Vaccine safety: announcement of the new Vaccine Adverse Event Reporting System (VAERS) 2.0 form

Advisory Committee on Immunization Practices
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Disclaimer

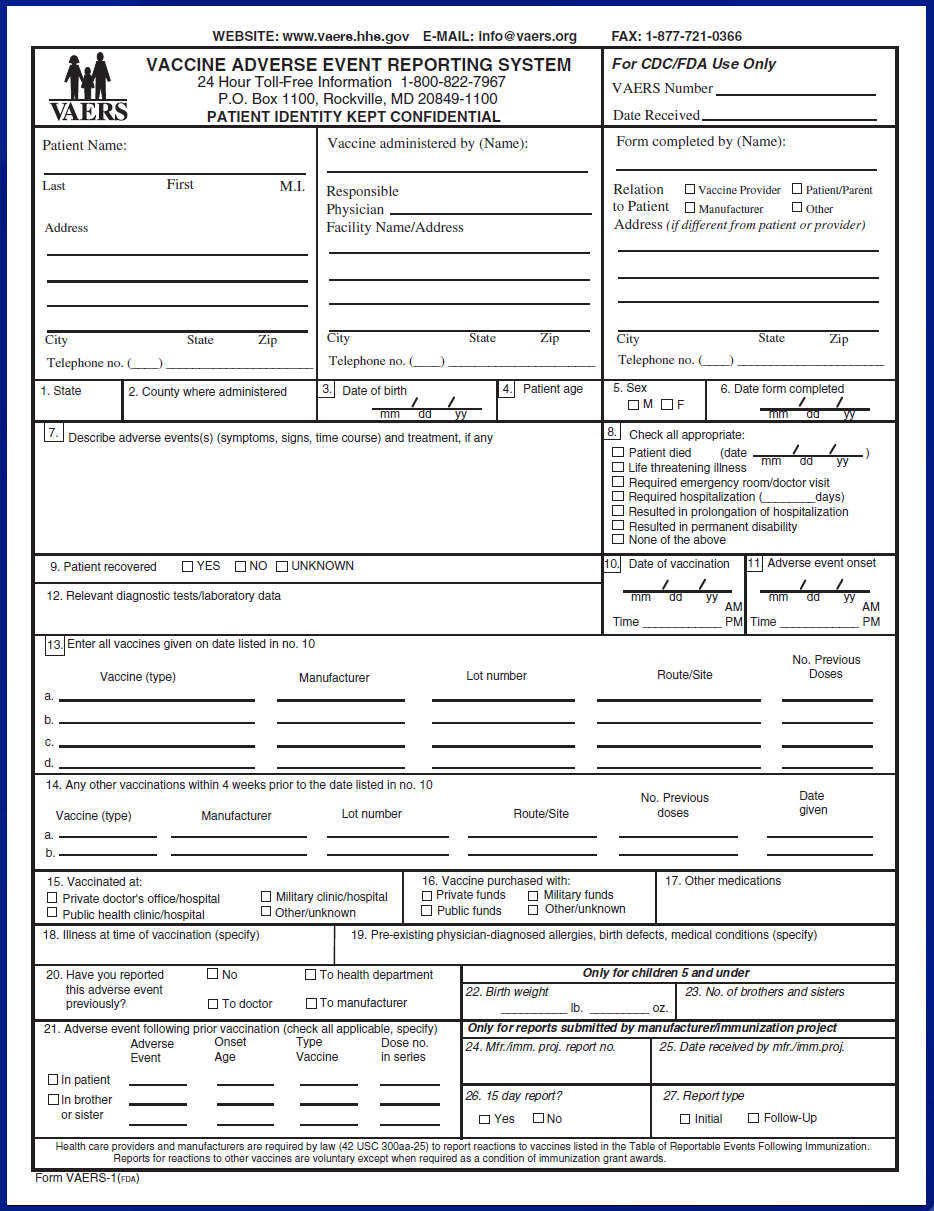
The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the CDC or FDA.

Vaccine Adverse Event Reporting System (VAERS) and VAERS reporting form

- VAERS is the national spontaneous reporting system for monitoring the safety of U.S.-licensed vaccines
- VAERS is co-managed by CDC and FDA
- The current VAERS form (VAERS-1 form) has been in use since 1990
- The paper version* of this form must be filled out by hand and mailed or faxed
- An online reporting tool allows for web-based reporting

*The VAERS-1 form is a PDF that does not have writable and savable features

VAERS-1 form (circa 1990)



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)

Vaccine Adverse Event Reporting System (VAERS) 2.0

- **VAERS 2.0 consists of two major initiatives**
  - **A new VAERS form with revised data elements**
    - **VAERS 2.0 reporting form**
  - **An updated processes for submitting VAERS reports**
    - **Option 1: updated online reporting tool**
    - **Option 2: writable PDF form combined with electronic document upload capability**

VAERS 2.0 development

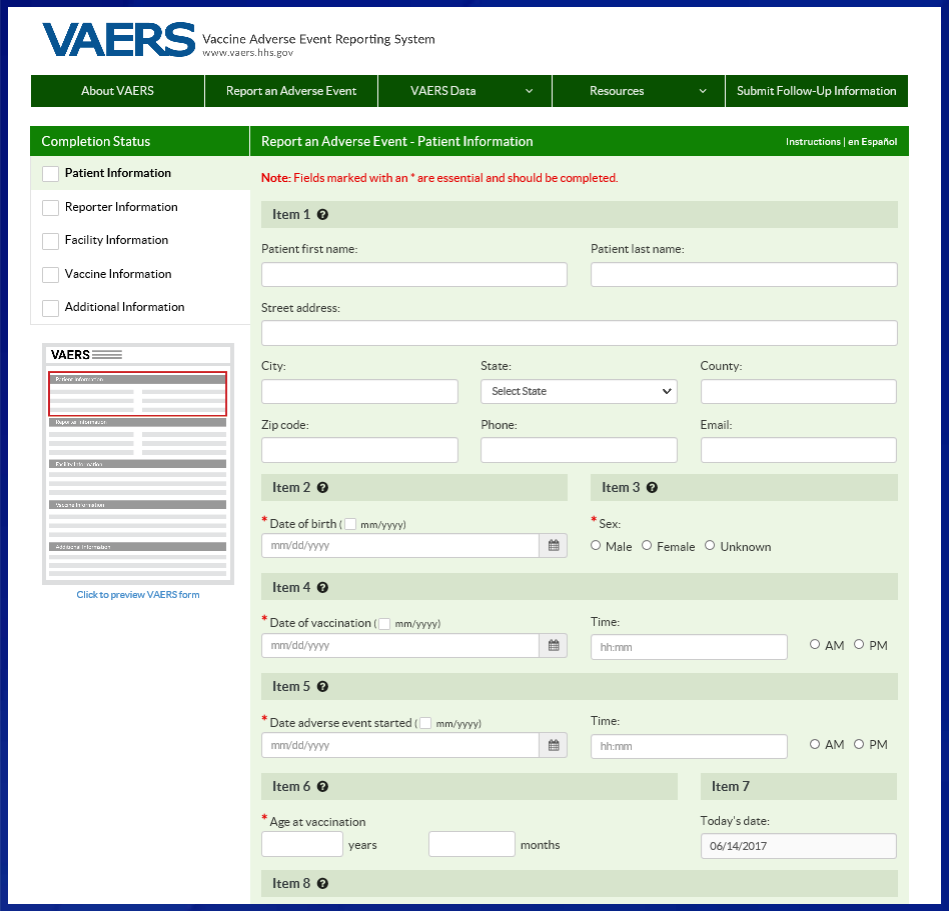
- Proposed changes to the current VAERS form were first presented to ACIP, NVAC and ACCV in September and October 2014
- Proposed changes were also posted on the Federal Register for public comment in November 2014 (https://www.federalregister.gov/documents/2014/11/24/2014-27678/request-for-comment-on-draft-vaccines-adverse-event-reporting-system-vaers-20-form)
- CDC conducted extensive user testing during development
- Changes to the VAERS form were finalized in 2016
- The new VAERS 2.0 form has updated data elements (e.g. pregnancy status, race and ethnicity) and new features including writable and savable options
- IT upgrades to the VAERS website were completed in 2017 to incorporate new data elements into a reconfigured online reporting tool and to accommodate a new electronic document upload process

Reporting using the VAERS 2.0 form

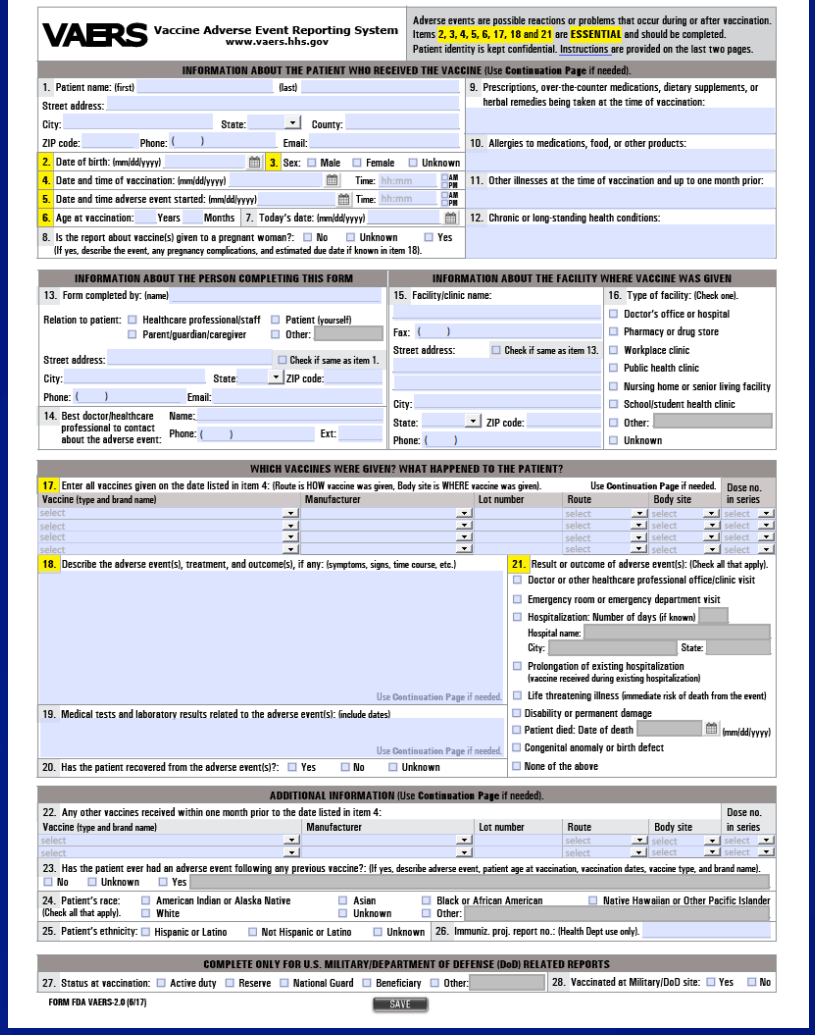
- Starting June 30, 2017 and extending through the end of December 2017, CDC and FDA will implement the VAERS 2.0 form and phase out the VAERS-1 form
- VAERS 2.0 is for reporting by:
  - Healthcare professionals, patients, parents, guardians, caregivers, and other non-manufacturer reporters
- Reporters will be able to:
  - Use the VAERS 2.0 online reporting tool to submit reports (i.e., direct online reporting)

    or
  - Download and complete the writable and savable VAERS 2.0 form and submit using an electronic document upload feature
- Vaccine manufacturers report through a different process using the FDA Electronic Submissions Gateway

Partial screen shot of VAERS 2.0 online reporting tool (direct online reporting)



VAERS 2.0 form (writable, savable and uploadable onto the VAERS website)



- "Essential" items (high value data elements) are highlighted with asterisks in the online reporting tool and with yellow boxes in the writable PDF form

VAERS 2.0 form (additional information)

- Instructions for reporting to VAERS will be available at https://vaers.hhs.gov/reportevent.html (URL will be activated June 30, 2017)
- Additional assistance is available via email at info@vaers.org or by phone at 1-800-822-7967
- Transition to the VAERS 2.0 form is expected to be completed by the end of December 2017
- Accommodations will be made for individuals unable to submit reports electronically

Centers for Disease Control and Prevention
Atlanta, GA

Division of Healthcare Quality Promotion – Immunization Safety Office
National Center for Emerging and Zoonotic Infectious Diseases

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