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Pennsylvania MEDICAL SOCIETY®

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INDEPENDENT REGULATORY
REVIEW COMMISSION

March 10, 2008

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Heather Stafford, Director
Division of Immunization
Department of Health
Room 1026
Health and Welfare Building
7th and Forester Streets
Harrisburg, PA 17120

Dear Ms. Stafford,

As President of the Pennsylvania Medical Society, I write to support the regulations regarding school immunizations with some recommendations for your consideration.

The Medical Society recommends that the Department give preference to combination vaccines. Specifically, the requirements for diphtheria, tetanus toxoids, and acellular pertussis vaccine (DTaP) and the measles, mumps, and rubella (MMR) vaccine. The use of licensed combination vaccines is preferred over separate, multiple injections and is recommended by the Centers for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP), as well as the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).

The advantages in using the combination vaccines are highlighted in the CDC's report, "Combination Vaccines for Childhood Immunization," (June, 1998). The report cites the combination vaccines as "a practical way to overcome the constraints of multiple injections, especially for starting the immunization series for children behind schedule. The use of combination vaccines might improve timely vaccination coverage." The report also takes into consideration the reduction in cost for multiple health visits, the costs associated with stocking and storing multiple vaccines, as well as the stress of putting a child through multiple injections in a single visit.

The Medical Society recommends that the Department of Health adopt language that allow practitioners to follow the most current CDC ACIP guidelines, thus eliminating the need to change the regulations every time the recommendations change.

§ 23.83. Immunization requirements

While the proposed regulations for diphtheria, tetanus, and pertussis have a sentence allowing for the antigens to be combined in one vaccine, the measles, mumps, and rubella immunizations state that the "vaccine may be administered as a single antigen vaccine." The Medical Society recommends that the Department stress the use of licensed combination vaccines as preferred over separate, multiple injections.

With regard to the polio vaccine, both the ACIP and the AAP recommend the injectible inactivated polio vaccine be used as the oral polio vaccine is no longer be considered the

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standard of care. The Medical Society recommends that the Department give preference to the injectible inactivated polio vaccine.

Under subsection (b) *Required for attendance*, the Medical Society recommends changing the language for diphtheria and tetanus from "One dose shall be administered on or after the 4th birthday," to "The final dose to be administered at four years of age." This clarifies that the initial three doses should have already been administered and that the booster shot be administered at four years of age.

The MMR and varicella vaccine should include language that the second dose of MMR at age 4 may be administered provided four weeks or more have elapsed since the first dose was given.

Additional Observations

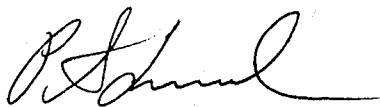
The fourth dose of necessary vaccines should be given between the ages of four and six as this reflects the recommendations of ACIP, AAP, and AAFP. This alters the language found in § 27.77(d)(1)(i) and (ii).

The Medical Society strongly recommends that the Department encourage the use of the combination vaccines where available and that when using the combination vaccines for diphtheria, tetanus, and pertussis that the appropriate vaccine be used. For example, children under the age of six should receive five doses of the DTaP and adolescents age eleven through eighteen should get one booster dose of the tetanus, diphtheria, and pertussis (Tdap) vaccine, as based on the CDC guidelines (attached) thus eliminating confusion between the two, very different, vaccines.

The Medical Society would like the Department to consider adding hepatitis A, rotavirus, haemophilus influenzae type b (as recommended by ACIP), as well as the human papillomavirus (HPV) vaccines.

The Pennsylvania Medical Society asks the Department of Health to consider these changes prior to the publication of the regulation as final. If there are any questions or concerns regarding these comments, please contact either Don McCoy (909-2649) or Catherine Wilson (909-2648) at the Medical Society.

Sincerely,



Peter S. Lund, MD, FACS
President

Attachments

Cc: Honorable Edwin B. Erickson, Chair
Senate Public Health and Welfare Committee
Honorable Frank L. Oliver, Chair
House Health and Human Services Committee
Arthur Coccodrilli, Chairman
Independent Regulatory Review Commission

Recommended Immunization Schedule for Persons Aged 0–6 Years—UNITED STATES • 2008

For those who fall behind or start late, see the catch-up schedule

Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B ¹	HepB	HepB	HepB	see footnote 1	HepB							
Rotavirus ²			Rota	Rota	Rota							
Diphtheria, Tetanus, Pertussis ³			DTaP	DTaP	DTaP	see footnote 3	DTaP					DTaP
Haemophilus influenzae type b ⁴			Hib	Hib	Hib ⁴	Hib						
Pneumococcal ⁵			PCV	PCV	PCV	PCV					PPV	
Inactivated Poliovirus			IPV	IPV		IPV						IPV
Influenza ⁶							Influenza (Yearly)					
Measles, Mumps, Rubella ⁷							MMR					MMR
Varicella ⁸							Varicella					Varicella
Hepatitis A ⁹							HepA (2 doses)				HepA Series	
Meningococcal ¹⁰											MCV4	

Range of recommended ages

Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2007, for children aged 0 through 6 years. Additional information is available at www.cdc.gov/vaccines/recs/schedules. Any dose not administered at the recommended age should be administered at any subsequent visit, when indicated and feasible. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not

contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective Advisory Committee on Immunization Practices statement for detailed recommendations, including for high risk conditions: <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete VAERS form is available at www.vaers.hhs.gov or by telephone, 800-822-7967.

1. Hepatitis B vaccine (HepB). (Minimum age: birth)

At birth:

- Administer monovalent HepB to all newborns prior to hospital discharge.
- If mother is hepatitis B surface antigen (HBsAg)-positive, administer HepB and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth.
- If mother's HBsAg status is unknown, administer HepB within 12 hours of birth. Determine the HBsAg status as soon as possible and if HBsAg-positive, administer HBIG (no later than age 1 week).
- If mother is HBsAg-negative, the birth dose can be delayed, in rare cases, with a provider's order and a copy of the mother's negative HBsAg laboratory report in the infant's medical record.

After the birth dose:

- The HepB series should be completed with either monovalent HepB or a combination vaccine containing HepB. The second dose should be administered at age 1–2 months. The final dose should be administered no earlier than age 24 weeks. Infants born to HBsAg-positive mothers should be tested for HBsAg and antibody to HBsAg after completion of at least 3 doses of a licensed HepB series, at age 9–18 months (generally at the next well-child visit).

4-month dose:

- It is permissible to administer 4 doses of HepB when combination vaccines are administered after the birth dose. If monovalent HepB is used for doses after the birth dose, a dose at age 4 months is not needed.

2. Rotavirus vaccine (Rota). (Minimum age: 6 weeks)

- Administer the first dose at age 6–12 weeks.
- Do not start the series later than age 12 weeks.
- Administer the final dose in the series by age 32 weeks. Do not administer any dose later than age 32 weeks.
- Data on safety and efficacy outside of these age ranges are insufficient.

3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). (Minimum age: 6 weeks)

- The fourth dose of DTaP may be administered as early as age 12 months, provided 6 months have elapsed since the third dose.
- Administer the final dose in the series at age 4–6 years.

4. Haemophilus influenzae type b conjugate vaccine (Hib). (Minimum age: 6 weeks)

- If PRP-OMP (PedvaxHIB[®] or ComVax[®] [Merck]) is administered at ages 2 and 4 months, a dose at age 6 months is not required.
- TriHIBit[®] (DTaP/Hib) combination products should not be used for primary immunization but can be used as boosters following any Hib vaccine in children age 12 months or older.

5. Pneumococcal vaccine. (Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPV])

- Administer one dose of PCV to all healthy children aged 24–59 months having any incomplete schedule.
- Administer PPV to children aged 2 years and older with underlying medical conditions.

6. Influenza vaccine. (Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 2 years for live, attenuated influenza vaccine [LAIV])

- Administer annually to children aged 6–59 months and to all close contacts of children aged 0–59 months.
- Administer annually to children 5 years of age and older with certain risk factors, to other persons (including household members) in close contact with persons in groups at higher risk, and to any child whose parents request vaccination.
- For healthy nonpregnant persons (those who do not have underlying medical conditions that predispose them to influenza complications) ages 2–49 years, either LAIV or TIV may be used.
- Children receiving TIV should receive 0.25 mL if age 6–35 mos or 0.5 mL if age 3 years or older.
- Administer 2 doses (separated by 4 weeks or longer) to children younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time last season, but only received one dose.

7. Measles, mumps, and rubella vaccine (MMR). (Minimum age: 12 months)

- Administer the second dose of MMR at age 4–6 years. MMR may be administered before age 4–6 years, provided 4 weeks or more have elapsed since the first dose.

8. Varicella vaccine. (Minimum age: 12 months)

- Administer second dose at age 4–6 years; may be administered 3 months or more after first dose.
- Don't repeat second dose if administered 28 days or more after first dose.

9. Hepatitis A vaccine (HepA). (Minimum age: 12 months)

- HepA is recommended for all children aged 1 yr (i.e., aged 12–23 months). The 2 doses in the series should be administered at least 6 months apart.
- Children not fully vaccinated by age 2 years can be vaccinated at subsequent visits.
- HepA is recommended for certain other groups of children, including in areas where vaccination programs target older children.

10. Meningococcal vaccine. (Minimum age: 2 years for meningococcal conjugate vaccine [MCV4] and for meningococcal polysaccharide vaccine [MPSV4])

- MCV4 is recommended for children aged 2–10 years with terminal complement deficiencies or anatomic or functional asplenia and certain other high-risk groups. Use of MPSV4 is also acceptable.
- Persons who received MPSV4 3 or more years prior and remain at increased risk for meningococcal disease should be vaccinated with MCV4.

The Recommended Immunization Schedules for Persons Aged 0–18 Years are approved by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/recs/acip), the American Academy of Pediatrics (<http://www.aap.org>), and the American Academy of Family Physicians (<http://www.aafp.org>).

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DIPHTHERIA TETANUS & PERTUSSIS VACCINES

WHAT YOU NEED TO KNOW

1 Why get vaccinated?

Diphtheria, tetanus, and pertussis are serious diseases caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts or wounds.

DIPHTHERIA causes a thick covering in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

TETANUS (Lockjaw) causes painful tightening of the muscles, usually all over the body.

- It can lead to “locking” of the jaw so the victim cannot open his mouth or swallow. Tetanus leads to death in up to 2 out of 10 cases.

PERTUSSIS (Whooping Cough) causes coughing spells so bad that it is hard for infants to eat, drink, or breathe. These spells can last for weeks.

- It can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death.

Diphtheria, tetanus, and pertussis vaccine (DTaP) can help prevent these diseases. Most children who are vaccinated with DTaP will be protected throughout childhood. Many more children would get these diseases if we stopped vaccinating.

DTaP is a safer version of an older vaccine called DTP. DTP is no longer used in the United States.

2 Who should get DTaP vaccine and when?

Children should get 5 doses of DTaP vaccine, one dose at each of the following ages:

- ✓ 2 months
- ✓ 4 months
- ✓ 6 months
- ✓ 15-18 months
- ✓ 4-6 years

DTaP may be given at the same time as other vaccines.

3

Some children should not get DTaP vaccine or should wait

- Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting DTaP vaccine.
- Any child who had a life-threatening allergic reaction after a dose of DTaP should not get another dose.
- Any child who suffered a brain or nervous system disease within 7 days after a dose of DTaP should not get another dose.
- Talk with your doctor if your child:
 - had a seizure or collapsed after a dose of DTaP,
 - cried non-stop for 3 hours or more after a dose of DTaP,
 - had a fever over 105°F after a dose of DTaP.

Ask your health care provider for more information. Some of these children should not get another dose of pertussis vaccine, but may get a vaccine without pertussis, called **DT**.

4

Older children and adults

DTaP is not licensed for adolescents, adults, or children 7 years of age and older.

But older people still need protection. A vaccine called **Tdap** is similar to DTaP. A single dose of Tdap is recommended for people 11 through 64 years of age. Another vaccine, called **Td**, protects against tetanus and diphtheria, but not pertussis. It is recommended every 10 years. There are separate Vaccine Information Statements for these vaccines.

Diphtheria/Tetanus/Pertussis

5/17/2007

5**What are the risks from DTaP vaccine?**

Getting diphtheria, tetanus, or pertussis disease is much riskier than getting DTaP vaccine.

However, a vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of DTaP vaccine causing serious harm, or death, is extremely small.

Mild Problems (Common)

- Fever (up to about 1 child in 4)
- Redness or swelling where the shot was given (up to about 1 child in 4)
- Soreness or tenderness where the shot was given (up to about 1 child in 4)

These problems occur more often after the 4th and 5th doses of the DTaP series than after earlier doses. Sometimes the 4th or 5th dose of DTaP vaccine is followed by swelling of the entire arm or leg in which the shot was given, lasting 1-7 days (up to about 1 child in 30).

Other mild problems include:

- Fussiness (up to about 1 child in 3)
- Tiredness or poor appetite (up to about 1 child in 10)
- Vomiting (up to about 1 child in 50)

These problems generally occur 1-3 days after the shot.

Moderate Problems (Uncommon)

- Seizure (jerking or staring) (about 1 child out of 14,000)
- Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)
- High fever, over 105°F (about 1 child out of 16,000)

Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after DTaP vaccine. These include:
 - Long-term seizures, coma, or lowered consciousness
 - Permanent brain damage.

These are so rare it is hard to tell if they are caused by the vaccine.

Controlling fever is especially important for children who have had seizures, for any reason. It is also important if another family member has had seizures. You can reduce fever and pain by giving your child an *aspirin-free* pain reliever when the shot is given, and for the next 24 hours, following the package instructions.

6**What if there is a moderate or severe reaction?****What should I look for?**

Any unusual conditions, such as a serious allergic reaction, high fever or unusual behavior. Serious allergic reactions are extremely rare with any vaccine. If one were to occur, it would most likely be within a few minutes to a few hours after the shot. Signs can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. If a high fever or seizure were to occur, it would usually be within a week after the shot.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice

7**The National Vaccine Injury Compensation Program**

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit the program's website at www.hrsa.gov/vaccinecompensation.

8**How can I learn more?**

- Ask your health care provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO)
 - Visit the National Immunization Program's website at www.cdc.gov/nip



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention

Vaccine Information Statement
DTaP (5/17/07)

42 U.S.C. § 300aa-26

TETANUS, DIPHTHERIA PERTUSSIS (Tdap) VACCINE

WHAT YOU NEED TO KNOW

1 Why get vaccinated?

Tdap (Tetanus, Diphtheria, Pertussis) vaccine can protect adolescents and adults against three serious diseases.

Tetanus, diphtheria, and pertussis are all caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts, scratches, or wounds.

TETANUS (Lockjaw) causes painful tightening of the muscles, usually all over the body.

- It can lead to “locking” of the jaw so the victim cannot open his mouth or swallow. Tetanus leads to death in up to 2 cases out of 10.

DIPHTHERIA causes a thick covering in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

PERTUSSIS (Whooping Cough) causes severe coughing spells, vomiting, and disturbed sleep.

- It can lead to weight loss, incontinence, rib fractures and passing out from violent coughing, pneumonia, and hospitalization due to complications.

In 2004 there were more than 25,000 cases of pertussis in the U.S. More than 8,000 of these cases were among adolescents and more than 7,000 were among adults. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications.

2 Tdap and related vaccines

Vaccines for Adolescents and Adults

- **Tdap** was licensed in 2005. It is the first vaccine for adolescents and adults that protects against all three diseases.
- **Td** (tetanus and diphtheria) vaccine has been used for many years as booster doses for adolescents and adults. It does not contain pertussis vaccine.

Vaccines for Children Younger than 7 Years

- **DTaP** vaccine is given to children to protect them from these three diseases. Immunity can fade over time, and periodic “booster” doses are needed by adolescents and adults to keep immunity strong. (**DTP** is an older version of DTaP. It is no longer used in the United States.)
- **DT** contains diphtheria and tetanus vaccines. It is used for children younger than 7 who should not get pertussis vaccine.

3 Who should get Tdap vaccine and when?

Adolescents 11 through 18 years of age should get one booster dose of Tdap.

- A dose of Tdap is recommended for **adolescents who got DTaP or DTP as children** but have not yet gotten a dose of Td. The preferred age is 11-12.
- **Adolescents who have already gotten a booster dose of Td** are encouraged to get a dose of Tdap as well, for protection against pertussis. Waiting at least 5 years between Td and Tdap is encouraged, but not required.
- **Adolescents who did not get all their scheduled doses of DTaP or DTP** as children should complete the series using a combination of Td and Tdap.

Adults 19 through 64 years of age should substitute Tdap for one booster dose of Td. Td should be used for later booster doses.

- **Adults who expect to have close contact with an infant** younger than 12 months of age should get a dose of Tdap. Waiting at least 2 years since the last dose of Td is suggested, but not required.
- **Healthcare workers who have direct patient contact** in hospitals or clinics should get a dose of Tdap. A 2-year interval since the last Td is suggested, but not required.

An adolescent or adult who gets a severe cut or burn might need protection against tetanus infection. Tdap may be used if the person has not had a previous dose.

Td should be used rather than Tdap if Tdap is not available, and for:

- Anybody who has already gotten Tdap,
- Adults 65 years of age and older,
- Children 7 through 9 years of age.

If vaccination is needed during **pregnancy**, Td usually is preferred over Tdap. Ask your doctor. **New mothers** who have never received a dose of Tdap should get a dose as soon as possible after delivery.

Tdap may be given at the same time as other vaccines.

4 Some people should not get Tdap vaccine or should wait.

- Anyone who has had a **life-threatening allergic reaction** after a dose of DTP, DTaP, DT, or Td vaccine should not get Tdap.
- Anyone who has a **severe allergy to any component of the vaccine** should not get Tdap. Tell your health care provider if the person getting the vaccine has any known severe allergies.

continued . . .

Talk with your doctor if the person getting the vaccine has a **severe allergy to latex**. Some Tdap vaccines should not be given to people with a severe latex allergy.

- Anyone who went into a **coma** or had a **long seizure** within 7 days after a dose of DTP or DTaP should not get Tdap, unless a cause other than the vaccine was found.
- Talk to your doctor if the person getting the vaccine:
 - has **epilepsy** or another **nervous system problem**,
 - had **severe swelling or severe pain** after a previous dose of any vaccine containing tetanus, diphtheria or pertussis,
 - has had **Guillain Barré Syndrome (GBS)**.

Anyone who has a **moderate or severe illness** on the day the shot is scheduled should usually wait until they recover before getting the vaccine. Those with a **mild illness or low fever** can usually be vaccinated.

5 What are the risks from Tdap vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.

If rare reactions occur with any new product, they may not be identified until many thousands, or even millions, of people have used the product. Like all vaccines, Tdap is being closely monitored for unusual or severe problems.

Clinical trials (testing before the vaccine was licensed) involved about 4,200 adolescents and about 1,800 adults. The following problems were reported. These are similar to problems reported after Td vaccine.

Mild Problems

(Noticeable, but did not interfere with activities)

- Pain (about 3 in 4 adolescents and 2 in 3 adults)
- Redness or swelling (about 1 in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents and 1 in 100 adults)
- Headache (about 4 in 10 adolescents and 3 in 10 adults)
- Tiredness (about 1 in 3 adolescents and 1 in 4 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents and 1 in 10 adults)
- Other mild problems reported include chills, body aches, sore joints, rash, and swollen lymph glands.

Moderate Problems

(Interfered with activities, but did not require medical attention)

- Pain at the injection site (about 1 in 20 adolescents and 1 in 100 adults)
- Redness or swelling (up to about 1 in 16 adolescents and 1 in 25 adults)
- Fever over 102°F (about 1 in 100 adolescents and 1 in 250 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 3 in 100 adolescents and 1 in 100 adults)
- Headache (1 in 300)

Severe Problems

(Unable to perform usual activities; required medical attention)

- None were seen among adolescents.
- In the adult clinical trial, two adults had nervous system problems after getting the vaccine. These may or may not have been caused by the vaccine. They went away on their own and did not cause any permanent harm.
- A severe allergic reaction could occur after any vaccine. They are estimated to occur less than once in a million doses.

A person who gets these diseases is much more likely to have severe complications than a person who gets Tdap vaccine.

6 What if there is a severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

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