DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interim DTP/DTaP Vaccine Information Materials

AGENCY: Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Notice.

SUMMARY: On July 31, 1996, the Food and Drug Administration (FDA) licensed an acellular pertussis vaccine (combined with diphtheria and tetanus toxoids) (DTaP) for administration to infants as young as 2 months of age. This recent development necessitates a revision of the vaccine information statement entitled, ''Diphtheria, Tetanus, and Pertussis Vaccine: What you need to know before your child gets the vaccine,'' which was developed by HHS as required by the National Childhood Vaccine Injury Act of 1986. A separate notice is being published in the Federal Register to begin formal revision of the statement under the procedures mandated by 42 U.S.C. § 300aa–26.

Pending completion of the formal revision process to revise the vaccine information statement, CDC is distributing the following interim statement which includes the new information regarding an acellular pertussis vaccine combined with diphtheria and tetanus toxoids (DTaP), to replace the current diphtheria, tetanus, and pertussis statement. This will ensure that individuals receiving the vaccine will have accurate up-to-date information which recognizes the recent licensure of an acellular pertussis vaccine combined with diphtheria and tetanus toxoids for administration to infants as young as 2 months of age.

DATES: Effective September 13, 1996.

FOR FURTHER INFORMATION CONTACT: Walter A. Orenstein, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention (CDC), Mailstop E–O5, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–8200.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Public Law 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 HHS to develop and disseminate vaccine information materials for distribution by health care providers to any patient (or to the parent or guardian in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

The vaccines currently covered under this 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 the covered vaccines is required to provide copies of the vaccine information materials prior to administration of any of these vaccines. The materials currently in use were published in a Federal Register notice on June 20, 1994 (59 FR 31888).

Development and revision of the vaccine information materials has been delegated by the Secretary to the 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 FDA. 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.

Interim DTP/DTaP Vaccine Information Materials

On July 31, 1996, the FDA licensed Connaught's Tripedia® combined diphtheria and tetanus toxoids and acellular pertussis vaccine for administration to infants as young as two months of age. This recent development requires revision of the vaccine information statement entitled, ''Diphtheria, Tetanus, and Pertussis Vaccine: What you need to know before your child gets the vaccine.'' A Federal Register notice is being published simultaneously with this notice to begin formal revision of the statement under the procedures mandated by 42 U.S.C. § 300aa–26.

Pending completion of the formal revision process, CDC is distributing the following interim statement which includes the new information regarding this acellular pertussis vaccine combined with diphtheria and tetanus toxoids (DTaP), to replace the current diphtheria, tetanus, and pertussis statement. As soon as practicable, and until a formal revision of the current version of the vaccine information statement can be completed, health-care providers should use this interim statement, so that individuals receiving pertussis vaccine will have accurate up-to-date information. Single copies of this statement are available from State health departments.

Diphtheria, Tetanus, and Pertussis Vaccines

What You Need To Know Before Your Child Gets the Vaccines

About the Diseases

Diphtheria, tetanus (lockjaw), and pertussis (whooping cough) are serious diseases. Diphtheria and pertussis spread when germs pass from an infected person to the nose or throat of others. Tetanus is caused by a germ that enters the body through a cut or wound.

Diphtheria causes: a thick coating in the nose, throat, or airway. It can lead to:

—breathing problems
—heart failure
—paralysis
—death

Tetanus causes: serious, painful spasms of all muscles. It can lead to:

—''locking'' of the jaw so the patient cannot open his or her mouth or swallow
—death

Pertussis causes: coughing and choking for several weeks (makes it hard for infants to eat, drink, or breathe). It can lead to:

—pneumonia
—seizures (jerking and staring spells)
—brain damage
—death

About the Vaccines

Benefits of Vaccination

Vaccination is the best way to protect against diphtheria, tetanus, and pertussis. Because most children get the vaccines, there are now many fewer cases of these diseases. There would be many more cases if we stopped vaccinating children.

The Vaccines

DTP (*D*iphtheria *T*etanus *P*ertussis) DTP vaccine prevents diphtheria, tetanus, and pertussis. It has been used for many years in the United States.

DTaP (*D*iphtheria *T*etanus *a*cellular *P*ertussis) DTaP prevents diphtheria, tetanus, and pertussis. It is less likely to cause the mild and moderate problems we see after DTP.

Both DTP and DTaP are very effective for preventing all three diseases.

DT (*D*iphtheria *T*etanus) Unlike DTP and DTaP, it does not prevent pertussis.

For this reason, it is usually not recommended.

Schedule

Most children should have a total of 5 DTP or DTaP vaccinations. They should get these vaccinations at:

✔2 months of age
✔4 months of age
✔6 months of age
✔12–18 months of age
✔4–6 years of age

Other vaccines may be given at the same time as DTP or DTaP.

Who Should Get DTP or DTaP Vaccine?

Most doctors recommend that almost all young children get DTP or DTaP vaccine. Some children should get DT. With all vaccines there are some cautions.

Tell your doctor or nurse if the child getting the vaccine:

- ever had a serious allergic reaction or other problem after getting DTP, DTaP, or DT
- now has a moderate or serious illness
- has ever had a seizure
- has a parent, brother, or sister who has had seizures
- has a brain problem that is getting worse.

If you are not sure, ask your doctor or nurse.

What Are the Risks From These Vaccines?

As with any medicine, there are very small risks that serious problems, even death, could occur after getting a vaccine.

The risks from the vaccines are *much smaller* than the risks from the diseases if people stopped using vaccine.

Below is a list of problems that may occur after getting the vaccine. If your child ever had one of the moderate or severe problems listed below or any other serious problem after DTP, DTaP, or DT, discuss it with your doctor or nurse before this vaccination.

Mild Problems

If these problems occur, they usually start within hours to a day or two after vaccination. They usually last up to 1–2 days:

- soreness, redness, or swelling where the shot was given
- fever
- fussiness, drowsiness, less appetite

These problems are much less likely to occur with DTaP than with DTP.

Acetaminophen or ibuprofen (not aspirin) may be used to prevent or reduce fever and soreness. This is especially important for children who have had seizures or have a parent, brother, or sister who has had seizures.

Moderate Problems

Once for every 100–1,000 doses of DTP (less after DTaP):

- on-going crying for 3 hours or more
- fever of 105° or higher
- an unusual, high-pitched cry

Once for 1,750 doses of DTP (less after DTaP):

- a seizure (jerking and staring spell) usually caused by fever
- ''shock-collapse'' (becomes pale, limp, and less alert)

Severe Problems

These problems happen very rarely:

- decreased consciousness, coma, or long seizure following DTP. Some of these children may have lasting brain damage. There is disagreement about whether or not DTP causes the lasting brain damage. If it does, it is very rare. The risk of decreased consciousness, coma, or long seizure after DTaP is not yet known, but experts believe it is even less likely to occur than after DTP.
- a serious allergic reaction

What to do if there is a serious reaction:

☞ Call a doctor or get the person to a doctor right away.
☞ Write down what happened and the date and time it happened.
☞ Ask your doctor, nurse, or health department to file a Vaccine Adverse Event Report form, or you can call: (800) 822–7967 (toll-free)

The National Vaccine Injury Compensation Program gives compensation (payment) for persons thought to be injured by vaccines. For details call: (800) 338–2382 (toll-free).

If you want to learn more, ask your doctor or nurse. She/he can give you the vaccine package insert or suggest other sources of information.

DTP/DTaP September 13, 1996, (Interim), Vaccine Information Statement, 42 U.S.C. § 300aa–26.

Dated: September 10, 1996.

Arthur C. (Jack) Jackson,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Revision—DTP/DTaP Vaccine Information Materials

AGENCY: Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Notice with comment period.

SUMMARY: Under section 2126 of the Public Health Service Act, the CDC must develop vaccine information materials which health care providers are required to provide to patients/parents prior to administration of specific vaccines. CDC proposes to revise the vaccine information materials pertaining to diphtheria, tetanus, and pertussis vaccines so that they reflect the recent Food and Drug Administration (FDA) licensure of an acellular pertussis vaccine combined with diphtheria and tetanus toxoids (DTaP) for administration to infants as young as 2 months of age. CDC seeks written comment on these proposed materials.

DATES: Written comments are invited and must be received on or before November 12, 1996.

ADDRESSES: Written comments should be addressed to Walter A. Orenstein, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention (CDC), Mailstop E–05, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

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