The Vaccine Adverse Event Reporting System (VAERS) form Version 2.0 (proposed)

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Advisory Committee on Immunization Practices (ACIP)
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Topics

- Background on VAERS
- VAERS 2.0 form (proposed)
- Activities and next steps

Vaccine Adverse Event Reporting System (VAERS)

- National spontaneous reporting system for adverse events after US-licensed vaccines
  - In recent years, received around 30,000 U.S. reports annually
  - Accepts reports from healthcare providers, manufacturers and the public
  - Signs/symptoms of adverse event coded using Medical Dictionary for Regulatory Activities (MedDRA) terms and entered into database
- Jointly administered by CDC and FDA
- Authorized by National Childhood Vaccine Injury Act of 1986

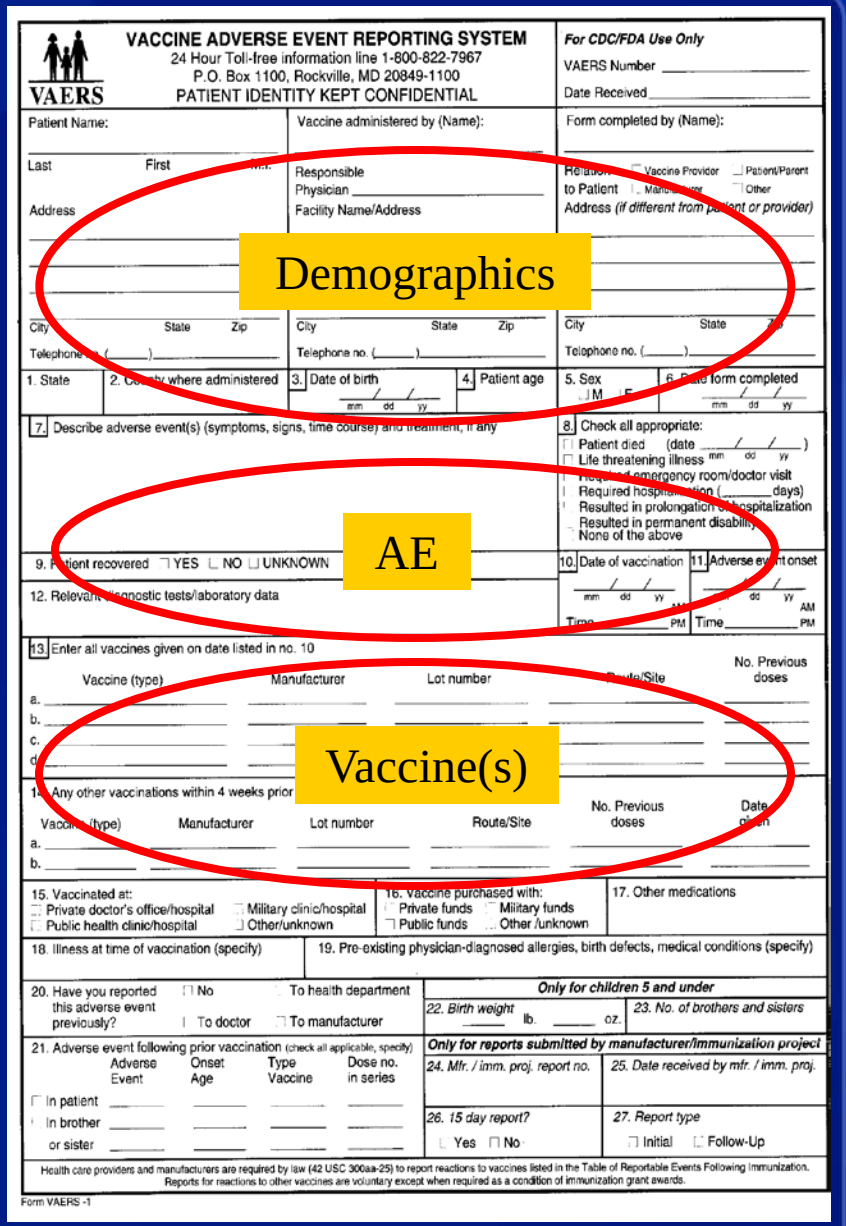
Submitting a VAERS report (currently)

- Secure online submission (~30% of reports in recent years)
- Mailed hardcopy of paper form
- Faxed hardcopy of paper form
- In rare instances via telephone through a VAERS customer service representative if no other way to submit a report

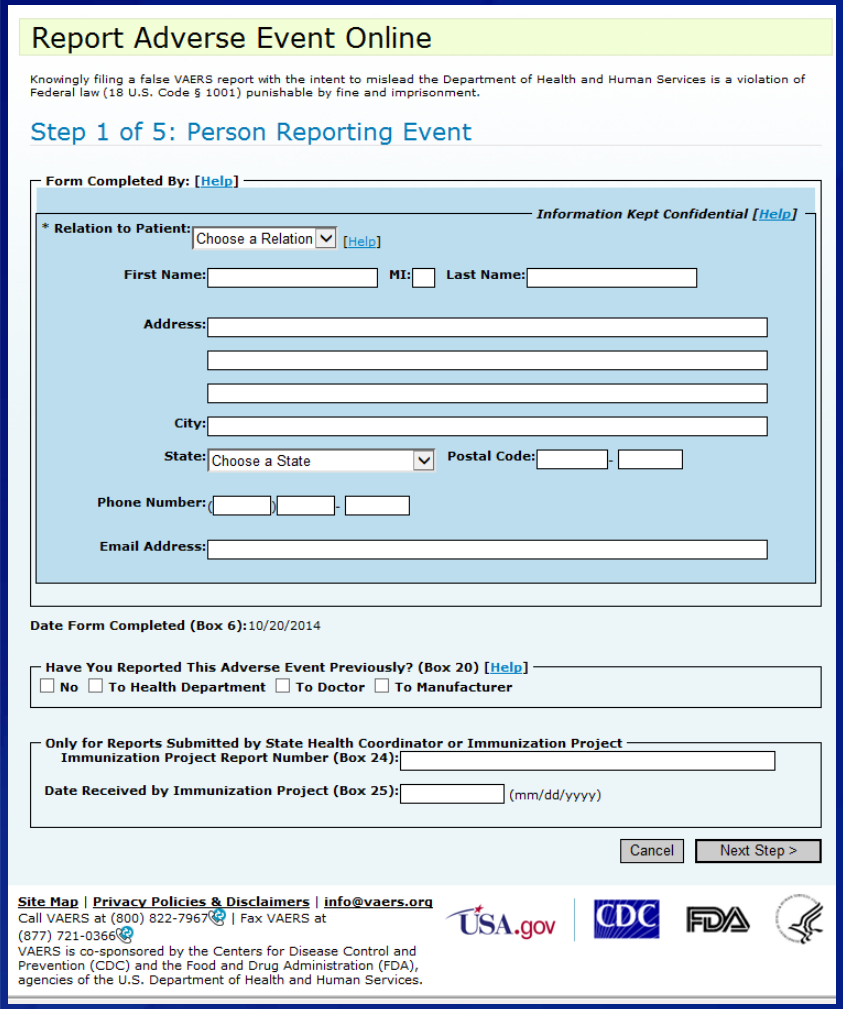
  - Reporter types overall
    - Vaccine provider (36%)
    - Vaccine manufacturer (34%)
    - Patient/parent (15%)
    - Other (15%)

VAERS-1 report form

- VAERS-1 paper form has been in use since 1990
- Must be completed by hand
- Forms are mailed or faxed to VAERS contractor
- Requires manual processing and data entry procedures
- Hardcopies scanned and uploaded to the VAERS image database



VAERS online reporting tool (screen shots)



Report Adverse Event Online

Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

Step 1 of 5: Person Reporting Event

Form Completed By: [Help]

Information Kept Confidential [Help]

* Relation to Patient: Choose a Relation [Help]

First Name: MI: Last Name:

Address:

City:

State: Choose a State Postal Code:

Phone Number: ( ) -

Email Address:

Date Form Completed (Box 6): 10/20/2014

Have You Reported This Adverse Event Previously? (Box 20) [Help]

No To Health Department To Doctor To Manufacturer

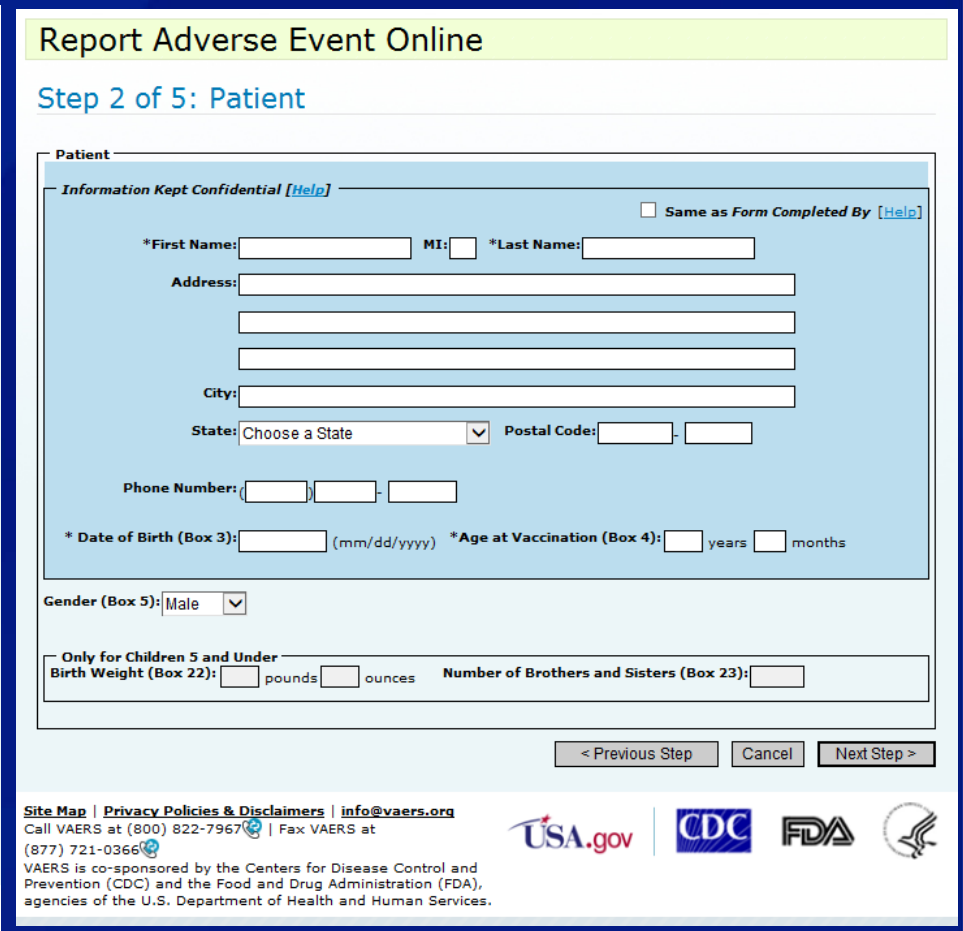
Only for Reports Submitted by State Health Coordinator or Immunization Project

Immunization Project Report Number (Box 24):

Date Received by Immunization Project (Box 25): (mm/dd/yyyy)

Cancel Next Step >

Site Map | Privacy Policies & Disclaimers | info@vaers.org
Call VAERS at (800) 822-7967 | Fax VAERS at (877) 721-0366
VAERS is co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), agencies of the U.S. Department of Health and Human Services.



Report Adverse Event Online

Step 2 of 5: Patient

Patient

Information Kept Confidential [Help]

Same as Form Completed By [Help]

*First Name: MI: *Last Name:

Address:

City:

State: Choose a State Postal Code:

Phone Number: ( ) -

* Date of Birth (Box 3): (mm/dd/yyyy) *Age at Vaccination (Box 4): years months

Gender (Box 5): Male

Only for Children 5 and Under

Birth Weight (Box 22): pounds ounces Number of Brothers and Sisters (Box 23):

< Previous Step Cancel Next Step >

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- Online reporting tool has same fields as VAERS-1 form in a different presentation
- Online interface will "time out" for security reasons after a period of inactivity so reports cannot be saved (i.e., report must be completed in a single setting)

Objectives for the VAERS 2.0 form (proposed)

- Create a fillable/savable electronic reporting form
- Update data fields to address current vaccine safety information needs and changes in vaccination practices over time (e.g., pregnancy, types of facilities, race/ethnicity)
- Modernize the appearance and format of the VAERS form
- Modernize reporting procedures (implement electronic document upload capability with the VAERS 2.0 form)
- Ensure data collected on the VAERS 2.0 form allows for comparisons to be made with older data (i.e., historical comparisons between VAERS-1 and VAERS 2.0 data)

Why revise the VAERS form?

- Some fields on the current VAERS form (VAERS-1) have limited public health and/or regulatory value
  - Other important information isn't being collected
- Some fields are no longer relevant due to changes in the immunization program
- The language in some fields is confusing and needs clarification
- Fields used in paper reporting and for manual processing will no longer be necessary (e.g., manufacturer fields after the transition to the the ICH E2B(R3) message standard)
- New fields, such as pregnancy, are needed because of new recommendations and patterns of vaccine uptake

Why revise the VAERS form? (cont.)

- Handwritten mailed/faxed paper reporting is an inefficient way to conduct vaccine safety surveillance
- Paperless reporting using an electronic form would
  - Eliminate most manual processing and much data entry
  - Mitigate problems with poor handwriting and non-standard reporting
  - Take advantage of smart features (auto-population, drop down menus, programmed check boxes, pop-up instructions/reminders, logic checks)
  - Allow for standardized data elements (dates and times)
  - Address the complaint of getting “timed out” on the online reporting tool (i.e., would offer an electronic alternative to using the online reporting tool)
- Manufacturers are transitioning to fully electronic reporting using the ICH E2B(R3) message standard

VAERS 2.0 form development

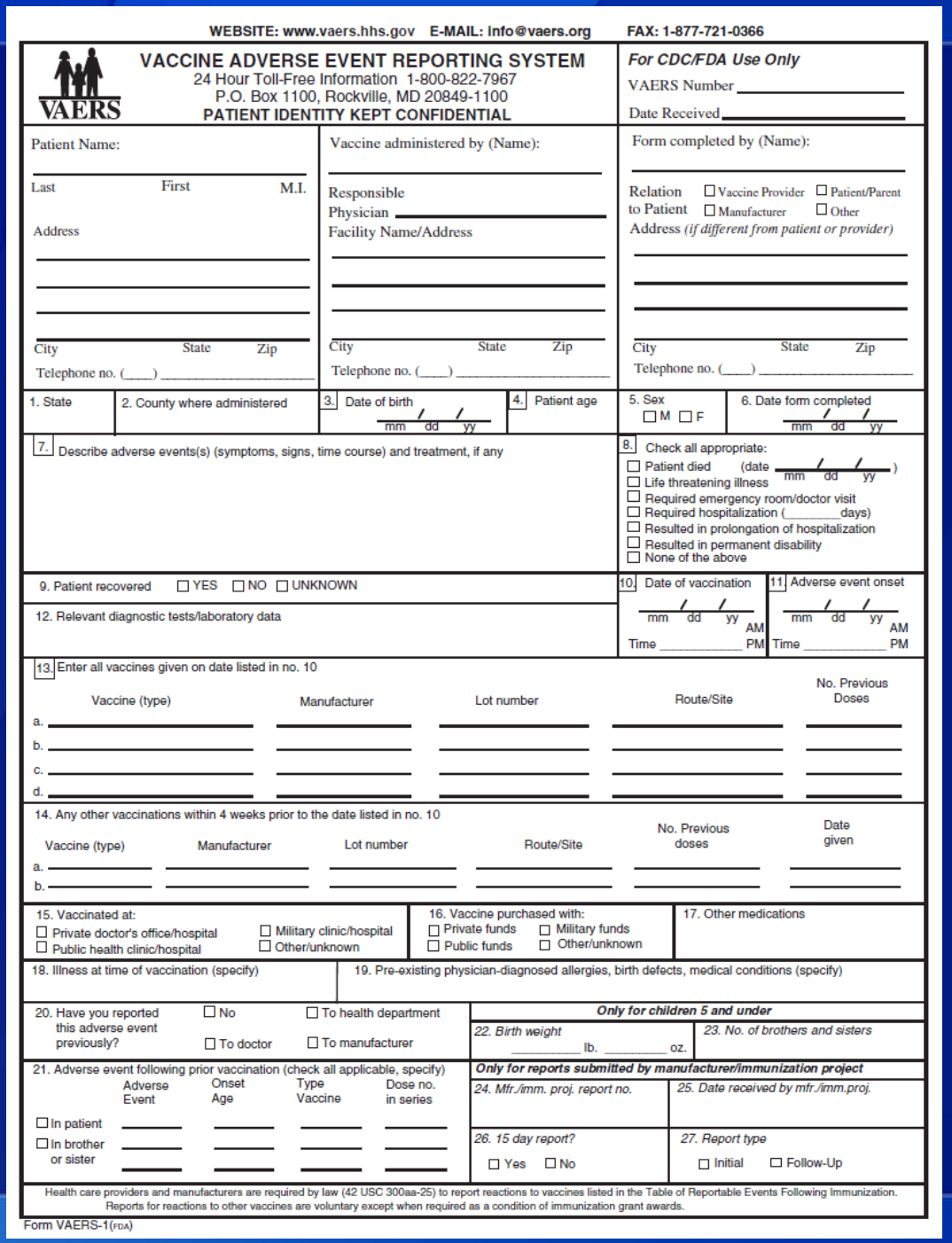
- **Actions that have already occurred**
  - Initial internal development and review/revision by CDC, FDA and VAERS contractor staff (review and revision is ongoing)
  - External review by immunization partners (CDC immunization program, NVPO, HRSA, DoD, ACIP liaison representatives, state immunization program officials, other partners)
  - Cognitive interviews with potential reporters (physicians, nurses, pharmacist, parents, patients) and revisions based on results of cognitive interviews
  - Presented to the Federal Immunization Safety Task Force (ISTF)
  - Follow up interviews with a sample of individuals that completed cognitive interviews to test the revised form
  - Presented to the Advisory Commission on Childhood Vaccines (ACCV) and the National Vaccine Advisory Committee (NVAC)
  - Computer testing “smart” form with potential reporters and revisions based on computer testing
  - Presented at the FDA Electronic Postmarket Safety Reporting Updates meeting

VAERS 2.0 electronic form reporting (proposed)

1. Reporter downloads the VAERS 2.0 form from the VAERS website
2. Reporter completes a VAERS 2.0 form on a computer (form is a fillable/savable PDF document)
3. Reporter saves the VAERS 2.0 report as an electronic document in a local environment
4. Reporter uploads the VAERS 2.0 report to the VAERS contractor through the VAERS website
5. VAERS contractor electronically extracts the data from the VAERS 2.0 report into the VAERS database (also reviews, redacts and performs Q&A on data)
6. VAERS contractor generates an individual report for the VAERS image database

VAERS-1 form (current)

www.vaers.hhs.gov/resources/vaers_form.pdf



WEBSITE: www.vaers.hhs.gov E-MAIL: info@vaers.org FAX: 1-877-721-0366

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number _____
Date Received _____

Patient Name: Last First M.I.
Address
City State Zip
Telephone no. (____) _____

Vaccine administered by (Name):
Responsible Physician _____
Facility Name/Address
City State Zip
Telephone no. (____) _____

Form completed by (Name):
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other
Address *(if different from patient or provider)*
City State Zip
Telephone no. (____) _____

1. State | 2. County where administered | 3. Date of birth mm dd yy | 4. Patient age | 5. Sex ☐ M ☐ F | 6. Date form completed mm dd yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm dd yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm dd yy Time _____ AM PM

11. Adverse event onset mm dd yy Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously? ☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under
22. Birth weight _____ lb. _____ oz.
23. No. of brothers and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project
24. Mfr./imm. proj. report no.
25. Date received by mfr./imm.proj.
26. 15 day report? ☐ Yes ☐ No
27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1 (FDA)

VAERS 2.0 form (proposed)

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

Items **2, 4, 5, 6, 17, 18 and 21** are **ESSENTIAL** and must be completed.
Patient identity kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient name: *(First)* _____ *(Last)* _____
Street address: _____
City: _____ State: _____ County: _____
ZIP code: _____ Tele: (____) _____ Email: _____

2. Date of birth: *(mm/dd/yyyy)* ____/____/____ | 3. Sex: ☐ Male ☐ Female ☐ Unknown

4. Date and time of vaccination: *(mm/dd/yyyy)* ____/____/____ Time: _____ ☐AM ☐PM

5. Date and time adverse event started: *(mm/dd/yyyy)* ____/____/____ Time: _____ ☐AM ☐PM

6. Age at vaccination: ____ Years ____ Months | 7. Today's date: *(mm/dd/yyyy)* ____/____/____

8. Report is about vaccine administered to a pregnant woman: ☐ No or unknown ☐ Yes
(If Yes, describe pregnancy history, estimated date of delivery, birth weight if available, and the event in no. 18)

9. Prescriptions, over-the-counter medications, dietary supplements or herbal remedies being taken at time of vaccination:

10. Allergies to medications, food, or other products:

11. Other illness 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 no. 1*
City: _____ State: _____ ZIP code: _____
Tele: (____) _____ Fax: (____) _____

14. Best doctor/healthcare professional to contact about the patient: Name: _____ Tele: (____) _____ Ext: _____

INFORMATION ABOUT FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: _____
Fax: (____) _____
Street address: ☐ *Check if same as no. 13* _____
City: _____
State: _____ ZIP code: _____
Tele: (____) _____

16. Type of facility:
☐ Doctor's office or hospital
☐ Pharmacy or drug store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School/student health clinic
☐ Other: _____
☐ Unknown

WHAT VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on date listed in no. 4: *(Route is HOW vaccine was given, body site is WHERE vaccine was given)* Use **Continuation Page** for no. 17, if necessary

Vaccine *(type and brand name)*	Manufacturer	Lot number	Route	Body site	Dose no. in series

18. Describe event(s), treatment and outcome(s), if any: *(symptoms, signs, time course, etc.)*

19. Medical tests and laboratory results related to event(s): *(Include dates)*

20. Patient has recovered from event: ☐ Yes ☐ No ☐ Unknown

21. Result or outcome of event: *(Check all that apply)*
☐ Doctor or other healthcare professional office/clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization: Number of days _____ *(if known)*
Hospital name: _____
City: _____ State: _____
☐ Prolongation of existing hospitalization
(Vaccine received during existing hospitalization)
☐ Life threatening illness
☐ Disability or permanent damage
☐ Patient died: Date of death ____/____/____ *(mm/dd/yyyy)*
☐ Congenital anomaly or birth defect
☐ None of the above

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in no. 4: Use **Continuation Page** for no. 22, if necessary

Vaccine *(type and brand name)*	Manufacturer	Lot number	Route	Body site	Dose no. in series

23. Has the patient ever had an adverse event following any previous vaccine: *(If yes, describe and include patient age, vaccination dates, and vaccine type and brand name)*
☐ No or unknown ☐ Yes _____

24. Patient's race: *(Check all that apply)* ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown ☐ Other: _____

25. Patient's ethnicity ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown | 26. Immuniz. proj. report no.: *(Health Dept use only)* _____

FOR U.S. MILITARY/DEPT OF DEFENSE (DoD) RELATED REPORTS *(Complete only if applicable)*

27. Status at time of vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Other: _____ | 28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

FORM FDA VAERS-2.0 (9/15)

Next steps

1. Present to the Advisory Committee on Immunization Practices (ACIP)
2. Public comment solicitation through Federal Register
3. Final revisions
4. Develop the platform to accept electronic VAERS 2.0 submissions and update the online reporting tool to reflect new data elements
5. Implement the VAERS 2.0 form
6. Evaluate completeness and quality of VAERS data (pre-post comparison)

Thank You

For more information please contact Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov