

Immunisation: Myths and Realities supplement

Thiomersal and Vaccines

What is thiomersal?

Thiomersal is an organic compound containing 49.6% mercury by weight. It is known as 'thimerosal' in the USA. One of the chemical names for thiomersal, which best describes its composition, is Sodium Ethylmercuric Thiosalicylate. It has been used in very small amounts in vaccines since the 1930s, as it prevents bacterial and fungal contamination.

What is mercury poisoning?

Most of the scientific information on the harmful effects of mercury is based on the known effects of methylmercury, which is excreted very slowly from the body. Mercury poisoning can be acute, but usually results from repeated, chronic exposure to methylmercury. In humans, this is usually due to eating contaminated foods (mainly fish). Mercury poisoning affects the central nervous system, with symptoms such as lethargy, loss of appetite, weight loss, tremor, memory loss, sleep disturbance and confusion. It can also cause inflammation of the gums, loose teeth and a rash.

How much mercury causes poisoning?

Mercury causes poisoning only after it reaches a certain level in the body. The toxicity depends on the amount of mercury consumed in relation to body weight. Therefore, for a fixed amount of exposure to mercury, infants are at greater risk than adults.

Different expert bodies have determined that safe levels of mercury consumption lie somewhere between 0.7 to 3.3 micrograms of mercury per kilogram of body weight per week. The US Environmental Protection Authority (EPA) has set the lowest cut-off point at 0.7 micrograms of mercury per kilogram of body weight per week, and the World Health Organization (WHO) has suggested 3.3 micrograms per kilogram of body weight per week. These levels are considered to be as much as ten times below the upper safety margin.

Does thiomersal in vaccines cause mercury poisoning?

In the very low doses contained in vaccines, there is no evidence that thiomersal in vaccines causes mercury poisoning. In the body, thiomersal is converted to ethylmercury, which is thought to be similar to methylmercury, but is broken down and excreted more rapidly than methylmercury. As such, its potential to cause toxicity is less than that of methylmercury. There is no scientific evidence that thiomersal in vaccines causes any adverse health effects in children. However, the possibility exists that vaccination of newborn babies, particularly those who have a low birth weight, with repeated doses of thiomersal-containing vaccines, may result in levels of mercury that are above the recommended guidelines. Theoretically, such infants may therefore be at risk of adverse effects from mercury.

How much mercury exposure results from vaccines?

Not all vaccines contain thiomersal, and not all children get all vaccines. In the USA, it was calculated that if all thiomersal-containing vaccines are given, the total exposure to mercury in the first 6 months of life may exceed the EPA guidelines. A recent US study measured blood mercury levels before and after a dose of hepatitis B vaccine given at birth. This study found raised blood mercury levels after hepatitis B vaccination in babies, particularly premature babies, but the levels were within the 'normal' range defined by the US Department of Health and Human Services.

Which childhood vaccines contain thiomersal?

The current National Health and Medical Research Council (NHMRC) Australian Standard Vaccination Schedule for children under the age of 5 years includes only one vaccine that contains thiomersal. This vaccine is monovalent hepatitis B vaccine, which contains 25 micrograms of thiomersal per dose. However, a thiomersal-free product is now

available. Vaccines that contain hepatitis B in combination with other vaccines (eg Infanrix-HepB and Comvax) do not contain thiomersal.

In the past, the only other vaccine containing thiomersal that was used in all children under the age of 6 months was Triple Antigen (diphtheria-tetanus-whole cell pertussis vaccine). This vaccine was replaced with DTPa (diphtheria-tetanus-acellular pertussis vaccine) by July 1999. The powder-form of Pedvax Hib vaccine also contained thiomersal. Even if the maximum possible number of doses of these vaccines were given, it is unlikely that the WHO recommended limit of exposure per kilogram of body weight would have been exceeded.

What is being done to address this issue?

In July 1999, the US Food and Drug Authority (FDA) issued a directive to all vaccine manufacturers to remove thiomersal from all vaccines, or to justify its continued use. The Australian Therapeutic Goods Administration (TGA) has written to sponsors of all vaccines included on the Australian Standard Vaccination Schedule, requesting removal of thiomersal or minimisation of thiomersal content. In response, a thiomersal-free monovalent hepatitis B vaccine was introduced in May 2000, and an equivalent product was introduced in August 2000. It is important to note that, for babies at high risk of hepatitis B, the risk of hepatitis B is far greater than the risk of thiomersal, and vaccination should not be delayed in this group.

What about vaccines for adults?

The levels of mercury in adults resulting from thiomersal-containing vaccines (such as influenza vaccine) are so low that expert bodies do not recommend any change in policy.

Vaccines containing thiomersal, July 2000*

Vaccine	Manufacturer	Level of thiomersal
DTPw (Triple Antigen)	CSL	50 micrograms
Combined diphtheria and tetanus vaccine (CDT)	CSL	50 micrograms
Adult diphtheria and tetanus vaccine (ADT)	CSL	50 micrograms

Vaccine	Manufacturer	Level of thiomersal
Diphtheria vaccine	CSL	50 micrograms
Haemophilus influenzae B OMP (Pedvax Hib, lyophilised/powder form only)	Merck Sharpe Dohme	25 micrograms
Hepatitis B (Engerix B)	SmithKline Beecham	25 micrograms
All influenza vaccines	CSL, Aventis Pasteur, Ebos, SmithKline Beecham	5 – 50 micrograms
Japanese encephalitis vaccine (JE Vax)	CSL	35 micrograms
Meningococcal vaccine (Menomune)	CSL/Aventis Pasteur	50 micrograms
Q fever vaccine (Q Vax)	CSL	50 micrograms

* all other vaccines available in Australia at July 2000 were thiomersal free

For information on the Immunise Australia program

Phone the Immunisation Infoline on 1800 671 811
 Visit the Immunise Australia Website on
<http://immunise.health.gov.au>

Further reading

- Statement on thimerosal by David Satcher, M.D., Ph.D, US Surgeon General, Assistant Secretary for Health, Department of Health and Human Services, USA
<http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/default.htm>
- Thimerosal in vaccines: a joint statement of the American Academy of Pediatrics and the Public Health Service. *Morbidity and Mortality Weekly Report* 1999;48(26):563-5.
<http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/thimerosal-AAP&PHS.htm>
- Centers for Disease Control - Questions and Answers about Thimerosal
<http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/thimerosal.htm>
- Recommendations regarding the use of vaccines that contain thimerosal as a preservative. *Morbidity and Mortality Weekly Report* 1999;48(43):996-8.
<http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4843a4.htm>
- Halsey NA. Limiting infant exposure to thimerosal in vaccines and other sources of mercury [editorial]. *Journal of the American Medical Association* 1999;282(18):1763-6.
- From the Centers for Disease Control and Prevention. Availability of hepatitis B vaccine that does not contain thimerosal as a preservative. *Journal of the American Medical Association* 1999;282(13):1219-20.
- Clements CJ, Ball LK, Ball R, Pratt D. Thiomersal in vaccines. *Lancet* 2000;355:1279-1280.
- Stajich GV, Lopez GP, Harry SW, Sexson WR. Iatrogenic exposure to mercury after hepatitis B vaccination in preterm infants. *J Pediatrics* 2000;136: 679-681.



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