



Seasonal Influenza (Flu)

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2011-2012 Flu Season

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Thimerosal and 2011-2012 Seasonal Flu Vaccines

Questions & Answers

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 germs, bacteria and fungi, that can contaminate them.

What are preservatives and why are they sometimes used in vaccines?

Preservatives have been used in vaccines for more than 70 years and are added to vaccines to prevent the growth of bacteria or fungi that could possibly make the vaccine in multi-dose vials unsafe. This may occur when a syringe needle enters a vial as a vaccine is being prepared for administration. Contamination by germs in a vaccine could cause serious infections.

Do the 2011-2012 seasonal flu vaccines contain thimerosal?

The Food and Drug

Join William L. Atkinson, MD as he discusses the safety profiles of licensed influenza vaccines as well as how to screen for contraindications and precautions.

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Administration (FDA) has approved several formulations of the seasonal flu vaccine, including multi-dose vials and single-dose units. (See [Table of Approved Influenza Vaccines for the U.S. 2011-2012 Season](#).) 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.

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The single-dose units are made without thimerosal as a preservative because they are intended to be opened and used only once. Additionally, the live-attenuated version of the vaccine (the nasal spray vaccine), is produced in single-dose units and does not contain thimerosal.

Is thimerosal being used in other 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 younger than 6 years of age have been thimerosal-free, or contain only trace amounts of thimerosal, except for multi-dose formulations of influenza vaccine. The most recent and rigorous scientific research does not support the argument that thimerosal-containing vaccines are harmful. However, CDC and FDA continually evaluate new scientific information about the safety of vaccines.

Is thimerosal in vaccines safe?

Yes. There is a large body of scientific evidence on the safety of thimerosal. Data from several studies show the low doses of thimerosal in vaccines do not cause harm, and are only associated with minor local injection site reactions like redness and swelling at the injection site.

Three U.S. health agencies (The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (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 medical community supports the use of thimerosal in influenza vaccines to protect against potential bacterial contamination of multi-dose vials.

Is thimerosal in vaccines linked to autism?

Numerous studies have found no association between thimerosal exposure and autism. CDC places a high priority on vaccine safety, surveillance, and research. CDC is aware that the presence of the preservative thimerosal in vaccines and allegations of a relationship to autism have raised public concerns. These concerns have made decisions surrounding vaccinations confusing and difficult for some people. 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 younger than 6 years of age have been thimerosal-free, or contain only trace amounts of thimerosal, except for some formulations of influenza vaccine. Unfortunately, reductions in the numbers of children identified with autism have not been observed indicating that the cause of autism is not related to a single exposure such as thimerosal.

The federal government is committed to ensuring the safety of vaccines. This is achieved by FDA oversight of rigorous pre-licensure trials and post-licensure monitoring by CDC and FDA. This commitment stems from scientific, medical and personal dedication.

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