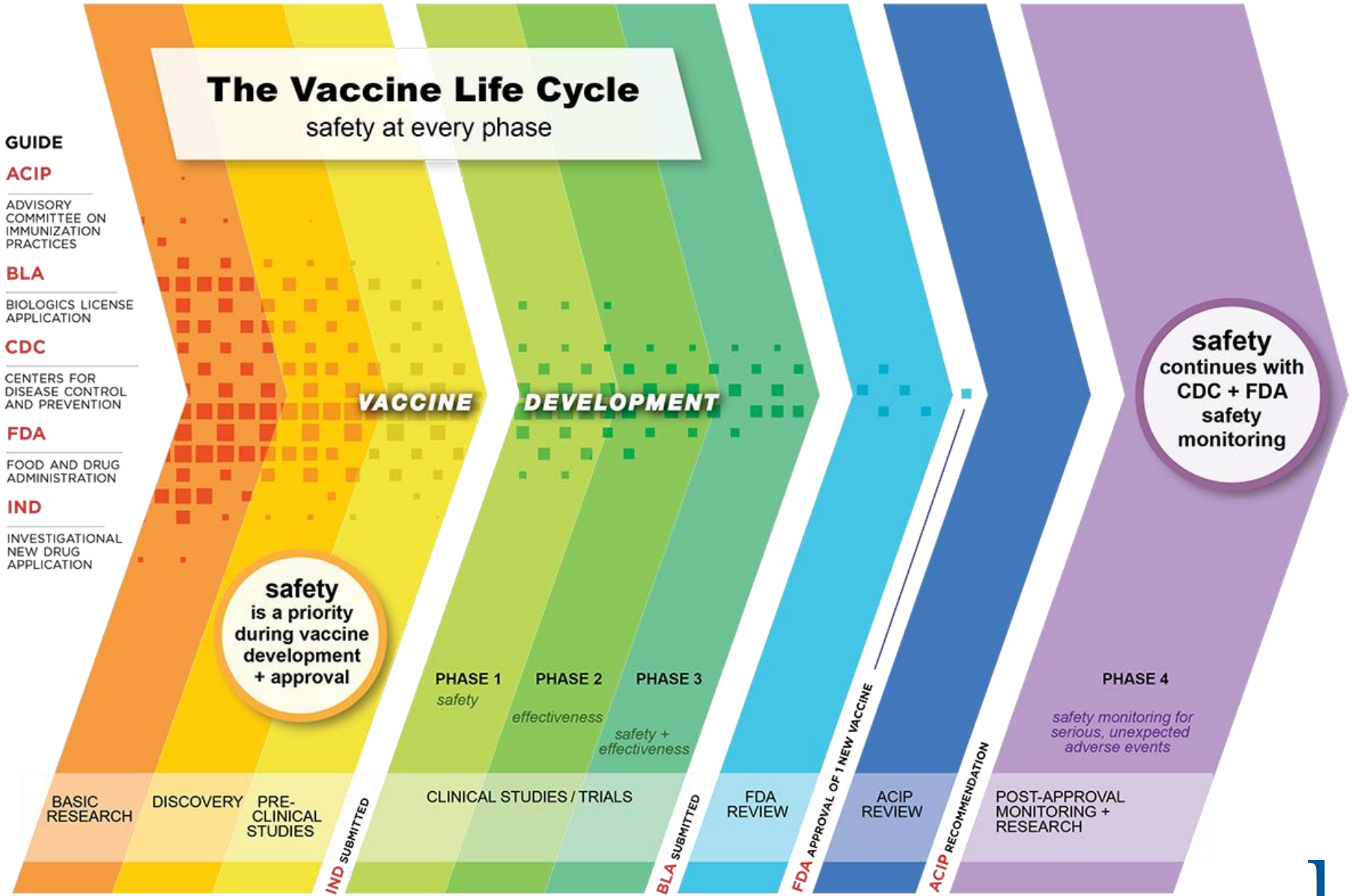
Vaccine Safety Systems

OREGON IMMUNIZATION PROGRAM
Private Provider Orientation, 6/25/24

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


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

Vaccine Safety Monitoring Systems

- Vaccine Adverse Events Reporting System (VAERS)
- Clinical Immunization Safety Assessment (CISA)
- Vaccine Safety Datalink (VSD)
- V-safe

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.

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VSD (Vaccine Safety Datalink)

VSD goals:

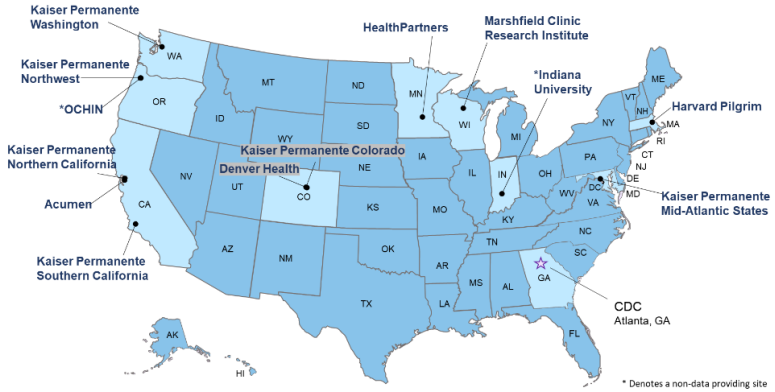
- Conduct research on important vaccine safety questions in large populations
- Conduct vaccine safety studies that come from questions or concerns in the medical literature or from other vaccine safety systems, like VAERS
- Monitor possible adverse events when new vaccines are licensed or when there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

Oregon Health Authority

VAERS

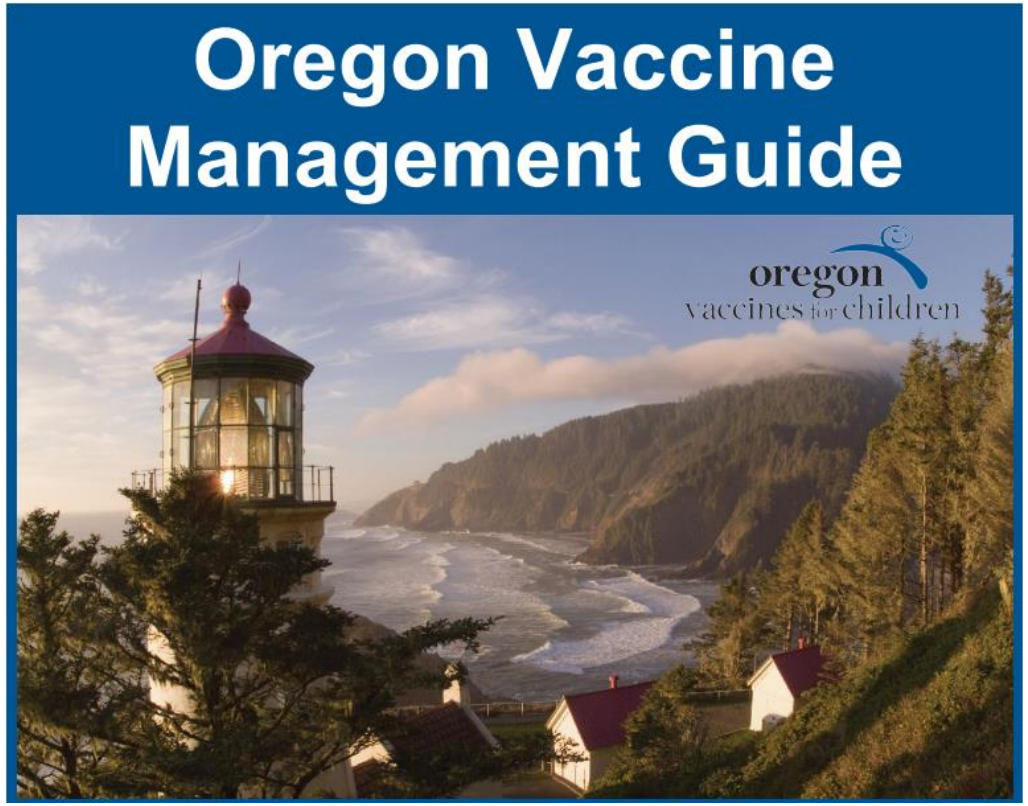
Vaccine Adverse Event Reporting System

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. This includes reports of vaccination errors.

See page 7 of Oregon's Vaccine Management Guide for more information.



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

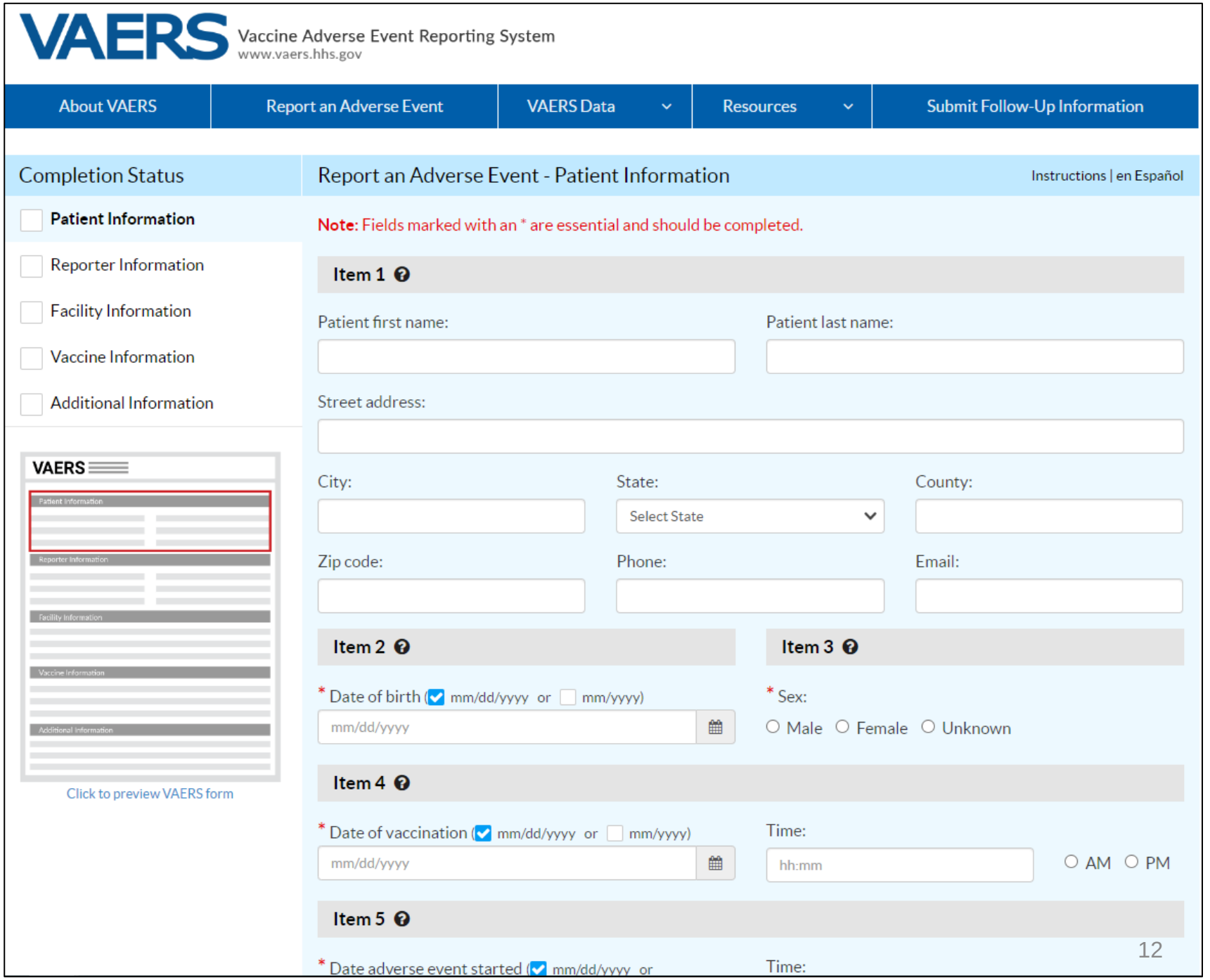
11. Adverse events reporting

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: Online



Submitting a report to VAERS: Writable PDF

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 ☐ Unknown
4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm ☐AM ☐PM
5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm ☐AM ☐PM
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

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

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.

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

For Assistance

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

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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