

# Human Papillomavirus (HPV) Infection

## FAST FACTS FOR HEALTH CARE PROVIDERS

### What is HPV infection and how common is it?

HPV is a common virus that is sexually transmitted via skin-to-skin contact. It is the most common sexually transmitted infection (STI) in the U.S., with approximately 20 million people infected at any given time. More than half of sexually active women and men will be infected with HPV at some point in their lives.

Each year, an additional 6.2 million people in the U.S. become newly infected. As many as half of infected males and females with HPV are adolescents and young adults 15-24 years of age. On average 60 Utah women are diagnosed with cervical cancer each year and an average of 17 women die each year from this cancer.

### What makes a person more likely to get HPV?

It is estimated that 50% of sexually active people acquire genital HPV at some point in their lives. Men and women are more likely to get the infection if they:

- have sex at an early age (16 years or younger);
- have had or have intimate sexual contact with multiple partners, and
- have had or have intimate sexual contact with a sex partner who has had many partners.

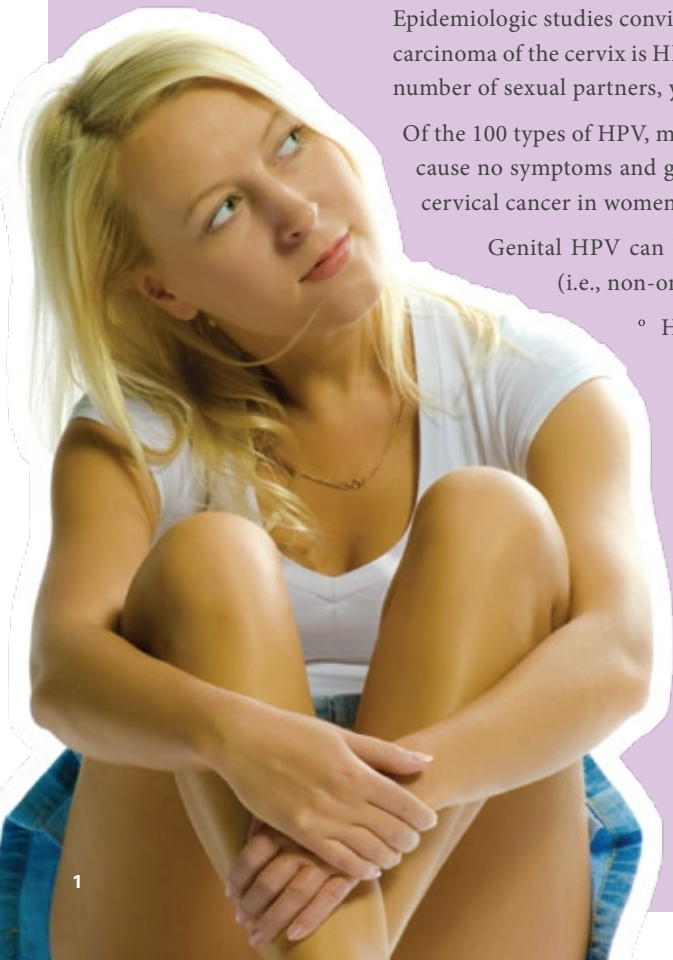
### How is HPV related to genital/cervical cancer?

Epidemiologic studies convincingly demonstrate that the major risk factor for development of preinvasive or invasive carcinoma of the cervix is HPV infection, which far outweighs other known risk factors such as high parity, increasing number of sexual partners, young age at first intercourse, low socioeconomic status, and positive smoking history.

Of the 100 types of HPV, more than 30 types can infect the genital areas of men and women. HPV infections usually cause no symptoms and go away on their own. However, persistent infection with high-risk HPV types can cause cervical cancer in women.

Genital HPV can be divided into “high-risk” (i.e., oncogenic or cancer-associated) types, and “low-risk” (i.e., non-oncogenic) types.

- HPV 16 and 18 are the most common high-risk types, which together are responsible for about 70% of cervical cancer cases. High-risk types also have been linked to other less common genital cancers—including cancers of the vagina, vulva, rectum, urethra, penis, anus, and some cancers of the oropharynx (the middle part of the throat that includes the soft palate, the base of the tongue, and the tonsils).
- HPV 6 and 11 are the most common low-risk types, which together cause about 90% of cases of genital warts but do not lead to cancer. About 1% of sexually active adults in the U.S. have visible genital warts at any point in time. Rarely, infections can be transmitted from mother to baby during delivery and cause respiratory tract warts in children.



## What is the natural progression of HPV infection?

Approximately 90% of women with HPV infection become HPV-negative within two years. The gradual development of an effective immune response is thought to be the likely mechanism for HPV DNA clearance. However, it is possible that the virus remains in a non-detectable dormant state and then reactivates years later.

About 10% of women infected with HPV develop persistent HPV infection. Women with persistent high-risk HPV infections are at greatest risk for developing pre-cancerous conditions and/or cervical cancer. Many women with transient HPV infections may develop mild Pap test abnormalities that spontaneously regress.

Currently, no data is available on the natural history of HPV infection in men.

## What are the treatment options for HPV and its associated diseases?

There is no treatment for HPV. But there are treatments for the health problems that HPV can cause, such as genital warts, cervical cell changes, and cancers of the cervix, vulva, vagina and anus. Treatment options, depending on the abnormality, may include:

- surgical removal (i.e., excision of warts);
- loop electrosurgical excision procedure (LEEP);
- conization (cone biopsy);
- cryosurgery;
- surgery, and
- radiation and/or chemotherapy, if cancer is diagnosed.

## What are the recommendations for prevention of cervical cancer?

The primary prevention strategies are:

- Avoiding genital contact with another individual.
- Being in a long-term, mutually faithful relationship with an uninfected partner. It is difficult, however, to determine whether a partner who has been sexually active in the past is currently infected.
- Vaccination of females 9-to-26 years of age with the HPV vaccine.
- Regular Pap tests by age 21 or within three years of onset of sexual activity, whichever happens first.

## HPV Vaccination

The HPV vaccine, Gardasil®, protects against four HPV types (6,11,16,18), which are responsible for 70% of cervical cancers and 90% of genital warts, and can cause abnormal Pap tests and low-grade cervical abnormalities. Clinical studies show that Gardasil® is highly effective in preventing cervical cancers and pre-cancers caused by HPV types 16 and 18.

HPV vaccine is routinely recommended for girls 11-to-12 years of age, but is recommended for all females 11 through 26 years of age who have not yet received or completed the vaccine series. Girls as young as 9 years of age may be vaccinated with HPV vaccine. It is not recommended for pregnant women or for men.

Ideally, the vaccine should be administered before the onset of sexual activity. However, females who are sexually active may also benefit from vaccination. Females who have not been infected with any HPV type would receive the full benefit of vaccination.

Females who have already been infected with one or more HPV types would still receive protection against the vaccine types they have not acquired. Currently, there is no test available for clinical use to determine whether a female has had any or all of the four HPV types in the vaccine.

The vaccine is delivered through a series of three intra-muscular injections over a six-month period. The second and third doses should be given two and six months after the first dose. The most common side effects are pain, swelling, itching and soreness at the injection site and fever.

The private sector list price of the HPV vaccine is approximately \$120.00 per dose (approximately \$360 for the full series).



## Cervical Cancer Screening

The most effective screening tool is the Pap test to check for the presence of HPV in the cervix.

A routine Pap test and pelvic exam are recommended for women at age 21, or within three years of the first time they have sexual intercourse, whichever happens first. National guidelines recommend that after a woman has a normal Pap test with no abnormalities each year for three years in a row, she can then get the Pap test once every 2–3 years. See “HPV Information for Clinicians” brochure for more screening recommendations.

The Food and Drug Administration has approved DNA HPV testing as a follow-up for women who have an ambiguous Pap test (ASC-US and low grade dysplasia). This HPV test can identify 13 of the high-risk types of HPV associated with the development of cervical cancer. The test can detect high-risk types of HPV even before any conclusive visible changes to the cervical cells are appreciated. There are currently no tests approved to detect HPV infection in men.

### References:

Centers for Disease Control and Prevention, Sexually Transmitted Diseases, Human Papillomavirus Infection, <http://www.cdc.gov/std/HPV/default.htm>

Challenges in Vaccine Policy: A Case Study of the HPV Vaccine, New England Healthcare Institute, August 2006.

Merck Product News: [http://www.merck.com/newsroom/press\\_releases/product/2007\\_0517.html](http://www.merck.com/newsroom/press_releases/product/2007_0517.html)

MMWR, March 12, 2007, Quadrivalent Human Papillomavirus Vaccine Recommendations - <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm>

National Cancer Institute, Cervical Cancer (PDQ) Treatment <http://www.cancer.gov/cancertopics/pdq/treatment/cervical/healthprofessional>

# HPV/Cervical Cancer Patient Education and Counseling

## OVERVIEW

### When should patient counseling and education about HPV take place?

- At Pap screening visits;
- When patients are sexually active (before sexual debut is recommended);
- When genital warts are diagnosed;
  - When a Pap test result is abnormal, and
  - When an HPV test is positive.

### What should counseling include?

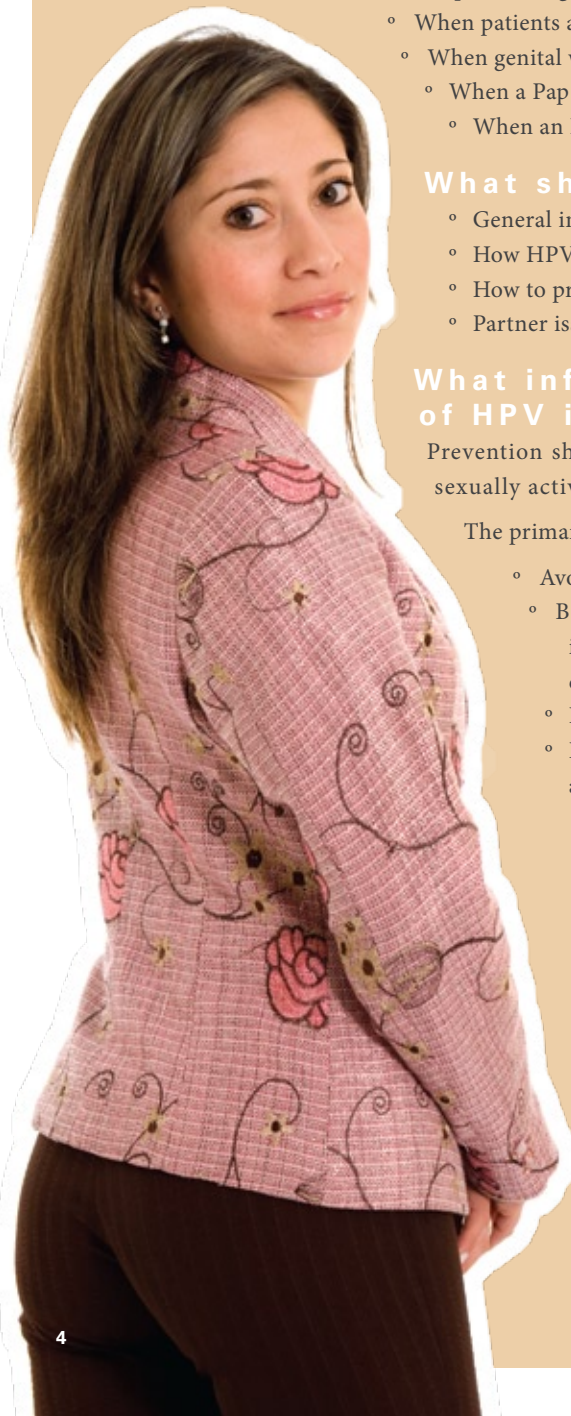
- General information about HPV infection;
- How HPV infection is transmitted;
- How to prevent HPV infection and its clinical manifestations, and
- Partner issues.

### What information should be given about prevention of HPV infection/cervical cancer?

Prevention should be strongly emphasized during patient education, especially for individuals who are sexually active.

The primary prevention strategies are:

- Avoiding genital contact with another individual;
- Being in a long-term, mutually faithful relationship with an uninfected partner. However, it is difficult to determine whether a partner who has been sexually active in the past is currently infected.
- HPV vaccination for females 9 to 26 years of age, and
- Regular Pap tests for women by age 21 or within three years of onset of sexual activity, whichever comes first.



# HPV Patient Education and Counseling

## KEY DISCUSSION POINTS FOR HEALTH CARE PROVIDERS

### General information about HPV infection:

HPV is short for human papillomavirus. This virus can cause changes in the cervix. HPV is NOT the same as HIV.

It is estimated that 50% of sexually active adults will become infected with genital HPV at some point in their lives.

Sometimes the HPV virus will go away on its own. However, persistent infection with some types of the HPV virus causes certain types of cancer.

Infection of the cervix with human papillomavirus is the most common cause of cervical cancer. Not all women with HPV infection will develop cervical cancer.

The time between when a person gets infected and when signs or symptoms show can vary, and it is often difficult to determine the source of infection.

Four of the most common types of HPV infection that cause 70% of all cervical cancers and 90% of genital warts can be prevented by getting the HPV vaccine.

Getting vaccinated does not eliminate the need for routine Pap tests.

### There are two types of genital HPV: low-risk and high-risk types.

**Low-risk** genital HPV types can cause mild changes in a woman's cervix. Changes caused by low-risk HPV types do not lead to cancer. Sometimes low-risk HPV types cause visible changes in the genital area, called genital warts. They are growths that are usually painless and may be raised, flat, small or large, and may appear as single or multiple warts.

Different treatment options exist for genital warts. They may be removed by applying topical solutions in a clinic or at home by the patient. They may also be removed surgically.

**High-risk** types are linked to cervical cancer as well as cancers of the vulva, anus and penis. Usually, high-risk HPV types do not cause health problems, but sometimes high-risk HPV types can cause cancer if they persist over many years and cause cell changes. If a Pap test is abnormal, further testing can help determine if the HPV infection is linked to cervical cancer and what type of treatment or follow-up care may be needed.

### Transmission of HPV:

HPV is transmitted by skin-to-skin contact—by sexual contact and not exchange of bodily fluids. It is usually difficult to determine the source of infection, and the onset of an HPV infection does always not mean a partner has been unfaithful. HPV infections may be present for many years with no symptoms.

Genital warts can be treated. However, even after genital warts are treated, it is common for them to reappear within the first several months. This does not mean the patient has a new infection. Treatment for genital warts can reduce HPV infection, but it may not reduce transmission of HPV or how long the infection will last.

## Strategies to prevent genital HPV infection:

The surest way to prevent genital HPV infection is to not have genital contact with another individual.

For those who choose to be sexually active, the risk of HPV infection can be reduced by being in a long-term, mutually faithful relationship with an uninfected partner. However, it is difficult to determine whether a partner who has been sexually active in the past is currently infected.

Regular condom use might reduce HPV infection and the risk for diseases that result from HPV (e.g., genital warts and cervical cancer). However, HPV infection can occur in areas that are not covered or protected by a condom. Condom use has been associated with a lower rate of cervical cancer, which is associated with HPV infection.

### Other strategies include:

- Vaccination with the HPV vaccine (See handout on HPV vaccine);
- Regular screening for cervical cancer (Pap test) for women by age 21 years or within three years of onset of sexual activity, whichever comes first (See handout on cervical cancer screening), and
- Limited number of sex partners.

## HPV Vaccine

The HPV vaccine, Gardasil, is highly effective in preventing HPV infection from four HPV types, which together cause 70% of cervical cancers and 90% of genital warts. The vaccine is given in a series of three shots over a period of six months. It is recommended for females 11-26 years of age, but can be given to girls starting at 9 years of age. It is not recommended for pregnant women or for men.

The vaccine is most effective in females who are not yet sexually active because they are unlikely to be infected with HPV. But the vaccine may also provide protection for sexually active females from HPV types with which they are not infected. Protection from the vaccine can last five years. The most common side effects are fever, pain, swelling, itching or soreness where the vaccine is given.

The HPV vaccine is available for qualified females 9-18 years of age through the Vaccines for Children (VFC) Program. Women 19-26 years of age who have no insurance or whose insurance does not pay for the HPV vaccine may also get the vaccine at a low cost in designated locations throughout Utah. See the Utah list of providers for low-cost HPV vaccine or call 1-800-717-1811 for more information about these services.

## Pap Test

The Pap test is the best way to screen for cervical cancer. Getting the HPV vaccine does not mean routine Pap tests are no longer needed because the vaccine does not protect against all types of HPV that cause cervical cancer. Women should begin having regular Pap tests and pelvic exams at age 21, or within three years of the first time they have sexual intercourse, whichever happens first. If Pap test results show there are no problems for three years in a row, then the Pap test is recommended once every 2-3 years.

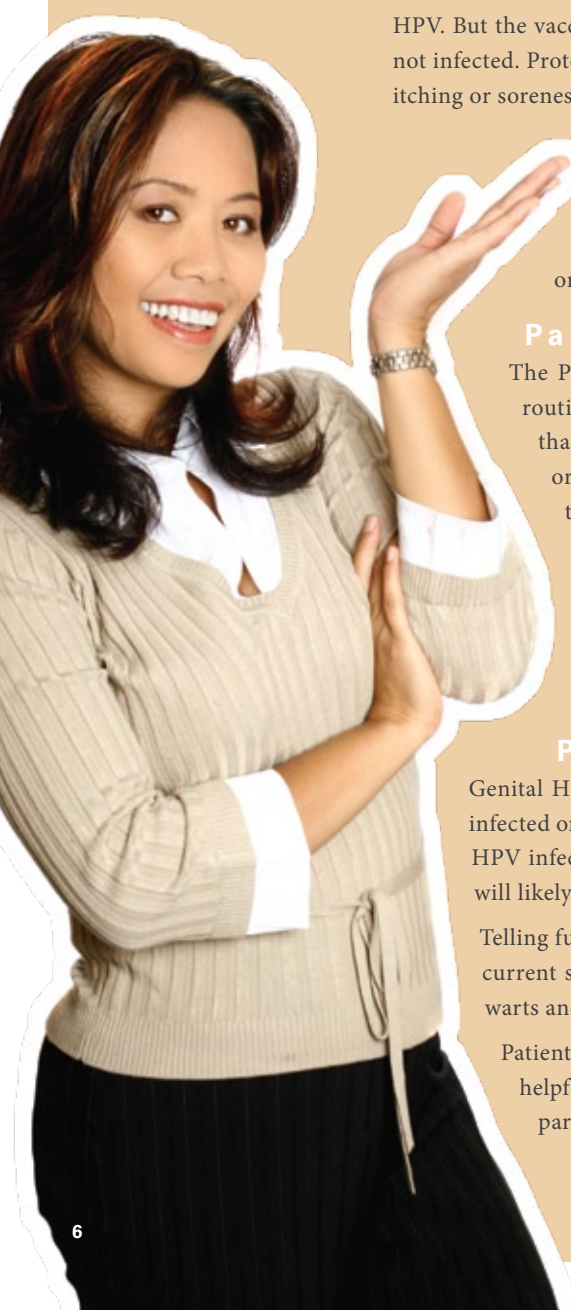
Women 50-to-64 years of age may qualify for a free mammogram and a Pap test, even if they have insurance. If cancer is detected, treatment may also be free. For more information about screening services, contact the Utah Cancer Control Program at 1-800-717-1811 or visit [www.utahcancer.org](http://www.utahcancer.org).

## Partner Issues:

Genital HPV is commonly transmitted between sexual partners, making it likely that partners are already infected once an HPV infection is detected. HPV infection does not mean that a partner has been unfaithful. HPV infections may be present for many years with no symptoms. In most cases, a healthy immune system will likely clear or suppress HPV, often within a year or two.

Telling future partners about a past HPV infection is a personal decision. However, it may be beneficial for current sex partners of those diagnosed with HPV infection or genital warts to get examined for genital warts and other sexually transmitted diseases.

Patients may not be able to answer all the questions their partners ask about HPV infection. It may be helpful to provide reliable information and resources to patients to help direct the discussion with their partners. Patients may also refer their partners to a health care provider for additional information.



## Accurate HPV Materials:

Providers should have appropriate patient information materials available, such as the HPV brochure, cancer fact sheets, vaccine information statements (VIS), and vaccine and cancer screening referral information.

## References:

Centers for Disease Control and Prevention, Sexually Transmitted Diseases, Human Papillomavirus Infection, Slide Show: Cervical Cancer Screening and Prevention - August 2005 <http://www.cdc.gov/std/HPV/default.htm>

Centers for Disease Control and Prevention, Sexually Transmitted Diseases, Human Papillomavirus Infection, Web Cast: HPV and Cervical Cancer: An Update on Prevention Strategies - 9 August 2005 - <http://www.cdc.gov/std/HPV/webcastQA-2005.htm>

MMWR, March 12, 2007, Quadrivalent Human Papillomavirus Vaccine Recommendations - <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm>

# HPV/Cervical Cancer Patient Resources

## Cervical Cancer Resources

Utah Cancer Control Hotline: 1-800-717-1811

Utah Cancer Control Program  
<http://www.utahcancer.org/>

American Cancer Society/Cervical Cancer  
[http://www.cancer.org/docroot/lrn/lrn\\_0.asp](http://www.cancer.org/docroot/lrn/lrn_0.asp)

American Social Health Association/HPV  
[http://www.ashastd.org/hpv/hpv\\_overview.cfm](http://www.ashastd.org/hpv/hpv_overview.cfm)

Centers for Disease Control  
and Prevention/Cervical Cancer  
<http://www.cdc.gov/cancer/cervical/>

Gynecologic Cancer Foundation – Women’s  
Cancer Network  
<http://www.wcn.org>

National Cancer Institute  
<http://www.cancer.gov/cancerinfo/>

The Center for Young Women’s Health,  
Boston Children’s Hospital  
[www.youngwomenshealth.org](http://www.youngwomenshealth.org)

## Human Papillomavirus Resources

Utah Immunization Hotline 1-800-275-0659

Utah Immunization Program  
<http://www.immunize-utah.org>

American Society of Colposcopy  
and Cervical Cancer Pathology  
[http://www.asccp.org/pdfs/patient\\_edu/women\\_should\\_know.pdf](http://www.asccp.org/pdfs/patient_edu/women_should_know.pdf)

Centers for Disease Control and Prevention/  
Human Papillomavirus Infection  
<http://www.cdc.gov/std/HPV/default.htm>

Cervical Cancer Vaccine Basics  
[www.cervicalcancercampaign.org/faqs.aspx](http://www.cervicalcancercampaign.org/faqs.aspx)

National HPV and Cervical Cancer Prevention  
Resource Center, created by the American  
Social Health Association  
<http://www.ashastd.org/hpvccrc/>

U.S. National Library of Medicine  
and National Institutes of Health: Medline Plus  
<http://medlineplus.gov/>

# Utah Low-Cost HPV Vaccine Providers By County

FOR QUALIFIED WOMEN 19-26

HD=HEALTH DEPARTMENT

CHC=COMMUNITY HEALTH CENTER

## Box Elder

Bear River HD-Brigham  
817 West 950 South  
Brigham City, UT 84302  
Ph 435-695-2073

Bear River HD-Tremonton  
125 South 100 West  
Tremonton, UT 84337  
Ph 435-257-3318

Clinica De Buena Salud CHC  
14 North 100 East  
Brigham City, UT 84302  
Ph 435-723-8276

## Cache

Bear River HD-Logan  
655 East 1300 North  
Logan, UT 84321  
Ph 435-792-6546

Intermountain Cache Valley  
Family Practice  
550 East 1400 North, Ste. Y  
Logan, UT 8434  
Ph 435-792-1600

Intermountain Summit Clinic  
502 South Main St.  
Smithfield, UT 84335  
Ph 435-563-3222

Smithfield Family Practice  
291 South Main St. Ste D  
Smithfield, UT 84335  
Ph 435-563-3940

## Carbon

Carbon Medical Service Assoc Inc  
305 Center St  
East Carbon, UT 84520  
Ph 435-888-4411

## Carbon

Southeastern HD-Price  
28 South 100 East  
Price, UT 84501  
Ph 435-637-3671

## Davis

Tanner Clinic-Kaysville  
380 North 400 West  
Kaysville, UT 84037  
Ph 801-773-4840

U of U Centerville  
26 South Main St.  
Centerville, UT 84014  
Ph 801-693-7905

## Emery

Southeastern HD-Castledale  
25 South Main St.  
Castle Dale, UT 84513  
Ph 435-381-2252

## Grand

Southeastern HD-Moab  
471 South Main St. #4  
Moab, UT 84532  
Ph 435-259-5602

## Rich

Bear Lake CHC  
325 West Logan Hwy  
Garden City, UT 84028  
Ph 435-946-3660

## Salt Lake

Community Nursing Services  
6949 South Hightech Dr.  
Midvale, UT 84047  
Ph 801-233-6214

## Salt Lake

Foothill Family Clinic  
6360 South 3000 East #100  
Salt Lake City, UT 84117  
Ph 801-365-1032

Intermountain Taylorsville  
Health Center  
3845 West 4700 South  
Taylorsville, UT 84118  
Ph 801-840-2100

Intermountain West Jordan  
Family Practice  
2655 West 9000 South  
West Jordan, UT 84088  
Ph 801-256-6343

Jordan Valley Family Health  
3570 West 9000 South Ste. 100  
West Jordan, UT 84088  
Ph 801-569-1999

Salt Lake Valley HD  
2001 South State St. S-2400  
Salt Lake City, UT 84190  
Ph 801-468-2841

University Family Health  
555 Foothill Blvd  
Salt Lake City, UT 84112  
Ph 801-581-8000

U of U Student Health Service  
50 North Medical Drive Clinic 6  
Salt Lake City, UT 84112  
Ph 801-585-9691

U of U Westridge  
3730 West 4700 South  
Salt Lake City, UT 84118  
Ph 801-213-9250

Wasatch Homeless Health Care  
4th Street Clinic CHC  
404 South 400 West  
Salt Lake City, UT 84101  
Ph 801-364-0058

## San Juan

Monument Valley Comm. Health Clinic  
4 Rock Door Canyon Road  
Monument Valley, UT 84536  
Ph 435-727-3242

Southeastern HD-Blanding  
196 East Center St.  
Blanding, UT 84511  
Ph 435-678-2723

## San Juan

Southeastern HD-Monticello  
117 South Main St.  
Monticello, UT 84535  
Ph 435-587-2021

## Sanpete

Intermountain Ephraim  
525 North Main St.  
Ephraim, UT 84627  
Ph 435-283-4076

Intermountain Mt Pleasant  
1100 South Medical Dr.  
Mt Pleasant, UT 84647  
Ph 435-462-3471

## Sevier

Central Utah Public HD  
70 Westview Dr.  
Richfield, UT 84701  
Ph 435-896-5451

Intermountain Richfield  
460 North Main St.  
Richfield, UT 84701  
Ph 435-896-5496

## Summit

Summit County HD-Coalville  
85 North 50 East  
Coalville, UT 84017  
Ph 435-336-3222

## Tooele

Tooele County HD  
151 North Main St.  
Tooele, UT 84074  
Ph 435-843-2315

## Utah

Intermountain Central Orem  
Family Practice  
505 West 400 North  
Orem, UT 84057  
Ph 801-714-3071

Intermountain Utah Valley  
Family Medicine  
475 West 940 North  
Provo, UT 84604  
Ph 801-357-7930

Tri-City Medical Clinic  
830 North 2000 West  
Pleasant Grove, UT 84062  
Ph 801-443-1180

## Utah

Utah County HD  
151 South University Ave. Ste. 190  
Provo, UT 84601  
Ph 801-851-7027

## Wasatch

Wasatch City/County HD  
55 South 500 East  
Heber, UT 84032  
Ph 801-825-2794

## Washington

Enterprise Valley Medical Clinic  
223 South 200 East  
Enterprise, UT 84725  
Ph 435-878-2281

Hurricane Family Practice  
11 South Main St.  
Hurricane, UT 84737  
Ph 435-635-9444

Medical Associates of St. George  
736 South 900 East Ste. 203  
St. George, UT 84790  
Ph 435-673-6131

Southwest Utah CHC  
168 North 100 East  
St. George, UT 84525  
Ph 435-986-2570

## Wayne

Wayne CHC  
128 South 300 West  
Bicknell, UT 84715  
Ph 435-425-374

## Weber

Intermountain Porter  
Family Practice  
4403 Harrison Blvd. Ste. A700  
Ogden, UT 84403  
Ph 435-387-5300

Midtown CHC  
2240 Adams Ave.  
Ogden, UT 84401  
Ph 801-395-8217

Weber/Morgan HD  
477 23rd St.  
Ogden, UT 84401  
Ph 801-399-7240

# HPV Vaccine Information

CDC QUESTIONS AND ANSWERS CONCERNING THE SAFETY AND EFFICACY OF GARDASIL®

## 1. What is the ability of Gardasil® to prevent cervical cancer in girls/young women?

Gardasil® protects against infection from 4 HPV types, including 2 types (HPV 16 and 18) that cause about 70% of cervical cancers. In clinical trials among women who had not yet been infected with a specific vaccine HPV type, the efficacy of the vaccine was close to 100% for prevention of pre-cancer lesions of the cervix due to that type. For example, a woman who participated in the study and who did not have HPV type 16 before vaccination was afforded almost 100% protection against cervical pre-cancer lesions caused by HPV type 16. Therefore, if girls/women are vaccinated before their first sexual experience, Gardasil® should be very effective in preventing about 70% of cervical cancers.

## 2. Are there any concerns about the safety of this vaccine?

The clinical trials found no increased number of serious adverse events in girls/women who received vaccine compared with those who received placebo. Before the Advisory Committee on Immunization Practice (ACIP) recommends any vaccine, it weighs the known and potential benefits against known risks. Like all vaccines, Gardasil® has some side effects, but ACIP determined that the benefits outweigh the risks.

Since the vaccine has been licensed, the most common reports to the Vaccine Adverse Events Reporting System (VAERS) have been local injection site reactions – as was seen in the clinical trials. There were some cases of fainting after vaccination. This has been found with other vaccines administered to adolescents. Many people have a fainting episode at some point in their life and there are many potential causes. The ACIP's general recommendations for all vaccines include a suggestion for a 15 minute post-vaccination waiting period.

Since the vaccine was licensed, there have been 13 reports of Guillain-Barre Syndrome (GBS) among persons who received Gardasil®. CDC investigators are in the process of confirming GBS. Of the 13 reports, six individuals received Gardasil® given alone, five received Gardasil® and Menactra®, one received Gardasil®, Menactra®, and Hepatitis A vaccine, and one received Gardasil® and Pneumococcal Polysaccharide Vaccine given within 30 days of one another. At least one media article has incorrectly reported the number of GBS cases as forty. Because GBS occurs at a rate of 1-2/100,000 person years during the second decade of life, some cases will occur by coincidence following vaccination (but not due to vaccination).

Since the vaccine was licensed, there have been three deaths reported among persons who received Gardasil®: One involving a pulmonary embolism; one involving myocarditis due to influenza A infection; and one from a blood clot. These deaths are being fully investigated. Since more than 5 million doses have been distributed, some deaths will occur coincidentally following vaccination (but not due to vaccination).



### **3. How is the safety of this vaccine being monitored?**

Before any vaccine is licensed and made available to the American public, the Food and Drug Administration (FDA) must approve it as safe and effective. Prior to being licensed by FDA in June 2006, the HPV vaccine was tested in more than 11,000 females, ages 9 through 26 years, from the U.S. and several countries around the world. There appeared to be no serious side effects, and the vaccine was found to be safe and effective. The most common side effect was brief soreness at the injection site.

Now that the vaccine is in general use, the CDC, working with FDA, continues to closely monitor the safety of the HPV vaccine. One tool that is used in monitoring vaccine safety is the Vaccine Adverse Event Reporting System (VAERS). VAERS is a national reporting system that accepts and monitors approximately 18,000 reports of adverse events submitted annually by a variety of sources.

VAERS serves as an early-warning system to detect problems that may be related to vaccines. CDC and FDA physicians and scientists review all reports of serious side effects reported to VAERS in order to identify potential new vaccine safety concerns that may need further study. It is important to know that many adverse events reported to VAERS may not be caused by vaccines. Reports to VAERS may be submitted by anyone, including healthcare providers, patients and family members. Because of this, VAERS is subject to several limitations including underreporting and incomplete information.

VAERS receives reports of many events that occur after immunization. Some of these events may occur coincidentally following vaccination, while others may be caused by vaccination. The fact that an adverse event occurred following immunization is not conclusive evidence that the event was caused by a vaccine. Factors such as medical history and other medications taken near the time of the vaccination must be examined to determine if they could have caused the adverse event.

### **4. Some people have said that boosters of HPV vaccine may be needed. If so, how might this change opinions about the vaccine?**

At this time, we don't know if boosters will be needed. Data available to date show persistent high protection from the vaccine through 5 years and suggest protection will last much longer. If boosters are needed, this would not change the recommendation for vaccination. It might change the cost effectiveness of the vaccine if boosters are needed. However, based on analyses by economic experts, vaccination is expected to remain cost-effective if booster doses are needed.

### **5. How likely is it that the vaccine might prevent pre-cancerous lesions yet not prevent the actual cancer?**

The vaccine trials used pre-cancer lesions of the cervix as the main endpoint to measure efficacy. The trials found the vaccine to have close to 100% efficacy in preventing pre-cancer lesions in women who had not yet been infected with any of the four HPV types contained in the vaccine. Most cancers progress through well-defined stages that include such pre-cancer lesions; therefore, prevention of the pre-cancer lesion will prevent the cancer. It is unethical to use cervical cancer as an endpoint since cervical cancer can be prevented by detection and treatment of pre-cancer lesions. Women's lesions would have to be left untreated and allowed to progress to cancer if cervical cancer was used an endpoint in the trials.

### **6. Will the HPV vaccine divert dollars and efforts away from Pap testing?**

No. Pap testing will remain one of the main public health measures to prevent cervical cancer.

ACIP recommendations state that vaccinated women should have regular Pap testing as currently recommended by national organizations. There are several reasons why women will still need regular cervical cancer screening:

- The vaccine does NOT protect against all HPV types that cause cancer. Approximately 30% of cervical cancers are caused by types not covered by the vaccine, so vaccinated women would still be at risk for some cancers,
- Women may not get the full benefit of vaccination if they receive it after they have already acquired one or more of the four HPV types covered by the vaccine. The vaccine does not treat existing HPV infections, nor does it prevent the development of diseases caused by existing infections.



**7. Some news articles have claimed that some women who received at least one shot of Gardasil® went on to develop pre-cancer lesions on their cervix within three years of vaccination, just 14% fewer than in a placebo control group.**

These results are from an analysis which included women who developed pre-cancer lesions caused by any HPV type, not just types prevented by the vaccine (specifically, HPV types 6,11,16 and 18). There are over 40 types of sexually transmitted HPV. Some of the pre-cancer lesions observed in the study may have been from any of these types. Additionally, since 27% of the women were already infected with an HPV type contained in the vaccine at the time of vaccination and the vaccine does not prevent disease due to an HPV type already present, some women in the study developed pre-cancer lesions due to the HPV vaccine types.

Women would have had to be followed for a longer time to see the full benefit of the vaccine. More benefit would be observed in vaccinated women because the vaccine would keep preventing new infections with HPV 6, 11, 16 and 18, while unvaccinated women in the placebo group would remain vulnerable to acquiring new infections and disease due to those four HPV types.

# Male HPV Fact Sheet

## What are the signs and symptoms of HPV in men?

Most men who get genital HPV do not have any symptoms. However, some types of HPV can cause genital warts. Genital warts are single or multiple growths that appear in the genital area. They may be raised, flat, or cauliflower shaped and may appear around the anus or on the penis, scrotum (testicles), groin or thighs. A person can have the type of HPV that causes genital warts, but never develop any warts.

## How is HPV spread?

- It is spread through any type of skin-to-skin genital contact with a person who has HPV.
- You are at higher risk of getting HPV if you have vaginal, anal or oral sex with a person who has genital HPV.
- But remember, you do not have to have sexual intercourse to get HPV.

## HPV is NOT spread by:

- Toilet seats
- Kissing on the mouth, hugging, or holding hands
- Poor personal hygiene
- Sharing food or utensils
  - Swimming in pools or hot tubs

## What is the connection between HPV and penile and anal cancers?

Certain types of HPV have been linked to cancer of the anus and penis in men. These cancers are rare—especially in men with healthy immune systems. The types of HPV that can cause genital warts are not the same as the types that can cause penile or anal cancer.

## How common is HPV and associated conditions in men?

Over half of sexually active men in the United States (U.S.) will have HPV at some time in their lives.

- About 1% of sexually active men in the U.S. have genital warts at any one time.
- The American Cancer Society (ACS) estimates that about 1,530 men will be diagnosed with penile cancer in the U.S. in 2006. In this country, penile cancer accounts for about 0.2% of all cancers in men. It is especially rare in circumcised men.
- ACS estimates that about 1,910 men will be diagnosed with anal cancer in 2006. The risk for anal cancer is 17 times higher among gay and bisexual men than among heterosexual men. The risk is also higher among men with compromised immune systems, including those with HIV.



## Is there a test for HPV in men?

Currently there is no test approved to detect HPV in men. However, there are ways to detect the most common problem caused by HPV in men, genital warts. Genital warts are usually diagnosed by visual inspection.

## Is there a test to screen for HPV-related cancers in men?

Currently no test is approved to detect early evidence of HPV-associated cancers in men, as there are for women (Pap tests).

## Is there a treatment or cure for HPV?

There is no treatment or cure for HPV. But there are ways to treat the health conditions associated with HPV in men, including genital warts, penile cancer and anal cancer.

Visible genital warts can be treated with medication, surgically removed or frozen off. It is not known whether treatment of genital warts will reduce the chance of passing the virus on to a sex partner. If left untreated, genital warts may go away, remain unchanged, or increase in size or number. They will not turn into cancer.

## Should I be worried that I cannot be tested or treated for HPV?

No. HPV is not like other sexually transmitted infections (STIs), which need to be detected and treated. HPV is a virus that lives in the skin, rather than in your body. For most men, there would be no need to treat HPV, even if treatment were available—since it usually goes away on its own.

## So why should I care about HPV?

Most men will not develop health problems from HPV; however, some men are at higher risk of disease from HPV. HIV-positive men are more likely to get severe and prolonged cases of genital warts, which may be more resistant to treatment. They are also more likely to develop anal cancer.

It is also important for men to realize that they can unknowingly transmit HPV to their female sex partners.

## Are there ways to reduce my chances of getting HPV?

The only sure ways to prevent it are not to have sex or to have sex with only one uninfected person who is only having sex with you. You can lower your risk by limiting your number of sex partners and choosing partners who have had few or no sex partners.

Use a condom every time you have sex. Condoms don't fully protect you against HPV, but can still significantly reduce the chance you'll get it. Condoms also protect against other sexually transmitted infections.

## Common questions for men and their female partners about HPV.

I hear there's a HPV test for women, but not for men. Why not?

There is now an HPV test for women, which can be used as part of cervical cancer screening and management. This test is not a general check for HPV, and it is not designed to find HPV in men.

There is no clear health benefit to knowing if one has the virus—since it usually causes no health problems and goes away on its own.

## My partner just found out she has HPV...

What does it mean for me?

Partners usually share HPV. If you have been partners for a long time, it is likely that you already have HPV. The types of HPV that put a woman at risk for cervical cancer very rarely cause any health problems for heterosexual men.

What does that mean for her?

This probably means she has a type of HPV on her cervix that could put her at risk for cervical cancer. She should follow up with her doctor or nurse as advised, so that she does not develop cervical cancer in the future. Also, she should know that most of the time, HPV goes away on its own without causing any health problems.

What does it mean for us?

HPV is not a sign that you or your partner has been unfaithful in the relationship. HPV can be silent in the body for many years before it is found on a test. She may have had HPV for many years, and there is no way to know when or from whom she got HPV.