



STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Chief of Staff

April 23, 2008

TO: Providers, Hospitals, and Local Health Departments

FROM: New York State Department of Health, Bureau of Communicable Disease Control, Immunization Program

HEALTH ADVISORY: EFFECTIVE JULY 1, 2008, NEW YORK STATE LAW PROHIBITS THE ADMINISTRATION OF VACCINES CONTAINING MORE THAN TRACE AMOUNTS OF THIMEROSAL TO CHILDREN LESS THAN 3 YEARS OF AGE AND PREGNANT WOMEN.

Please distribute to the Infection Control Department, Emergency Department, Employee Health Service, Infectious Disease Department, Director of Nursing, Medical Director, Pharmacy Department, Pediatrics, Obstetrics and all primary care providers.

Summary

- Effective July 1, 2008, New York State Public Health Law (PHL) §2112 prohibits the administration of vaccines containing more than trace amounts of thimerosal, a mercury-containing preservative, to children less than 3 years of age and women who know they are pregnant.
- Multiple scientific studies and an extensive review by the Institute of Medicine have shown no evidence of adverse health effects due to thimerosal.
- Since 2001, thimerosal has not been used as a preservative in routinely recommended childhood vaccines, with the exception of some influenza vaccines.
- For all routinely recommended vaccines there are formulations available that meet the requirements of PHL §2112.
- Use of vaccines containing more than a trace amount of thimerosal is permitted when there is a shortage of vaccine and during an outbreak when thimerosal-free vaccine is not available.
- For the 2008-2009 influenza season, health care providers should order a sufficient supply of thimerosal-free or single-dose preparations of influenza vaccine to adequately immunize children less than 3 years of age and women who know they are pregnant.
- Providers are expected to seek out vaccine that complies with PHL §2112. However, in those instances when providers have in good faith sought out influenza vaccine that

complies with PHL §2112 but such vaccine cannot be obtained, vaccination of children under 3 years old and pregnant women is still recommended because the substantial risk of complications or death from influenza disease in these groups outweighs the unproven risk of vaccination with thimerosal-containing vaccine.

- When vaccinating these groups with thimerosal-containing vaccines, informed consent is required.

I. Provisions of Public Health Law §2112

A. Effective July 1, 2008, New York State Public Health Law (PHL) §2112 prohibits the administration of vaccines containing more than trace amounts of thimerosal, a mercury-containing preservative, to children less than 3 years of age and women who know they are pregnant. The definition of the term “trace” as referred to in this health advisory depends on the type of vaccine.

- For all vaccines except influenza vaccine the term “trace” means no more than 0.5 micrograms of mercury per 0.5 milliliter dose.
- For children under 3 years of age, an influenza vaccine may contain no more than 0.625 micrograms of mercury per 0.25 milliliter dose.
- For pregnant women, an influenza vaccine may contain no more than 1.25 micrograms of mercury per 0.50 milliliter dose.

B. The restriction on the administration of influenza vaccine containing no more than 1.25 micrograms of mercury per 0.5 milliliter dose will not apply to pregnant women unless the Commissioner of Health makes a yearly determination that there is an adequate supply of influenza vaccine that has no more than this amount.

C. The Commissioner of Health may authorize the use of vaccines containing more than trace amounts of mercury, including influenza vaccine, for children less than 3 years of age and women who know they are pregnant when it is necessary to prevent or respond to an outbreak of disease and there are insufficient amounts of vaccine available that is thimerosal-free or contains only trace amounts of thimerosal. The authorization will continue until the Commissioner determines that the threat of an outbreak or the outbreak has ended. Informed consent is not required during an outbreak.

D. The Commissioner of Health may authorize the use of vaccines containing more than trace amounts of thimerosal, including influenza vaccine, for children less than 3 years of age and women who know they are pregnant when the Commissioner determines that a vaccine that meets the requirements of PHL §2112 is not available for distribution in this state. The parent/guardian of a child less than 3 years of age or the pregnant woman receiving a vaccine containing more than trace amounts of thimerosal must provide informed consent prior to receiving such vaccine.

II. Background

Thimerosal is an organic compound containing approximately 49% ethyl mercury and has been used in some vaccines and other products since the 1930s. There is no scientific evidence of

harm caused by the low doses of thimerosal in vaccines except for minor reactions like redness and swelling at the injection site. Publicized adverse health effects from mercury have involved methyl mercury which is not contained in thimerosal.

Despite its record of use without adverse health effects, in July 1999 the Public Health Service agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines. Since 2001, thimerosal has not been used as a preservative in routinely recommended childhood vaccines, with the exception of some influenza vaccines. However, influenza vaccine that does not contain more than trace amounts of mercury is available (see Table 1). For all routinely recommended vaccines there are formulations available that meet the requirements of PHL §2112. Several other vaccines, principally tetanus-containing vaccines not recommended for routine use contain thimerosal (see Table 2). One travel vaccine, Japanese B Encephalitis has no thimerosal-free alternative.

It is important to emphasize with patients that, after multiple scientific studies and an extensive review by the Institute of Medicine, there is no evidence that thimerosal causes harm to patients. The known risk of disease from lack of vaccination far outweighs the unproven risk of harm, if any, from thimerosal. For example, in the 2007-2008 influenza season, the New York State Department of Health (NYSDOH) received reports of six deaths in unvaccinated children due to influenza.

III. Anticipated Influenza Vaccines for the 2008-09 Influenza Season

Each year, the formulation of the influenza vaccine is determined in February. The vaccine is manufactured in a process that takes about six months. Barring problems with the manufacturing process, supplies are generally available starting in September. (In 2004, the failure of one manufacturer's vaccine production led to severe shortages which were announced in October). The exact amount of vaccine produced by each manufacturer is generally known in late summer. However, based on limited information available at this time on the anticipated influenza vaccine supply for the 2008-09 influenza season, it appears there will be an adequate supply of mercury-free influenza vaccine or vaccine containing no more than trace amounts of mercury for vaccination of both pregnant women and children less than 3 years of age. A final determination of the adequacy of the supply will be made by August 15th. In the event of late failure of vaccine production, it may be necessary for the NYSDOH to modify its determination.

IV. Implications for Health Care Providers

Health care providers should order sufficient supplies of thimerosal-free or single-dose preparations of influenza vaccine to adequately immunize children less than 3 years of age and pregnant women.

The NYSDOH is aware that, in past years, the supply of influenza vaccine containing only trace amounts of thimerosal appeared to be adequate on national and statewide levels, but some New York State providers were not able to obtain this vaccine because of restrictions on ordering. For example, during at least one recent influenza season, providers were not allowed initially to pre-

book influenza vaccine and, when finally allowed to order, the vaccine was no longer available from distributors or manufacturers.

Providers are expected to seek out vaccine that complies with PHL §2112. However, in those instances when providers have in good faith sought out influenza vaccine that complies with PHL §2112 but such vaccine cannot be obtained, vaccination of children under 3 years old and pregnant women is still recommended because the substantial risk of complications or death from influenza disease outweighs the unproven risk of vaccination with thimerosal-containing vaccine. For example, during the 2007-2008 influenza season, NYSDOH received reports of 6 deaths of unvaccinated children due to influenza. When vaccinating these groups with thimerosal-containing vaccines, informed consent is required (see below).

In instances where providers cannot purchase vaccine that complies with PHL §2112, providers must document the attempts that were made to locate and obtain this vaccine, and should contact the NYSDOH or the New York City Department of Health and Mental Hygiene (NYCDOHMH) at the numbers provided below to discuss their inability to obtain the vaccine. The NYSDOH and NYCDOHMH will analyze the reasons why providers were unable to obtain vaccine and make efforts to ensure that vaccines that comply with PHL §2112 are available to all New York State providers.

Providers who stock both thimerosal-free and thimerosal-containing vaccines to immunize adults and pregnant women should consider reserving thimerosal-free doses for pregnant women. This would insure that sufficient doses of vaccine that are compliant with the law are available to vaccinate these individuals.

V. Informed Consent

Informed consent must be obtained prior to administering a vaccine that contains more than trace amounts of thimerosal as set forth in PHL§ 2112.

- The fact that verbal or written consent has been obtained should be documented. This information may be included in a documentation/consent form, or may be documented in a notation in the patient's medical record or on the immunization record.
- The patient or the patient's parent or guardian must receive the most current vaccine information statement (VIS). The VIS for influenza vaccine contains information on thimerosal and mercury used in the vaccine and can be used as background information for the purpose of obtaining informed consent. The information contained in the influenza VIS concerning thimerosal can also be helpful when obtaining informed consent prior to administering other vaccines that contain more than trace amounts of mercury. The influenza VIS can be obtained at http://www.immunize.org/vis/vis_fluinactive.asp.

VII. Testing for Pregnancy

PHL §2112 only applies to women who know that they are pregnant. It is not necessary to test women for pregnancy before administering influenza vaccine or other vaccines that contain more than traces amounts of mercury.

VIII. Use of Other Vaccines that Contain Thimerosal

Health care providers who vaccinate children less than 3 years of age or women who know they are pregnant should be aware that, according to the federal Food and Drug Administration (FDA) (see at <http://www.fda.gov/cber/vaccine/thimerosal.htm>), the following vaccines contain more than trace amounts of thimerosal:

- Adult tetanus and diphtheria (Td) obtained from the Massachusetts Department of Public Health,
- All formulations of tetanus toxoid (TT),
- Meningococcal polysaccharide vaccine (Menomune or MPSV) in multi-dose vials and
- Japanese B encephalitis vaccine (no thimerosal-free alternative).

These particular vaccine formulations are not routinely recommended for children and pregnant women. Alternative formulations which are thimerosal-free are available such as DTaP for children and Tdap for adolescents and adults. However, there may be rare situations where use of these formulations are indicated. One example would be for wound prophylaxis against tetanus, if thimerosal-free tetanus containing vaccine is not available or there is a contraindication to another component of the vaccine. Recommendations from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) indicate a preference for the use of Td or Tdap in wound prophylaxis against tetanus in adolescents and adults. (For a list of all vaccines that contain diphtheria, pertussis and tetanus please see Table 2.) MPSV is being phased out by the manufacturer and is not likely to be available in the future. Japanese B encephalitis vaccine is contraindicated for pregnant women and children under 1 year of age. The need for Japanese B encephalitis vaccine needs to be determined based on the planned itinerary. For more information on Japanese B encephalitis vaccine please see the CDC travel website at <http://www.cdc.gov/travel/content/Vaccinations.aspx>.

IX. Additional Information

Additional information regarding vaccine safety, including the use of thimerosal in vaccines, can be obtained at the CDC's National Immunization Program website at <http://www.cdc.gov/od/science/iso/> and at the website of the U.S. Food and Drug Administration at <http://www.fda.gov/cber/vaccine/thimerosal.htm>.

For further information, please contact your local health department or your regional NYSDOH Immunization Program at the following:

Western Regional Office

Buffalo: 716-847-4385
Rochester: 585-423-8114

Capital District Regional Office

Troy: 518-408-5278
Oneonta: 607-432-2890

Central New York Regional Office

Syracuse: 315-477-8164
Herkimer: 315-866-6879

Metropolitan Area Regional Office

New Rochelle: 914-654-7149
Central Islip: 631-851-3096

Saranac Lake: 518-891-4172

Providers and facilities in **New York City** should contact the NYC DOHMH at 212-676-2323. For questions about ordering vaccine in New York City VFC providers can call 212-447-8175 during business hours.

Table 1. Anticipated Influenza Vaccines for 2008-09 Season

| Vaccine | Package | Dose (ml) | Approved Ages | Thimerosal | Mercury (mcg/0.5 ml) |
|---|-----------------------|---------------|---------------|------------|----------------------|
| Afluria – trivalent inactivated vaccine (TIV) (CSL Limited) | Single-dose syringe | 0.5 | ≥18 yrs | No | |
| | Multidose vial | 0.5 | ≥18 yrs | Yes | 24.5 |
| Fluzone - TIV (Sanofi Pasteur) | Multidose vial | Age-dependent | ≥6 mos | Yes | 25 |
| | Single-dose syringe | 0.25 | 6-35 mos | No | |
| | Single-dose syringe | 0.5 | ≥36 mos | No | |
| | Single-dose vial | 0.5 | ≥36 mos | No | |
| Fluvirin - TIV (Novartis) | Single-dose syringe | 0.5 | ≥4 yrs | Trace | ≤0.98 |
| | Multidose vial | 0.5 | ≥4 yrs | Yes | 25 |
| Fluarix – TIV (GSK) | Single-dose syringe | 0.5 | ≥18 yrs | Trace | ≤1 |
| | Multidose vial | 0.5 | ≥18 yrs | Yes | 25 |
| Flulaval – TIV (GSK) | Single-dose syringe | 0.5 | ≥18 yrs | Trace | ≤1 |
| | Multidose vial | 0.5 | ≥18 yrs | Yes | 25 |
| FluMist – live attenuated influenza virus (LAIV) (MedImmune) | Single-dose dispenser | 0.2 | 2 – 49 yrs | No | |

Table 2. Available Formulations for Diphtheria, Tetanus, and Pertussis Containing Vaccines

| Vaccine | Trade Name | Manufacturer | Thimerosal Concentration | Mercury |
|----------------|-------------------|---------------------|---------------------------------|-----------------------|
| DTaP | Tripedia | Sanofi Pasteur | <=0.00012% | <=0.3 mcg/0.5 ml dose |
| DTaP | Infanrix | GlaxoSmithKline | 0 | 0 |
| DTaP | Daptacel | Sanofi Pasteur | 0 | 0 |
| DTaP-HepB-IPV | Pediarix | GlaxoSmithKline | 0 | 0 |
| DT | None | Sanofi Pasteur | <0.00012% (single dose) | <0.3 mcg/0.5 ml dose |
| Td | None | Mass Public Health | 0.0033% | 8.3 mcg/0.5 ml dose |
| Td | Decavac | Sanofi Pasteur | <=0.00012% | <=0.3 mcg/0.5 ml dose |
| Td | None | Sanofi Pasteur | 0 | 0 |
| Tdap | Adacel | Sanofi Pasteur | 0 | 0 |
| Tdap | Boostrix | GlaxoSmithKline | 0 | 0 |
| TT | None | Sanofi Pasteur | 0.01% | 25 mcg/0.5 ml dose |