

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Immunization Program

PLEASE COPY THIS FOR ALL HEALTH CARE PROVIDERS IN YOUR PRACTICE

TO: Health Care Providers

**FROM: Mick Bolduc-Vaccine Coordinator
Connecticut Vaccine Program (CVP)**

A handwritten signature in black ink, appearing to read "Mick Bolduc".

DATE: July 14, 2017

SUBJECT: Updated VAERS Reporting Form & Submitting Process

The primary purpose of this communication is to inform you of a new Vaccine Adverse Events Reporting form and mechanism for reporting adverse events.

VAERS Form

The Vaccine Adverse Event Reporting System (VAERS), co-managed by CDC and the Food and Drug Administration (FDA), is the national post-marketing safety monitoring system that accepts reports about adverse events that occur after administration of U.S. licensed vaccines. On June 30, 2017, CDC and FDA implemented a revised reporting form and a new process for submitting reports to VAERS. Persons reporting adverse events are now able to use the VAERS 2.0 online reporting tool to submit reports directly online. Providers will no longer have to send in reports of vaccine adverse events to the CVP. Enclosed is the new VAERS form along with instructions on how to complete the form. The newly revised form can also be found at:

https://vaers.hhs.gov/pdf/vaers_form.pdf

Please begin using the new form immediately and discard any previous versions. Instructions for submitting the form online are available at: <https://vaers.hhs.gov/reportevent.html>

As always, if you have any questions, please feel free to contact me at (860) 509-7940.



Phone: (860) 509-7929 • Fax: (860) 509-7945
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

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INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed).

1. Patient name: (first) _____ (last) _____
Street address: _____
City: _____ State: _____ County: _____
ZIP code: _____ Phone: _____ Email: _____

2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: Male Female Unknown

4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: _____ AM PM

5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: _____ AM PM

6. Age at vaccination: _____ Years _____ Months 7. Today's date: (mm/dd/yyyy) _____

8. Is the report about vaccine(s) given to a pregnant woman?: No Unknown Yes
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18).

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination: _____

10. Allergies to medications, food, or other products: _____

11. Other illnesses at the time of vaccination and up to one month prior: _____

12. Chronic or long-standing health conditions: _____

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) _____
Relation to patient: Healthcare professional/staff Patient (yourself)
 Parent/guardian/caregiver Other: _____
Street address: _____ Check if same as item 1.
City: _____ State: _____ ZIP code: _____
Phone: _____ Email: _____

14. Best doctor/healthcare professional to contact about the adverse event: Name: _____
Phone: _____ Ext: _____

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: _____
Fax: _____
Street address: _____ Check if same as item 13.
City: _____
State: _____ ZIP code: _____
Phone: _____

16. Type of facility: (Check one).
 Doctor's office or hospital
 Pharmacy or drug store
 Workplace clinic
 Public health clinic
 Nursing home or senior living facility
 School/student health clinic
 Other: _____
 Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED 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 vaccine was given). Use Continuation Page if needed. Dose no. in series

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Use Continuation Page if needed.

19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use Continuation Page if needed.

20. Has the patient recovered from the adverse event(s)?: Yes No Unknown

21. Result or outcome of adverse event(s): (Check all that apply).
 Doctor or other healthcare professional office/clinic visit
 Emergency room or emergency department visit
 Hospitalization: Number of days (if known) _____
Hospital name: _____
City: _____ State: _____
 Prolongation of existing hospitalization (vaccine received during existing hospitalization)
 Life threatening illness (immediate risk of death from the event)
 Disability or permanent damage
 Patient died: Date of death _____ (mm/dd/yyyy)
 Congenital anomaly or birth defect
 None of the above

ADDITIONAL INFORMATION (Use Continuation Page if needed).

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series

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).
 No Unknown Yes _____

24. Patient's race: American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander
(Check all that apply). White Unknown Other: _____

25. Patient's ethnicity: Hispanic or Latino Not Hispanic or Latino Unknown 26. Immuniz. proj. report no.: (Health Dept use only). _____

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: Active duty Reserve National Guard Beneficiary Other: _____ 28. Vaccinated at Military/DoD site: Yes No

17. Enter all vaccines given on the date listed in item 4 (continued):

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series

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	Dose no. in series

Use the space below to provide any additional information (indicate Item number):

RETURN TO PAGE 1

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 report is about a vaccine given to a pregnant woman, 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, intradermal, jet injection, and unknown)
 - By mouth/oral
 - Other (specify)
 - In nose/intranasal
 - Unknown

For body site, the options include:

- Right arm
- Left arm
- Arm (side unknown)
- Right thigh
- Left thigh
- Thigh (side unknown)
- Nose
- Mouth
- Other (specify)
- 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 no. 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.