

*epi*TRENDS

A Monthly Bulletin on Communicable Disease Epidemiology and
Public Health Practice in Washington State

Reporting Adverse Events from Vaccines

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A new influenza A virus strain, first identified in April 2009, has now caused a global pandemic. This strain is not included in this year's seasonal influenza vaccines. Immunization with a vaccine specifically for this new 2009 H1N1 influenza virus will be the major disease control measure for this new virus.



Influenza vaccine
Image courtesy of CDC

Production of the 2009 H1N1 monovalent influenza vaccine uses the same manufacturing processes and quality testing used for all seasonal influenza vaccines. In addition, the new vaccine is administered at the same dosage and uses the same diluent as current seasonal influenza vaccines. In 2009, all seasonal and pandemic influenza vaccines in the United States will be produced from egg cultures; none contain an adjuvant. As a result, this 2009 H1N1 influenza vaccine has the same precautions and contraindications as the current seasonal influenza vaccine and has been approved for use by the U.S. Food and Drug Administration using the same criteria as for seasonal influenza vaccine.

More testing has been done for the 2009 H1N1 vaccine than is usually done for seasonal influenza vaccine. This testing has been to determine the proper administration intervals relative to seasonal influenza vaccine administration and immunogenicity.

The Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is the primary system to collect and analyze voluntary reports of adverse events following receipt of 2009 H1N1 monovalent vaccine. VAERS is a national program that monitors the safety of vaccines after they are licensed. VAERS is managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA).

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Influenza vaccines prevent infection, serious illnesses and death in persons who receive them. Despite this clear benefit, anyone who receives flu vaccine should still be informed about both the benefits and risks of vaccination. Each year, after an influenza vaccine is licensed, VAERS has been used as one way to monitor the “adverse events” that happen after influenza vaccination.

Guillain-Barré Syndrome (GBS), an autoimmune disease in which the body damages its own nerves to cause muscle weakness and paralysis, has been reported as a possible complication of influenza, influenza-like illness due to other viruses, and influenza vaccine. The risk of GBS after influenza vaccine is estimated to be only 0.1 per 100,000 vaccine doses. For comparison, the incidence of GBS after influenza-like illness is more than 10 times greater than GBS after influenza vaccine and the overall risk of death due to influenza-specific illness is 120 per 100,000 infections.

**Most Frequently Reported Adverse Events
(VAERS) Following TIV *
1990 – 2008**

**Serious AEs
(N = 3199)**

- Guillain-Barré-syndrome (20%)
- Fever (19%)
- Asthenia (17%)
- Paresthesia (14%)
- Pain (13%)

**Non-serious AEs
(N = 21549)**

- Pain (17%)
- Fever (16%)
- Injection site pain (14%)
- Pruritus (12%)
- Myalgia (10%)

* Trivalent Inactivated Influenza Vaccine
Source: CDC Immunization Safety Office

***epi*TRENDS
Monthly Posting
Alert**

To receive monthly e-mail notification of *epi*TRENDS, please register at this website:

[http://
listserv.wa.gov/
archives/
epitrends.html](http://listserv.wa.gov/archives/epitrends.html)

Choose the option to join the listserve. Enter your name and email address.

Since 1990, VAERS has been used to continuously monitor the occurrence of GBS following receipt of influenza vaccine. CDC’s Advisory Committee on Immunization Practices has reviewed these data and has stated that the potential benefits in preventing serious illness and death greatly outweigh the risk of developing GBS related to flu vaccine.

In addition to VAERS, several other adverse event monitoring systems have been established (http://www.cdc.gov/h1n1flu/vaccination/vaccine_safety_qa.htm).

Despite this history of safety, because no vaccine (or medicine) is completely free of risk, adverse events are possible and should be monitored. Some of these adverse events are so rare that, even with careful studies before licensing, adverse events may not be found until a vaccine is given to millions of people.

Adverse events following receipt of a licensed vaccine should be reported through VAERS. Patients, parents, vaccine manufacturers, health care providers and others can submit a report. FDA and CDC encourage anybody who experiences any problems after vaccination to provide a VAERS report. Healthcare providers are required by law to report certain problems such as an adverse event listed by the vaccine manufacturer as a contraindication to receiving further doses of the vaccine or as a specific severe reaction associated with a particular vaccine.

By continual monitoring, VAERS helps to make sure that the benefits of vaccines are far greater than the risks. However, VAERS is unable to determine whether a vaccine actually caused a reported adverse event. Sometimes people who are vaccinated get sick from another reason unrelated to the vaccine. Despite this limitation, the reports to VAERS give FDA and CDC important information that might signal a problem with a vaccine. In some cases FDA and CDC investigate the reports further.

Influenza Vaccination Cards

CDC has packaged influenza vaccination cards that will be sent to vaccine providers at the same time 2009 H1N1 monovalent vaccine is distributed. CDC encourages the use of these cards throughout the country. All vaccine and healthcare providers, the vaccinee, and other partners should be aware of the important information included on them.

These cards contain space to document influenza vaccination location, date, vaccine type, lot number and dose. The cards will also be pre-populated with key information regarding an adverse event and how to report clinically significant adverse events to VAERS.

The cards are intended to be given to the vaccinee (or parent or caregiver) when they receive their first 2009 H1N1 monovalent vaccination. They should be kept by the vaccinee for one year after they receive their last influenza vaccine in the 2009-10 season.

Influenza Vaccination Record	
Provider: (name, address, phone)	
Full name / Nombre completo:	
Date of birth / Fecha de nacimiento:	__ / __ / __
	mm dd yy/aa

(side 1)

Influenza Vaccination Information				
Vaccine	Dose	Lot Number	Manufacturer	Date
2009 H1N1	1 st			__ / __ / __
Adjuvant				mm dd yy
2009 H1N1	2 nd			__ / __ / __
Adjuvant				mm dd yy
2009-2010 Seasonal	1 st			__ / __ / __
	2 nd			__ / __ / __
				mm dd yy

**Reminder! Return for a second dose! /
¡Recuerde! ¡Regrese por la segunda dosis!**

2009 H1N1 influenza vaccine Date/Fecha: __ / __ / __
Vacuna contra la influenza H1N1 2009

2009-2010 seasonal influenza vaccine Date/Fecha: __ / __ / __
Vacuna contra la influenza estacional 2009-2010

(side 2)

Reporting to VAERS

It is very easy to report to VAERS (<http://vaers.hhs.gov/esub/index#fax>).

Online: You can report on-line at <https://secure.vaers.org>

Reporting forms: Report forms are available for printing at www.vaers.hhs.gov/resources/vaers_form.pdf or by calling the VAERS information line at 1-800-822-7967 (9:00 a.m. to 5:00 p.m. Eastern time Monday through Friday)

Fax: Completed report forms can be faxed to 1-877-721-0366 or

Mail: Completed report forms can be mailed to:

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

After you submit a form, VAERS staff may contact you for additional information.

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

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 _____

Form completed by (Name): _____

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. (____) _____

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 event(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) 11. Adverse event onset Time (mm/ dd/ yy AM/ PM) (mm/ dd/ yy AM/ 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 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, medical conditions (specify) _____

20. Have you reported this adverse event previously? No To health department To doctor To manufacturer

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	_____	_____	_____

22. Birth weight _____ lb. _____ oz. 23. No. of brothers and sisters _____

24. Mfr./mm. prep. report no. _____ 25. Date received by mfr./mm. prep. _____

26. 15 day report? Yes No 27. Report type Initial Follow-Up

Health care providers and manufacturers are required by law (42 USC 90aa-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 (rev. 1)

"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. 1885 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 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.

Facsimile of both sides of the Vaccine Adverse Event Reporting System ("VAERS") form