SAN JOAQUIN COUNTY PUBLIC HEALTH SERVICES FOLLOW-UP OF THE NON-SAFETY RELATED VOLUNTARY RECALL OF CERTAIN LOTS OF H1N1 NASAL SPRAY VACCINE

This San Joaquin County Public Health Services Media Advisory addresses the Centers for Disease Control and Prevention (CDC) non-safety related voluntary recall of certain lots of MedImmune’s nasal spray monovalent 2009 H1N1 influenza vaccine. The purpose of the recall is to remove from future use any unused H1N1 nasal spray flu vaccine from several specified lots or batches, as they have lost some of their effectiveness or potency since being distributed.

Persons who received this H1N1 nasal spray vaccine should not be concerned about this recall. No additional action or medical follow up is needed. Regardless of the current recall, it is recommended that children under 10 year of age who receive H1N1 influenza vaccination (either nasal spray or injection) get a second dose approximately 4 weeks after the first dose.

On Dec 18 and 21, the manufacturer notified CDC and the Food and Drug Administration (FDA) that the potency in 13 batches (called "lots") of nasal spray H1N1 flu vaccine had decreased below the pre-specified limit or were at risk of falling below the limit within the upcoming weeks. Potency, or strength, is determined by the measurement of the concentration of the active component in the 2009 H1N1 vaccine. While vaccines are distributed by the manufacturer with an anticipated expiration date, they are routinely checked in advance of the posted date to ensure that they remain potent. In this case, several batches of H1N1 nasal spray, or flu mist, lost their potency sooner than expected. Any unused vaccine in these batches is recalled by the manufacturer.

San Joaquin County Public Health Services reviewed its H1N1 vaccine inventory records and determined that it and several other local providers had received vaccine from some of the affected batches during the past few months. Much of the vaccine received here that was in these lots is likely to have been fully potent at the time of dispensing. The CDC says that the vaccine in the recalled lots is still expected to be effective in stimulating a protective response, and the vaccine dose does not need to be repeated. Nor does it pose a health threat to the recipients.

Attached is a copy of the CDC Questions and Answers fact sheet entitled “Voluntary Non-Safety-Related Recall of Specific Lots of Nasal Spray Vaccine for 2009 H1N1 Influenza”. For more information, and complete details on the recall including lot numbers go to http://www.cdc.gov/h1n1flu/

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VOLUNTARY NON-SAFETY-RELATED RECALL OF SPECIFIC LOTS OF NASAL SPRAY VACCINE FOR 2009 H1N1 INFLUENZA

Questions and Answers

Why are some lots of the nasal spray 2009 H1N1 flu vaccine being recalled from the market?

As part of its quality assurance program, the manufacturer of the nasal spray monovalent 2009 H1N1 flu vaccine, MedImmune, performs routine, ongoing stability testing of the vaccine. Stability testing means measuring the strength (also called potency) of the vaccine over time to make sure it does not go below a pre-specified limit during the vaccine’s “shelf life”. On December 18 and 21, the manufacturer notified CDC and FDA that the potency in 13 batches (called “lots”) of nasal spray vaccine had decreased below the pre-specified limit or were at risk of falling below that limit within the upcoming week. The vaccine was within the specified range at the time the vaccine was distributed. The slight decrease in potency should not affect how the vaccine works. However, the manufacturer will send providers directions for returning any unused vaccine from these lots.

What does potency mean for the nasal spray 2009 H1N1 vaccine?
Potency (or strength) is determined by the measurement of the concentration of the active component in the 2009 H1N1 vaccine.

Are there any concerns about safety of vaccines from these lots?
No. There are no safety concerns with these lots of 2009 H1N1 vaccine. All lots successfully passed pre-release testing for safety, purity and potency.

Should people who received vaccines from these lots be revaccinated?
No. The vaccine potency is or will soon be only slightly below the limit. In addition, much of this vaccine has already been administered while fully potent and within specifications. The vaccine in these lots is still expected to be effective in stimulating a protective response. There is no need to re-administer a dose to those who received vaccine from these lots.

What action(s) should persons who have received vaccine from the recalled lots take?
Persons who received vaccine from the recalled lots do not need to take any special actions. As is recommended for all 2009 H1N1 vaccines, all children younger than 10 years old should get the recommended two doses of 2009 H1N1 vaccine approximately a month apart for the optimal immune response. Therefore, children younger than 10 years old who have only received one dose of the nasal spray vaccine thus far should still receive a second dose of 2009 H1N1 vaccine. It is best to use the same type of vaccine for the first and second dose.

What are the affected lot numbers?
The affected lot numbers are:
- 500754P
- 500751P
- 500756P
- 500757P
How many doses are in these lots?
There were approximately 4.7 million doses in these lots that were distributed to providers. Most of the doses were shipped to vaccine providers in October and early November, during a time when the vaccine potency was still at or above the recommended level. The manufacturer is recalling any doses from these lots that may still be unused.

Is the potency issue related to this recall isolated to just the 13 lots of nasal spray vaccine?
The voluntary recall described here is specific to the 13 lots of nasal spray 2009 H1N1 flu vaccine noted above. Subsequent lots of the vaccine were produced with a slightly higher potency to decrease the chance that they would fall “below specification” before their expiration dates. As per their routine practice, the manufacturer will continue to monitor the potency of those lots, and will notify healthcare providers if the shelf life of any additional lots is shorter than expected.

This recall does not affect 2009 H1N1 vaccine produced by other manufacturers. However, a similar recall was conducted recently which involved lots of Sanofi Pasteur’s pediatric 2009 H1N1 vaccine in 0.25 mL pre-filled syringes.

What testing was performed on these lots of vaccine before they were released?
Before they were shipped, the lots being recalled now passed all quality controls and met all specifications for safety, purity, and potency.