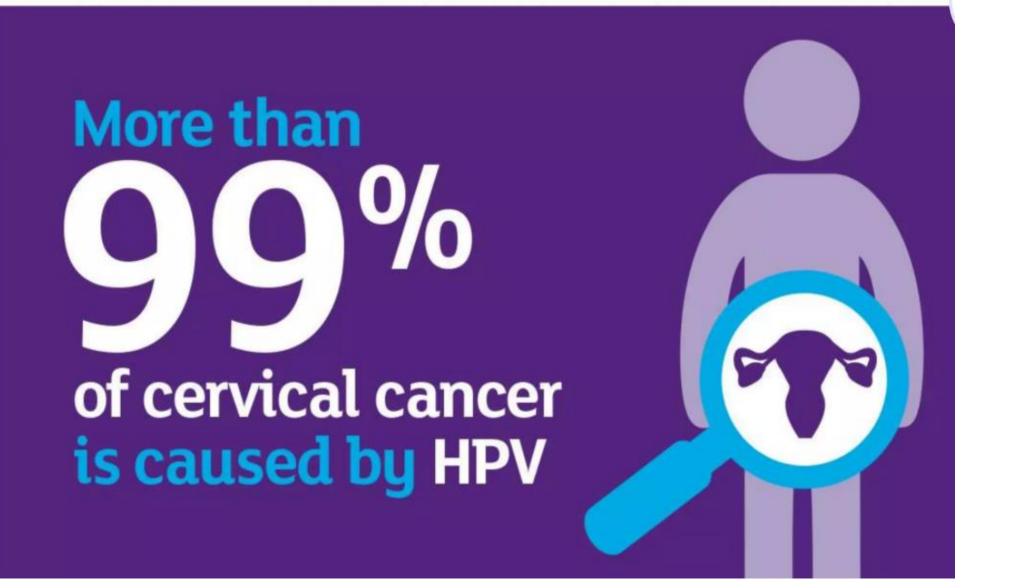


# **HPV VACCINATION**

## **HPV & CERVICAL CANCER**



# **HPV & OTHER CANCERS**

### **HPV** is linked with:

91%

of cervical and anal cancers 70%

of oropharyngeal cancers

63%

of penile cancers

#### THE CAUSE

HPV infection is a necessary cause of cervical cancer and is linked to several other anogenital diseases

Percent of cases attributable to HPV infection 1,2 ~100% Cervical Cancer Penile 50% 70% Cancer Vaginal Cancer Orophar **HPV** 13-56% yngeal 43% Vulvar Cancer Cancer 88% Genital Anal Warts Cancer ~100% HPV Causes More Than Cervical Cancer

## **HPV Vaccination: The Basis of Cancer Control**

**Vaccination** 

**Palliative** care **Cancer treatment** Secondary prevention: **Screening and treatment** of precancers **Primary prevention:** 

# WHY VACCINATION?

- HPV vaccines are highly effective at preventing the infection of susceptible women with the HPV types covered by the vaccine.
- HPV vaccine should be given to females before they reach an age when the risk of HPV infection increases and they are at subsequent risk of cervical cancer.
- HPV vaccine can be given to all female between 9 to 45 years of age group.
- HPV faccine is given as 3 doses over a period of 6 months.

**Gardasil**: Quadrivalent

Cervix: Bivalent

Nonovalent (2016)

### **HPV TYPES**

- > 100 types of HPV, 14 are cancer causing
- Transmitted through sexual contact
- HPV types 16 & 18 cause >70% of cervical precancer:
  & cancers
- HPV types 6 & 11 cause genital warts

# WHO NEEDS IT & WHAT IS THE DOSE?

- > 9 to 14 years, 2 doses (CDC)
- > 15 to 26 years, three doses (CDC)

> 9 to 45 years (US FDA)

# WHO SHOULDN'T GET THE VACCINE?



- > PREGNANCY
- > SEVERELY ILL
- > REACTION AT ITS LAST DOSE

## **ANY SIDE EFFECTS?**

- > COMMON SORENESS, SWELLING AT INJECTION SITE
- **➤ OCCASIONAL N, V, DIZZINESS, FAINTING**

# IS IT EFFECTIVE IF YOU ARE SEXUALLY ACTIVE?

- > YES
- > PROTECTION FROM OTHER STRAINS
- BUT CANNOT TREAT EXISTING HPV INFECTION



# **AVAILABLE VACCINES**



Six different vaccines, which vary in the number of HPV types they contain and target, have been clinically developed, although not all are available in all locations:

The vaccines should be administered IM in the deltoid region. the standared dose is 0.5 ml. uadrival

- Human papillomavirus 4-valent vaccines target HPV types 6, 11, 16, and 18.
- O Human papillomavirus **9-valent vaccine** (Gardasil 9) targets the same HPV types as the 4-valent vaccine (6,11, 16, and 18) as well as types 31, 33, 45, 52, and 58.
- Human papillomavirus bivalent vaccines target HPV types 16 and 18.

## PRIMARY PREVENTION



**BIVALENT HPV** 16,18



QUADRIVALEN T HPV 6,11,16,18



# **HPV Vaccine**



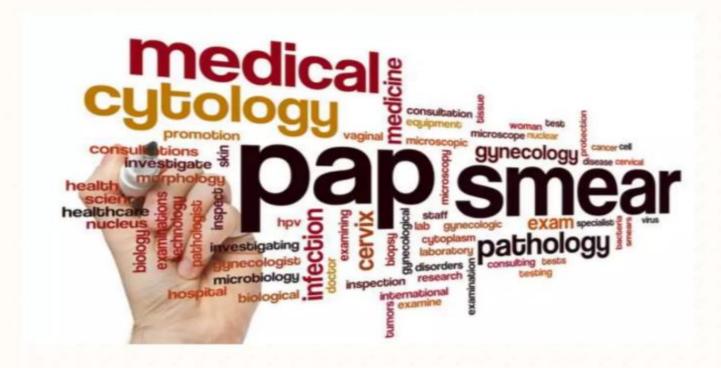


Quadrivalent/HPV4 (Gardasil)	Name	Bivalent/HPV2 (Cervarix)
Merck	Manufacturer	GlaxoSmithKline
6, 11, 16, 18	Types	16, 18
Females: Anal, cervical, vaginal and vulvar precancer and cancer; Genital warts Males: Anal precancer and cancer; Genital warts	Indications	Females: Cervical precancer and cancer  Males: Not approved for use in males
Pregnancy Hypersensitivity to yeast	Contraindications	Pregnancy Hypersensitivity to latex (latex only contained in pre-filled syringes, not single-dose vials)
3 dose series: 0, 2, 6 months	Schedule (IM)	3 dose series: 0, 1, 6 months

# WHAT TO DO IF YOU ARE NOT IN RECOMMENDED VACCINE AGE GROUP?

- > REGULAR PAP
- USE CONDOMS (ORAL, VAGINAL OR ANAL SEX)
- AVOID SMOKING
- WARNING SIGN: POSTCOITAL OR POSTMENOPAUSAL BLEEDING

## DO WOMEN STILL NEED PAP TEST?



- > YES
- > IT HASN'T REPLACED PAP TESTS

## **VACCINE + SCREEN**

➤ COMBINING HPV VACCINE WITH SCREENING
WILL HAVE THE GREATEST IMPACT ON REDUCING THE
FUTURE BURDEN OF CERVICAL CANCER

#### Vaccine wont work if infected with HPV

Vaccine prevents against other strains even if infected with one or two strains



# Contracting HPV doesn't mean you will not get again

There are more than 100 strains of HPV. Having immunity to a single strain doesn't preclude a person from being infected with another.

## **RATIONALE**

#### **Females**

HPV types **16** and **18**, which are targeted by all three HPV vaccines, cause approximately **70 percent** of all cervical cancers worldwide.

HPV types **31**, **33**, **45**, **52**, and **58**, which are additionally targeted by the **9**-valent vaccine, cause an additional **20 percent**.

HPV types 16 and 18 also cause nearly 90 percent of anal cancers and a substantial proportion of vaginal, vulvar, and oropharyngeal cancers.

90 percent of anogenital warts caused by HPV types 6 and 11

# Male

— HPV vaccination provides a direct **benefit** to male recipients by safely protecting against cancers that can result from persistent HPV infection.

HPV types **16** and **18** cause nearly *90 percent* of anal cancers and substantial proportion of **oropharyngeal** and **penile cancers**.



# Indications and age range

\_\_\_ Routine HPV vaccination is recommended at 11 to 12 years.

It can be administered starting at **9 years** of age.

For adolescents and adults aged **13 to 26** years who have not been previously vaccinated or who have not completed the vaccine series, catch-up vaccination is recommended.

For adults **27** years and older, catch-up vaccination is not routinely recommended; the ACIP notes that the decision to vaccinate people in this age group should be made on an

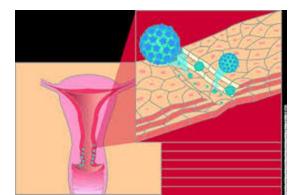
individual basis.

we also suggest HPV vaccination for health care workers who may be at risk for occupational exposure to HPV, even if they are older than 26 years.

Studies have suggested that HPV vaccination is immunogenic, efficacious, and safe in females older than 25 years.

HPV vaccination of individuals older than 26 years may not be covered by insurance providers or other payers, and this may affect the decision to vaccinate.

In the United States, the HPV vaccine is approved through age 45.

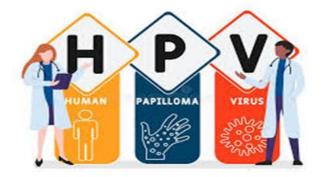


# **Optimal timing**

— Within the recommended age range, the optimal time for HPV immunization is prior to an **individual's** sexual debut.

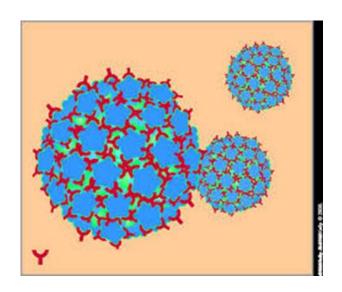
Clinical trial data of vaccine efficacy in males and females suggest that immunization with HPV vaccine is most **effective among individuals who have not been infected with HPV.** 

Individuals who are sexually active should still be vaccinated consistent with agespecific recommendations.



history of an abnormal Papanicolaou test, genital warts, or HPV infection is **NOT** a contraindication to HPV immunization.

However, immunization is **less beneficial** for those who have already been infected with one or more of the HPV vaccine types.



## Choice of vaccine

 Not all HPV vaccines are available in all locations. Some countries have manufactured their own HPV vaccines.

we recommend the human papillomavirus 9-valent vaccine.

However, if the HPV vaccine formulation initially used is unknown or unavailable, or if the 9-valent vaccine is being introduced into the formulary, a different HPV vaccine formulation can be used to complete the series.



## Immunization schedule

Individuals initiating the vaccine series at 9 to 14 years of age — Two doses of HPV vaccine should be given at 0 and at 6 to 12 months.

If the second dose was administered less than five months after the first, the dose should be repeated a minimum of 12 weeks after the second dose and a minimum of five months after the initial vaccine dose.

➤ Individuals initiating the vaccine series at 15 years of age or older — Three doses f HPV vaccine should be given at 0, 1 to 2 (typically 2), and 6 months.

The minimum intervals between the first two doses is four weeks, between the second and third doses is 12 weeks, and between the first and third dose is five months.

➤If a dose was administered at a shorter interval, it should be repeated once the minimum recommended interval since the most recent dose has passed.

Immunocompromised patients – Three doses of HPV vaccine should be given at 0, 1 to 2, and 6 months regardless of age.

The two-dose and one-dose series are recommended by the WHO and in many other countries.

HPV vaccine can be safely administered at the same time as other age-appropriate vaccines at a different anatomic site.

Administering HPV vaccine at the same time as certain other vaccines (ie, tetanus, acellular pertussis, and diphtheria vaccine and inactivated poliovirus vaccine) does not appear to adversely affect the immune response to either the HPV vaccine or the concomitant vaccine.

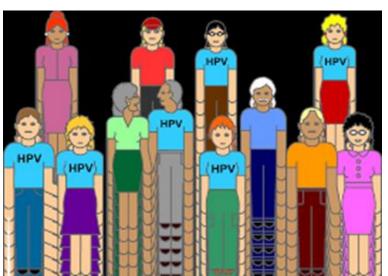


Missed doses — Patients often do not follow up for their immunizations on schedule.

The ACIP recommends that if the vaccination series is interrupted for any length of time, it can be resumed without restarting the series.

**Postvaccination instructions** — Because of a potential for syncope with any vaccine, and particularly with the HPV vaccine, a routine 15-minute waiting period in a **sitting** or **supine position** following HPV vaccination is recommended.

This may decrease the risk of syncope with subsequent injury.



# **Unnecessary evaluation**

#### Prevaccination assessment —

- Serologic or HPV DNA testing is not warranted prior to immunization
- Pregnancy testing is also not necessary

**Postvaccination serology** — There is no evidence that the measurement of postvaccination antibody titers to monitor immunity is useful for determining who is protected against infection by the vaccine-targeted types.

#### Limited benefit of revaccination —

There is no evidence that revaccination is necessary



### SPECIAL POPULATIONS

**Pregnant or breastfeeding patients** — HPV vaccination during pregnancy is **not recommended**.

Thus, if an individual is found to be pregnant after initiating the vaccination series, they can be reassured that available evidence does not indicate any increase in risk of adverse pregnancy outcome with vaccination.

Nevertheless, the remainder of the series should be delayed until the patient is no longer pregnant.

Lactating patients can receive the immunization series since subunit vaccines do not affect the safety of infant breastfeeding.

# Pre-existing HPV-associated disease

Vaccination is still recommended in individuals within the recommended age range who have evidence of **prior HPV** infection, as it can still provide protection against infection with HPV vaccine types not already acquired.

However, these patients should be advised that vaccination will have **no therapeutic effect on pre-existing HPV infection** or HPV-associated disease, and the potential benefit of HPV vaccination is not as great as if they were vaccinated before their sexual debut.

# Patients with HIV or immunocompromising conditions

— Immunocompromised patients, particularly transplant recipients and patients with **HIV** and CD4 cell counts <200 cells/microL, are at especially high risk for HPV-related disease.

HPV vaccination with a **three-dose** schedule (at 0, 1 to 2, and 6 months) is recommended for all immunocompromised patients.

## **EFFICACY AND IMMUNOGENICITY**

## **Immunogenicity**

Excellent antibody responses have been reported following immunization with the hpv 9-valent, hpv quadrivalent, and hpv bivalent vaccines, with seroconversion rates of 93 to 100 percent in females and 99 to 100 percent in males.

This suggests that the titers resulting from **natural infection**, which are an order of magnitude **lower than** those elicited in vaccine studies, provide some level of protection against reinfection with the same HPV type.

# Efficacy

**Cervical, vaginal, and vulvar disease** — HPV vaccination is effective in preventing cervical disease, including cervical intraepithelial neoplasia (CIN2 or 3) and adenocarcinoma in situ.

Large observational studies have also shown substantial decreases in cervical cancer incidence following initiation of national HPV vaccination programs.

In addition, quadrivalent and 9-valent HPV vaccines have been demonstrated to reduce the incidence of vaginal and vulvar intraepithelial neoplasia (VAIN and VIN 1-3).

Vaccine efficacy is greatest in those who do not have prior HPV infection.

# **Duration of protection**

HPV vaccines have shown excellent duration of protection for the time periods through which they have been studied.

Continued protection against high-grade intraepithelial neoplasia or condyloma has been observed through at least **10 years** following vaccination among both female and male trial participants.

Persistent antibody levels and protection against HPV infection have also been reported up to **10 years** following vaccination.



### **HUMAN PAPILLOMA VIRUS**





# ALMOST ALL CASES OF CERVICAL CANCER

ARE CAUSED BY



#### HPV is a virus.

You can catch it by sexual contact.

#### **OUT OF EVERY 10 TEEN GIRLS...**



#### **MOST HPV GOES AWAY**

(Though you can catch it again!)

BUT SOME HPV GIVES YOU WARTS ......down there

AND SOME HPV CAN GIVE YOU CANCER

1 In 3 women who get cancer will DIC.

Luckily, the HPV Vaccine is a safe and effective way to protect yourself from getting HPV

