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## QUESTIONS AND ANSWERS

MAY 2004

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### Thimerosal in Vaccines and Autism

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#### What is thimerosal?

Thimerosal is a mercury-based preservative used in the manufacturing process of vaccines and in certain multi-dose vials of vaccines in order to prevent the growth of bacteria and fungi and to stabilize the vaccine so that it remains effective over time.

#### What the difference between a single dose and a multi-dose vaccine?

A single dose vaccine is one that is stored in a single vial that is disposed of after the one dose is given to a person. With a multi-dose vaccine, multiple vaccine doses are stored in a single vial and the doses from the same vial are given to different people.

#### Is thimerosal in all vaccines?

No. Most vaccines licensed in Canada do not contain thimerosal. Since 1994, all routine childhood vaccines, with the exception of the flu vaccine, administered in Canada have not contained thimerosal. Thimerosal is not added to single dose vaccines.

In Canada, vaccines to prevent the following diseases are used for routine immunization of children and do not contain thimerosal:

- diphtheria
- tetanus (lockjaw)
- pertussis (whooping cough)
- polio
- rubella (German measles)
- measles (red measles)
- mumps
- hepatitis B (available free to children only in some provinces and territories)
- Haemophilus influenzae type b disease
- Meningococcal C
- Pneumococcal
- Varicella

For immunization of infants against hepatitis B, parents or guardians in some provinces and territories have the choice of a thimerosal-free vaccine.

#### Why is thimerosal a concern now?

There is ongoing discussion in the media on whether or not thimerosal in vaccines causes neurological damage, including autism.

#### Does thimerosal cause autism?

The best available science to date has shown that there is no link between vaccines containing thimerosal and autism or other behaviour disorders. International bodies, such as the World Health Organization (WHO), the U.S. Food and Drug Administration (U.S. FDA) and the Institute of Medicine in the U.S., share this opinion.

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The National Advisory Committee on Immunization (NACI) has reviewed the safety of thimerosal and concluded that the alleged adverse health effect from thimerosal in vaccines has never been substantiated. Nevertheless, as a precautionary measure, NACI, as well as other international advisory bodies, has suggested using vaccines without thimerosal to reduce unnecessary exposure to mercury.

**What about studies that have claimed to find a relationship between the two?**

Health Canada evaluates vaccines for their safety and effectiveness on an ongoing basis. Health Canada also monitors and analyses the latest information available in order to protect the health of Canadians.

A study published in the February 2004 edition of *Molecular Psychiatry* suggested that thimerosal and a number of other chemicals may affect the development of the nervous system and lead to an increased risk of neurological disorders such as autism.

Health Canada has reviewed this study and found that the data does not support this conclusion. The study looked at the impact of low concentrations of thimerosal on cancer cells in a tissue culture. Since the particular study was performed on a cell culture, it is not clear what the findings mean for people. Many drugs have effects in cell culture but have no effect when given to people. We know that mercury can damage the brain if enough of it reaches brain cells, but the study does not look at how much thimerosal in vaccines would actually reach brain cells.

Health Canada encourages Canadians to be immunized. The benefits of immunization outweigh any real or perceived risks.

**Are there studies out there that counter any links made between thimerosal and autism?**

Yes. In May 2004, the Institute of Medicine (IOM) published a report concluding that based on numerous epidemiological studies, the MMR vaccine and thimerosal-containing vaccines do not cause autism. The Immunization Safety Review Committee of the IOM concluded that any links between these vaccines and autism are theoretical and that the causes for autism remain unknown. This report is a follow-up of a report published in 2001 on measles-mumps-rubella (MMR) that stimulated epidemiological research used in the 2004 report.

In the 2001 report, the IOM concluded there was not enough scientific evidence of an association between thimerosal and autism to accept or reject a causal relationship. The Committee was asked to revisit the causal association between MMR and autism, resulting in this new report. The Committee first looked at whether the measles-mumps-rubella (MMR) vaccine can cause autism. Shortly after, the focus shifted to thimerosal-containing vaccines because people were concerned about them.

For more information on the IOM review, please visit <http://www.nap.edu/catalog/10208.html>.

In a study published in 2003, Danish researchers examined records for all children born in Denmark between January 1, 1990, and December 31, 1996. They compared all the children vaccinated with vaccines containing thimerosal to those vaccinated with thimerosal-free vaccines. The study found that the risk of autism was similar in children regardless of the type of vaccine and concluded that the results did not support a direct link between childhood vaccination with thimerosal-containing vaccines and autism.

A U.S. study published in 2002 described the metabolism of thimerosal in vaccines in 40 full-term infants aged 6 months and younger. The study did not find raised levels of blood concentrations of mercury above safe values (as established by expert panels) in infants. On average, children in the U.S. receive more doses of vaccine than in many other countries (as boosters) and would have received higher levels of thimerosal than children in other parts of the world.

Health Canada will continue to monitor any studies on this subject.

**Why is thimerosal used in the flu vaccine if other vaccines do not contain it?**

The flu vaccine is generally marketed in a multi-dose vial and thimerosal is added to the manufacturing process to maintain sterility of the vaccine. Thimerosal also has a stabilizing effect in the vaccines, ensuring that they are effective.

The flu vaccine contains thimerosal as a preservative, but, for the 2005/2006 season, manufacturers are developing a thimerosal-free, stable, vaccine available for children. Thimerosal will continue to be used in multi-dose vaccines until a safe alternative is found.

**Could another preservative be used in multi-dose vaccines like the flu vaccine?**

Yes. Pharmaceutical companies are actively working on alternatives to thimerosal as a preservative. If alternatives are used, they will need to be tested in clinical trials to evaluate their safety and effectiveness as preservatives. In some initial tests, alternative stabilizers have actually made the vaccines less effective.

**Are children at an increased risk for developing neurological disorders like autism or Attention Deficit Hyperactivity Disorder (ADHD) if they received a flu shot?**

No. The best available science to date has shown that there is no link between vaccines and autism or ADHD.

**For additional information on thimerosal and vaccines, please visit:**

National Advisory Committee Statement on Thimerosal

<http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/03vol29/acs-dcc-1/index.html>

National Advisory Committee on Immunization Statement on Thimerosal in Vaccines

<http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/99vol25/25sup/acs7.html>

Exposure to Thimerosal in Vaccines used in Canadian Infant Immunization Programs, with respect to risk of neurological disorders

<http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/02vol28/dr2809ea.html>

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