



Public Health
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Region IV Public Health
Clark, Cowlitz, Skamania, Wahkiakum counties
and Cowlitz Tribe

Health Advisory

Please deliver a copy of the accompanying alert to each provider in your organization.

Thank you

Questions regarding this alert may be directed to the office of:

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Health Officer

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**Clark County Public Health
Cowlitz County Health Department
Skamania County Health Department
Wahkiakum County Department of Health and Human Services
(360) 397-8412
Please Distribute**

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for specific incident for situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; no immediate action necessary.



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HEALTH ADVISORY

2 February 2010

This Advisory has three purposes:

- 1. To inform healthcare providers about non-safety related voluntary recalls of certain lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) vaccine and one lot of Sanofi Pasteur H1N1 vaccine for older children and adults (0.5 mL) in single-dose pre-filled syringes**
- 2. To inform healthcare providers about the acyclovir shortage**
- 3. To inform healthcare providers about the reinstatement of universal purchase of all childhood vaccines in Washington**

Non-safety related voluntary recalls of certain lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) vaccine and one lot of Sanofi Pasteur H1N1 vaccine for older children and adults (0.5 mL) in single-dose pre-filled syringes

In performing routine, ongoing testing of vaccine, Sanofi Pasteur has found that it has distributed five additional lots of single-dose, pre-filled syringe pediatric (0.25 mL) vaccine and one additional lot of single-dose pre-filled syringe vaccine for older children and adults (0.5 mL) with antigen content slightly lower than required potency levels. The manufacturer is now conducting a non-safety related voluntary recall of these affected lots of vaccine. They include:

- 0.25 mL pre-filled syringes, 10-packs (NDC # 49281-650-25, sometimes coded as 49281-0650-25): UT023AA, UT023BA, UT023CA, UT023EA, UT023FA
- 0.5 mL pre-filled syringes, 25-packs (NDC # 49281-650-90, sometimes coded as 49281-0650-90): UT037AA

25,800 doses of 0.25mL H1N1 pediatric vaccine and 1,500 doses of 0.5mL H1N1 vaccine with these lot numbers were shipped to Washington State local health jurisdictions, including Region IV health departments, and providers between 11/09/09 –12/27/09. While the potency of these lots is now below the manufacturer's specification for the product, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have not identified any safety concerns. You do not need to revaccinate children and adults who have already received vaccine from these lots as the amount of antigen decline is small and the CDC expects the slightly reduced concentration of antigen in these lots will be effective in stimulating a protective response. However, as is recommended for all 2009 H1N1 vaccines, all children less than 10 years old should get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response. So, children less than 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.

In the meantime, please do not use any additional vaccine from the six recalled lots. Instead, when vaccinating children 6 months of age and older, use the vaccine available in multidose vials. This vaccine is safe and effective vaccine for children. One difference between vaccine in pre-filled syringes and the multidose vials is that the multidose vials contain a preservative (thimerosal). The standard dose for this preparation for administration to infants 6-35 months old is the same as for the pre-filled syringes, 0.25 mL. For healthy children at least 2 years of age, the nasal spray (live, attenuated influenza vaccine) is also an option. The nasal spray vaccine produced in single units does not contain thimerosal.

Please do not dispose of any unused vaccine from these six lots. We will notify any healthcare providers who received any of the recalled vaccine and provide them with directions on how to return unused vaccine to the manufacturer, Sanofi Pasteur. We will also continue to keep you informed through these advisories and through our website as www.flunewssouthwestwashington.org

For more information:

- For questions and answers related to the withdrawn vaccine see http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm.
- Call CDC's toll-free information line, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, which is available 24 hours a day, every day.

Acyclovir shortage

On January 21, 2010, the FDA reported a shortage of acyclovir, a recommended therapy for genital herpes. Acyclovir tablets are currently available in limited supplies. The availability may vary in different geographic locations. For additional information about the availability of acyclovir, visit the FDA Drug Shortage Web site at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm>. The CDC has published an alert on its Web site at www.cdc.gov/std/treatment. The CDC Web site includes links to additional information, including other recommended therapies for genital herpes. Guidance on these recommended therapies is included in the 2006 STD Treatment Guidelines at <http://www.cdc.gov/std/treatment/2006/genital-ulcers.htm#genulc3>. CDC will continue to publish updates, which we will share with you as new information becomes available.

Reinstatement of universal purchase of all childhood vaccines in Washington

Due to a committed private and public partnership, Washington State's vaccine program will become a universal purchase program for **all** childhood vaccines again on May 1, 2010. Starting May 1, 2010, Washington providers enrolled in the Childhood Vaccine Program will not need to purchase any private childhood vaccines for children 0-18 years of age. The universal purchase system will cover all childhood vaccines, **including HPV and influenza** for children less than 19 years of age. We understand that providers will have questions about implementation, including billing and coding. At this time, we believe the new system will be similar to the current system, but we will keep you informed with updated advisories as we learn more.

Alan Melnick, MD, MPH, CPH
Region IV Health Officer