THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM

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

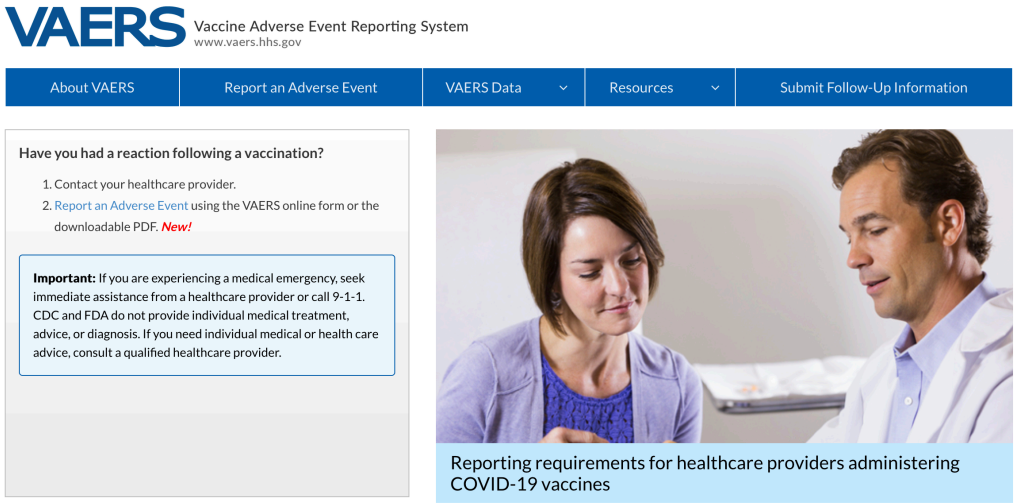
November 1, 2023

Jessica Rose, PhD

WHAT IS VAERS?

Vaccine Adverse Event Reporting System

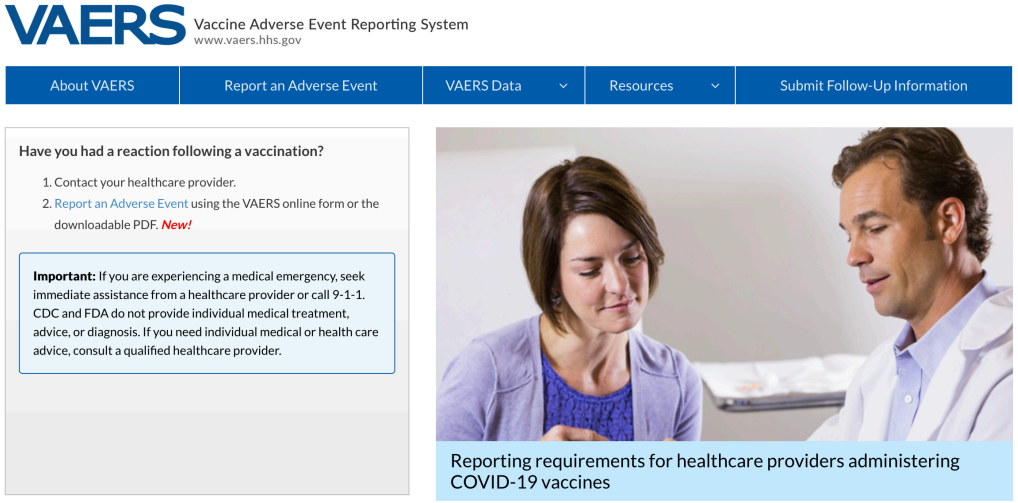
- VAERS was created in 1990 by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to receive reports of AEs that may be associated with vaccines.
- The primary purpose for maintaining the database is to serve as an early warning or signaling system for adverse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



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**.



Reporting requirements for healthcare providers administering COVID-19 vaccines

Lazarus, Ross et al. Grant Final Report. Grant ID: R18 HS 017045. Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS). Submitted to **The Agency for Healthcare Research and Quality (AHRQ)**

Rose, J. 2021, Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System? **Science, Public Health Policy & the Law** Volume 3:100–129

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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

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).

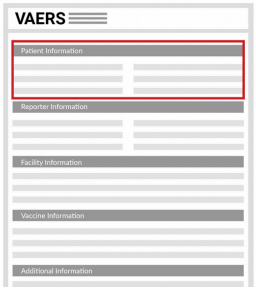
28 items – 6 time-limited e-pages

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

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

Completion Status

- Patient Information
- Reporter Information
- Facility Information
- Vaccine Information
- Additional Information



Report an Adverse Event - Patient Information Instructions | en Español

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

Item 1

Patient first name: | Patient last name:

Street address:

City: | State: Select State | County:

Zip code: | Phone: | Email:

Item 2

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

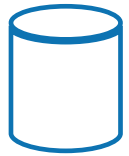
Item 3

* Sex: Male Female Unknown

https://vaers.hhs.gov/esub/index.jsp

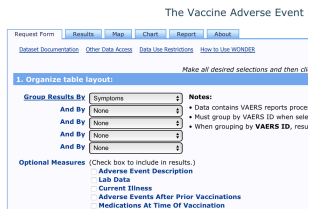
FRONT END DATA NOT THE FULL STORY

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



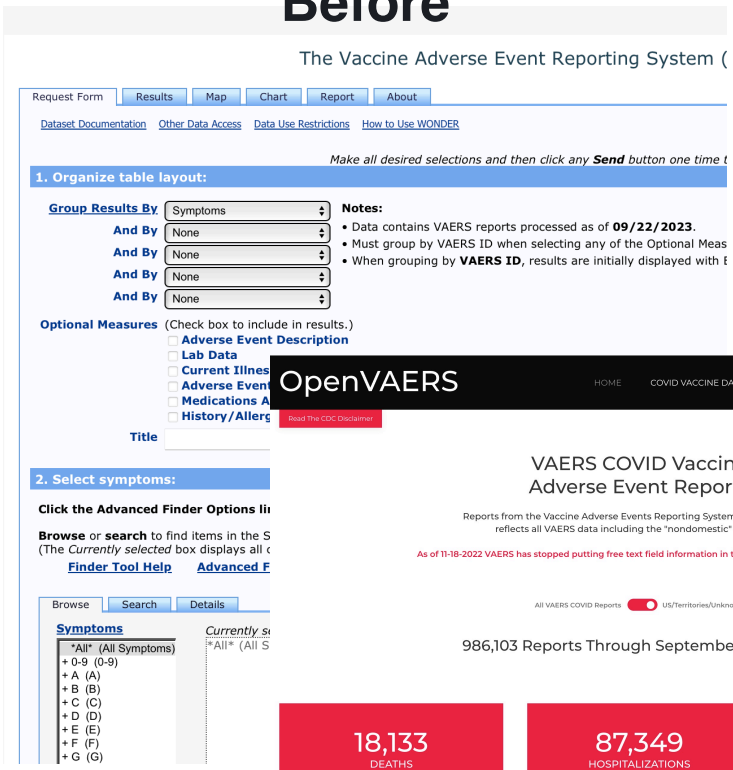
WONDER
Wide-ranging Online Data
for Epidemiological Research

A NOTE ON OPENVAERS

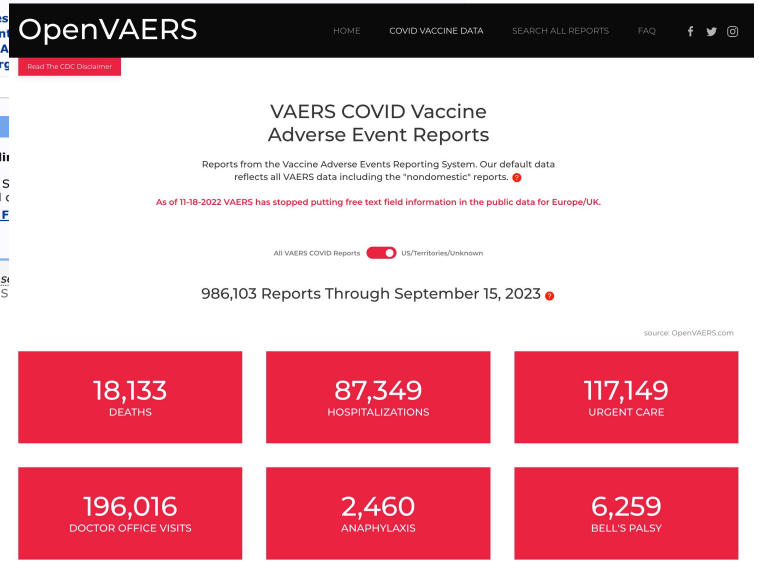
What is OpenVAERS.com?

- 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



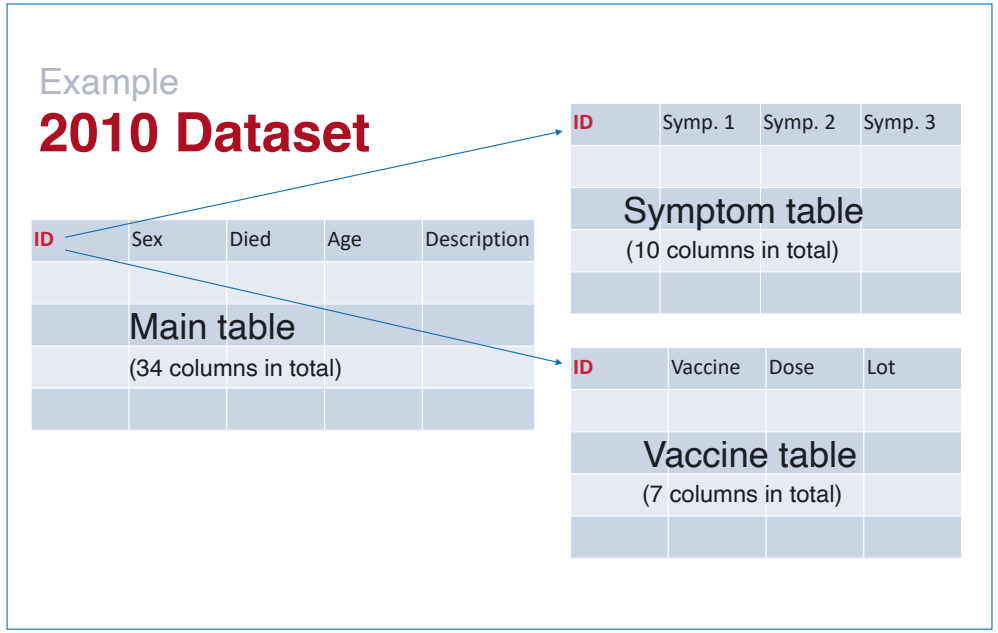
After



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?

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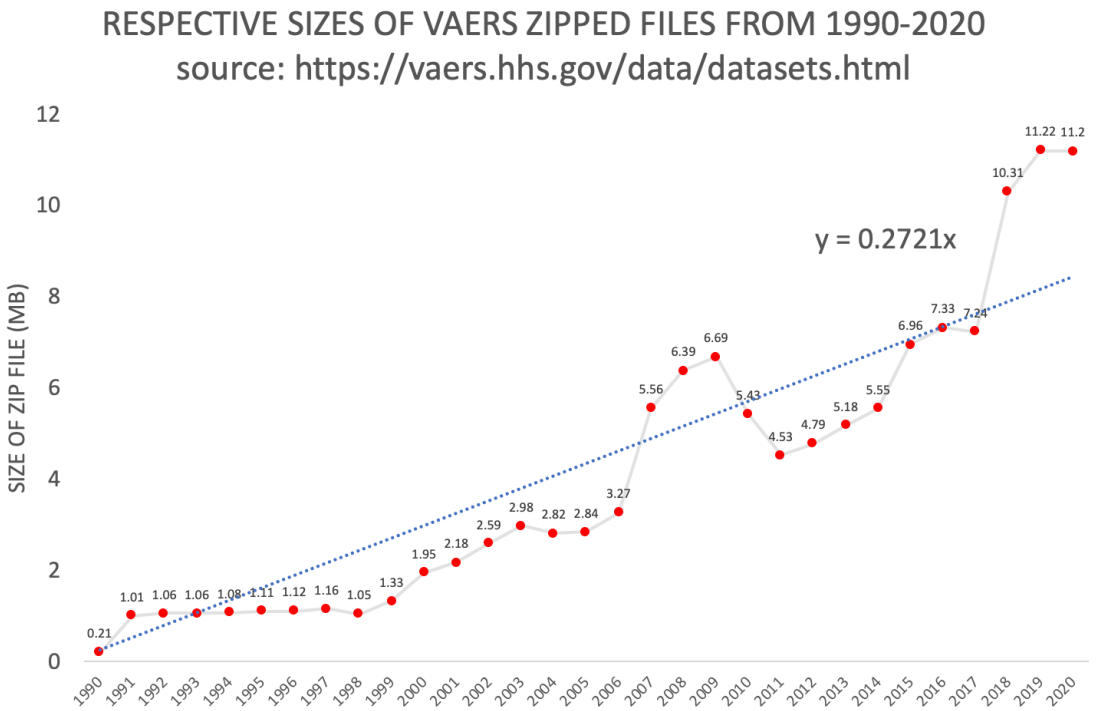
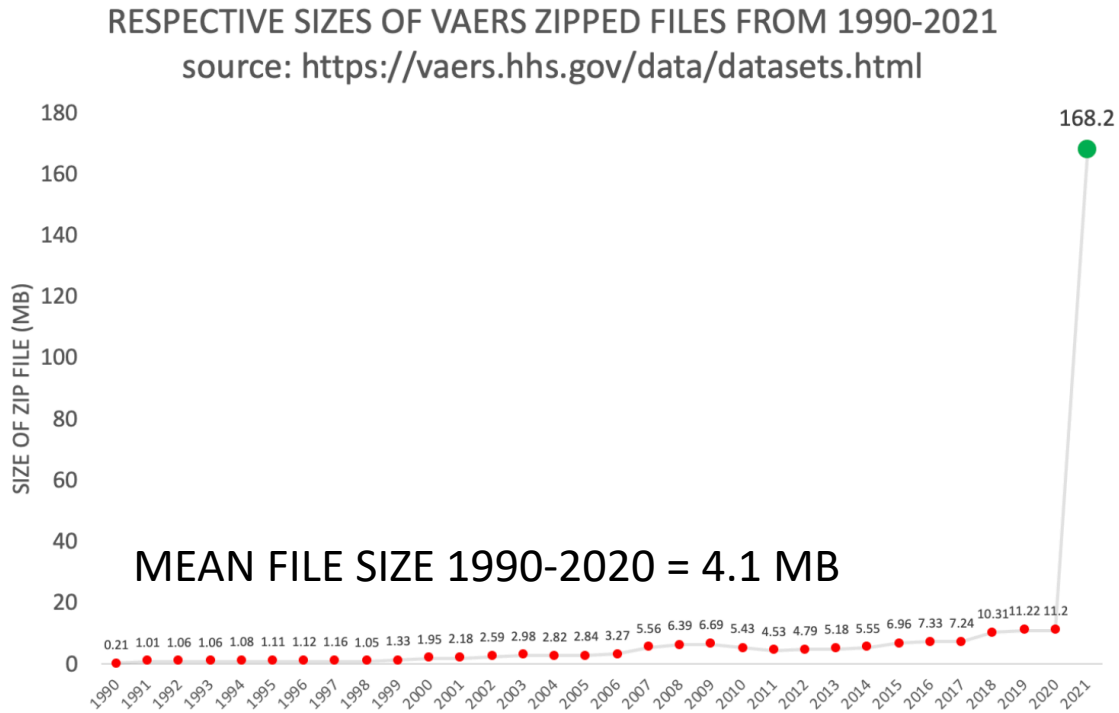
THE TREND OF INCREASING PRODUCTS ON MARKET AND ADVERSE EVENT (AE) DATA INPUT

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





https://vaers.hhs.gov

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

From presentation to World Council for Health: 12/28/23

VAERS WORKS AS A PHARMACOVIGILANCE SYSTEM

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

Volume 131, Issue 6
June 2013

Previous Article
Next Article

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**

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

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

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

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VAERS SINCE 2021
(COVID-19 INJECTABLE PRODUCTS)

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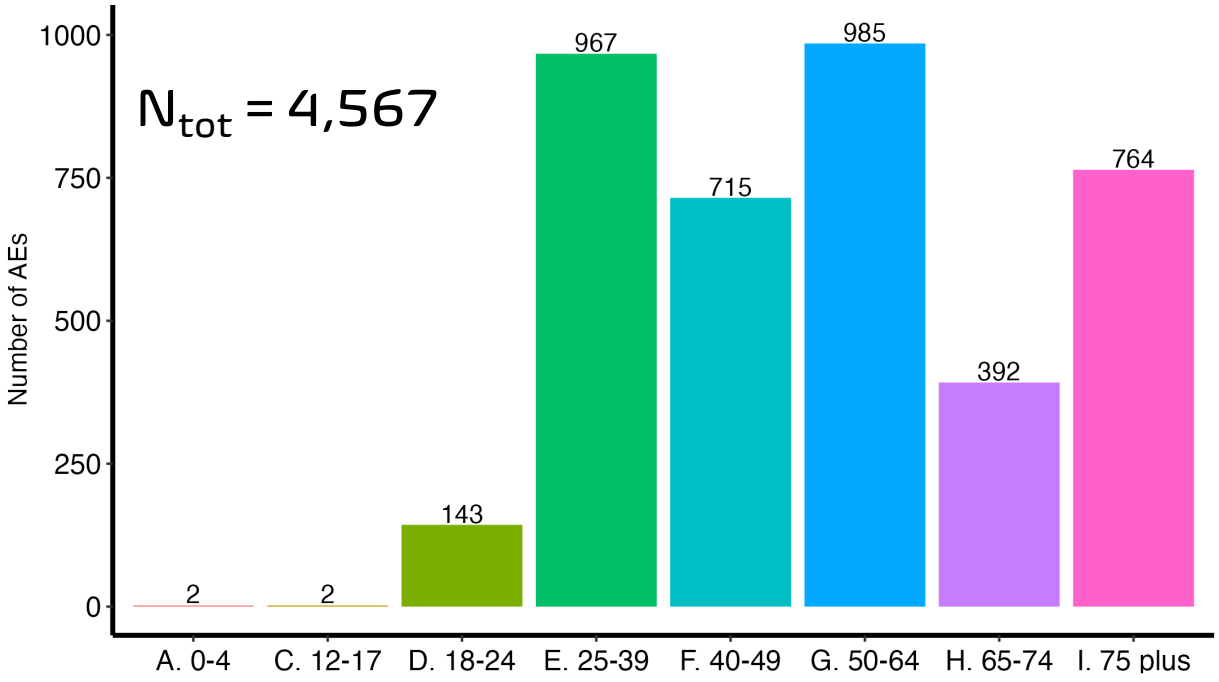
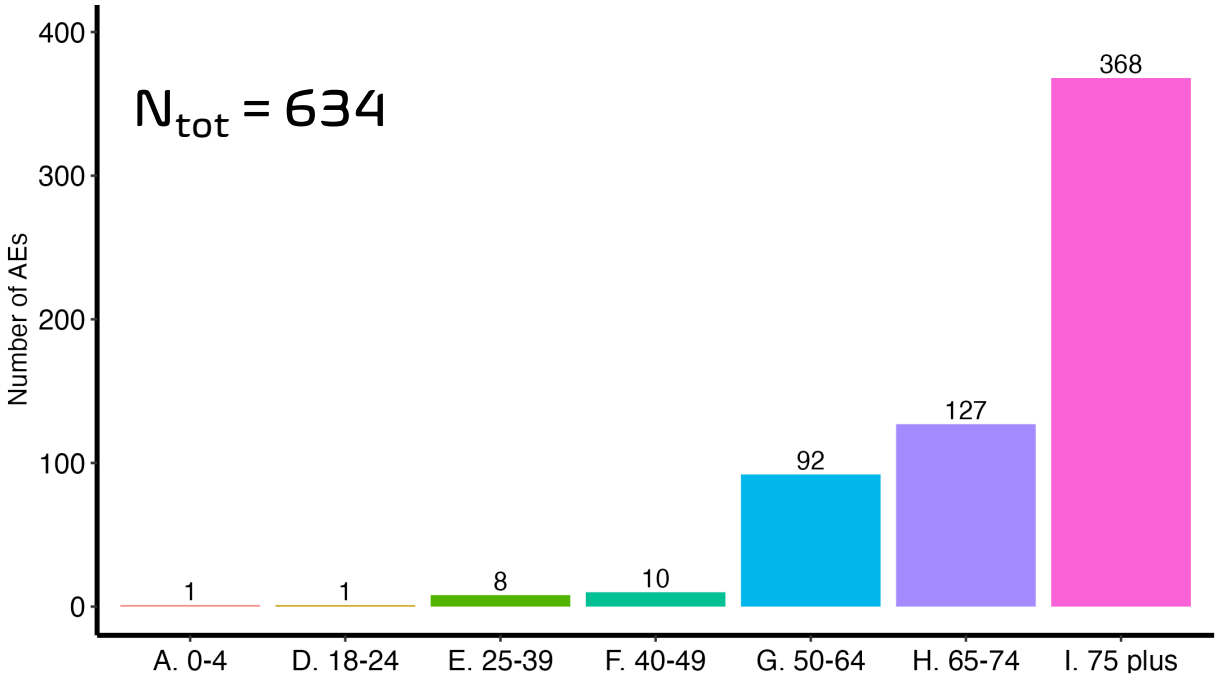
SAFETY SIGNAL IN VAERS IN JANUARY 2021 TO STOP THE COVID-19 PRODUCT ROLL-OUT

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

https://vaers.hhs.gov

Lazarus, Ross et al. Grant Final Report. Grant ID: R18 HS 017045. Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS). Submitted to The Agency for Healthcare Research and Quality (AHRQ)

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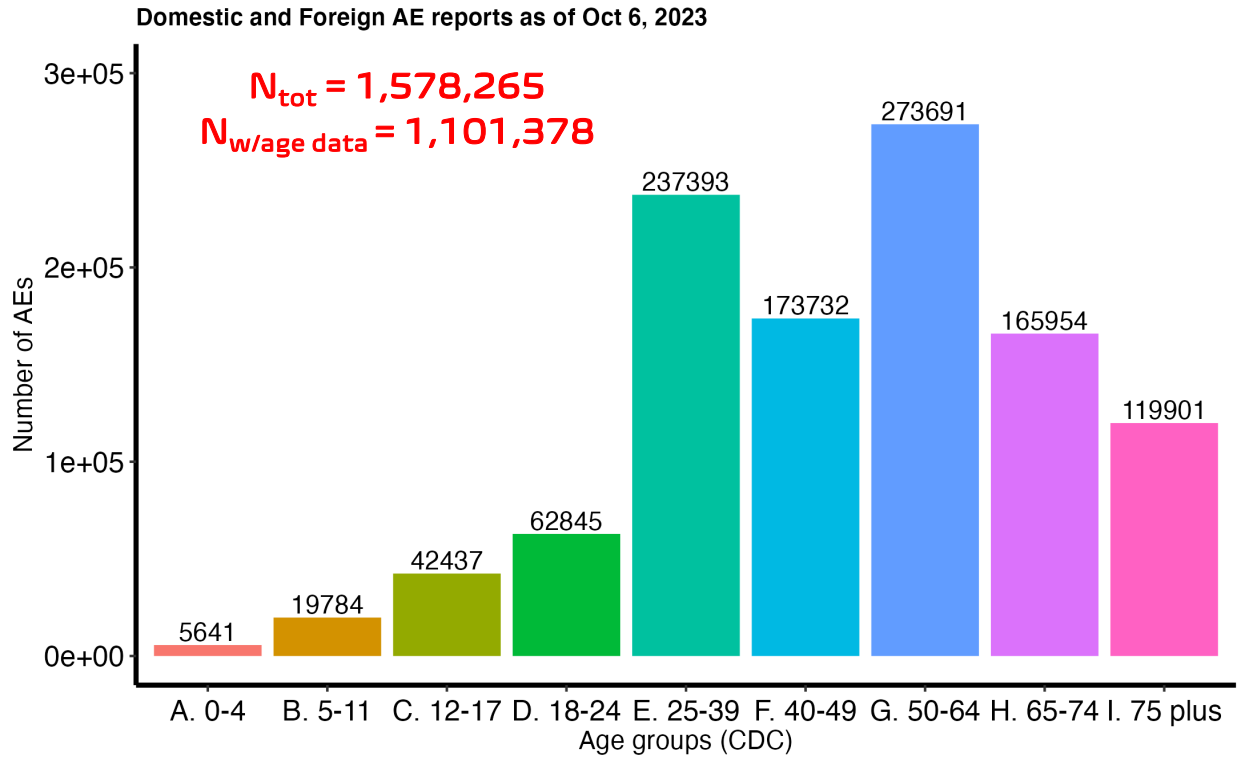
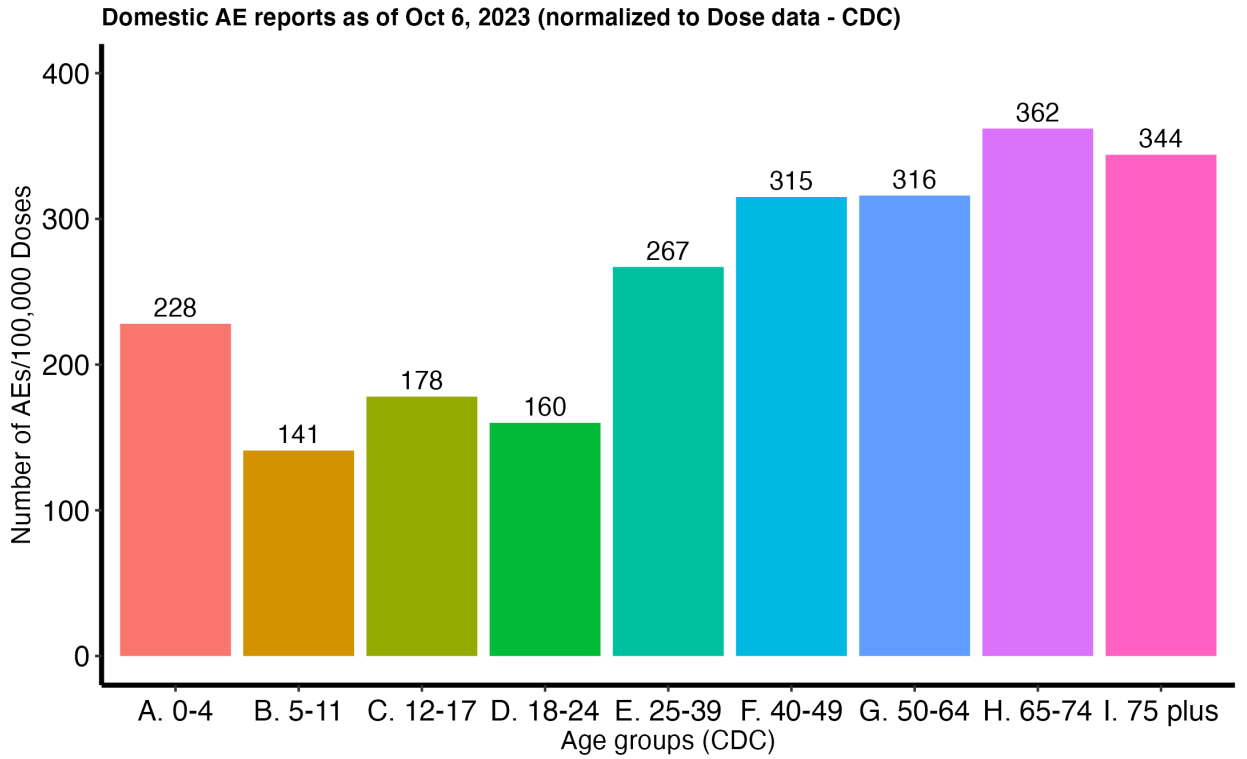
VAERS REPORTS (BY ID) OF AES STRATIFIED BY AGE GROUP AS OF OCTOBER 6, 2023

THERE ARE SAFETY SIGNALS EMITTED ACROSS ALL AGE GROUPS





https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Demographics-in-the-United-St/km4m-vcsb
https://vaers.hhs.gov

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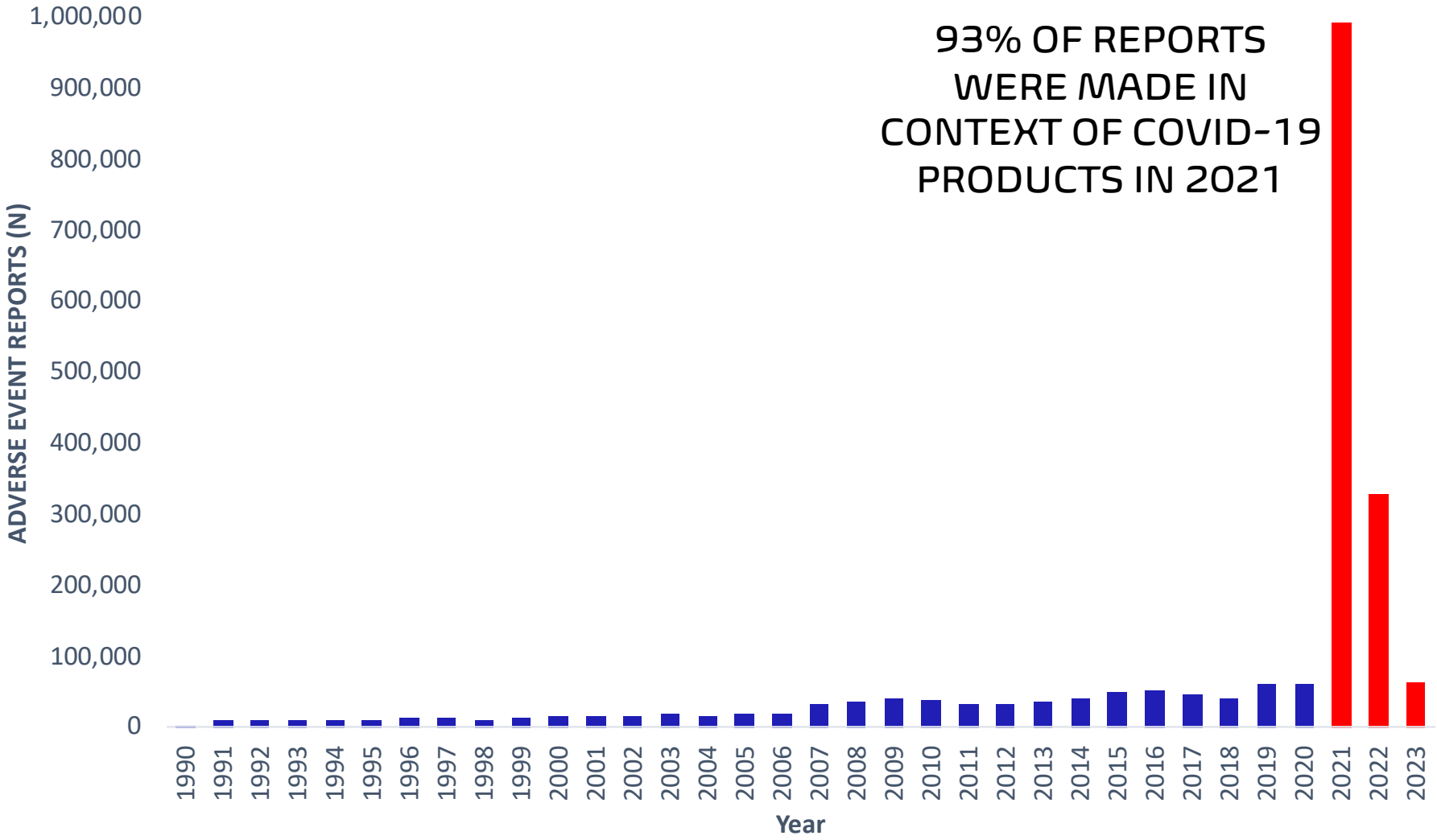
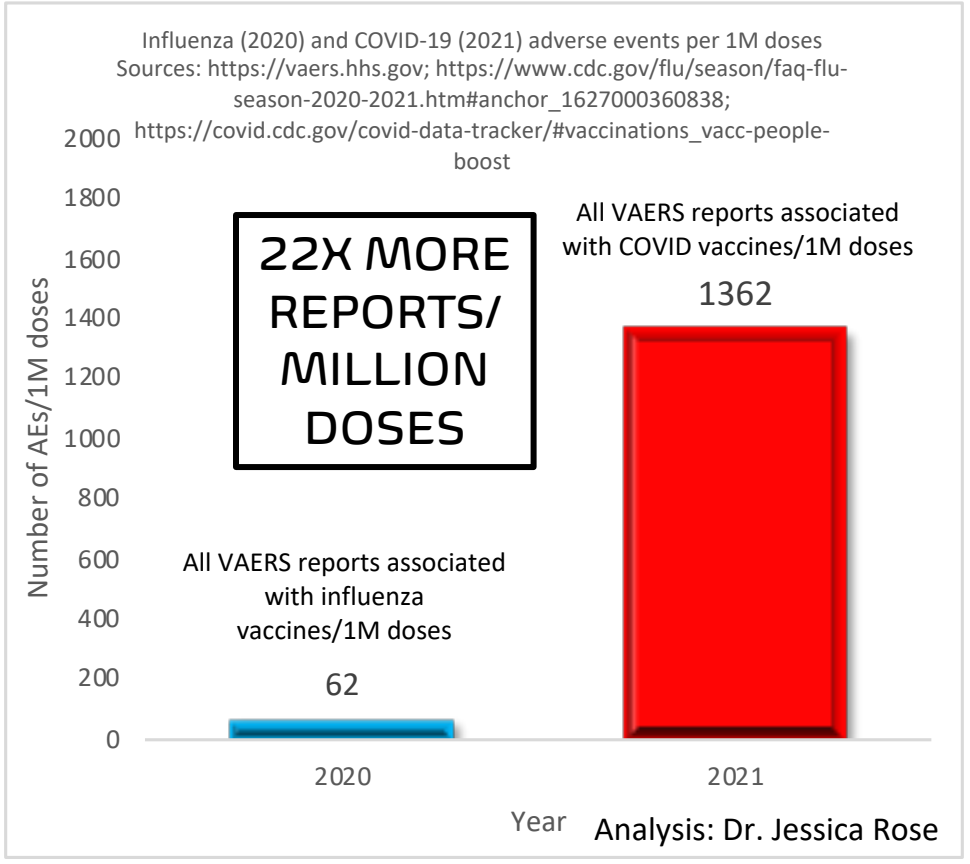
SOME PERSPECTIVE - THE PAST 30 YEARS OF REPORTS VAERS



https://vaers.hhs.gov

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



https://jessicar.substack.com/p/lets-put-the-its-cuz-there-are-so
https://www.cdc.gov/flu/season/faq-flu-season-2020-2021.htm#anchor_1627000360838
https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-boost

HOW DO WE ANALYZE THE DATA?

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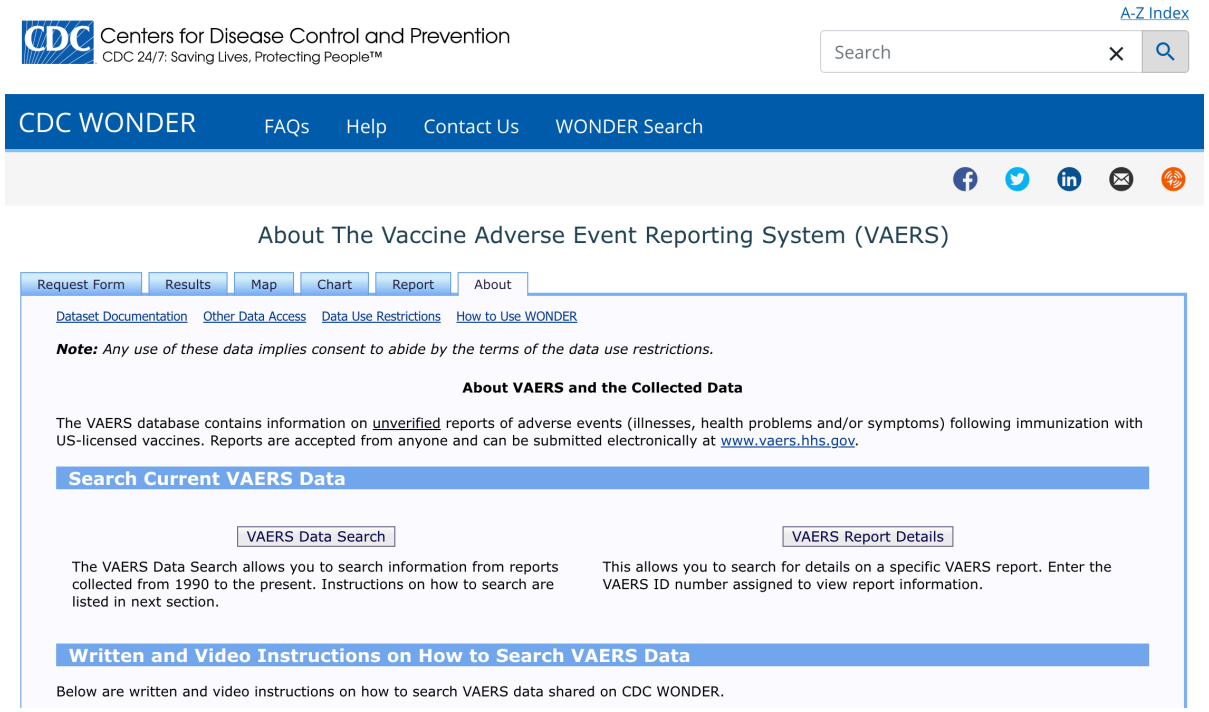
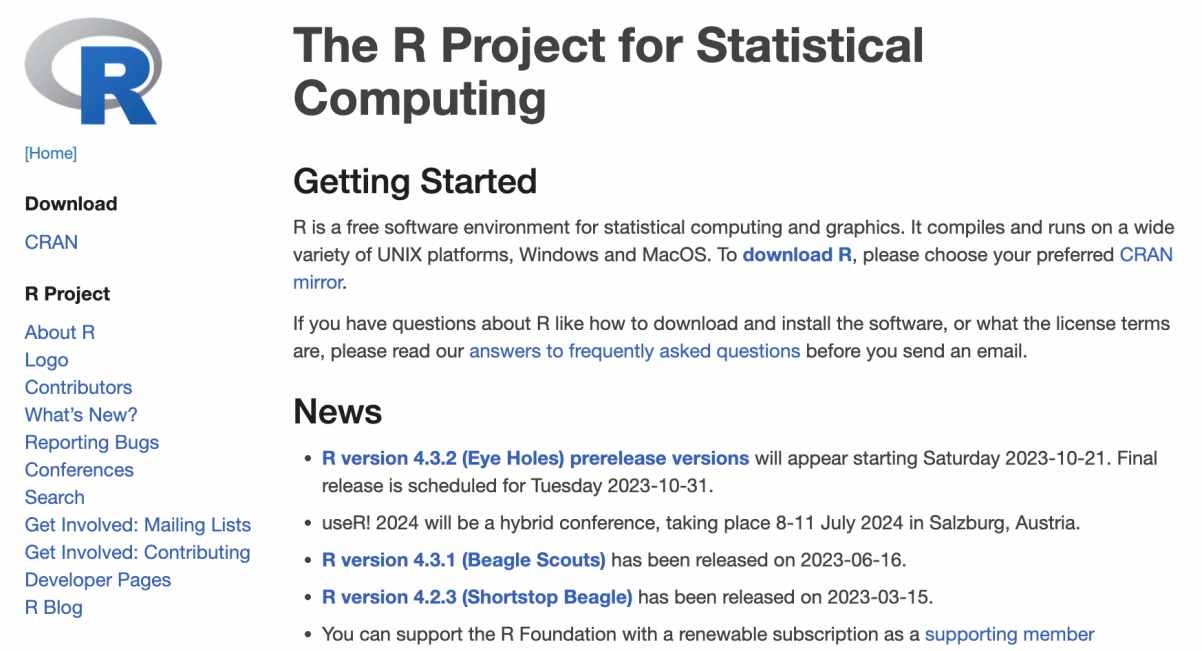
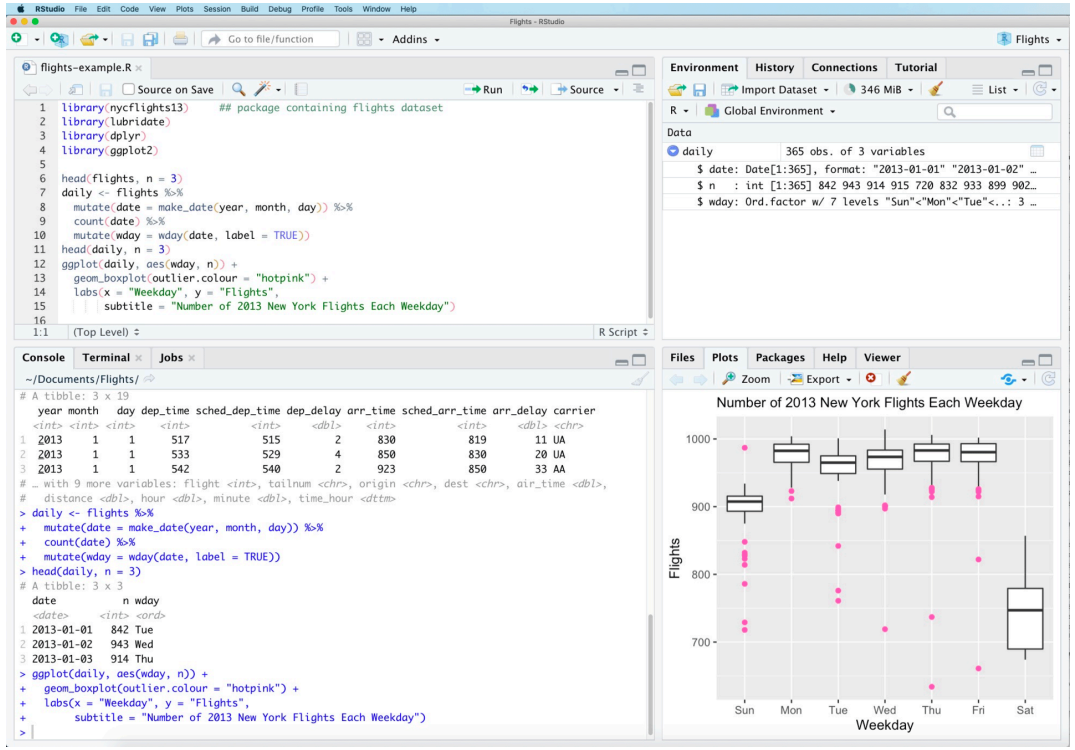
ANALYZING VAERS DATA: CDC WONDER SYSTEM; DATA ANALYSIS SOFTWARE LIKE R; EXCEL





https://vaers.hhs.gov
https://www.r-project.org/

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

RStudio Education

Beginners

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

- **Install R, 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/

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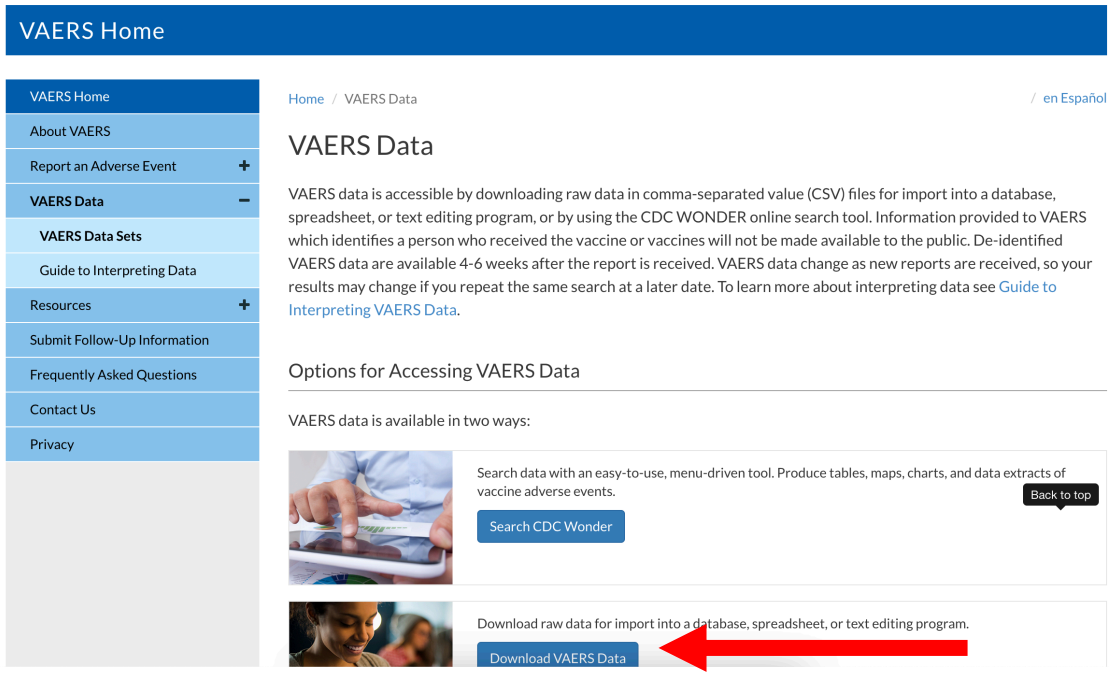
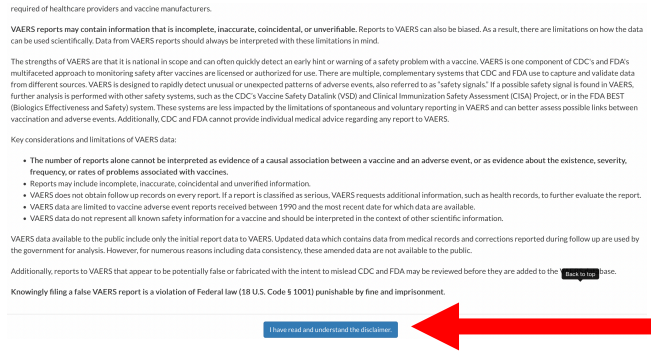
DOWNLOADING VAERS DATA FOR USE IN RSTUDIO

https://vaers.hhs.gov



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



3. Agree to disclaimer after reading it

Select the desired time interval to download VAERS data. Each data set is available for download as a compressed (ZIP) file or as individual CSV files. Each compressed file contains the three CSV files listed for a specific data set.

Last updated: October 6, 2023.

(** Data contains VAERS reports processed as of: 09/29/2023.*)

Excel or a text editor.

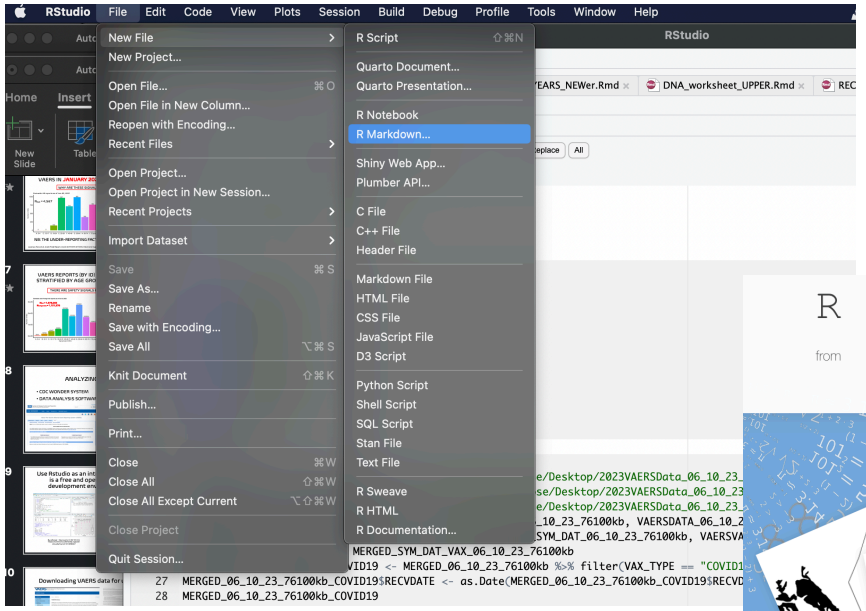
Note for Internet Explorer users: Due to security reasons in your browser's settings you might be prompted to select "show restricted content" in order to view the .csv file as a spreadsheet.

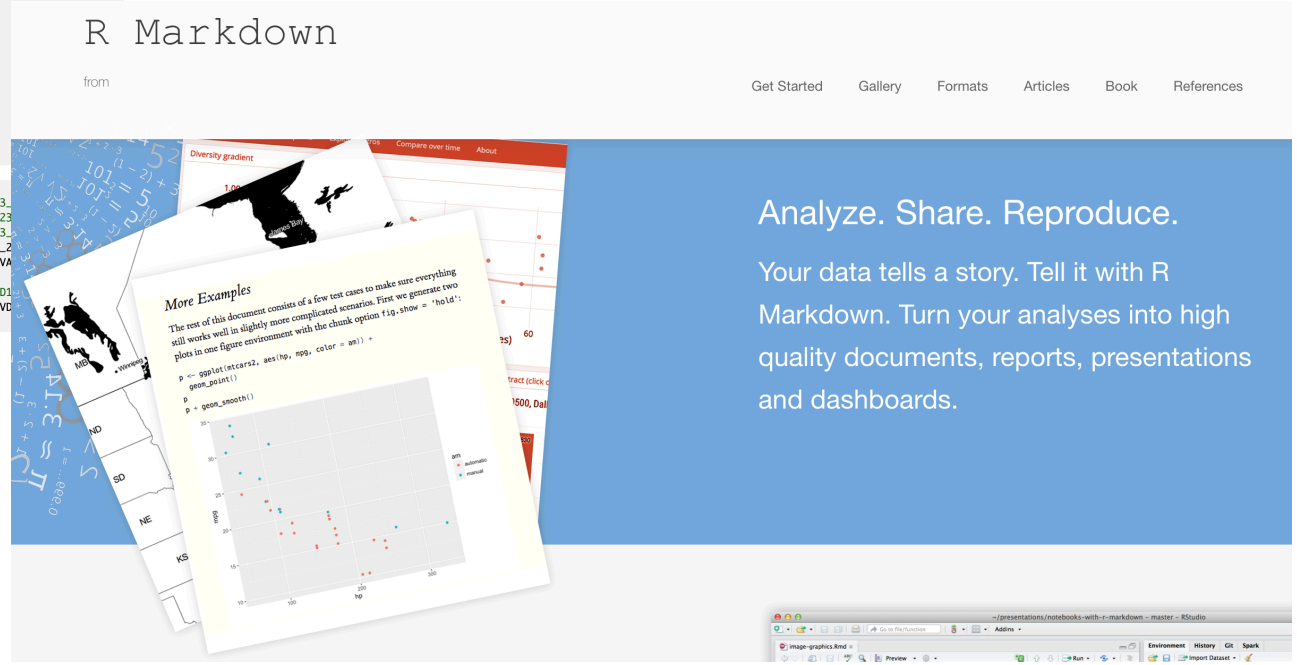
Year	Zip File	CSV File (VAERS DATA)	CSV File (VAERS Symptoms)	CSV File (VAERS Vaccine)
All Years Data*	482.23 MB			
2023*	18.24 MB			7.37 MB
2022	62.14 MB	263.84 MB	26.46 MB	20.96 MB
2021	168.80 MB	623.18 MB	77.17 MB	57.25 MB
2020	11.19 MB	41.73 MB	4.51 MB	4.45 MB
2019	11.21 MB	41.35 MB	4.70 MB	4.45 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>	SYMPTO… <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
```

grouped_df
12326 x 38

grouped_df
13994 x 38

A tibble: 13,994 × 38 | Groups: VAERS_ID [13,994]

VAERS_ID <chr>
2547856
2548065
2548790
2548806
2548831
2548861
2548882
2548892
2548900
2548976

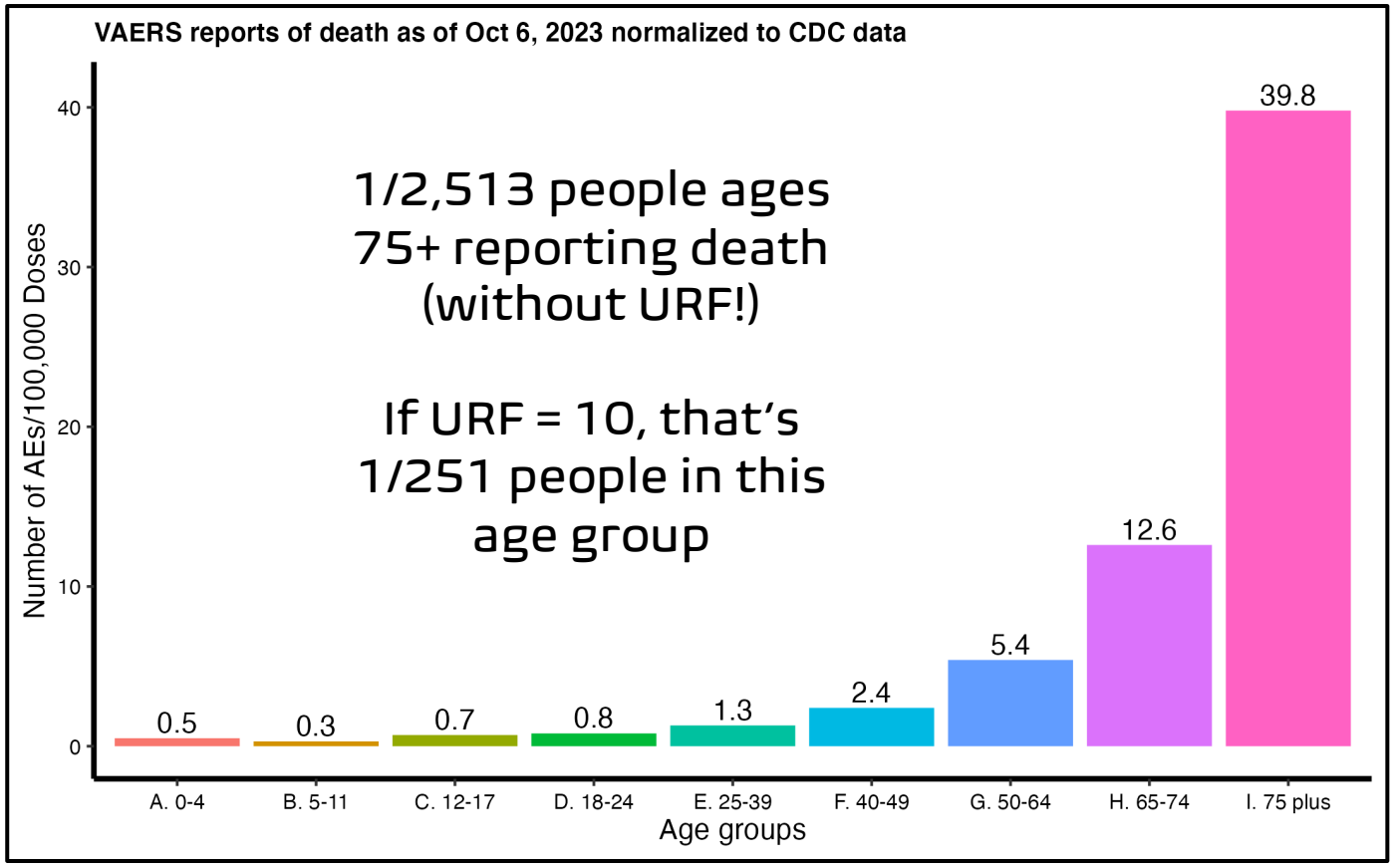
There are 12,326 reports of death for the Domestic data set when counting the "Y"s.

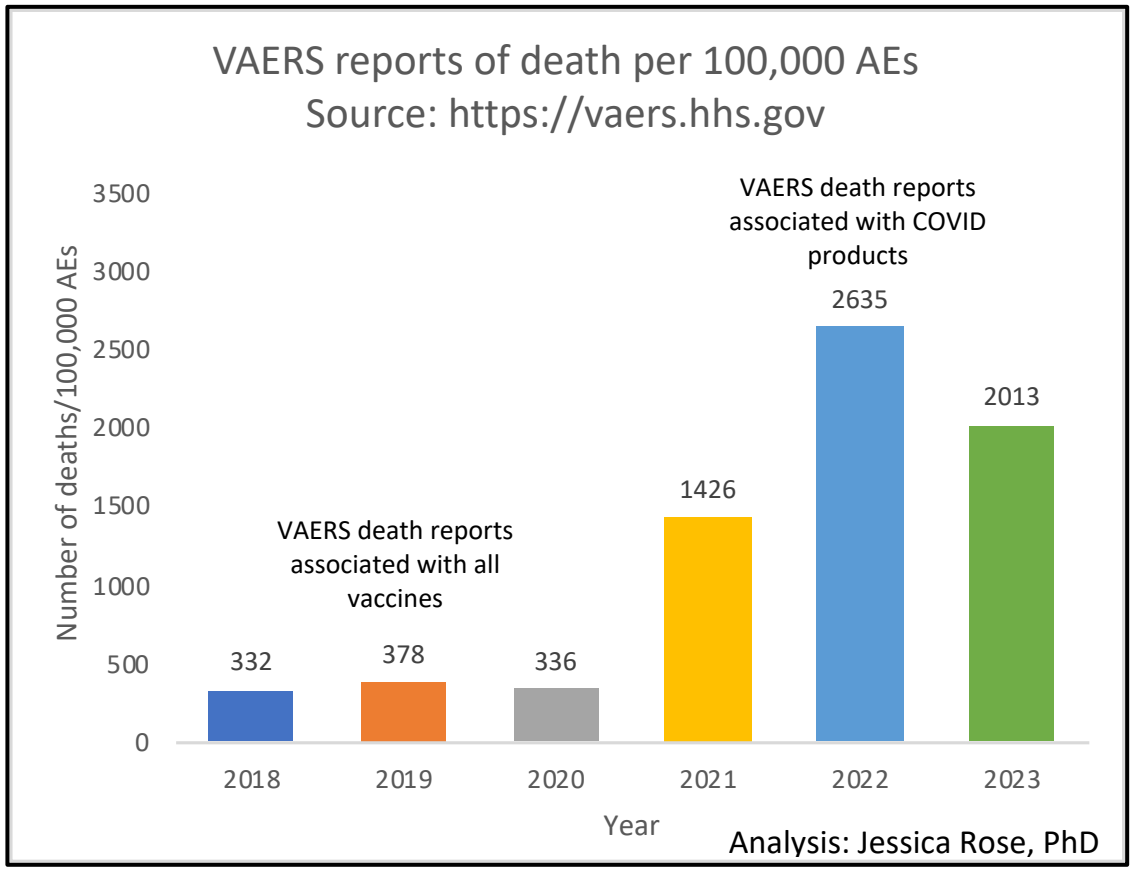
However, there are 13,994 reports when querying true deaths. Last time I checked, vivisection was illegal.

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





Query of Domestic data: DIED == "Y"; https://vaers.hhs.gov
https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Demographics-in-the-United-St/km4m-vcsb
Lazarus, Ross et al. Grant Final Report. Grant ID: R18 HS 017045. Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS). Submitted to The Agency for Healthcare Research and Quality (AHRQ)

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?

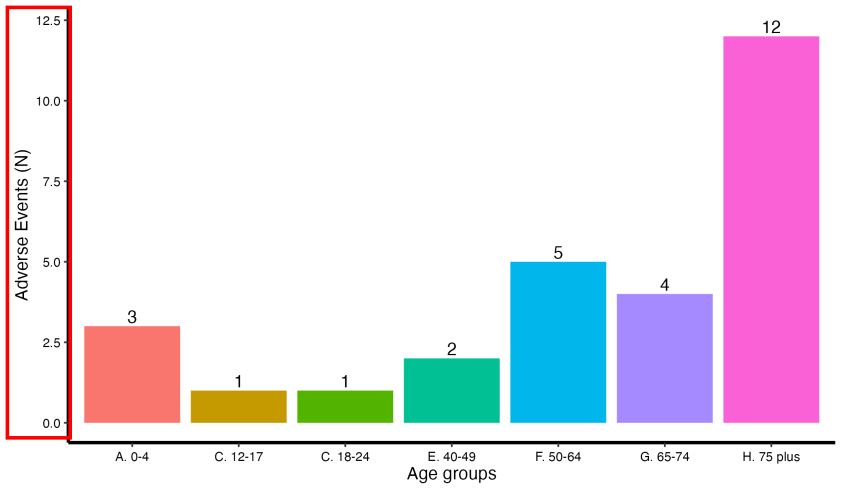
Jessica Rose, PhD

1/11/23

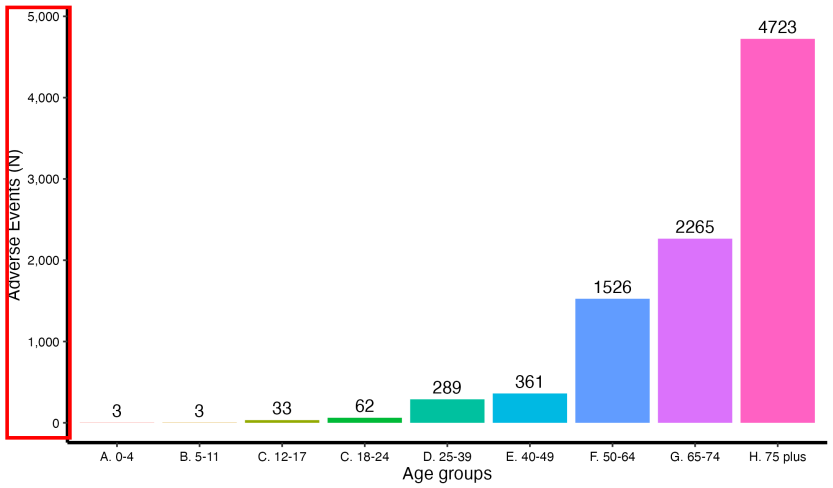
VAERS INFLUENZA VS COVID DEATH REPORTS FOR 2020 AND 2021, RESPECTIVELY

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

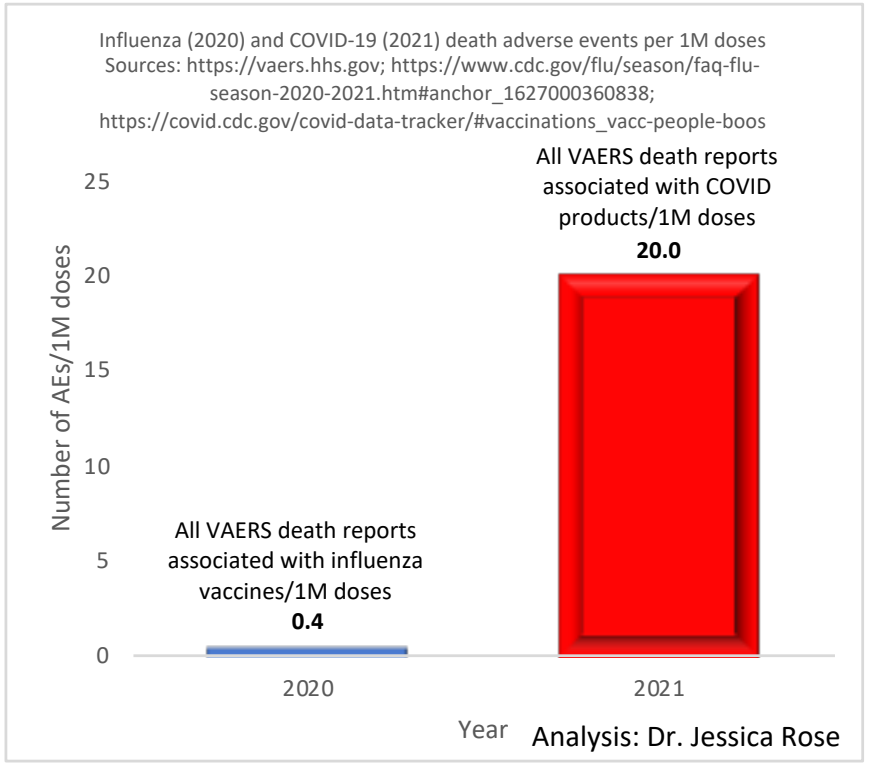
VAERS reports of death associated with influenza vaccines in 2020



VAERS reports of death associated with COVID products in 2021



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)



https://vaers.hhs.gov

https://www.cdc.gov/flu/season/faq-flu-season-2020-2021.htm#anchor_1627000360838; https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-boost

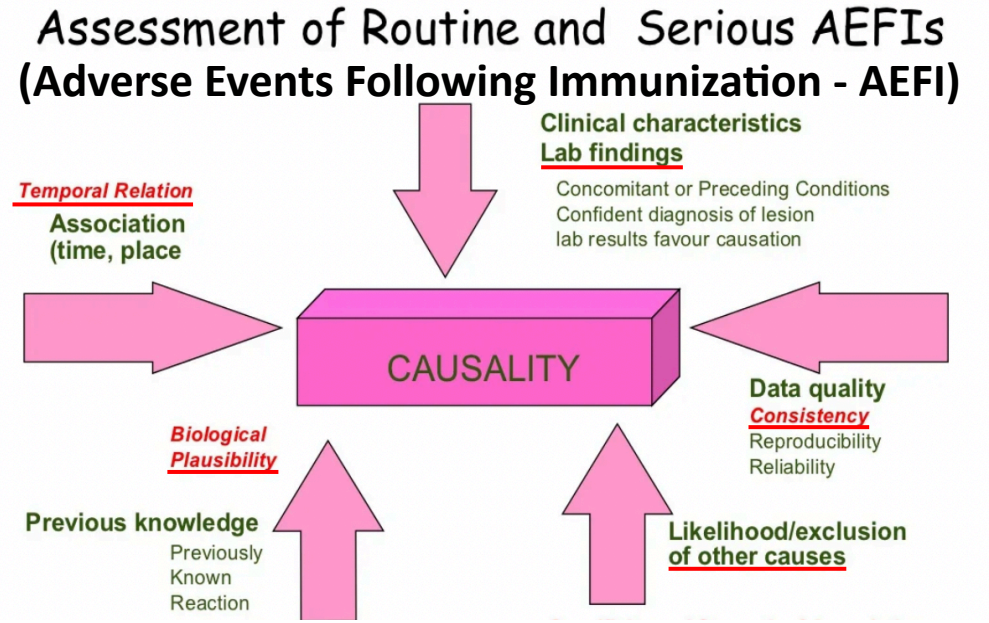
*196,000,000 vs. 515,850,000 million doses administered for Influenza vs. COVID, respectively

Jessica Rose, PhD

1/11/23

USING VAERS TO PROVIDE EVIDENCE OF CAUSATION USING BRADFORD HILL CRITERIA

WHO CRITERIA



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

WHO VACCINE CAUSALITY ASSESSMENT FORM

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

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)

Identification: [ ] Vaccine(s): ____

1. Primary reason for reporting: ____ **Code**: [ ][ ]

1.1 Agreement with report:

Agree ☐

Disagree ☐ ..... Error of coding? Yes ☐ No ☐ New coding [ ][ ]
Is the event severe? Yes ☐ No ☐

Insufficient data ☐ ..... To be reviewed again? Yes ☐ No ☐

2. These questions are related to the primary reason for reporting only:

2.1 Frequency of occurrence of the adverse event	NPR* ☐	Rare ☐	Intermediate ☐	Common ☐
2.2 Similar events known to occur with other disease		Yes ☐	No ☐	
2.3 Event is known to be related to this vaccine		Yes ☐	No ☐	
2.4 Event is explainable by the biological properties of the vaccine		Yes ☐	No ☐	Unknown ☐
2.5 Vaccine-event interval compatible with the event	n/a ☐	Typical ☐	Compatible ☐	Incompatible ☐
2.6 The patient had similar symptoms in the past	n/a ☐	Yes ☐	No ☐	Unknown ☐
2.7 Concomitant or preceding drug therapy		Yes ☐	No ☐	Unknown ☐
2.8 Concomitant or preceding condition	Rel.* ☐	Yes ☐	No ☐	Unknown ☐
2.9 Other contributing factors		Yes ☐	No ☐	Unknown ☐

* **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 ☐ 1 No ☐ 2

4. Comments: This case is most compatible with bronciolitis 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 DTwP.

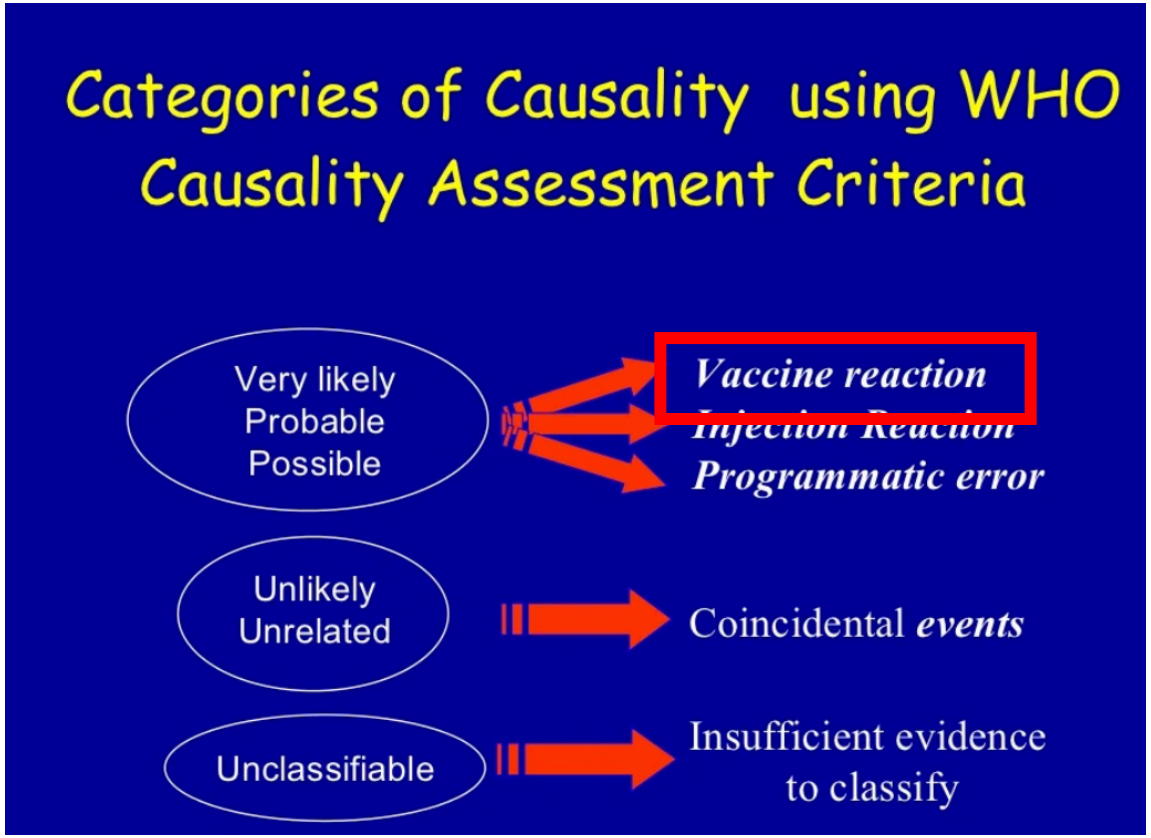
5. Recommendations: Education

6. Useful for Education: YesX ☐ No ☐

1. Review criteria for with HCW for anaphylaxis
2. 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 X ☐

WHO DEFINES CAUSALITY



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

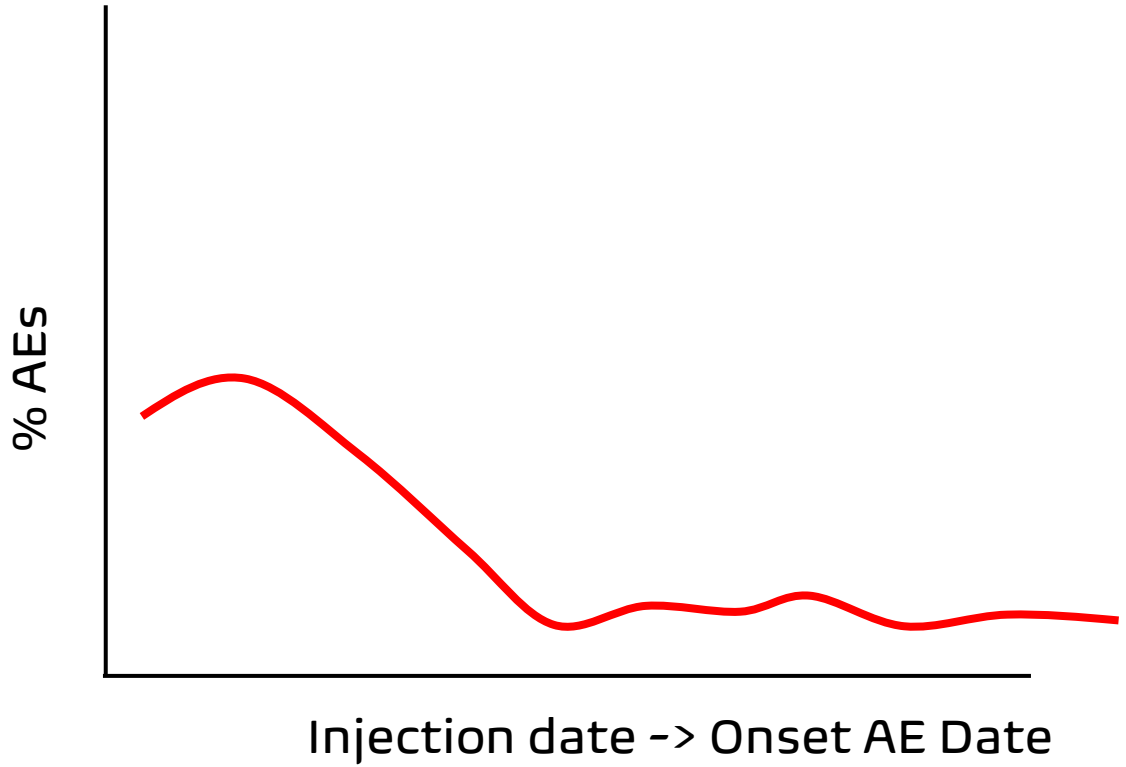
http://www.rho.org/files/rb3/AEFI_Causality_Assessment_WHO_2005.pdf

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).

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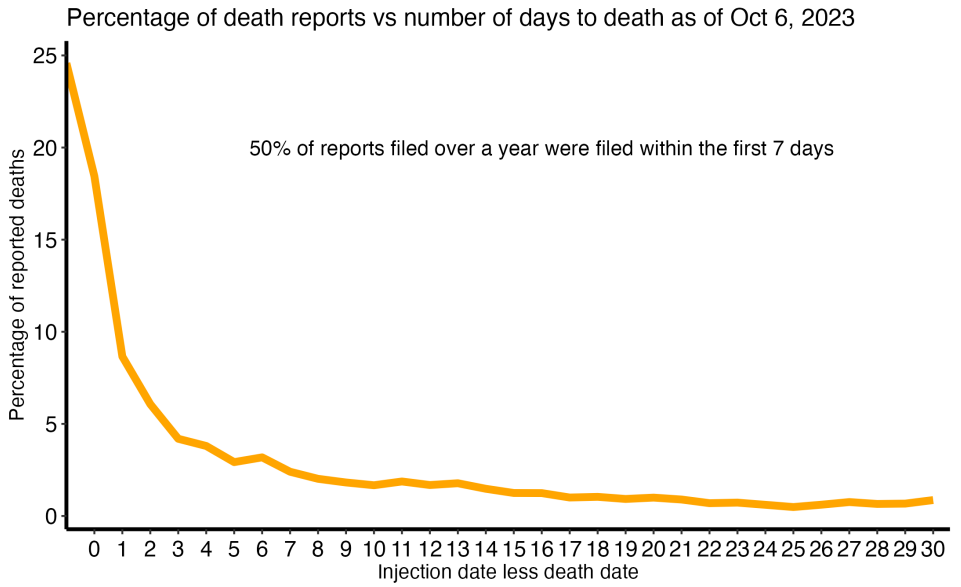
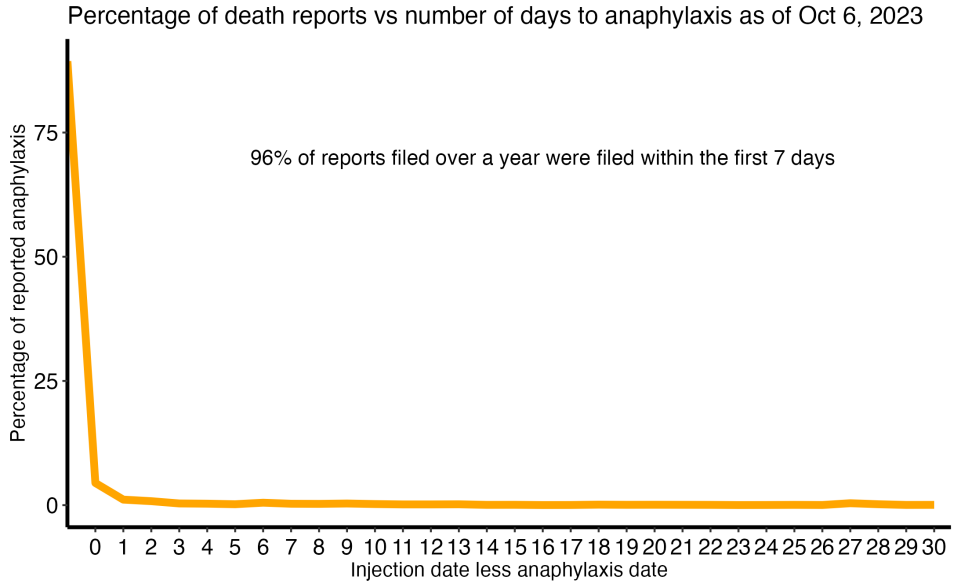
TEMPORALITY



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)

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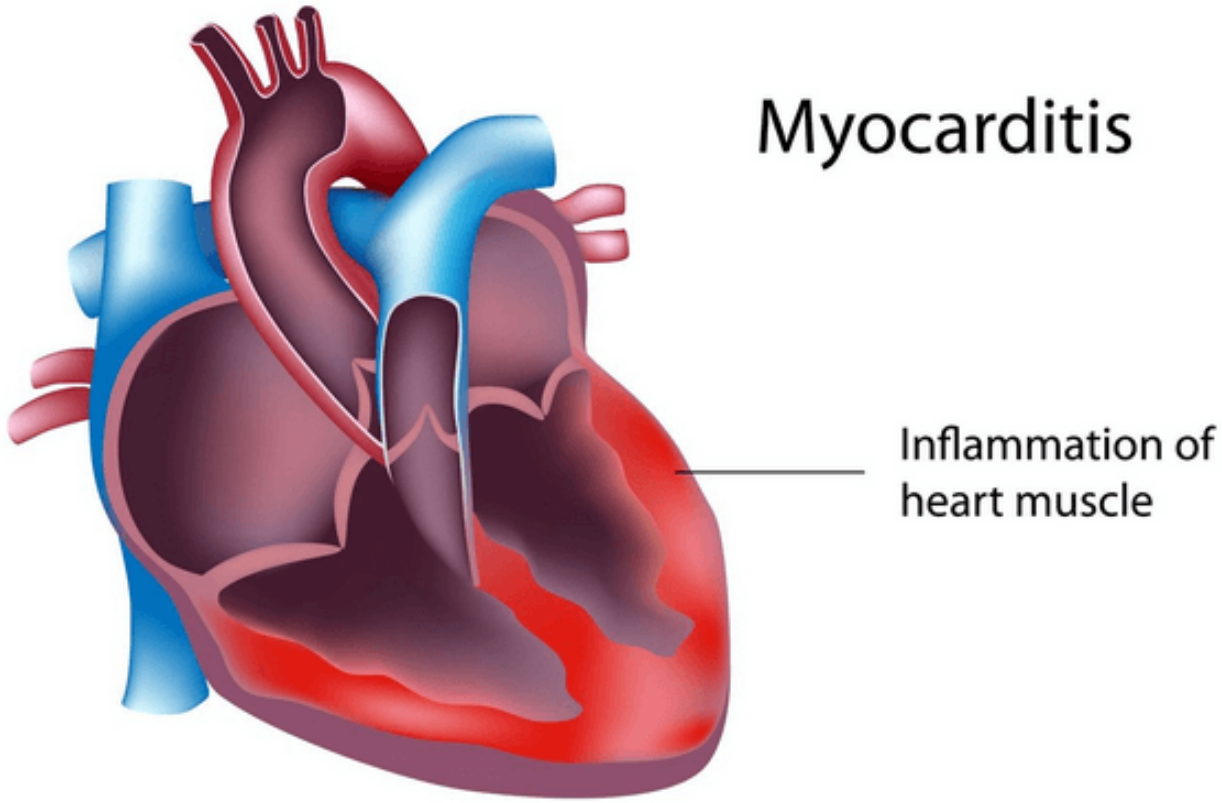
DOSE RESPONSE: DOES *MORE* OF A RESULT IN *MORE* OF B?



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.

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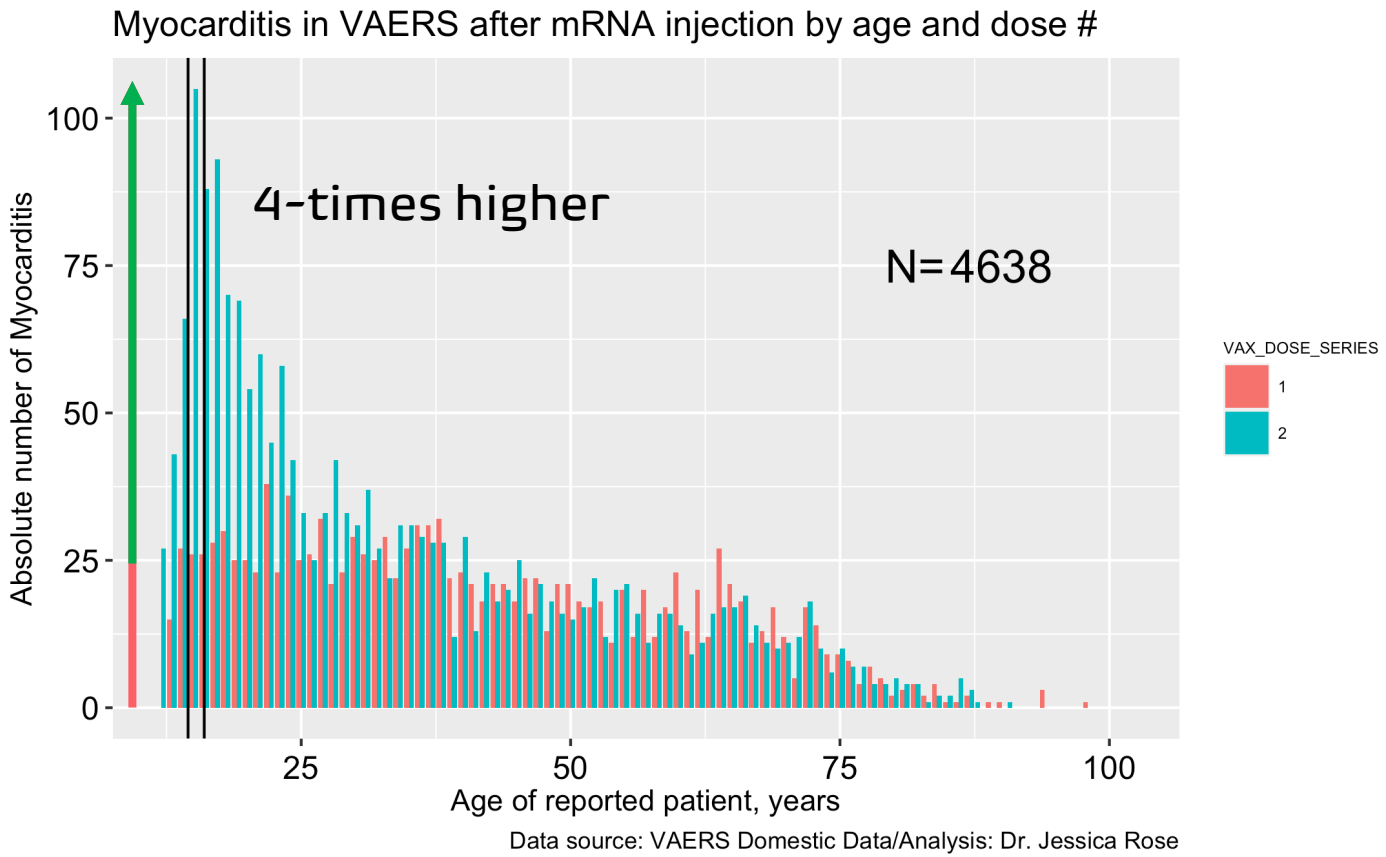
DOSE RESPONSE



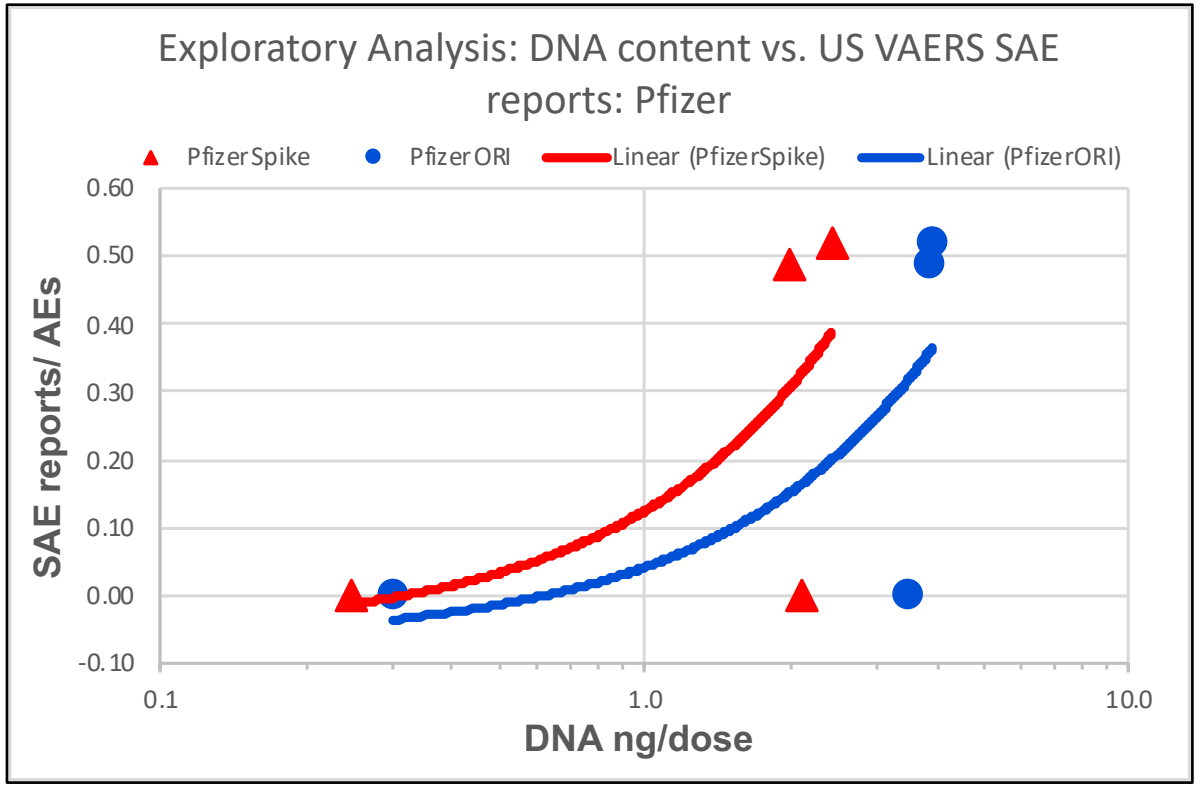
5. Biological gradient (dose-response relationship): Greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect.

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

Dose response

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

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



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.

Speicher, D. J., Rose, J., Gutschi, L. M., Wiseman, D. M., PhD, & McKernan, K. (2023, October 19). DNA fragments detected in monovalent and bivalent Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada: Exploratory dose response relationship with serious adverse events. OSF preprints. https://doi.org/10.31219/osf.io/mjc97

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

Rose, J. 2021, Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System? Science, Public Health Policy & the Law Volume 3:100–129