Reporting Adverse Events for COVID-19 Vaccines

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July 13, 2022

Empowering patients, families and caregivers to achieve health care quality improvement

About Gray

- Social epidemiologist = disease detective through biostatistics
- Artist
- Bilingual (Spanish, English)
- No conflicts of interest.

Agenda

- Vaccine myths

- COVID-19 vaccines

- Vaccine Adverse Event Reporting System (VAERS)

- Interpreting results

- Clinical Immunization Safety Assessment (CISA) Project

- Patient/provider resources

Vaccine Myths and Public Health

All models are wrong but some are useful.

—George E.P. Box

The First Vaccine: Smallpox or Cow Pox, 1802

Smallpox Vaccine Causes Syphilis?

Minimizing Threats and Risk of Illnesses

Lack of Social Connection, Access to Education
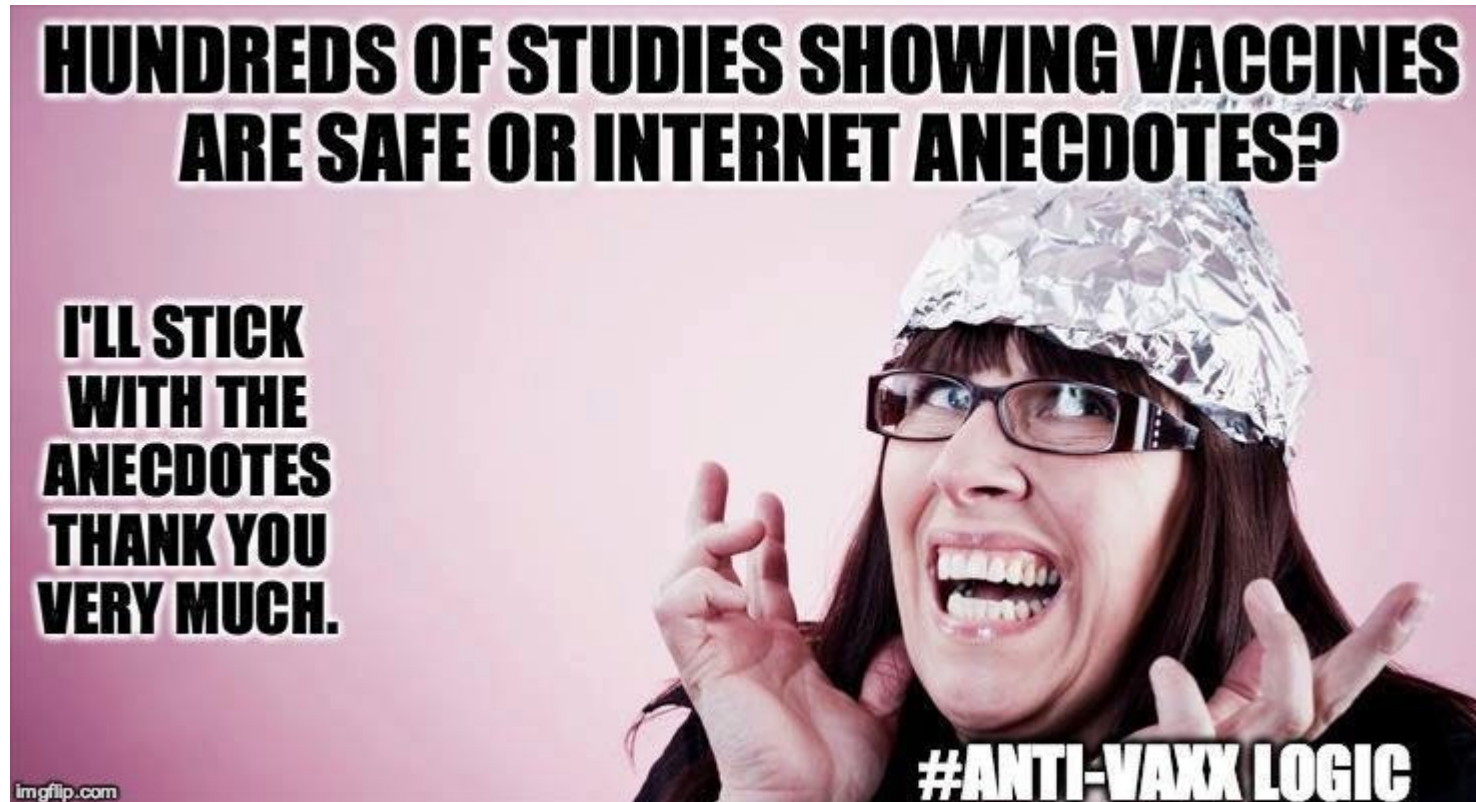
Herd Immunity: Public Health is Not My Problem
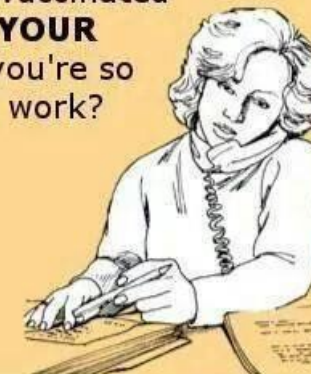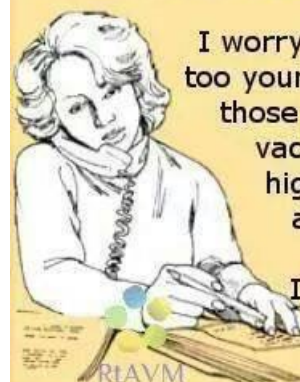
Correlation Does Not Equal Causation

Multiple vaccine doses have resulted in up to 145,000 child deaths in past 20 years

According to data compiled from the government's Vaccine Adverse Events Reporting System (VAERS), as many as 145,000 children or more have died in the past 20 years as a result of this multiple vaccine dose approach, and few parents are aware of this shocking fact.

DANGER
CHILD VACCINE
(TOXIC WASTE)

TRIUMPH OF DE-JENNER-ATION.

[The Bill for the encouragement of Small Pox awaits Third Reading in the Commons.]

1898

Vaccine Myths: Summary

1. Vaccines can cause the disease they are trying to prevent.
2. Vaccines can cause additional diseases and health problems.
3. Vaccines are unnecessary; illness is not to be taken seriously.
4. Vaccines are a widespread cause of death.

Vaccine Myths: Root Causes

- Fear of the unknown
- Minimizing/dismissing threats of disease
- Only those with weak moral and physical character get sick
- Short collective memories
- Mistrust of authority, intellectuals
- Misunderstanding data
- Groupthink
- Lack of social connection/access to education and money

Concrete Examples:
Reliable vs. Unreliable Information

- Online shopping
- **Trip Advisor vs. U.S. Government visas**
- Yelp
- The Earth is flat
- Lack of regulation of vitamins and pharmaceuticals

COVID-19 Vaccines

COVID-19 Vaccines Licensed and Available in the U.S.

Center for Disease Control and Prevention (CDC)

- Moderna

- Pfizer-BioNTech

- Johnson & Johnson's (J&J) Janssen

U.S. Food and Drug Administration (FDA) approved vaccines:

- Comirnaty (generic: Pfizer-BioNTech)

- Spikevax (generic: Moderna)

- Janssen (generic: Johnson & Johnson's (J&J) Janssen)

COVID-19 Vaccines Available Outside the US

Vaccines listed for emergency use by the World Health Organization (WHO), which currently include:

- Moderna

- Pfizer-BioNTech

- J&J Janssen

- AstraZeneca

- Covaxin

- Covishield

- BIBP/Sinopharm

- Sinovac

- Novavax/Covovax

- Convidecia

COVID-19 Unvaccinated Risk

COVID-19 Vaccinated vs. Unvaccinated Cases and Deaths
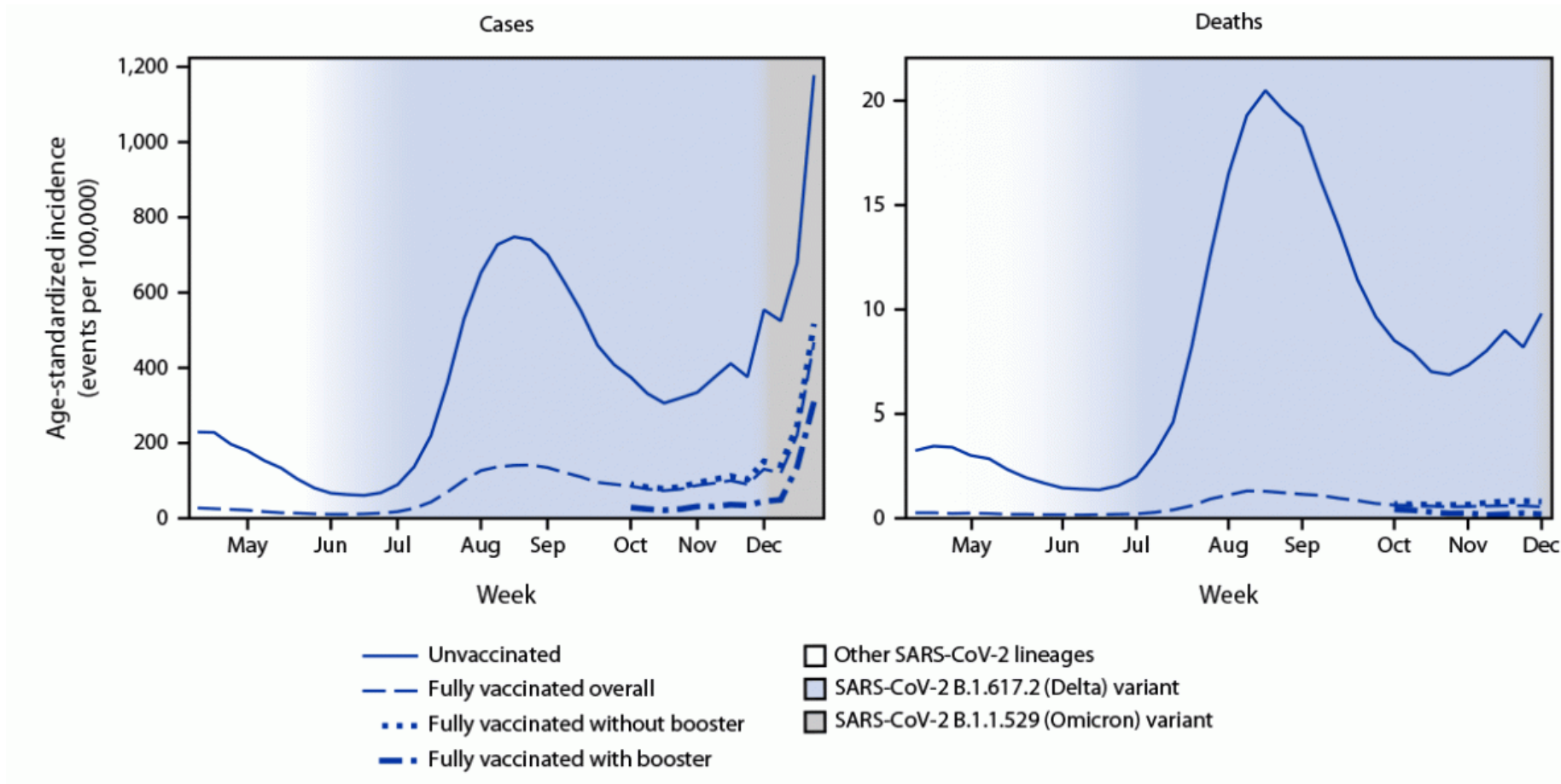
Vaccine Adverse Event Reporting System (VAERS)

What is VAERS?

VAERS = Vaccine Adverse Event Reporting System

- Subset of CDC WONDER (U.S. Reporting Data Access website)
- National early warning system.
- **Possible** side effects following vaccination.
- **Not** designed to detect if a vaccine **caused** an adverse event.
- Can identify unusual or unexpected patterns of reporting.
- Might indicate possible safety problems requiring a closer look.
- **Examples**

VAERS Managing Agencies

Co-administered:

- CDC
- FDA
- Agencies of the U.S. Department of Health and Human Services (HHS)

VAERS Strengths

- CDC WONDER collects national data from all U.S. states and territories.
- Accepts reports from anyone.
- Data collection includes information about the vaccine, the person vaccinated and the adverse event.
- Data are publicly available.
- Matches a specific identifying number with each report for follow-up.
- Fraudulent claims identified by the CDC and FDA can have legal consequences.

VAERS Limitations

- Cannot determine if the vaccine caused the reported adverse event.

- Publicly available data from CDC WONDER caused confusion, specifically regarding the number of reported deaths.

- Instances where people have misinterpreted reports of deaths following vaccination as deaths caused by the vaccines; that is not accurate.

- VAERS accepts all reports of adverse health events following vaccinations without judging whether the vaccine caused the adverse health event.

- Some reports to VAERS represent true vaccine reactions and others are coincidental adverse health events and not related to vaccination.

- Overall, a **causal relationship cannot** be established using information from VAERS report alone.

VAERS Limitations Continued

- Submitted reports often lack details and sometimes contains errors.

- Serious adverse events are more likely to be reported than non-serious events.

- Numbers of reports may increase in response to media attention and increased public awareness.

- VAERS data cannot be used to determine rates of adverse events (multiple reports of same adverse event or missing adverse events).

- No way of knowing if vaccines cause any adverse events using VAERS alone.

CDC WONDER: VAERS Results as of July 1, 2022

Vaccine	Events Reported	Percent of 1,603,515 total VAERS reports since 1990
COVID-19: JANSSEN, 1203	69,893	4.36%
COVID-19: MODERNA, 1201	400,289	24.96%
COVID-19: PFIZER-BIONTECH, 1200	410,106	25.58%
COVID-19: UNKNOWN, 1202	2,930	0.18%

VAERS WONDER CDC: COVID-19 Vaccine Events Since July 7, 2022

Event Category	Events Reported	Percent
Death	16,202	1.01%
Life Threatening	14,426	0.90%
Permanent Disability	16,393	1.02%
Congenital Anomaly / Birth Defect	629	0.04%
Hospitalized	79,569	4.96%
Existing Hospitalization Prolonged	446	0.03%
Emergency Room / Office Visit	123	0.01%
Emergency Room	109,202	6.81%
Office Visit	178,617	11.14%
None of the above	576,808	35.97%
Total	**992415**	**61.89%**

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

SUPERIOR HEALTH
Quality Alliance

VAERS Events by Vaccine Type: Janssen (1203)

Event Type	Number Events Reported	Percent of 1,603,515 total VAERS reports since 1990
Death	1,663	0.10%
Life Threatening	1,544	0.10%
Permanent Disability	1,470	0.09%
Congenital Anomaly / Birth Defect *	49	0.00%
Hospitalized	6,712	0.42%
Existing Hospitalization Prolonged	49	0.00%
Emergency Room / Office Visit **	9	0.00%
Emergency Room *	9,868	0.62%
Office Visit *	13,811	0.86%
None of the above	44,596	2.78%
Total	**79,771**	**4.97%**

VAERS Events by Vaccine Type: Moderna (1201)

Event Type	Number Events Reported	Percent of 1,603,515 total VAERS reports since 1990
Death	6,747	0.42%
Life Threatening	5,667	0.35%
Permanent Disability	6,248	0.39%
Congenital Anomaly / Birth Defect *	223	0.01%
Hospitalized	30,517	1.90%
Existing Hospitalization Prolonged	161	0.01%
Emergency Room / Office Visit **	45	0.00%
Emergency Room *	41,240	2.57%
Office Visit *	73,771	4.60%
None of the above	277,160	17.28%
Total	**441,779**	**27.55%**

VAERS Events by Vaccine Type: COVID-19 Pfizer-Biontech (1200)

Event Type	Number Events Reported	Percent of 1,603,515 total VAERS reports since 1990
Death	7,734	0.48%
Life Threatening	7,135	0.44%
Permanent Disability	8,631	0.54%
Congenital Anomaly / Birth Defect *	351	0.02%
Hospitalized	41,867	2.61%
Existing Hospitalization Prolonged	235	0.01%
Emergency Room / Office Visit **	69	0.00%
Emergency Room *	57,797	3.60%
Office Visit *	90,730	5.66%
None of the above	253,083	15.78%
Total	**467,632**	**29.16%**

VAERS Events by Vaccine Type: COVID-19 Unknown (1202)

Event Type	Number Events Reported	Percent of 1,603,515 total VAERS reports since 1990
Death	58	0.00%
Life Threatening	80	0.00%
Permanent Disability	44	0.00%
Congenital Anomaly / Birth Defect *	6	0.00%
Hospitalized	473	0.03%
Existing Hospitalization Prolonged	1	0.00%
Emergency Room / Office Visit **	297	0.02%
Emergency Room *	305	0.02%
Office Visit *	1,969	0.12%
None of the above	3,233	0.20%
Total	**58**	**0.00%**

Vaccine Adverse Event Reporting System

1. Have you had a reaction following a vaccination?

2. Contact your health care provider.

3. New: report an Adverse Event using the [VAERS online form](#) or the downloadable PDF.

4. Important: if you are experiencing a medical emergency, seek immediate assistance from a health care 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 health care provider.

VAERS [website](#)

VAERS Provider Reporting

Legal requirements for providers VAERS reporting:

- Any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccination.

- Adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.

VAERS Provider Reporting
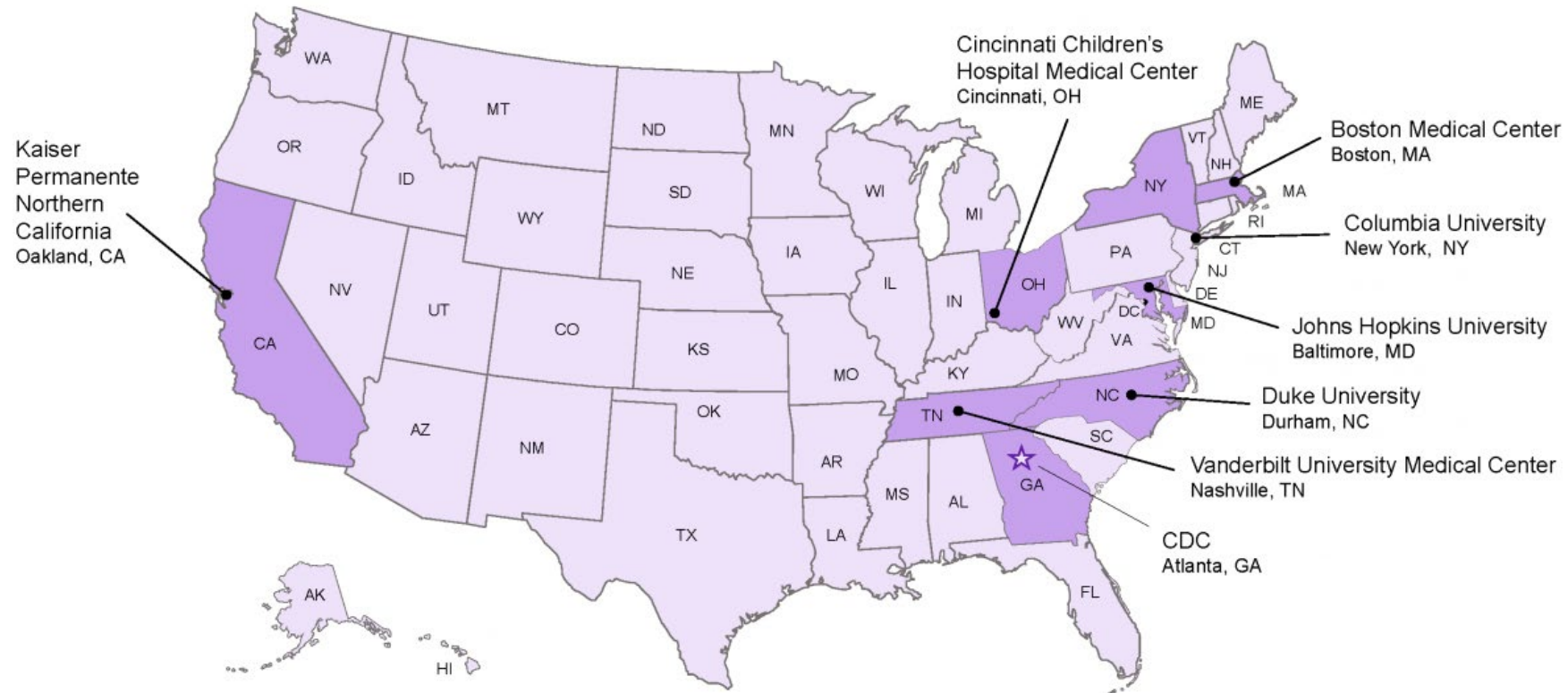
Strongly encouraged provider VAERS reporting:

- Any adverse event that occurs after the administration of a vaccine licensed in the U.S., **whether or not** it is clear a vaccine caused the adverse event.

- Vaccine administration errors.

- Vaccine manufacturers are required to report ALL adverse events that come to their attention.

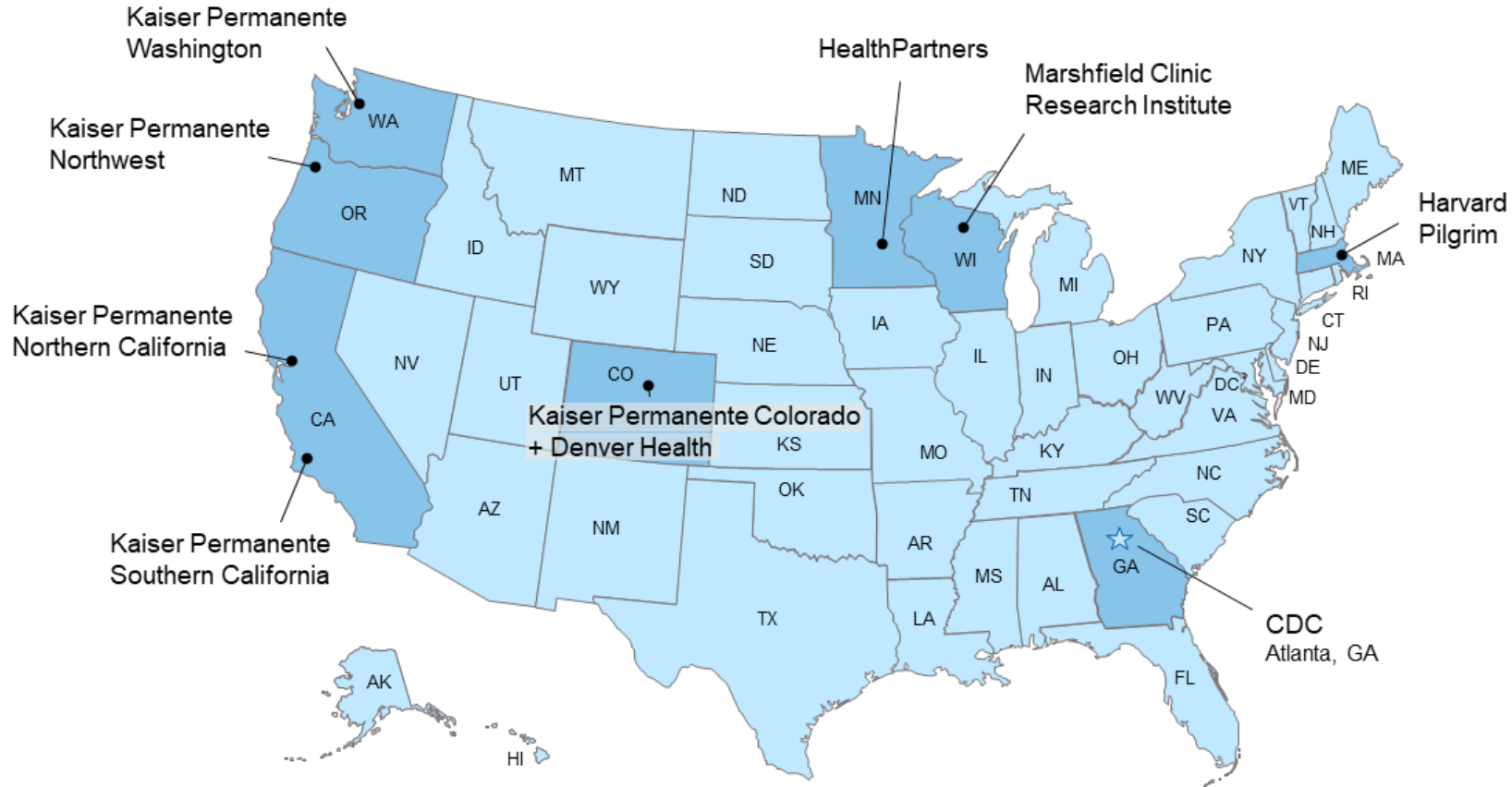# Reliable Information: CISA and VICP

Clinical Immunization Safety Assessment (CISA) Project

- CDC established in 2001.

- Provides a comprehensive vaccine safety public health service to the nation.

- Addresses the unmet vaccine safety clinical research needs of the U.S.

- National network of vaccine safety experts including:
  - Immunization Safety Office (ISO), part of CDC
  - Seven medical research centers
  - Additional partners

CISA Reporting Partners

Cincinnati Children's Hospital Medical Center
Cincinnati, OH

Boston Medical Center
Boston, MA

Columbia University
New York, NY

Johns Hopkins University
Baltimore, MD

Duke University
Durham, NC

Vanderbilt University Medical Center
Nashville, TN

CDC
Atlanta, GA

Kaiser Permanente Northern California
Oakland, CA

CDC Vaccine Safety Datalink Partners Map

Vaccine Injury Compensation Program (VICP)

- Separate program from VAERS and CISA.

- Administered by the Health Resources and Services Administration (HRSA).

- Reporting an adverse event to VAERS does not constitute filing a claim with the VICP.

- For more information about the VICP, call (800) 338-2382 or visit the VICP website.

CDC Vaccine Safety Public Resources

- Providers and Patients
    - [VEARS Brochures](#)

- Providers and Researchers
    - [ACIP COVID-19 Vaccine Safety Update (March 1, 2021)](#):
    - [Vaccine Safety Datalink (VSD) Data Dictionary](#)
    - [How to Access Data from CDC's VAERS WONDER System](#) (YouTube video)
    - [COVID-19 Vaccines: How Do We Know They Are Safe?](#) (CDC YouTube video)

Questions?

Gray Ficker, MPH

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Resource Citations

- [The World Health Organization](#)
- [The Center for Disease Control and Prevention](#)
- [CDC Epidemiologist Definition](#)
- Green, Alex. Going viral in the online anti-vaccine wars. *Wellcome Collection*. December 7, 2017.
- [CDC COVID-19 Vaccines](#)
- [FDA COVID-19 Vaccines](#)
- [WHO COVID-19 Vaccines](#)
- [COVID-19 Incidence and Death Rates Among Unvaccinated and Fully Vaccinated Adults with and Without Booster Doses During Periods of Delta and Omicron Variant Emergence](#) — 25 U.S. Jurisdictions, April 4–December 25, 2021. *Morbidity and Mortality Weekly Report* Jan 28, 2022.
- [VAERS Frequently Asked Questions](#)

Resource Citations Continued

- VAERS Table of Reportable Events Following Vaccination (RET). March 21, 2017.
- United States Department of Health and Human Services, Department of Health and Human Services (DHHS), Public Health Service (PHS), FDA / CDC, Vaccine Adverse Event Reporting System (VAERS) 1990 - last Friday, CDC WONDER Online Database.
- Vaccine Adverse Event Reporting System (VAERS)
- Report an Adverse Event to VAERS
- CISA
- CISA Reporting Partners Map
- CDC Vaccine Safety Datalink (VSD)
- CDC VSD Partners Map
- VAERS Print and Web Educational Materials

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https://bit.ly/3BhfHc1

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