

# AMERICAN ACADEMY OF PEDIATRICS

Committee on Infectious Diseases and Committee on Environmental Health

## Thimerosal in Vaccines—An Interim Report to Clinicians

ABBREVIATIONS. AAP, American Academy of Pediatrics; USPHS, US Public Health Service; FDA, Food and Drug Administration; IPV, inactivated polio vaccine; OPV, oral polio vaccine; DTP, diphtheria-tetanus-pertussis (vaccine); Hib, *Haemophilus influenzae* type b (vaccine); EPA, Environmental Protection Agency; ATSDR, Agency for Toxic Substances and Disease Registry; HBsAg, hepatitis B surface antigen; HBIG, hepatitis B immune globulin.

On July 7, 1999, the American Academy of Pediatrics (AAP) issued with the US Public Health Service (USPHS) a joint statement alerting clinicians and the public of concern about thimerosal, a mercury-containing preservative used in some vaccines. That statement was disseminated widely, including on the AAP members e-mail list, and was posted on the AAP web site since July 7, 1999. The AAP Board of Directors recognizes that in the light of these concerns, clinicians need guidelines today on their infant immunization practices.

What follows is information prepared by our technical committees as sections introduced by the following headings: Thimerosal, Mercury Exposure and Toxicity, Federal Guidelines, and Risk of Withholding Vaccines. The AAP Board of Directors then offers specific interim guidelines based on its understanding of the information that is currently available. This material should allow clinicians to inform parents about thimerosal. It takes advantage of the flexibility of the 1999 Recommended Childhood Immunization Schedule of the American Academy of Pediatrics, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), and the American Academy of Family Physicians (AAFP) with modest modifications, which provide an expansion of the margin of safety for small infants. It is important not to compromise the remarkable protection immunization now offers during that particularly vulnerable time of life.

### THIMEROSAL

Thimerosal has been used as an additive to biologics and vaccines since the 1930s because it is very effective for killing bacteria used in several vaccines

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.  
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and for preventing bacterial contamination, particularly in opened multidose containers. Some but not all of the vaccines recommended routinely for children in the United States contain thimerosal.<sup>1</sup> Thimerosal contains 49.6% mercury by weight and is metabolized to ethyl mercury and thiosalicylate. Data are limited regarding potential differences in toxicity between ethyl mercury and methyl mercury. Both forms of organic mercury are associated with neurotoxicity in high doses, and definitive data regarding the doses at which developmental effects occur in infants are not available. When vaccines containing thimerosal have been administered in the recommended doses, hypersensitivity has been noted, but no other harmful effects have been reported.<sup>2</sup> Massive overdoses from inappropriate use of thimerosal-containing products have resulted in toxicity.<sup>3-7</sup> As part of an ongoing review of biologic products in response to the Food and Drug Administration (FDA) Modernization Act of 1997, the FDA has determined that infants who receive thimerosal-containing vaccines at several visits may be exposed to more mercury than recommended by federal guidelines for total mercury exposure.

The thimerosal content of vaccines commonly used in children is shown in Table 1. No polio (IPV [inactivated polio vaccine] or OPV [oral polio vaccine]), measles, mumps, rubella, varicella, rotavirus, or Lyme disease vaccines contain thimerosal.<sup>8</sup> All whole-cell diphtheria-tetanus-pertussis (DTP) preparations contain thimerosal; one acellular product does not. There are several *Haemophilus influenzae* type b vaccine (Hib) products available that do not contain thimerosal.

### MERCURY EXPOSURE AND TOXICITY

Mercury occurs in three forms: the metallic element, inorganic salts, and organic compounds (eg, methyl mercury, ethyl mercury, and phenyl mercury). The toxicity of mercury is complex and dependent on form of mercury, route of entry, dose, and age at exposure. Mercury is present in the environment in inorganic and organic forms and everyone is exposed to small amounts.<sup>9,10</sup> The primary environmental exposure to organic mercury is from consumption of predator fish.

As an example of the mercury content of food commonly eaten by older children and adults, an FDA study has indicated that a 6-ounce can of tuna contains an average of 17  $\mu\text{g}$  (range, 1.7–127  $\mu\text{g}$ ) of

**TABLE 1.** Thimerosal Content in Some US-Licensed Vaccines

Vaccine	Brand Name	Manufacturer	% Thimerosal Concentration <sup>1</sup>	Mercury $\mu\text{g}/0.5 \text{ mL}$	
DTaP	Acel-Imune	Lederle Laboratories	.01	25	
	Tripedia	Pasteur Merieux Connaught	.01	25	
	Certiva	North American Vaccine	.01	25	
	Infanrix	SmithKline Beecham	0	0	
DTwP	All products		.01	25	
DT	All products		.01	25	
Td	All products		.01	25	
TT	All products		.01	25	
DTwP-Hib	Tetramune	Lederle Laboratories	.01	25	
Hib	ActHIB	Pasteur Merieux Connaught	0	0	
	TriHIBit	Pasteur Merieux Connaught	.01	25	
	HibTITER (multidose)	Lederle Laboratories	.01	25	
	Single dose		0	0	
	Omni HIB	SmithKline Beecham	0	0	
	PedvaxHIB liquid <sup>2</sup>	Merck	0	0	
	COMVAX <sup>3</sup>	Merck	0	0	
	ProHIBit <sup>4</sup>	Pasteur Merieux Connaught	.01	25	
	Hepatitis B virus	Engerix-B	SmithKline Beecham	.005	12.5
		Recombivax HB	Merck	.005	12.5
Hepatitis A	Havrix	SmithKline Beecham	0	0	
	Vaqa	Merck	0	0	
IPV	IPOL	Pasteur Merieux Connaught	0	0	
OPV	Orimune	Lederle Laboratories	0	0	
MMR	MMR-II	Merck	0	0	
Varicella	Varivax	Merck	0	0	
Rotavirus	Rotashield	Wyeth-Ayerst	0	0	
Lyme	LYMERix	SmithKline Beecham	0	0	
Influenza	All		.01	25	
Meningococcal	Menomune A, C, AC and A/C/Y/W-135	CLI	.01	25	
Pneumococcal	Pnu-Imune 23	Lederle Laboratories	.01	25	
	Pneumovax 23	Merck	0	0	
Rabies	Rabies Vaccine Adsorbed	BioPort Corporation	.01	25	
	IMOVAX	Pasteur Merieux Connaught	0	0	
	Rabavert	Chiron	0	0	
Typhoid fever	Typhim Vi	Pasteur Merieux Connaught	0	0	
	Typhoid Ty21a	Vivotef Berna	0	0	
	Typhoid vaccine	Wyeth-Ayerst	0	0	
Yellow fever	YF-Vax	Pasteur Merieux Connaught	0	0	
Anthrax	Anthrax vaccine	BioPort Corporation	0	0	

<sup>1</sup> A concentration of 1:10 000 is equivalent to a 0.01 concentration. Thimerosal is approximately 50% Hg by weight. A 1:10 000 concentration contains 25  $\mu\text{g}$  of Hg per 0.5 mL.

<sup>2</sup> A previously marketed lyophilized preparation contained .005% thimerosal.

<sup>3</sup> COMVAX is not approved for use under 6 weeks of age because of decreased response to the Hib component.

<sup>4</sup> ProHIBit is recommended by the Academy only for children 12 months of age and older.

mercury.<sup>11</sup> In some areas of the United States, freshwater fish (eg, walleye, pike, muskie, and bass) may contain elevated concentrations of mercury as well.

Local fish advisories and bans provide information to people about the safety of eating fish. The Environmental Protection Agency (EPA) points of contact for such local advisories include:

- EPA National Center for Environmental Publications and Information (513) 489-8190
- EPA Office of Water (202) 260-1305/fax (202) 260-9830
- EPA Web site address <http://www.epa.gov/OST/fish/>.

The major toxicity of organic mercury compounds is expressed in the central nervous system, though the kidneys and the immune system also may be affected.<sup>9,10,12</sup> Organic mercury readily crosses the placenta and blood-brain barrier. When fish taken from waters heavily contaminated with methyl mercury have been ingested during pregnancy, severe developmental and

neurologic impairment have occurred in children exposed in utero.<sup>9,10</sup> Other in utero toxic exposures have occurred when methyl mercury-contaminated seed grain was consumed by women.<sup>13-15</sup>

Organic mercury compounds are readily absorbed by ingestion, and inhalation and through the skin. Methyl mercury is distributed to all tissues but concentrates in blood and brain. Ninety percent of methyl mercury is excreted through bile in feces. The average half-life for methyl mercury in blood is 40 to 50 days (range, 20-70 days) for adults and breastfeeding infants.<sup>9,15</sup> Although methyl mercury can be measured in blood or hair specimens, collection of specimens requires special mercury-free collection materials and rigorous control of contamination. Such testing is usually carried out in a research setting.

#### FEDERAL GUIDELINES FOR LIMITING MERCURY EXPOSURE

In recent years, several agencies have been working toward reducing mercury exposure. Guidelines

have been established by the EPA,<sup>16</sup> the FDA,<sup>17</sup> and the Agency for Toxic Substances and Disease Registry (ATSDR)<sup>18</sup> in an effort to minimize preventable exposures to mercury from food and other environmental sources. Based on the assumption that exposures will continue for long periods, maximum recommended allowable daily exposures are as follows: EPA, 0.1 micrograms of mercury per kilogram per day<sup>19</sup>; ATSDR, 0.3  $\mu\text{g}/\text{kg}/\text{day}$ ; and FDA, 0.4  $\mu\text{g}/\text{kg}$ .<sup>16</sup> The small variability in guidelines from different organizations reflects subtle differences in the populations studied, methods of calculation, the uncertainty inherent in extrapolations, and use of different safety factors.

The primary purpose of the guidelines is to prevent exposure of women of childbearing age to amounts of mercury that might be toxic to the rapidly developing brain of the fetus, which is much more susceptible to toxicity than is the adult brain.<sup>9</sup> The specific window of highest susceptibility is not known, but exposure after birth should be associated with less toxicity than in utero exposure. The federal guidelines for mercury exposure are based on extrapolations from blood and/or hair concentrations of mercury in pregnant women after inadvertent exposures to high concentrations of methyl mercury from consumption of contaminated grain or fish. The mercury concentrations in blood or hair from exposed women were used to estimate maximum daily oral intakes of methyl mercury during pregnancy that were not associated with measurable adverse outcomes in their children. In earlier studies, blood levels of 100 to 200 micrograms of mercury per liter in pregnant women were not associated with detectable abnormalities in the children exposed in utero.<sup>13-15</sup> Some recent data suggest that exposure in utero to mercury at levels previously thought to be safe may have subtle adverse effects on the developing brain.<sup>20</sup> Additional studies are ongoing as data are limited with regard to the effects of low dose or intermittent exposures.<sup>21,22</sup> The federal guidelines were not designed for intermittent or bolus exposures.

### RISKS OF WITHHOLDING VACCINES

Children who do not receive recommended immunizations are at increased risk of acquiring serious diseases.<sup>23</sup> When immunization acceptance has declined, epidemics of vaccine-preventable diseases have occurred as evidenced by the measles outbreaks in the United States in 1989-1991; resurgence of pertussis in Japan, Sweden, and the United Kingdom in the late 1970s; and the recent diphtheria epidemic in the former Soviet Union.<sup>23,24</sup> Children who acquire diphtheria have a 3% to 23% chance of dying; 25% of children with pertussis are hospitalized, 22% develop pneumonia, and 3% have encephalopathy and often suffer permanent sequelae or death. Hepatitis B kills several thousand Americans every year attributable to liver cancer and cirrhosis of the liver.<sup>25</sup> Hib vaccines have resulted in the near elimination of meningitis, pneumonia, and sepsis from this organism. Approximately 5% of children with Hib meningitis die, and 50% of the survivors have neurologic

sequelae, including deafness, impaired vision, and mental retardation.<sup>26</sup> Although these diseases have been reduced to record low numbers, the organisms that cause these diseases are still present, and unvaccinated children will be at risk. These serious diseases can be prevented through immunization. If thimerosal-free vaccines are not available, physicians and parents must balance the known risks of serious complications from these diseases against the unknown but much smaller risks associated with thimerosal in some vaccines. In high-risk situations, such as infants born to hepatitis B surface antigen (HBsAg)-positive mothers, the known risks of serious consequences from the preventable infections far outweigh the risks of adverse consequences from vaccines, even if thimerosal-free products are not available.

### RECOMMENDATIONS

The AAP urges government agencies to work rapidly toward reducing children's exposure to mercury from all sources. Because any potential risk is of concern, the AAP and the USPHS agree that the use of thimerosal-containing vaccines should be reduced or eliminated. The AAP believes that physicians should minimize children's exposure to thimerosal, but they should not compromise the health of children by withholding routinely recommended immunizations. This should be possible given the flexibility in the current immunization schedule (eg, see recommendations number 2 and 3 below).

The following recommendations are made to optimize vaccine administration and minimize exposure to thimerosal. If there are limited supplies of thimerosal-free products available, priority should be given to use in premature infants.

1. All children should be immunized to protect them against the diseases listed in the 1999 Recommended Childhood Immunization Schedule of the AAP, ACIP, and AAFP.
2. Because any potential risk is of concern, the Academy and the USPHS agree that the use of thimerosal-containing vaccines should be reduced or eliminated. The benefits and risks of vaccines containing thimerosal should be discussed with parents. The use of products containing thimerosal is preferable to withholding vaccinations, which protect against diseases that represent immediate threats to young infants (eg, pertussis and *Haemophilus influenzae*). For hepatitis B vaccine, adjustments in timing within the ranges proposed in the immunization schedule provide additional opportunities to minimize exposure of small infants to thimerosal.
3. The AAP recommendations for prevention of hepatitis B infection are:
  - In infants born to HBsAg-positive women\* and women not tested for HBsAg during pregnancy, recommendations remain unchanged from the 1999 Recommended Childhood

\*Note that hepatitis B immune globulin (HBIG) products currently available in the United States do not contain thimerosal.



Immunization Schedule of the AAP, ACIP, and AAFP.

- At this time the only thimerosal-free hepatitis B vaccine available (COMVAX) also contains Hib vaccine (PRP-OMP). This product is not approved for use before 6 weeks of age because of decreased response to the Hib component. For that reason, where available, this thimerosal-free vaccine may be given to infants born to HBsAg-negative women beginning at the 2-month visit. If thimerosal-free vaccine is not available, hepatitis B virus vaccination should be initiated at 6 months of age. Based on the current immunization schedule, for most infants, either of these approaches should allow completion of the necessary 3 doses of vaccine by 18 months of age. Until thimerosal-free vaccine is available, immunization for the small, prematurely born infant should be deferred until the infant reaches a size and developmental level that corresponds to the term infant (as noted above).
  - A hepatitis B vaccine, which does not contain thimerosal, is expected to be made available in the near future. When sufficient supplies of this vaccine are available, it will be appropriate to resume the previous recommendation that immunization may begin in the newborn period.
4. Manufacturers and the FDA are urged to work toward rapid reduction or elimination of mercury-containing preservatives in vaccines.
  5. Infants and children who have received thimerosal-containing vaccines do not need to have blood, urine, or hair tested for mercury because the concentrations of mercury would be quite low and would not require treatment.
  6. Pediatricians should urge pregnant women, nursing mothers, and young children to follow fish advisories from state health, environmental, and conservation officials and should counsel parents about reducing exposures to other sources of mercury. The Academy is developing additional information on this subject.
  7. The benefits and risks of vaccines containing thimerosal should be discussed with parents (as with all vaccines). The larger risks of not vaccinating children far outweigh any known risk of exposure to thimerosal-containing vaccines.

As more information becomes available, the Academy will provide updates.

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