

General Questions and Answers on Thimerosal

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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.

What are preservatives and why are they used in vaccines?

In vaccines, preservatives are used to prevent the growth of bacteria and fungi in the event that they get into the vaccine. 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 illness or death. In some vaccines, preservatives are added during the manufacturing process to prevent microbial growth.

Will 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 vaccine manufacturers will be producing 2009 H1N1 influenza vaccine 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.

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 thimerosal safe when used as a preservative in vaccines?

CDC places a high priority on vaccine safety, surveillance, and research. CDC is aware that the presence of the preservative thimerosal in vaccines and suggestions of a relationship to autism has raised concerns. These concerns make the decisions surrounding vaccinations confusing and difficult for some people, especially parents. Numerous studies have found no association between thimerosal exposure and autism. 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 some formulations of influenza vaccine. Unfortunately, we have not seen reductions in the numbers of children identified with autism indicating that the cause of autism is not related to a single exposure such as thimerosal.

The federal government is committed to assuring 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 not only stems from our scientific and medical dedication, it is also personal – for most of us who work at CDC are also parents and grandparents. We too, place tremendous value on the health and safety of children.