18 months

VACCINE INFORMATION STATEMENT

DTaP Vaccine

What You Need to Know

(Diphtheria, Tetanus and Pertussis)

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

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.

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 doctor 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.



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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.

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What if there is a serious reaction?

What should I look for?

 Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS).
 Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS is only for reporting reactions. They do not give medical advice.



The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

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How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement

DTaP Vaccine

5/17/2007

42 U.S.C. § 300aa-26



VACCINE INFORMATION STATEMENT

Hepatitis A Vaccine

What You Need to Know

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What is hepatitis A?

Hepatitis A is a serious liver disease caused by the hepatitis A virus (HAV). HAV is found in the stool of people with hepatitis A.

It is usually spread by close personal contact and sometimes by eating food or drinking water containing HAV. A person who has hepatitis A can easily pass the disease to others within the same household.

Hepatitis A can cause:

- · "flu-like" illness
- jaundice (yellow skin or eyes, dark urine)
- severe stomach pains and diarrhea (children)

People with hepatitis A often have to be hospitalized (up to about 1 person in 5).

Adults with hepatitis A are often too ill to work for up to a month.

Sometimes, people die as a result of hepatitis A (about 3–6 deaths per 1,000 cases).

Hepatitis A vaccine can prevent hepatitis A.

Who should get hepatitis A vaccine and when?

WHO

Some people should be routinely vaccinated with hepatitis A vaccine:

- All children between their first and second birthdays (12 through 23 months of age).
- Anyone 1 year of age and older traveling to or working in countries with high or intermediate prevalence of hepatitis A, such as those located in Central or South America, Mexico, Asia (except Japan), Africa, and eastern Europe. For more information see www.cdc. gov/travel.
- Children and adolescents 2 through 18 years of age who live in states or communities where routine vaccination has been implemented because of high disease incidence.
- · Men who have sex with men.
- · People who use street drugs.
- · People with chronic liver disease.

- People who are treated with clotting factor concentrates.
- People who work with HAV-infected primates or who work with HAV in research laboratories.
- Members of households planning to adopt a child, or care for a newly arriving adopted child, from a country where hepatitis A is common.

Other people might get hepatitis A vaccine in certain situations (ask your doctor for more details):

- Unvaccinated children or adolescents in communities where outbreaks of hepatitis A are occurring.
- Unvaccinated people who have been exposed to hepatitis A virus.
- Anyone 1 year of age or older who wants protection from hepatitis A.

Hepatitis A vaccine is not licensed for children younger than 1 year of age.

WHEN

For children, the first dose should be given at 12 through 23 months of age. Children who are not vaccinated by 2 years of age can be vaccinated at later visits.

For others at risk, the hepatitis A vaccine series may be started whenever a person wishes to be protected or is at risk of infection.

For travelers, it is best to start the vaccine series at least one month before traveling. (Some protection may still result if the vaccine is given on or closer to the travel date.)

Some people who cannot get the vaccine before traveling, or for whom the vaccine might not be effective, can get a shot called immune globulin (IG). IG gives immediate, temporary protection.

Two doses of the vaccine are needed for lasting protection. These doses should be given at least 6 months apart.

Hepatitis A vaccine may be given at the same time as other vaccines.



Some people should not get hepatitis A vaccine or should wait.

- Anyone who has ever had a severe (life threatening) allergic reaction to a previous dose of hepatitis A vaccine should not get another dose.
- Anyone who has a severe (life threatening) allergy to any vaccine component should not get the vaccine.
- Tell your doctor if you have any severe allergies, including a severe allergy to latex. All hepatitis A vaccines contain alum, and some hepatitis A vaccines contain 2-phenoxyethanol.
- Anyone who is moderately or severely ill at the time the shot is scheduled should probably wait until they recover. Ask your doctor. People with a mild illness can usually get the vaccine.
- Tell your doctor if you are pregnant. Because hepatitis
 A vaccine is inactivated (killed), the risk to a pregnant
 woman or her unborn baby is believed to be very low.
 But your doctor can weigh any theoretical risk from
 the vaccine against the need for protection.

What are the risks from hepatitis A vaccine?

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

Getting hepatitis A vaccine is much safer than getting the disease.

Mild problems

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- soreness where the shot was given (about 1 out of 2 adults, and up to 1 out of 6 children)
- headache (about 1 out of 6 adults and 1 out of 25 children)
- loss of appetite (about 1 out of 12 children)
- tiredness (about 1 out of 14 adults)

If these problems occur, they usually last 1 or 2 days.

Severe problems

 serious allergic reaction, within a few minutes to a few hours after the shot (very rare).

What if there is a serious reaction?

What should I look for?

 Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS).
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Vaccine Information Statement (Interim)

Hepatitis A Vaccine

10/25/2011

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