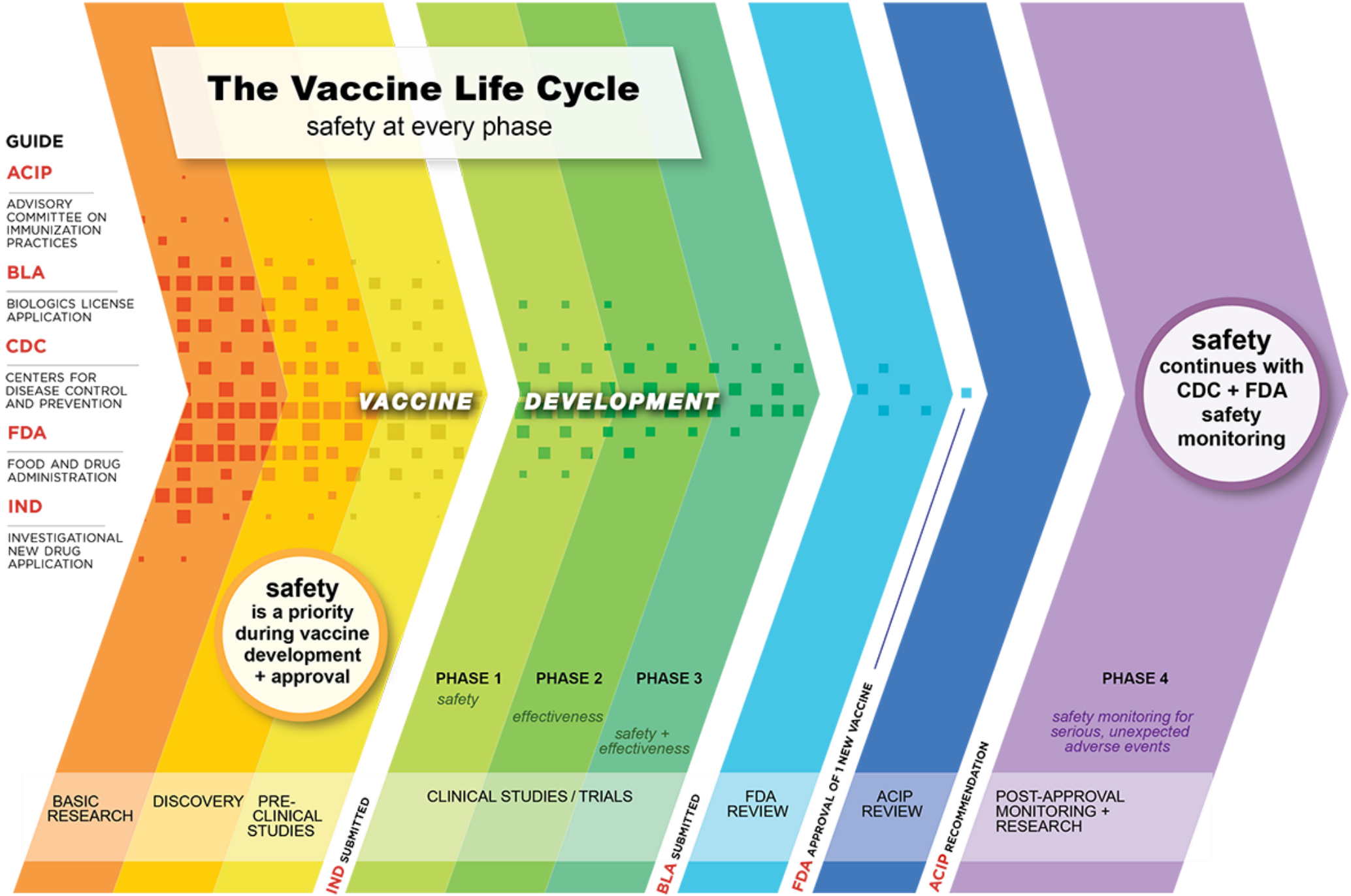
OREGON HEALTH AUTHORITY

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
PHASE 1
safety
PHASE 2
effectiveness
PHASE 3
safety + effectiveness
PHASE 4
safety monitoring for serious, unexpected adverse events
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

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)

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:

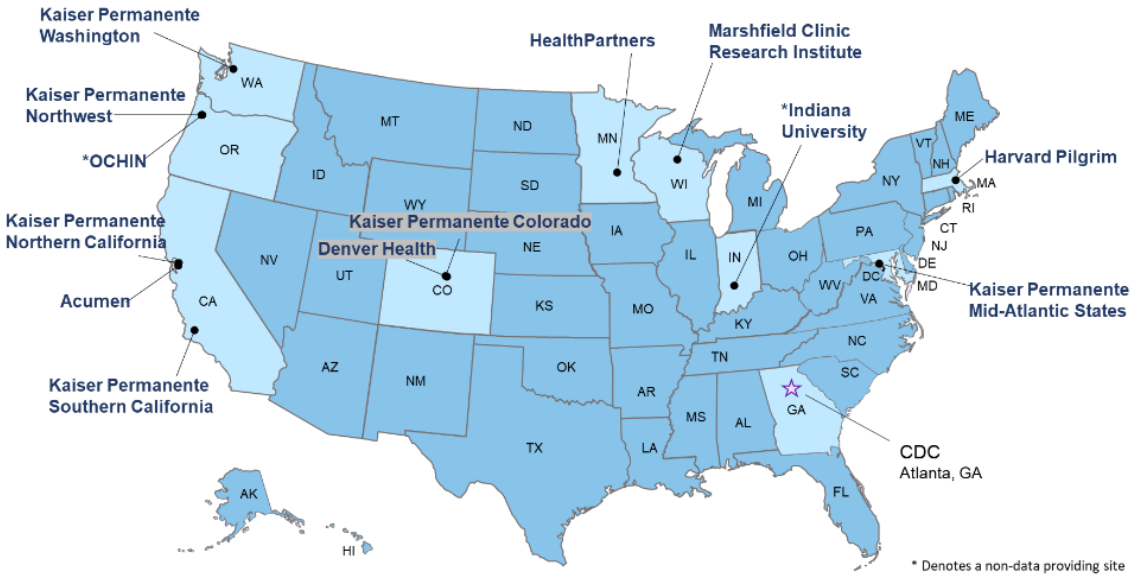
- Conduct research on important vaccine safety questions in large populations
- Conduct vaccine safety studies that come from questions or concerns in the medical literature or from other vaccine safety systems, like VAERS
- Monitor possible adverse events when new vaccines are licensed or when there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



V-safe

- 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

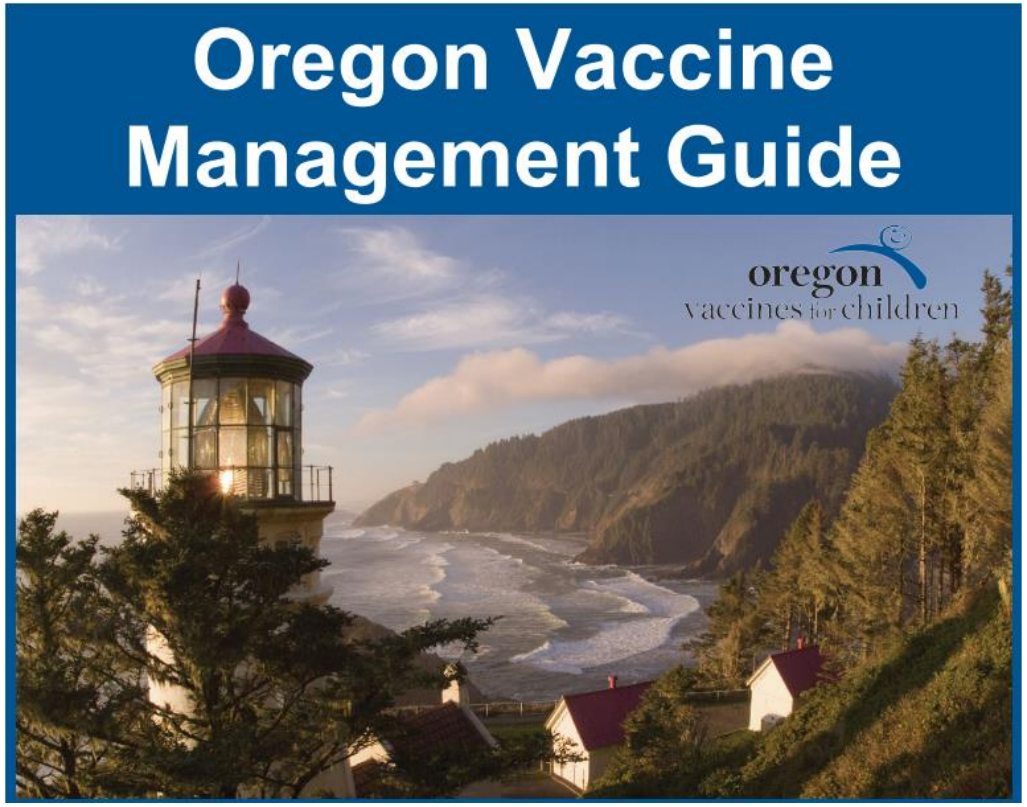
VAERS (Vaccine Adverse Event Reporting System)

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.



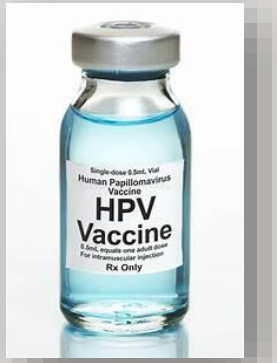
Model Immunization Protocol
List of Adverse Events

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

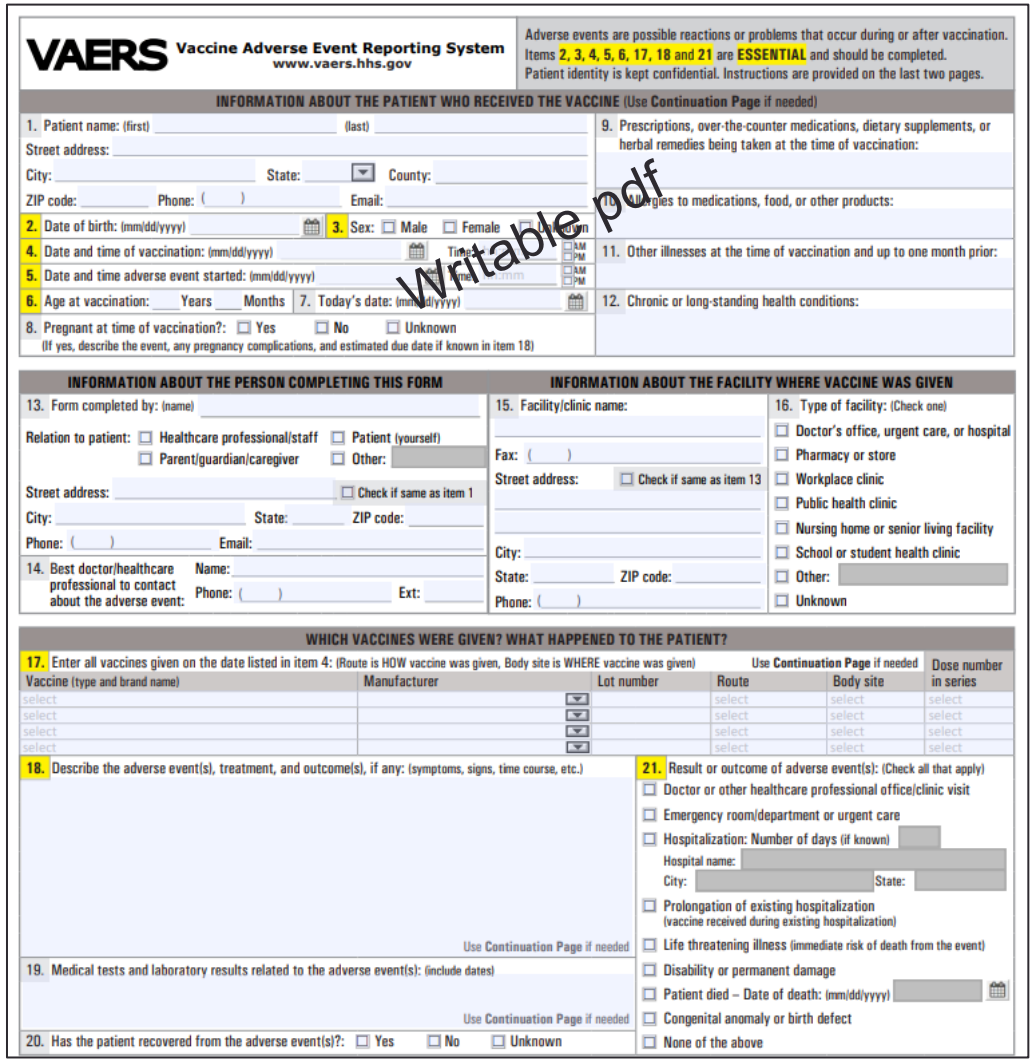
Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html.

VAERS Reporting Table:
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

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)

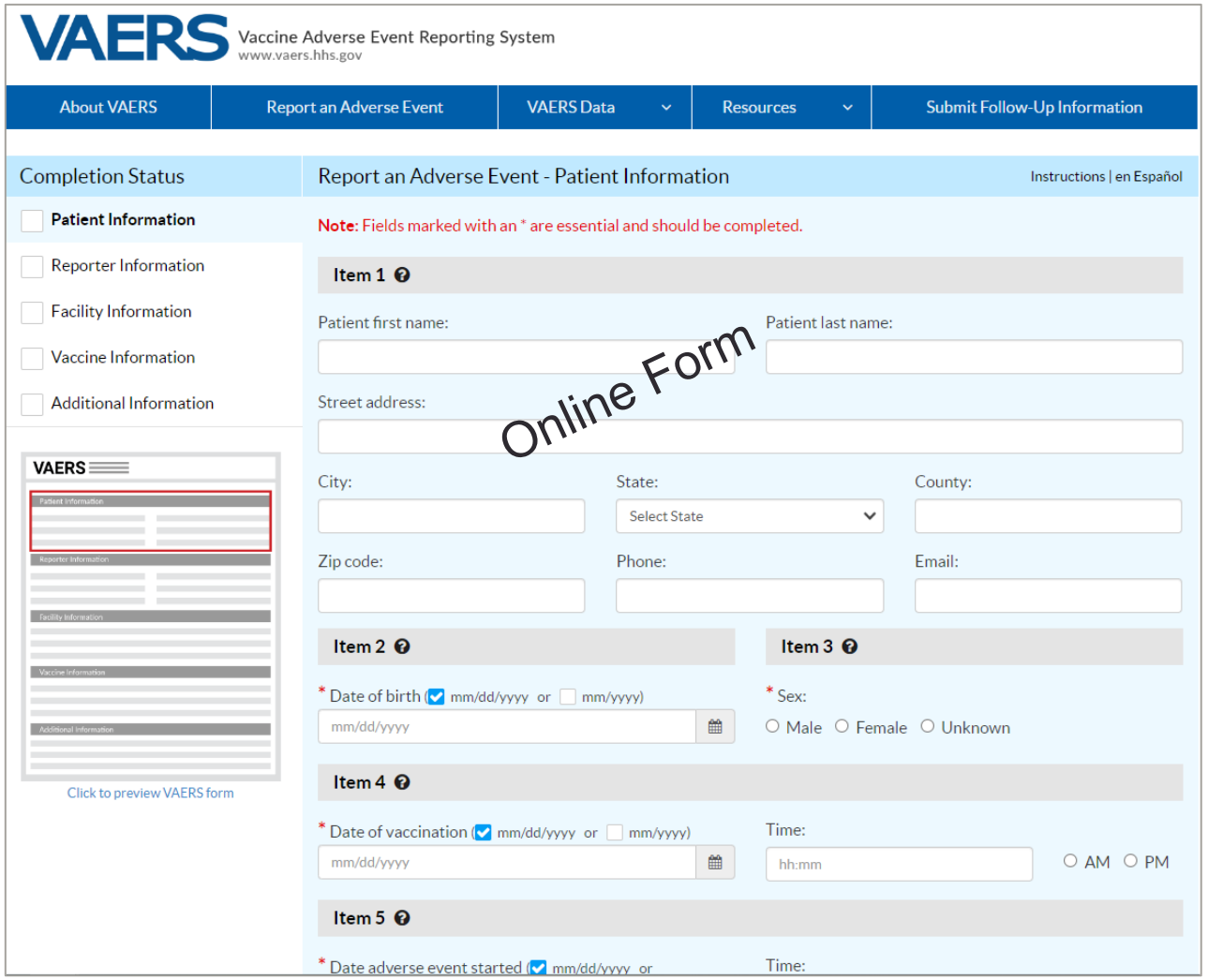
Submitting a Report to VAERS

- 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



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.



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 to you.

Reporting Vaccine Administration Errors

- 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)

Vaccine Error Guidance, Immunize.org

To Report an Adverse Event after Beyfortus (nirsevimab)

One difference

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

- 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!

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.

Public Health Division
Oregon Immunization Program
800 NE Oregon St. Suite 370
Portland, OR 97232
800-980-9431
www.healthoregon.org/imm

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

Jill Johnson, RN BSN MEM
Clinical Vaccine Specialist
(971) 378-5691
jill.m.johnson2@oha.oregon.gov

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