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# VACCINE INFORMATION STATEMENTS

WHAT YOU NEED TO KNOW

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By Federal law, all vaccine providers should provide patients with the appropriate Vaccine Information Statement (VIS) whenever a vaccine is given.

This booklet contains guidelines for using Vaccine Information Statements, frequently-asked questions, and camera-ready copies of all currently-available VIS's.

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Camera-ready copies of current VIS's, as of September, 2001.

**NEW**  
Replaces Previous  
Versions



October 1, 2001

# VIS BASICS

## **WHAT** is a Vaccine Information Statement?

*A Vaccine Information Statement (VIS) is a one-page (two-sided) information sheet, produced by CDC, informing vaccine recipients — or their parents or legal representatives — of the benefits and risks of a vaccine. The law requires them to be given out whenever certain vaccinations are given.*

## **WHO** must give out VIS's?

*All provider of vaccines, both public and private sector.*

## **WHY** must VIS's be used?

*It is a requirement of the **National Childhood Vaccine Injury Act of 1986**. Their purpose is to inform vaccine recipients, or parents of children getting vaccines, about the benefits and risks of vaccines.*

## **WHEN** must VIS's be given out?

*They must be given out at the time of each vaccination — prior to administration of the vaccine.*

## **WHICH** VIS's must I use?

*A VIS must be provided for any vaccine that is covered by the **Vaccine Injury Compensation Program** (i.e., appears on the Vaccine Injury Table). As of September 2001, VIS's that must be used are: DTaP, Td, MMR, Polio, Hepatitis B, Hib, Varicella, and Pneumococcal Conjugate.\* Other VIS's that are available are Influenza, Hepatitis A, Pneumococcal Polysaccharide, Meningococcal, Lyme Disease, and Anthrax. Their use is not required by the National Childhood Injury Act, but is strongly encouraged – and they must be used when giving vaccines purchased through a CDC contract.*

\*Rotavirus is also covered, even though the vaccine is no longer recommended.

# VIS DETAILS

## 1. PROVIDER RESPONSIBILITIES:

### Providers Should

- Give the appropriate VIS to the recipient or to the recipient's parent or legal representative with each dose of vaccine. A VIS must be given out *prior* to administration of the vaccine, and it must be given out *each time* the vaccine is given.
- Record the following information in the patient's permanent medical record:
  - Which VIS was given.
  - Date of publication of the VIS.
  - Date the VIS was given.

and record the following information in either the patient's permanent medical record or in a permanent office log (the record should be both *permanent* and *accessible*):

- The name, address, and title of the person who administered the vaccine.
  - The date of administration.
  - The vaccine manufacturer.
  - The vaccine lot number.
- As needed, supplement VIS's orally, with videotapes, with additional printed material, or in any other way that will help recipients understand the disease and vaccine.

### Providers Should Not

- Change a VIS or make your own VIS. The law requires providers to use those developed by CDC. (NOTE: The law doesn't actually say this. It *used* to say that providers could produce their own VIS-like materials, but that provision was removed from the law in the 1993 amendment.)

### Providers May

- Add your practice's name, address, or phone number to an existing VIS. If you have a copy on which the publication date was cut off, you may add the date.
- Give out VIS's at other times, in addition to prior to vaccine administration, (e.g., pre-natal visits).
- Have a recipient or their parent or legal representative sign a separate "informed consent" form *if it is required by your state*. There is no Federal requirement for written informed consent for vaccinations, and VIS's are not informed consent forms, but some states have such requirements.

## 2. TYPES OF VIS'S AND WHEN TO USE THEM

There are 2 types of VIS's: those for vaccines that are covered by the **National Childhood Vaccine Injury Act**, and those for vaccines that are not.

They are identical, except those covered by the Act bear a reference to the law (42 U.S.C. § 300aa-26) and contain information about the National Vaccine Injury Compensation Program, while those not covered by the Act do not.

### **Vaccines Covered by the National Childhood Vaccine Injury Act:**

Vaccines covered by the National Childhood Vaccine Injury Act are:

Tetanus	Measles	Varicella	Hepatitis B
Pertussis	Mumps	Pneumococcal Conjugate	
Polio	Rubella	<i>Haemophilus influenzae</i> type B	

**These VIS's must always be used.** Every time one of these vaccines is given — regardless of what combination it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — regardless of the age of the recipient — the appropriate VIS must be given out at the time of the vaccination.

VIS's in this category (as of September, 2001), and the dates they were issued, are:

**DTaP** (includes DT): 7/30/01  
**Td**: 6/10/94  
**MMR**: 12/16/98  
**Polio**: 1/1/00  
**Hib**: 12/16/98  
**Hepatitis B**: 7/11/01  
**Varicella**: 12/16/98  
**Pneumococcal Conjugate**: 7/9/01

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Note: When giving combination vaccines for which no separate VIS exists (e.g., DTP/Hib, Hib/Hepatitis B) give out *all* relevant VIS's.

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### **Vaccines NOT Covered by the National Childhood Vaccine Injury Act:**

VIS's exist for several vaccines not covered by the Act. **These VIS's must be used *when the vaccine given has been purchased under CDC contract.*** The legal basis for this is not the Vaccine Injury Act, but the "Duty to Warn" clause in CDC's vaccine contracts.

VIS's in this category (as of September, 2001), and the dates they were issued, are:

**Influenza**: 4/24/01 (updated annually)  
**Hepatitis A**: 8/25/98  
**Pneumococcal Polysaccharide**: 7/29/97  
**Lyme Disease**: 11/1/99  
**Meningococcal**: 3/31/00  
**Anthrax**: 11/6/00



### 3. HOW TO GET VIS'S:

- **The Internet.** All current VIS's are available on the internet at two websites — the National Immunization Program ([www.cdc.gov/nip](http://www.cdc.gov/nip)) and the Immunization Action Coalition ([www.immunize.org](http://www.immunize.org)).
  - ✓ You can download all VIS's as .pdf documents. These can, ideally, then be printed out to look exactly like their print counterparts — and therefore be used as camera-ready copy. In reality, they don't always print out perfectly. Sometimes the graphics don't come through clearly, and sometimes parts of the forms don't print out at all. Here are some tips that might help if you have problems:
    - Make sure you have Adobe Acrobat Reader 3.01 or later. Version 3.0 has some printing problems that were corrected in 3.01.
    - Download the file directly to disk by holding down the shift key when you click on the link to the .pdf file. Save the file to disk and then open Acrobat Reader and print the file.
    - Print one page at a time. If your printer is limited in memory, this can help.
  - ✓ You can also order single hard copies of the VIS's using NIP's Online Order Form (at [https://www2.cdc.gov/nchstp\\_od/PIWeb/niporderform.htm](https://www2.cdc.gov/nchstp_od/PIWeb/niporderform.htm)).
- **State Health Department.** CDC sends each state health department's immunization program camera-ready copies when a new VIS is published. The immunization program in turn provides copies to providers within the state.
- **National Immunization Information Hotline.** Call 1-800-232-2522 (English) or 1-800-232-0233 (Spanish).
- **CDC's "Fax-Back" System.** Anyone wanting a single copy of a VIS can get it through the CDC Fax-Back system. Call 1-888-232-3299 (1-888-CDC-FAXX) and, when prompted, enter document number 600502. An NIP "Resource Request List" will be faxed to you, from which you can order VIS's, as well as other NIP documents.

### TRANSLATIONS

VIS's are translated into a number of languages by the California and Minnesota immunization programs. Availability of VIS's in languages other than English is evolving, but they should be available in at least these languages:

Arabic	Farsi	Japanese	Romanian	Spanish
Armenian	French	Korean	Russian	Tagalog
Cambodian	German	Laotian	Samoan	Thai
Chinese	Haitian Creole	Portugese	Serbo-Croatian	Turkish
Croatian (Serbian)	Hmong	Punjabi	Somali	Vietnamese

Translations can currently be found on two websites: the Minnesota Health Department ([www.health.state.mn.us/divs/dpc/adps/translte/htm](http://www.health.state.mn.us/divs/dpc/adps/translte/htm)) and the Immunization Action Coalition ([www.immunize.org](http://www.immunize.org)). For more information, call California at (510) 540-2065 or Minnesota at (612) 676-5237.

A set of 7 videotapes of VIS's (MMR, DTP, Polio, Hepatitis B, Hib, Varicella, and Pneumococcal Conjugate) is available in Spanish from the University of Michigan. Tapes run approximately 5-9 minutes each, and a set costs \$25. For information, call (517) 353-2596.

## QUESTIONS & ANSWERS

**Q** What is the difference between VIS's, Important Information Statements, Vaccine Information Pamphlets, and Vaccine Information Materials?

**A** Technically, the term **Vaccine Information Statement** applies to those statements dealing with vaccines covered by the National Childhood Vaccine Injury Act (NCVIA). But for convenience sake, we use the term for *all* current information statements. **Important Information Statements (IIS's)** is a term that was used prior to the NCVIA (1986), and is still used sometimes to describe non-NCVIA materials. **Vaccine Information Pamphlets (VIP's)** were the first materials developed after NCVIA was passed. They were multi-page booklets rather than single-sheet documents like the current VIS's. **Vaccine Information Materials (VIM's)** is a generic term that has been used to describe any of these materials.

**Q** Can I still use old materials, such as IIS's or VIP's?

**A** No. You should use only the most recent materials.

**Q** Should the VIS's be used for adults getting vaccines as well as for children?

**A** Yes. Under the National Childhood Vaccine Injury Act, anyone receiving a covered vaccine should be given the appropriate VIS. The VIS's are designed to be used by adults as well as children. The one current exception is the DTP VIS, since pertussis vaccine is not licensed for adults. Adults should use the VIS for adult Td vaccine.

**Q** Are VIS's "informed consent" forms?

**A** No. In fact, even when vaccine information materials had tear-off sheets for parents to sign, they were not technically informed consent forms. The signature was simply to confirm that the "Duty to Warn" clause in the vaccine contract was being fulfilled. There is no Federal requirement for informed consent. VIS's are written to fulfill the information requirements of the NCVIA. But because they cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed. Some *states* may have informed consent laws, covering either procedural requirements (e.g., whether consent may be oral or must be written) or substantive requirements (e.g., types of information required). Check your state medical consent law to determine if there are any specific informed consent requirements relating to immunization.

**Q** The law states that vaccine information materials be given to a child's legal representatives. How is "legal representative" defined?

**A** A "legal representative" is a parent or other individual who is qualified *under state law* to consent to the immunization of a minor. There is not an overriding Federal definition.

**Q** Must the patient, parent, or legal representative physically take away a copy of each VIS, or can we simply let them read a copy and make sure they understand it?

**A** Ideally the person getting the shot, or their representative, should actually take each VIS home. They contain information that may be needed later (e.g., the recommended vaccine schedule, information about what to do in the case of an adverse reaction). Patients may choose not to take the VIS, but the provider should offer them the opportunity to do so.

**Q** How should we comply with the law for patients who cannot read the VIS's (e.g., those who are illiterate or blind)?

**A** The NCVIA requires providers to supplement the VIS's with "visual presentations" or oral "explanations" as needed. If patients are unable to read the VIS's, it is up to the provider to ensure that they have that information. VIS's can be read to these patients, or videotapes can be used as supplements. At least one CD-ROM is being produced on which users can hear the VIS's read.

**Q** When are new VIS's developed?

**A** Generally there are two reasons for developing a new VIS: (1) When a vaccine is added to the Vaccine Injury Table, a VIS must be developed for it. (2) When new ACIP recommendations are published on a vaccine, affecting how the vaccine is used or containing new information on its safety, a new VIS is developed to reflect those changes. A third reason would be licensure of a new vaccine that is routinely used, even if it is not covered by the National Childhood Vaccine Injury Act.

**Q** When do providers have to start using a new VIS?

**A** Once a new VIS has been developed, the date for its required use is announced when the final draft is published in the *Federal Register*.



# THE LAW

## (Development, Content, and Use of VIS's)

### 42 § 300aa-26. Vaccine Information

#### (a) General Rule

Not later than 1 year after the effective date of this subpart, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

#### (b) Development and Revision of Materials

Such materials shall be developed or revised—

- (1) after notice to the public and 60 days of comment thereon, and
- (2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

#### (c) Information Requirements

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall 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.

#### (d) Health Care Provider Duties

On and after a date determined by the Secretary which is—

- (1) after the Secretary develops the information materials required by subsection (a) of this section, and
- (2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a) of this section, supplemented with visual presentation or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.



# **THE LAW**

## **(Recording Patient Information & Reporting Adverse Events)**

### **42 § 300aa-25. Recording and Reporting of Information**

#### **(a) General Rule**

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in each person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

- (1) the date of administration of the vaccine,
- (2) the vaccine manufacturer and lot number of the vaccine,
- (3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and
- (4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

#### **(b) Reporting**

- (1) Each health care provider and vaccine manufacturer shall report to the Secretary—
  - (A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 2114(b) which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,
  - (B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and
  - (C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after the effective date of this part [Effective December 22, 1987]. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of the effective date of this part [December 22, 1987].

#### **(c) Release of Information**

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, United States Code, or otherwise, to any person except—

- (A) the person who received the vaccine, or
- (B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such persons relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

# Instructions for the Use of Vaccine Information Statements

## Required Use

### 1. Provide VIS when vaccination is given.

As required under the National Childhood Vaccine Injury Act, all health care providers in the United States who administer any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), or pneumococcal conjugate vaccine shall **prior to administration of each dose of the vaccine**, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- to the parent or legal representative\* of any child to whom the provider intends to administer such vaccine, or
- to any adult to whom the provider intends to administer such vaccine.

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

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

### 2. Record information for each VIS provided.

Health care providers shall make a notation in each patient's permanent medical record at the time VISs are provided indicating:

- (1) the edition date of the materials, and
- (2) 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):

- (3) the name, address and title of the individual who administers the vaccine,
- (4) the date of administration, and
- (5) the vaccine manufacturer and lot number of the vaccine used.

## Additional Recommended Use

Health care providers may also want to give parents copies of all vaccine information materials prior to the first immunization visit, such as at the first well baby visit.

### Applicability of State Law

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

### Availability of Copies

Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are also available on the Centers for Disease Control and Prevention's website at <http://www.cdc.gov/nip/publications/VIS>. Copies are available in English and in other languages.

### Current Editions of VISs

Diphtheria, Tetanus, Pertussis (DTaP/DT): 7/30/01  
Tetanus Diphtheria (Td): 6/10/94  
Measles, Mumps, Rubella (MMR): 12/16/98  
Hepatitis B: 7/11/01  
Polio: 1/1/00  
*Haemophilus influenzae* type b: 12/16/98  
Varicella (chickenpox): 12/16/98  
Pneumococcal conjugate: 7/9/01

Reference 42 U.S.C. § 300aa-26

10/1/2001





# ANTHRAX VACCINE

## WHAT YOU NEED TO KNOW

### 1 What is anthrax?

Anthrax is a serious disease that can affect both animals and humans. It is caused by bacteria called *Bacillus anthracis*. People can get anthrax from contact with infected animals, wool, meat, or hides. In its most common form, anthrax is a skin disease that causes skin ulcers and usually fever and fatigue. Up to 20% of these cases are fatal if untreated.

When *B. anthracis* is inhaled, as when used as a biological weapon, it is much more serious. The first symptoms may include a sore throat, mild fever and muscle aches. But within several days these symptoms are followed by severe breathing problems, shock, and often meningitis (inflammation of the brain and spinal cord covering). Once symptoms appear, this form of anthrax is almost always fatal, despite treatment with antibiotics.

### 2 What is anthrax vaccine?

Anthrax vaccine protects against anthrax disease. The U.S. vaccine does not contain actual *B. anthracis* cells and it does not cause anthrax disease. Anthrax vaccine was licensed in 1970.

Based on limited but convincing evidence, the vaccine protects against both cutaneous (skin) and inhalational anthrax.

### 3 Who should get anthrax vaccine and when?

People 18 to 65 years of age potentially exposed to large amounts of *B. anthracis* bacteria on the job, such as laboratory workers.

Military personnel who may be at risk of anthrax exposure from weapons.

The basic vaccine series consists of 6 doses.

- The first three doses are given at two-week intervals.
- Three additional doses are given, each one 6 months after the previous dose.

Annual booster doses are needed for ongoing protection.

If a dose is not given at the scheduled time, the series does not have to be started over. Resume the series as soon as practical.

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

### 4 Some people should not get anthrax vaccine or should wait

Anyone who has had a serious allergic reaction to a previous dose of anthrax vaccine should not get another dose.

Anyone who has recovered from cutaneous (skin) anthrax should not get the vaccine.

Pregnant women should not be routinely vaccinated with anthrax vaccine. This is merely a precaution. There is no evidence that the vaccine is harmful to either a pregnant woman or her unborn baby. Vaccination *may* be recommended for pregnant women who have been exposed, or are likely to be exposed, to anthrax.

There is no reason to delay childbearing after either the man or the woman gets anthrax vaccine.

Vaccines, including anthrax vaccine, are safe to give to breast-feeding women.

**5****What are the risks from anthrax vaccine?**

Getting anthrax disease is much more dangerous than any risk from the vaccine.

Like any medicine, a vaccine is capable of causing serious problems, such as severe allergic reactions. The risk of anthrax vaccine causing serious harm, or death, is extremely small.

**Mild Problems**

- Soreness, redness, or itching where the shot was given (about 1 out of 10 men, about 1 out of 6 women)
- A lump where the shot was given (about 1 person out of 2)
- Muscle aches or joint aches (about 1 person out of 5)
- Headaches (about 1 person out of 5)
- Fatigue (about 1 out of 15 men, about 1 out of 6 women)
- Chills or fever (about 1 person out of 20)
- Nausea (about 1 person out of 20).

**Moderate Problems**

- Large areas of redness where the shot was given (up to 1 person out of 20).

**Severe Problems**

- Serious allergic reaction (very rare - less than once in 100,000 doses).

As with any vaccine, other severe problems have been reported. But these events appear to occur no more often among anthrax vaccine recipients than among unvaccinated people.

There is no evidence that anthrax vaccine causes sterility, birth defects, or long-term health problems.

Independent civilian committees have not found anthrax vaccination to be a factor in unexplained illnesses among Gulf War veterans.

**6****What if there is a moderate or 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 happen 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 health care provider to file a Vaccine Adverse Event Reporting System (VAERS) form if you have *any* reaction to the vaccine, or call VAERS yourself at 1-800-822-7967.

**7****How can I learn more?**

- Ask your doctor or other health care provider. They can give you the vaccine package insert or suggest other sources of information.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-2522 (English)
  - Call 1-800-232-0233 (Español)
  - Visit the CDC's website at [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/anthrax\\_g.htm](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/anthrax_g.htm)
- Contact the U.S Department of Defense (DoD):
  - Call 1-877-438-8222
  - Visit the DoD website at [www.anthrax.osd.mil](http://www.anthrax.osd.mil)



**U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES**  
Centers for Disease Control and Prevention  
National Immunization Program



# CHICKENPOX VACCINE

## WHAT YOU NEED TO KNOW

### 1 Why get vaccinated?

Chickenpox (also called varicella) is a common childhood disease. It is usually mild, but it can be serious, especially in young infants and adults.

- The chickenpox virus can be spread from person to person through the air, or by contact with fluid from chickenpox blisters.
- It causes a rash, itching, fever, and tiredness.
- It can lead to severe skin infection, scars, pneumonia, brain damage, or death.
- A person who has had chickenpox can get a painful rash called shingles years later.
- About 12,000 people are hospitalized for chickenpox each year in the United States.
- About 100 people die each year in the United States as a result of chickenpox.

### Chickenpox vaccine can prevent chickenpox.

Most people who get chickenpox vaccine will not get chickenpox. But if someone who has been vaccinated *does* get chickenpox, it is usually very mild. They will have fewer spots, are less likely to have a fever, and will recover faster.

### 2 Who should get chickenpox vaccine and when?

- ✓ Children should get 1 dose of chickenpox vaccine between 12 and 18 months of age, or at any age after that if they have never had chickenpox.

People who do not get the vaccine until 13 years of age or older should get 2 doses, 4-8 weeks apart.

Ask your doctor or nurse for details.

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

### 3

### Some people should not get chickenpox vaccine or should wait

- People should not get chickenpox vaccine if they have ever had a life-threatening allergic reaction to **gelatin**, the antibiotic **neomycin**, or (for those needing a second dose) a **previous dose of chickenpox vaccine**.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting chickenpox vaccine.
- Pregnant women should wait to get chickenpox vaccine until after they have given birth. Women should not get pregnant for 1 month after getting chickenpox vaccine.
- Some people should check with their doctor about whether they should get chickenpox vaccine, including anyone who:
  - Has HIV/AIDS or another disease that affects the immune system
  - Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer
  - Has any kind of cancer
  - Is taking cancer treatment with x-rays or drugs
- People who recently had a transfusion or were given other blood products should ask their doctor when they may get chickenpox vaccine.

Ask your doctor or nurse for more information.

**4****What are the risks from chickenpox vaccine?**

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

Getting chickenpox vaccine is much safer than getting chickenpox disease.

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

**Mild Problems**

- Soreness or swelling where the shot was given (about 1 out of 5 children and up to 1 out of 3 adolescents and adults)
- Fever (1 person out of 10, or less)
- Mild rash, up to a month after vaccination (1 person out of 20, or less). It is possible for these people to infect other members of their household, but this is *extremely* rare.

**Moderate Problems**

- Seizure (jerking or staring) caused by fever (less than 1 person out of 1,000).

**Severe Problems**

- Pneumonia (very rare)

Other serious problems, including severe brain reactions and low blood count, have been reported after chickenpox vaccination. These happen so rarely experts cannot tell whether they are caused by the vaccine or not. If they are, it is extremely rare.

**5****What if there is a moderate or severe reaction?****What should I look for?**

Any unusual condition, such as a serious allergic reaction, high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness within a few minutes to a few hours after the shot. A high fever or seizure, if it occurs, would happen 1 to 6 weeks after the shot.

**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 doctor, nurse, or health department to file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at 1-800-822-7967.

**6****The National Vaccine Injury Compensation Program**

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help you pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit the program's website at <http://www.hrsa.gov/bhpr/vicp>

**7****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's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-2522 (English)
  - Call 1-800-232-0233 (Español)
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**U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES**  
Centers for Disease Control and Prevention  
National Immunization Program



# DIPHTHERIA TETANUS & PERTUSSIS

# VACCINES

## WHAT YOU NEED TO KNOW

### 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 about 1 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.

### 2 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 health care provider 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 should not be given to anyone 7 years of age or older because pertussis vaccine is only licensed for children under 7.

But older children, adolescents, and adults still need protection from tetanus and diphtheria. A booster shot called Td is recommended at 11-12 years of age, and then every 10 years. There is a separate Vaccine Information Statement for Td vaccine.

**5****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.

**6****What if there is a moderate or severe reaction?****What should I look for?**

Any unusual conditions, such as a serious allergic reaction, high fever or unusual behavior. Serious allergic reactions are extremely rare with any vaccine. If one were to occur, it would most likely be within a few minutes to a few hours after the shot. Signs can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. If a high fever or seizure were to occur, it would usually be within a week after the shot.

**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 doctor, nurse, or health department to file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at 1-800-822-7967.

**7****The National Vaccine Injury Compensation Program**

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

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Vaccine Information Statement

DTaP (7/30/01)

42 U.S.C. § 300aa-26



# INFLUENZA VACCINE

WHAT YOU NEED TO KNOW

## 2001-2002

### 1 Why get vaccinated?

Influenza is a serious disease.

It is caused by a virus that spreads from infected persons to the nose or throat of others. The "influenza season" in the U.S. is from November through April each year.

Influenza can cause:

- fever
- sore throat
- cough
- headache
- chills
- muscle aches

People of any age can get influenza. Most people are ill with influenza for only a few days, but some get much sicker and may need to be hospitalized. Influenza causes thousands of deaths each year, mostly among the elderly.

Influenza vaccine can prevent influenza.

### 2 Influenza vaccine

Influenza viruses change often. Therefore, influenza vaccine is updated each year to make sure it is as effective as possible.

Protection develops about 2 weeks after getting the shot and may last up to a year.

### 3 Who should get influenza vaccine?

People at risk for getting a serious case of influenza or influenza complications, and people in close contact with them (including all household members) should get the vaccine. An annual flu shot is recommended for these groups:

- Everyone 50 years of age or older.
- Residents of long term care facilities housing persons with chronic medical conditions.

- Anyone who has a serious long-term health problem with:
  - heart disease
  - lung disease
  - asthma
  - kidney disease
  - metabolic disease, such as diabetes
  - anemia, and other blood disorders

- Anyone whose immune system is weakened because of:
  - HIV/AIDS or other diseases that affect the immune system
  - long-term treatment with drugs such as steroids
  - cancer treatment with x-rays or drugs

- Anyone 6 months to 18 years of age on long-term aspirin treatment (who could develop Reye Syndrome if they catch influenza).

- Women who will be past the 3rd month of pregnancy during the influenza season.

- Physicians, nurses, family members, or anyone else coming in close contact with people at risk of serious influenza

Others who should consider getting influenza vaccine:

- People who provide essential community services
- Persons traveling to the Southern hemisphere between April and September, or to the tropics at any time
- Persons living in dormitories or in other crowded conditions, to prevent outbreaks
- Anyone who wants to reduce their chance of catching influenza

### 4 When should I get influenza vaccine?

Because influenza activity can start as early as December, the best time to get influenza vaccine is during October and November. But getting the vaccine after November can still provide protection. A new shot is needed each year.

- People 9 years of age and older need *one shot*.
- Children less than 9 years old need *two shots*, given one month apart, the first time they get vaccinated against influenza.

Influenza vaccine can be given at the same time as other vaccines, including pneumococcal vaccine.

**5****Can I get influenza even if I get the vaccine this year?**

Yes. Influenza viruses change often, and they might not always be covered by the vaccine. But vaccinated people who *do* get influenza often have a milder case than those who did not get the shot.

Also, many people call any illness with fever and cold symptoms “the flu.” They may expect influenza vaccine to prevent these illnesses. But influenza vaccine is effective only against illness caused by influenza viruses, and not against other illnesses.

**6****Some people should talk with a doctor before getting influenza vaccine.**

Talk with a doctor before getting an influenza vaccination if you:

- 1) ever had a serious allergic reaction to *eggs* or to a *previous dose of influenza vaccine*  
or
- 2) have a history of Guillain-Barré Syndrome (GBS).

If you have a fever or are severely ill at the time the shot is scheduled you should usually wait until you recover before getting influenza vaccine. Talk to your doctor or nurse about whether to reschedule the vaccination.

**7****What are the risks from influenza vaccine?**

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small. Almost all people who get influenza vaccine have no serious problems from it. *The viruses in the vaccine are killed, so you cannot get influenza from the vaccine.*

**Mild problems:**

- soreness, redness, or swelling where the shot was given
- fever
- aches

If these problems occur, they usually begin soon after the shot and last 1-2 days.

**Severe problems:**

- Life-threatening allergic reactions are very rare. If they do occur, it is within a few minutes to a few hours after the shot.
- In 1976, swine flu vaccine was associated with a severe paralytic illness called Guillain-Barré Syndrome (GBS). Influenza vaccines since then have not been clearly linked to GBS. However, if there *is* a risk of GBS from current influenza vaccines, it is estimated at 1 or 2 cases per million persons vaccinated . . . much less than the risk of severe influenza, which can be prevented by vaccination.

**8****What if there is a moderate or severe reaction?****What should I look for?**

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

**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 doctor, nurse, or health department to file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at **1-800-822-7967**.

**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.
- Contact the Centers for Disease Control and Prevention (CDC):
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**U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES**  
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National Immunization Program



# *Haemophilus Influenzae* Type b (Hib) Vaccine

## WHAT YOU NEED TO KNOW

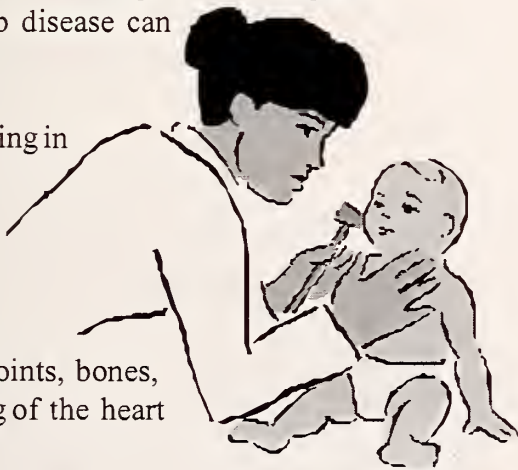
### 1 What is Hib disease?

*Haemophilus influenzae* type b (Hib) disease is a serious disease caused by a bacteria. It usually strikes children under 5 years old.

Your child can get Hib disease by being around other children or adults who may have the bacteria and not know it. The germs spread from person to person. If the germs stay in the child's nose and throat, the child probably will not get sick. But sometimes the germs spread into the lungs or the bloodstream, and then Hib can cause serious problems.

Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the brain and spinal cord coverings, which can lead to lasting brain damage and deafness. Hib disease can also cause:

- pneumonia
- severe swelling in the throat, making it hard to breathe
- infections of the blood, joints, bones, and covering of the heart
- death



Before Hib vaccine, about 20,000 children in the United States under 5 years old got severe Hib disease each year and nearly 1,000 people died.

**Hib vaccine can prevent Hib disease.**

Many more children would get Hib disease if we stopped vaccinating.

### 2 Who should get Hib vaccine and when?

Children should get Hib vaccine at:

- ✓ 2 months of age
- ✓ 4 months of age
- ✓ 6 months of age\*
- ✓ 12-15 months of age

\* Depending on what brand of Hib vaccine is used, your child might not need the dose at 6 months of age. Your doctor or nurse will tell you if this dose is needed.

If you miss a dose or get behind schedule, get the next dose as soon as you can. There is no need to start over.

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

#### Older Children and Adults

Children over 5 years old usually do not need Hib vaccine. But some older children or adults with special health conditions should get it. These conditions include sickle cell disease, HIV/AIDS, removal of the spleen, bone marrow transplant, or cancer treatment with drugs. Ask your doctor or nurse for details.

### 3 Some people should not get Hib vaccine or should wait

- People who have ever had a life-threatening allergic reaction to a previous dose of Hib vaccine should not get another dose.
- Children less than 6 weeks of age should not get Hib vaccine.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting Hib vaccine.

Ask your doctor or nurse for more information.

**4****What are the risks from Hib vaccine?**

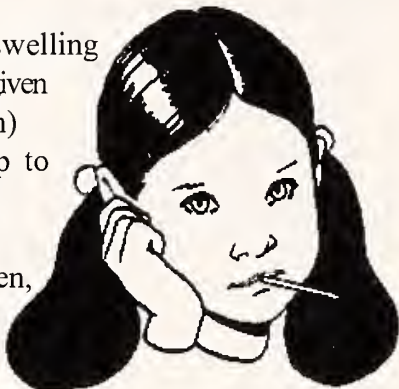
A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of Hib vaccine causing serious harm or death is extremely small.

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

**Mild Problems**

- Redness, warmth, or swelling where the shot was given (up to 1/4 of children)
- Fever over 101°F (up to 1 out of 20 children)

If these problems happen, they usually start within a day of vaccination. They may last 2-3 days.

**5****What if there is a moderate or severe reaction?****What should I look for?**

Any unusual condition, such as a serious allergic reaction, high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat, or dizziness within a few minutes to a few hours after the shot.

**What should I do?**

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National Immunization Program

Vaccine Information Statement

Hib (12/16/98)

42 U.S.C. § 300aa-26



# HEPATITIS A VACCINE

## WHAT YOU NEED TO KNOW

### 1 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 persons with hepatitis A. It is usually spread by close personal contact and sometimes by eating food or drinking water containing HAV.

Hepatitis A can cause:

- mild “flu-like” illness
- jaundice (yellow skin or eyes)
- severe stomach pains and diarrhea

People with hepatitis A infection often have to be hospitalized.

In rare cases, hepatitis A causes death.



A person who has hepatitis A can easily pass the disease to others within the same household.

Hepatitis A vaccine can prevent hepatitis A.

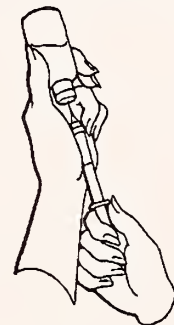
### 2 Who should get hepatitis A vaccine and when?

- Persons 2 years of age and older traveling or working in countries with high rates of hepatitis A, such as those located in Central or South America, the Caribbean, Mexico, Asia (except Japan), Africa, and southern or eastern Europe. *The vaccine series should be started at least one month before traveling.*
- Persons who live in communities that have prolonged outbreaks of hepatitis A.

- Persons who live in communities with high rates of hepatitis A: for example, American Indian, Alaska Native, and Pacific Islander communities and some religious communities.
- Men who have sex with men.
- Persons who use street drugs.
- Persons with chronic liver disease.
- Persons who receive clotting factor concentrates.

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

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



### 3

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

People who have ever had a serious allergic reaction to a previous dose of hepatitis A vaccine should not get another dose.

People who are mildly ill at the time the shot is scheduled should get hepatitis A vaccine. People with moderate or severe illnesses should usually wait until they recover. Your doctor or nurse can advise you.

The safety of hepatitis A vaccine for pregnant women is not yet known. But any risk to either the pregnant woman or the fetus is thought to be very low.

Ask your doctor or nurse for details.

## 4

### What are the risks from hepatitis A vaccine?

A vaccine, like any medicine, is capable of causing 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

- soreness where the shot was given (*about 1 out of 2 adults, and up to 1 out of 5 children*)
- headache (*about 1 out of 6 adults and 1 out of 20 children*)
- loss of appetite (*about 1 out of 12 children*)
- tiredness (*about 1 out of 14 adults*)

If these problems occur, they usually come 3-5 days after vaccination and last for 1 or 2 days.

#### Severe problems

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

## 5

### What if there is a moderate or severe reaction?

#### What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat, or dizziness.

#### 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 doctor, nurse, or health department to file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at 1-800-822-7967.

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### How can I learn more?

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  - Call 1-800-232-2522 (English)
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### IMMUNE GLOBULIN (IG)

Immune globulin can provide *temporary* immunity to hepatitis A.

#### Who should get IG?

- Persons who have been exposed to HAV and can get IG within 2 weeks of that exposure.
- Travelers to areas with high rates of hepatitis A, if they do not receive hepatitis A vaccine.

#### When should IG be given?

It can be given before exposure to HAV or within 2 weeks after exposure

#### Benefits

IG protects against HAV for 3-5 months, depending on dosage.

#### Risks

Rare: swelling, hives, or allergic reaction.



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# HEPATITIS B VACCINE

## WHAT YOU NEED TO KNOW

### 1 Why get vaccinated?

Hepatitis B is a serious disease.

The hepatitis B virus (HBV) can cause short-term (acute) illness that leads to:

- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- pain in muscles, joints, and stomach

It can also cause long-term (chronic) illness that leads to:

- liver damage (cirrhosis)
- liver cancer
- death

About 1.25 million people in the U.S. have chronic HBV infection.

Each year it is estimated that:

- 80,000 people, mostly young adults, get infected with HBV
- More than 11,000 people have to stay in the hospital because of hepatitis B
- 4,000 to 5,000 people die from chronic hepatitis B

Hepatitis B vaccine can prevent hepatitis B. It is the first anti-cancer vaccine because it can prevent a form of liver cancer.

### 2 How is hepatitis B virus spread?

Hepatitis B virus is spread through contact with the blood and body fluids of an infected person. A person can get infected in several ways, such as:

- by having unprotected sex with an infected person
- by sharing needles when injecting illegal drugs
- by being stuck with a used needle on the job
- during birth when the virus passes from an infected mother to her baby

About 1/3 of people who are infected with hepatitis B in the United States don't know how they got it.

### 3 Who should get hepatitis B vaccine and when?

- 1) Everyone 18 years of age and younger
- 2) Adults over 18 who are at risk

Adults at risk for HBV infection include:

- people who have more than one sex partner in 6 months
- men who have sex with other men
- sex contacts of infected people
- people who inject illegal drugs
- health care and public safety workers who might be exposed to infected blood or body fluids
- household contacts of persons with chronic HBV infection
- hemodialysis patients

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

- ✓ People should get 3 doses of hepatitis B vaccine according to the following schedule. *If you miss a dose or get behind schedule, get the next dose as soon as you can. There is no need to start over.*

Hepatitis B Vaccination Schedule		WHO?		
		Infant whose mother is infected with HBV	Infant whose mother is not infected with HBV	Older child, adolescent, or adult
WHEN?	First Dose	Within 12 hours of birth	Birth - 2 months of age	Any time
	Second Dose	1 - 2 months of age	1 - 4 months of age (at least 1 month after first dose)	1 - 2 months after first dose
	Third Dose	6 months of age	6 - 18 months of age	4 - 6 months after first dose

- The second dose must be given at least 1 month after the first dose.
- The third dose must be given at least 2 months after the second dose and at least 4 months after the first.
- The third dose should *not* be given to infants under 6 months of age, because this could reduce long-term protection.

Adolescents 11 to 15 years of age may need only two doses of hepatitis B vaccine, separated by 4-6 months. Ask your health care provider for details.

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

**4****Some people should not get hepatitis B vaccine or should wait**

People should not get hepatitis B vaccine if they have ever had a life-threatening allergic reaction to **baker's yeast** (the kind used for making bread) or to a **previous dose of hepatitis B vaccine**.

People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting hepatitis B vaccine.

Ask your doctor or nurse for more information.

**5****What are the risks from hepatitis B vaccine?**

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

Getting hepatitis B vaccine is much safer than getting hepatitis B disease.

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

**Mild problems**

- soreness where the shot was given, lasting a day or two (up to 1 out of 11 children and adolescents, and about 1 out of 4 adults)
- mild to moderate fever (up to 1 out of 14 children and adolescents and 1 out of 100 adults)

**Severe problems**

- serious allergic reaction (very rare)

**6****What if there is a moderate or severe reaction?****What should I look for?**

Any unusual condition, such as a serious allergic reaction, high fever or unusual behavior. Serious allergic

reactions are extremely rare with any vaccine. If one were to occur, it would be within a few minutes to a few hours after the shot. Signs can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

**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.
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- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-2522** or **1-888-443-7232** (English)
  - Call **1-800-232-0233** (Español)
  - Visit the National Immunization Program's website at <http://www.cdc.gov/nip> or CDC's Division of Viral Hepatitis website at <http://www.cdc.gov/hepatitis>



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Centers for Disease Control and Prevention  
National Immunization Program

Vaccine Information Statement

Hepatitis B (7/11/01)

42 U.S.C. § 300aa-26



# LYME DISEASE VACCINE

## WHAT YOU NEED TO KNOW

### 1 What is Lyme disease?

Lyme disease is caused by infection with a bacteria. People get Lyme disease by being bitten by an infected tick.

You can not get Lyme disease from another person or from an infected animal.

A common sign of Lyme disease is a round, red, expanding rash 2 inches or more in diameter, which appears between 3 days and a month after the tick bite. People with Lyme disease might get chills and fever, headaches, or muscle and joint pain, and often feel tired.

If Lyme disease isn't treated properly, other signs can appear weeks or months after the tick bite. These include:

- arthritis (pain and swelling in the joints, especially the knees)
- numbness or paralysis (often in the face muscles)
- problems with the heart rhythm
- problems with memory or concentration

Very few, if any, people die from Lyme disease.

About 12,000 - 15,000 cases of Lyme disease are reported each year in the United States, mainly in the Northeast and North Central parts of the country and in parts of California.

**Lyme disease vaccine can help prevent Lyme disease.**

### 2 Who should get Lyme disease vaccine and when

Lyme disease vaccine may be given to people between 15 and 70 years of age.

The vaccine should be considered for people in this age range who live in areas where Lyme disease is a problem, and who work or spend leisure time in wooded, brushy, or overgrown areas where ticks live.



People who travel to areas where Lyme disease is common may consider the vaccine if they plan to spend time in wooded or overgrown areas.

The vaccine is not recommended for people with little or no exposure to wooded or overgrown areas that are infested by Lyme disease-bearing ticks.

The Lyme disease vaccine is given as an injection. **Three doses are recommended:**

- ✓ The 1st dose may be given at any time, but ideally should be given in January, February, or March.
- ✓ The 2nd dose should be given 1 month after the first
- ✓ The 3rd dose should be given 12 months after the first

It is not known yet how long protection lasts. But no schedule for booster doses has been determined at this time.

**Effective Date: November 1, 1999**

**3****Some people should not get Lyme disease vaccine or should wait**

- Children younger than 15 years of age should not get Lyme disease vaccine.
- Pregnant women should not get Lyme disease vaccine.
- Anyone with arthritis caused by a previous case of Lyme disease, which has not responded to antibiotic treatment, should not get Lyme disease vaccine. (Others who have had Lyme disease may get the vaccine.)
- Anyone who has had an allergic reaction to a previous dose of Lyme disease vaccine should not get another dose.
- People with immune system problems should check with their doctor before getting Lyme disease vaccine.

**4****What are the risks from Lyme disease vaccine?**

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

In clinical trials, Lyme disease vaccine has been associated only with mild problems, such as soreness where the shot is given.

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

**Mild problems**

- soreness where the shot was given (about 1 person out of 4)
- redness or swelling where the shot was given (less than 1 person out of 50)
- muscle aches, joint pain, fever, chills (about 1 person out of 15 or less)

**5****What if there is a moderate or severe reaction?****What should I look for?**

Any unusual condition, such as a high fever or discomfort. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness, occurring within a few minutes to a few hours after the vaccination. A high fever, should it occur, would be within a week after the vaccination.

**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 doctor, nurse, or health department to file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at 1-800-822-7967.

**6****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.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-2522 (English)
  - Call 1-800-232-0233 (Español)
  - Visit the National Immunization Program's website at <http://www.cdc.gov/nip>



**U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES**  
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# MEASLES MUMPS & RUBELLA

# VACCINES

## WHAT YOU NEED TO KNOW

### 1 Why get vaccinated?

Measles, mumps, and rubella are serious diseases.

#### Measles

- Measles virus causes rash, cough, runny nose, eye irritation, and fever.
- It can lead to ear infection, pneumonia, seizures (jerking and staring), brain damage, and death.

#### Mumps

- Mumps virus causes fever, headache, and swollen glands.
- It can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries, and, rarely, death.

#### Rubella (German Measles)

- Rubella virus causes rash, mild fever, and arthritis (mostly in women).
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

You or your child could catch these diseases by being around someone who has them. They spread from person to person through the air.

Measles, mumps, and rubella (MMR) vaccine can prevent these diseases.

Most children who get their MMR shots will not get these diseases. Many more children would get them if we stopped vaccinating.

### 2 Who should get MMR vaccine and when?

Children should get 2 doses of MMR vaccine:

- ✓ The first at **12-15 months of age**
- ✓ and the second at **4-6 years of age**.

These are the recommended ages. But children can get the second dose at any age, as long as it is at least 28 days after the first dose.

Some **adults** should also get MMR vaccine:

Generally, anyone 18 years of age or older, who was born after 1956, should get at least one dose of MMR vaccine, unless they can show that they have had either the vaccines or the diseases.

Ask your doctor or nurse for more information.

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

### 3

#### Some people should not get MMR vaccine or should wait

- People should not get MMR vaccine who have ever had a life-threatening allergic reaction to **gelatin**, the antibiotic **neomycin**, or a **previous dose of MMR vaccine**.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting MMR vaccine.
- Pregnant women should wait to get MMR vaccine until after they have given birth. Women should not get pregnant for 3 months after getting MMR vaccine.
- Some people should check with their doctor about whether they should get MMR vaccine, including anyone who:
  - Has HIV/AIDS, or another disease that affects the immune system
  - Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer.
  - Has any kind of cancer
  - Is taking cancer treatment with x-rays or drugs
  - Has ever had a low platelet count (a blood disorder)

Over . . .



- People who recently had a transfusion or were given other blood products should ask their doctor when they may get MMR vaccine

Ask your doctor or nurse for more information.

## 4 What are the risks from MMR vaccine?

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

Getting MMR vaccine is much safer than getting any of these three diseases.

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

### Mild Problems

- Fever (up to 1 person out of 6)
- Mild rash (about 1 person out of 20)
- Swelling of glands in the cheeks or neck (rare)

If these problems occur, it is usually within 7-12 days after the shot. They occur less often after the second dose.

### Moderate Problems

- Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)

### Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been known to occur after a child gets MMR vaccine. But this happens so rarely, experts cannot be sure whether they are caused by the vaccine or not. These include:
  - Deafness
  - Long-term seizures, coma, or lowered consciousness
  - Permanent brain damage

## 5 What if there is a moderate or severe reaction?

### What should I look for?

Any unusual conditions, such as a serious allergic reaction, high fever or behavior changes. Signs of a

serious allergic reaction include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness within a few minutes to a few hours after the shot. A high fever or seizure, if it occurs, would happen 1 or 2 weeks after the shot.

### 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 doctor, nurse, or health department to file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at 1-800-822-7967.

## 6 The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help you pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit the program's website at <http://www.hrsa.gov/bhpr/vicp>

## 7 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's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-2522 (English)
  - Call 1-800-232-0233 (Español)
  - Visit the National Immunization Program's website at <http://www.cdc.gov/nip>



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# MENTINGOCOCCAL VACCINE

## WHAT YOU NEED TO KNOW

### 1 What is meningococcal disease?

Meningococcal disease is a serious illness, caused by a bacteria. It is the leading cause of bacterial meningitis in children 2-18 years old in the United States. Meningitis is an infection of the brain and spinal cord coverings. Meningococcal disease can also cause blood infections.

About 2,600 people get meningococcal disease each year in the U.S. 10-15% of these people die, in spite of treatment with antibiotics. Of those who live, another 10% lose their arms or legs, become deaf, have problems with their nervous systems, become mentally retarded, or suffer seizures or strokes.

Anyone can get meningococcal disease. But it is most common in infants less than one year of age, and in people with certain medical conditions. College freshmen, particularly those who live in dormitories, have a slightly increased risk of getting meningococcal disease.

**Meningococcal vaccine can prevent 2 of the 3 important types of meningococcal disease in older children and adults.**

Meningococcal vaccine is not effective in preventing all types of the disease. But it does help to protect many people who might become sick if they don't get the vaccine.

Drugs such as penicillin can be used to treat meningococcal infection. Still, about 1 out of every ten people who get the disease dies from it, and many others are affected for life. This is why it is important that people with the highest risk for meningococcal disease get the vaccine.



### 2 Who should get meningococcal vaccine and when?

Meningococcal vaccine is not routinely recommended for most people. People who *should* get the vaccine include:

- U.S. Military recruits
- People who might be affected during an outbreak of certain types of meningococcal disease.
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as West Africa.
- Anyone who has a damaged spleen, or whose spleen has been removed.
- Anyone who has terminal complement component deficiency (an immune system disorder).

The vaccine should also be *considered* for:

- Some laboratory workers who are routinely exposed to the meningococcal bacteria.

The vaccine may also be given to college students who choose to be vaccinated. College freshmen, especially those who live in dormitories, and their parents should discuss the risks and benefits of vaccination with their health care providers.

Meningococcal vaccine is usually not recommended for children under two years of age. But under special circumstances it may be given to infants as young as 3 months (the vaccine does not work as well in very young children). Ask your health care provider for details.

#### How many doses?

- ✓ For people 2 years of age and over: 1 dose (Sometimes an additional dose is recommended for people who continue to be at high risk. Ask your provider.)
- ✓ For children 3 months to 2 years of age who need the vaccine: 2 doses, 3 months apart

**Meningococcal - 3/31/2000**



**3****Some people should not get meningococcal vaccine or should wait**

People should not get meningococcal vaccine if they have ever had a serious allergic reaction to a previous dose of the vaccine.

People who are mildly ill at the time the shot is scheduled can still get meningococcal vaccine. People with moderate or severe illnesses should usually wait until they recover. Your provider can advise you.

Meningococcal vaccine may be given to pregnant women.

**4****What are the risks from meningococcal vaccine?**

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of the meningococcal vaccine causing serious harm, or death, is extremely small.

Getting meningococcal vaccine is much safer than getting the disease.

*Mild problems*

Some people who get meningococcal vaccine have mild side effects, such as redness or pain where the shot was given. These symptoms usually last for 1-2 days.

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

**5****What if there is a serious reaction?***What should I look for?*

Look for any unusual condition, such as a severe allergic reaction, high fever, or unusual behavior. If a serious allergic reaction occurred, it would happen within a few minutes to a few hours 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 health care provider to file a Vaccine Adverse Events Reporting System (VAERS) form, or call VAERS yourself at 1-800-822-7967.

**6****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's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-2522 (English)
  - Call 1-800-232-0233 (Español)
  - Visit the National Immunization Program's website at <http://www.cdc.gov/nip>
  - Visit the National Center for Infectious Disease's meningococcal disease website at [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/meningococcal\\_g.htm](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/meningococcal_g.htm)



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National Immunization Program

Vaccine Information Statement  
Meningococcal

(3/31/2000)



# PNEUMOCOCCAL CONJUGATE VACCINE

## WHAT YOU NEED TO KNOW

### 1 Why get vaccinated?

Infection with *Streptococcus pneumoniae* bacteria can cause serious illness and death. Invasive pneumococcal disease is responsible for about 200 deaths each year among children under 5 years old. It is the leading cause of bacterial meningitis in the United States. (Meningitis is an infection of the covering of the brain).

Each year pneumococcal infection causes severe disease in children under five years old:

- over 700 cases of meningitis,
- 13,000 blood infections, and
- about 5 million ear infections.

It can also lead to other health problems, including:

- pneumonia,
- deafness,
- brain damage.



Children under 2 years old are at highest risk for serious disease.

Pneumococcus bacteria are spread from person to person through close contact.

Pneumococcal infections can be hard to treat because the bacteria have become resistant to some of the drugs that have been used to treat them. This makes **prevention** of pneumococcal infections even more important.

Pneumococcal conjugate vaccine can help prevent serious pneumococcal disease, such as meningitis and blood infections. It can also prevent some ear infections. But ear infections have many causes, and pneumococcal vaccine is effective against only some of them.

### 2 Pneumococcal conjugate vaccine

Pneumococcal conjugate vaccine is approved for infants and toddlers. Protection lasts at least 3 years, so children who are vaccinated when they are infants will be protected when they are at greatest risk for serious disease.

Some older children and adults may get a different vaccine called pneumococcal polysaccharide vaccine. There is a separate Vaccine Information Statement for people getting this vaccine.

### 3 Who should get the vaccine and when?

#### • Children Under 2 Years of Age

The routine schedule for pneumococcal conjugate vaccine is 4 doses, one dose at each of these ages:

- ✓ 2 months
- ✓ 4 months
- ✓ 6 months
- ✓ 12-15 months

Children who weren't vaccinated at these ages can still get the vaccine. The number of doses needed depends on the child's age. Ask your health care provider for details.

#### • Children Between 2 and 5 Years of Age

Pneumococcal conjugate vaccine is also recommended for children between 2 and 5 years old who have not already gotten the vaccine and are at high risk of serious pneumococcal disease. This includes children who:

- have sickle cell disease,
- have a damaged spleen or no spleen,
- have HIV/AIDS,
- have other diseases that affect the immune system, such as diabetes, cancer, or liver disease, or who
- take medications that affect the immune system, such as chemotherapy or steroids, or
- have chronic heart or lung disease.

The vaccine should be considered for other children who are at increased risk of serious pneumococcal disease. This includes children who:

- are under 3 years of age,
- are of Alaska Native, American Indian or African American descent, or
- attend group day care.

The number of doses needed depends on the child's age. Ask your health care provider for more details.

Pneumococcal conjugate vaccine may be given at the same time as other vaccines.

**4****Some children should not get pneumococcal conjugate vaccine or should wait**

Children should not get pneumococcal conjugate vaccine if they had a serious (life-threatening) allergic reaction to a previous dose of this vaccine, or have a severe allergy to a vaccine component. Tell your health-care provider if your child has ever had a severe reaction to any vaccine, or has any severe allergies.

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 the vaccine.

**5****What are the risks from pneumococcal conjugate vaccine?**

In studies (nearly 60,000 doses), pneumococcal conjugate vaccine was associated with only mild reactions:

- Up to about 1 infant out of 4 had redness, tenderness, or swelling where the shot was given.
- Up to about 1 out of 3 had a fever of over 100.4°F, and up to about 1 in 50 had a higher fever (over 102.2°F).
- Some children also became fussy or drowsy, or had a loss of appetite.

So far, no serious reactions have been associated with this vaccine. However, a vaccine, like any medicine, could cause serious problems, such as a severe allergic reaction. The risk of this vaccine causing serious harm, or death, is extremely small.

**6****What if there is a moderate or severe reaction?****What should I look for?**

Look for any unusual condition, such as a serious allergic reaction, high fever, or unusual behavior.

Serious allergic reactions are extremely rare with any vaccine. If one were to occur, it would most likely be within a few minutes to a few hours after the shot. Signs can include:

- |                          |                   |            |
|--------------------------|-------------------|------------|
| - difficulty breathing   | - weakness        | - hives    |
| - hoarseness or wheezing | - fast heart beat | - paleness |
| - swelling of the throat | - dizziness       |            |

**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 health care provider to file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at **1-800-822-7967**.

**7****The National Vaccine Injury Compensation Program**

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit their website at <http://www.hrsa.gov/bhpr/vicp>

**8****How can I learn more?**

- Ask your health care provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-2522** (English)
  - Call **1-800-232-0233** (Español)
  - Visit the National Immunization Program's website at <http://www.cdc.gov/nip>



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National Immunization Program

Vaccine Information Statement

Pneumococcal Conjugate Vaccine (7/9/01) 42 U.S.C. § 300aa-26



# PNEUMOCOCCAL POLYSACCHARIDE VACCINE

## WHAT YOU NEED TO KNOW

### 1 Why get vaccinated?

Pneumococcal disease is a serious disease that causes much sickness and death. In fact, pneumococcal disease kills more people in the United States each year than all other vaccine-preventable diseases combined. Anyone can get pneumococcal disease. However, some people are at greater risk from the disease. These include people 65 and older, the very young, and people with special health problems such as alcoholism, heart or lung disease, kidney failure, diabetes, HIV infection, or certain types of cancer.

Pneumococcal disease can lead to serious infections of the lungs (pneumonia), the blood (bacteremia), and the covering of the brain (meningitis). About 1 out of every 20 people who get pneumococcal pneumonia dies from it, as do about 2 people out of 10 who get bacteremia and 3 people out of 10 who get meningitis. People with the special health problems mentioned above are even more likely to die from the disease.

Drugs such as penicillin were once effective in treating these infections; but the disease has become more resistant to these drugs, making treatment of pneumococcal infections more difficult. This makes prevention of the disease through vaccination even more important.

### 2 Pneumococcal polysaccharide vaccine (PPV)

The pneumococcal polysaccharide vaccine (PPV) protects against 23 types of pneumococcal bacteria. Most healthy adults who get the vaccine develop protection to most or all of these types within 2 to 3 weeks of getting the shot. Very old people, children under 2 years of age, and people with some long-term illnesses might not respond as well or at all.

### 3 Who should get PPV?

- All adults 65 years of age or older.
- Anyone over 2 years of age who has a long-term health problem such as:
  - heart disease
  - sickle cell disease
  - alcoholism
  - leaks of cerebrospinal fluid
  - lung disease
  - diabetes
  - cirrhosis
- Anyone over 2 years of age who has a disease or condition that lowers the body's resistance to infection, such as:
  - Hodgkin's disease
  - kidney failure
  - nephrotic syndrome
  - damaged spleen, or no spleen
  - organ transplant
  - lymphoma, leukemia
  - multiple myeloma
  - HIV infection or AIDS
- Anyone over 2 years of age who is taking any drug or treatment that lowers the body's resistance to infection, such as:
  - long-term steroids
  - radiation therapy
  - certain cancer drugs
- Alaskan Natives and certain Native American populations.





## 4

### How many doses of PPV are needed?

Usually one dose of PPV is all that is needed.

However, under some circumstances a second dose may be given.

- A second dose is recommended for those people aged 65 and older who got their first dose when they were under 65, if 5 or more years have passed since that dose.
- A second dose is also recommended for people who:
  - have a damaged spleen or no spleen
  - have sickle-cell disease
  - have HIV infection or AIDS
  - have cancer, leukemia, lymphoma, multiple myeloma
  - have kidney failure
  - have nephrotic syndrome
  - have had an organ or bone marrow transplant
  - are taking medication that lowers immunity (such as chemotherapy or long-term steroids)

Children 10 years old and younger may get this second dose 3 years after the first dose. Those older than 10 should get it 5 years after the first dose.

## 5

### Other facts about getting the vaccine

- Otherwise healthy children who often get ear infections, sinus infections, or other upper respiratory diseases do not need to get PPV because of these conditions.
- PPV may be less effective in some people, especially those with lower resistance to infection. But these people should still be vaccinated, because they are more likely to get seriously ill from pneumococcal disease.
- **Pregnancy:** The safety of PPV for pregnant women has not yet been studied. There is no evidence that the vaccine is harmful to either the mother or the fetus, but pregnant women should consult with their doctor before being vaccinated. Women who are at high risk of pneumococcal disease should be vaccinated before becoming pregnant, if possible.

## 6

### What are the risks from PPV?

PPV is a very safe vaccine.

About half of those who get the vaccine have very mild side effects, such as redness or pain where the shot is given.

Less than 1% develop a fever, muscle aches, or more severe local reactions.

Severe allergic reactions have been reported very rarely.

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

Getting the disease is much more likely to cause serious problems than getting the vaccine.

## 7

### What if there is a serious reaction?

**What should I look for?**

- Severe allergic reaction (hives, difficulty breathing, shock)

**What should I do?**

- Call a doctor, or get 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 Reporting System (VAERS) form, or call VAERS yourself at 1-800-822-7967.

## 8

### 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.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-7468 (English)
  - OR
  - Call 1-800-232-0233 (Spanish)
  - OR
  - Visit the National Immunization Program website at <http://www.cdc.gov/nip>



# POLIO VACCINE

## WHAT YOU NEED TO KNOW

### 1 What is polio?

Polio is a disease caused by a virus. It enters a child's (or adult's) body through the mouth. Sometimes it does not cause serious illness. But sometimes it causes *paralysis* (can't move arm or leg). It can kill people who get it, usually by paralyzing the muscles that help them breathe.

Polio used to be very common in the United States. It paralyzed and killed thousands of people a year before we had a vaccine for it.

### 2 Why get vaccinated?

**Inactivated Polio Vaccine (IPV) can prevent polio.**

**History:** A 1916 polio epidemic in the United States killed 6,000 people and paralyzed 27,000 more. In the early 1950's there were more than 20,000 cases of polio each year. **Polio vaccination was begun in 1955.** By 1960 the number of cases had dropped to about 3,000, and by 1979 there were only about 10. The success of polio vaccination in the U.S. and other countries sparked a world-wide effort to eliminate polio.

**Today:** No wild polio has been reported in the United States for over 20 years. But the disease is still common in some parts of the world. It would only take one case of polio from another country to bring the disease back if we were not protected by vaccine. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine. Until then, we need to keep getting our children vaccinated.

#### Oral Polio Vaccine: No longer recommended

There are two kinds of polio vaccine: **IPV**, which is the shot recommended in the United States today, and a live, oral polio vaccine (**OPV**), which is drops that are swallowed.

Until recently OPV was recommended for most children in the United States. OPV helped us rid the country of polio, and it is still used in many parts of the world.

Both vaccines give immunity to polio, but OPV is better at keeping the disease from spreading to other people. However, for a few people (about one in 2.4 million), OPV actually causes polio. Since the risk of getting polio in the United States is now extremely low, experts believe that using oral polio vaccine is no longer worth the slight risk, except in limited circumstances which your doctor can describe. The polio shot (IPV) does not cause polio. **If you or your child will be getting OPV, ask for a copy of the OPV supplemental Vaccine Information Statement.**

### 3 Who should get polio vaccine and when?

IPV is a shot, given in the leg or arm, depending on age. Polio vaccine may be given at the same time as other vaccines.

#### Children

Most people should get polio vaccine when they are children. Children get 4 doses of IPV, at these ages:

- ✓ A dose at 2 months
- ✓ A dose at 4 months
- ✓ A dose at 6-18 months
- ✓ A booster dose at 4-6 years

#### Adults

Most adults do not need polio vaccine because they were already vaccinated as children. But three groups of adults are at higher risk and *should* consider polio vaccination:

- (1) people traveling to areas of the world where polio is common,
- (2) laboratory workers who might handle polio virus, and
- (3) health care workers treating patients who could have polio.

Adults in these three groups who **have never been vaccinated against polio** should get 3 doses of IPV:

- ✓ The first dose at any time,
- ✓ The second dose 1 to 2 months later,
- ✓ The third dose 6 to 12 months after the second.

Adults in these three groups who **have had 1 or 2 doses** of polio vaccine in the past should get the remaining 1 or 2 doses. It doesn't matter how long it has been since the earlier dose(s).

Adults in these three groups who **have had 3 or more doses** of polio vaccine (either IPV or OPV) in the past may get a booster dose of IPV.

Ask your health care provider for more information.



**4****Some people should not get IPV or should wait.****These people should not get IPV:**

- Anyone who has ever had a life-threatening allergic reaction to the antibiotics **neomycin**, **streptomycin** or **polymyxin B** should not get the polio shot.
- Anyone who has a severe allergic reaction to a polio shot should not get another one.

**These people should wait:**

- Anyone who is moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting polio vaccine. People with minor illnesses, such as a cold, *may* be vaccinated.

Ask your health care provider for more information.

**5****What are the risks from IPV?**

Some people who get IPV get a sore spot where the shot was given. The vaccine used today has never been known to cause any serious problems, and most people don't have any problems at all with it.

However, a vaccine, like any medicine, could cause serious problems, such as a severe allergic reaction. *The risk of a polio shot causing serious harm, or death, is extremely small.*

**6****What if there is a serious reaction?****What should I look for?**

Look for any unusual condition, such as a serious allergic reaction, high fever, or unusual behavior.

If a serious allergic reaction occurred, it would happen within a few minutes to a few hours 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 doctor, nurse, or health department to file a Vaccine Adverse Event Reporting System (VAERS) form, or call the VAERS toll-free number yourself at 1-800-822-7967.

Reporting reactions helps experts learn about possible problems with vaccines.

**7****The National Vaccine Injury Compensation Program**

In the rare event that you or your child has a serious reaction to a vaccine, there is a federal program that can help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit the program's website at <http://www.hrsa.gov/bhpr/vicp>

**8****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's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-2522 (English)
  - Call 1-800-232-0233 (Español)
  - Visit the National Immunization Program's website at <http://www.cdc.gov/nip>



**U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES**  
Centers for Disease Control and Prevention  
National Immunization Program



# TETANUS AND DIPHTHERIA VACCINE (Td)

What you need to know before you or your child gets the vaccine



## ABOUT THE DISEASES

Tetanus (lockjaw) and diphtheria are serious diseases. Tetanus is caused by a germ that enters the body through

a cut or wound. Diphtheria spreads when germs pass from an infected person to the nose or throat of others.

**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

**Diphtheria causes**  
a thick coating in the nose, throat, or airway

**It can lead to:**  
- breathing problems  
- heart failure  
- paralysis  
- death

## ABOUT THE VACCINES

### Benefits of the vaccines

Vaccination is the best way to protect against tetanus and diphtheria. Because of vaccination, there are many fewer cases of these diseases. Cases are rare in children because most get DTP (Diphtheria, Tetanus, and Pertussis), DTaP (Diphtheria, Tetanus, and acellular Pertussis), or DT (Diphtheria and Tetanus) vaccines. There would be many more cases if we stopped vaccinating people.

### When should you get Td vaccine?

Td is made for people 7 years of age and older.

People who have not gotten at least 3 doses of any tetanus and diphtheria vaccine (DTP, DTaP or DT) during their lifetime should do so using Td. After a person gets the third dose, a Td dose is needed every 10 years all through life.

Other vaccines may be given at the same time as Td.

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

- ever had a serious allergic reaction or other problem with Td, or any other tetanus and diphtheria vaccine (DTP, DTaP or DT)
- now has a moderate or severe illness
- is pregnant

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

### What are the risks from Td vaccine?

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

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

Almost all people who get Td have no problems from it.



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Centers for Disease Control  
and Prevention

## Mild problems

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

- soreness, redness, or swelling where the shot was given

These problems can be worse in adults who get Td vaccine very often.

Acetaminophen or ibuprofen (non-aspirin) may be used to reduce soreness.

## Severe problems

These problems happen very rarely:

- serious allergic reaction
- deep, aching pain and muscle wasting in upper arm(s). This starts 2 days to 4 weeks after the shot, and may last many months.

## 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 call:  
(800) 822-7967 (toll-free)

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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)

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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.







