Vaccine Safety Systems

OREGON IMMUNIZATION PROGRAM
Public Provider Orientation 3/12/24

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

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

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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:

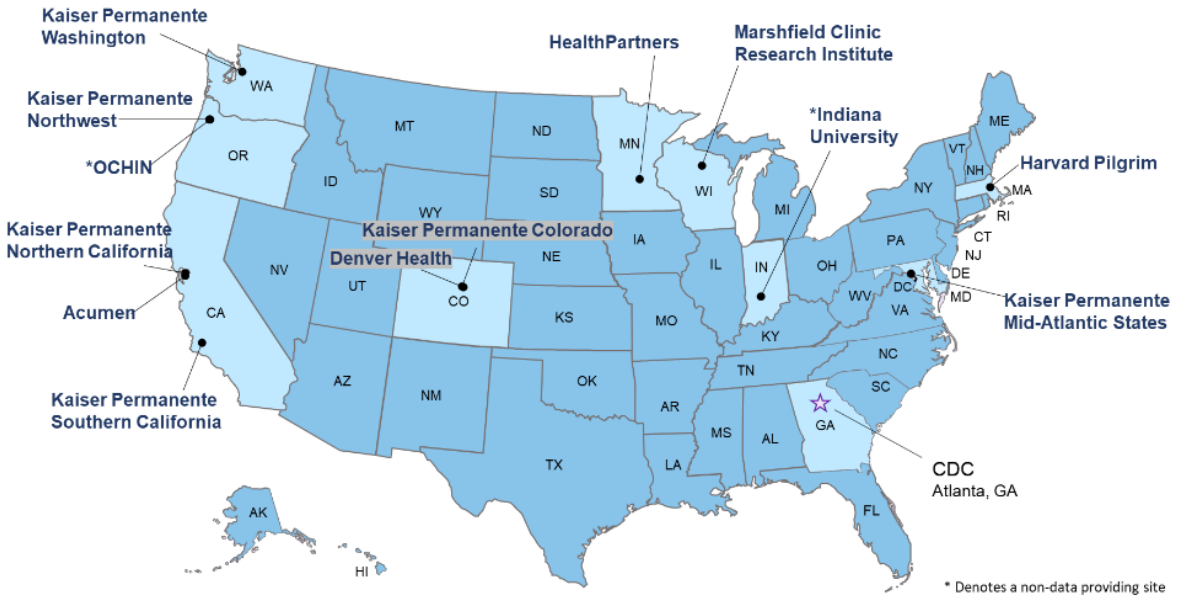
- Conduct research on important vaccine safety questions in large populations
- Conduct vaccine safety studies that come from questions or concerns in the medical literature or from other vaccine safety systems, like VAERS
- Monitor possible adverse events when new vaccines are licensed or when there 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

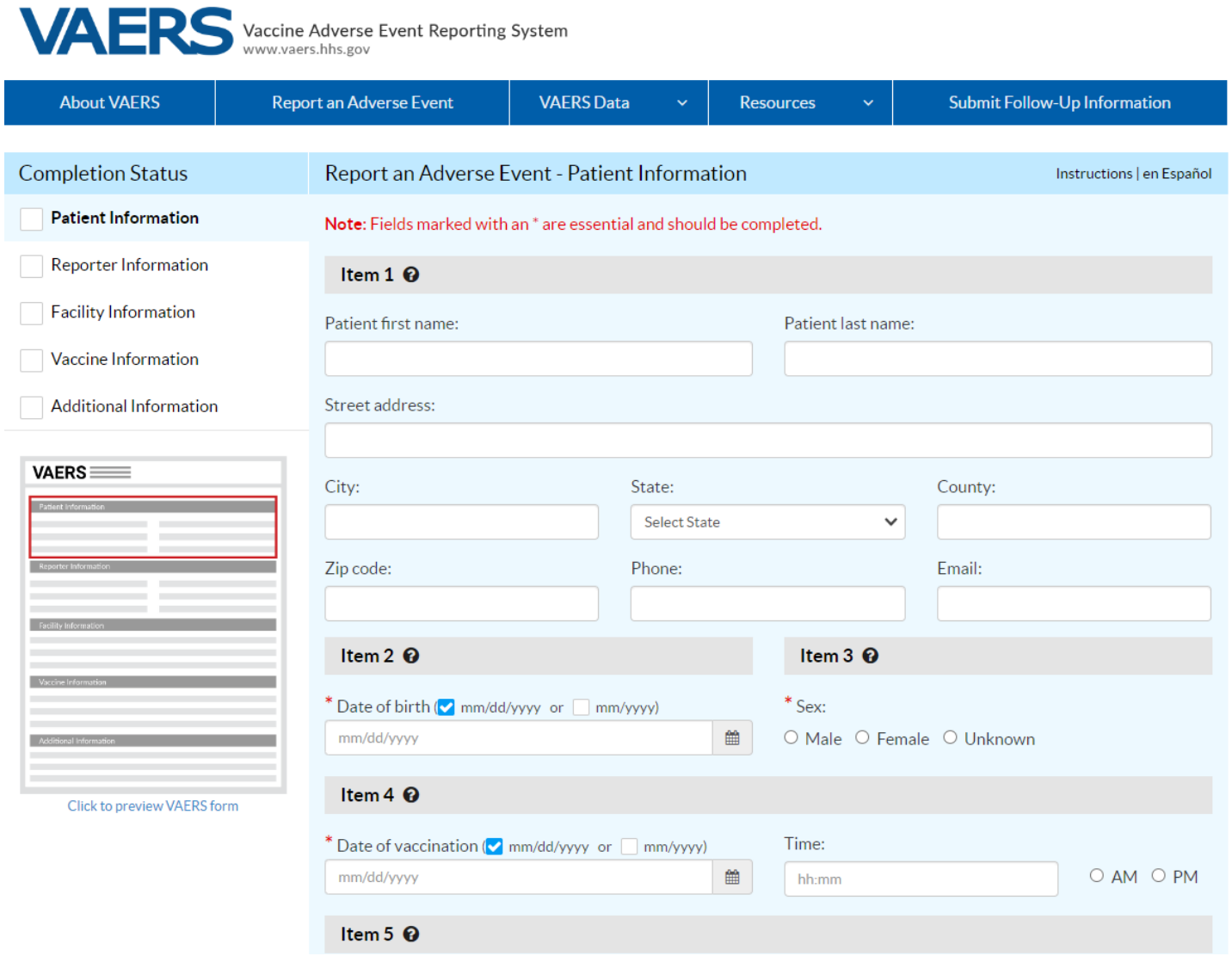
11. Adverse events reporting

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

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 option 1



Submitting a VAERS report option 2

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

About VAERS | Report an Adverse Event | VAERS Data | Resources | Submit Follow-Up Information

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:

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.
- 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)

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)

If Nirsevimab was given alone with no other vaccinations on the same visit:
Report to MedWatch at MedWatch Online Voluntary Reporting Form (fda.gov)

* 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 Health Authority

Oregon Immunization Program Help Desk
1-800-980-9431
VFC.help@odhsoha.oregon.gov

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971-378-5691
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References

- 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)

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