VACCINE INFORMATION STATEMENT

Td or Tdap (Tetanus-Diphtheria or Tetanus-Diphtheria-Pertussis) Vaccine

What You Need to Know

1 Why get vaccinated?

Tetanus, diphtheria, and pertussis can be very serious diseases.

TETANUS (Lockjaw) causes painful muscle spasms and stiffness, usually all over the body.
- It can lead to tightening of muscles in the head and neck so the victim cannot open his mouth or swallow, or sometimes even breathe. Tetanus kills about 1 out of 5 people who are infected.

DIPHTHERIA can cause a thick membrane to cover the back of the throat.
- It can lead to breathing problems, paralysis, heart failure, and even death.

PERTUSSIS (Whooping Cough) causes severe coughing spells which can lead to difficulty breathing, vomiting, and disturbed sleep.
- It can lead to weight loss, incontinence, rib fractures and passing out from violent coughing. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, including pneumonia and death.

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

The United States saw as many as 200,000 cases a year of diphtheria and pertussis before vaccines were available, and hundreds of cases of tetanus. Since then, tetanus and diphtheria cases have dropped by about 99% and pertussis cases by about 92%.

Children 6 years of age and younger get DTaP vaccine to protect them from these three diseases. But older children, adolescents, and adults need protection too.

2 Vaccines for adolescents and adults: Td and Tdap

Two vaccines are available to protect people 7 years of age and older from these diseases:
- Td vaccine has been used for many years. It protects against tetanus and diphtheria.
- Tdap vaccine was licensed in 2005. It is the first vaccine for adolescents and adults that protects against pertussis as well as tetanus and diphtheria.

A Td booster dose is recommended every 10 years. Tdap is given only once.

3 Which vaccine, and when?

Ages 7 through 18 years
- A dose of Tdap is recommended at age 11 or 12. This dose could be given as early as age 7 for children who missed one or more childhood doses of DTaP.

- Children and adolescents who did not get a complete series of DTaP shots by age 7 should complete the series using a combination of Td and Tdap.

Age 19 years and Older
- All adults should get a booster dose of Td every 10 years.
- Adults under 65 who have never gotten Tdap should get a dose of Tdap as their next booster dose. Adults 65 and older may get one booster dose of Tdap.

- Adults (including women who may become pregnant and adults 65 and older) who expect to have close contact with a baby younger than 12 months of age should get a dose of Tdap to help protect the baby from pertussis.

- Healthcare professionals who have direct patient contact in hospitals or clinics should get one dose of Tdap.

Protection After a Wound
- A person who gets a severe cut or burn might need a dose of Td or Tdap to prevent tetanus infection. Tdap should be used for anyone who has never had a dose previously. Td should be used if Tdap is not available, or for:
- anybody who has already had a dose of Tdap,
- children 7 through 9 years of age who completed the childhood DTaP series, or
- adults 65 and older.

Pregnant Women
- Pregnant women who have never had a dose of Tdap should get one, after the 20th week of gestation and preferably during the 3rd trimester. If they do not get Tdap during their pregnancy they should get a dose as soon as possible after delivery. Pregnant women who have previously received Tdap and need tetanus or diphtheria vaccine while pregnant should get Td.

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

4 Some people should not be vaccinated or should wait

- Anyone who has had a life-threatening allergic reaction after a dose of any tetanus, diphtheria, or pertussis containing vaccine should not get Td or Tdap.

- Anyone who has a severe allergy to any component of a vaccine should not get that vaccine. Tell your doctor if the person getting the vaccine has any severe allergies.

- Anyone who had a coma, or long or multiple seizures within 7 days after a dose of DTP or DTaP should not get Tdap, unless a cause other than the vaccine was found. These people may get Td.
• Talk to your doctor if the person getting either vaccine:
  • Has epilepsy or another nervous system problem,
  • Has severe swelling or severe pain after a previous dose of
    DTP, DTwP, DT, Td, or Tdap vaccine, or
  • 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 Tdap or Td vaccine. A person with a mild illness or
low fever can usually be vaccinated.

5 What are the risks from Tdap
   and Td vaccines?

With a vaccine, as with any medicine, there is always a small
risk of a life-threatening allergic reaction or other serious
problem.

Brief fainting spells and related symptoms (such as jerking
movements) can happen after any medical procedure, including
vaccination. Sitting or lying down for about 15 minutes
after a vaccination can help prevent fainting and injuries
caused by falls. Tell your doctor if the patient feels dizzy or
light-headed, or has vision changes or ringing in the ears.

Getting tetanus, diphtheria or pertussis disease would be much
more likely to lead to severe problems than getting either Td
or Tdap vaccine.

Problems reported after Td and Tdap vaccines are listed below.

Mild Problems
(Noticeable, but did not interfere with activities)

Tdap
• Pain (about 3 in 4 adolescents and 2 in 3 adults)
• Redness or swelling at the injection site (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)
• Chills, body aches, sore joints, rash, swollen glands
  (uncommon)

Td
• Pain (up to about 8 in 10)
• Redness or swelling at the injection site (up to about 1 in 3)
• Mild fever (up to about 1 in 15)
• Headache or tiredness (uncommon)

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

Tdap
• Pain at the injection site (about 1 in 20 adolescents and 1 in
  100 adults)
• Redness or swelling at the injection site (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)
• Headache (1 in 300)
• Nausea, vomiting, diarrhea, stomach ache (up to 3 in 100
  adolescents and 1 in 100 adults)

Td
• Fever over 102°F (rare)

Tdap or Td
• Extensive swelling of the arm where the shot was given (up
  to about 3 in 100).

Severe Problems
(Unable to perform usual activities; required medical attention)

Tdap or Td
• Swelling, severe pain, bleeding and redness in the arm
  where the shot was given (rare).

A severe allergic reaction could occur after any vaccine. They
are estimated to occur less than once in a million doses.

6 What if there is a severe reaction?

What should I look for?
Any unusual condition, such as a severe allergic reaction or
a high fever. If a severe allergic reaction occurred, it would
be within a few minutes to an hour after the shot. Signs of
a serious allergic reaction can include difficulty breathing,
weakness, hoarseness or wheezing, a fast heart beat, hives,
dizziness, paleness, or swelling of the throat.

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 provider to report the reaction by filing a Vaccine
  Adverse Event Reporting System (VAERS) form. Or you can
  file this report through the VAERS website 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

The National Vaccine Injury Compensation Program (VICP)
was created in 1986.

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.

8 How can I learn more?
• Your doctor 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 (Interim)

Td & Tdap Vaccines

1/24/2012

42 U.S.C. § 300aa-26
Education:
This vaccine prevents three serious diseases: Tetanus, Diphtheria, and Pertussis. They can cause permanent damage and death.

- **Tetanus** (lockjaw) causes painful tightening of the muscles. It can lead to “locking” of the jaw and inability to swallow. Approximately 30% of people (3,000 out of every 10,000) who get tetanus die from the disease and many more suffer permanent damage.
- **Diphtheria** causes a thick coating in the back of the throat which can cause breathing problems. Diphtheria can also lead to paralysis and heart failure. Approximately 5% of people (500 out of 10,000) who develop diphtheria die from the disease and many more suffer permanent damage.
- **Pertussis** (Whooping Cough) causes severe coughing spells, vomiting, and disturbed sleep. It can lead to weight loss, incontinence, rib fractures, passing out from violent coughing, pneumonia, and hospitalization due to complications.

For those people who receive the full series of Td vaccines, including a booster once every 10 years, nearly 100% are protected from tetanus and 95% are protected from diphtheria.

Reactions:
About half of the people who receive the vaccine will have no side effects at all, and most other people will have only a mild local reaction.

- Mild reactions include soreness or redness where the shot was given.
  - Aspirin-free pain reliever can be used to reduce fever and soreness.
- In rare cases (less than 1 out of 10,000), people can have a moderate reaction.
  - This reaction consists of a painful swelling of the arm from the shoulder to elbow several hours after receiving the injection, fever >102, redness, swelling, nausea, vomiting or diarrhea
- In very rare cases (far less than 1 out of 10,000), people can have a serious allergic reaction.

Signs of a serious reaction include having trouble breathing, getting hives, becoming pale or weak, having a very fast heart beat or feeling dizzy. If you notice any serious allergic reaction, notify the nurse immediately.

Contra-indications: hypersensitivity to any components of Tetanus, Diphtheria, or Pertussis vaccine or prior allergic reaction.

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, and children 7 through 9 years of age.

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Nurse use only:

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I have received & read the Vaccine Information Sheet dated 1/24/12. I have been allowed to asked questions. I choose to receive the vaccine today.

Signature ___________________________ Date: __________

maj - 1/5/11, nr07/01/11, sm05/22/12