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# Vaccine Safety Systems



OREGON IMMUNIZATION PROGRAM  
Public Provider Orientation 9.26.2023

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# Objectives & Summary

## Education Objectives

- Increase awareness, understanding, and usability of vaccine safety systems
- Increase awareness of timely detection of vaccine safety signals
- Increase awareness of VAERS reporting requirements

## Summary

- Overview of Vaccine Safety Data Systems with a VAERS focus.

# Vaccine Safety Monitoring Systems

- **VAERS** - Vaccine Adverse Events Reporting System
- **CISA** - Clinical Immunization Safety Assessment
- **VSD** - Vaccine Safety Datalink
- **Emergency Preparedness**
  - V-Safe after vaccination health checker

# CISA – Clinical Immunization Safety Assessment

## 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.
  - COVID-19 vaccine CISA Consultation
  - All the other vaccines and unrelated to COVID-19 vaccine



## 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

## Vaccine Safety Monitoring

### 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

# Emergency Preparedness

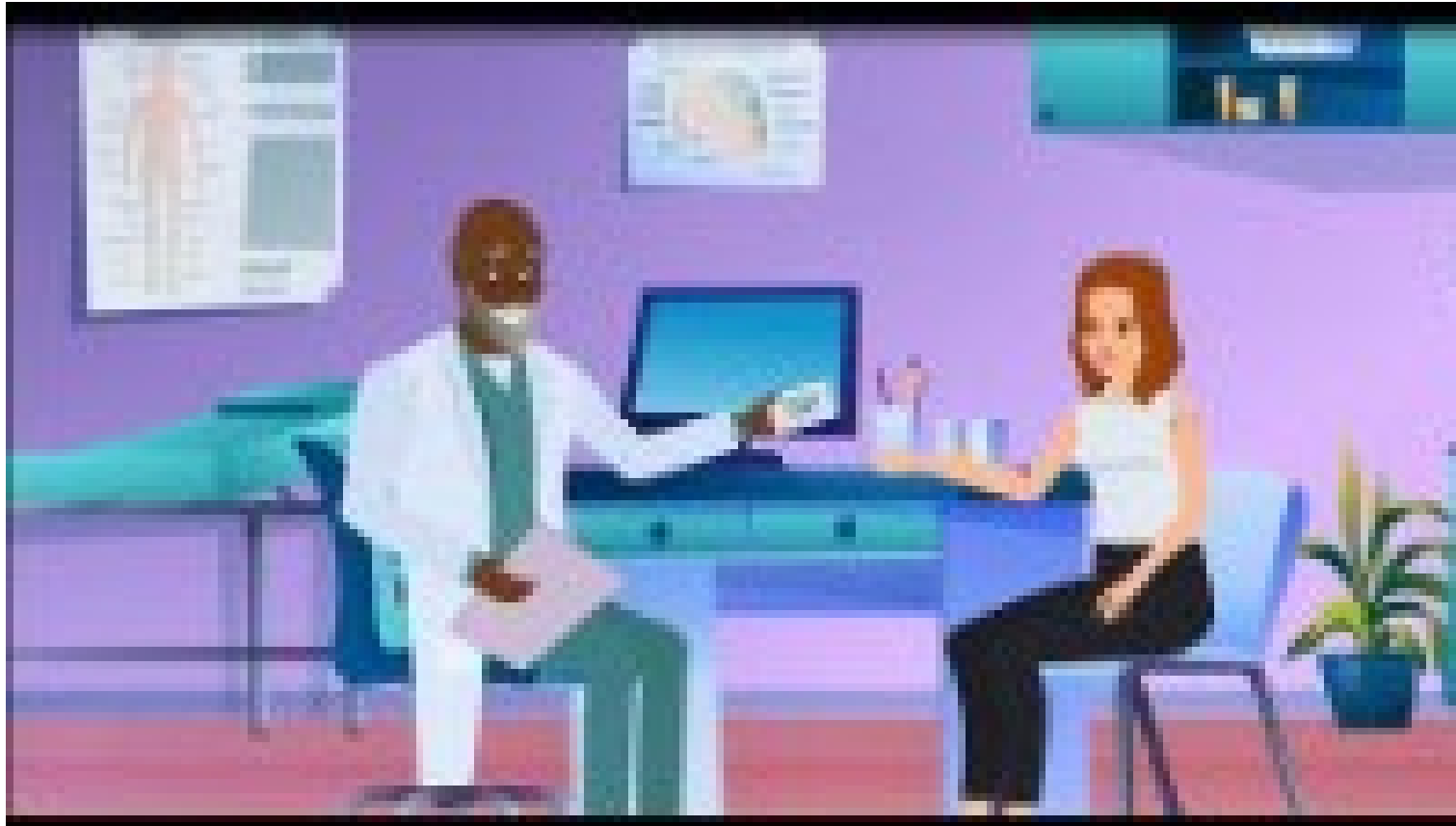
- CDC's Immunization Safety Office (ISO) prepares for emergencies by ensuring that robust systems are in place to rapidly monitor vaccine safety in the event of a large-scale or emergency response vaccination program, which is particularly important when new vaccines are involved.



- Launched December 2020.
  - 10.1 million v-safe participants completed more than 151 million health surveys about their experiences following COVID-19 vaccination.
  - V-safe data included in more than 20 scientific publications

# VAERS

Vaccine Adverse Event Reporting System



# Program Element #43

## i. Adverse Events Following Immunizations

- LPHA must complete and electronically file a VAERS form if:
  - (1) An adverse event following immunization administration occurs, as listed in "Reportable Events Following Immunization", available for review at <http://vaers.hhs.gov/professionals/index#Guidance1>
  - (2) An event occurs that the package inserts lists as a contraindication to additional vaccine doses.
  - (3) OHA requests a follow-up report to an earlier reported adverse event; or
  - (4) Any other event LPHA believes to be related directly or indirectly to the receipt of any vaccine administered by LPHA or others occurs within 30 days of vaccine administration and results in either the death of the person or the need for the person to visit a licensed health care provider or hospital.



# Model Immunization Protocol

## 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

## 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)

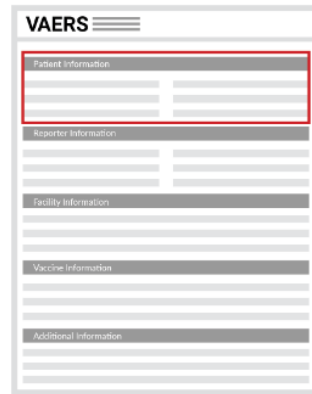
### Event and interval from vaccination

- 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)



Completion Status

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



[Click to preview VAERS form](#)

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:  County:

Zip code:  Phone:  Email:

**Item 2** ⓘ

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

**Item 3** ⓘ

\* Sex:  Male  Female  Unknown

**Item 4** ⓘ

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

Time:   AM  PM

**Item 5** ⓘ

Submitting  
a report to  
VAERS  
option 1

### Report an Adverse Event with a Writable PDF Form

#### Step 1 - Instructions for Downloading the Writable PDF Form



**Download the form and save it to your computer**

Right click on the "Download the Writable PDF Form" button below, then select "Save Link As" or "Save Target As" to save the form to your computer. Form last updated on **August 2023**.



**Complete the form electronically on your own time**

Use **Acrobat 5.0** (or later) to open the file and fill the VAERS Writable PDF Form.



**Save your completed form**

Use a computer where you can securely save a document that contains protected health information, personal identifiers or other sensitive personal or patient information.



Submit to VAERS using the "Upload the Writable PDF Form" button in Step 2

**Important:** Use a desktop or laptop computer on which you can securely save a document that contains protected health information, personal identifiers or other sensitive personal or patient information.

[Download the Writable PDF Form](#)

#### Step 2 - Instructions for Uploading the Writable PDF Form

- Verify you are using the latest version of the form, updated **August 2023** (available in Step 1 section of this page).
- Enter your name and email address.
- Click on the "Browse" button, then navigate to the folder where you have saved the completed **Writable PDF form**.
- Select the **Writable PDF form** to upload.
- Verify that you would like to proceed to upload the file by typing the characters shown in the picture and click "Upload the Writable PDF Form".
- You will be provided an E-number for your reference on successful submission.

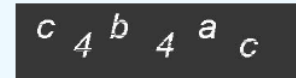
All fields marked with \* are required.

Your Name:

Your Email:

\* PDF File:

[Browse...](#)



\* Word Verification:

Type the characters shown in the picture above. Letters are not case sensitive.

[Upload the Writable PDF Form](#)

Submitting  
a VAERS  
report  
option 2

# Anyone can report to VAERS

- 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 you.**



required vs encouraged



# Vaccine administration errors

*strongly encouraged vs required*

- Healthcare providers are **strongly encouraged** to report all vaccine administration errors.
- Healthcare providers who administer COVID-19 vaccines are **required** to report COVID-19 vaccine administration errors to VAERS
- Healthcare providers who administer Jynneos (Mpox vaccine) or ACAM2000 (small pox vaccine) are **required** to report vaccine administration errors to VAERS.



# Beyfortus

To report an adverse event after Beyfortus (Nirsevimab)\*

If Nirsevimab was given at the same visit with one or more vaccinations:

Report to VAERS at [VAERS - Report an Adverse Event \(hhs.gov\)](https://vaers.hhs.gov)

If Nirsevimab was given alone with no other vaccinations on the same visit:

Report to MedWatch at [MedWatch Online Voluntary Reporting Form \(fda.gov\)](https://www.fda.gov/medwatch)

\* Beyfortus (Nirsevimab) is not a vaccine. It is a monoclonal antibody given by injection and used in newborns, infants, and young children to protect them from respiratory syncytial virus (RSV). It may be given at the same time that vaccinations are given.

Oregon Immunization Program Help Desk  
1-800-980-9431

[VFC.help@odhsoha.oregon.gov](mailto:VFC.help@odhsoha.oregon.gov)

Wendy Neu, RN, BSN  
971-229-9557

[wendy.neu@oha.oregon.gov](mailto:wendy.neu@oha.oregon.gov)







[www.cdc.gov/vaccinesafety/index.html](http://www.cdc.gov/vaccinesafety/index.html)

<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html>

[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)

<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDER/RESOURCES/Pages/stdgordr.aspx>