Update on CDC's COVID-19 Vaccine Safety Monitoring

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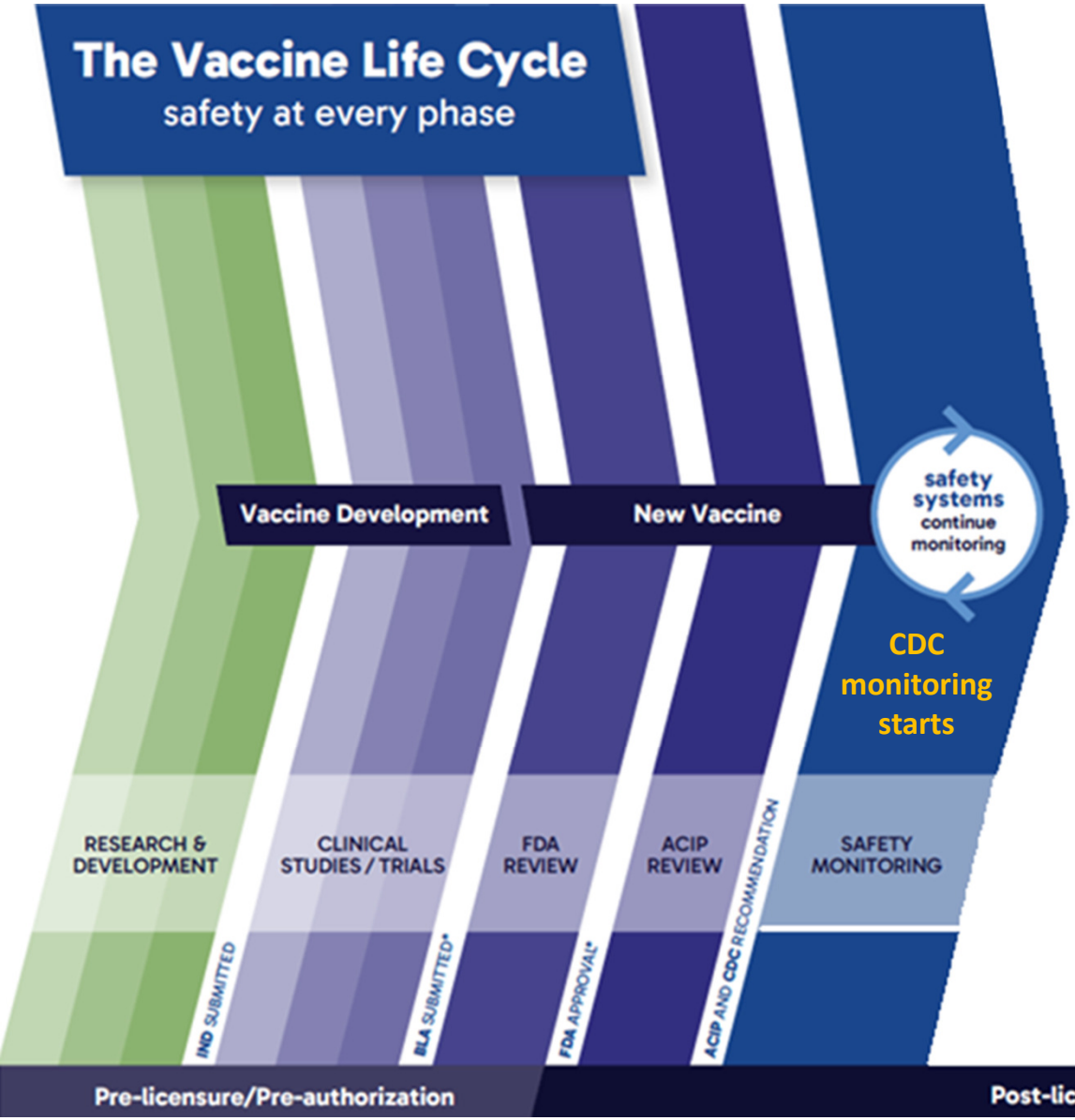
Director, CDC's Immunization Safety Office

June 25, 2025

Key Points

- CDC and interagency partners launched an extensive vaccine safety monitoring program for COVID-19 vaccines
- Many potential safety outcomes were rigorously assessed through complementary passive and active systems
- Myocarditis is causally associated with mRNA COVID-19 vaccines
  - Adverse events common to all vaccines were also observed (e.g., local and systemic reactions, allergic reactions)
- CDC continues to monitor the safety of COVID-19 vaccines



Interagency collaboration to monitor post-licensure safety

CDC's Immunization Safety Office Monitors Vaccine Safety Through Strong, Complementary Systems

VAERS	VSD	CISA Project	V-safe
			
1990	*1990*	*2001*	*2020*

Systems work together to rapidly detect and assess potential safety concerns to help inform public health actions

Vaccine Adverse Event Reporting System (VAERS)

The Nation's Early Warning System for Vaccine Safety

VAERS

- Co-managed by CDC and FDA
- Nationwide spontaneous reporting system that can rapidly detect safety signals, including rare events
- Mandated reporting by healthcare providers and manufacturers, and encouraged from anyone (e.g., patients)
- A report to VAERS does not mean that a vaccine caused an adverse event
- Used for signal detection and hypothesis generation, not typically for assessing causality

Vaccine Safety Datalink (VSD)

Collaborative Model for High-Quality Vaccine Safety Data

VSD

- 13 integrated healthcare organizations, covering >15.5 million people per year
- Active monitoring using electronic medical records (EMR) and chart reviews
- Rapid monitoring for pre-specified events as well as monitoring for unexpected events
- Can detect and assess safety signals
- Develops innovative methods for monitoring safety

Clinical Immunization Safety Assessment (CISA) Project

Network to Guide Vaccine Safety from the Individual to Population Level

CISA Project

- 8 medical research centers with vaccine safety experts
- Provides expert clinical consultation on complex immunization issues
- Conducts clinical research on vaccine safety
- Helps to inform CDC public health guidance on clinical immunization safety issues

V-safe: After-Vaccination Health Checker

CDC's Tool for Direct-to-Consumer Vaccine Safety Monitoring

V-safe

- Web-based, self-reported active monitoring system established during COVID-19 pandemic
- Can serve as earliest source of information for new vaccines and in populations excluded from clinical trials
  - Used to recruit women for COVID-19 Vaccine Pregnancy Registry
- Important tool for emergency preparedness and response
- Integrated with VAERS to help streamline reporting of serious adverse events

CDC's Comprehensive Approach to Studying COVID-19 Vaccine Safety

Surveillance
Analyze spontaneously reported events

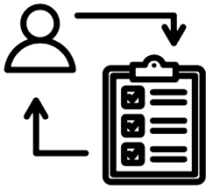
Epidemiologic studies
Assess specific safety questions

Clinical Research
Safety studies to guide clinical practice

Pregnancy Registry
Longitudinal assessment of maternal and infant outcomes

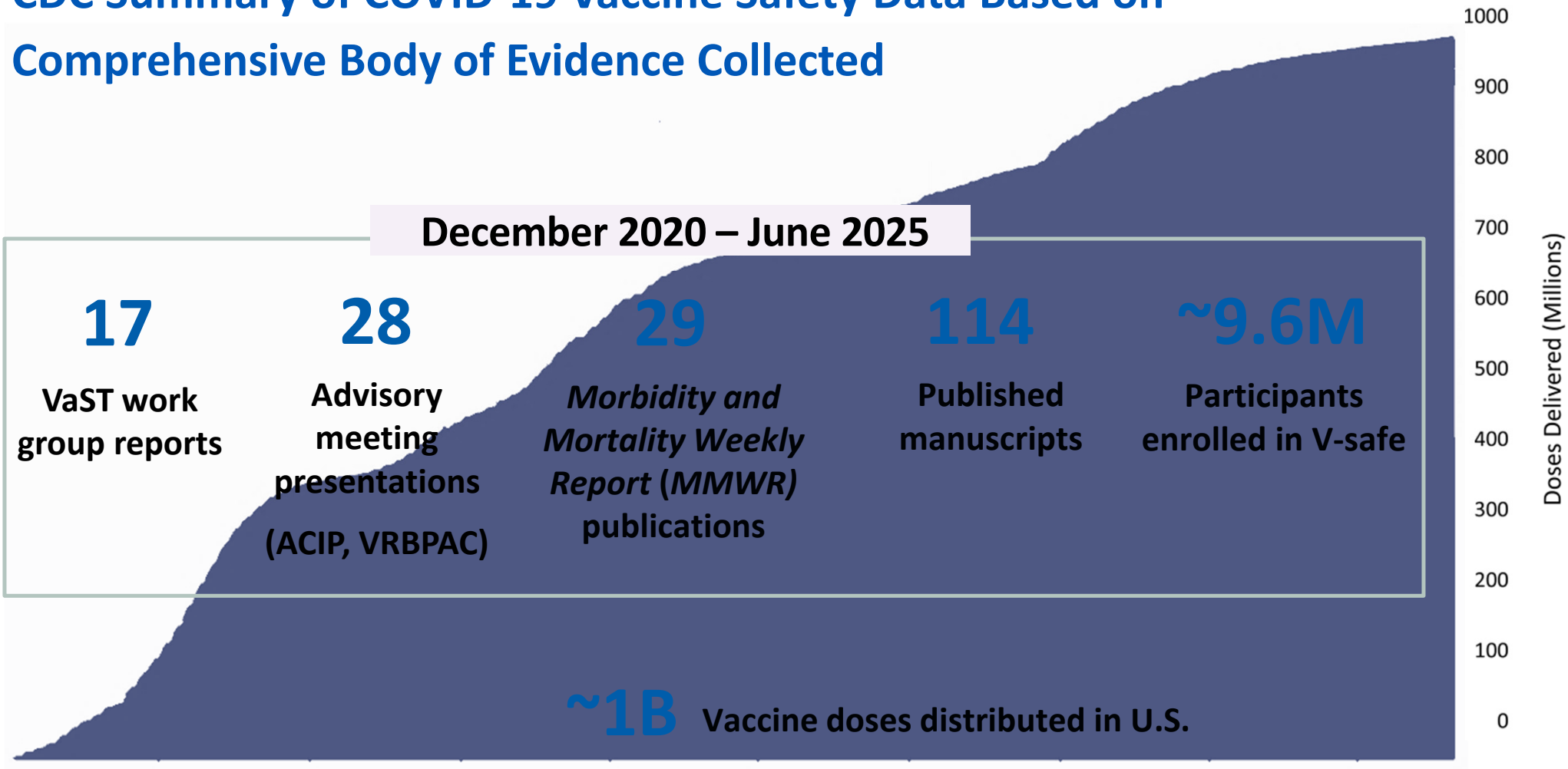
Rapid cycle analyses
Quickly detect potential concerns for investigation

Data mining
Assess >60,000 outcomes for unexpected events



Patient surveys
Assess symptoms and health impacts

CDC Summary of COVID-19 Vaccine Safety Data Based on Comprehensive Body of Evidence Collected



December 2020 – June 2025

17
VaST work group reports

28
Advisory meeting presentations (ACIP, VRBPAC)

29
Morbidity and Mortality Weekly Report (*MMWR*) publications

114
Published manuscripts

~9.6M
Participants enrolled in V-safe

~1B Vaccine doses distributed in U.S.

ACIP: Advisory Committee on Immunization Practices; VRBPAC: Vaccines and Related Biological Products Advisory Committee; VaST: Vaccine Safety Technical Work Group

Three Types of COVID-19 Vaccine Received FDA Authorization or Approval in the United States

mRNA

Pfizer-BioNTech
Moderna

Protein-based

Novavax

Viral Vector

Janssen

Janssen Use Limited After Detection of Safety Concerns in April 2021, and No Longer Authorized in U.S. as of June 2023

mRNA

Pfizer-BioNTech
Moderna

Protein-based

Novavax

Viral Vector

Janssen

- By April 2021, VAERS detects 6 reports of thrombosis w/ thrombocytopenia syndrome (TTS); FDA and CDC issue a 10-day pause in use before resuming
- In December 2021, ACIP issues preferential recommendation for mRNA vaccines
- In June 2023, FDA revokes EUA

EUA: Emergency Use Authorization

Oliver S, et al. Development of COVID-19 vaccine policy — United States, 2020–2023 - ScienceDirect

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Highlights an example of federal safety systems working to rapidly identify and mitigate a vaccine safety issue

EUA: Emergency Use Authorization

Oliver S, et al. Development of COVID-19 vaccine policy — United States, 2020–2023 - ScienceDirect

Limited Post-Authorization Safety Data Available for Novavax

mRNA

Pfizer-BioNTech
Moderna

Protein-based

Novavax

Limited post-authorization safety data available:

- Authorized later than other products (July 2022)
- Limited uptake in the U.S.

Viral Vector

Janssen

Focus on mRNA COVID-19 Vaccines For This Presentation

mRNA

Pfizer-BioNTech
Moderna

Protein-based

Novavax

Viral Vector

Janssen

Monitoring Safety of COVID-19 Vaccines

What we have learned

CDC Has Evaluated At Least 65 Specific Outcomes to Assess COVID-19 Vaccine Safety Using a Variety of Systems and Epidemiologic Methods

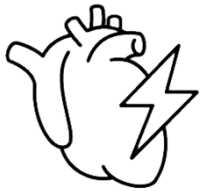
Acute myocardial infarction • ICU admission • Acute disseminated encephalomyelitis • Thrombotic thrombocytopenic Purpura • Encephalopathy • Gestational diabetes • Trigeminal neuralgia and related disorders • Meningitis • Deep vein thrombosis • Anaphylaxis • Thrombocytopenia • Postmenopausal bleeding • Myocarditis • Cataplexy • Myelitis • Chronic inflammatory demyelinating polyneuropathy • Non-COVID mortality • Pulmonary embolism • Stillbirth • Major birth defects • Encephalitis • Local reactions • Vaccine-Associated Enhanced Disease after COVID-19 Vaccines • Hemorrhagic stroke • Administration errors • Acute respiratory distress syndrome • Narcolepsy • Perinatal death • Bell's Palsy • Thrombosis with thrombocytopenia syndrome • Multiple sclerosis • Systemic reactions • Spontaneous abortion • Ataxia • Hospitalization • Acute disseminated encephalomyelitis • Menstrual irregularities • Immune thrombocytopenic purpura • All-cause mortality • Pericarditis • Early childhood infections in infants of vaccinated mothers • Ischemic stroke • Shoulder injuries • Multisystem Inflammatory Syndrome in Children • Multisystem Inflammatory Syndrome in Adults • Tinnitus • Disseminated intravascular coagulation • Acute respiratory distress syndrome • Venous thromboembolism • Arthritis • Seizure • Kawasaki Disease • Arthralgia • Menstrual irregularities • NICU admission • Chronic inflammatory demyelinating polyneuropathy • Small-for-gestational age • Post-COVID conditions • Trigeminal neuralgia and related disorders

Weekly, Sequential Monitoring of Pre-Specified Outcomes in the VSD

- Rapid cycle analyses (RCAs) conducted weekly since December 2020 of up to 23 pre-specified outcomes among over 12 million people
  - Outcomes selected based on clinical trial data, known safety findings with other vaccines, or biological plausibility
- Sequential statistical testing using automated ICD-10-CM codes
  - Compare incidence in vaccinated people during post-vaccination risk interval vs. vaccinated people in a comparison window
- If potential "statistical signal" detected, additional analyses and/or chart reviews conducted
  - System designed to be sensitive; not all detected signals represent a true safety concern

Evaluation of Statistical Signals Detected for mRNA COVID-19 Vaccines through VSD's Rapid Cycle Analyses – 2020-2025

8 statistical signals detected

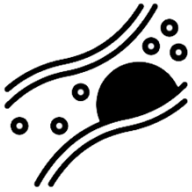


Acute myocardial infarction
Age 18+ years

Immune Thrombocytopenic Purpura
Age 65+ years

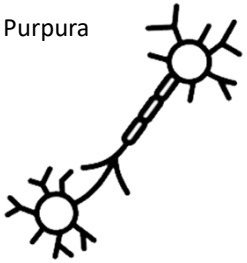
Seizure
18-64 years

Bell's Palsy
Age 12+ years



Venous thromboembolism
Age 12+ years

Ischemic stroke
Age 50+ years



Guillain-Barré syndrome
Age 65+ years

Myocarditis
Age 12+ years

COVID-19 Vaccine Safety Technical (VaST) Work Group: Enhancing vaccine safety monitoring during the pandemic – ScienceDirect and CDC unpublished data

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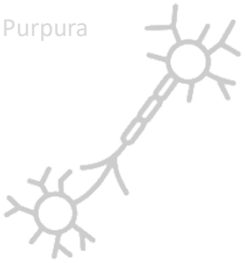
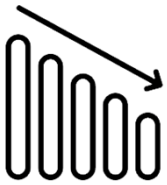


Guillain-Barré syndrome
Age 65+ years

Myocarditis
Age 12+ years

Further investigations

Chart reviews



Trend analysis

Additional studies
(e.g., self-controlled
case series)

FDA
VA
VAERS

Query other
systems

[COVID-19 Vaccine Safety Technical (VaST) Work Group: Enhancing vaccine safety monitoring during the pandemic – ScienceDirect](#) and CDC unpublished data

Evaluation of Statistical Signals Detected for mRNA COVID-19 Vaccines through VSD's Rapid Cycle Analyses – 2020-2025

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- Acute myocardial infarction, Age 65+ years
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- Seizure, 18-64 years
- Bell's Palsy, Age 12+ years
- Venous thromboembolism, Age 12+ years
- Ischemic stroke, Age 50+ years
- Guillain-Barré syndrome, Age 65+ years
- Myocarditis, Age 12+ years

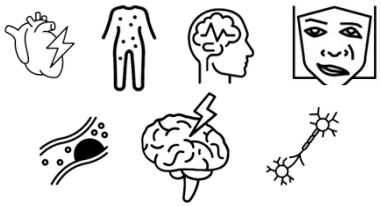
Further investigations

- Chart reviews
- Trend analysis
- Additional studies (e.g., self-controlled case series)
- FDA VA VAERS: Query other system

Safety assessment

Increased risk for myocarditis following mRNA COVID-19 vaccines

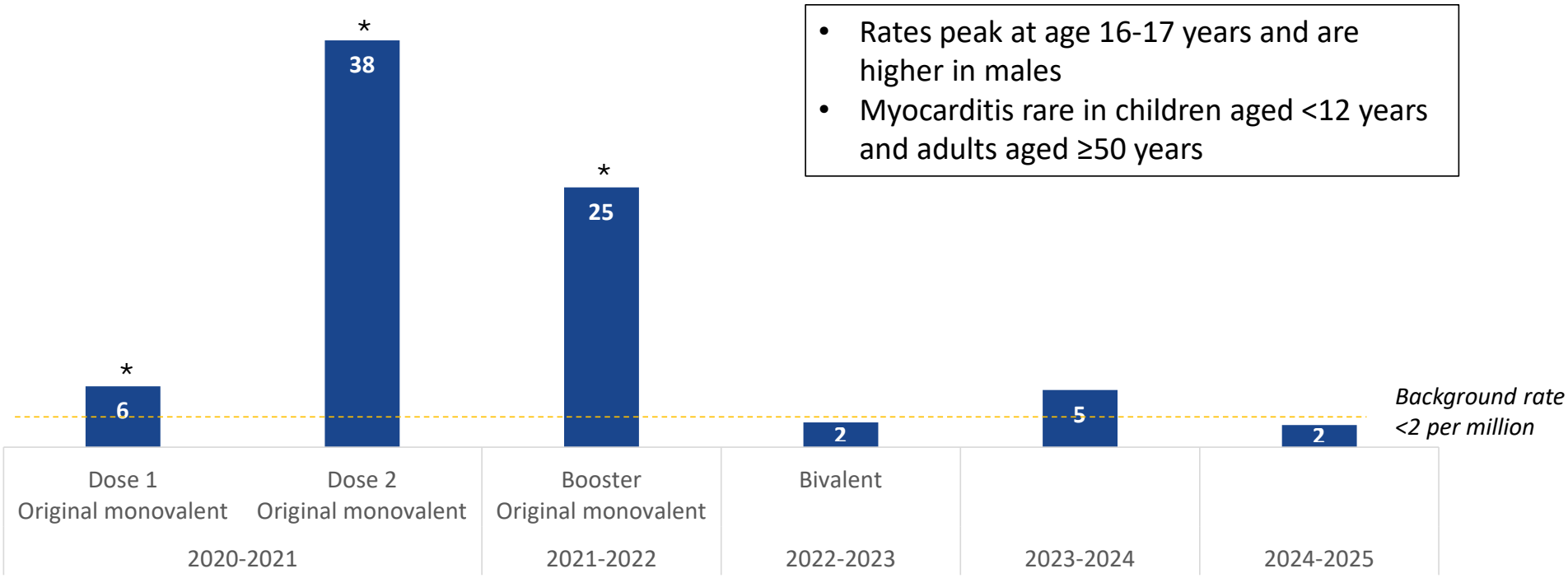
No clear or consistent evidence of a safety concern for the others



COVID-19 Vaccine Safety Technical (VaST) Work Group: Enhancing vaccine safety monitoring during the pandemic – ScienceDirect and CDC unpublished data

Myocarditis Following mRNA COVID-19 Vaccination Among People Ages 12–39 Years in the Vaccine Safety Datalink

Incidence of myocarditis within 7 days of vaccination per million mRNA vaccine doses administered



*Statistically significant increased rate ratio in vaccinated concurrent comparator analysis. Source: CDC Immunization Safety Office

Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination in FDA's Biologics Effectiveness and Safety System (BEST), 2023—2024 Season

Incidence (cases per million doses) during days 1—7 following vaccine administration

Population	No. Doses	No. Cases	Rate Per Million Vaccine Doses (95% CI)
All persons 6 months–64 years of age	3,574,262	30	8.4 (5.7, 12.0)
Males 12–24 years of age	185,969	5	26.9 (8.7- 62.7)

FDA issued Safety Labeling Change (SLC) notification letters to the manufacturers on April 17, 2025, and initiated the SLC process to include new safety information on myocarditis and pericarditis for Comirnaty and Spikevax. Under the labeling negotiations, FDA has notified sponsors of the above data

2025 Safety and Availability Communications | FDA; Information courtesy of FDA

Follow-up CDC Studies Demonstrate Most Adolescents and Young Adults Have Recovered From Myocarditis

- Surveys of individuals aged 12-29 years with myocarditis after mRNA COVID-19 vaccine, and their healthcare providers, for whom a VAERS report was filed during January 12-November 5, 2021
- Based on cardiologist or other healthcare provider assessment:

83%

Fully or probably fully recovered by at least 90 days after myocarditis onset

→

>90%

Overall, fully or probably fully recovered by at least a 1 year after myocarditis onset

- Among patients with abnormal cardiac MRI at 1-year evaluation, most common abnormality was late gadolinium enhancement
  - clinical significance unclear; majority considered recovered and cleared for all physical activity
- No known deaths or cardiac transplants

Outcomes at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study - The Lancet Child & Adolescent Health; Outcomes at ≥1 year based on unpublished data

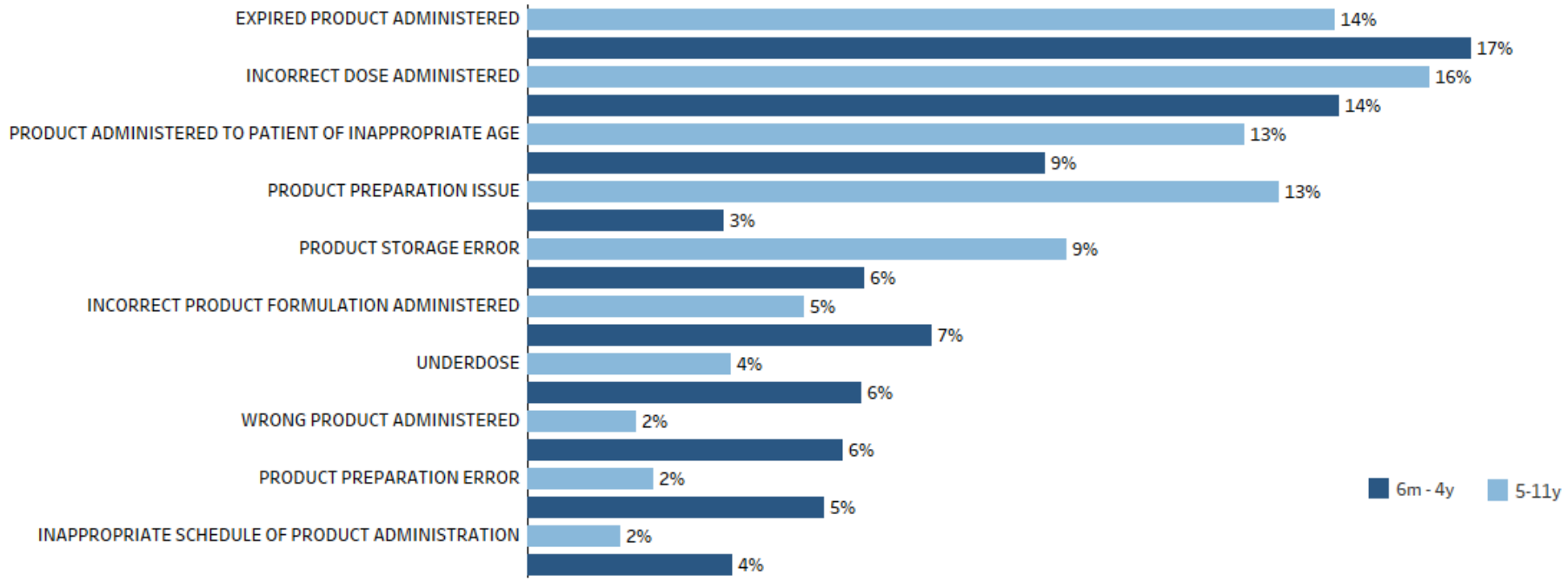
COVID-19 Vaccine Safety in Children Ages 6 Months to 11 Years

- Risk of myocarditis following COVID-19 vaccines in children aged <12 years is low, particularly for those aged 6 months to 5 years
  - Active, sequential analyses in the Vaccine Safety Datalink have demonstrated no statistical signals for myocarditis in children
  - No confirmed myocarditis cases in children aged <5 years in VAERS or VSD
- Rapid cycle analyses in the VSD demonstrate no increased risks for 22 other pre-specified outcomes following COVID-19 vaccination
- Evaluations to assess multisystem inflammatory syndrome in children (MIS-C) following COVID-19 vaccination demonstrated that most patients had evidence of preceding SARS-CoV-2 infection

Safety of COVID-19 Vaccination in United States Children Ages 5 to 11 Years | Pediatrics | American Academy of Pediatrics; Safety Monitoring of mRNA COVID-19 Vaccine Third Doses Among Children Aged 6 Months–5 Years — United States, June 17, 2022–May 7, 2023 | MMWR; COVID-19 Vaccine Safety First Year Findings in Adolescents | Pediatrics | American Academy of Pediatrics; Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Children Aged 5–11 Years — United States, October 12–January 1, 2023 | MMWR; COVID-19 mRNA Vaccine Safety Among Children Aged 6 Months–5 Years — United States, June 18, 2022–August 21, 2022 | MMWR; Safety of COVID-19 mRNA Vaccination Among Young Children in the Vaccine Safety Datalink | Pediatrics | American Academy of Pediatrics; Surveillance for Multisystem Inflammatory Syndrome in US Children Aged 5-11 Years Who Received Pfizer-BioNTech COVID-19 Vaccine, November 2021 through March 2022 – PubMed; Reported cases of multisystem inflammatory syndrome in children aged 12–20 years in the USA who received a COVID-19 vaccine, December, 2020, through August, 2021: a surveillance investigation - The Lancet Child & Adolescent Health

Majority of COVID-19 Vaccine Reports to VAERS in Children Aged <12 Years Include at Least One Vaccine Administration Error

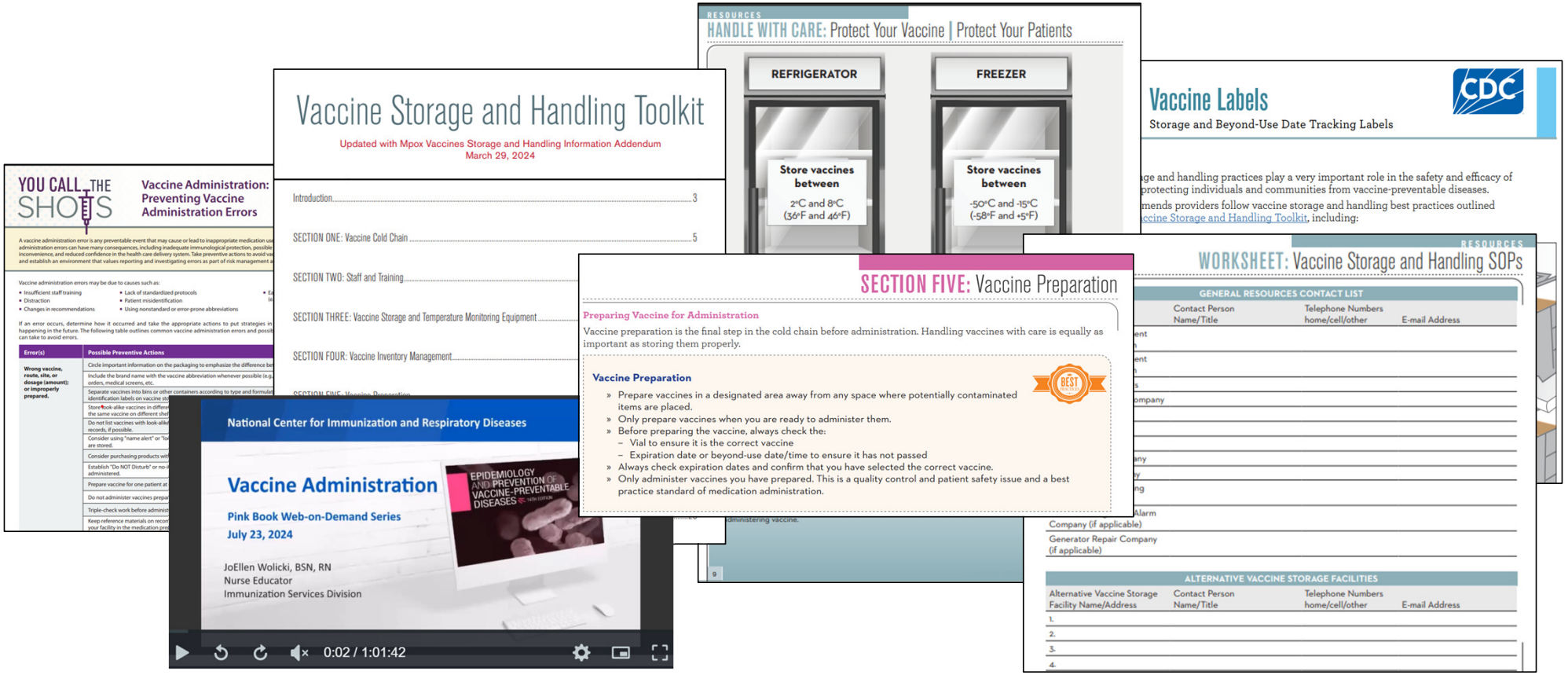
Approximately 77% of reports in children aged 6 months-4 years and 70% of reports in children aged 5-11 years related to administration errors between October 21, 2021 – April 30, 2025



Data source: https://wonder.cdc.gov

VAERS reports may include more than one administration error type

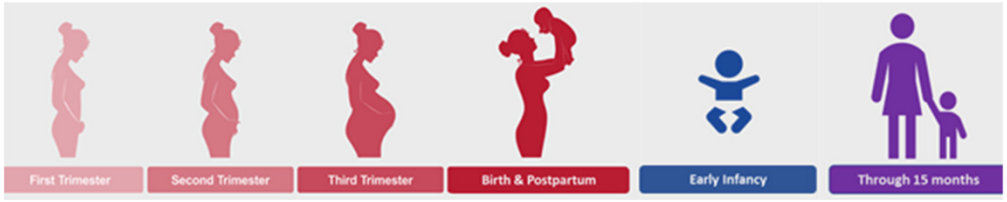
CDC Is Expanding Its Work to Prevent Vaccine Administration Errors



[Vaccine Administration Protocols | CDC]

Evaluating Safety of COVID-19 Vaccines in Pregnant Women

CDC COVID-19 Vaccine Pregnancy Registry



- >23,000 pregnant women
- 7 analyses
- Observational studies based on survey and medical record information

Vaccine Safety Datalink

- >45,000 pregnant women
- 11 analyses to date
- Cohort, case-control, and surveillance evaluations

COVID-19 Vaccine Safety During Pregnancy

Across CDC studies, evidence shows NO increased risk of:

Maternal outcomes

- 25 medically-attended adverse events
- Serious adverse events
- Pregnancy-related conditions
- Maternal ICU admission

Pregnancy outcomes

- Miscarriage
- Stillbirth
- Preterm birth
- Small-for-gestational age

Infant outcomes

- Major birth defects
- Neonatal ICU admission
- Infant death

Evaluation of Acute Adverse Events after Covid-19 Vaccination during Pregnancy | New England Journal of Medicine; Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020–July 22, 2021 | MMWR; Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion | New England Journal of Medicine; Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy | Public Health | JAMA | JAMA Network; COVID-19 Booster Vaccination in Early Pregnancy and Surveillance for Spontaneous Abortion; Coronavirus Disease 2019 (COVID-19) Vaccination and Stillbirth in the Vaccine Safety Datalink; Medically Attended Acute Adverse Events in Pregnant Women : Obstetric Complications and Birth Outcomes After Antenatal Coronavirus Disease 2019 (COVID-19) Vaccination; COVID-19 Vaccination in the First Trimester and Major Structural Birth Defects Among Live Births ; Accumulating Robust Evidence for Reducing Vaccine Hesitancy in Early Pregnancy—Reply

Examples of CDC Studies to Address Vaccine Safety Concerns from the Public

Abnormal uterine bleeding

- Conducted studies in VAERS, VSD, and v-safe for abnormal uterine bleeding
- VSD studies demonstrated:
  - Availability of COVID-19 vaccines was not associated with a change in incidence of medically-attended abnormal uterine or post-menopausal bleeding
  - Receipt of COVID-19 vaccine not associated with greater bleeding severity

Tinnitus

- Conducted data mining to assess tinnitus:
  - VAERS empirical Bayesian data mining did not find disproportionate reporting of tinnitus
  - VSD tree-based data mining found no signals for tinnitus
- Taken together, findings do not support an increased risk of tinnitus after COVID-19 vaccine

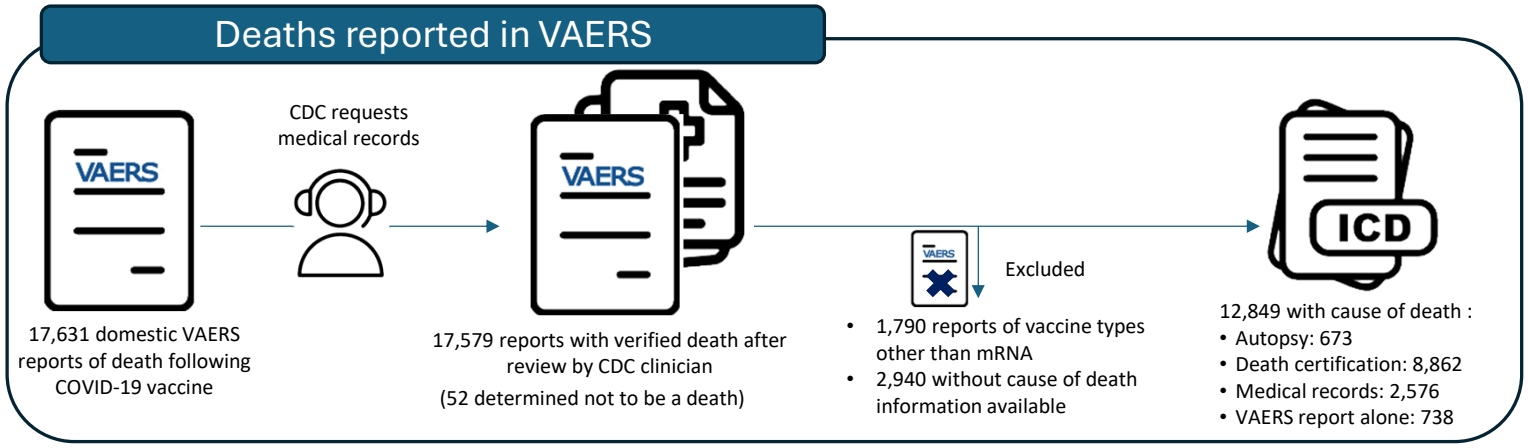
Abnormal uterine bleeding diagnoses and care following COVID-19 vaccination – ScienceDirect
Postmenopausal bleeding after COVID-19 vaccination – PubMed
Postmenopausal Bleeding After Coronavirus Disease 2019 (COVID-19) Vaccination: Vaccine Adverse Event Reporting System – PubMed
Menstrual irregularities and vaginal bleeding after COVID-19 vaccination reported to v-safe active surveillance, USA in December, 2020-January, 2022: an observational cohort study – PubMed
Tinnitus after COVID-19 vaccination: Findings from the vaccine adverse event reporting system and the vaccine safety datalink - ScienceDirect

Safety Monitoring of Death Reports Following mRNA COVID-19 Vaccination in VAERS

- As of May 30, 2025, there have been 19,417 domestic deaths reported to VAERS after COVID-19 vaccination
- Important considerations related to evaluation of death reports in VAERS
  - FDA Emergency Use Authorizations and CDC COVID-19 Vaccination Provider Enrollment Agreements required healthcare provider to report **all deaths** following COVID-19 vaccination to VAERS, regardless of cause or circumstances surrounding death (requirement does not apply to other vaccines)
  - VAERS generally cannot assess causality of adverse reports, including deaths
- We conducted an evaluation of deaths following mRNA COVID-19 vaccination in VAERS through January 31, 2023

Vaccine Adverse Event Reporting System. VAERS Reporting Information for COVID-19 Vaccines. https://vaers.hhs.gov/reportevent.html

Safety Monitoring of Death Reports Following mRNA* COVID-19 Vaccination in VAERS – December 22, 2020 – January 31, 2023



* Includes reports with missing vaccine type, but excludes reports known to be after Janssen or Novavax COVID-19 vaccine
Reports to the Vaccine Adverse Event Reporting System (VAERS) reviewed and processed during December 22, 2020 — January 31, 2023; reported date of vaccination during December 22, 2020 — January 31, 2023 or missing

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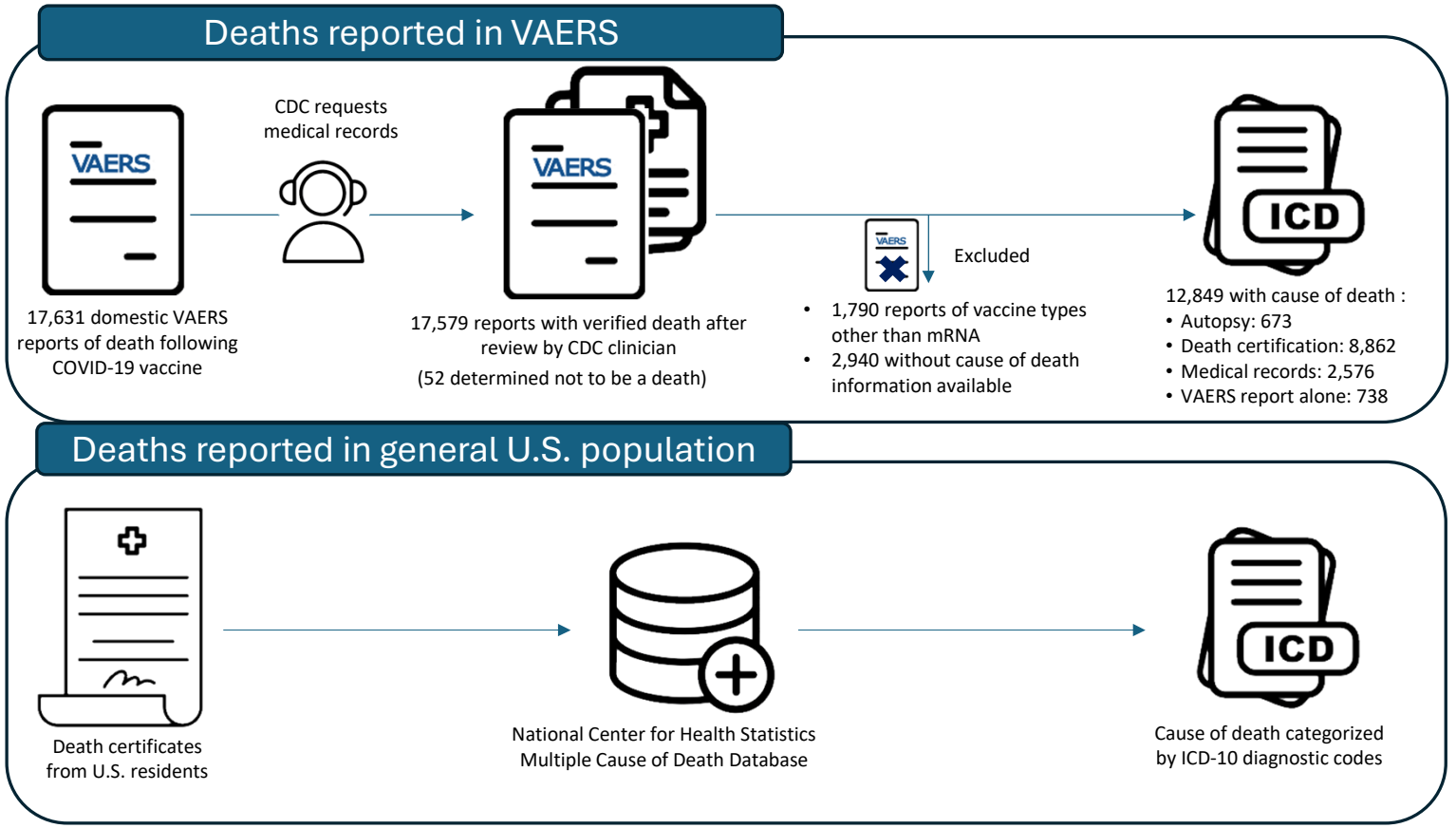

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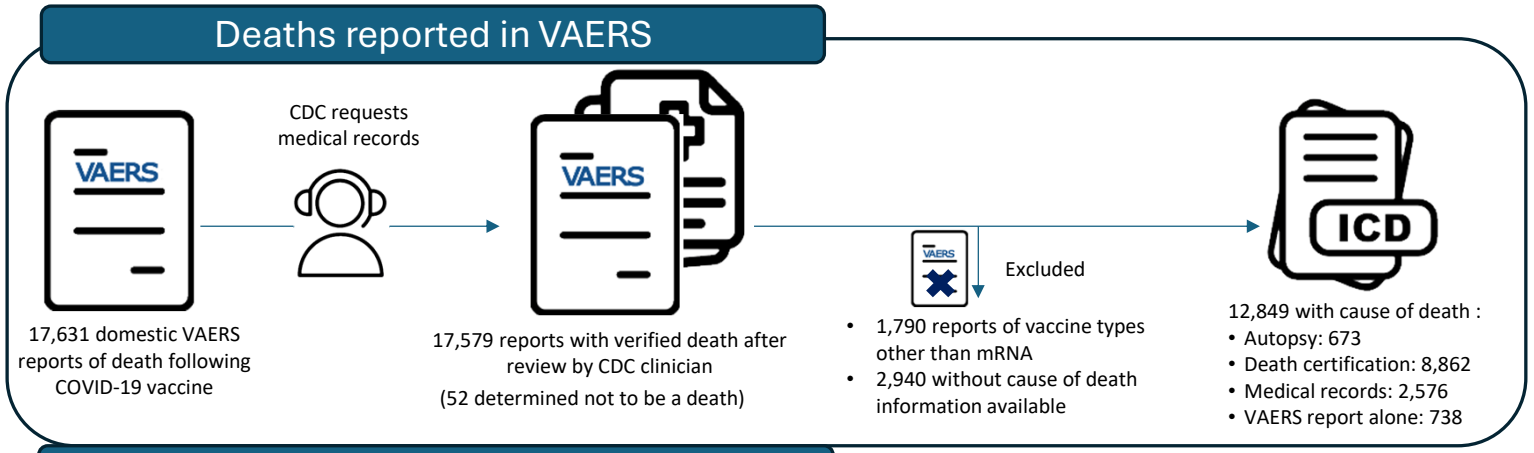

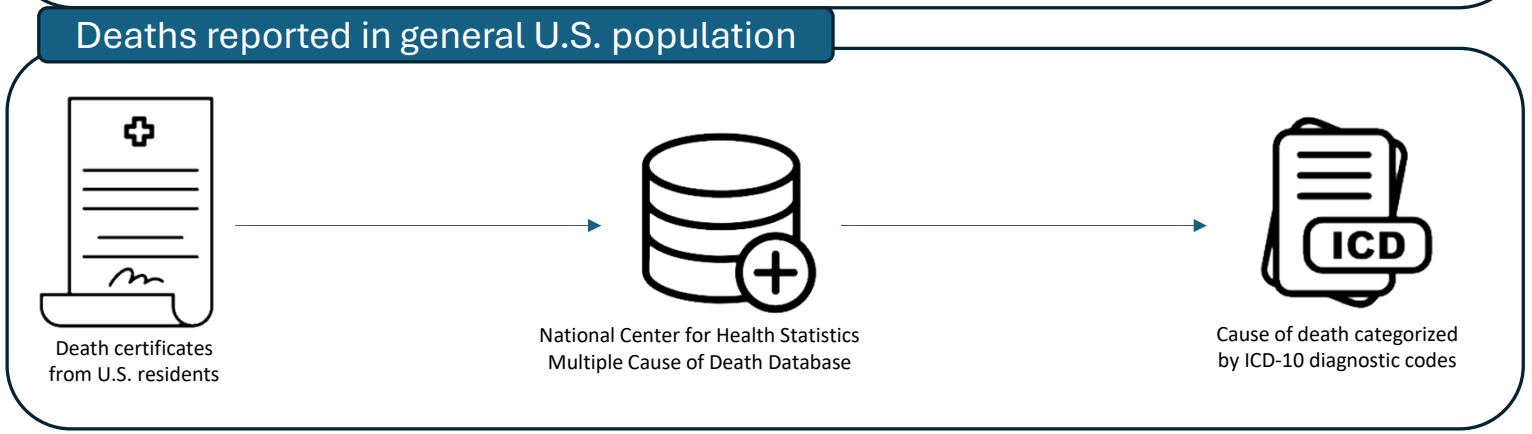

Observed Rate

Number of deaths (cause-specific)
100,000 persons vaccinated

Within 42 days of vaccination

Expected Rate

Number of deaths (cause-specific)
100,000 persons in U.S. population

Within 42 days of vaccination

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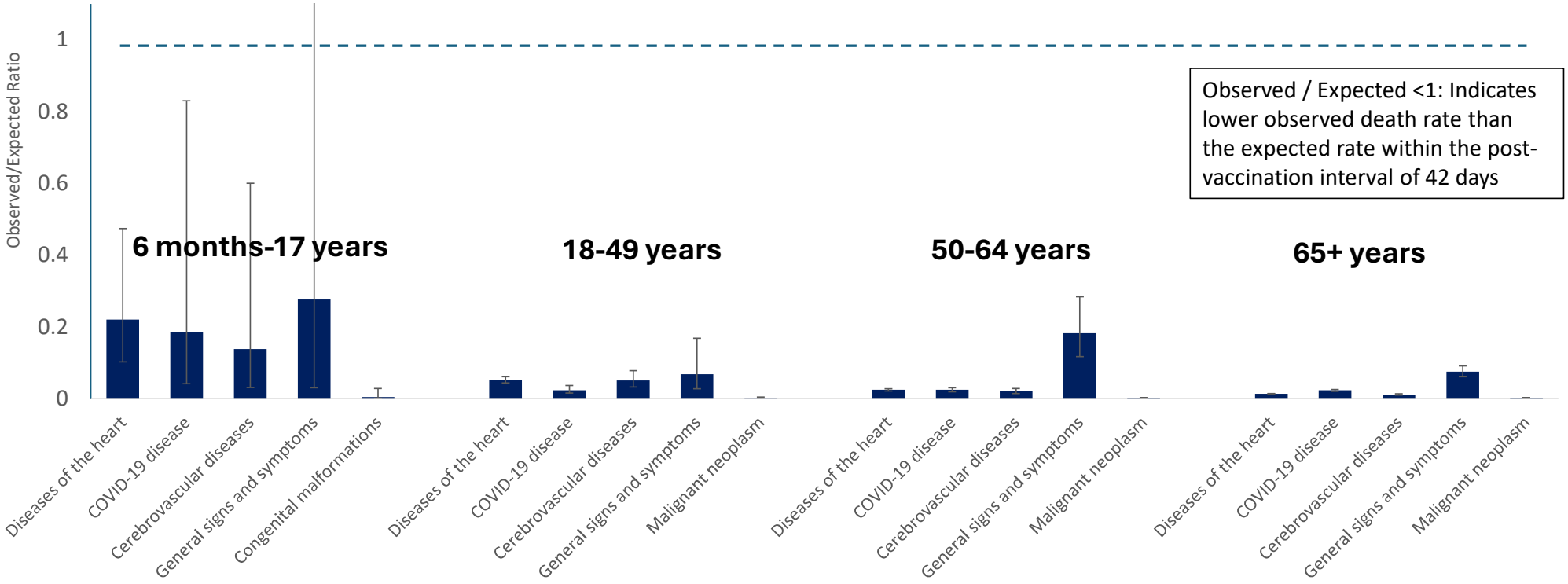
Abara WE, et al. Expected Rates of Select Adverse Events After Immunization for Coronavirus Disease 2019 Vaccine Safety Monitoring | The Journal of Infectious Diseases; Mahaux O, et al. Pharmacoepidemiological considerations in observed-to-expected analyses for vaccines

Reporting Rates of Death After mRNA* COVID-19 Vaccination Were Below Background Rates of Death in the General U.S. Population

The most common causes of death reported to VAERS are consistent with the leading causes of death in the U.S. population



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Hoyert DL, Xu J. Deaths: preliminary data for 2011. Natl Vital Stat Rep. 2012; 61:1–51 ; U.S. Centers for Disease Control and Prevention. CDC WONDER. Available at https://wonder.cdc.gov/controller/datarequest/D157 Accessed March 20, 2025

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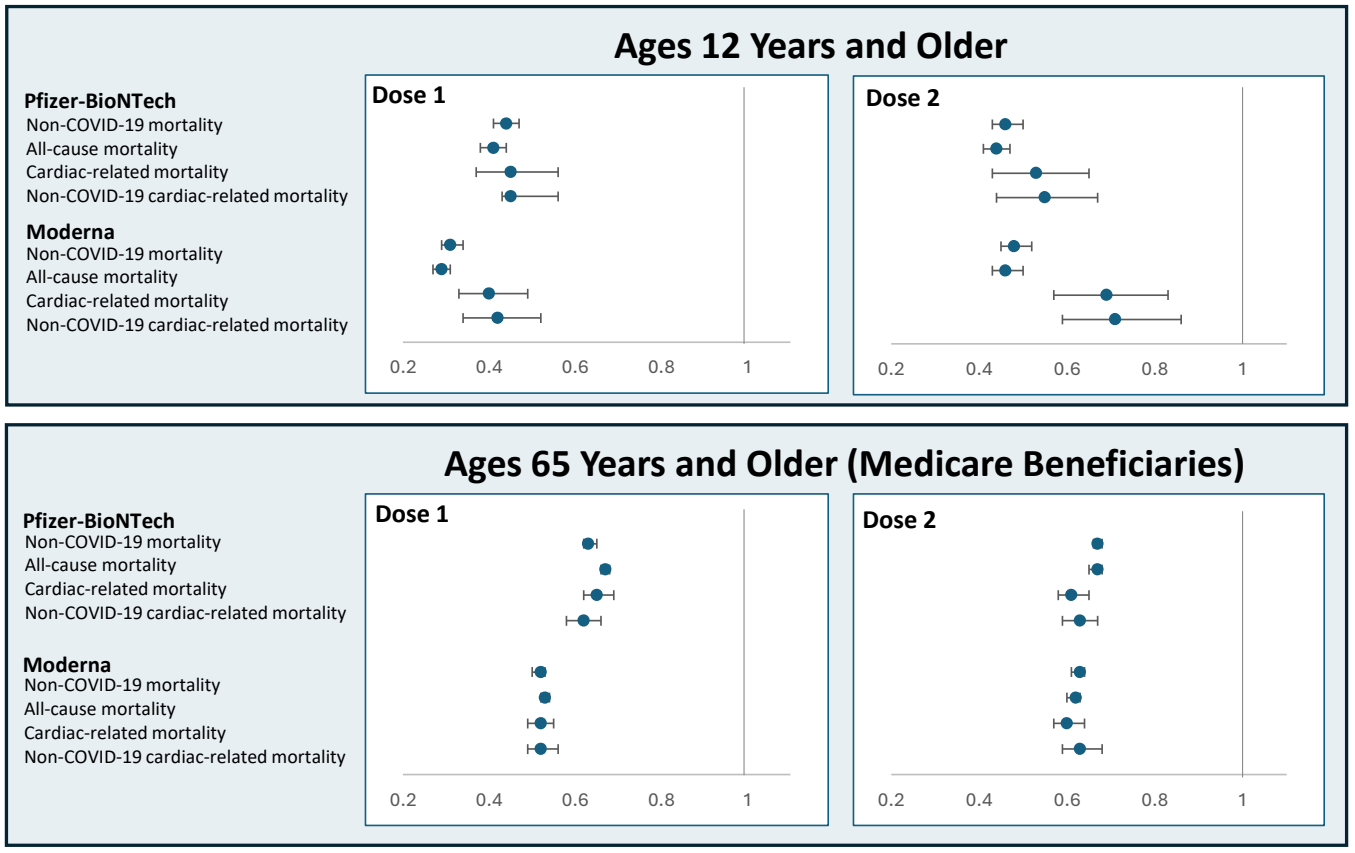
National Center for Health Statistics, National Vital Statistics System. Deaths: Leading Causes of Death for 2021. 73:4. Published April 8, 2024. https://www.cdc.gov/nchs/data/nvsr/nvsr73/nvsr73-04.pdf National Center for Health Statistics, National Vital Statistics System. Deaths: Leading Causes of Death for 2020. 72:13. Published December 5, 2023. https://www.cdc.gov/nchs/data/databriefs/db492-tables.pdf#4

Data From CDC's Vaccine Safety Datalink Shows No Increased Risk of Death Following mRNA COVID-19 Vaccines

- 2 self-controlled case series evaluations
- No increased risk in the 28 days after vaccination of:
  - Non-COVID mortality
  - All-cause mortality
  - Cardiac-related mortality
  - Non-COVID cardiac-related mortality
- Similar findings in VSD cohort study of people ages 12+ years



X axis: Relative Incidence and 95% Confidence Intervals

Mortality risk after COVID-19 vaccination: A self-controlled case series study
https://pubmed.ncbi.nlm.nih.gov/38388239/
A Modified Self-Controlled Case Series on Mortality Risk following Primary Series Doses of COVID-19 Vaccines in U.S. Medicare Beneficiaries Aged 65 Years and Older - Acumen and Vaccine Safety Datalink, unpublished pending review at journal
A safety study evaluating non-COVID-19 mortality risk following COVID-19 vaccination - PubMed
Data from December 14, 2020 through August 11, 2021

Using Data Mining to Assess for Unexpected Events After COVID-19 Vaccination

- >60,000 possible adverse events assessed in the 70 days after vaccination using tree-based data mining of ICD-10 codes in the VSD for:
  - Primary series
  - Initial booster
  - Bivalent booster

- No new safety concerns identified outside of known events
  - E.g., myocarditis/pericarditis, allergic reactions, common local and systemic reactions

A broad assessment of covid-19 vaccine safety using tree-based data-mining in the vaccine safety datalink - PubMed
Tree-based data mining for safety assessment of first COVID-19 booster doses in the Vaccine Safety Datalink – PubMed
Safety signal identification for COVID-19 bivalent booster vaccination using tree-based scan statistics in the Vaccine Safety Datalink - PubMed

Summary

CDC Summary: Adverse Events Associated with mRNA COVID-19 Vaccines

Occur with any vaccines:

- Local reactions
- Systemic reactions
- Acute allergic reactions (e.g., anaphylaxis)
- Syncope (fainting)
- Shoulder injuries

Occur with COVID-19 vaccines:

- Myocarditis and pericarditis

CDC evaluated at least 65 specific safety outcomes, conducted data mining of >60,000 potential outcomes for unexpected concerns, investigated numerous signals, and conducted many epidemiologic studies

NASEM Consensus Report on Adverse Effects of COVID-19 Vaccines – 2024

- Commissioned by Health Resources and Services Administration (HRSA)
- Reviewed nearly 600 studies on safety of COVID-19 vaccines
- Concluded evidence supported causal association between mRNA COVID-19 vaccines and myocarditis
  - Evidence favors rejection of causal relationship between vaccination and 6 additional outcomes

Front Matter | Evidence Review of the Adverse Effects of COVID-19 Vaccination and Intramuscular Vaccine Administration | The National Academies Press

COVID-19 Vaccines Have Been Evaluated Under the Most Extensive Safety Monitoring Program in U.S. History

- Safety surveillance identified and characterized the risk of myocarditis after mRNA COVID-19 vaccination
- No other risks confirmed in the current U.S.-licensed vaccines except those seen with other vaccines (e.g., local and systemic reactions, allergic reactions)
- CDC continues to prioritize the monitoring of COVID-19 vaccine safety, with at least 30 ongoing studies or activities
- CDC continues to monitor the safety of COVID-19 vaccines