



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  
*Executive Deputy Commissioner*

December 18, 2008

Dear Doctor:

The purpose of this letter is to share with you guidance for the vaccination of women of reproductive age. The attached document outlines the guidelines for immunizing women before, during and after pregnancy. It was developed based on current recommendations from the Centers for Disease Control and Prevention, the Advisory Committee on Immunization Practices and the American College of Obstetricians and Gynecologists. With the introduction of the human papillomavirus vaccine, more women, pregnant or not, are seeking vaccines from their obstetric/gynecologic providers. Women's healthcare providers have a very unique opportunity to ensure the future well being of women and children.

Immunization is important for the health of both mother and infant. The consequences of acquiring a vaccine-preventable disease during pregnancy can be severe. For example, a pregnant woman who develops measles is at risk for preterm labor, spontaneous abortion or a low birth weight infant.

I hope that you will find this information useful in your practice. In addition, I have included information about the New York State Public Health Law section 2112 requiring providers to use vaccines that do not contain more than trace amounts of thimerosal when vaccinating pregnant women.

For additional information or to access various educational brochures and materials, we encourage you to contact the New York State Department of Health Immunization Program at (518) 473-4437 or visit our website at: <http://www.nyhealth.gov/prevention/immunization>.

Sincerely,



Kimberly A. Noyes, M.D., M.P.H.  
Assistant Medical Director  
Immunization Program

## VACCINATING WOMEN OF REPRODUCTIVE AGE RECOMMENDATIONS AND GUIDELINES

### INTRODUCTION

The New York State Department of Health Immunization Program developed these guidelines using the current recommendations from the Centers for Disease Control and Prevention, the Advisory Committee on Immunization Practices and the American College of Obstetricians and Gynecologists. This document serves to guide best practices. However, guidelines never replace the need to evaluate each patient individually and utilize sound clinical judgment. These guidelines are based on the best available evidence and will provide a foundation from which women's health care providers can achieve optimal quality in patient care.

### IMMUNIZATIONS IN THE PRECONCEPTION AND INTERCONCEPTION PERIOD

Ideally, all women should be up-to-date with their vaccinations before they become pregnant. It is known that approximately 50% of all pregnancies are unplanned;<sup>1</sup> therefore, it is important to keep women of reproductive age current with immunizations, regardless of whether they are actively trying to conceive.

The following immunizations are **strongly recommended**:

- Influenza – Women who want to reduce their chances of developing influenza or who have other medical or occupational indications should receive an annual dose of influenza vaccine. Healthy, non-pregnant women under the age of 50 without high-risk medical conditions and who are not close contacts of severely immunocompromised persons can receive live attenuated influenza vaccine (LAIV) or trivalent inactivated vaccine (TIV).<sup>2</sup>
- Td/Tdap – Women who have completed a primary series of diphtheria- and tetanus toxoid-containing vaccine should receive a booster dose of tetanus and diphtheria vaccine (Td) every 10 years. One dose of tetanus, diphtheria and acellular pertussis vaccine (Tdap) should be substituted for the Td booster in women who have not previously received Tdap.<sup>3</sup> Ensuring that women are current with their Td/Tdap boosters helps protect newborns from neonatal tetanus and pertussis.

The following immunizations are **recommended** for women at risk for these diseases and who do not have a history of immunity, or for anyone who would like to receive the vaccine:

- Hepatitis A – Women at risk for hepatitis A virus (HAV) infection or anyone who requests the vaccine should receive a 2-dose single antigen series at 0 and 6 months or the 3-dose combination hepatitis A and hepatitis B vaccine, Twinrix, at 0, 1 and 6 months.<sup>4</sup>
- Hepatitis B – Women at risk for hepatitis B virus (HBV) infection or anyone who requests the vaccine should receive the 3-dose primary series at 0, 1-2

and 4-6 months.<sup>4</sup> Infants who acquire HBV perinatally are at very high risk of developing chronic HBV which can lead to chronic liver disease, cirrhosis and primary hepatocellular carcinoma in early adulthood.

- Human papillomavirus (HPV) – Women ages 9 through 26 years should receive 3 doses of HPV vaccine at 0, 2 and 6 months. Genital HPV is the most common sexually transmitted infection in the United States. The currently available quadrivalent HPV vaccine, Gardasil, protects against HPV serotypes 6, 11, 16 and 18. Protection against these four HPV serotypes can prevent the occurrence of up to 90% of genital warts and 70% of cervical cancers in women.<sup>5</sup>
- Measles, mumps and rubella (MMR) – Women who have no history of previous immunization or lack laboratory evidence of rubella immunity should receive at least 1 dose of MMR vaccine. In addition to protecting individual women, MMR vaccine helps to prevent the occurrence of congenital rubella syndrome in newborns.<sup>9</sup> As it is a live virus vaccine, women should be counseled to avoid pregnancy for 4 weeks after receiving the MMR vaccine.<sup>4</sup>
- Meningococcal – Women at risk for meningococcal infection, due to occupational or medical risk factors, should receive 1 dose of meningococcal conjugate vaccine (MCV4). Medical indications include anatomic or functional asplenia or terminal complement component deficiencies. Those with occupational indications include military recruits, first-year college students living in dormitories, microbiologists who are exposed to *N. meningitidis* and persons who live in or travel to countries where meningococcal disease is widespread.<sup>6</sup>
- Pneumococcal – Women with certain high-risk medical indications should receive 1 dose of pneumococcal polysaccharide vaccine (PPV23). These high-risk medical indications include smoking (if  $\geq 19$  years of age), chronic pulmonary disease (including asthma), chronic cardiovascular disease, diabetes, chronic liver disease, chronic alcoholism, chronic renal failure, nephrotic syndrome, functional or anatomic asplenia, HIV infection, immunosuppressive conditions, cochlear implants and cerebrospinal fluid leaks. A second dose should be repeated 5 years later for those with chronic renal failure, nephrotic syndrome, functional or anatomic asplenia or immunosuppressive conditions.<sup>6</sup>
- Varicella (chickenpox) – Women who have previously been immunized with 1 dose of varicella vaccine should receive a second dose at least 4 weeks after the first dose. Women without a history of varicella infection should receive a total of 2 doses of varicella vaccine, 4-8 weeks apart. Infants of women without a history of immunity may be at risk for congenital varicella syndrome and neonatal varicella infection. Pregnant women infected with varicella may also be at higher risk of developing a severe case of varicella pneumonia. As it is a live virus vaccine, women should be counseled to avoid pregnancy for 4 weeks after receiving the varicella vaccine.<sup>7,8</sup>

## IMMUNIZATIONS IN THE PRENATAL PERIOD

Pregnancy is not an absolute contraindication to any vaccination. On the contrary, some vaccines are strongly recommended for pregnant women during the prenatal period. Therefore, the prenatal visit is an ideal time to assess a woman's need for vaccines.

All pregnant women should be evaluated for serologic evidence of immunity to rubella at their first prenatal visit, unless known to be immune by a previous test.<sup>8,9</sup> Varicella immunity should also be assessed by either a reliable history of disease, laboratory evidence of previous disease or documented receipt of 2 doses of vaccine.<sup>8</sup> Birth before 1980 is not considered evidence for varicella immunity.<sup>7</sup> In addition, New York State Public Health Law 2500-e requires that every pregnant woman be tested for the presence of hepatitis B surface antigen (HBsAg) and that the test result and date are documented in the prenatal record.

The following immunization is **strongly recommended** for all pregnant women:

- Influenza – Due to the increased risk of influenza-related complications among pregnant women, TIV is recommended for all women who are or will be pregnant during the flu season (September through March). TIV can be given during any trimester. As it is a live virus vaccine, LAIV is contraindicated for use in pregnant women.<sup>2</sup>

The following immunizations are **recommended** for women at risk for these diseases and who do not have a history of immunity or for anyone who would like to receive the vaccine:

- Hepatitis B – A woman's risk of acquiring HBV should be assessed along with her risk of acquiring other sexually transmitted infections. Pregnant women who have been identified as being at risk for HBV infection should be vaccinated. Pregnancy is not a contraindication for HBV vaccination, and limited evidence does not suggest any fetal harm from the HBV vaccine.<sup>10</sup>
- Td/Tdap – Pregnant women who have not received a Td booster within the last 10 years and require immediate protection against tetanus and diphtheria (ie. wound prophylaxis) should be vaccinated with Td during the 2<sup>nd</sup> or 3<sup>rd</sup> trimester. Td may be deferred and should be substituted with Tdap in the immediate postpartum period if it is felt that the woman is likely to have sufficient protection against tetanus and diphtheria. Tdap is not contraindicated during pregnancy; however, data on its safety and effect on newborn immune response to the primary DTaP series is limited. Tdap may be administered during pregnancy if the woman requires protection from pertussis. Tdap administration during pregnancy should be reported to the appropriate manufacturer's pregnancy registry.<sup>11</sup>

Pregnancy is considered a precaution for most other inactivated vaccines, including HAV, PPV23 and MCV4. Immunization with these vaccines should only occur if the

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benefits of vaccination outweigh the risks of not vaccinating. The only inactivated vaccine that should not be given during pregnancy is HPV vaccine due to a lack of safety and efficacy data in pregnant women. If a woman starts the HPV vaccine series then becomes pregnant, the remainder of the series should be postponed until after delivery and administration during pregnancy should be reported to the manufacturer's pregnancy registry.<sup>5</sup>

All live attenuated vaccines are contraindicated in pregnancy due to a theoretical risk to the fetus, although no evidence of any harm from live vaccines has been documented. The one exception is vaccinia vaccine which has a small but documented risk to the fetus if given during pregnancy.<sup>10</sup>

The following live virus vaccines should not be given during pregnancy:

- LAIV
- MMR
- Varicella
- Zoster (shingles)
- Vaccinia (smallpox)

If a woman is vaccinated with a live virus vaccine then discovers that she might have been pregnant at the time or within 4 weeks after vaccination, she should be counseled about the theoretical risk to her fetus. Because no evidence exists of any harm to fetuses that have been exposed to live virus vaccines during this period, she should not be advised to terminate her pregnancy. There is a small, but documented risk from vaccinia vaccination during pregnancy; however, it is still not considered a reason to terminate the pregnancy if exposure has occurred.

### IMMUNIZATIONS IN THE POSTPARTUM PERIOD

The period after delivery and before discharge from the hospital is an ideal time to administer both live and inactivated vaccines. It ensures that both the woman and her child will be protected from preventable diseases after leaving the birthing facility, when they are especially vulnerable. Women who plan to breastfeed can and should receive vaccinations as no evidence exists of any risk to a mother or her infant if she is vaccinated while breastfeeding. Breastfeeding is not a contraindication to any vaccination, with the exception of vaccinia vaccine.<sup>4</sup>

The following vaccinations are **recommended** for women at risk for these diseases or for those who do not have a history of immunity:

- Influenza – Women should receive an annual dose of influenza vaccine, either TIV or LAIV, if they have not already been immunized during their pregnancy. Influenza vaccine should be given **before leaving the hospital**.
- Rubella (MMR) – Women born on or after January 1, 1957, without evidence of immunity to rubella should be vaccinated with 1 dose of the MMR vaccine **before leaving the hospital**. Single antigen rubella vaccine should not be used.

- Tdap – Women who have not previously received 1 dose of Tdap should receive Tdap **before leaving the hospital**. Tdap can be given as soon as 2 years following the last Td booster. Immunizing the mother with Tdap will help protect the newborn during their first few months of life when they are most vulnerable to pertussis.
- Varicella – Women without evidence of immunity to varicella should be vaccinated with the 1<sup>st</sup> dose of varicella vaccine **before leaving the hospital**. The second dose should be given at the postpartum visit, 6-8 weeks after delivery. As it is a live virus vaccine, women should be counseled to avoid pregnancy for 4 weeks after receiving the varicella vaccine.<sup>7</sup>
- HPV – Women ages 9 through 26 years who have not completed a primary series should receive 3 doses of HPV vaccine at 0, 2 and 6 months. If the HPV series was started prior to pregnancy, the series can be completed postpartum without repeating the initial dose(s).<sup>5</sup>

### **IMMUNIZATION OF CLOSE CONTACTS OF PREGNANT WOMEN**

Vaccines should not be withheld from household or close contacts of pregnant women. Rather, ensuring that close contacts are up-to-date with their immunizations can help protect the health of the mother and her fetus. It is especially important that household contacts be current with their influenza and Tdap vaccines. The only vaccine that should not be given to close contacts of pregnant women is vaccinia vaccine due to the small but serious risk of fetal vaccinia.<sup>4</sup>

### **SPECIAL SITUATIONS**

Certain medical situations may arise during or after a pregnancy that have implications for the receipt of certain vaccines.

- Anti-Rho(D) immune globulin administration
  - Postpartum vaccination should not be delayed because of anti-Rho(D) immune globulin receipt. Live virus vaccines, such as MMR and varicella, should be administered simultaneously with anti-Rho(D) immune globulin in the immediate postpartum period. Women who have received both MMR vaccine and anti-Rho(D) immune globulin should be serologically tested 3 months after vaccination to ensure that immunity has developed to rubella and measles, if appropriate.<sup>4,12</sup>
- Vaccine-preventable disease exposure
  - Passive immunization
    - Any pregnant woman who is exposed to a vaccine-preventable disease to which they have no immunity should consult their provider about passive immunization. For example, in the event a pregnant woman is exposed to varicella disease and does not have evidence of immunity, varicella zoster immune globulin can be given.

- Rabies exposure
  - Due to the severe course of rabies infection, pregnancy is not a contraindication to post-exposure prophylaxis of rabies. No data exists that suggests any harm from rabies vaccination. For women who are pregnant and at high risk of exposure to rabies, pre-exposure prophylaxis to rabies may be warranted.<sup>13</sup>

### **IMMUNIZATIONS PRIOR TO INTERNATIONAL TRAVEL**

Pregnant women planning to travel to areas where other diseases are endemic may need certain vaccines. Pregnant women who are immunized with these vaccines should be counseled about potential risk to the fetus, as often there is little or no data on the safety of these vaccines in pregnancy.

The following vaccines are recommended for pregnant women planning to travel to endemic areas where there is a high risk of exposure:<sup>10</sup>

- Anthrax
- Inactivated polio
- Japanese encephalitis
- Meningococcal conjugate
- Typhoid
- Yellow fever

The following vaccines are not recommended for pregnant women planning to travel:<sup>10</sup>

- Bacille Calmette-Guérin (BCG) – tuberculosis
- Vaccinia (smallpox)

### **PREGNANCY VACCINE REGISTRIES**

Several registries have been established by vaccine manufacturers for women who have received certain vaccines during pregnancy. Providers should contact the appropriate registry if their patients have been exposed to the following vaccines during any trimester:

- HPV
  - Gardasil (Merck): (800) 986-8999
- Tdap
  - Boostrix (GlaxoSmithKline): (888) 825-5249
  - Adacel (sanofi pasteur): (800) 822-2463
- Varicella
  - Varivax (Merck): (800) 986-8999
    - Exposure to Varivax during pregnancy, as well as 3 months prior to becoming pregnant, should be reported to the Varivax Pregnancy Registry.<sup>7</sup>
- Smallpox
  - National Smallpox Vaccine in Pregnancy Registry<sup>14</sup>

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- Civilian and military cases – Department of Defense: (619) 553-9255

### ADDITIONAL INFORMATION

Additional information on immunizations can be found at the following websites:

- New York State Department of Health Immunization Program:  
<http://www.nyhealth.gov/prevention/immunization>
- CDC's National Center for Immunization and Respiratory Diseases (NCIRD)  
<http://www.cdc.gov/vaccines/spec-grps/pregnant.htm>
- The American College of Obstetricians and Gynecologists (ACOG):  
<http://www.acog.org>
- Immunization Action Coalition:  
<http://www.immunize.org/pregnancy/index.htm>

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<sup>1</sup> Williams L., Morrow B., Shulman H., Stephens R., D'Angelo D., & Fowler C.I. (2006). *PRAMS 2002 Surveillance Report*. Atlanta, GA: Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention.

<sup>2</sup> Centers for Disease Control and Prevention. Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2007. *MMWR* 2007; 56(RR-6): 1-54.

<sup>3</sup> Centers for Disease Control and Prevention. Preventing Tetanus, Diphtheria, and Pertussis Among Adults: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and Recommendation of ACIP, supported by the Healthcare Infection Control Practices Advisory Committee (HICPAC), for Use of Tdap Among Health-Care Personnel. *MMWR* 2006; 55(RR-17): 1-37

<sup>4</sup> Centers for Disease Control and Prevention. General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2006; 55(RR-15): 1-48.

<sup>5</sup> Centers for Disease Control and Prevention. Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2007; 56(RR-2): 1-23.

<sup>6</sup> Centers for Disease Control and Prevention. Recommended Adult Immunization Schedule – United States, October 2007 – September 2008. *MMWR* 2007; 56(41): Q1-Q4.

<sup>7</sup> Centers for Disease Control and Prevention. Prevention of Varicella: Recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2007; 56(RR-4): 24-28.

<sup>8</sup> American Academy of Pediatrics & the American College of Obstetricians and Gynecologists (2007). Chapter 9: Perinatal Infections. In Lemnos, J.A. & Lockwood, C.J. (Eds.), *Guidelines for Perinatal Care, Sixth Edition* (pp. 303-348). Washington, DC: American Academy of Pediatrics & the American College of Obstetricians and Gynecologists.

<sup>9</sup> Centers for Disease Control and Prevention. Measles, Mumps, and Rubella – Vaccine Use and Strategies for Elimination of Measles, Rubella, and Congenital Rubella Syndrome and Control of Mumps: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1998; 47(RR-8): 18.

<sup>10</sup> Centers for Disease Control and Prevention (2007). Guidelines for Vaccinating Pregnant Women: from Recommendations of the Advisory Committee on Immunization Practices. Retrieved June 12, 2008 from <http://www.cdc.gov/vaccines/pubs/preg-guide.htm>.

<sup>11</sup> Centers for Disease Control and Prevention. Prevention of Pertussis, Tetanus, and Diphtheria Among Pregnant and Postpartum Women and Their Infants: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2008; 57 (RR-4): 1-51

<sup>12</sup> American Academy of Pediatrics (2006). Rubella. In Pickering, L.K., Baker, C.J., Long, S.S., & McMillan, J.A. (Eds.), *Red Book: 2006 Report of the Committee on Infectious Disease*, 27<sup>th</sup> ed. (pp. 574-579). Elk Grove Village, IL: American Academy of Pediatrics.

<sup>13</sup> Centers for Disease Control and Prevention. Human Rabies Prevention – United States, 2008. Recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2008; 57(RR-3): 20-21.

<sup>14</sup> Centers for Disease Control and Prevention. Women with Smallpox Vaccine Exposure During Pregnancy Reported to the National Smallpox Vaccine in Pregnancy Registry —United States, 2003. *MMWR* 2003; 52(17): 386-388.

# IMMUNIZATION & Pregnancy

Vaccines help keep a pregnant woman and her growing family healthy.



Vaccine	<i>Before pregnancy</i>	<i>During pregnancy</i>	<i>After pregnancy</i>	Type of Vaccine	Route
Hepatitis A	If at high risk for disease	If at high risk for disease	If at high risk for disease	Inactivated	IM
Hepatitis B	Yes, if at risk	Yes, if at risk	Yes, if at risk	Inactivated	IM
Human Papillomavirus (HPV)	Yes, if 9 through 26 years of age	No, under study	Yes, if 9 through 26 years of age	Inactivated	IM
Influenza-TIV, IM	Yes	Yes	Yes	Inactivated	IM
Influenza LAIV	Yes, if less than 50 years of age and healthy	No	Yes, if less than 50 years of age and healthy	Live	Nasal spray
MMR	Yes, avoid conception for 4 weeks	No	Yes, avoid conception for 4 weeks	Live	SC
Meningococcal: •polysaccharide •conjugate	If indicated	If indicated	If indicated	Inactivated Inactivated	SC IM
Pneumococcal Polysaccharide	If indicated	If indicated	If indicated	Inactivated	IM or SC
Tetanus/Diphtheria Td	Yes, Tdap preferred	If indicated	Yes, Tdap preferred	Toxoid	IM
Tdap, one dose only	Yes, preferred	If high risk of pertussis	Yes, preferred	Toxoid	IM
Varicella	Yes, avoid conception for 4 weeks	No	Yes, avoid conception for 4 weeks	Live	SC

For information on all vaccines, including travel vaccines, use this table with [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

Get an answer to your specific question by e-mailing [cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov) or calling 800-CDC-INFO (232-4636) • 24/7 • English or Spanish



**New York State Public Health Law §2112**  
**Important Information for Physicians Caring for Pregnant Women**

**What is Public Health Law §2112?**

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 women who know they are pregnant and children less than three years of age, with certain exceptions.

**What is thimerosal and does it have any risk?**

Thimerosal is an organic compound containing approximately 49% ethyl mercury and has been used in some vaccines and other products since the 1930s. Since 2001, with the exception of some influenza vaccines, thimerosal is not used as a preservative in routinely recommended childhood vaccines. In addition, there are thimerosal-free preparations for most vaccines recommended for adults. Multiple scientific studies and an extensive review by the Institute of Medicine have shown no evidence of adverse health effects due to thimerosal.

**How do you define “trace” amounts of mercury?**

For the purposes of this law, the definition of the term “trace” depends on the type of vaccine. For pregnant women, an influenza vaccine may contain no more than 1.25 micrograms of mercury per 0.5 milliliter dose. All other vaccines may contain no more than 0.5 micrograms of mercury per 0.5 milliliter dose.

**What should I do differently in my practice?**

Plan ahead when ordering vaccines. Order a sufficient supply of thimerosal-free or single-dose preparations of influenza vaccine and other vaccines to adequately immunize your pregnant patients. If you stock both thimerosal-free and thimerosal-containing vaccines to immunize your patients, consider reserving thimerosal-free doses for your pregnant patients to ensure that sufficient doses of vaccine that are compliant with the law are available to vaccinate these individuals.

**What should I do if I have already ordered vaccine that does not comply with PHL §2112?**

If you have already placed your influenza vaccine order for the 2008-2009 season, the vaccine manufacturers have stated that orders can still be changed. Please call the vaccine manufacturer you placed your order with to change your order to vaccine that complies with PHL §2112.

**Should I be performing pregnancy tests on all of my patients before giving vaccines?**

No. This law only applies to women who know they are pregnant. It is not necessary to test women for pregnancy before administering influenza vaccine or other vaccines that contain more than a trace amount of mercury.

**There have been vaccine shortages in the past. What do I do if I can't get vaccines that comply with PHL §2112?**

If vaccine that complies with the law is not available for distribution in the state, the State Commissioner of Health can authorize the use of other vaccine. For the influenza vaccine, the Commissioner will make a yearly determination as to whether there is an adequate supply of vaccine that complies with the law.

If the State Commissioner of Health has not authorized the use of other vaccines, or has determined that there is an adequate supply of influenza vaccine that complies with the law, you are expected to seek out vaccine that complies with PHL §2112. In instances when you have sought out vaccine with no more than trace amounts of thimerosal but such vaccine cannot be obtained, you must document the attempts that were made to locate and obtain this vaccine, and should contact the New York State Department of Health (NYSDOH) or the New York City Department of Health and Mental Hygiene at the phone numbers provided below to discuss your inability to obtain the vaccine.

**Is there anything special I must do if I need to give vaccines that have more than a trace amount of thimerosal?**

Pregnant women should still be vaccinated. Before you administer a vaccine that contains more than trace amounts of thimerosal, you must obtain informed consent from the pregnant woman. Informed consent should be documented. A consent form may be used, or consent may be documented in a notation in the patient's medical record or on the immunization record.

Federal law requires that you provide the patient with 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](http://www.immunize.org/vis/vis_fluinactive.asp).

**What about disease outbreaks in my community? Will there be enough vaccine?**

The State Commissioner of Health may authorize the use of vaccines containing more than trace amounts of thimerosal, including influenza vaccine, for pregnant women when it is necessary to prevent or respond to an outbreak of disease and there are insufficient amounts of vaccine available that contain only trace amounts of thimerosal. During an outbreak, informed consent is not required.

**How do I counsel my patients about the risk of thimerosal?**

It is important to emphasize with patients that, after multiple scientific studies, there is no evidence that thimerosal causes harm to patients. The real risk of disease from lack of vaccination far outweighs the unproven risk of harm, if any, from thimerosal. For example, the risk of complications due to influenza disease among pregnant women is high. Providers should administer available influenza vaccine to these patients.

**Where can I get more information?**

An official notification about PHL §2112 was released on April 23, 2008, in the form of a Health Advisory and can be viewed at:

[https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/doc080423\\_0.pdf](https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/doc080423_0.pdf).

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

For questions about ordering vaccine in New York State (outside of New York City), Vaccines for Children (VFC) providers can call 518-474-2506 during business hours.

Providers and facilities in **New York City** should contact the New York City Department of Health and Mental Hygiene at 212-676-2323. For questions about ordering vaccine in New York City, VFC providers can call 212-447-8175 during business hours.