

8-11 VACCINE ADVERSE EVENT REPORT SYSTEM

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

 <p>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</p>		<p><i>For CDC/FDA Use Only</i></p> 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 <input type="checkbox"/> Vaccine Provider <input type="checkbox"/> Patient/Parent to Patient <input type="checkbox"/> Manufacturer <input type="checkbox"/> 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 <input type="checkbox"/> M <input type="checkbox"/> 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: <input type="checkbox"/> Patient died (date mm / dd / yy) <input type="checkbox"/> Life threatening illness <input type="checkbox"/> Required emergency room/doctor visit <input type="checkbox"/> Required hospitalization (____ days) <input type="checkbox"/> Resulted in prolongation of hospitalization <input type="checkbox"/> Resulted in permanent disability <input type="checkbox"/> None of the above		
9. Patient recovered <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> 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
a. _____		_____	_____	_____	_____
b. _____		_____	_____	_____	_____
15. Vaccinated at: <input type="checkbox"/> Private doctor's office/hospital <input type="checkbox"/> Public health clinic/hospital		<input type="checkbox"/> Military clinic/hospital <input type="checkbox"/> Other/unknown		16. Vaccine purchased with: <input type="checkbox"/> Private funds <input type="checkbox"/> Military funds <input type="checkbox"/> Public funds <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> To health department <input type="checkbox"/> To doctor <input type="checkbox"/> To manufacturer			<i>Only for children 5 and under</i>		
			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 _____			<i>Only for reports submitted by manufacturer/immunization project</i>		
			24. Mfr./imm. proj. report no.	25. Date received by mfr./imm.proj.	
			26. 15 day report? <input type="checkbox"/> Yes <input type="checkbox"/> No	27. Report type <input type="checkbox"/> Initial <input type="checkbox"/> 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)

"Fold in thirds, tape & mail — DO NOT STAPLE FORM"



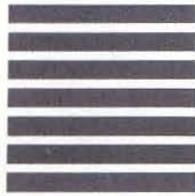
NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

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



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.