



OREGON  
**HEALTH**  
AUTHORITY

September 24, 2024

# Vaccine Safety Monitoring Systems

# Objectives

- Increase awareness, understanding and usability of vaccine safety systems.
- Convey importance of timely detection of vaccine safety signals.
- Share reporting requirements for the Vaccine Adverse Event Reporting System (VAERS).



# The Vaccine Life Cycle

safety at every phase

## GUIDE

### ACIP

ADVISORY  
COMMITTEE ON  
IMMUNIZATION  
PRACTICES

### BLA

BIOLOGICS LICENSE  
APPLICATION

### CDC

CENTERS FOR  
DISEASE CONTROL  
AND PREVENTION

### FDA

FOOD AND DRUG  
ADMINISTRATION

### IND

INVESTIGATIONAL  
NEW DRUG  
APPLICATION

## VACCINE DEVELOPMENT

**safety**  
is a priority  
during vaccine  
development  
+ approval

**safety**  
continues with  
CDC + FDA  
safety  
monitoring

BASIC  
RESEARCH

DISCOVERY

PRE-  
CLINICAL  
STUDIES

IND  
SUBMITTED

CLINICAL STUDIES / TRIALS

BLA  
SUBMITTED

FDA  
REVIEW

FDA  
APPROVAL OF 1 NEW VACCINE

ACIP  
REVIEW

ACIP  
RECOMMENDATION

POST-APPROVAL  
MONITORING +  
RESEARCH

PHASE 1  
*safety*

PHASE 2  
*effectiveness*

PHASE 3  
*safety +  
effectiveness*

PHASE 4

*safety monitoring for  
serious, unexpected  
adverse events*

# CDC Vaccine Safety Monitoring

CDC monitors the safety of vaccines using strong, complementary systems

V-safe



VAERS



VSD



CISA Project



Vaccine Adverse Reporting System (VAERS), Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment (CISA)  
<https://www.cdc.gov/vaccine-safety-systems/index.html>



# CISA (Clinical Immunization Safety Assessment)

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## **The goals of CISA:**

- Serve as a vaccine safety resource for U.S. healthcare providers with complex vaccine safety questions about a specific patient to assist with immunization decision-making.
- Assist CDC and its partners in evaluating emerging vaccine safety issues.
- Conduct clinical research studies to better understand vaccine safety and identify preventive strategies for adverse events following immunization.

## **Who can request a CISA Clinical Consultation?**

Healthcare providers or health departments

## **What happens if there is an emergency clinical vaccine safety inquiry?**

CDC Emergency Operations Center Watch Desk will route the call to on-call staff.

# VSD (Vaccine Safety Datalink)

## VSD goals:

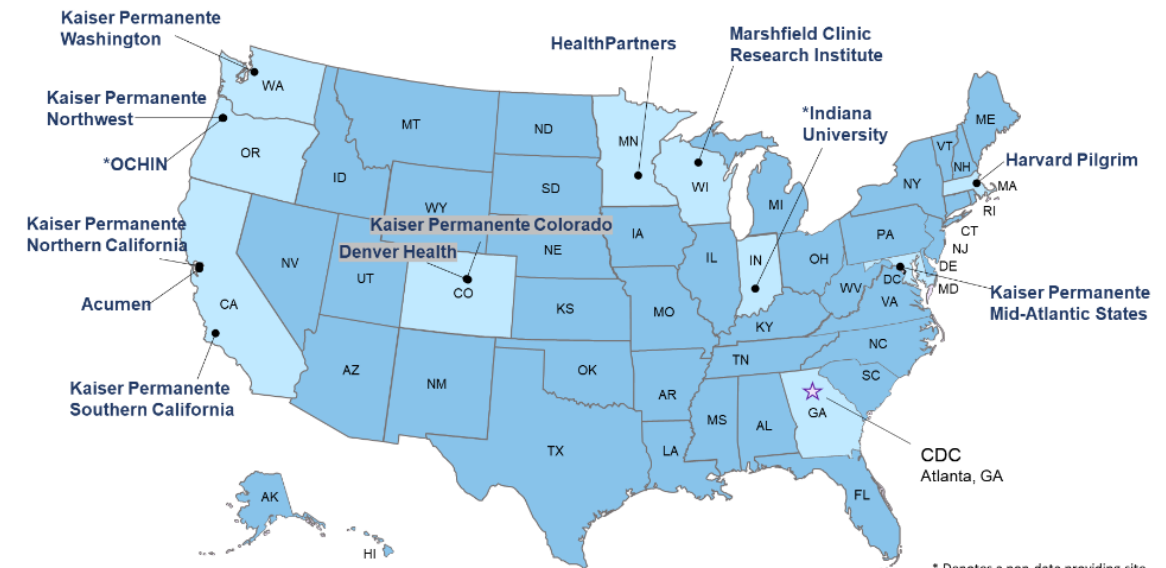
- Conduct research on important vaccine safety questions in large populations
- Conduct vaccine safety studies that come from questions or concerns in the medical literature or from other vaccine safety systems, like VAERS
- Monitor possible adverse events when new vaccines are licensed or when there are new vaccine recommendations
- Provide information to committees who make vaccine safety recommendations for the nation

## Rapid Cycle Analysis (RCA)

Allows for quick detection


## Evaluating Safety of Vaccines in Pregnancy

High priority to protect our littlest





- CDC's Immunization Safety Office (ISO) prepares for emergencies by ensuring that robust systems are in place to rapidly monitor vaccine safety in the event of a large-scale or emergency response vaccination program, which is particularly important when new vaccines are involved.
- Monitoring system that sends a daily health check-in during the week after vaccination and then weekly for six weeks. For maternal RSV vaccine, check-ins continue until delivery.
- Available languages: English, Spanish, Chinese, Korean, Vietnamese
- For more information and to register: <https://vsafe.cdc.gov>



**Sign up for V-safe if you recently got a COVID-19 or RSV vaccine.**

**What is V-safe?**  
V-safe is an innovative vaccine safety monitoring system that allows you or your dependent to quickly and easily get a vaccine. It takes just a few minutes and you will receive V-safe notifications through text messages or emails to complete **short, confidential health check-ins**. Your participation in V-safe makes a difference—it helps others know what to expect in the days following vaccination, and it helps CDC monitor the safety of vaccines for everyone.

**V-safe features:**

- Receive health check-ins via text or email after vaccination.
- Enroll your dependents and complete check-ins on their behalf.
- Share how you feel after getting a vaccine dose.


**How can I enroll, and how does it work?**  
V-safe is available for several vaccines. Go to [vsafe.cdc.gov](https://vsafe.cdc.gov) to find out if you are eligible to enroll. If you are eligible, follow the prompts to register for V-safe health check-ins. During the first week after vaccination, V-safe will send you a text message or email notification each day to ask how you are feeling. Then you will get check-in messages once a week for up to 5 weeks. Depending on your answers, V-safe may send you a link to submit a report in the Vaccine Adverse Event Reporting System (VAERS).  
You can opt out at any time by texting "STOP" when V-safe sends you a text message or by clicking "unsubscribe" when V-safe sends you an email. You can also opt back in by changing your preferred method of contact, found in your user profile. **Your personal information in V-safe is protected so that it stays confidential and private.\***

**How can I enroll my dependent?**  
To enroll a dependent in V-safe, **add them to your existing account, or create a new account** if you don't have one yet. Enrolling a dependent does not require you to enter your own vaccination information or complete health check-ins for yourself.  
Need step-by-step instructions? Go to: [www.cdc.gov/vsafe](https://www.cdc.gov/vsafe)

**Sign up with your smartphone, tablet, or computer at [vsafe.cdc.gov](https://vsafe.cdc.gov)**

OR

**Aim your smartphone's camera at this code**




**Need help with V-safe?**

Call  
1-833-748-1979

Email  
[CARS\\_HelpDesk@cdc.gov](mailto:CARS_HelpDesk@cdc.gov)

Visit  
[www.cdc.gov/vsafe](https://www.cdc.gov/vsafe)



\*V-safe gathers data employing strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws including the Privacy Act of 1974, standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Federal Information Security Management Act, and the Freedom of Information Act.

C5324195-V 10/05/2023

# VAERS (Vaccine Adverse Event Reporting System)



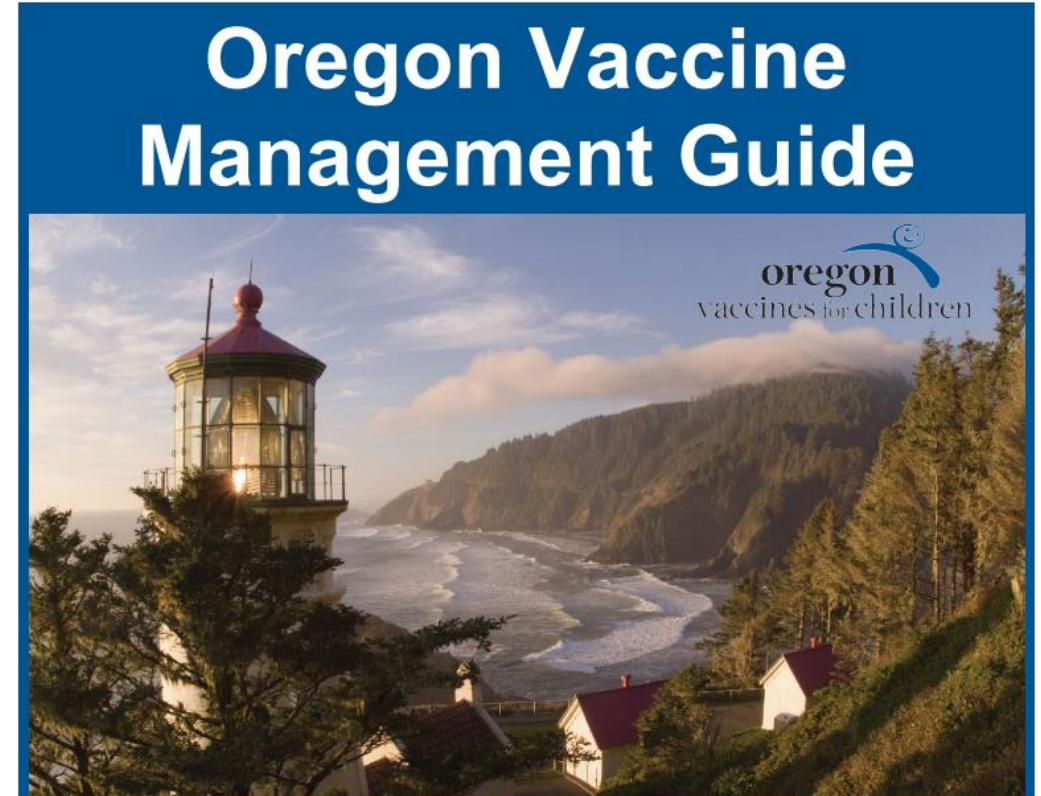


# Documenting Adverse Events

In Oregon, VFC providers must report all clinically significant adverse events that occur after administration of vaccines to the Vaccine Adverse Event Reporting System (VAERS).

- They must do so, even if they are not sure whether the vaccine caused the adverse event.
- VAERS accepts all reports, including reports of vaccination errors.

See page 7 of [Oregon's Vaccine Management Guide](#) for more information.



# Model Immunization Protocol

## List of Adverse Events

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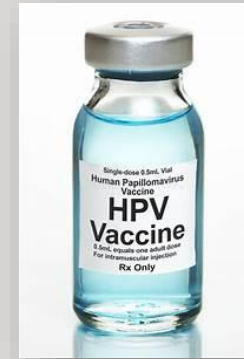
### 10. Storage and handling

## 11. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at <https://vaers.hhs.gov/reportevent.html>. VAERS Reporting Table: <https://vaers.hhs.gov/resources/infoproviders.html>

### Event and interval from vaccination

- A. Anaphylaxis or anaphylactic shock (7 days)
- B. Shoulder Injury Related to Vaccine Administration (7 days)
- C. Vasovagal syncope (7 days)
- D. Any acute complication or sequelae (including death) of above events (interval—not applicable)
- E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval—see package insert).



### 12. References

# Model Immunization Protocol

## List of Adverse Events

### 11. Adverse events reporting

Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at <https://vaers.hhs.gov/reportevent.html>.

VAERS Reporting Table:

[https://vaers.hhs.gov/docs/VAERS\\_Table\\_of\\_Reportable\\_Events\\_Following\\_Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf)

#### Event and interval from vaccination

- A. Anaphylaxis or anaphylactic shock (7 days)
- B. Disseminated varicella vaccine-strain viral disease.
  - a. Vaccine-strain virus identified (time interval unlimited) o
  - b. If strain determination is not done or if laboratory testing is inconclusive (42 days)
- C. Varicella vaccine-strain viral reactivation (time interval unlimited )
- D. Shoulder Injury Related to Vaccine Administration (7 days)
- E. Vasovagal syncope (7 days)
- F. Any acute complication or sequelae (including death) of above events (interval - not applicable)
- G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)



# Submitting a Report to VAERS

- Two options for making a VAERS report – digital or downloadable pdf.
- New portal allows bulk upload for healthcare providers at: <https://vaers.hhs.gov/vip/>
- Available languages: English and Spanish
- More information and electronic form available at: <https://vaers.hhs.gov>

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

Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

**INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE** (Use Continuation Page if needed)

1. Patient name: (first) \_\_\_\_\_ (last) \_\_\_\_\_  
Street address: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ County: \_\_\_\_\_  
ZIP code: \_\_\_\_\_ Phone: ( ) \_\_\_\_\_ Email: \_\_\_\_\_

2. Date of birth: (mm/dd/yyyy) \_\_\_\_\_ 3. Sex:  Male  Female  Other \_\_\_\_\_

4. Date and time of vaccination: (mm/dd/yyyy) \_\_\_\_\_ Time: \_\_\_\_\_  
5. Date and time adverse event started: (mm/dd/yyyy) \_\_\_\_\_  
6. Age at vaccination: \_\_\_\_\_ Years \_\_\_\_\_ Months 7. Today's date: (mm/dd/yyyy) \_\_\_\_\_

8. Pregnant at time of vaccination?:  Yes  No  Unknown  
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination: \_\_\_\_\_  
10. Allergies to medications, food, or other products: \_\_\_\_\_  
11. Other illnesses at the time of vaccination and up to one month prior: \_\_\_\_\_  
12. Chronic or long-standing health conditions: \_\_\_\_\_

**INFORMATION ABOUT THE PERSON COMPLETING THIS FORM**

13. Form completed by: (name) \_\_\_\_\_  
Relation to patient:  Healthcare professional/staff  Patient (yourself)  
 Parent/guardian/caregiver  Other: \_\_\_\_\_  
Street address: \_\_\_\_\_  Check if same as item 1  
City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP code: \_\_\_\_\_  
Phone: ( ) \_\_\_\_\_ Email: \_\_\_\_\_

14. Best doctor/healthcare professional to contact about the adverse event: Name: \_\_\_\_\_  
Phone: ( ) \_\_\_\_\_ Ext: \_\_\_\_\_

**INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN**

15. Facility/clinic name: \_\_\_\_\_  
Fax: ( ) \_\_\_\_\_  
Street address: \_\_\_\_\_  Check if same as item 13  
City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP code: \_\_\_\_\_  
Phone: ( ) \_\_\_\_\_

16. Type of facility: (Check one)  
 Doctor's office, urgent care, or hospital  
 Pharmacy or store  
 Workplace clinic  
 Public health clinic  
 Nursing home or senior living facility  
 School or student health clinic  
 Other: \_\_\_\_\_  
 Unknown

**WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?**

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use Continuation Page if needed Dose number in series

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)  
\_\_\_\_\_  
Use Continuation Page if needed

19. Medical tests and laboratory results related to the adverse event(s): (include dates)  
\_\_\_\_\_  
Use Continuation Page if needed

20. Has the patient recovered from the adverse event(s)?:  Yes  No  Unknown

21. Result or outcome of adverse event(s): (Check all that apply)  
 Doctor or other healthcare professional office/clinic visit  
 Emergency room/department or urgent care  
 Hospitalization: Number of days (if known) \_\_\_\_\_  
Hospital name: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_  
 Prolongation of existing hospitalization (vaccine received during existing hospitalization)  
 Life threatening illness (immediate risk of death from the event)  
 Disability or permanent damage  
 Patient died – Date of death: (mm/dd/yyyy) \_\_\_\_\_  
 Congenital anomaly or birth defect  
 None of the above

# New Feature: V-safe integration with VAERS

- Participants who report a medically attended event after vaccination are prompted to complete a VAERS report after finishing their V-safe survey.
- Software link to pre-populate fields in VAERS with information already provided to V-safe.

**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 | Report an Adverse Event - Patient Information | Instructions | en Español

Patient Information  
 Reporter Information  
 Facility Information  
 Vaccine Information  
 Additional Information

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

**Item 1**

Patient first name:  Patient last name:

Street address:

City:  State:  County:

Zip code:  Phone:  Email:

**Item 2**

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

\* Sex:  Male  Female  Unknown

**Item 4**

\* Date of vaccination  mm/dd/yyyy or  mm/yyyy

Time:   AM  PM

**Item 5**

\* Date adverse event started  mm/dd/yyyy or  mm/yyyy

Click to preview VAERS form

# Anyone Can Report to VAERS

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Everyone is encouraged to report possible adverse events after vaccination to VAERS, even if they are not sure whether the vaccine caused the problem.

**In general, you should report any side effect or health problem after vaccination that is concerning to you.**

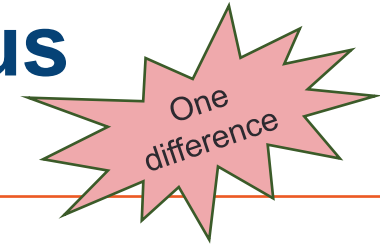


# Reporting Vaccine Administration Errors

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- Healthcare providers are **strongly encouraged** to report all vaccine administration errors.
- Health care providers are **required** to report all vaccine administration errors for:
  - COVID-19 vaccines given under Emergency Use Authorization (EUA)
  - Jynneos (Mpox vaccine) or ACAM2000 (smallpox vaccine)

# To Report an Adverse Event after Beyfortus (nirsevimab)



If nirsevimab was given:

- **With one or more vaccinations** on the same visit, report to VAERS (<https://vaers.hhs.gov>)
- **Alone with no other vaccinations** on the same visit, report to MedWatch (<https://www.fda.gov/medwatch>)





# References

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- [Vaccine Safety Information \(CDC\)](#)
- [How to Report Adverse Events to VAERS \(CDC\)](#)
- [VAERS Table of Reportable Events Following Vaccination \(VAERS\)](#)
- [MedWatch: The FDA Safety Information and Adverse Event Reporting System \(FDA\)](#)
- [MedWatch Online Voluntary Reporting Form \(FDA\)](#)
- [Model Immunization Protocols \(Oregon Immunization Program\)](#)

# Thank you!

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You can get this document in other languages, large print, braille or a format you prefer free of charge. Contact the Oregon Immunization Program at 800-980-9431. We accept all relay calls.

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Oregon Immunization Program  
800 NE Oregon St. Suite 370  
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800-980-9431  
[www.healthoregon.org/imm](http://www.healthoregon.org/imm)

Oregon Immunization Program  
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