COVID-19 Vaccine Safety Update

MDHHS Noontime Knowledge

MDHHS
Michigan Department of Health & Human Services
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Housekeeping

- **How to Ask Questions**
  - Click on the 

 icon found at the bottom part of your screen
  - A box will open where you can type in questions, comments, indicate sound problems, etc.
  - Use this throughout the webinar to ask questions

- **Slides & Recording**
  - This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at: www.michigan.gov/COVIDvaccine → Provider Guidance and Education

Topics

- Vaccine safety monitoring mechanisms & the vaccine provider role

- COVID-19 vaccine – safety experience & profile to date

Vaccine Safety: Some Basic Principles

- Efficacy and Safety are both paramount in vaccine use
- Safety a top consideration:
  - Vaccines are held to an even higher standard of safety than other pharmaceutical products
    - Vaccines are given to healthy persons to prevent illness, to keep healthy
    - Medications given to ill persons for curative purposes
  - Safety is studied throughout all stages of vaccine development and clinical phase investigations
  - Public health recommendations for vaccine programs and practices represent a dynamic balancing of risks and benefits
  - Importantly, vaccine safety monitoring & assessment continue even after vaccine licensure or authorization
    - Rare adverse events may only manifest when vaccine is used broadly

Vaccine Safety Monitoring Mechanisms & the Role of Vaccine Providers

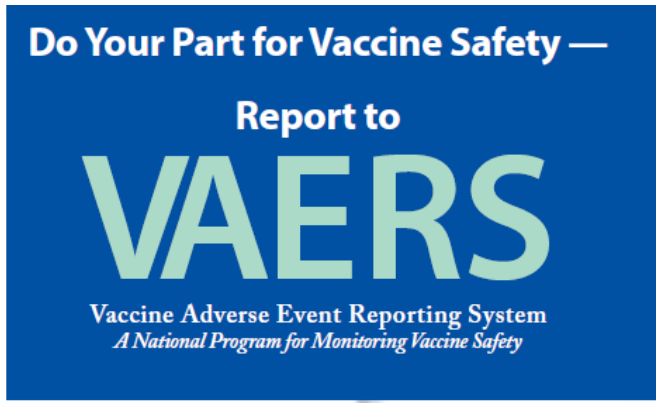
Mechanisms for Vaccine-Safety Monitoring After Approval/Authorization

- VAERS – Vaccine Adverse Event Reporting System
- VSD – Vaccine Safety Datalink
- CISA – Clinical Immunization Safety Assessment Project
- V-safe – new program for COVID-19 vaccine – “after vaccination health checker” – uses cell phone text messages and website surveys

v-safe℠
after vaccination
health checker

V-safe

- Provider gives written info at time of vaccination
- Vaccinee strongly encouraged to register
- Text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)
- If clinically important (medically-attended) event reported, VAERS personnel follow up, take/submit VAERS report



VAERS

- "Early warning system for vaccine safety"
- Intentionally casts "wide net"
  - Anything considered clinically significant can be reported
  - Anyone can report (though best by provider/person with knowledge of vaccination given and event that occurred)
- *Use VAERS to also report **vaccine administration errors** (even if no adverse event occurred)
- Can detect possible problems – "signals"
- Cannot assess causality
- Extremely useful in generating hypotheses that can be studied with other systems

Why VAERS Alone Can't Study Vaccine-AE Associations and Determine Causality

- To study associations, need:
  - Rate of adverse event/reaction among vaccinated persons

– And –

  - Rate of adverse event/reaction among un-vaccinated persons

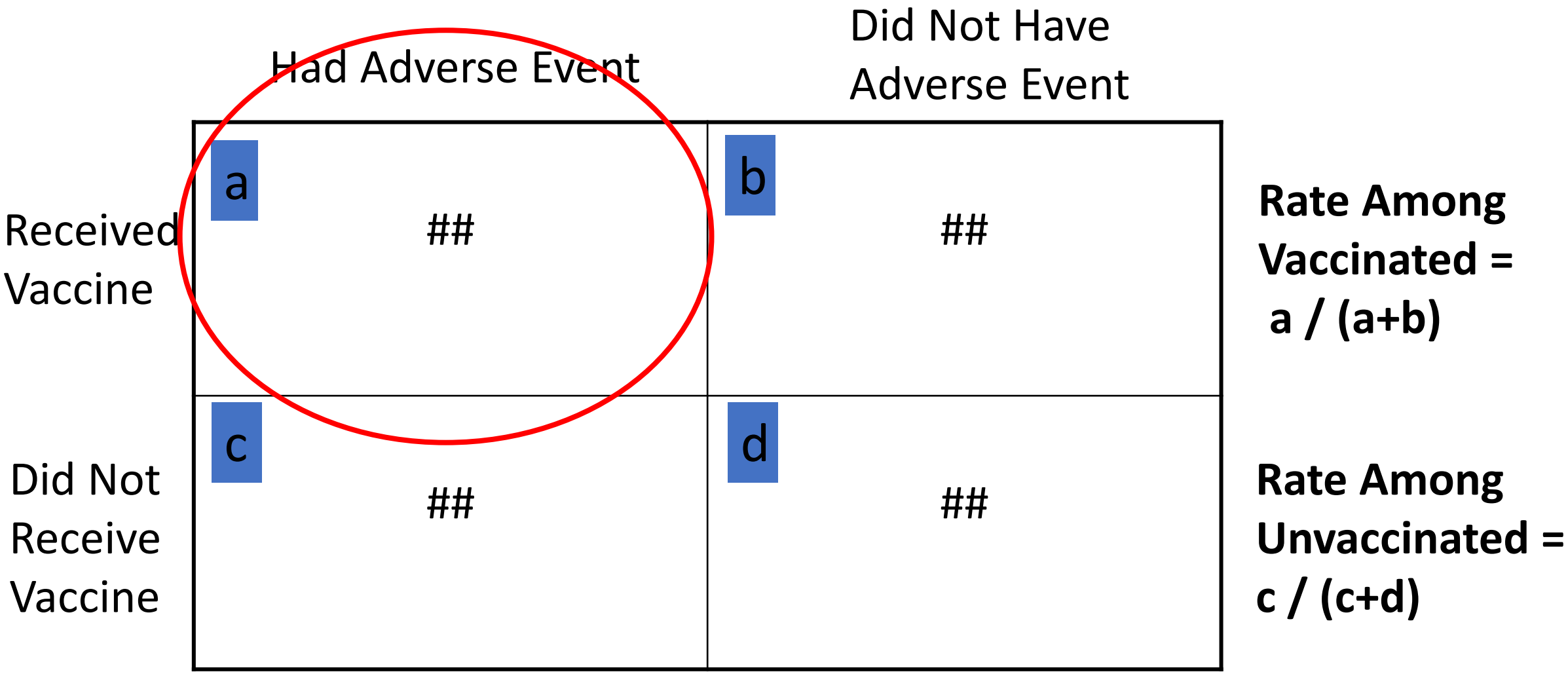
Statistical/Epidemiologic Approach to Determining Associations

	Had Adverse Event	Did Not Have Adverse Event
Received Vaccine	a ##	b ##
Did Not Receive Vaccine	c ##	d ##

Rate Among Vaccinated = a / (a+b)

Rate Among Unvaccinated = c / (c+d)

VAERS Can Only Provide Cell ‘a’ Data



VAERS – About Reporting

- Encouraged: any clinically-significant event following vaccination
- Required - Serious Adverse Events regardless of causality:
  - Death
  - Life-threatening event
  - Hospitalization or prolongation of hospitalization
  - Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - Birth defect
  - * **Vaccine administration errors**, whether or not associated with an adverse event

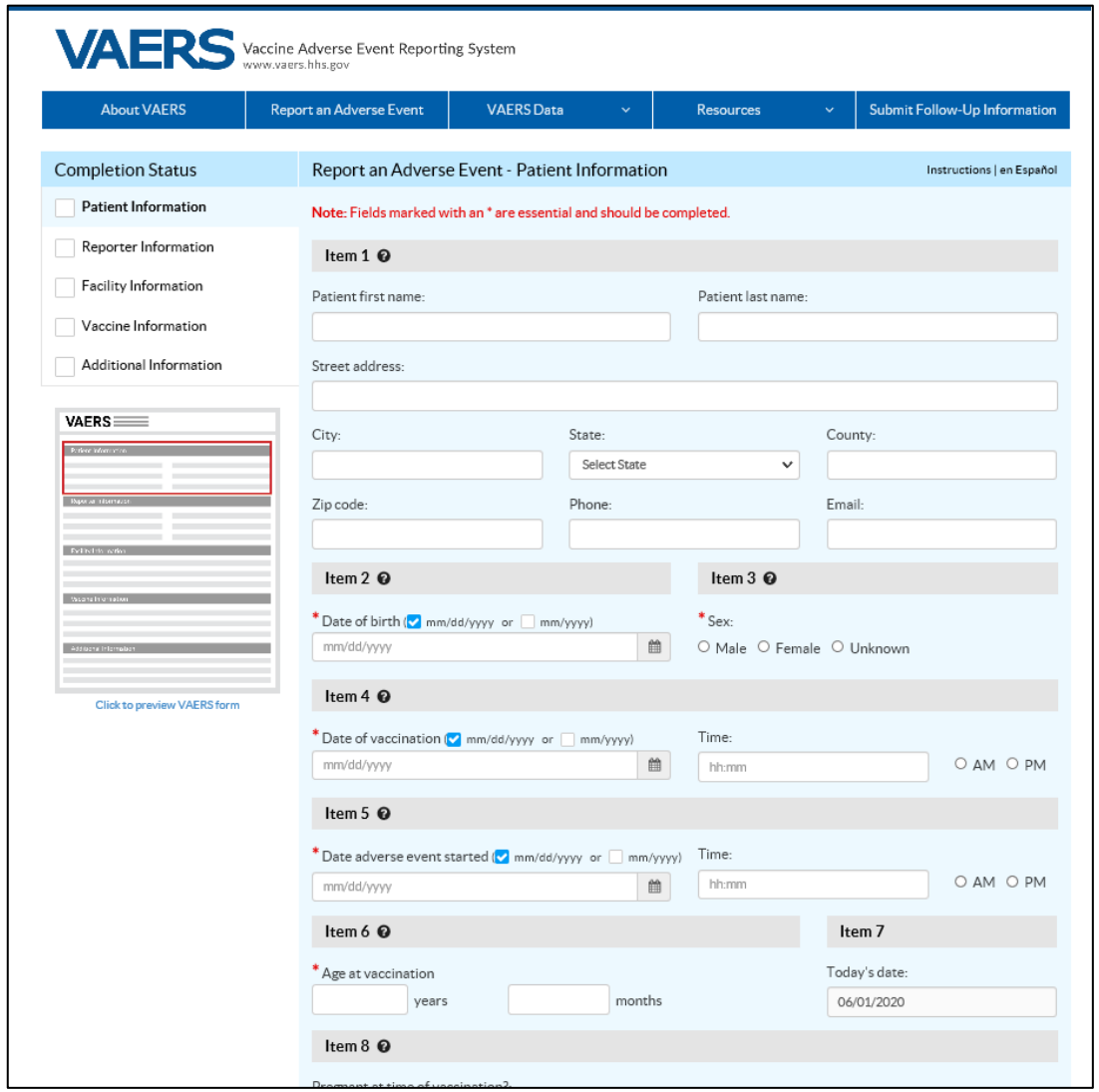
Submit reports online at www.vaers.hhs.gov

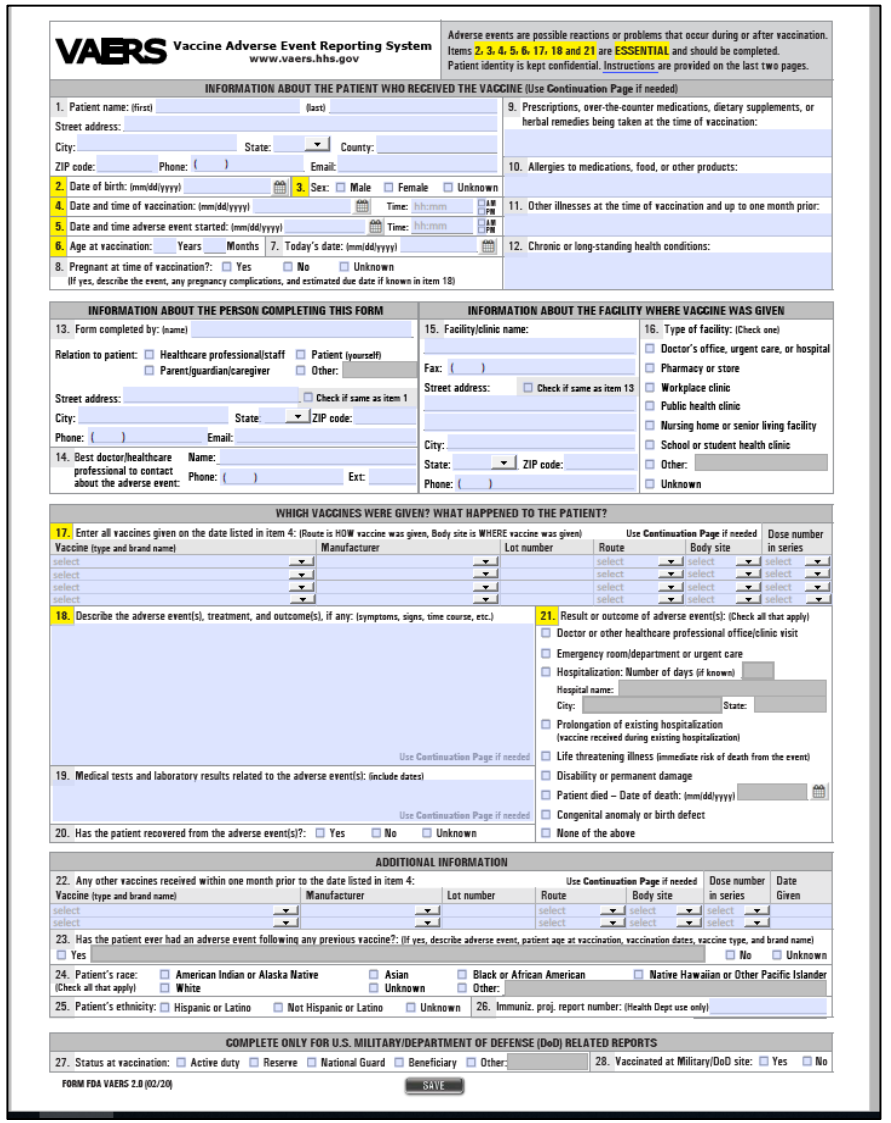
Reporting to VAERS – 2 Options

Online Form Direct Entry

www.vaers.hhs.gov

Writeable .PDF Upload





COVID-19 – Provider Role in Vaccine Safety

- Promote use of V-safe
  - Give vaccinees V-safe info
- Report to VAERS

Get vaccinated.
Get your smartphone.
Get started with v-safe.

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's ***v-safe*** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in ***v-safe*** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from ***v-safe*** around 2 p.m. local time. To opt out, simply text "STOP" when ***v-safe*** sends you a text message. You can also start ***v-safe*** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, ***v-safe*** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions ***v-safe*** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, ***v-safe*** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in ***v-safe*** is protected so that it stays confidential and private.*

*To the extent ***v-safe*** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity.

12/11/20

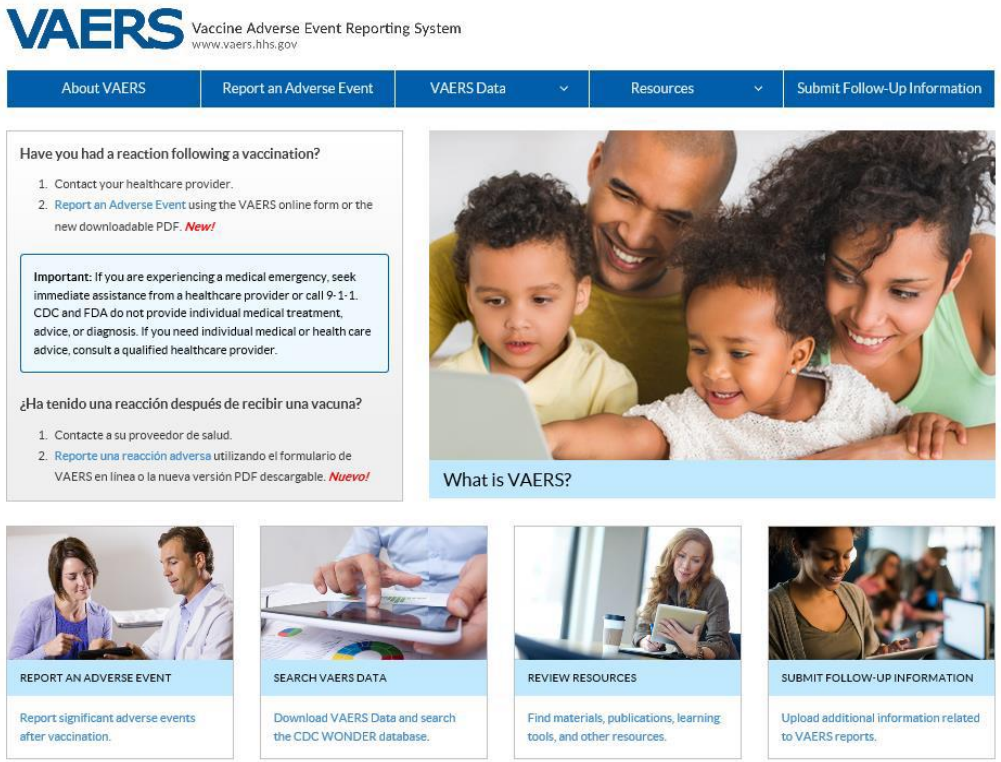
v-safe™
after vaccination health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code



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 new 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.

¿Ha tenido una reacción después de recibir una vacuna?

1. Contacte a su proveedor de salud.
2. Reporte una reacción adversa utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. *Nuevo!*

What is VAERS?

REPORT AN ADVERSE EVENT
Report significant adverse events after vaccination.

SEARCH VAERS DATA
Download VAERS Data and search the CDC WONDER database.

REVIEW RESOURCES
Find materials, publications, learning tools, and other resources.

SUBMIT FOLLOW-UP INFORMATION
Upload additional information related to VAERS reports.

COVID-19 Vaccine
Safety Experience to Date

Info From COVID-19 Vaccine Clinical Trials

Local reactions (at/near injection site):

- Pain 75-90%
- Redness 2 - 9%
- Swelling 4-12%

Systemic reactions

- Fever 1-17%
- Fatigue 35-68%
- Headache 25-63%
- Muscle pain 14-61%
- Joint pain 9-45%

Info From COVID-19 Vaccine Clinical Trials and V-safe (as of 1/14/2021)

	Clinical Trials	V-safe
Local reactions (at/near injection site):		
• Pain	75-90%	70.7%
• Redness	2 - 9%	
• Swelling	4-12%	11.0%
Systemic reactions		
• Fever	1-17%	11.4%
• Fatigue	35-68%	33.4%
• Headache	25-63%	29.4%
• Muscle pain	14-61%	22.8%
• Joint pain	9-45%	10.4%

Clinical Trial Findings, Continued

Systemic adverse reactions:

- More commonly reported after the 2nd dose than after 1st dose
- More frequent and severe in persons aged 18–64 years than in those aged ≥65 years

Update: Estimated Anaphylaxis Reporting Rates Following COVID-19 Vaccines Based on VAERS Reports and Reported Doses Administered*

Reported Vaccine Doses Administered	Anaphylaxis Cases	Reporting Rate (Dec 14 – Jan 18) - Per 10^6 Doses Admin	Previous Estimate - Per 10^6 Doses Admin
Pfizer-BioNTech: 9,943,247	50	**5.0**	11.1 Dec. 14-23 (MMWR Jan 15, 2021 / 70(2);46–51)
Moderna: 7,581,429	21	**2.8**	2.5 Dec 21- Jan 10 (MMWR Jan 29, 2021 / 70(4);125–129)

* Data through January 18, 2021

Reports of Deaths and Mortality Following COVID-19 Vaccination

Reports of deaths (due to any cause) following COVID-19 vaccination to VAERS* (N = 196)

Characteristics	Reports of death (N = 196)
Median age, years (range)	79 (25–104)
Age <65 years (%)	43 (22)
Female (%)	91 (46)
Long-term care facility (LTCF) resident (%)	129 (66)
Pfizer-BioNTech vaccine	113
Moderna vaccine	83

- These reports of death to VAERS involve temporally associated deaths following vaccination due to any cause; adverse event reports to VAERS, including deaths, should not be assumed to be causally related to vaccination

* Data through January 18, 2021

Reports of Death Following COVID-19 Vaccination: Background Mortality in Long-Term Care Facility (LTCF) Residents

Estimated background mortality in LTCF residents

- Estimated 2 million COVID-19 vaccine doses administered in LTCFs through January 18, 2021 (CDC COVID Data Tracker)
  - Assume 65% administered to LTCF residents (1.3 million residents)
  - Assume a 22% annual mortality rate* (n = 286,000)
- Risk period
  - Assume December 21 was when vaccinations commenced in LTCFs
  - Therefore, risk period=29 days (December 21-January 18)
  - Assume each resident contributes 14.5 person-days (~ mid-point of risk period)
  - 14.5 days = 4% of a calendar year

* Thomas et al, J Gerontol A Biol Sci Med Sci, 2019, Vol. 74, 219–225

Estimated background mortality in LTCF residents (cont.)

- Among 1.3 million LTCF residents (2M x 65%) vaccinated over the 29-day risk period (December 21-January 18)
  - Expect **11,440 deaths** among LTCF residents (= 286,000*4%) following vaccination
- By comparison, VAERS received **129 reports of deaths** following COVID-19 vaccination in LTCF residents through January 18, 2021
- Mortality in LTCF residents is high and substantial numbers of deaths in this population will occur following vaccination as temporally-associated coincidental events

Impression on Deaths and Mortality in LTCF Residents Following COVID-19 Vaccination

- Mortality in LTCF residents is high due to the underlying health status of the LTCF resident population
- The available evidence from VAERS monitoring, and other population-based surveillance, does not suggest a safety problem with respect to deaths in older adults residing in LTCFs
- Case reports of deaths in LTCF residents following COVID-19 vaccination to VAERS include many persons: With multiple co-morbidities, including some with cognitive impairment
- In ill health and declining states health
- In hospice or DNR or DNI status (in one-third of reported deaths)
- Deaths in LTCF residents following COVID-19 vaccination are consistent with expected all cause mortality in this population

Reports of Deaths Following COVID-19 Vaccination in Community Dwelling Adults Aged <65 years

Background: Sudden cardiac death in community residents

- Rate of sudden cardiac death = 29.6 per 100,000 person-years*
  - Out-of-hospital cardiac arrest in people 18–90 years of age in San Francisco County
    - Inclusion criteria: sudden unexpected death either within 1 hour of symptom onset (event witnessed), or within 24 hours of having been observed alive and symptom free (unwitnessed)
    - Excludes: (1) subjects with chronic/terminal illness in which imminent death not unexpected; (2) hospice residents; (3) subjects with identifiable noncardiac etiology of death at presentation, including drug abuse/overdose, trauma, homicide, or suicide; (4) subjects with hospital admission within prior 30 days for noncardiac illness or surgical procedure.

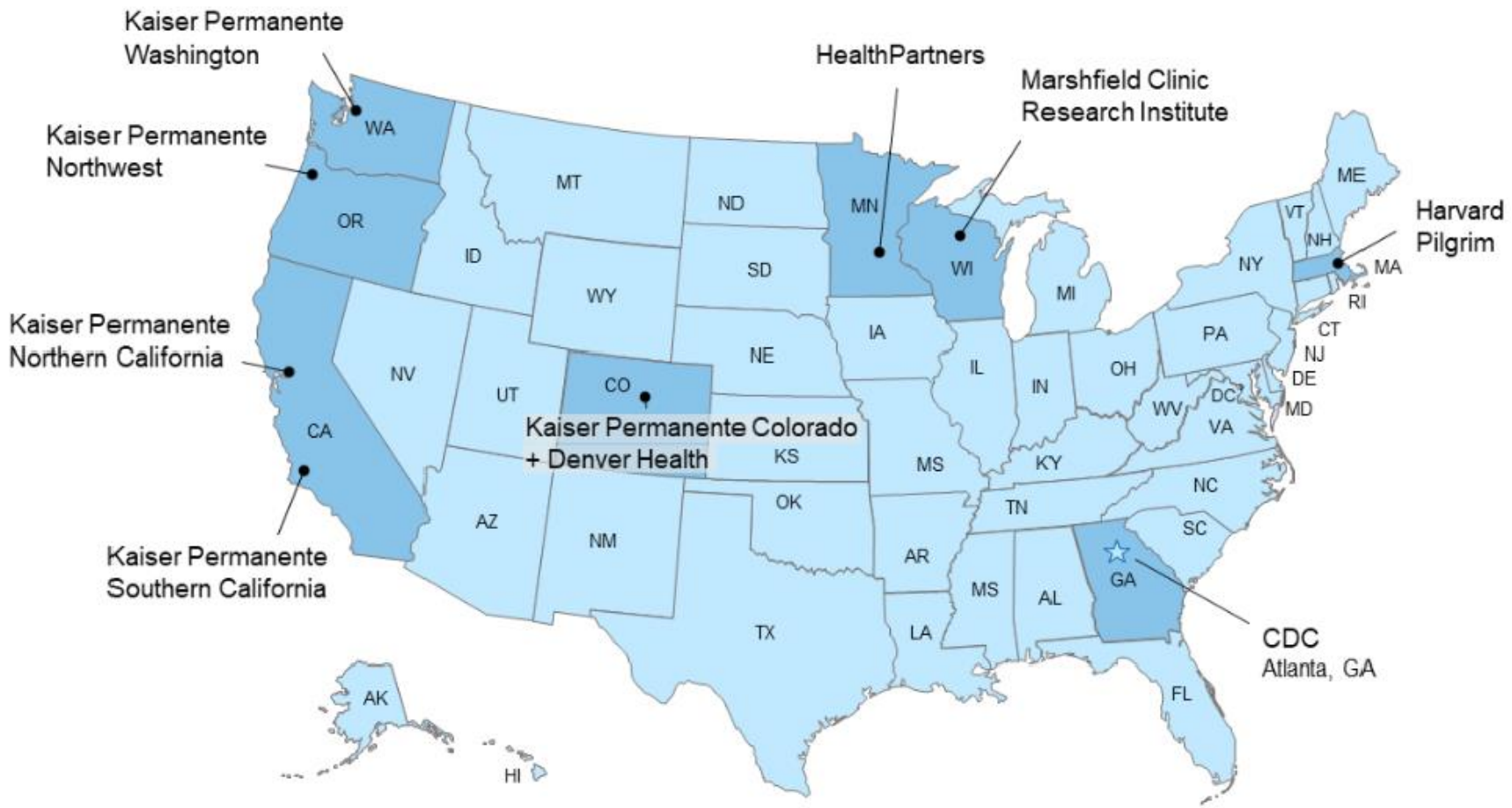
* Tseng et al, Circulation. 2018;137:2689–2700

Background: Sudden cardiac death in community residents

- Estimate ~13.7 million community residents vaccinated December 14–January 18, 2021 (CDC COVID Data Tracker)
- Risk period
  - Risk period = 35 days (December 14–January 18)
  - Assume each resident contributes 15 person-days (~ mid-point of risk period, adjusted downward to account for Moderna not used until December 21)
  - Total person-years contributed = 566,650 ([13.7million*15 days]/365.25)
- Expected sudden cardiac death count: 168 deaths (29.6*5.66)
- *Reported* VAERS sudden cardiac death count following COVID vaccination: 18 deaths

VSD

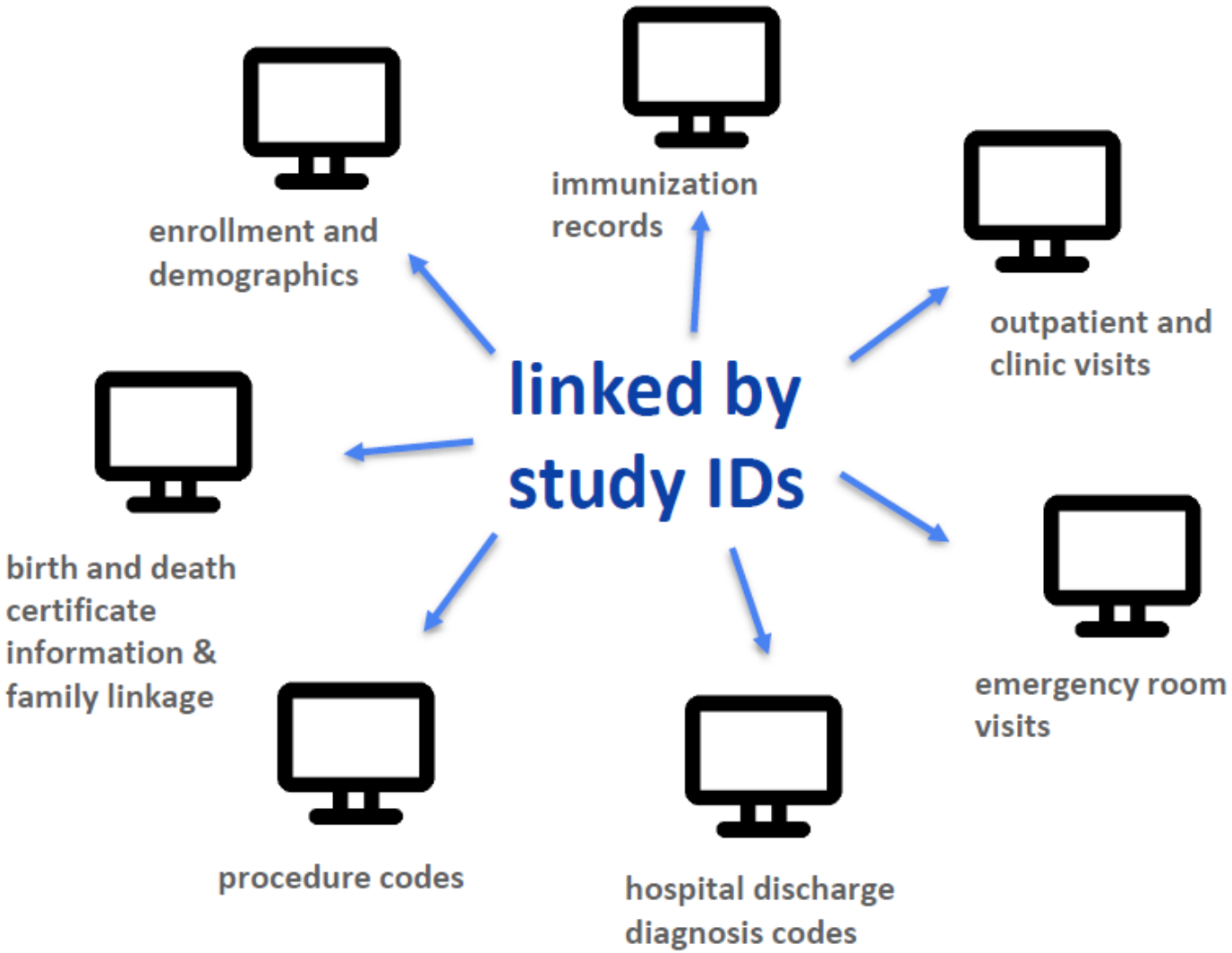
Vaccine Safety Datalink

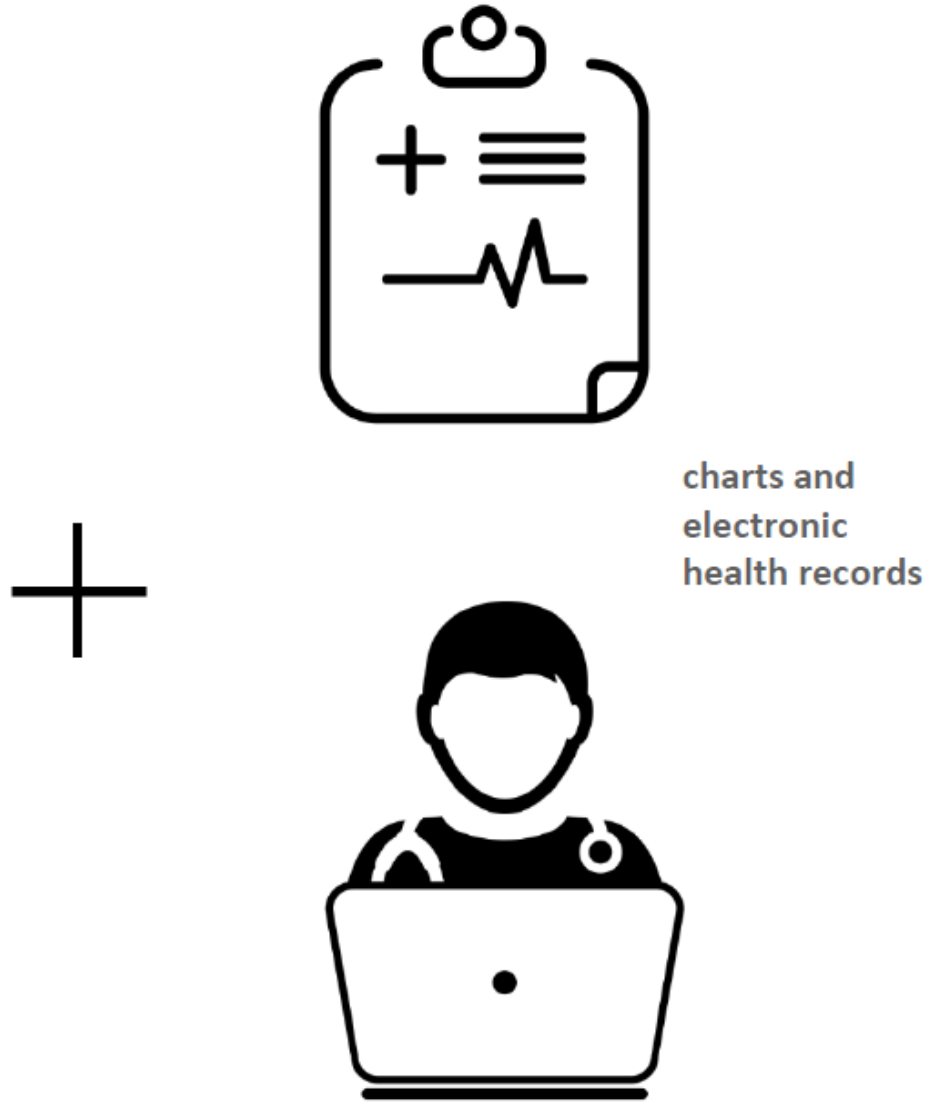


9 participating integrated healthcare organizations

data on over **12 million** persons per year

Types of information in VSD





Images created by Wilson Joseph, Megan Mitchell, Ananth, and Iga from the noun project

VSD RCA outcomes for COVID-19 vaccines	Concurrent comparator	Risk interval	Events in vaccinated	Events in unvaccinated	Signal (Y/N)
Acute disseminated encephalomyelitis	Unvaccinated	1-21 days	0	0	N
Acute myocardial infarction	Unvaccinated	1-21 days	1	179	N
Acute respiratory distress syndrome	Unvaccinated	1-21 days	0	4	N
Anaphylaxis	Unvaccinated	0-1 days	0	8	N
Appendicitis	Unvaccinated	1-21 days	5	267	N
Bell's palsy	Unvaccinated	1-21 days	4	358	N
Convulsions / seizures	Unvaccinated	1-21 days	0	39	N
Disseminated intravascular coagulation	Unvaccinated	1-21 days	0	14	N
Encephalitis / myelitis / encephalomyelitis	Unvaccinated	1-21 days	0	6	N
Guillain-Barré syndrome	Unvaccinated	1-21 days	0	4	N
Thrombotic thrombocytopenic purpura	Unvaccinated	1-21 days	0	4	N
Immune thrombocytopenia	Unvaccinated	1-21 days	0	21	N
Kawasaki disease	Unvaccinated	1-21 days	0	1	N
MIS-C and MIS-A	Unvaccinated	NA	0	NA	N
Myocarditis / pericarditis	Unvaccinated	1-21 days	0	12	N
Narcolepsy and cataplexy	Unvaccinated	N/A	0	8	N
Stroke, hemorrhagic	Unvaccinated	1-21 days	1	85	N
Stroke, ischemic	Unvaccinated	1-21 days	0	197	N
Transverse myelitis	Unvaccinated	1-21 days	0	0	N
Venous thromboembolism	Unvaccinated	1-21 days	3	408	N
Pulmonary embolism (subset of VTE)	Unvaccinated	1-21 days	0	132	N

- Preliminary results of VSD unvaccinated concurrent comparator analyses for COVID-19 vaccine safety
- No signals as of January 16

Some Take-Home Messages

- **No concerning safety issues or signals with COVID vaccines to date** (~41M doses administered)
- Safety profile consistent with what observed in clinical trials
- Anaphylaxis possible but rare
- The data do not suggest a signal with respect to overall safety or deaths following vaccination in older adult residents of LTCFs
- Local & systemic reactions are common (COVID-19 vaccines are reactogenic)
  - Reactions following 2nd dose more common than after 1st dose (2-3x)
  - Mostly systemic (fever, headache, fatigue, chills, muscle/joint pain)