

Frequently Asked Questions on Thimerosal

The Minnesota Department of Health (MDH) encourages healthcare providers to talk with their patients or parents of patients on vaccine safety issues. Recently, many media sources have focused on the use of thimerosal in vaccines. To help you discuss this with your patients, MDH has put together this compilation of answers to frequently asked questions about thimerosal. You can use this for your reference. If you have further questions, please call the health department's immunization hotline at 651-201-5414 or 1-800-657-3970 and ask to talk with one of our vaccine safety staff persons.

What is thimerosal?

Thimerosal is an organic mercury-based preservative used in some vaccines since the 1930s to prevent contamination in vials containing multiple doses of a vaccine and other medical products. Thimerosal contains ethyl mercury. This is not the same as the methyl mercury found in fish or emitted by power plants.

Why was thimerosal added to vaccines, especially if it contained mercury?

Thimerosal has been one of the most widely used preservatives for multi-dose vials of vaccines to prevent contamination. Prior to its introduction in the 1930s, studies showed that in the small amounts used it was both safe and effective preventing growth of bacterial and fungus.

What does “trace amounts” of thimerosal in a vaccine mean and how is this different than thimerosal being used a preservative?

Thimerosal is still used in the early stages of manufacturing of a few vaccines to ensure the production line is sterile, but is removed through a purification process, with only trace, or insignificant, amounts remaining. This is different than the few vaccines that contain thimerosal as a preservative. The thimerosal in those vaccines is left in after production to prevent contamination when multi-dose vaccines are used.

Manufacturers are working to remove this trace amount even though the Food and Drug Administration (FDA) considers these vaccines thimerosal-free.

Why did the CDC recommend that thimerosal be removed from vaccines in 1999?

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 precautionary measure. This action was taken not because there were any indications that the amount of thimerosal in vaccines caused health problems, but because it was one of the few sources of mercury exposure that could be reduced.

Is there any thimerosal in vaccines today?

Today, with the exception of some flu vaccines, all routinely recommended vaccines for children under age 6 are thimerosal-free. There are a couple vaccines that continue to contain the preservative thimerosal, but they are not routinely given. They include a meningococcal vaccine, Japanese encephalitis, tetanus toxoid (Tt) for adults, and one of the Td vaccines for adults.



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Are older lots of pediatric vaccines that contain thimerosal as a preservative still on the shelves in doctor's offices?

The last lots of recommended childhood vaccines that contained thimerosal as a preservative expired by early 2003. If providers have such expired vaccines in their stocks, they should discard them.

Did the measles, mumps, and rubella (MMR) vaccine ever contain thimerosal?

No, the MMR vaccine does not and never did contain thimerosal. Varicella (chickenpox), inactivated polio (IPV), and pneumococcal conjugate vaccines have also never contained thimerosal.

Does the flu vaccine contain thimerosal?

Influenza (flu) vaccine is a new addition to the recommended childhood immunization schedule. For the 2005-2006 influenza season, there were 6-8 million doses of inactivated influenza vaccine without thimerosal as a preservative available in the United States. This represented a substantial increase in the available amount of inactivated influenza vaccine without thimerosal as a preservative, compared with about 3.2 million doses that were available during the 2003-04 influenza season.

The total amount of flu vaccine without thimerosal as a preservative will be increased as vaccine manufacturing capabilities are expanded. In the meantime, it is important to keep in mind that the benefits of influenza vaccination outweigh the theoretical risk, if any, for exposure to thimerosal. Each year, an average of about 36,000 people in the United States die from influenza, and 114,000 have to be admitted to the hospital as a result of influenza. People age 65 years and older, people of any age with chronic medical conditions, and very young children are more likely to get complications from influenza.

If I can't find a thimerosal-free flu shot for my baby, just how much mercury am I exposing my baby to?

There is 12.5 micrograms of mercury in a dose of thimerosal-containing flu vaccine that is given to infants. A can of tuna typically has about 11 micrograms. Breast milk contains between 1.4 to 1.7 micrograms of methyl mercury per liter. If a baby is fed exclusively up to six months, the baby will consume about 360 micrograms of mercury. Vaccines with trace amounts of thimerosal have 1 microgram or less of mercury.

I've heard that children may be getting toxic levels of mercury from vaccines. Is that true?

No. Even in 1999, when national officials recommended that thimerosal be removed from vaccines, they did so strictly as a precaution. The FDA calculated various weights of infants and various combinations of vaccine formulations and found that by six months old, some infants received a thimerosal dose that exceeded one of the three national guidelines for safe exposure to methylmercury. These guidelines are much lower than the toxic levels that would cause concern.

There is no evidence of harm caused by the minute doses 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-free vaccines have been licensed. With the newly formulated vaccines, the maximum cumulative exposure during the first six months of life will now be less than three micrograms of mercury if infants are given certain combination vaccines. This is 99.4% less than in 1999.

It is also important to remember we are all exposed to mercury through air, water, and the food we eat. Mercury coal powered plants are the greatest emitters of mercury pollution.

Does thimerosal cause autism or any other neurological disorders?

MDH has reviewed much of the science regarding this and has found no conclusive evidence that any vaccine or vaccine additive increases the risk of developing autism or any other behavior disorder. Rather, accumulating evidence indicates a lack of a connection between neurological disorders and 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.

What about the new study that claims that autism rates in California have declined at the same time that thimerosal was removed from vaccines?

Two outspoken critics of thimerosal, Dr. Mark and David Geier, recently published a study in the Journal of American Physicians and Surgeons reporting that two separate data sources showed decreases in autism during the period 2002-2005, after thimerosal was removed from all vaccines routinely administered to children during the first six months of life. They used the Vaccine Adverse Event Reporting System (VAERS) and quarterly data from the California Department of Developmental Services for their study.

There are two major problems that invalidate their results. First, VAERS data cannot be used to estimate the incidence of anything, especially autism. It is a passive reporting system. People report things to VAERS that they think might be caused by vaccines. If people think autism is related to vaccines they will report it.

Second, and more disconcerting, is their misinterpretation of the California autism data. The California data actually show no evidence of a decrease in autism, although the rate of increase has slowed.

What about the studies that prove that children with autism had high levels of mercury compared to children without autism? Doesn't that prove that thimerosal in mercury causes autism?

These studies demonstrate that children with autism may handle heavy metals differently. But there are several other considerations to think about regarding these studies. Most of the authors cite fish consumption as the most significant source of heavy metal exposure that has occurred in these children, not thimerosal in vaccines. They even state that they were not specifically finding an association between thimerosal in vaccines and autism. Also, some of the heavy metal testing that was done is not standardized, so its reliability may be of concern.

Why can't they just take thimerosal out of vaccines?

Vaccine manufacturing and product licensing is a long and complicated process intended to ensure the safety of vaccines. A manufacturer cannot just create a new vaccine or change an existing line in a few weeks. Manufacturers have worked as quickly as possible to reduce and/or eliminate thimerosal in vaccines given to children without reducing the vaccine supply, which could place infants and children at risk for potentially serious vaccine preventable diseases.

Why weren't thimerosal-containing vaccines taken off the market?

Scientific data have not established that vaccines containing thimerosal create an imminent or substantial hazard to public health or are in violation of FDA laws or regulations; therefore they do not justify such a recall. A mandatory recall requires that the product present “an imminent or substantial hazard to the public health.”

The FDA is responsible for voluntary and mandatory recalls of drug and vaccine products. They continuously monitor the safety of these products.

Is the Centers for Disease Control (CDC) studying this issue of thimerosal-containing vaccines and autism?

Yes. The CDC is conducting a study looking at children who received a lot of thimerosal from their vaccines, children who received a little thimerosal from vaccines, and children who received no thimerosal to determine if any of these groups had a higher incidence of autism. To do this, the CDC is using the Vaccine Safety Data Link, which contains information from three large HMOs around the country. They hope to have the results in two years.

For a comprehensive discussion about thimerosal in vaccines, see FDA's Website at www.fda.gov/cber and click on vaccines.
