

There has been a recent recall of some H1N1 vaccine for pediatric patients due to potency concerns. It has been confirmed that Dupage Medical Group had a very small amount of the affected vaccine, with the lot number UTO28DA. Children who have been vaccinated with the vaccine are not at risk, and do not need to "re-do" their immunization. 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.

Below are some common questions regarding this recall.

For more information, please visit:

http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm

Why are some lots of pediatric H1N1 vaccine manufactured by Sanofi Pasteur in pre-filled syringes being recalled from the market?

As part of its quality assurance program, the manufacturer, Sanofi Pasteur, performs routine, ongoing stability testing of its influenza A (H1N1) vaccine after the vaccine has been shipped to providers. Stability testing means measuring the strength (also called potency) of a vaccine over time. It is performed because sometimes the strength of a vaccine can go down over time. On December 7, Sanofi Pasteur notified CDC and FDA that the potency in one batch (called a "lot") of pediatric syringes that had been distributed was later found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed also had an antigen content that, while properly filled at the time of manufacturing, was later measured to be below pre-specified limits. This means that doses from these four vaccine lots no longer meet the manufacturer's specifications for potency. Sanofi Pasteur will send providers directions for returning any unused vaccine from these lots.

What does potency mean for the H1N1 vaccine?

Potency (or strength) is determined by the measurement of the concentration of the active ingredient (also called antigen) 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 less than 10 years old should get the recommended two doses of H1N1 vaccine approximately a month

apart for the optimal immune response. Therefore, 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.

What action(s) should parents of children who have received vaccine from the recalled lots take?

Parents of children who received vaccine from the recalled lots do not need to take any action, other than to complete the two-dose immunization series if not already completed.