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

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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 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, but has plateaued)
- Mailed written hardcopy of paper form
- Faxed hardcopy
- Via telephone through a VAERS customer service representative
VAERS-1 report form*

- Paper form; must be completed by hand or using a typewriter
- Forms are mailed or faxed to VAERS contractor
- Requires manual receipt, processing and data entry procedures
- Hardcopies scanned and uploaded to the VAERS image database
- Resource intensive to manage paper reporting

*Online reporting form has same fields in a different presentation
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
- 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 ICH E2B(R3) message standard)
- Federal advisory committees and other stakeholders have expressed interest in collecting information on pregnancy status, race and ethnicity
Why revise the VAERS form? (cont.)

- Handwritten and mailed/faxed copies of paper reports 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 (drop down menus, 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

- Manufacturers will be transiting to fully electronic reporting using the ICH E2B(R3) message standard
VAERS 2.0 form development

Actions that have already occurred

- Initial VAERS 2.0 development by CDC, FDA and VAERS contractor staff
- Internal (CDC, FDA and VAERS contractor) review and revision; review and revision is an ongoing activity
- Initial 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)
- Major revisions based on results of cognitive interviews
- Presented to internal and selected external partners (CDC immunization program, state Vaccine Safety Coordinators, others)
- 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)
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 secure environment per instructions
4. Reporter uploads saved 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 2.0 form (proposed)
Next steps

1. Present the VAERS 2.0 form to NVAC and ACIP
2. Create “smart” electronic form
3. Computer test form with potential reporters
4. Public comment solicitation through Federal Register
5. Make final revisions based on computer testing results and comments
6. Develop the platform to accept electronic VAERS 2.0 submissions and update the online reporting tool
7. Implement the VAERS 2.0 form
8. Evaluate completeness and quality of VAERS data (pre-post comparison)
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Thank You

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.