

Cook County Department of Public Health

Thimerosal and Influenza Vaccines

What is thimerosal?

Thimerosal is a mercury-based preservative that has been used for decades in the United States in multi-dose vials (vials containing more than one dose) of some vaccines to prevent the growth of microorganisms, such as bacteria and fungi, which may contaminate them.

Thimerosal is a very effective preservative that has been used since the 1930s to prevent contamination in some multi-dose vials of vaccines (preservatives are not required for vaccines in single dose vials). Thimerosal contains approximately 49% ethylmercury. There is no convincing evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site. However, in July 1999 the Public Health Service (PHS) agencies, the American Academy of Pediatrics (AAP), and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precaution.

I have concerns about the use of thimerosal. Is thimerosal still being used?

People have a right to expect the vaccines they receive are safe and effective. CDC and FDA also hold vaccines to the highest standards of safety. That is why CDC and FDA continually evaluate new scientific information about the safety of vaccines. Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative, and all vaccines routinely recommended by CDC for children under six years of age have been thimerosal-free, or contain only trace amounts, except for multi-dose formulations of influenza vaccine. This was done as a precautionary step and not because there was evidence confirming that thimerosal-containing vaccines were causing health problems. The most recent and rigorous scientific research does not support the hypothesis that thimerosal-containing vaccines are harmful.

Thimerosal is an important preservative that protects vaccines against potential microbial contamination, which may occur in opened multi-dose vials of vaccine. Such contamination could cause serious illness or death. Since seasonal influenza vaccine is produced in large quantities for annual immunization campaigns, some of the vaccine is produced in multi-dose vials, and contains thimerosal to safeguard against possible contamination of the vial once it is opened.

Three leading federal agencies (CDC, FDA, and NIH) have reviewed the published research on thimerosal and found it to be a safe product to use in vaccines. Three independent organizations [The National Academy of Sciences' Institute of Medicine, Advisory Committee on Immunization Practices (ACIP), and the American Academy of Pediatrics (AAP)] reviewed the published research and also found thimerosal to be a safe product to use in vaccines. The scientific community supports the use of thimerosal in influenza vaccines.

Is it safe for children to receive an influenza vaccine that contains thimerosal?

Yes. There is no convincing evidence of harm caused by the small amount of thimerosal in vaccines, except for minor effects like swelling and redness at the injection site due to sensitivity to thimerosal. Most importantly, since 1999, newly formulated thimerosal preservative-free childhood vaccines (Hepatitis B, Hib, and DTaP) have been licensed. With the newly formulated childhood vaccines, the maximum total exposure during the first six months of life will now be less than three micrograms of mercury. Based on guidelines established by the FDA, the Environmental Protection Agency (EPA) and the Agency for Toxic Substances and Disease Registry (ATSDR), no child will receive excessive mercury from childhood vaccines regardless of whether or not their flu shot contains thimerosal as a preservative.

Vaccination with either reduced or standard thimerosal-content flu vaccine is recommended for children between the ages of 6 and 59 months by CDC's Advisory Committee on Immunization Practices.

Is it safe for pregnant women to receive an influenza vaccine that contains thimerosal?

Yes. Because pregnant women are at increased risk for influenza-related complications and because a substantial safety margin has been incorporated into the health guidance values for organic mercury exposure, the benefits of influenza vaccine with reduced or standard thimerosal content outweighs the theoretical risk, if any, of thimerosal.

Does the 2009 H1N1 influenza vaccine contain thimerosal?

The 2009 H1N1 influenza vaccines that FDA is licensing (approving) will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a preservative. Multi-dose vials of seasonal influenza vaccine also contain thimerosal to prevent potential contamination after the vial is opened.

Some 2009 H1N1 influenza vaccines will be available in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal.

Does thimerosal cause autism?

There is no conclusive evidence that any vaccine or vaccine additive increases the risk of developing autism or any other behavior disorder. Rather, evidence is accumulating of lack of any harm resulting from exposure to vaccine containing-thimerosal as a preservative. In a 2004 report, the Institute of Medicine (IOM) concluded that there is no association between autism and vaccines that contain thimerosal as a preservative.

Nonetheless, given the level of concern among parents and others regarding vaccines and autism, the CDC is committed to investigating this issue to the fullest extent possible, using the best scientific methods available.

References:

<http://www.cdc.gov/vaccinesafety/updates/thimerosal.htm>

<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228>

http://www.cdc.gov/vaccinesafety/updates/thimerosal_faqs_thimerosal.htm

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

<http://www.iom.edu/Reports/2004/Immunization-Safety-Review-Vaccines-and-Autism.aspx>

http://www.immunizationinfo.org/immunization_science.cfm?cat=1

TABLE. Seasonal Influenza Vaccine Manufacturers for the 2009-2010 Influenza Season

| Manufacturer | Vaccine | Formulation | Thimerosal preservative | Age indication |
|--|---------------------------------|---|--|-----------------------------|
| sanofi pasteur, Inc. | Fluzone®, Inactivated TIV | Multi-dose vial | Yes | 6 months and older |
| | | Single-dose pre-filled 0.25 mL syringe | None | 6-35 months |
| | | Single-dose pre-filled 0.5 mL syringe or vial | None | 36 months and older |
| Novartis Vaccine (formerly Chiron Corporation) | Fluvirin® Inactivated TIV | Multi-dose vial | Yes | 4 years and older |
| | | Single-dose pre-filled 0.5mL syringe | Preservative free (1 mcg or less mercury/0.5mL dose) | 4 years and older |
| MedImmune Vaccines, Inc. | FluMist® LAIV | Single-dose sprayer | None | Healthy* persons 2-49 years |
| CSL Biotherapies | Afluria® Inactivated TIV | Single-dose pre-filled 0.5mL syringe | None | 18 years and older |
| | | Multi-dose vial | Yes | 18 years and older |
| GlaxoSmithKline Biologicals (subsidiary of GlaxoSmithKline PLC) | Fluarix™ Inactivated TIV | Single-dose pre-filled 0.5 mL syringe | Preservative free (1 mcg or less mercury/0.5mL dose) | 18 years and older |
| ID Biomedical Corporation (subsidiary of GlaxoSmithKline PLC) | FluLaval™ Inactivated TIV | Multi-dose vial | Yes | 18 years and older |