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Non-Safety-Related Voluntary Recall: Certain Lots of sanofi pasteur H1N1 Pre-Filled Syringes (0.25 mL, for 6-35 month olds) Questions & Answers

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On December 15, the CDC announced that certain lots of sanofi pasteur's H1N1 vaccine packaged as pre-filled 0.25mL syringes were being recalled. There are no safety or efficacy issues with these lots, and all other brands and presentations of H1N1 vaccine are entirely unaffected. The Q&A about this recall were adapted from: http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm

Why are some lots of sanofi pasteur's pediatric H1N1 vaccine in pre-filled syringes being recalled?

Background: After its influenza A (H1N1) vaccine has been shipped to providers, sanofi pasteur routinely tests the vaccine's *stability* on an ongoing basis, which means measuring the potency (strength) of a vaccine over time. These tests are performed because sometimes the strength of a vaccine can go down over time.

Through this testing, sanofi pasteur found that four lots of pediatric syringes had an antigen content that had dropped below pre-specified limits after distribution, meaning that doses from these four vaccine lots no longer meet the manufacturer's specifications for potency.

What does potency mean for the H1N1 vaccine?

Potency is determined by the measurement of the concentration of antigen(the active ingredient) in the H1N1 vaccine.

Are there any concerns about safety of vaccines from these lots?

No. There are no safety concerns with these lots of H1N1 vaccine. All lots successfully passed pre-release testing for purity, potency and safety.

Should infants and children who received vaccines from these lots be revaccinated?

No. The vaccine potency is only slightly below the "specified" range. The vaccine in these lots is still expected to be effective in stimulating a protective response despite this slight reduction in the concentration of antigen. ***There is no need to re-administer a dose to those who received vaccine from these lots.*** However, as is recommended for all 2009 H1N1 vaccines, all children who were less than 10 years old at the time they received their first H1N1 vaccine should get the recommended second doses of H1N1 vaccine approximately a month later for the optimal immune response. Therefore, children who were less than 10 years old at the time they received their first H1N1 vaccine and have received only one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.

What is the message to parents?

The message regarding this recall is two-fold:

1. There are no safety or efficacy issues with this or any other H1N1 vaccine.
2. Parents of children who received vaccine from the recalled lots do not need to take any action, unless the child needs two doses and has not yet completed their two-dose H1N1 series.

What are the lot numbers affected by this recall?
Vaccine doses with the following lot numbers are included in the recall:

- 0.25 ml pre-filled syringes, 10-packs (NDC # 49281-650-25, sometimes coded as 49281-0650-25):
  - **UT023DA**
  - **UT028DA**
  - **UT028CB**
- 0.25 ml pre-filled syringes, 25-packs (NDC # 49281-650-70, sometimes coded as 49281-0650-70):
  - **UT030CA**

Are other H1N1 vaccines affected by this same issue?
The potency problem described here is specific to the four lots of sanofi pasteur's pediatric H1N1 vaccine in 0.25 mL pre-filled syringes. sanofi pasteur is investigating what caused the problem. The same vaccine packaged in other dosing forms, such as pre-filled syringes for older children, adults, and multi-dose vials, continues to meet specifications.

Also, this recall does not affect H1N1 vaccine produced by other manufacturers.

Were these lots of vaccine shipped after failing a required test?
No. The lots being recalled passed all quality controls and met all specifications before they were shipped. All vaccines are routinely tested for purity, potency and safety prior to release. The four lots of vaccine met all required specifications at the time of release and shipment to distribution centers.

What is the Philadelphia Immunization Program doing for providers who received vaccine from the affected lots?
The Immunization Program will pick up any vaccine from the affected lots and replace those doses with a similar, unaffected product (you may receive MDV from another manufacturer, for example). In the next few days, you will receive a packet of information from sanofi asking you to return affected lots back to the manufacturer. **Do not send affected lots back to sanofi.**

For all Philadelphia providers with affected lots, the Immunization program will be sending out Immunization staff to retrieve affected lots and replace them with H1N1 vaccine immediately. This way, providers do not have to wait to receive replacement vaccine from sanofi, but instead, providers are immediately replenished so that they can continue to vaccinate children in need of H1N1 vaccine.

What should we do with vaccine from the affected lots?
First, identify any affected vaccine and set it aside, clearly marking it "DO NOT USE." Although sanofi pasteur may send you instructions for returning vaccine to them, providers participating in Philadelphia's H1N1 Vaccine Program should hold affected lots until pickup.

Is this a local issue?
No, vaccine from these four lots was distributed throughout the United States – about 800,000 doses.

For U.S. children 6-35 months old, what other options are available currently for vaccination against H1N1 influenza?
For children 6 months of age and older, vaccine is available in multidose vials. The vaccine in multidose vials has not experienced this drop in potency and meets all standards of safety, purity and potency. As with all multidose vials of vaccines, these multidose vials contain a preservative (thimerosal) to prevent potential contamination after the vial is opened. The standard dose for this preparation in the 6-35 month age group 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. This vaccine is produced in single-units that do not contain thimerosal. However, it is important that children receive both doses of H1N1 vaccine from the same type of vaccine (both doses as inactivated, injectible, or both doses as live, attenuated, nasal spray vaccine).