

Human Papilloma Virus Vaccine

HPV (Human Papillomavirus) Vaccination Level II

Skill Level: RN, LPN

Definition: The HPV Vaccine protects against certain subtypes of the Human Papillomavirus (HPV) that are associated with Cervical Cancer in women. It can also help prevent Venereal Warts.

Procedure:

1. Verify patient identity. Verify patient has not already completed vaccine course. If patient has had 3 doses of HPV vaccine over a 6 month period, verify and document. If patient has had one or two doses of HPV vaccine in the past, get the history and consult the institution's medical provider or chief medical officer.
2. Verify that female patient is 26 years of age or under.
3. ODOC is currently using Gardasil™, which is given in three doses on a 0 month, 2 months, and 6 months schedule.

Vaccination Procedure:

1. Have the patient review Vaccine Information Statement (VIS) Gardasil™ and answer any questions they have. Screen for Contraindications. Do not give if patient is allergic to Gardasil™ or any of its components (yeast, amorphous aluminum hydroxyphosphate sulfate, polysorbate 80). Gardasil™ is not recommended for use in pregnant women.
2. Obtain signed ODOC informed consent form. File in chart.
3. Give first dose of Gardasil™ vaccine 0.5 ml Intra-Muscular in the Deltoid muscle. Schedule the subsequent two (2) immunizations in two months and again in six months. Document the injections on the MAR and on the immunization section on the problem list.
4. At first dose enter the patient into the Health Status Condition: INF HPV I.
5. Give an *individualized personal immunization record card* provided by the Health Department to the inmate and update it with each dose.
6. Fill out the "ALERT SUBMISSION FORM" for each inmate/client/patient encounter. Put a patient information sticker in the top upper corner box, and fill in the patient's Mother's Maiden Name. Be sure to attach identifying barcode and forward to ALERT. Put the remainder of the bar-coded sheet in patient Health Care Record for future use. Match appropriate barcode and affix to form and date form in upper left hand corner each time immunization is given and forward to ALERT. Forward forms to ALERT once a month to the Oregon Public Health Division Immunization Program. (Fax to: Cessa Karson 971-673-0278).

Human Papilloma Virus Vaccine

Nursing and Patient Information:

1. Vaccination against Human Papillomavirus is used for girls and women 9-26 years of age to help protect against the following diseases caused by the Human Papillomavirus:
 - Cervical Cancer
 - Vulvar and vaginal cancers
 - Genital Warts
 - Abnormal and precancerous cervical, vaginal, and vulvar lesions
2. These diseases have many causes and the vaccine does not protect against every subtype of HPV. It does help prevent subtypes commonly associated with cancer (Subtypes 6, 11, 16 and 18). The vaccine does not prevent disease that is caused by other subtypes of HPV, other viruses or bacteria.
3. Gardasil does not help with Venereal Warts that are already present, but having venereal warts in the past should not keep you from vaccinating against HPV subtypes that might cause more serious illness like cancer.
4. Patients cannot get HPV or any of the above diseases from the vaccine itself.
5. Gardasil is not recommended for use during pregnancy, or if the patient has had a prior allergic reaction to Gardasil or any of its components (yeast, amorphous aluminum hydroxyphosphate sulfate, polysorbate 80).
6. Women still need to do routine PAP smear screening after HPV vaccination


APPROVED:

Medical Services Manager

Date

Chief Medical Officer

Date



Medical Director

6/27/2010
Date

Effective Date: June 2010
Revised: June 2010

HPV (HUMAN PAPILOMAVIRUS) VACCINE

Gardasil®

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See <http://www.immunize.org/vls>.

1 What is HPV?

Genital human papillomavirus (HPV) is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause **cervical cancer** in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 10,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women and other types of cancer in both men and women. It can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

2 HPV vaccine - Why get vaccinated?

HPV vaccine is important because **it can prevent most cases of cervical cancer** in females, if it is given before a person is exposed to the virus.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.

The vaccine you are getting is one of **two vaccines that can be given to prevent HPV**. It may be given to both males and females. In addition to preventing cervical cancer, it can also prevent **vaginal and vulvar cancer** in females, and **genital warts** in both males and females.

The other vaccine is given to females only, and only for prevention of cervical cancer.

3 Who should get this HPV vaccine and when?

Females: *Routine Vaccination*

- HPV vaccine is recommended for girls **11 or 12 years of age**. It may be given to girls starting at age 9.

Why is HPV vaccine given to girls at this age?

It is important for girls to get HPV vaccine **before** their first sexual contact – because they won't have been exposed to human papillomavirus.

Once a girl or woman has been infected with the virus, the vaccine might not work as well or might not work at all.

Females: *Catch-Up Vaccination*

- The vaccine is also recommended for girls and women **13 through 26 years of age** who did not get all 3 doses when they were younger.

Males

Males **9 through 26 years of age** may get HPV vaccine to prevent genital warts. As with females, it is best to be vaccinated before the first sexual contact.

HPV vaccine is given as a 3-dose series

1st Dose	Now
2nd Dose	1 to 2 months after Dose 1
3rd Dose	6 months after Dose 1

Additional (booster) doses are not recommended.

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

4 Some people should not get HPV vaccine or should wait

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to yeast.

Human Papilloma Virus Vaccine

- HPV vaccine is not recommended for **pregnant women**. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.

Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's **HPV in pregnancy registry** at 800-986-8999. This will help us learn how pregnant women respond to the vaccine.

- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a **moderate or severe illness** should wait until they are better.

5 What are the risks from this vaccine?

This HPV vaccine has been used in the U.S. and around the world for several years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Several **mild to moderate problems** are known to occur with HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given:
 - Pain (about 8 people in 10)
 - Redness or swelling (about 1 person in 4)
- 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)
 - Fainting. Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. **Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls.** Tell your provider if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

6 What if there is a severe reaction?

What should I look for?

Serious allergic reactions including rash; swelling of the hands and feet, face, or lips; and breathing difficulty.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at <http://www.vaers.hhs.gov>, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

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

Persons who believe they may have been injured by a vaccine may file a claim with VICP by calling 1-800-338-2382 or visiting their website at <http://www.hrsa.gov/vaccinecompensation>.

8 How can I learn more?

- Ask your provider. 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 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at <http://www.cdc.gov/hpv> and <http://www.cdc.gov/vaccines>



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)
Human Papillomavirus (HPV) *Gardasil* 3/30/2010

Human Papilloma Virus Vaccine



GARDASIL
[Human Papillomavirus Quadrivalent
(Types 6, 11, 16, and 18) Vaccine, Recombinant]

Read this Information with care before getting GARDASIL¹. You (the person getting GARDASIL) will need 3 doses of the vaccine. It is important to read this leaflet when you get each dose. This leaflet does not take the place of talking with your health care provider about GARDASIL.

What is GARDASIL?

GARDASIL is a vaccine (injection/shot) that is used for girls and women 9 through 26 years of age to help protect against the following diseases caused by Human Papillomavirus (HPV):

- ▶ Cervical cancer
- ▶ Vulvar and vaginal cancers
- ▶ Genital warts
- ▶ Abnormal and precancerous cervical, vaginal, and vulvar lesions
 - The diseases listed above have many causes, and GARDASIL only protects against diseases caused by certain kinds of HPV (called Type 6, Type 11, Type 16, and Type 18). Most of the time, these 4 types of HPV are responsible for the diseases listed above.
 - GARDASIL cannot protect you from a disease that is caused by other types of HPV, other viruses, or bacteria.
 - GARDASIL does not treat HPV infection.
 - You cannot get HPV or any of the above diseases from GARDASIL.

GARDASIL is used for boys and men 9 through 26 years of age to help protect against genital warts.

What important information about GARDASIL should I know?

- ▶ You should continue to get routine cervical cancer screening.
- ▶ GARDASIL may not fully protect everyone who gets the vaccine.
- ▶ GARDASIL will not protect against HPV types that you already have.

Who should not get GARDASIL?

- You should not get GARDASIL if you have, or have had:
- ▶ an allergic reaction after getting a dose of GARDASIL.
 - ▶ a severe allergic reaction to yeast, amorphous aluminum hydroxyphosphate sulfate, polysorbate 80.

What should I tell my health care provider before getting GARDASIL?

Tell your health care provider if you:

- ▶ are pregnant or planning to get pregnant. GARDASIL is not recommended for use in pregnant women.
- ▶ have immune problems, like HIV infection, cancer, or you take medicines that affect your immune system.
- ▶ have a fever over 100°F (37.8°C).
- ▶ had an allergic reaction to another dose of GARDASIL.
- ▶ take any medicines, even those you can buy over the counter.

Your health care provider will help decide if you should get the vaccine.

How is GARDASIL given?

GARDASIL is a shot that is usually given in the arm muscle. You will need 3 shots given on the following schedule:

- ▶ Dose 1: at a date you and your health care provider choose.
- ▶ Dose 2: 2 months after Dose 1.
- ▶ Dose 3: 6 months after Dose 1.

Fainting can happen after getting GARDASIL. Sometimes people who faint can fall and hurt themselves. For this reason, your health care provider may ask you to sit or lie down for 15 minutes after you get GARDASIL. Some people who faint might shake or become stiff. This may require evaluation or treatment by your health care provider.

Make sure that you get all 3 doses on time so that you get the best protection. If you miss a dose, talk to your health care provider.

Patient Information about GARDASIL[®] (pronounced "gard-Ah-sill")
Generic name: [Human Papillomavirus Quadrivalent
(Types 6, 11, 16, and 18) Vaccine, Recombinant]

What are the possible side effects of GARDASIL?

The most common side effects with GARDASIL are:

- ▶ pain, swelling, itching, bruising, and redness at the injection site
- ▶ headache
- ▶ fever
- ▶ nausea
- ▶ dizziness
- ▶ vomiting
- ▶ fainting

Tell your health care provider if you have any of the following problems because these may be signs of an allergic reaction:

- ▶ difficulty breathing
- ▶ wheezing (bronchospasm)
- ▶ hives
- ▶ rash

Tell your health care provider if you have:

- ▶ swollen glands (neck, armpit, or groin)
- ▶ joint pain
- ▶ unusual tiredness, weakness, or confusion
- ▶ chills
- ▶ generally feeling unwell
- ▶ leg pain
- ▶ shortness of breath
- ▶ chest pain
- ▶ aching muscles
- ▶ muscle weakness
- ▶ seizure
- ▶ bad stomach ache
- ▶ bleeding or bruising more easily than normal

Contact your health care provider right away if you get any symptoms that concern you, even several months after getting the vaccine.

For a more complete list of side effects, ask your health care provider.

What are the ingredients in GARDASIL?

The ingredients are proteins of HPV Types 6, 11, 16, and 18, amorphous aluminum hydroxyphosphate sulfate, yeast protein, sodium chloride, L-histidine, polysorbate 80, sodium borate, and water for injection.

This leaflet is a summary of information about GARDASIL. If you would like more information, please talk to your health care provider or visit www.gardasil.com.

Manufactured and Distributed by:
MERCK & CO., Inc.
Whitehouse Station, NJ 08889, USA
Issued October 2009
9883612



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20906176(1)-11/09-GRD

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Human Papilloma Virus Vaccine

ALERT Submission Form For Use By OYA/Dept. of Corrections/Job Corps/Jail Staff Only

Submit one page per client for each date of service, mail to ALERT

Demographic Information

Place OYA/Dept. of Corrections/Job Corps/Jail Client Sticker/Identifier Here	Special Instructions/Comments:
Local ID #:	
Client Name: _____ Last First Middle	Date of Birth ____ / ____ / ____ MM DD YYYY
Home Address (if known): _____ Street Number Apt. Number City State Zip	
Phone Number: () -	Mother's Maiden Name:
Medicaid #:	Social Security #:

Immunization Information

Date of Service ____ / ____ / ____ MM DD YYYY			
Site Location OYA: <input type="checkbox"/> Eastern OR <input type="checkbox"/> Hillcrest <input type="checkbox"/> MacClaren <input type="checkbox"/> North Coast <input type="checkbox"/> Oak Creek <input type="checkbox"/> Riverbend <input type="checkbox"/> Rogue Valley <input type="checkbox"/> Tillamook DOC: <input type="checkbox"/> Coffee Creek <input type="checkbox"/> Columbia River <input type="checkbox"/> Deer Ridge <input type="checkbox"/> Eastern Oregon <input type="checkbox"/> Mill Creek <input type="checkbox"/> Oregon Corrections Intake Center <input type="checkbox"/> Oregon State Correctional Institution <input type="checkbox"/> Oregon State Penitentiary <input type="checkbox"/> OSPM <input type="checkbox"/> Powder River <input type="checkbox"/> Santiam <input type="checkbox"/> Shutter Creek <input type="checkbox"/> South Fork <input type="checkbox"/> Snake River <input type="checkbox"/> Two Rivers <input type="checkbox"/> Warner Creek Job Corps: <input type="checkbox"/> Angell <input type="checkbox"/> Springdale <input type="checkbox"/> Timberlake <input type="checkbox"/> Tongue Point <input type="checkbox"/> Wolf Creek County Jail: _____ (must specify site name)	Vaccine (Check all shots given)	Brand name	Code
	<input type="checkbox"/> Hep A	Vaqta/Havrix	85
	<input type="checkbox"/> Hep B, adolescent or pediatric	Recombivax/ Engerix	8
	<input type="checkbox"/> Hep B, adult	Recombivax/ Engerix	43
	<input type="checkbox"/> Hep A – Hep B	Twinrix	104
	<input type="checkbox"/> Influenza – split – inactivated	Fluzone	15
	<input type="checkbox"/> Influenza – Intranasal	Flu Mist	111
	<input type="checkbox"/> Meningococcal (MCV4)	Menactra	114
	<input type="checkbox"/> Meningococcal (MPSV4)	Menomune	32
	<input type="checkbox"/> MMR	MMR	3
	<input type="checkbox"/> Pneumococcal (PPV23)	Pneumovax 23	33
	<input type="checkbox"/> Td/Preservative Free	Td Adult	113
	<input type="checkbox"/> Tdap	Adacel/ Boostrix	115
	<input type="checkbox"/> Variceila	Varivax	21
	<input type="checkbox"/> Other _____		
	<input type="checkbox"/> Other _____		
To contact ALERT: Phone: 800-980-9431; 971-673-0275 Fax: 971-673-0276 Email: OHD.ALERT@state.or.us	ALERT Mailing Address: Oregon Immunization ALERT 800 NE Oregon St, Suite 370 Portland, OR 97232	ALERT will provide postage-paid envelopes	

Optional: Attach a copy of the client's prior immunization record to this form and ALERT will enter the full immunization history.

Oregon Department of Corrections

IMPORTANT --- INFORMED CONSENT
HPV (Gardasil™) Vaccination

I have read or have had explained to me the information about **Human Papilloma Virus** (Gardasil™) vaccine. I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks of the vaccine and ask that the vaccine be given to me.

_____ Date

_____ Signature

_____ Date

_____ Witness

Dose #1

Vaccine Manufacturer: _____

Vaccine Lot #: _____

Expiration Date: _____

Site of Injection: _____

_____ Nurse Signature

Dose #2 (Due date _____)

Vaccine Manufacturer: _____

Vaccine Lot #: _____

Expiration Date: _____

Site of Injection: _____

_____ Nurse Signature

Dose #3 (Due date _____)

Vaccine Manufacturer: _____

Vaccine Lot #: _____

Expiration Date: _____

Site of Injection: _____

_____ Nurse Signature

Name _____
SID# _____