

VACCINE INFORMATION STATEMENT

Tdap Vaccine

What You Need to Know

(Tetanus, Diphtheria and Pertussis)

Many Vaccine Information Statements are available in Spanish and other languages. See www.hhs.gov/vaccines for more information.

1 Why get vaccinated?

Tetanus, diphtheria and pertussis are very serious diseases. Tdap vaccine can protect us from these diseases. And, Tdap vaccine given to pregnant women can protect newborn babies against pertussis.

TETANUS (Lockjaw) is rare in the United States today. It causes painful muscle tightening and stiffness, usually all over the body.

- It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 10 people who are infected even after receiving the best medical care.

DIPHTHERIA is also rare in the United States today. It can cause a thick coating to form in the back of the throat.

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

PERTUSSIS (Whooping Cough) causes severe coughing spells, which can cause difficulty breathing, vomiting and disturbed sleep.

- It can also lead to weight loss, incontinence, and rib fractures. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, which could include pneumonia or death.

These diseases are caused by bacteria. Diphtheria and pertussis are spread from person to person through secretions from coughing or sneezing. Tetanus enters the body through cuts, scratches, or wounds.

Before vaccines, as many as 200,000 cases of diphtheria, 200,000 cases of pertussis, and hundreds of cases of tetanus, were reported in the United States each year. Since vaccination began, reports of cases for tetanus and diphtheria have dropped by about 99% and for pertussis by about 80%.

2 Tdap vaccine

Tdap vaccine can protect adolescents and adults from tetanus, diphtheria, and pertussis. One dose of Tdap is routinely given at age 11 or 12. People who did not get Tdap at that age should get it as soon as possible.

Tdap is especially important for healthcare professionals and anyone having close contact with a baby younger than 12 months.

Pregnant women should get a dose of Tdap during every pregnancy, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

Another vaccine, called Td, protects against tetanus and diphtheria, but not pertussis. A Td booster should be given every 10 years. Tdap may be given as one of these boosters if you have never gotten Tdap before. Tdap may also be given after a severe cut or burn to prevent tetanus infection.

Your doctor or the person giving you the vaccine can give you more information. Tdap may safely be given at the same time as other vaccines.

3 Some people should not get this vaccine

- A person who has ever had a life-threatening allergic reaction after a previous dose of any diphtheria, tetanus or pertussis-containing vaccine, OR has a severe allergy to any part of this vaccine, should not get Tdap vaccine. Tell the person giving the vaccine about any severe allergies.

- Anyone who had coma or long repeated seizures within 7 days after a childhood dose of DTP or DTPa, or a previous dose of Tdap, should not get Tdap, unless a cause other than the vaccine was found. They can still get Td.

- Talk to your doctor if you:
 - have seizures or another nervous system problem,
 - had severe pain or swelling after any vaccine containing diphtheria, tetanus or pertussis,
 - ever had a condition called Guillain-Barre Syndrome (GBS),
 - aren't feeling well on the day the shot is scheduled.



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4 Risks

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Serious reactions are also possible, but are rare.

Most people who get Tdap vaccine do not have any problems with it.

Mild problems following Tdap (Did not interfere with activities)

- Pain where the shot was given (about 3 in 4 adolescents or 3 in 100 adults)
- Redness or swelling where the shot was given (about 1 person in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents or 1 in 100 adults)
- Headache (about 3 or 4 people in 10)
- Tiredness (about 1 person in 3 or 4)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents or 1 in 10 adults)
- Chills, sore joints (about 1 person in 10)
- Body aches (about 1 person in 3 or 4)
- Rash, swollen glands (uncommon)

Moderate problems following Tdap (Interfered with activities, but did not require medical attention)

- Pain where the shot was given (up to 1 in 5 or 6) (up to about 1 in 500 adults)
- Fever over 102°F (about 1 in 100 adolescents or 1 in 250 adults)
- Headache (about 1 in 7 adolescents or 1 in 10 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 or 3 people in 100)
- Swelling of the entire arm where the shot was given (up to about 1 in 500 adults)

Severe problems following Tdap (Unable to perform usual activities; required medical attention)

- Swelling, severe pain, bleeding and redness in the arm where the shot was given (rare)

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious problem?

What should I look for?

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

- 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 usually 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 should 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 does not give medical advice.

6 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. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your doctor, if he or she can give you the vaccine package insert or suggest other sources of information.
- 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 Tdap Vaccine

2/24/2015

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VACCINE INFORMATION STATEMENT

Meningococcal ACWY Vaccines—MenACWY and MPSV4: What You Need to Know

1 Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Meningococcal disease often occurs without warning—even among people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

There are at least 12 types of *N. meningitidis*, called "serogroups." Serogroups A, B, C, W, and Y cause most meningococcal disease.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of *N. meningitidis*
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, amputations, nervous system problems, or severe scars from skin grafts.

Meningococcal ACWY vaccines can help prevent meningococcal disease caused by serogroups A, C, W, and Y. A different meningococcal vaccine is available to help protect against serogroup B.

2 Meningococcal ACWY Vaccines

There are two kinds of meningococcal vaccines licensed by the Food and Drug Administration (FDA) for protection against serogroups A, C, W, and Y: meningococcal conjugate vaccine (MenACWY) and meningococcal polysaccharide vaccine (MPSV4).



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Two doses of MenACWY are routinely recommended for adolescents 11 through 18 years old: the first dose at 11 or 12 years old, with a booster dose at age 16. Some adolescents, including those with HIV, should get additional doses. Ask your health care provider for more information.

In addition to routine vaccination for adolescents, MenACWY vaccine is also recommended for certain groups of people:

- People at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- Anyone whose spleen is damaged or has been removed
- Anyone with a rare immune system condition called "persistent complement component deficiency"
- Anyone taking a drug called eculizumab (also called Soliris®)
- Microbiologists who routinely work with isolates of *N. meningitidis*
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as parts of Africa
- College freshmen living in dormitories
- U.S. military recruits

Children between 2 and 23 months old, and people with certain medical conditions need multiple doses for adequate protection. Ask your health care provider about the number and timing of doses, and the need for booster doses.

MenACWY is the preferred vaccine for people in these groups who are 2 months through 55 years old, have received MenACWY previously, or anticipate requiring multiple doses.

MPSV4 is recommended for adults older than 55 who anticipate requiring only a single dose (travelers, or during community outbreaks).

3 Some people should not get this vaccine

Tell the person who is giving you the vaccine:

- If you have any severe, life-threatening allergies.
- If you have ever had a life-threatening allergic reaction after a previous dose of meningococcal ACWY vaccine, or if you have a severe allergy to any part of this vaccine, you should not get this vaccine. Your provider can tell you about the vaccine's ingredients.
- If you are pregnant or breastfeeding.

There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.

If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own within a few days, but serious reactions are also possible.

As many as half of the people who get meningococcal ACWY vaccine have mild problems following vaccination, such as redness or soreness where the shot was given. If these problems occur, they usually last for 1 or 2 days. They are more common after MenACWY than after MPSV4.

A small percentage of people who receive the vaccine develop a mild fever.

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
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- Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness—usually within 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 and get to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor should 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 does not give medical advice.

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Vaccine Information Statement Meningococcal ACWY Vaccines

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