

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Revised Diphtheria, Tetanus, and Pertussis (DTP/DTaP/DT) Vaccine Information Materials**

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Under the National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-26), the CDC must develop vaccine information materials that health care providers, either public or private, are required to distribute to patients/parents prior to administration of each dose of specific vaccines. On September 13, 1996, CDC published a notice in the **Federal Register** (61 FR 48597) seeking public comment on proposed revision of the diphtheria, tetanus, and pertussis vaccine information materials to reflect Food and Drug Administration (FDA) licensure of acellular pertussis vaccine combined with diphtheria and tetanus toxoids (DTaP) for administration to infants as young as two months of age. The 60-day comment period ended on November 12, 1996. Following review of the comments submitted and consultation as required under the law, CDC has finalized the revised diphtheria, tetanus, and pertussis vaccine information materials. Those final materials are contained in this notice.

DATES: Effective January 9, 1998. Beginning as soon as practicable, each health care provider who administers any vaccine that contains diphtheria, tetanus, or pertussis vaccine (except Td vaccine), shall, prior to administration of each dose of the vaccine, provide a copy of the vaccine information materials contained in this notice to the parent or legal representative of any child to whom such provider intends to administer the vaccine. (See below, for information regarding the Td (tetanus, diphtheria vaccine formulated for administration to individuals seven years of age and older) vaccine information materials.)

FOR FURTHER INFORMATION CONTACT: José Cordero, M.D., Acting Director, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639-8200.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act

of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. § 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by health care providers to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines originally covered under the National Vaccine Injury Compensation Program are diphtheria, tetanus, pertussis, measles, mumps, rubella, and poliomyelitis vaccines. Since April 15, 1992, any health care provider who intends to administer one of these vaccines is required to provide copies of the vaccine information materials prior to administration of any of these vaccines. The materials currently in use for measles, mumps, and rubella vaccines and the Td tetanus diphtheria vaccine are dated June 10, 1994, and were published in a **Federal Register** notice on June 20, 1994, (59 FR 31888). The current materials for polio vaccine are dated February 6, 1997, and were published in a **Federal Register** notice on February 6, 1997, (62 FR 5696). Single camera-ready copies of the vaccine information materials are available from State health departments. A list of contact telephone numbers for obtaining camera-ready copies is included in this notice. Copies are available in English and other languages.

(Effective August 6, 1997, hepatitis B, haemophilus influenzae type b, and varicella

(chicken pox) vaccines were added for coverage under the National Vaccine Injury Compensation Program. Development of vaccine information materials for these vaccines is underway. As part of the process for developing these new materials, CDC will publish draft materials for public comment and will consult with affected parties as required by the statute. Distribution of the vaccine information materials for these newly covered vaccines will be required following publication of the final version of each vaccine's materials in the **Federal Register**. We anticipate that they will be published in the second quarter of 1998.)

Revised Diphtheria, Tetanus, and Pertussis (DTP, DTaP, DT) Vaccine Information Materials

Prior to July 31, 1996, all combined diphtheria and tetanus toxoids and acellular pertussis vaccines (DTaP) were licensed only for administration as the fourth or fifth doses of the DTP series. On that date, the FDA licensed a DTaP vaccine for administration to infants as young as two months of age (i.e., to include the first three doses of the DTP series). Since that date, the FDA has licensed additional DTaP vaccines to cover all five doses. Licensure of these vaccines requires revision of the vaccine information statement entitled, "Diphtheria, Tetanus, and Pertussis Vaccine: What you need to know before your child gets the vaccine."

On September 13, 1996, CDC published a notice in the **Federal Register** (61 FR 48597) seeking public comment on proposed diphtheria, tetanus, and pertussis vaccine information materials that were revised to reflect the FDA licensure of acellular pertussis vaccine combined with diphtheria and tetanus toxoids (DTaP) for administration to infants as young as two months of age. (In addition, interim vaccine information materials pertaining to acellular pertussis vaccine combined with diphtheria and tetanus toxoids (DTaP) were published in the **Federal Register** on September 13, 1996, (61 FR 48596) for use by health care providers pending completion of this formal revision process.)

The 60-day comment period ended on November 12, 1996. Comments were submitted by a few individuals and organizations in response to the September 13, 1996, notice. As required by the statute, CDC has also consulted with various groups, including the Advisory Commission on Childhood Vaccines, Food and Drug Administration, American Academy of Family Practitioners, American Academy of Pediatrics, American College of Osteopathic Pediatricians, American Nurses Association, Association of Maternal and Child

Health Programs, Association of State and Territorial Health Officials, Council of State and Territorial Epidemiologists, Dissatisfied Parents Together, Immunization Education and Action Committee: Healthy Mothers/Healthy Babies Coalition, National Association of County Health Officials, National Association of Hispanic Nurses, National Black Nurses' Association, National Coalition of Hispanic Health and Human Services Organizations (COSSMHO), National Council of La Raza, National Medical Association, and Ohio Parents for Vaccine Safety. Comments from the consultants, along with the comments submitted in response to the **Federal Register** notice, were fully considered in revising the vaccine information materials.

Following consultation and review of comments submitted, revised diphtheria, tetanus, and pertussis (DTP, DTaP, DT) vaccine information materials that comply with the provisions of the National Childhood Vaccine Injury Act have been finalized and are contained in this notice. They are entitled "Diphtheria, Tetanus, and Pertussis Vaccines: What You Need to Know."

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Instructions for Use of Vaccine Information Materials (Vaccine Information Statements)

Required Use

As required under the National Childhood Vaccine Injury Act (42 U.S.C. 300aa-26), all health care providers in the United States who administer any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, or polio vaccine shall, prior to administration of *each dose* of the vaccine, provide a copy of the relevant vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

(a) To the parent or legal representative of any child to whom the provider intends to administer such vaccine, and

(b) To any adult to whom the provider intends to administer such vaccine.

The materials shall be supplemented with visual presentations or oral explanations, in appropriate cases.

"Legal representative" is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor.

Additional Recommended Use of Materials

Health care providers may also want to give parents copies of all vaccine information materials prior to the first

visit for immunization, such as at the first well baby visit.

Use of Revised Diphtheria, Tetanus, and Pertussis (DTP/DTaP/DT) Vaccine Information Materials

Beginning as soon as practicable after January 9, 1998, health care providers shall distribute copies of the August 15, 1997, version of the diphtheria, tetanus, and pertussis (DTP/DTaP/DT) vaccine information materials to replace the June 10, 1994, version or the September 13, 1996, interim version of the diphtheria, tetanus, and pertussis materials.

Use of Revised Polio Vaccine Information Materials

Beginning as soon as practicable after February 6, 1997, health care providers shall distribute copies of the February 6, 1997, version of the polio vaccine information materials to replace the June 10, 1994, version of the polio materials.

Current Editions of Vaccine Information Materials for Other Covered Vaccines

The June 10, 1994, version of the following vaccine information materials shall be distributed prior to administration of the vaccines (whether combined or single antigen vaccines are used): measles, mumps, and rubella (MMR) vaccine information materials, and tetanus, diphtheria (Td) vaccine information materials.

Recordkeeping

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided indicating the edition (date of publication) of the materials distributed and the date these materials were provided. This recordkeeping requirement supplements the requirement of 42 U.S.C. 300aa-25 that all health care providers administering these vaccines must record in the patient's permanent medical record (or in a permanent office log) the name, address, and title of the individual who administers the vaccine, the date of administration, and the vaccine manufacturer and lot number of the vaccine used.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State law.

Availability of Copies

Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are available in English and in other languages.

Dated: January 9, 1998.

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List of Contact Telephone Numbers for Copies of Vaccine Information Materials

Single camera-ready copies of the vaccine information materials are available by calling the telephone number listed below for your location:

Alabama (334) 242-5023
 Alaska (907) 561-4406
 American Samoa 011-684-633-4606
 Arizona (602) 230-5845
 Arkansas (501) 661-2723
 California (510) 540-2065
 Chicago (312) 746-5380
 Colorado (303) 692-2669
 Connecticut (860) 509-7929
 Delaware (302) 739-4746
 Detroit (313) 876-4606
 Florida (904) 487-2755
 Georgia (404) 657-3158
 Guam 011-671-734-7135
 Hawaii (808) 973-9678
 Houston (713) 794-9267
 Idaho (208) 334-5942
 Illinois (217) 785-1455
 Indian Health Service (505) 248-4226
 Indiana (317) 233-7010
 Iowa (515) 281-4917
 Kansas (913) 296-5593
 Kentucky (502) 564-4478
 Los Angeles (213) 580-9800
 Louisiana (504) 483-1900
 Maine (207) 287-3746
 Mariana Islands 011-670-234-8950, x2001
 Marshall Islands 011-692-625-3480
 Maryland (410) 767-6679
 Massachusetts (617) 983-6807
 Michigan (517) 335-8159
 Micronesia 011-691-320-2619
 Minnesota (612) 623-5237
 Mississippi (601) 960-7751
 Missouri (573) 751-6133
 Montana (406) 444-0065
 Nebraska (402) 471-2937
 Nevada (702) 687-4800
 New Jersey (609) 588-7520
 New York City (212) 676-2339
 New Hampshire (603) 271-4485
 New Mexico (505) 827-2369
 New York State (518) 473-4437
 North Carolina (919) 733-7752
 North Dakota (701) 328-2378
 Ohio (614) 466-4643
 Oklahoma (405) 271-4073
 Oregon (503) 731-4020
 Palau 011-160-680-1757
 Pennsylvania (717) 787-5681
 Philadelphia (215) 685-6749

Puerto Rico (787) 274-5612
 Rhode Island (401) 277-1185, ext. 188
 San Antonio (210) 207-8794
 South Carolina (803) 737-4160
 South Dakota (605) 773-3737
 Tennessee (615) 741-7343
 Texas (512) 458-7284
 Utah (801) 538-9450
 Vermont (802) 863-7638
 Virgin Islands (809) 776-8311, ext. 2148
 Virginia (804) 786-6246 or 6247
 Washington, DC (202) 576-7130
 Washington (360) 753-3495
 West Virginia (304) 558-2188
 Wisconsin (608) 266-1339
 Wyoming (307) 777-7952

Diphtheria, Tetanus, & Pertussis Vaccines; What You Need to Know

1. Why get vaccinated?

Diphtheria, pertussis and tetanus are serious diseases.

Diphtheria

- 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)

- Tetanus causes painful tightening of the muscles, usually all over the body.
- It can lead to "locking" of the jaw so the person cannot open his mouth or swallow. Tetanus can lead to death.

Pertussis (Whooping Cough)

- Pertussis causes coughing spells so bad that it is hard for infants to eat, drink, or breathe. These can last for weeks.
- It can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death.

Diphtheria, tetanus, and pertussis vaccines prevent these diseases.

Most children who get all their shots will be protected during childhood.

Many more children would get these diseases if we stopped vaccinating.

2. Diphtheria, Tetanus, and Pertussis Vaccines

DTP Vaccine

- Protects against diphtheria, tetanus, and pertussis.
- Used for many years.

DTaP Vaccine

- Protects against diphtheria, tetanus, and pertussis.
- Newer than DTP.

The Centers for Disease Control and Prevention (CDC) recommends DTaP over DTP. This is because DTaP is less likely to cause reactions than DTP.

Related Vaccines

- *Combinations:* To reduce the number of shots a child must get, DTP or DTaP may be available in combination with other vaccines.
- *DT* protects against diphtheria and tetanus, *but not pertussis*. It only is recommended for children who should not get pertussis vaccine.

3. What Are the Risks From These Vaccines?

- As with any medicine, vaccines carry a small risk of serious harm, such as a severe allergic reaction or even death.
- If there are reactions, they usually start within 3 days and don't last long.
- Most people have no serious reactions from these vaccines.

Possible Reactions to These Vaccines

Mild Reactions (common).

- Sore arm or leg.
- Fever.
- Fussy.
- Less appetite.
- Tired.
- Vomiting.

Mild reactions are much less likely after DTaP than after DTP. Moderate to Serious Reactions (uncommon)

Moderate to serious reactions have been uncommon with DTP vaccine:

- Non-stop crying (3 hours or more)—100 of every 10,000 doses.
- Fever of 105° or higher—30 of every 10,000 doses.
- Seizure (jerking or staring)—6 of every 10,000 doses.
- Child becomes limp, pale, less alert—6 of every 10,000 doses.

With DTaP vaccine, these reactions are much less likely to happen.

Severe Reactions (very rare).

There are two kinds of serious reactions:

- Severe allergic reaction (breathing difficulty, shock).
- Severe brain reaction (long seizure, coma or lowered consciousness). Is there lasting damage?
- Experts disagree on whether pertussis vaccines cause lasting brain damage.
- If they do, it is very rare.

Most experts believe serious reactions will be more rare after DTaP than after DTP.

4. When Should my Child get Vaccinated?

Most children should get a dose at these ages: 2 Months, 4 Months, 6 Months, 12-18 Months, 4-6 Years.

At 11-12 years of age and every 10 years after that you should get a booster to prevent diphtheria and tetanus.

5. What Can Be Done To Reduce Possible Fever and Pain After This Vaccine?

Give your child an *aspirin-free* pain reliever for 24 hours after the shot.

This is important if your child has had a seizure or has a parent, brother, or sister who has had a seizure.

6. Some Children Should Not get These Vaccines or Should Wait

Tell your doctor or nurse if your child:

- Ever had a moderate or serious problem after getting vaccinated.
- Ever had a seizure.
- Has a parent, brother, or sister who has had a seizure.
- Has a brain problem that is getting worse.
- Now has a moderate or severe illness.

Your doctor or nurse has information on what to do in this case (for example, give one of these vaccines, wait, give medicine to prevent fever).

7. What if There Is a Moderate to Severe Reaction?

What should I look for?

- Any unusual conditions, such as those in item 3.

What should I do?

- Call a doctor or get the child 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 file a Vaccine Adverse Event Report (VAERS) form, or call VAERS yourself at: 1-800-822-7967.

8. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program is a Federal program that helps pay for the care of those seriously injured by vaccines.

For details, call 1-800-338-2382 or visit the program's website at <http://www.hrsa.dhhs.gov/bhpr/vicp/new.htm>

9. *How Can I Learn More?*

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.

- Call your local or state health department. They can give you the *Parents Guide to Childhood Immunization* or other information.

- Contact the Centers for Disease Control and Prevention (CDC):

Call 1-800-232-2522 (English)

or

Call 1-800-232-0233 (Spanish)

or

Visit the CDC website at <http://www.cdc.gov/nip>.

DTP/DTaP/DT (8/15/97), Vaccine Information Statement, 42 U.S.C. § 300aa-26.

Dated: January 5, 1998.

Arthur C. Jackson,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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