



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 Vaccine Provider Patient/Parent
 to Patient 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 _____ / _____ / _____)
 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

12. Relevant diagnostic tests/laboratory data

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

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

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, medial 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 brother and sisters _____

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

Adverse Event	Onset Age	Type Vaccine	Dose no. in series
<input type="checkbox"/> In patient _____	_____	_____	_____
<input type="checkbox"/> 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.

“Fold in thirds, tape & mail - DO NOT STAPLE FORM”



NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE



VAERS
P.O. Box 1100
Rockville MD 20849-1100

Series of horizontal lines for postage meter or tracking information.



DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed)

GENERAL

Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)

Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.

Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility. These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.

Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

- Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms diagnosis, treatment and recovery should be noted.
- Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
- Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please
- Item 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
- Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
- Item 13: List ONLY those vaccines given on the day listed in Item 10.
- Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
- Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
- Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
- Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
- Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.
- Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
- Item 26: This space is for manufacturers' use only.