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Global Advisory Committee on Vaccine Safety

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Thiomersal and vaccines: questions and answers

What is thiomersal?

Thiomersal (also known as thimerosal, mercurothiolate and sodium 2-ethylmercuriothio-benzoate) is a mercury-containing compound used to prevent bacterial and fungal growth in some vaccines during storage, and especially during use of opened multi-dose vials. It has also been used during vaccine production both to inactivate certain organisms and toxins and to maintain a sterile production line. Thiomersal has been used since the 1930s in the manufacture of some vaccines and other medical products.

Do all vaccines contain thiomersal?

Many licensed vaccines do not contain thiomersal. Such vaccines include vaccines in single-dose presentation or vaccines for which thiomersal would interfere with vaccine efficacy such as live vaccines including MMR, oral and inactivated polio, yellow fever, and BCG vaccine. These vaccines, however, when in multi-dose presentations, have to be discarded at the end of the immunization session. Other vaccines may contain trace amounts of thiomersal (<0.5 µg per dose), if the preservative has been used in the production process, but has not been added to the final product. A third group of vaccines have thiomersal added in varying concentrations (10 to 50 µg per dose) as a preservative to prevent contamination with microorganisms when formulated in multi-dose vials. Such vaccines include vaccines against diphtheria, tetanus and pertussis (DTP), diphtheria and tetanus toxoids (DT), tetanus toxoid (TT), hepatitis B, *Haemophilus influenzae* type b (Hib), and influenza.

Can vaccines be made thiomersal free?

Any change in the formulation of a licensed vaccine, including changes to the thiomersal content, may have an impact on the quality, safety and efficacy of vaccines and further trials are likely to be required before the reformulated product can be licensed. Replacing thiomersal with a different inactivating agent and/or preservative during the production process and/or in the final product, will require a new licensing process with a series of preclinical and clinical trials to ensure the quality, safety and efficacy of the vaccine. For vaccines used in multi-dose formulations thiomersal offers better protection from contamination than other preservatives such as 2-phenoxy ethanol.

Can vaccines be supplied in single-dose vials?

Vaccines could be supplied in single-dose vials, but this option requires a significant increase in production capacity and has a high cost. Single-dose vials require significantly larger cold storage space as well as increased transport needs. This is currently not feasible for the majority of countries. For some vaccines, it is more cost effective to use multi-dose vials. However if thiomersal is used as the inactivating agent in the production process, and is not added as a preservative, this will only result in traces of thiomersal in the final product, both in single and multi-dose presentations.

What is the recommendation of the GACVS on the safety of thiomersal-containing

vaccines?

Upon review of the current epidemiologic evidence and pharmacokinetic profile of thiomersal, the Global Advisory Committee on Vaccine Safety concluded that there is currently no evidence of mercury toxicity in infants, children, or adults exposed to thiomersal in vaccines. It also concluded that there is no reason to change current immunization practices with thiomersal-containing vaccines on the grounds of safety. The safety of thiomersal-containing vaccines is reviewed at regular intervals. In the meantime, the available evidence warrants the recommendation that current WHO immunization policy with respect to thiomersal-containing vaccines should not be changed.

Is thiomersal the same as methyl mercury?

No, there are several forms of mercury occurring in the environment, however by far the most common organic mercury compound is methyl mercury. The main hazard for methyl mercury is its ability to accumulate in the body and to remain there for a long time. The exposure to this naturally-occurring compound and its toxic effects on humans have been well studied. As most humans are exposed to mercury in some form, WHO and some national regulatory authorities defined safe levels for exposure to mercury and the values reflect exposure mainly to methyl mercury. Thiomersal contains a different form of mercury i.e. ethyl mercury which does not accumulate and is metabolized and removed from the body much faster than is methyl mercury.

Why are some countries withdrawing thiomersal if there is no risk?

Some national public health authorities are striving to replace thiomersal-containing vaccines as a precautionary measure. There is currently no evidence of toxicity from mercury contained in vaccines. There are only a few tested, efficacious and safe alternatives to thiomersal-containing vaccines. Current production capacity for such vaccines is limited and insufficient to cover global needs.

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