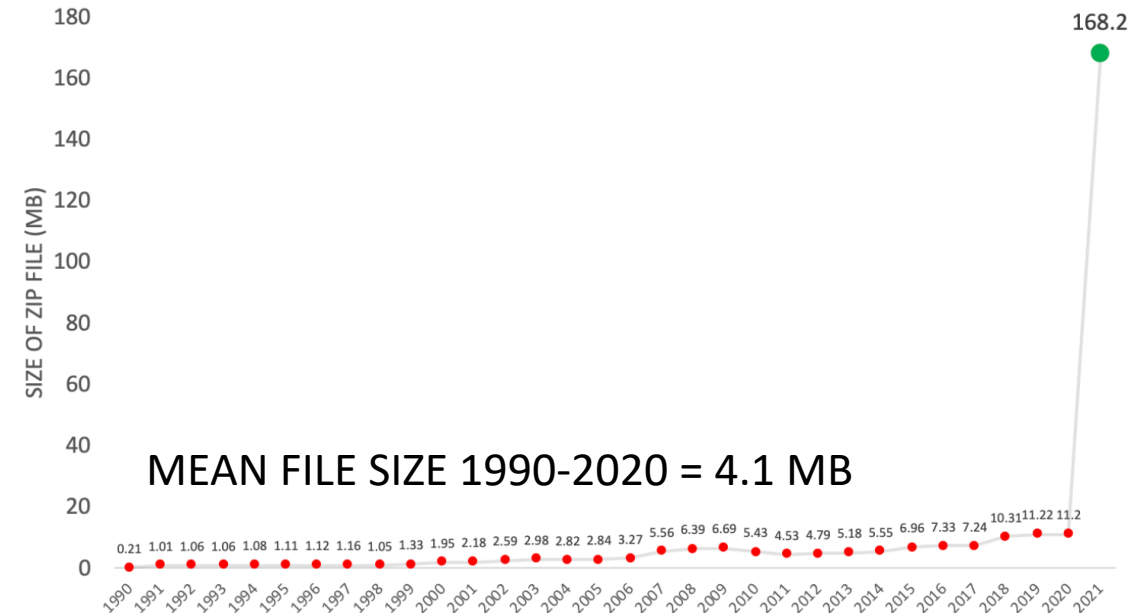
THE TREND OF INCREASING PRODUCTS ON MARKET AND ADVERSE EVENT (AE) DATA INPUT

THE INCREASE IN REPORTS IN **2021** IS A CLEAR DIVERGENCE FROM THE PROPORTIONAL INCREASE IN REPORTS (RELATED TO PRODUCT NUMBER) OVER THE PAST 30 YEARS

RESPECTIVE SIZES OF VAERS ZIPPED FILES FROM 1990-2020
source: <https://vaers.hhs.gov/data/datasets.html>



RESPECTIVE SIZES OF VAERS ZIPPED FILES FROM 1990-2021
source: <https://vaers.hhs.gov/data/datasets.html>



PHARMACO VIGILANCE

- SCIENCE AND ACTIVITIES RELATING TO THE DETECTION, ASSESSMENT, UNDERSTANDING AND **PREVENTION** OF AES
- THIS APPLIES **THROUGHOUT THE LIFE CYCLE** OF A MED - EQUALLY TO THE PRE-APPROVAL STAGE AS TO THE POST APPROVAL

PROPORTIONAL REPORTING RATIO (PRR)S, CAUSALITY ASSESSMENTS OR BAYESIAN ANALYSES CAN BE DONE TO ASSESS SAFETY SIGNAL SIGNIFICANCE

VAERS WORKS AS A PHARMACOVIGILANCE SYSTEM

584 CASES OF REPORTED INTUSSUSCEPTION IN VAERS RESULTED IN WITHDRAWAL OF ROTAVIRUS VACCINE

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Volume 131, Issue 6
June 2013

ARTICLE | JUNE 01 2013

Intussusception After Rotavirus Vaccines Reported to US VAERS, 2006–2012 📄

Penina Haber, MPH ✉; Manish Patel, MD; Yi Pan, PhD; James Baggs, PhD; Michael Haber, PhD; Oidda Museru, MPH; Xin Yue, MS; Paige Lewis, MSPH; Frank DeStefano, MD; Umesh D. Parashar, MBBS

Address correspondence to Penina Haber, MPH, 1600 Clifton Rd, MS D-26 Atlanta, GA 30333. E-mail: pyh0@cdc.gov

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

Pediatrics (2013) 131 (6): 1042–1049.
<https://doi.org/10.1542/peds.2012-2554> [Article history](#) 📄

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🔧 Tools ▾

BACKGROUND:
In 2006 and 2008, 2 new rotavirus vaccines (RotaTeq [RV5] and Rotarix [RV1]) were introduced in the United States.

◀ Previous Article

Next Article ▶

September 2001

The Rotavirus Vaccine's Withdrawal and Physicians' Trust in Vaccine Safety Mechanisms

Heather A. McPhillips, MD, MPH; Robert L. Davis, MD, MPH; Edgar K. Marcuse, MD, MPH; [et al](#)

» [Author Affiliations](#) | [Article Information](#)

Arch Pediatr Adolesc Med. 2001;155(9):1051-1056. doi:10.1001/archpedi.155.9.1051

🔗 **Related Articles**

Abstract

Objective To determine how the withdrawal from the market of the rotavirus vaccine has affected physicians' trust in vaccine safety mechanisms, future adherence to vaccine recommendations, and willingness to use a new rotavirus vaccine.

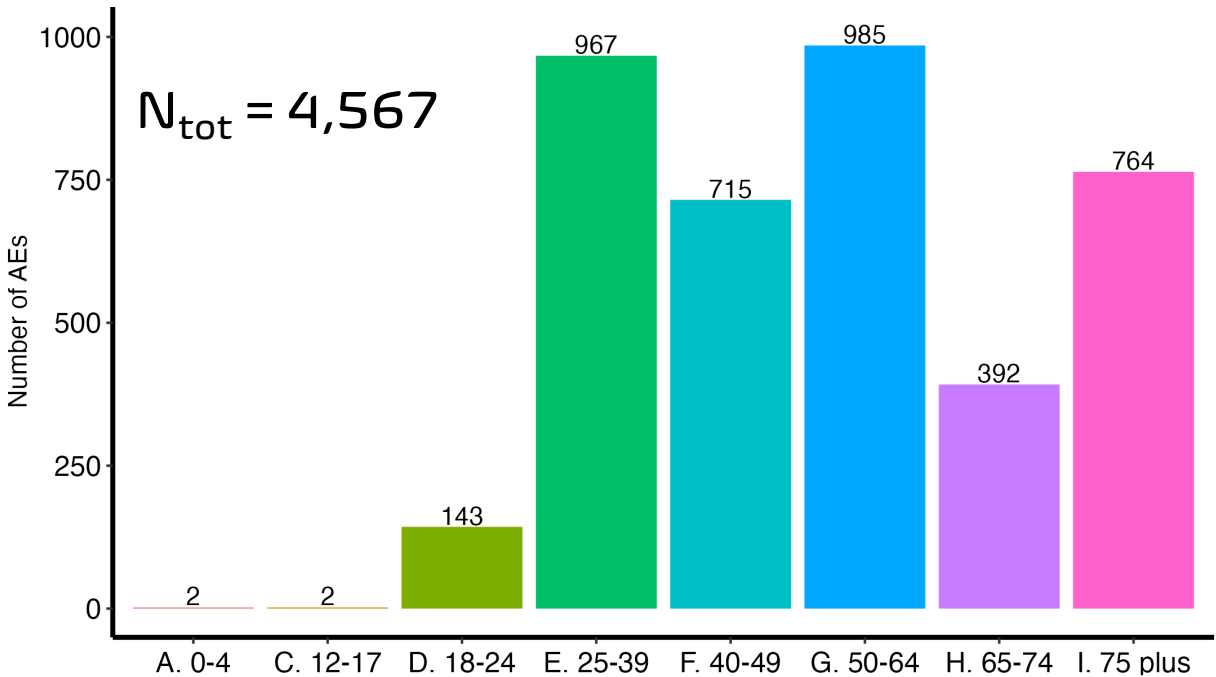
Penina Haber, Manish Patel, Yi Pan, James Baggs, Michael Haber, Oidda Museru, Xin Yue, Paige Lewis, Frank DeStefano, Umesh D. Parashar; Intussusception After Rotavirus Vaccines Reported to US VAERS, 2006–2012. *Pediatrics* June 2013; 131 (6): 1042–1049. 10.1542/peds.2012-2554
McPhillips HA, Davis RL, Marcuse EK, Taylor JA. The Rotavirus Vaccine's Withdrawal and Physicians' Trust in Vaccine Safety Mechanisms. *Arch Pediatr Adolesc Med.* 2001;155(9):1051–1056. doi:10.1001/archpedi.155.9.1051

VAERS SINCE 2021 (COVID-19 INJECTABLE PRODUCTS)

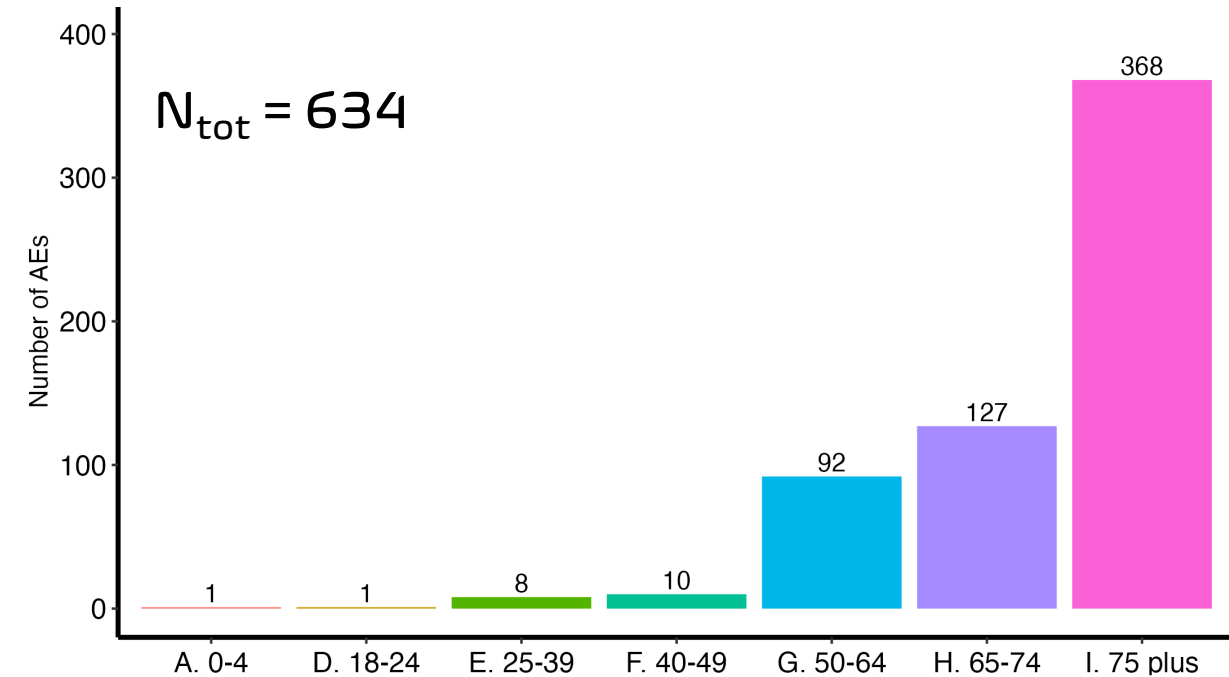
SAFETY SIGNAL IN VAERS IN **JANUARY 2021** TO STOP THE COVID-19 PRODUCT ROLL-OUT

WHY ARE THESE SIGNALS IGNORED BY CDC/HHS/FDA?

Domestic AE reports as of Jan 30, 2021



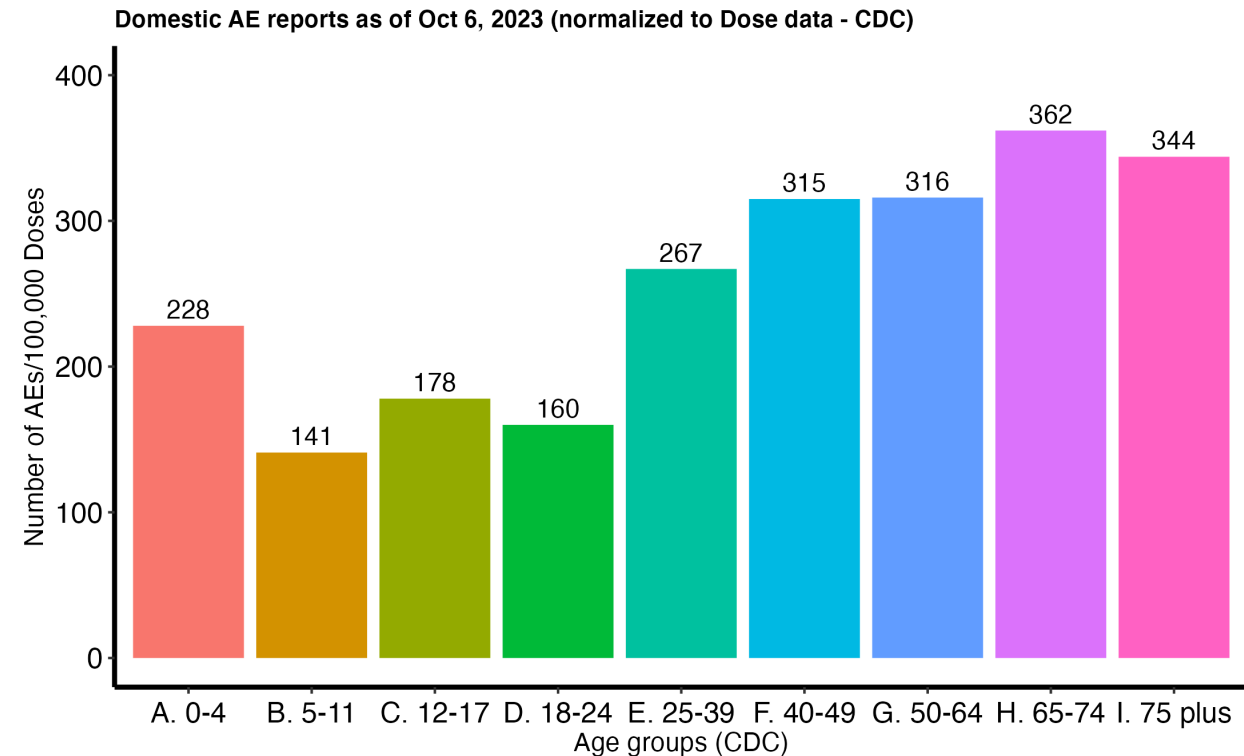
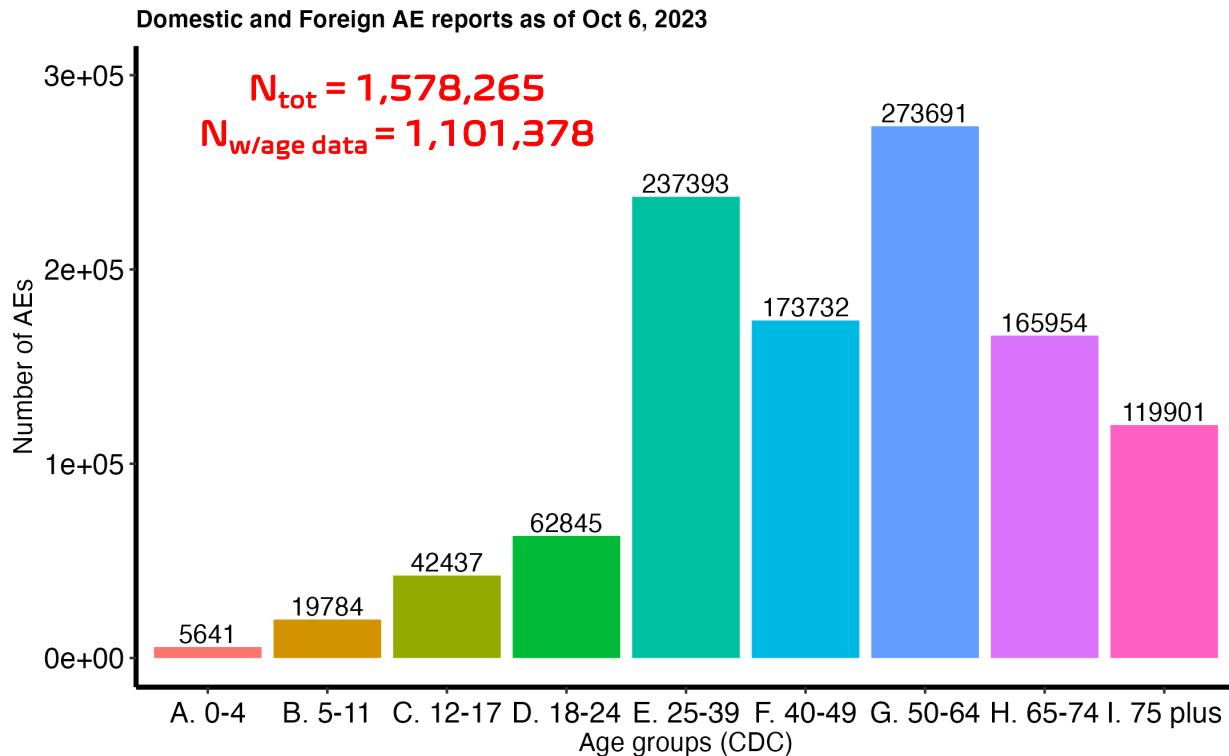
Domestic Death reports as of Jan 30, 2021



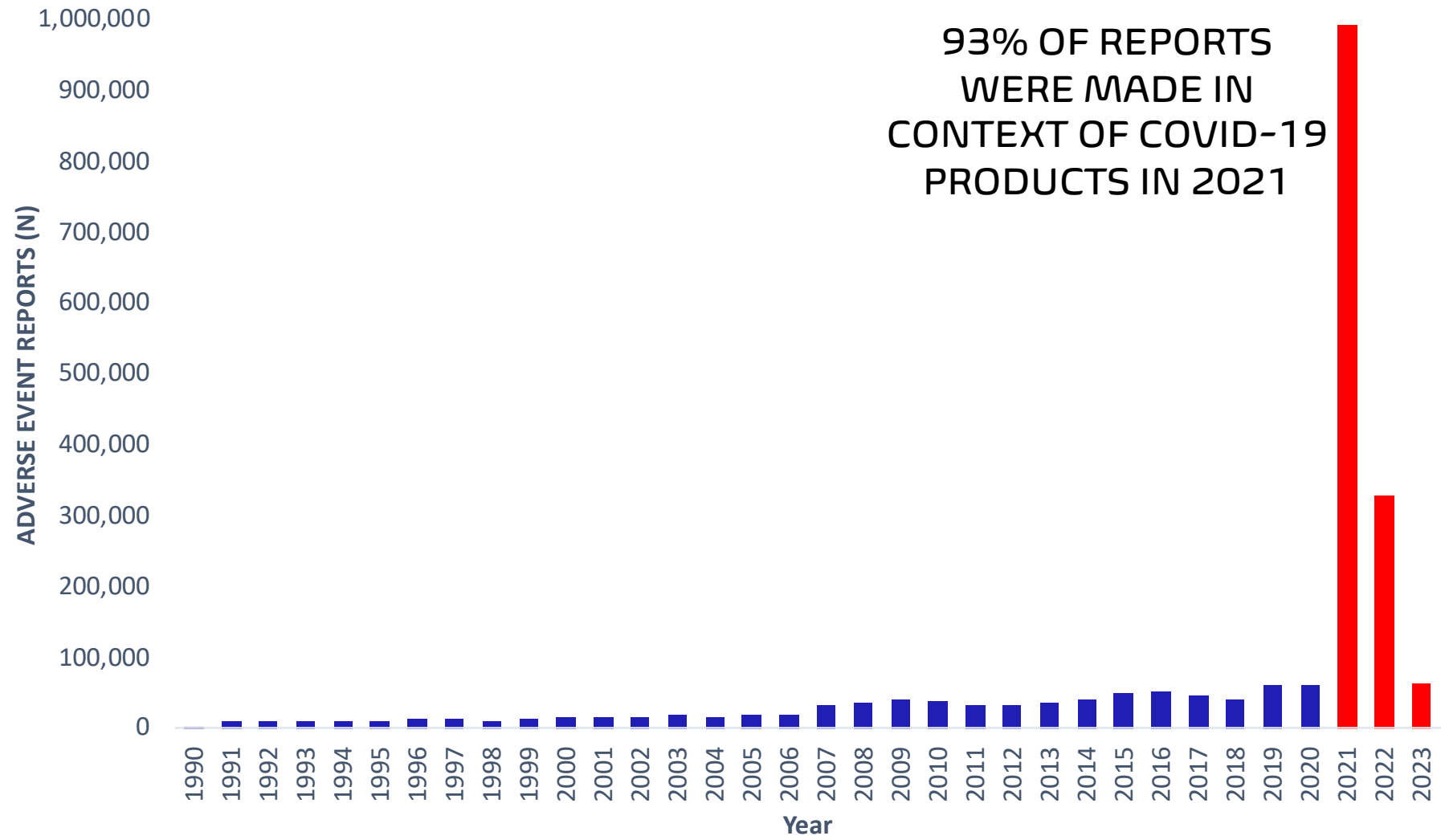
NB: THE UNDER-REPORTING FACTOR (URF) IS NOT CONSIDERED HEREIN

VAERS REPORTS (BY ID) OF AES STRATIFIED BY AGE GROUP AS OF OCTOBER 6, 2023

THERE ARE SAFETY SIGNALS EMITTED ACROSS ALL AGE GROUPS

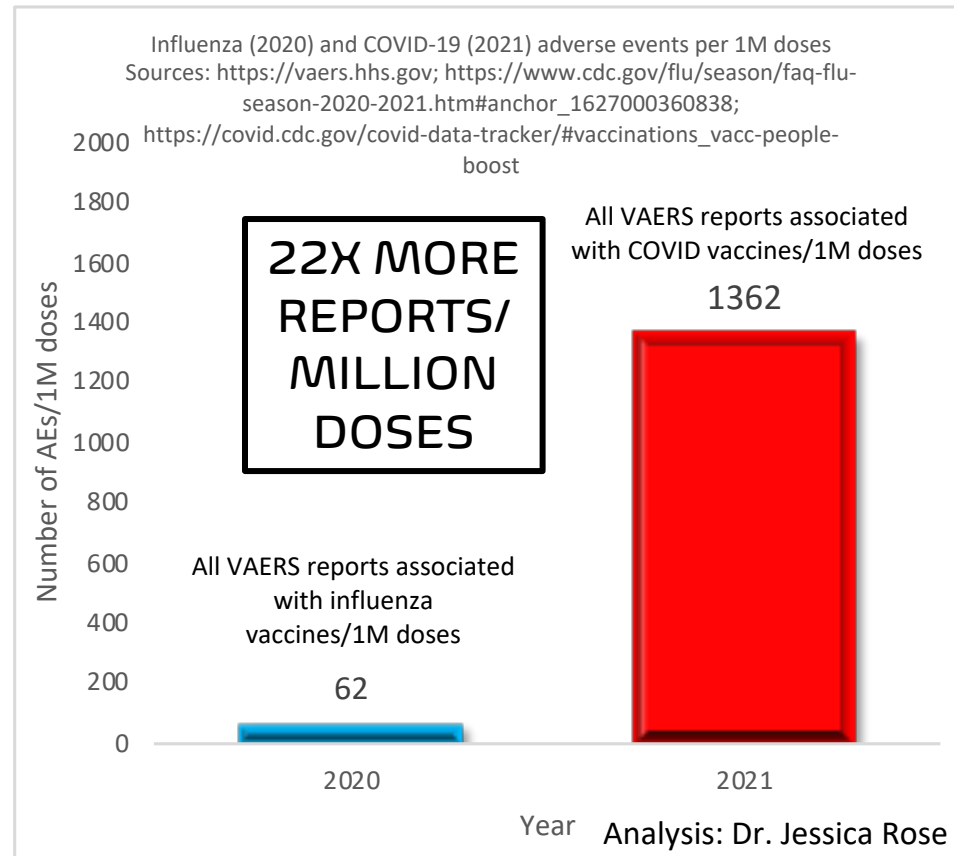


SOME PERSPECTIVE - THE PAST 30 YEARS OF REPORTS VAERS



NUMBER OF VAERS REPORTS FOR FLU (2020)/1M DOSES VS. COVID (2021)/1M DOSES

THIS EFFECT IS NOT DUE TO MORE SHOTS HAVING BEEN ADMINISTERED



HOW DO WE ANALYZE THE DATA?

ANALYZING VAERS DATA: CDC WONDER SYSTEM; DATA ANALYSIS SOFTWARE LIKE R; EXCEL

 Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People™

[A-Z Index](#)

Search X 🔍

CDC WONDER FAQs Help Contact Us WONDER Search

[f](#) [t](#) [in](#) [✉](#) [🌐](#)

About The Vaccine Adverse Event Reporting System (VAERS)

Request Form Results Map Chart Report About

[Dataset Documentation](#) [Other Data Access](#) [Data Use Restrictions](#) [How to Use WONDER](#)

Note: Any use of these data implies consent to abide by the terms of the data use restrictions.

About VAERS and the Collected Data

The VAERS database contains information on unverified reports of adverse events (illnesses, health problems and/or symptoms) following immunization with US-licensed vaccines. Reports are accepted from anyone and can be submitted electronically at www.vaers.hhs.gov.

Search Current VAERS Data

The VAERS Data Search allows you to search information from reports collected from 1990 to the present. Instructions on how to search are listed in next section.

This allows you to search for details on a specific VAERS report. Enter the VAERS ID number assigned to view report information.

Written and Video Instructions on How to Search VAERS Data

Below are written and video instructions on how to search VAERS data shared on CDC WONDER.



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R Project

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The R Project for Statistical Computing

Getting Started

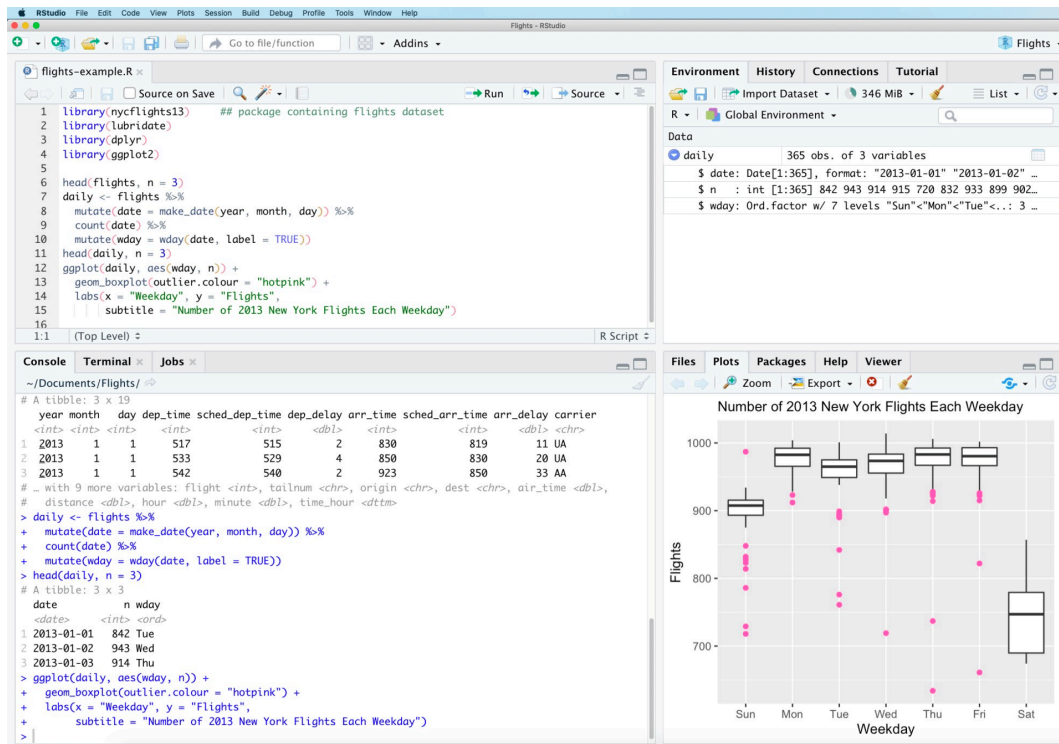
R is a free software environment for statistical computing and graphics. It compiles and runs on a wide variety of UNIX platforms, Windows and MacOS. To [download R](#), please choose your preferred [CRAN mirror](#).

If you have questions about R like how to download and install the software, or what the license terms are, please read our [answers to frequently asked questions](#) before you send an email.

News

- [R version 4.3.2 \(Eye Holes\) prerelease versions](#) will appear starting Saturday 2023-10-21. Final release is scheduled for Tuesday 2023-10-31.
- useR! 2024 will be a hybrid conference, taking place 8-11 July 2024 in Salzburg, Austria.
- [R version 4.3.1 \(Beagle Scouts\)](#) has been released on 2023-06-16.
- [R version 4.2.3 \(Shortstop Beagle\)](#) has been released on 2023-03-15.
- You can support the R Foundation with a renewable subscription as a [supporting member](#)

USE RSTUDIO AS AN INTERFACE - THE RSTUDIO IDE IS A FREE AND OPEN SOURCE INTEGRATED DEVELOPMENT ENVIRONMENT (IDE) FOR R




By cdhowe - Own work, CC BY-SA 4.0,
<https://commons.wikimedia.org/w/index.php?curid=101293607>

R Studio Education

Beginners



No one starting point will serve all beginners, but here are 6 ways to begin learning R.

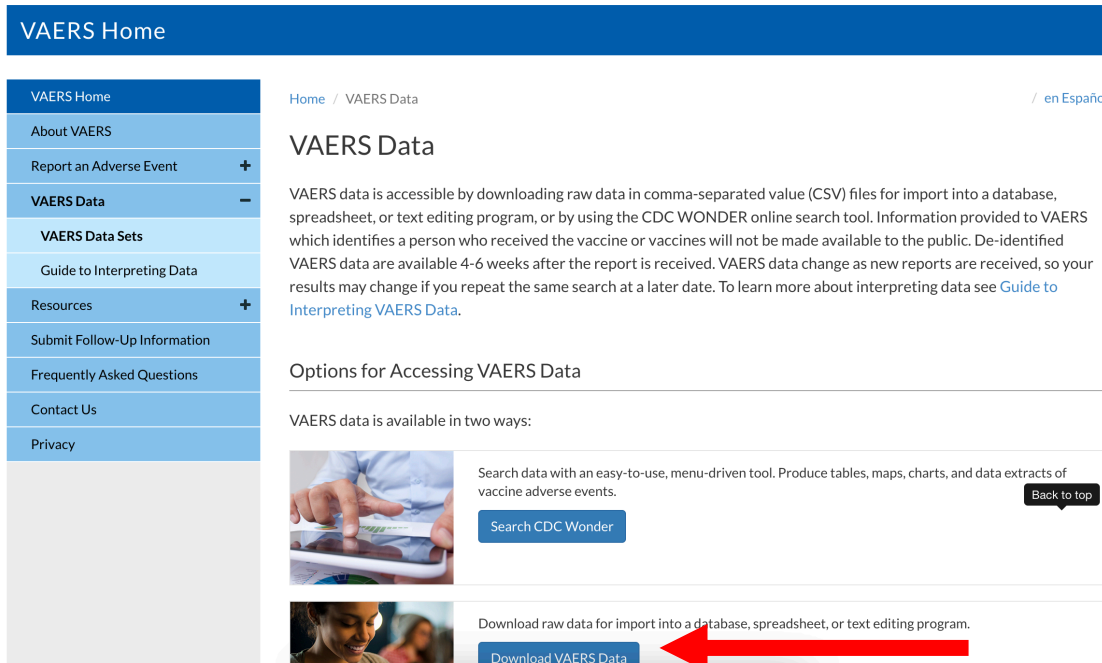
- Install , **RStudio**, and R packages like the **tidyverse**. These three installation steps are often confusing to first-time users. For beginner-friendly installation instructions, we recommend the free online ModernDive chapter *Getting Started with R and RStudio*. You may also enjoy the *Basic Basics*

<https://commons.wikimedia.org/w/index.php?curid=101293607>

<https://education.rstudio.com/>

DOWNLOADING VAERS DATA FOR USE IN RSTUDIO

<https://vaers.hhs.gov> 



VAERS Home

Home / VAERS Data / en Español

VAERS Data

VAERS data is accessible by downloading raw data in comma-separated value (CSV) files for import into a database, spreadsheet, or text editing program, or by using the CDC WONDER online search tool. Information provided to VAERS which identifies a person who received the vaccine or vaccines will not be made available to the public. De-identified VAERS data are available 4-6 weeks after the report is received. VAERS data change as new reports are received, so your results may change if you repeat the same search at a later date. To learn more about interpreting data see [Guide to Interpreting VAERS Data](#).

Options for Accessing VAERS Data

VAERS data is available in two ways:

- Search data with an easy-to-use, menu-driven tool. Produce tables, maps, charts, and data extracts of vaccine adverse events. [Search CDC Wonder](#)
- Download raw data for import into a database, spreadsheet, or text editing program. [Download VAERS Data](#)

1. Go to website <https://vaers.hhs.gov>
2. Click on Download VAERS data

required of healthcare providers and vaccine manufacturers.

VAERS reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Reports to VAERS can also be biased. As a result, there are limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can often quickly detect an early hint or warning of a safety problem with a vaccine. VAERS is one component of CDC's and FDA's multifaceted approach to monitoring safety after vaccines are licensed or authorized for use. There are multiple, complementary systems that CDC and FDA use to capture and validate data from different sources. VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also referred to as "safety signals." If a possible safety signal is found in VAERS, further analysis is performed with other safety systems, such as the CDC's Vaccine Safety Datalink (VSD) and Clinical Immunization Safety Assessment (CISA) Project, or in the FDA BEST (Biological Effectiveness and Safety) system. These systems are less impacted by the limitations of spontaneous and voluntary reporting in VAERS and can better assess possible links between vaccination and adverse events. Additionally, CDC and FDA cannot provide individual medical advice regarding any report to VAERS.

Key considerations and limitations of VAERS data:


- The number of reports alone cannot be interpreted as evidence of a causal association between a vaccine and an adverse event, or as evidence about the existence, severity, frequency, or rates of problems associated with vaccines.
- Reports may include incomplete, inaccurate, coincidental and unverifiable information.
- VAERS does not obtain follow up records on every report. If a report is classified as serious, VAERS requests additional information, such as health records, to further evaluate the report.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

VAERS data available to the public include only the initial report data to VAERS. Updated data which contains data from medical records and corrections reported during follow up are used by the government for analysis. However, for numerous reasons including data consistency, these amended data are not available to the public.

Additionally, reports to VAERS that appear to be potentially false or fabricated with the intent to mislead CDC and FDA may be reviewed before they are added to the [data analysis base](#).

Knowingly filing a false VAERS report is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

3. Agree to disclaimer after reading it

[I have read and understand the disclaimer.](#) 

SELECT OF A TEXT CONTROL.

Note for Internet Explorer users: Due to security reasons in your browser's settings you might be prompted to select "show restricted content" in order to view the .csv file as a spreadsheet.

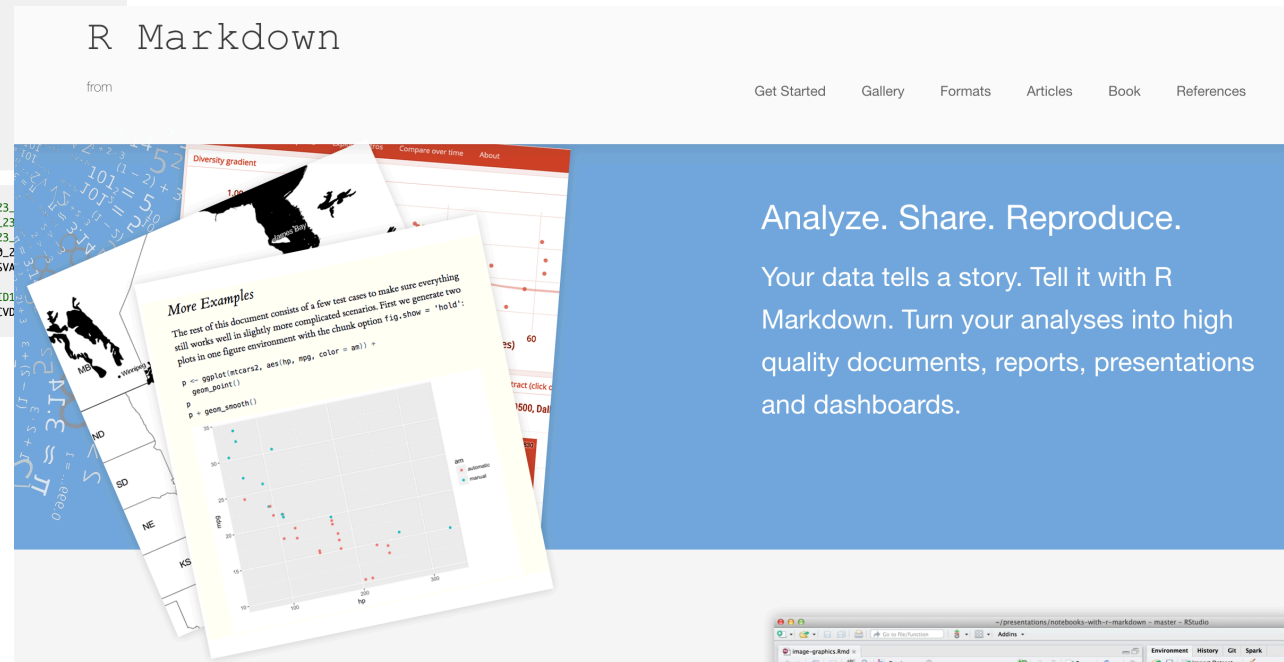
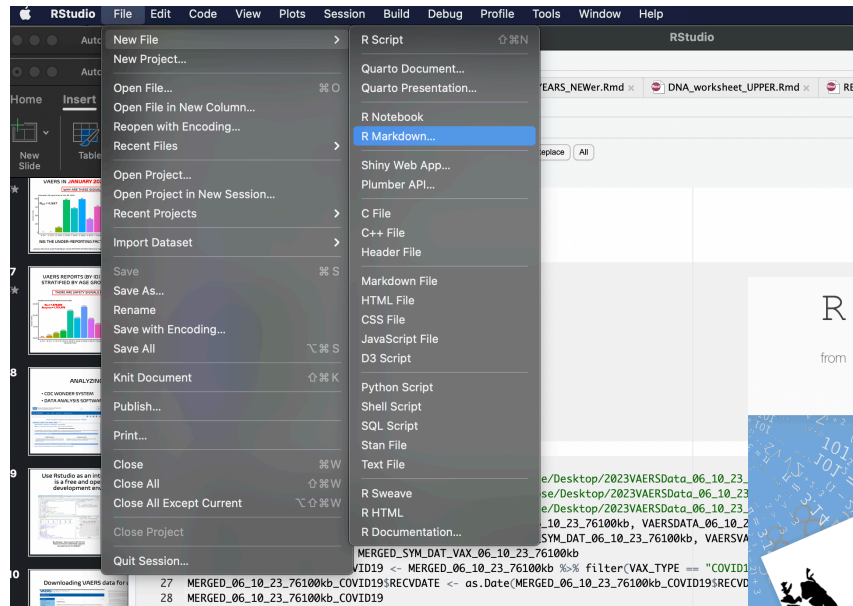
Last updated: October 6, 2023.
 (* Data contains VAERS reports processed as of: 09/29/2023.)

Year	Zip File	CSV File (VAERS DATA)	CSV File (VAERS Symptoms)	CSV File (VAERS Vaccine)
All Years Data*	482.23 MB			
2023*	18.24 MB			7.37 MB
2022	62.14 MB	263.84 MB	26.46 MB	20.96 MB
2021	168.80 MB	623.18 MB	77.17 MB	57.25 MB
2020	11.19 MB	41.73 MB	4.51 MB	4.45 MB
2019	11.21 MB	41.35 MB	4.70 MB	4.45 MB
1991	1.01 MB	2.83 MB	0.63 MB	1.09 MB
1990	0.21 MB	0.58 MB	0.14 MB	0.19 MB
Non-Domestic	103.14 MB			59.44 MB

Disclaimer: At the request of European regulators, CDC and FDA have removed certain data fields (country codes; reported symptom case narrative free text; diagnostic laboratory data free text field; illness at time of vaccination free text field; chronic conditions free text medical history field; allergies free text field) from foreign VAERS reports which were submitted to VAERS and may not comply with European regulations. Domestic (U.S.) VAERS reports are not affected by this process.

4. Download Zip File for the year of interest
5. Download Non-Domestic Zip File as well if you wish

IF USING R, READ IN DATA, VAX AND SYMPTOM .CSV (+ NON-DOMESTIC) FILES DOWNLOADED FROM VAERS



MERGE THE DATA, SYMPTOM AND VAX FILES

1. Merging the 3 downloaded VAERS files according to the VAERS_ID variable allows a comprehensive data frame for as many people as possible
2. If you only want to examine only adverse events, you can simply read the 'symptoms' file without merging

Vaccine Adverse Event Reporting System (VAERS) Data

The VAERS database was analyzed using the Language and Environment for Statistical Computing package in R,⁸ and included data spanning December 17, 2020 through October 6, 2023. The VAERS data is available for download in three separate comma separated values (csv) data files representing: i) general data for each report; ii) the reported AEs or 'symptoms', and iii) vaccine data including vaccine manufacturer and lot number.⁵ A VAERS ID number is assigned to preserve confidentiality when a report is

LET'S GET CREATIVE WITH DEATH REPORTS

There are 2 ways you can pull death reports out of VAERS (and I always count people – by the way)

- Count the number of “Y”s in the “DIED” column
- Query the word ‘death’ or ‘died’ or ‘autopsy’ or ‘abortion’ in the symptom columns

A tibble: 1,578,265 × 38 Groups: VAERS_ID [1,578,265]

VAX_MANU <chr>	VAX_LOT <chr>	VAX_DOSE_SERIES <chr>	VAX_SITE <chr>	DIED <chr>	HOSPITAL <chr>	ER_ED_VISIT <chr>	DISABLE <chr>
MODERNA	AS7147B	UNK	RA	NA	NA	NA	NA
MODERNA	AS7143C	5	RA	NA	NA	NA	NA
MODERNA	NA	6	NA	NA	Y	NA	NA
MODERNA	023h22a	4	RA	NA	NA	NA	NA
MODERNA	005M21A	4	NA	NA	Y	NA	NA
PFIZER\BIONTECH	NA	3	AR	NA	NA	Y	NA
MODERNA	033F21A	3	LA	NA	NA	NA	NA
MODERNA	022M20A	2	LA	NA	NA	NA	Y
MODERNA	046821A	1	LA	Y	Y	Y	NA
PFIZER\BIONTECH	EW0196	2	RA	NA	NA	NA	NA

211-220 of 1,578,265 rows | 18-27 of 38 columns Previous 1 ... 20 21 22 23 24 ... 100 Next

VAERS_ID <chr>	SYMPTOM1 <chr>	SYMPTOM2 <chr>	SYMPTOM3 <chr>	SYMPTOM4 <chr>	SYMPTOM5 <chr>	DIED <chr>
1514899	Abortion spontaneous	Autopsy	Investigation	Vaginal haemorrhage	NA	NA
2096990	Abortion spontaneous	Autopsy	COVID-19	Drug ineffective	SARS-CoV-2 test	Y
2280247	Abortion induced	Autopsy	Foetal malformation	Maternal exposure during pregnancy	Ultrasound antenatal screen	Y
2282507	Abortion induced	Autopsy	COVID-19 immunisation	Maternal exposure during pregnancy	Ultrasound antenatal screen	NA
2286049	Abortion spontaneous	Autopsy	Maternal exposure during breast feeding	Maternal exposure during pregnancy	Scan	Y
2416410	Abortion spontaneous	Autopsy	COVID-19 immunisation	NA	NA	NA

SYMPTOM3 <chr>	SYMPTOM4 <chr>	SYMPTOM5 <chr>	DIED <chr>
Decreased appetite	Sudden death	Vomiting	Y
Death	NA	NA	Y
Condition aggravated	Death	Headache	Y
Pulmonary embolism	NA	NA	Y
NA	NA	NA	Y
NA	NA	NA	Y
NA	NA	NA	Y
Death	NA	NA	Y
Cardioversion	Death	Dyspnoea	Y
Cough	Death	Drug screen positive	NA

LET'S GET CREATIVE WITH DEATH REPORTS

I concatenate the SYMPTOM1, SYMPTOM2, SYMPTOM3, ... SYMPTOMn columns so query is for one variable and not up to 20...

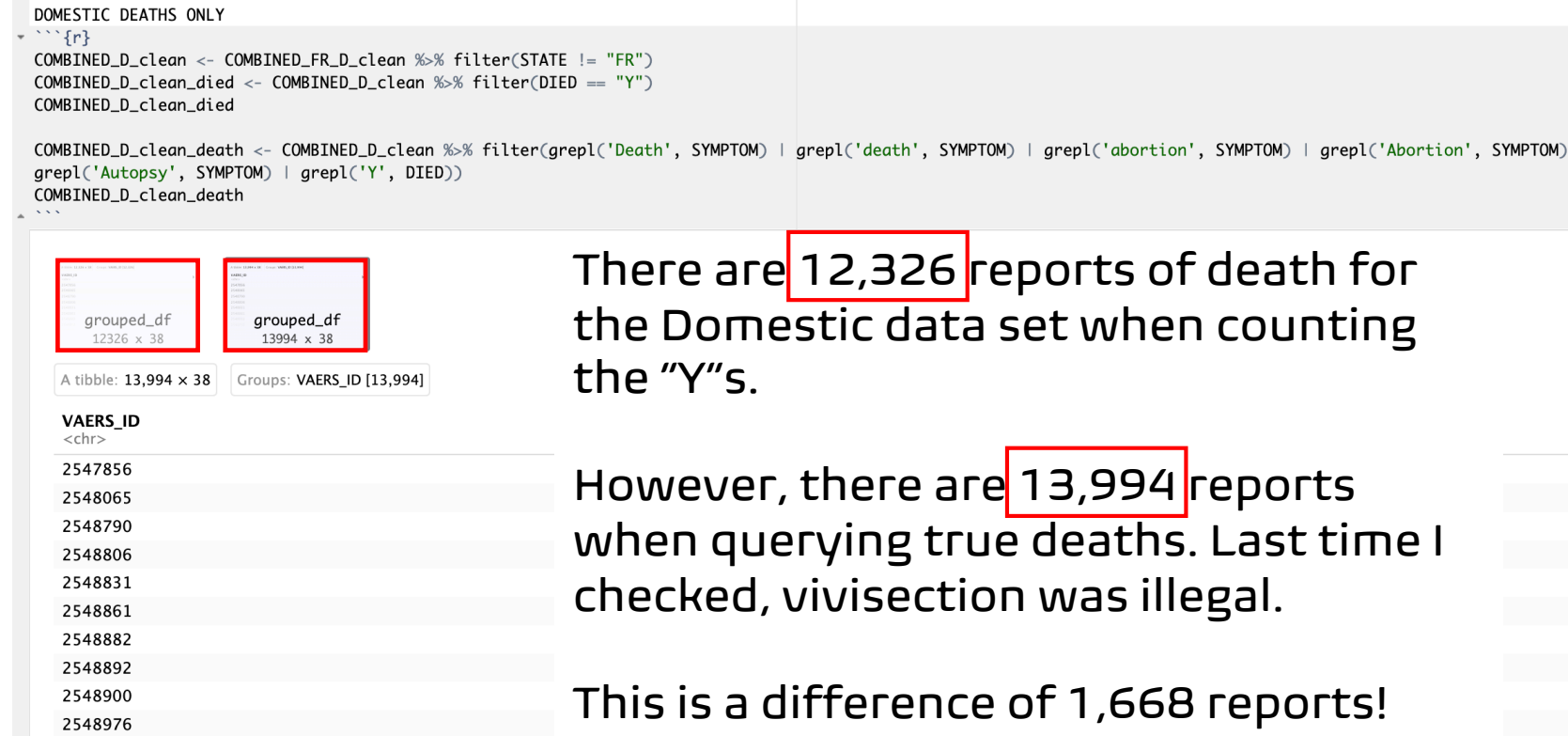
- The number of "Y"s in the "DIED" column is 1,668 fewer than the actual number of reports of death

```

DOMESTIC DEATHS ONLY
```{r}
COMBINED_D_clean <- COMBINED_FR_D_clean %>% filter(STATE != "FR")
COMBINED_D_clean_died <- COMBINED_D_clean %>% filter(DIED == "Y")
COMBINED_D_clean_died

COMBINED_D_clean_death <- COMBINED_D_clean %>% filter(grepl('Death', SYMPTOM) | grepl('death', SYMPTOM) | grepl('abortion', SYMPTOM) | grepl('Abortion', SYMPTOM) | grepl('Autopsy', SYMPTOM) | grepl('Y', DIED))
COMBINED_D_clean_death
```

```



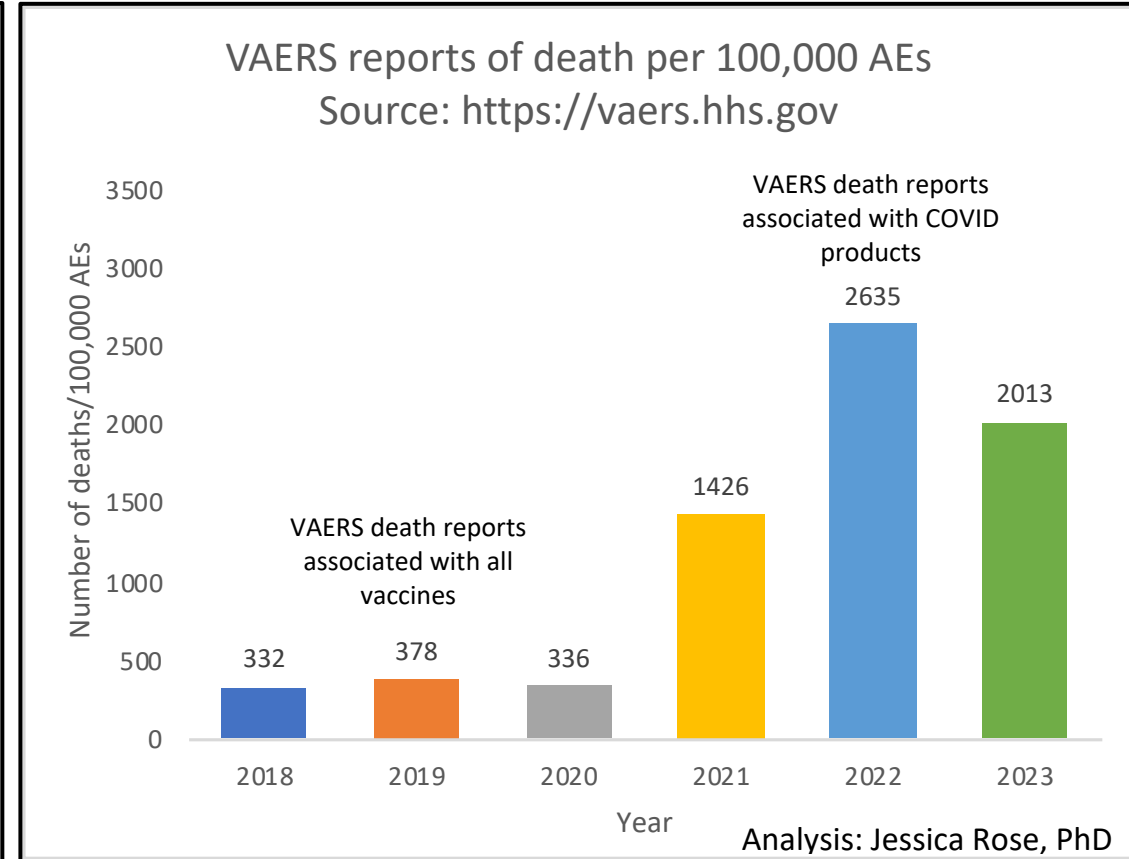
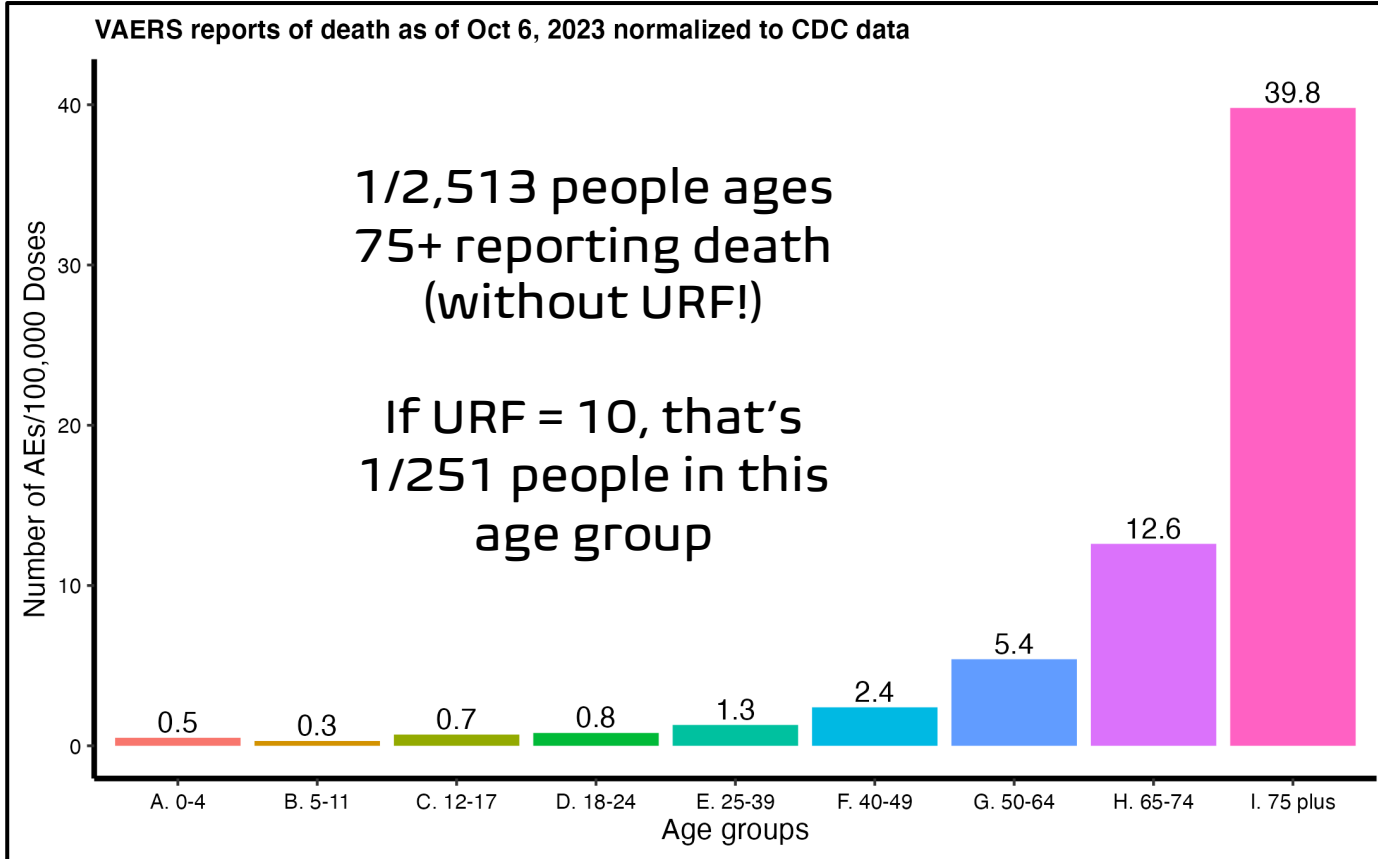
There are 12,326 reports of death for the Domestic data set when counting the "Y"s.

However, there are 13,994 reports when querying true deaths. Last time I checked, vivisection was illegal.

This is a difference of 1,668 reports!

N.B. It is important to stick with CDC 'numbers' when publishing data. The numbers must match Wonder, so even though we know there are many more deaths reported in VAERS, we will use the **under-represented** count for our data presentation.

VAERS DEATH REPORTS AS OF OCTOBER 6, 2023



OPENVAERS CHARTING OF DEATH FOR THE PAST 30 YEARS

Before and After the Introduction of the Covid Vaccine

US Reports Through August 18, 2023

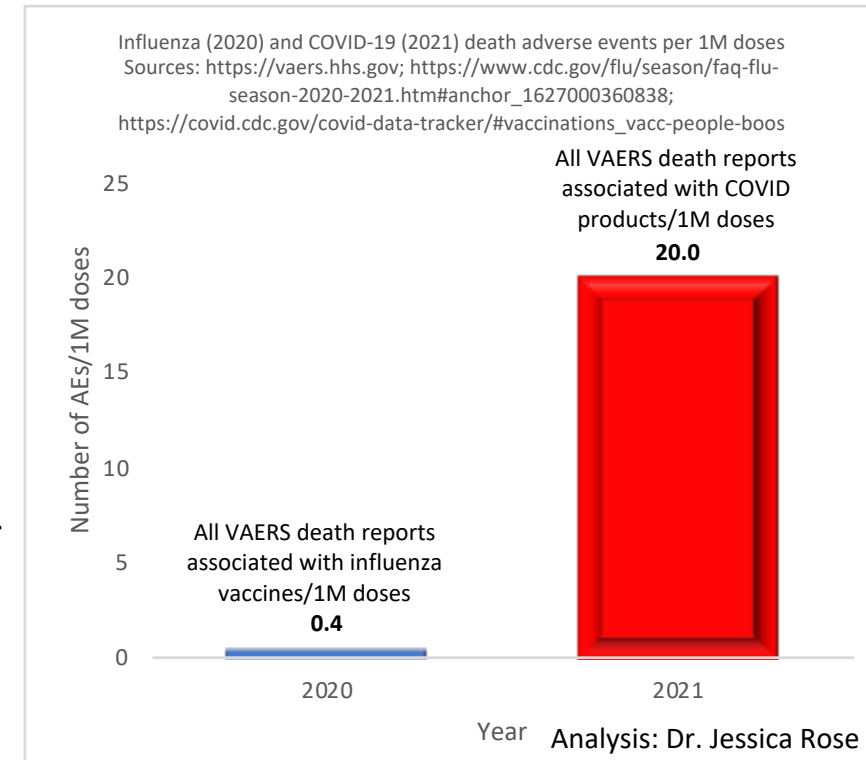
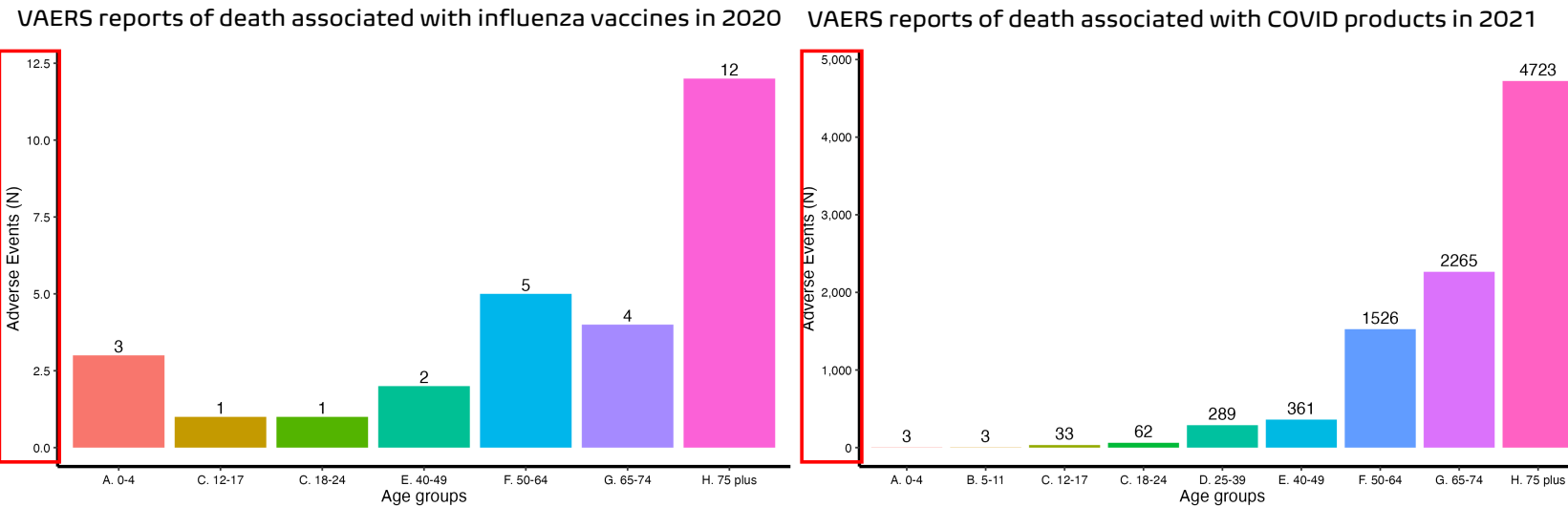
US TOTALS

| | 1990-2019 | Per Year | 2021-2023* | Per Year | % Increase/Year |
|----------------------|-----------|----------|------------|----------|-----------------|
| Reports of Death | 4,729 | 163 | 18,579 | 6,985 | 4185% |
| Hospitalizations | 35,749 | 1,233 | 89,403 | 33,610 | 2626% |
| Permanent Disability | 10,862 | 375 | 19,056 | 7,164 | 1810% |
| Life Threatening | 9,217 | 318 | 15,298 | 5,751 | 1708% |

**HOW CAN WE USE VAERS TO SHOW THAT IT'S
NOT BECAUSE OF THE NUMBER OF SHOTS?**

VAERS INFLUENZA VS COVID DEATH REPORTS FOR 2020 AND 2021, RESPECTIVELY

The plots below demonstrate the relative (to influenza vs. COVID shots) numbers of deaths according to age group

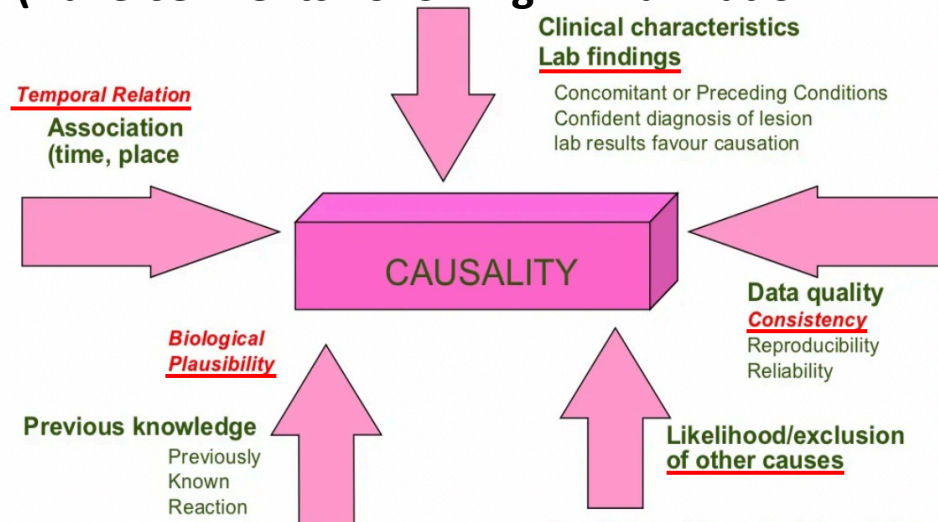


The normalized plot to the right represents all deaths (regardless of age) in the context of administered doses per million for influenza (left - blue) and COVID (right - red)

USING VAERS TO PROVIDE EVIDENCE OF CAUSATION USING BRADFORD HILL CRITERIA

WHO CRITERIA

Assessment of Routine and Serious AEFIs (Adverse Events Following Immunization - AEFI)



From presentation to World Council
for Health: 05/02/22

Hills Criteria of Causation

- Austin Bradford Hill (1897-1991), a British medical statistician as a way of determining the causal link between a specific factor (e.g., cigarette smoking) and a disease (such as emphysema or lung cancer).
- *Hill's Criteria* form the basis of modern epidemiological research, which attempts to establish scientifically valid causal connections (disease – and its cause)
- Temporal Relationship
- **Strength**
- **Dose-Response Relationship**
- Consistency
- Plausibility
- Consideration of Alternate Explanations
- Experiment
- **Specificity**
- **Coherence**
- **Reversibility**

Vaccine Causality Assessment (Part 1): Initial Case Assessment Form

Note: A copy of the reporting form (and any follow up information) for each specific AEFI to be reviewed by committee should be appended to this cover page

WHO VACCINE CAUSALITY ASSESSMENT FORM

| | | | | |
|--|--------------------------------|----------------------------------|---------------------------------------|---------------------------------------|
| Identification: _____ | | Vaccine(s): _____ | | |
| 1. Primary reason for reporting: _____ | | | | Code: [] [] |
| 1.1 Agreement with report: | | | | |
| Agree <input type="checkbox"/> | | | | |
| Disagree <input type="checkbox"/> | | | | |
| Insufficient data <input type="checkbox"/> | | | | |
| Error of coding? Yes <input type="checkbox"/> No <input type="checkbox"/> New coding [] [] | | | | |
| Is the event severe? Yes <input type="checkbox"/> No <input type="checkbox"/> | | | | |
| To be reviewed again? Yes <input type="checkbox"/> No <input type="checkbox"/> | | | | |
| 2. These questions are related to the primary reason for reporting only: | | | | |
| 2.1 Frequency of occurrence of the adverse event | NPR* <input type="checkbox"/> | Rare <input type="checkbox"/> | Intermediate <input type="checkbox"/> | Common <input type="checkbox"/> |
| 2.2 Similar events known to occur with other disease | Yes <input type="checkbox"/> | | No <input type="checkbox"/> | |
| 2.3 Event is known to be related to this vaccine | Yes <input type="checkbox"/> | | No <input type="checkbox"/> | |
| 2.4 Event is explainable by the biological properties of the vaccine | Yes <input type="checkbox"/> | | No <input type="checkbox"/> | |
| 2.5 Vaccine-event interval compatible with the event | n/a <input type="checkbox"/> | Typical <input type="checkbox"/> | Compatible <input type="checkbox"/> | Incompatible <input type="checkbox"/> |
| 2.6 The patient had similar symptoms in the past | n/a <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Unknown <input type="checkbox"/> |
| 2.7 Concomitant or preceding drug therapy | Yes <input type="checkbox"/> | | No <input type="checkbox"/> | |
| 2.8 Concomitant or preceding condition | Rel.* <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Unknown <input type="checkbox"/> |
| 2.9 Other contributing factors | Yes <input type="checkbox"/> | | No <input type="checkbox"/> | |
| * Rel: assessment of causality to be done in context of relevant condition. NPR: not previously reported | | | | |

| | | |
|--|-----------------------|-----------------------------|
| 3. Conclusion with regard to the primary reason for reporting: | | |
| 3.1 The association is: | | 3.2 Possible new entity [] |
| [] 1 Very likely - certain | [] 4 Unlikely | |
| [] 2 Probable | [X] 5 Unrelated | |
| [] 3 Possible | [] 6 Unclassifiable: | 3.3 insufficient data [] |
| 3.4 The case would benefit from a second review: Yes <input type="checkbox"/> No <input type="checkbox"/> | | |
| 4. Comments: This case is most compatible with bronchiolitis possibly due to RSV with shock like picture. This is NOT anaphylaxis as timing and symptoms not compatible with diagnosis. This is NOT hypotonic, hyporesponsive episode (HHE) as had lowered BP- not seen in HHE. The seizure 3 hours after immunization was not associated with rapidly rising fever – usual pattern for febrile seizure with DTaP. | | |
| 5. Recommendations: Education | | |

6. Useful for Education: Yes No

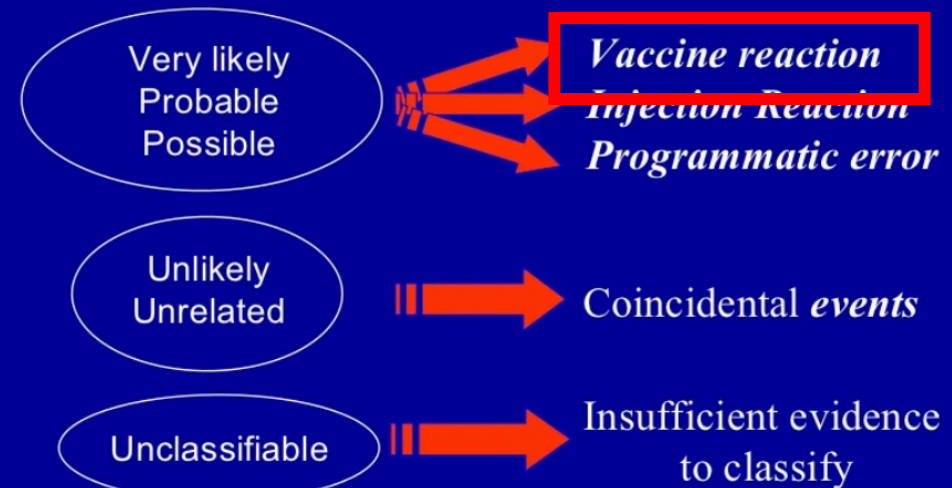
- Review criteria for with HCW for anaphylaxis
- Note delay in recognition that child had serious problem unrelated to vaccine- distracted by history of vaccine. Education about this case for local MDs.

7. Useful for Publication: Yes No

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WHO DEFINES CAUSALITY

Categories of Causality using WHO Causality Assessment Criteria



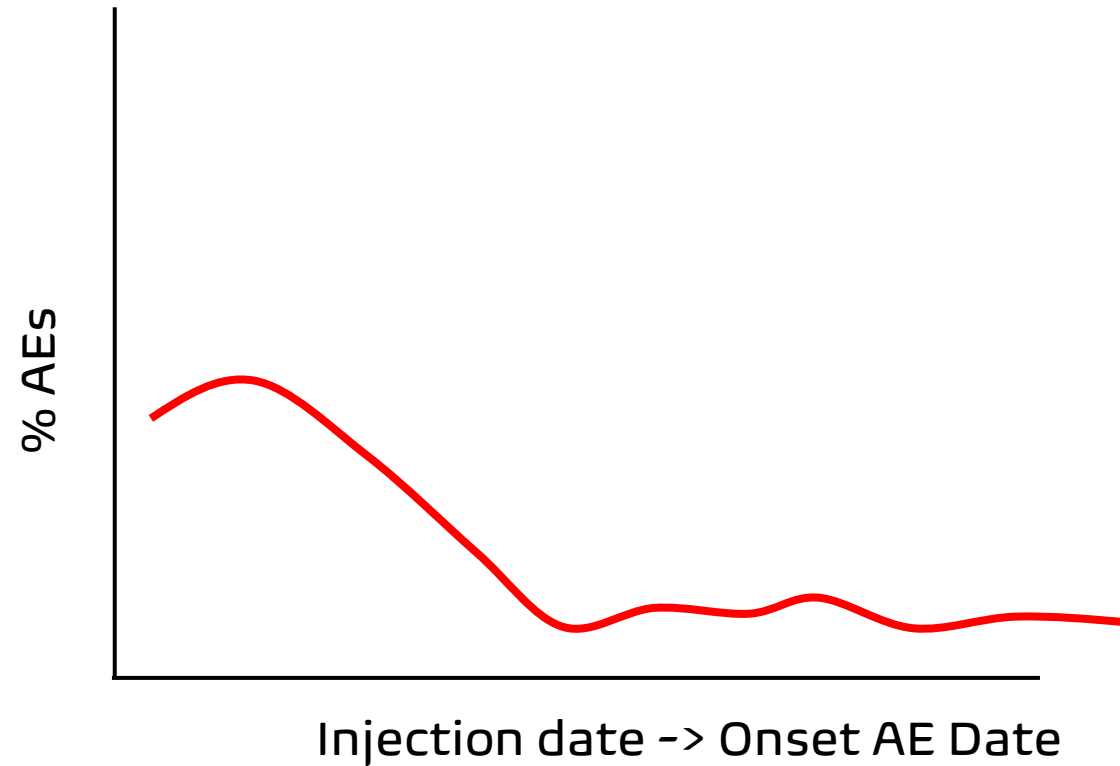
From presentation to World Council
for Health: 05/02/22

EVIDENCE OF CAUSATION USING BRADFORD HILL

From presentation to World Council
for Health: 05/02/22

1. **Strength (effect size):** A small association does not mean that there is not a causal effect, though the larger the association, the more likely that it is causal.
2. **Consistency (reproducibility):** Consistent findings observed by different persons in different places with different samples strengthens the likelihood of an effect.
3. **Specificity:** Causation is likely if there is a very specific population at a specific site and disease with no other likely explanation. The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship.
4. **Temporality:** The effect has to occur after the cause (and if there is an expected delay between the cause and expected effect, then the effect must occur after that delay).
5. **Biological gradient (dose-response relationship):** Greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect. In other cases, an inverse proportion is observed: greater exposure leads to lower incidence.
6. **Plausibility:** A plausible mechanism between cause and effect is helpful (but Hill noted that knowledge of the mechanism is limited by current knowledge).
7. **Coherence:** Coherence between epidemiological and laboratory findings increases the likelihood of an effect. However, Hill noted that "... lack of such (laboratory) evidence cannot nullify the epidemiological effect on associations".
8. **Experiment:** "Occasionally it is possible to appeal to experimental evidence".
9. **Analogy:** The use of analogies or similarities between the observed association and any other associations.
10. **Reversibility:** If the cause is deleted then the effect should disappear as well.

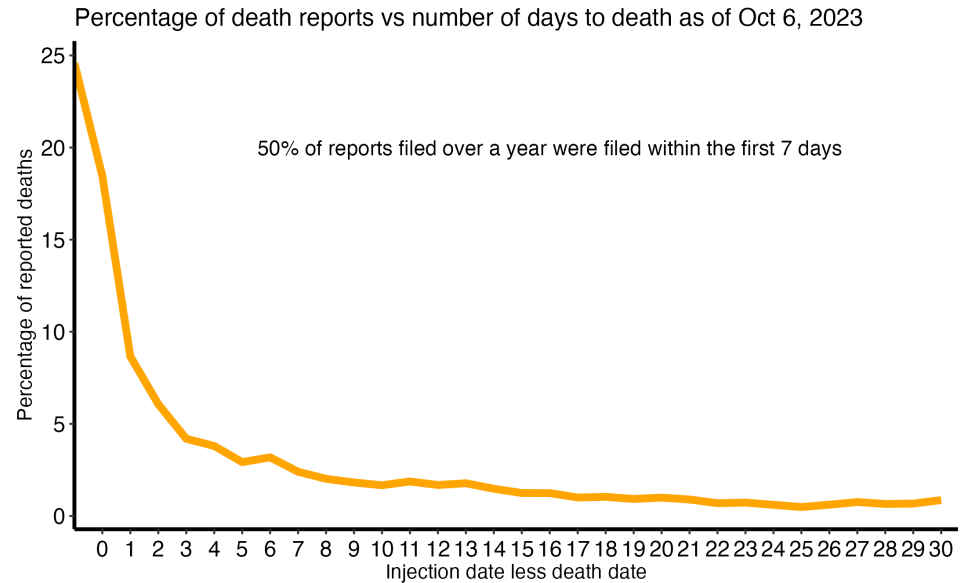
TEMPORALITY: DOES A COME BEFORE B?



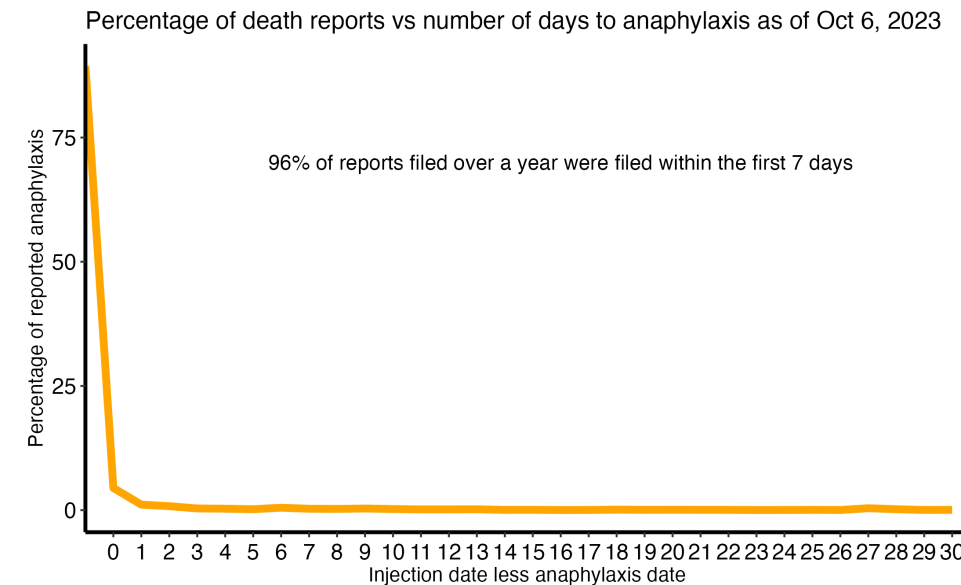
4. Temporality: The effect has to occur after the cause (and if there is an expected delay between the cause and expected effect, then the effect must occur after that delay).

TEMPORALITY

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for Health: 05/02/22



50% of death reports filed within a year were filed within 7 days of injection

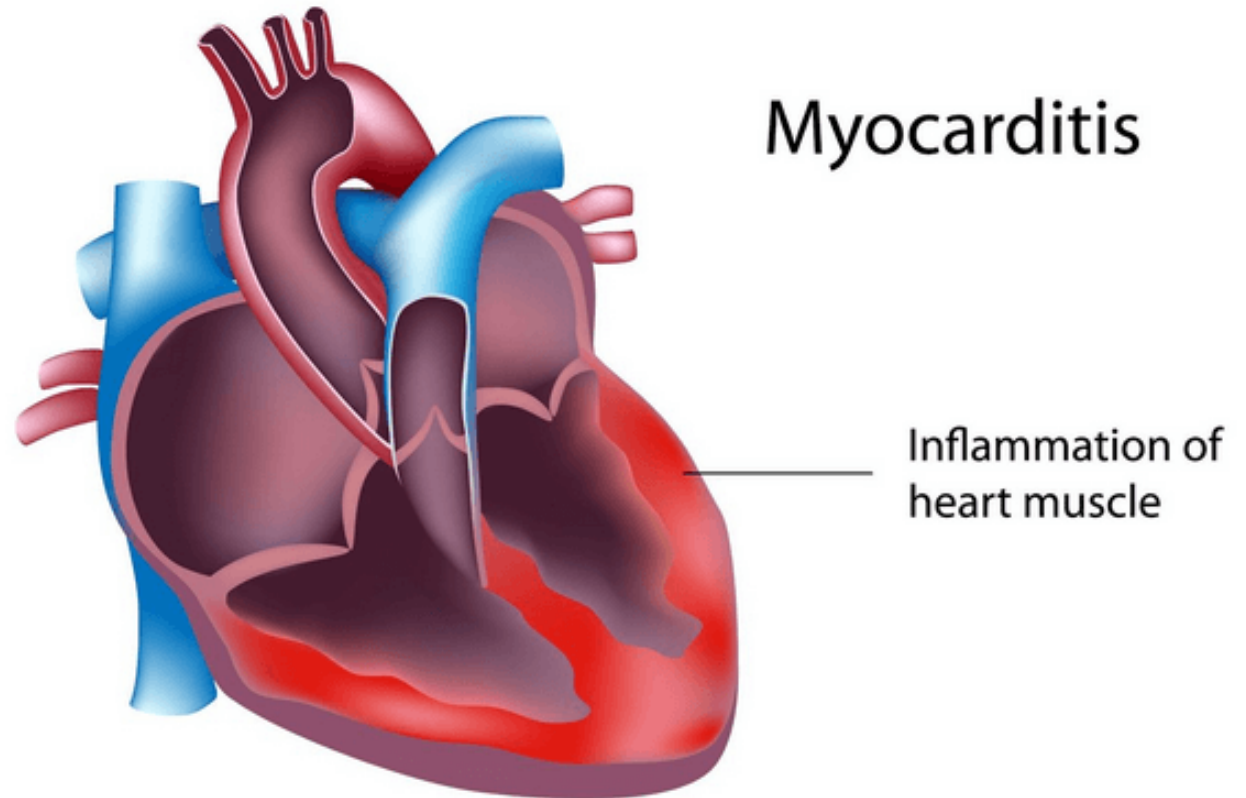


96% of anaphylaxis reports filed within a year were filed within 7 days

(92.5% were filed within 24 hours)

DOSE RESPONSE: DOES MORE OF A RESULT IN MORE OF B?

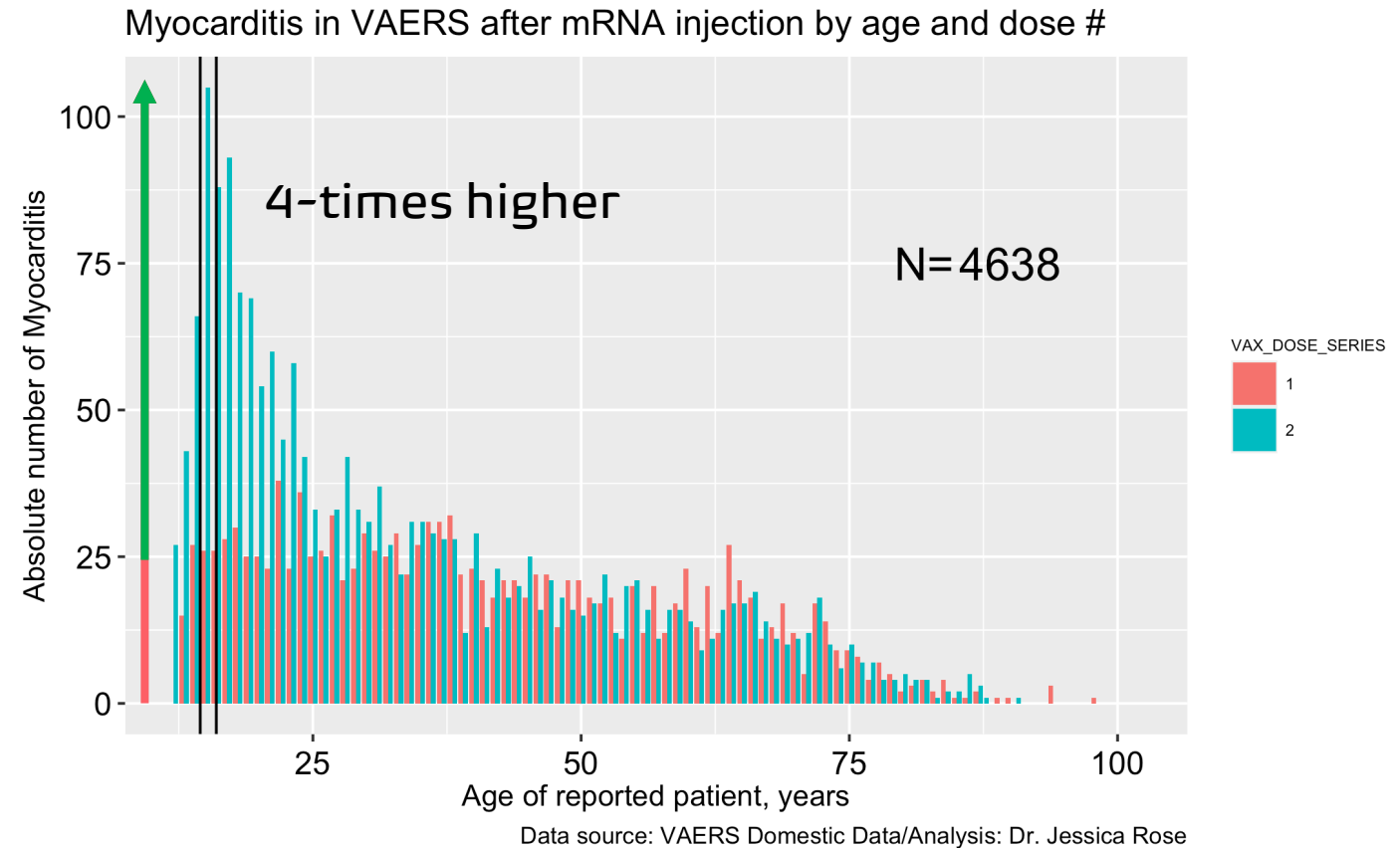
From presentation to World Council
for Health: 05/02/22



5. Biological gradient (dose-response relationship): Greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect.

DOSE RESPONSE

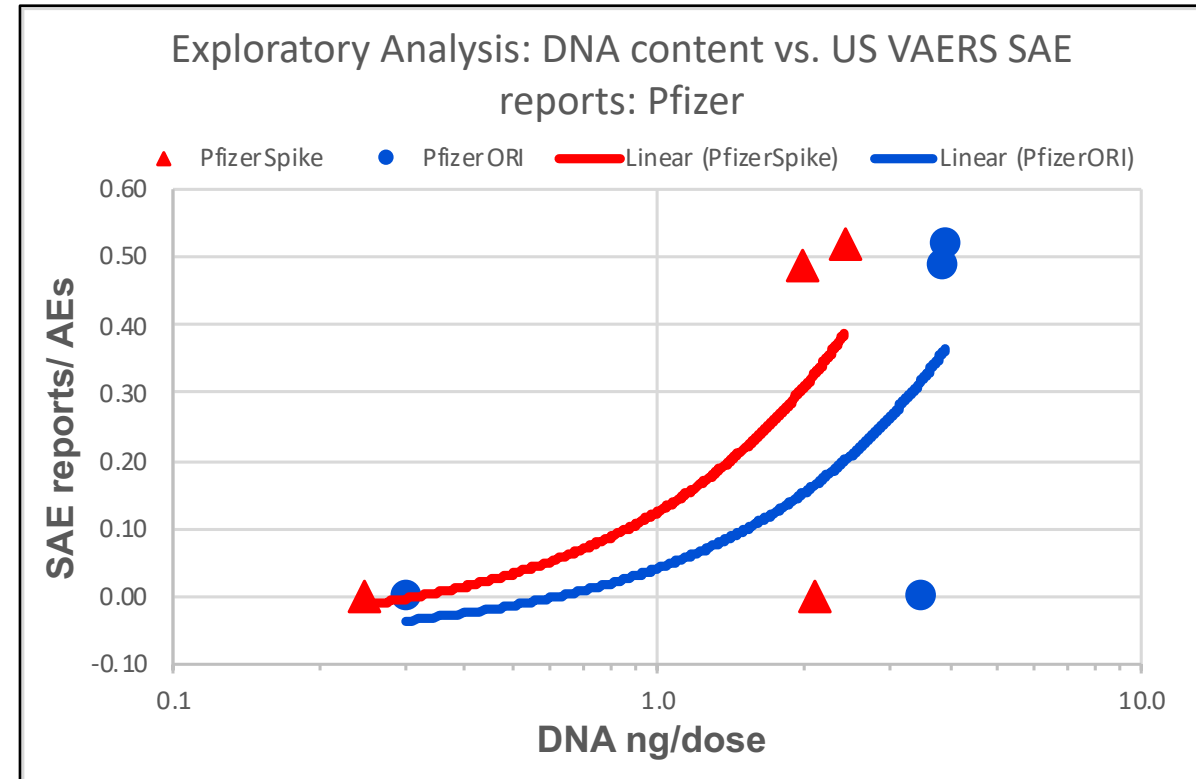
From presentation to World Council
for Health: 05/02/22



5. Biological gradient (dose-response relationship):
Greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect.

Comparison of residual DNA content of spike (red) and ori (blue) and the total number of adverse events (orange) reported to VAERS

Dose response



5. Biological gradient (dose-response relationship): Greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect.

From presentation to World Council for Health: 05/02/22

THE CDC ALSO USES PROPORTIONAL REPORTING RATIO (PRR)

The total number of AEs for flu is 12,076 (D) and the total number of deaths is 74 (C).

(The total number of people who succumbed to death from FLU VAXXES is 74 and the total number of people who succumbed to AEs from FLU VAXXES is 12,076.)

The total number of AEs for COVID-19 is 702,449 (B) and the total number of deaths is 10,306 (A).

(The total number of people who succumbed to death from COVID19 VAXXES is 10,036 and the total number of people who succumbed to AEs from COVID19 is 702,449.)

But what needs to be defined here for A, B, C and D are the number of people who succumbed to a specific AE and all AEs combined for both COVID and FLU. Therefore, A = specific AE (death) for specific VAX (COVID19) and B = all other AEs for specific VAX (COVID19) and C = specific AE (death) for specific VAX (FLU (all FLU products)) and D = all other AEs for specific VAX (FLU (all FLU products)).

If the PRR > 1 then there is a risk

```
```{r}
```

```
A <- 10306
```

```
B <- 702449
```

```
C <- 74
```

```
D <- 12076
```

```
PRR <- (A/(A+B))/(C/(C+D))
```

```
PRR
```

```
```
```

```
[1] 2.374075
```

- PRR > 1 suggests that an AE is more commonly reported for individuals taking the drug of interest, relative to the comparison drugs indicating that the AE is caused by the drug of interest and therefore a "side effect".
- Since 2.374075 > 1, then death is more commonly reported with COVID injection than from flu vaccine indicating that death is caused by the COVID-19 injections

As a point of concern with regards to CDC safety signal metrics, as defined in section 2.3.1 in the SOP, the proportional reporting ratio (PRR) is used to define safety signals originating from VAERS. The PRR is a metric that compares the ratio of specific AEs to total AEs for vaccine products. It is defined as:

$$PRR = \frac{\left[\frac{a}{(a+b)} \right]}{\left[\frac{c}{(c+d)} \right]}$$

where a = specific AE for specific vaccine; b = all other AEs for specific vaccine; c = specific AE for all other vaccines; d = all other AEs for all other vaccines [36,37]. However, this technique is