

# Screening Checklist for Contraindications to Vaccines for Children and Teens

PATIENT NAME \_\_\_\_\_

DATE OF BIRTH \_\_\_\_/\_\_\_\_/\_\_\_\_  
month / day / year

**For parents/guardians:** The following questions will help us determine which vaccines your child may be given today. If you answer “yes” to any question, it does not necessarily mean your child should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	yes	no	don't know
1. Is the child sick today?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the child have allergies to medications, food, a vaccine component, or latex?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has the child had a serious reaction to a vaccine in the past?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Has the child had a health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If the child to be vaccinated is 2 through 4 years of age, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. If your child is a baby, have you ever been told he or she has had intussusception?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. In the past 3 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Is the child/teen pregnant or is there a chance she could become pregnant during the next month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Has the child received vaccinations in the past 4 weeks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FORM COMPLETED BY \_\_\_\_\_ DATE \_\_\_\_\_

FORM REVIEWED BY \_\_\_\_\_ DATE \_\_\_\_\_

Did you bring your immunization record card with you?    yes     no

It is important to have a personal record of your child's vaccinations. If you don't have one, ask the child's healthcare provider to give you one with all your child's vaccinations on it. Keep it in a safe place and bring it with you every time you seek medical care for your child. Your child will need this document to enter day care or school, for employment, or for international travel.

# Information for Healthcare Professionals about the Screening Checklist for Contraindications (Children and Teens)

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the references listed at the end.

## 1. Is the child sick today? [all vaccines]

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events (1, 2). However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as otitis media, upper respiratory infections, and diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

## 2. Does the child have allergies to medications, food, a vaccine component, or latex? [all vaccines]

An anaphylactic reaction to latex is a contraindication to vaccines that contain latex as a component or as part of the packaging (e.g., vial stoppers, prefilled syringe plungers, prefilled syringe caps). If a person has anaphylaxis after eating gelatin, do not administer vaccines containing gelatin. A local reaction to a prior vaccine dose or vaccine component, including latex, is not a contraindication to a subsequent dose or vaccine containing that component. For information on vaccines supplied in vials or syringes containing latex, see reference 3; for an extensive list of vaccine components, see reference 4. An egg-free recombinant influenza vaccine (RIV3) may be used in people age 18 years and older with egg allergy of any severity who have no other contraindications. Children and teens younger than age 18 years who have experienced a serious systemic or anaphylactic reaction (e.g., hives, swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs can usually be vaccinated with inactivated influenza vaccine (IIV); consult ACIP recommendations (see reference 4).

## 3. Has the child had a serious reaction to a vaccine in the past? [all vaccines]

History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses (1). History of encephalopathy within 7 days following DTP/DTaP is a contraindication for further doses of pertussis-containing vaccine. Precautions to DTaP (not Tdap) include the following: (a) seizure within 3 days of a dose, (b) pale or limp episode or collapse within 48 hours of a dose, (c) continuous crying for 3 or more hours within 48 hours of a dose, and (d) fever of 105°F (40°C) within 48 hours of a previous dose. There are other adverse events that might have occurred following vaccination that constitute contraindications or precautions to future doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

## 4. Has the child had a health problem with lung, heart, kidney, or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy? [LAIV]

The safety of LAIV in children and teens with lung, heart, kidney, or metabolic disease (e.g., diabetes), or a blood disorder has not been established. These conditions, including asthma in children ages 5 years and older, should be considered precautions for the use of LAIV. Children on long-term aspirin therapy should not be given LAIV; instead, they should be given IIV.

## 5. If the child to be vaccinated is 2 through 4 years of age, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months? [LAIV]

Children ages 2 through 4 years who have had a wheezing episode within the past 12 months should not be given LAIV. Instead, these children should be given IIV.

## 6. If your child is a baby, have you ever been told that he or she has had intussusception? [Rotavirus]

Infants who have a history of intussusception (i.e., the telescoping of one portion of the intestine into another) should not be given rotavirus vaccine.

## 7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problem? [DTaP, Td, Tdap, IIV, LAIV, MMRV]

DTaP and Tdap are contraindicated in children who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of DTaP and Tdap. For children with stable neurologic disorders (including seizures) unrelated to vaccination, or for children with a family history of seizures,

vaccinate as usual (exception: children with a personal or family [i.e., parent or sibling] history of seizures generally should not be vaccinated with MMRV; they should receive separate MMR and VAR vaccines). A history of Guillain-Barré syndrome (GBS) is a consideration with the following: 1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give age-appropriate Tdap instead of Td if no history of prior Tdap, to improve pertussis protection; 2) Influenza vaccine (IIV or LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccination, vaccinate with IIV if at high risk for severe influenza complications.

## 8. Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem? [LAIV, MMR, MMRV, RV, VAR]

Live virus vaccines (e.g., MMR, MMRV, varicella, rotavirus, and the intranasal live, attenuated influenza vaccine [LAIV]) are usually contraindicated in immunocompromised children. However, there are exceptions. For example, MMR is recommended for asymptomatic HIV-infected children who do not have evidence of severe immunosuppression. Likewise, varicella vaccine should be considered for HIV-infected children with age-specific CD4+ T-lymphocyte percentage at 15% or greater and may be considered for children age 8 years and older with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/μL. Immunosuppressed children should not receive LAIV. Infants who have been diagnosed with severe combined immunodeficiency (SCID) should not be given a live virus vaccine, including rotavirus (RV) vaccine. Other forms of immunosuppression are a precaution, not a contraindication, to rotavirus vaccine. For details, consult the ACIP recommendations (1, 6, 7, 8).

## 9. In the past 3 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatments? [LAIV, MMR, MMRV, VAR]

Live virus vaccines (e.g., LAIV, MMR, VAR, ZOS) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACIP statement (1). Some immune mediator and immune modulator drugs (especially the antitumor-necrosis factor agents adalimumab, infliximab, and etanercept) may be immunosuppressive. The use of live vaccines should be avoided in persons taking these drugs (MMWR 2011;60 [RR2]:23). To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see reference 9. LAIV can be given only to healthy non-pregnant people ages 2 through 49 years.

## 10. In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? [LAIV, MMR, MMRV, VAR]

Certain live virus vaccines (e.g., LAIV, MMR, MMRV, varicella) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations or the current Red Book for the most current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines (1, 2).

## 11. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? [LAIV, MMR, MMRV, VAR]

Live virus vaccines (e.g., MMR, MMRV, varicella, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus (1, 2). Sexually active young women who receive a live virus vaccine should be instructed to practice careful contraception for one month following receipt of the vaccine (7, 10). On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if risk of exposure is imminent (e.g., travel to endemic areas) and immediate protection is needed. Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester (5, 11)

## 12. Has the child received vaccinations in the past 4 weeks? [LAIV, MMR, MMRV, VAR, yellow fever]

Children who were given either LAIV or an injectable live virus vaccine (e.g., MMR, MMRV, varicella, yellow fever) should wait 28 days before receiving another vaccination of this type. Inactivated vaccines may be given at the same time or at any spacing interval.

## REFERENCES

1. CDC. General recommendations on immunization. at [www.cdc.gov/mmwr/pdf/rr/r6002.pdf](http://www.cdc.gov/mmwr/pdf/rr/r6002.pdf).
2. AAP. Red Book: Report of the Committee on Infectious Diseases at [www.aapredbook.org](http://www.aapredbook.org).
3. Latex in Vaccine Packaging: [www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf)
4. Table of Vaccine Components: [www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/exipient-table-2.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/exipient-table-2.pdf).
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6. CDC. Measles, mumps, and rubella – vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps. MMWR 1998; 47 (RR-8).
7. CDC. Prevention of varicella: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2007; 56 (RR-4).
8. Rubin LG, Levin MJ, Ljungman P. 2013 IDSA Clinical practice guideline for vaccination of the immunocompromised host. Clinical Infectious Diseases 2014;58(3):e44–100.
9. Tomblin M, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic stem cell transplant recipients: a global perspective. BiolBloodMarrowTransplant 15:1143–1238; 2009 at [www.cdc.gov/vaccines/pubs/hemato-cell-transplants.htm](http://www.cdc.gov/vaccines/pubs/hemato-cell-transplants.htm).
10. CDC. Notice to readers: Revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine. MMWR 2001; 50 (49).
11. CDC. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants: Recommendations of the ACIP. MMWR 2008; 57 (RR-4).

DATE \_\_\_\_\_  
 Tobacco user \_\_\_\_\_ non-user \_\_\_\_\_  
 Advised to quit? yes \_\_\_\_\_ no \_\_\_\_\_ NA \_\_\_\_\_  
 Cessation Referral Offered? Yes NO NA \_\_\_\_\_  
 Are you exposed to SHS Yes \_\_\_\_\_ No \_\_\_\_\_

I acknowledge that the PCHD has provided me with their notice of privacy practices.

29  
 North Dakota

Information collected on this form will be used for the North Dakota Immunization Information System (NDIIS) with other entities in accordance with North Dakota Century Code 23-01-05.3.

Patient's name: (Last, First, Middle) \_\_\_\_\_

Hispanic or Latino: (Circle) Yes \_\_\_\_\_ No \_\_\_\_\_

Date of birth: \_\_\_\_\_ Age: \_\_\_\_\_ Gender (Circle): Male \_\_\_\_\_ Female \_\_\_\_\_

Address: (Street or P.O. box) \_\_\_\_\_

Race: (Check box)  
 American Indian or Alaskan Native  
 Asian  
 Black or African American  
 Native Hawaiian or other Pacific Islander  
 White

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip code: \_\_\_\_\_ County: \_\_\_\_\_ Birth state or birth country (if not U.S.): \_\_\_\_\_

Primary telephone number: \_\_\_\_\_ Work telephone number: \_\_\_\_\_ E-mail address: \_\_\_\_\_

Mother's name (if patient is 18 years or younger): Last, First, Middle \_\_\_\_\_ Mother's maiden name (if patient is 18 years or younger): \_\_\_\_\_

A copy of the appropriate Centers for Disease Control and Prevention Vaccine Information Statement(s) has been provided. I have read, or have had explained, the information about the disease(s) and the vaccine(s) listed below. There was an opportunity to ask questions and all questions were answered satisfactorily. I believe that I understand the benefits and risks of the vaccine(s) cited, and ask that the vaccine(s) listed below be given to me or to the person named above (for whom I am authorized to make this request).

Signature – Person to receive vaccine or person authorized to sign on the patient's behalf: \_\_\_\_\_ Date: \_\_\_\_\_

**VFC eligibility status: (Check all that apply)**  
 American Indian     Medicaid-eligible     No insurance     Underinsured (vaccines not covered by health insurance)  
 Not eligible (vaccines covered by health insurance)     Other state eligible

✓	Vaccine(s) to be given	Route <sup>1</sup>	VIS date <sup>2</sup>	Manufacturer <sup>3</sup>	Lot number	S/P <sup>4</sup>	Admin. site <sup>5</sup>	Person admin. <sup>6</sup>
	DTaP	IM		GSK SP				
	DTaP-HepB-IPV (Pediarix <sup>®</sup> )	IM		GSK				
	DTaP-IPV/Hib (Pentacel <sup>®</sup> )	IM		SP				
	DTaP-IPV (Kinrix <sup>®</sup> )	IM		GSK				
	Hepatitis A	IM		GSK MSD				
	Hepatitis B	IM		GSK MSD				
	Hep A-Hep B (Twinrix <sup>®</sup> )	IM		GSK				
	Hib ( <i>H. influenzae</i> type B)	IM		GSK MSD SP				
	HPV2 or HPV4 or HPV9 (circle)	IM		GSK MSD				
	Influenza	ID/IM/IN						
	IPV	IM/SQ		SP				
	MMR	SQ		MSD				
	MMRV	SQ		MSD				
	Meningococcal Group B	IM		GSK PFZ				
	MCV4	IM		GSK SP				
	Pneumococcal Conjugate	IM		PFZ				
	Pneumococcal Polysaccharide	IM/SQ		MSD				
	Rotavirus	PO		GSK MSD				
	Td	IM		MBL SP				
	Tdap	IM		GSK SP				
	Varicella	SQ		MSD				
	Zoster	SQ		MSD				

Exemption or contraindication<sup>7</sup>: \_\_\_\_\_ Date of exemption or contraindication: \_\_\_\_\_

Signature and title of person administering vaccine: \_\_\_\_\_ Date vaccine administered: \_\_\_\_\_

## VACCINE INFORMATION STATEMENT

# Tdap Vaccine

## What You Need to Know

(Tetanus,  
Diphtheria and  
Pertussis)

Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

### 1 Why get vaccinated?

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

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

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

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

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

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

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

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

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

### 2 Tdap vaccine

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

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

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

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

Your doctor or the person giving you the vaccine can give you more information.

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

### 3 Some people should not get this vaccine

- A person who has ever had a life-threatening allergic reaction after a previous dose of any diphtheria, tetanus or pertussis containing vaccine, OR has a severe allergy to any part of this vaccine, should not get Tdap vaccine. Tell the person giving the vaccine about any severe allergies.
- Anyone who had coma or long repeated seizures within 7 days after a childhood dose of DTP or DTaP, or a previous dose of Tdap, should not get Tdap, unless a cause other than the vaccine was found. They can still get Td.
- Talk to your doctor if you:
  - have seizures or another nervous system problem,
  - had severe pain or swelling after any vaccine containing diphtheria, tetanus or pertussis,
  - ever had a condition called Guillain-Barré Syndrome (GBS),
  - aren't feeling well on the day the shot is scheduled.



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

## 4

### Risks

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

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

#### Mild problems following Tdap

*(Did not interfere with activities)*

- Pain where the shot was given (about 3 in 4 adolescents or 2 in 3 adults)
- Redness or swelling where the shot was given (about 1 person in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents or 1 in 100 adults)
- Headache (about 3 or 4 people in 10)
- Tiredness (about 1 person in 3 or 4)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents or 1 in 10 adults)
- Chills, sore joints (about 1 person in 10)
- Body aches (about 1 person in 3 or 4)
- Rash, swollen glands (uncommon)

#### Moderate problems following Tdap

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

- Pain where the shot was given (up to 1 in 5 or 6)
- Redness or swelling where the shot was given (up to about 1 in 16 adolescents or 1 in 12 adults)
- Fever over 102°F (about 1 in 100 adolescents or 1 in 250 adults)
- Headache (about 1 in 7 adolescents or 1 in 10 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 or 3 people in 100)
- Swelling of the entire arm where the shot was given (up to about 1 in 500).

#### Severe problems following Tdap

*(Unable to perform usual activities; required medical attention)*

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

#### Problems that could happen after any vaccine:

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

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

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

## 5

### What if there is a serious problem?

#### What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.
- Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

#### What should I do?

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

VAERS does not give medical advice.

## 6

### The National Vaccine Injury Compensation Program

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

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation). There is a time limit to file a claim for compensation.

## 7

### How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC's website at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

### Vaccine Information Statement Tdap Vaccine

2/24/2015

42 U.S.C. § 300aa-26

Office Use  
Only



# Meningococcal ACWY Vaccines – MenACWY and MPSV4: *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1 Why get vaccinated?

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

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

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

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

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

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

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

## 2 Meningococcal ACWY Vaccines

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

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

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

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

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

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

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



### 3

## Some people should not get this vaccine

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.**

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

- **If you are pregnant or breastfeeding.**

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

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

### 4

## Risks of a vaccine reaction

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

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

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

### Problems that could happen after any injected vaccine:

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

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

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

### 5

## What if there is a serious reaction?

### What should I look for?

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

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

### What should I do?

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

*VAERS does not give medical advice.*

### 6

## The National Vaccine Injury Compensation Program

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

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation). There is a time limit to file a claim for compensation.

### 7

## How can I learn more?

- Ask your health care provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

## Vaccine Information Statement Meningococcal ACWY Vaccines

03/31/2016

42 U.S.C. § 300aa-26

Office Use Only



# HPV (Human Papillomavirus) Vaccine— Gardasil®-9: *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1 Why get vaccinated?

Gardasil-9 prevents human papillomavirus (HPV) types that cause many cancers, including:

- **cervical cancer** in females,
- **vaginal and vulvar cancers** in females,
- **anal cancer** in females and males,
- **throat cancer** in females and males, and
- **penile cancer** in males.

In addition, Gardasil-9 prevents HPV types that cause **genital warts** in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. Gardasil-9 can prevent most of these cases of cervical cancer.

*Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests.*

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans, including teens, get infected every year. Most infections will go away and not cause serious problems. But thousands of women and men get cancer and diseases from HPV.

## 2 HPV vaccine

Gardasil-9 is an FDA-approved HPV vaccine. It is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 years through age 26 years.

Three doses of Gardasil-9 are recommended with the second dose given 1–2 months after the first dose and the third dose given 6 months after the first dose.

## 3 Some people should not get this vaccine

- Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.
- Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.

*Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.*

- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or your baby. Any woman who learns she was pregnant when she got Gardasil-9 vaccine is encouraged to contact the manufacturer's registry for HPV vaccination during pregnancy at 1-800-986-8999. Women who are breastfeeding may be vaccinated.
- If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.



## 4 Risks of a vaccine reaction

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

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

### Mild or moderate problems following Gardasil-9:

- Reactions in the arm where the shot was given:
  - Soreness (about 9 people in 10)
  - Redness or swelling (about 1 person in 3)
- Fever:
  - Mild (100°F) (about 1 person in 10)
  - Moderate (102°F) (about 1 person in 65)
- Other problems:
  - Headache (about 1 person in 3)

### Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
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### What should I do?

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Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling **1-800-822-7967**.

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