

### 7. What if There Is a Serious Reaction?

What should I look for?

- See item 4 on the other side for possible risks.

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.

### 8. 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.dhhs.gov/bhpr/vicp>.

### 9. How Can I Learn More?

- Ask your doctor or nurse. She/he 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

Polio (2/1/99) (Interim) Vaccine Information Statement 42 U.S.C. 300aa-26

Dated: February 17, 1999.

**Jeffrey P. Koplan,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### New Vaccine Information Materials for Hepatitis B, Haemophilus influenzae type b (Hib), and Varicella (Chickenpox) Vaccines, and Revised Vaccine Information Materials for Measles, Mumps, Rubella (MMR) Vaccines

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** Under the National Childhood Vaccine Injury Act (42 U.S.C. 300aa-26), the CDC must develop vaccine information materials that all health care providers, whether public or private, are required to distribute to patients/parents prior to administration of each dose of specific vaccines. On September 3, 1998, CDC published a notice in the **Federal Register** (63 FR 47026) seeking public comment on proposed vaccine information materials for the newly covered vaccines hepatitis B, Haemophilus influenzae type b, and varicella vaccines, and also seeking comment on proposed revised vaccine information materials for measles, mumps, rubella (MMR) vaccines. The 60 day comment period ended on November 2, 1998. Following review of the comments submitted and consultation as required under the law, CDC has finalized these vaccine information materials. The final materials are contained in this notice.

**DATES:** Effective June 1, 1999, each health care provider who administers any vaccine that contains hepatitis B, Haemophilus influenzae type b (Hib), varicella (chickenpox), measles, mumps, or rubella vaccines shall, prior to administration of each dose of the vaccine, provide a copy of the relevant vaccine information materials contained in this notice to the parent or legal representative of any child to whom such provider intends to administer the vaccine and to any adult to whom such provider intends to administer the vaccine.

See Instructions for Use of Vaccine Information Materials (Vaccine Information Statements), in the Supplementary Information section of this notice, for information on required use of previously available vaccine information materials.

**FOR FURTHER INFORMATION CONTACT:** Walter A. Orenstein, M.D., Director, National Immunization Program,

Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, N.E., Atlanta, Georgia 30333, telephone (404) 639-8200.

**SUPPLEMENTARY INFORMATION:** The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by health care providers to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) a concise description of the benefits of the vaccine,
- (2) a concise description of the risks associated with the vaccine,
- (3) a statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella, and poliomyelitis vaccines. Since April 15, 1992, any health care provider who intends to administer one of the covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines.

The materials currently in use for measles, mumps, and rubella vaccines and the Td tetanus diphtheria vaccine were published in a **Federal Register** notice on June 20, 1994 (59 FR 31888). The current materials for diphtheria, tetanus, and pertussis containing vaccines, other than Td vaccine, were published in a **Federal Register** notice on January 9, 1998 (63 FR 1730). Elsewhere in this issue of the **Federal Register**, we are publishing revised interim polio vaccine information

materials for use pending formal revision of those materials as required under the statute. (The polio vaccine information materials are being revised to inform patients/parents of the most recent recommendations for use of the two polio vaccines.)

(Rotavirus vaccine is in the process of being added to the National Vaccine Injury Compensation Program. Development of vaccine information materials for this vaccine is underway. As part of the process for developing these new materials, CDC will publish draft materials in the **Federal Register** for public comment and will consult with affected parties as required by the statute. Distribution of the vaccine information materials for this newly covered vaccine will be required following publication of the final version of the rotavirus vaccine information materials in the **Federal Register**.)

#### Newly Covered Vaccines

With passage of Public Law 105-34, Congress expanded coverage of the National Vaccine Injury Compensation Program, effective August 6, 1997, to include the following additional vaccines: hepatitis B, Haemophilus influenzae type b (Hib), and varicella (chickenpox) vaccines. Therefore, as required under 42 U.S.C. 300aa-26, the CDC has developed vaccine information materials covering these vaccines.

Included in this notice are vaccine information materials covering hepatitis B, Haemophilus influenzae type b (Hib), and varicella vaccines.

#### Revised Measles, Mumps, Rubella Vaccine Information Materials

In addition to vaccine information materials for these newly covered vaccines, this notice also includes revised vaccine information materials for measles, mumps, rubella (MMR) vaccines. The MMR materials are being revised to follow the format of the materials published since 1997.

#### Development of New/Revised Vaccine Information Materials

On September 3, 1998, CDC published a notice in the **Federal Register** (63 FR 47026) seeking public comment on proposed new vaccine information materials for hepatitis B, Haemophilus influenzae type b, and varicella vaccines, and revised vaccine information materials for measles, mumps, rubella vaccines.

The 60-day comment period ended on November 2, 1998. Comments were submitted by a few individuals and organizations. As required by the statute, CDC has also consulted with

various groups, including the Advisory Commission on Childhood Vaccines, Food and Drug Administration, American Academy of Pediatrics, American Nurses Association, Dissatisfied Parents Together, Healthy Start, Immunization Action Coalition, Immunization Education and Action Committee: Healthy Mothers/Healthy Babies Coalition, National Association of Pediatric Nurse Associates and Practitioners, National Association of County Health Officials, National Coalition for Adult Immunization, National Coalition of Hispanic Health and Human Services Organizations (COSSMHO), National Council of La Raza, National Vaccine Advisory Committee, and the National Vaccine Injury Compensation Program. Also, CDC provided copies of the draft materials to other organizations and sought their consultation; however, those organizations did not provide comments. In addition to consultation with these groups, the CDC presented drafts of these vaccine information materials to parents gathered in 18 ethnically and geographically diverse focus groups. Comments provided by the consultants and focus groups, along with the comments submitted in response to the September 3, 1998 **Federal Register** notice, were fully considered in revising the proposed vaccine information materials.

Following consultation and review of comments submitted, the hepatitis B, Haemophilus influenzae type b, varicella, and measles, mumps, rubella vaccine information materials have been finalized and are contained in this notice. They are entitled "Hepatitis B Vaccine: What You Need to Know," "Haemophilus influenzae type b (Hib) Vaccine: What You Need to Know," "Chickenpox Vaccine: What You Need to Know," and "Measles, Mumps & Rubella Vaccines: What You Need to Know."

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#### INSTRUCTIONS FOR USE OF VACCINE INFORMATION MATERIALS (VACCINE INFORMATION STATEMENTS)

##### Required Use

As required under the National Childhood Vaccine Injury Act (42 U.S.C. 300aa-26), 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), or varicella (chickenpox) vaccine shall, prior to administration of each dose of the vaccine, provide a copy of the relevant vaccine information materials that have

been produced by the Centers for Disease Control and Prevention (CDC):

(a) to the parent or legal representative of any child to whom the provider intends to administer such vaccine, and

(b) to any adult to whom the provider intends to administer such vaccine.

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

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

#### Additional Recommended Use of Materials

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

#### Effective Date for Required Use of New Vaccine Information Materials

Effective June 1, 1999, each health care provider who administers any vaccine that contains hepatitis B, Haemophilus influenzae type b (Hib), varicella (chickenpox), measles, mumps, or rubella vaccines shall, prior to administration of each dose of the vaccine, provide a copy of the relevant vaccine information materials, dated December 16, 1998, to the parent or legal representative of any child to whom such provider intends to administer the vaccine and to any adult to whom such provider intends to administer the vaccine.

#### Use of Interim Polio Vaccine Information Materials

Beginning as soon as practicable after February 23, 1999, health care providers should distribute copies of the interim polio vaccine information materials, dated February 1, 1999, in place of the February 6, 1997 version of the polio materials.

#### Current Editions of Vaccine Information Materials for Other Covered Vaccines

Diphtheria, Tetanus, Pertussis (DTP/DTaP/DT) Vaccine Information Materials, dated August 15, 1997

Tetanus, Diphtheria (Td) Vaccine Information Materials, dated June 10, 1994

Measles, Mumps, Rubella Vaccine Information Materials, dated June 10, 1994; to be replaced no later than June 1, 1999 by the December 16, 1998 revised Measles, Mumps, Rubella materials

**Recordkeeping**

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided indicating (1) the edition date of the materials distributed 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) the name, address and title of the individual who administers the vaccine, the date of administration and the vaccine manufacturer and lot number of the vaccine used.

**Applicability of State Law**

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

**Availability of Copies**

Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are available in English and in other languages.

February 23, 1999

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**List of Contact Telephone Numbers for Copies of Vaccine Information Materials**

Single camera-ready copies of the vaccine information materials, and copies of the instructions for their use, are available by calling the telephone number listed below for your location:

Alabama (334) 242-5023

Alaska (907) 269-8000

American Samoa 011-684-633-4606

Arizona (602) 230-5832

Arkansas (501) 661-2723

California (510) 540-2065

Los Angeles (213) 580-9800

Colorado (303) 692-2669

Connecticut (860) 509-7929

Delaware (302) 739-4746

Florida (850) 487-2755

Georgia (404) 657-3158

Guam (671) 734-7135

Hawaii (808) 586-8330

Idaho (208) 334-5942

Illinois (217) 785-1455

Chicago (312) 746-6120

Indian Health Service (505) 248-4226

Indiana (317) 233-7010

Iowa (515) 281-4917

Kansas (785) 296-5593

Kentucky (502) 564-4478

Louisiana (504) 483-1900

Maine (207) 287-3746

Mariana Islands (670) 234-8950, x2005

Marshall Islands 011-692-625-3480

Maryland (410) 767-6679

Massachusetts (617) 983-6807

Michigan (517) 335-8159

Detroit (313) 876-4606

Micronesia 011-691-320-2619

Minnesota (612) 676-5569

Mississippi (601) 576-7751

Missouri (573) 751-6133

Montana (406) 444-5580

Nebraska (402) 471-2937

Nevada (702) 684-5900

New Hampshire (603) 271-4485

New Jersey (609) 588-7520

New Mexico (505) 827-2369

New York State (518) 473-4437

New York City (212) 676-2293

North Carolina (919) 733-7752

North Dakota (701) 328-2378

Ohio (614) 466-4643

Oklahoma (405) 271-4073

Oregon (503) 731-4020

Palau 011-680-488-1757

Pennsylvania (717) 787-5681

Philadelphia (215) 685-6749

Puerto Rico (787) 274-5612

Rhode Island (401) 222-4603

South Carolina (803) 898-0460

South Dakota (605) 773-3737

Tennessee (615) 741-7343

Texas (512) 458-7284

Houston (713) 794-9267

San Antonio (210) 207-8794

Utah (801) 538-9450

Vermont (802) 863-7638

Virgin Islands (809) 776-8311, ext. 2151

Virginia (804) 786-6246 or 6247

Washington, D.C. (202) 576-7130

Washington (360) 236-3541

West Virginia (304) 558-2188

Wisconsin (608) 266-1339

Wyoming (307) 777-6001

**Hepatitis B Vaccine: What You Need To Know****1. Why get vaccinated?**

Hepatitis B is a serious disease

The hepatitis B virus 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 hepatitis B virus infection.

Each year it is estimated that:

- 200,000 people, mostly young adults, get infected with hepatitis B virus
- 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:

- during birth when the virus passes from an infected mother to her baby
- by having sex with an infected person
- by injecting illegal drugs
- by being stuck with a used needle on the job
- by sharing personal items, such as a razor or toothbrush with an infected person

People can get hepatitis B virus infection without knowing how they got it. About 1/3 of hepatitis B cases in the United States have an unknown source.

**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 hepatitis B virus infection include people who have more than one sex partner, men who have sex with other men, injection drug users, health care workers, and others who might be exposed to infected blood or body fluids.

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

When?	Who?		
	Infant whose mother is infected with hepatitis B virus	Infant whose mother is not infected with hepatitis B virus	Older child, adolescent, or adult
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 younger than 6 months of age.

All three doses are needed for full and lasting immunity.

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 behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. If such a reaction were to occur, it would be within a few minutes to a few hours 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 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.dhhs.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 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 Hepatitis Branch website at <http://www.cdc.gov/ncidod/diseases/hepatitis/>

U.S. Department of Health & Human Services, Centers for Disease Control and Prevention, National Immunization Program.

Hepatitis B (12/16/98) Vaccine Information Statement 42 U.S.C. 300aa-26

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**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 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 problem?

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?

- 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.dhhs.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>

U.S. Department of Health & Human Services, Centers for Disease Control and Prevention, National Immunization Program.

Hib (12/16/98) Vaccine Information Statement 42 U.S.C. § 300aa–26.

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#### 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.

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800-338-2382 or visit the program's website at <http://www.hrsa.dhhs.gov/bhpr/vicp>

#### 7. How can I learn more?

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- 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.

Varicella (12/16/98) Vaccine Information Statement 42 U.S.C. §300aa-26

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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)

- 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 condition, 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.dhhs.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>.

U.S. Department of Health & Human Services, Centers for Disease Control and Prevention, National Immunization Program.

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**Jeffrey P. Koplan,**

*Director, Centers for Disease Control and Prevention (CDC).*

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