

Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)									
1. Patient name: (first) (last)			9. Prescriptions, over-the-counter medications, dietary supplements, or						
Street address:			herbal remedies being taken at the time of vaccination:						
ty: State: County:									
ZIP code: Phone:	Email:			10. Allergies to medications, food, or other products:					
2. Date of birth: (mm/dd/yyyy)	<mark>B.</mark> Sex: 🗆 Male 🗆 Fema	ale 🗆 Unknown							
4. Date and time of vaccination: (mm/dd/yyyy)	math Time:	□AM 	11. Other illnesses at the time of vaccination and up to one month prior:						
5. Date and time adverse event started: (mm/dd/yyyy)	Time:	□AM □PM							
6. Age at vaccination:Years Months 7. Too	lay's date: (mm/dd/yyyy)		12. Chronic or long-standing health conditions:						
8. Pregnant at time of vaccination?:									
INFORMATION ABOUT THE PERSON COMPLI	TING THIS FORM	INFORM	MATION	ABOUT THE FAC	ILITY WHERE VAI	CCINE WAS GIV	/EN		
13. Form completed by: (name)		15. Facility/clinic							
Relation to patient: ☐ Healthcare professional/staff ☐ Patient (yourself)					☐ Doctor's	☐ Doctor's office, urgent care, or hospita			
·	Other:	Fax:			Dharmac	☐ Pharmacy or store			
Chroat address.	Charlest annual states 1	Street address:		Check if same as iten	n 13 🗆 Workplad	☐ Workplace clinic			
Street address:	ZIP code:				Dublic he	☐ Public health clinic			
,					□ Nursing h	nome or senior liv	ing facility		
		City:				☐ School or student health clinic			
14. Best doctor/healthcare	Ext:	State:	State: ZIP code:			□ Other:			
about the adverse event:	EXI	Phone:			Unknowr	□ Unknown			
WHIC	H VACCINES WERE GIVE	N? WHAT HAPPEN	IED TO	THE PATIENT?					
17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vac			E vaccine was given) Use Continuation Page if needed Dose number						
Vaccine (type and brand name)	Manufacturer		Lot number Route Body sit			ody site	in series		
18. Describe the adverse event(s), treatment, and outco	ne(s), if any: (symptoms, sign	s, time course, etc.)		21. Result or out	come of adverse ev	ent(s): (Check all	that apply)		
			☐ Doctor or other healthcare professional office/clinic visit						
			☐ Emergency room/department or urgent care						
				☐ Hospitalization	: Number of days (if known)	_		
				Hospital name:					
				City: State:					
				☐ Prolongation o (vaccine receive	f existing hospitalized during existing hosp	zation iitalization)			
Use Continuation Page if no									
19. Medical tests and laboratory results related to the adverse event(s): (include dates)				☐ Disability or pe			•		
					Date of death: (mm	ı/dd/yyyy)	=		
Use Continuation Page if			needed	☐ Congenital and	maly or birth defec	et			
20. Has the patient recovered from the adverse event(s)?: ☐ Yes ☐ No ☐ Unknown			□ None of the above						
ADDITIONAL INFORMATION									
22. Any other vaccines received within one month prior				Use Continu a	tion Page if needed	Dose number	Date		
Vaccine (type and brand name)	Manufacturer	Lot number		Route	Body site	in series	Given		
23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name) □ Yes □ No □ Unknown									
24. Patient's race: American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander									
(Check all that apply)	Unknow	n 🗆 Other:					Joine Islanuel		
25. Patient's ethnicity: ☐ Hispanic or Latino ☐ No	t Hispanic or Latino 🗆	Unknown 26. In	nmuniz.	proj. report number	: (Health Dept use on	ly)			
COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (Dod) RELATED REPORTS									

FORM FDA VAERS 2.0 (02/22) SAVE

27. Status at vaccination: □ Active duty □ Reserve □ National Guard □ Beneficiary □ Other:

CONTINUATION PAGE (Use only if you need more space from the front page)

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Vaccine (type and brand name) Manufacturer	17. Enter all vaccines given on the date listed in item 4 (co	17. Enter all vaccines given on the date listed in item // (continued):						Dose number		
22. Any other vaccines received within one month prior to the date listed in item 4 (continued): Vaccine (type and brand name) Manufacturer Lot number Route Body site in series Given				Lot nur	Lot number Route		ute Body site			
Vaccine (type and brand name) Manufacturer Lot number Route Body site in series Given										
Vaccine (type and brand name) Manufacturer Lot number Route Body site in series Given										
Vaccine (type and brand name) Manufacturer Lot number Route Body site in series Given										
Use the space below to provide any additional information (indicate item number):					Route		Body site			
Use the space below to provide any additional information findicate item number):										
Use the space below to provide any additional information (indicate item number):										
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COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile/.
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an
 email to info@vaers.org.
- Fill out the VAERS form as completely as possible and use the Continuation Page if needed. Use a separate VAERS form for
 each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether
 the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.html for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who
 administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS

Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed.

- Items 4 and 5: Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- Item 6: If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (item 2) and date and time of vaccination (item 4).
- Item 8: If the patient who received the vaccine was pregnant at time of vaccination, select "Yes" and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- Item 9: List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/alternative medicines being taken by the patient when the vaccine(s) was given.
- Item 10: List any allergies the patient has to medications, foods, or other products.
- Item 11: List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- Item 12: List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- Item 13: List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
- Item 14: List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- Item 15: Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- Item 16: Select the option that best describes the type of facility where the vaccine(s) was given.



- Item 17: Include only vaccines given on the date provided in item 4. The vaccine route options include:
 - Injection/shot (intramuscular, subcutaneous,
- By mouth/oral
- Other (specify)

- intradermal, jet injection, and unknown)
- In nose/intranasal

Unknown

For body site, the options include:

• Right arm

• Right thigh

- Nose
- Other (specify)

Left arm

Left thigh

- Mouth
- Unknown

Arm (side unknown)

Thigh (side unknown)

For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose number in series."

- Item 18: Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- Item 19: List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- Item 20: Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- Item 21: Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- Item 22: List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- Item 23: Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.
- Item 24: Check all races that apply.
- Item 25: Check the single best answer for ethnicity.
- Item 26: For health department use only.
- Items 27 and 28: Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

GENERAL INFORMATION

- VAERS (www.vaers.hhs.gov) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.