



**Indiana State
Department of Health**
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I want to reassure parents the recent recall of some lots of the 2009 H1N1 flu vaccine is NOT due to safety concerns. According to the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), there is also no need to re-vaccinate persons who have received the vaccine from these lots. Indiana received about 10,000 doses of the affected lots, and the Indiana State Department of Health is working closely with local health departments and other providers of the H1N1 flu vaccine to locate any unused vaccine from the affected lots that have been shipped to Indiana, so they can be returned to the manufacturer.

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. These vaccine lots were routinely tested after distribution and were found to have a decreased level of antigen, which decreases the potency of the vaccine. The slightly reduced concentration of vaccine antigen found in retesting these lots is still expected to be effective in stimulating a protective response.

Again, 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. 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.

Sanofi Pasteur has discontinued distribution of the 0.25 mL syringes of H1N1 pediatric vaccines. For children 6 months of age and older, vaccine is available in multi-dose vials. The vaccine in multi-dose vials is safe and effective vaccine for children. One difference between vaccine in pre-filled syringes and the multi-dose vials is that the multi-dose vials contain a preservative (thimerosal) to prevent potential contamination after the vial is opened. 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 is produced in single units that do not contain thimerosal.

State Health Commissioner Judy Monroe, M.D.