



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 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 AM
Time _____ PM

11. Adverse event onset
mm / dd / yy AM
Time _____ 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
 Public health clinic/hospital
 Military clinic/hospital
 Other/unknown

16. Vaccine purchased with:
 Private funds
 Public funds
 Military 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 |
|--------------------------|----------------------|-----------|--------------|--------------------|
| <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

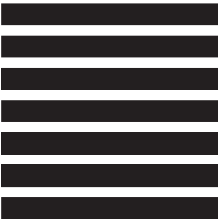
Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.



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



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
- and 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.