



HUMAN PAPILLOMAVIRUS(HPV) VACCINATION

FOR CERVICAL CANCER PREVENTION

INTRODUCTION

Cervical cancer is the second most common cancer in Indian women and fourth globally.¹ Cervical cancer is a preventable and curable type of a cancer, as long as it is detected early and managed effectively. India has a population of 51.14 crore women age of and above 15 years who are at risk of developing cervical cancer.² The number of new cases of cervical cancer in 2022 were 127,526 and deaths due to cervical cancer were estimated at 79,906.¹

Human papillomavirus (HPV) is the most common infection causing a range of conditions in men and women such as cancers of cervix, head, neck, oropharynx, and anogenital area, as well as with anogenital warts and respiratory papillomatosis. Most HPV infections are asymptomatic and resolve spontaneously within 1-2 years.³ Almost all cervical cancers are caused by persistent infection with human papillomavirus (HPV), HPV types 16 and 18 accounting for 80 - 85% of cervical cancers in India and 73% of cervical cancers globally.²

In 2020, World Health Organization (WHO) launched a global strategy to eliminate cervical cancer by achieving three key pillars by 2030: Fully vaccinating 90% of the girls by the age 15 years; screening 70% of the eligible women with high performance test by the age of 35 and again by the age of 45, and 90% of women with precancer treated and 90% of women with invasive cancer is managed.

The emphasis should be on screening all eligible women to detect the disease at the precancerous stage through Visual Inspection after Application of Acetic Acid (VIA) or liquid based cytology or HPV DNA testing irrespective of whether they have any complaints, because there are often no signs and symptoms of cervical precancers. Systematic referral for further management must be established if not provided at our clinic.

HPV vaccination prevents new HPV infections but does not treat existing HPV infections or diseases. Most sexually active adults have already been exposed to HPV, although not necessarily all of the HPV types targeted by vaccination. At any age, having a new sex partner is a risk factor for getting a new HPV infection. People who are in a long-term, mutually monogamous relationship are not likely to get a new HPV infection. The most favourable time to take the vaccine is "Before the Sexual Debut". HPV vaccine was introduced in 2008, however it is yet to be included in country's Universal Immunization Programme (UIP).

HPV VACCINES LICENSED IN INDIA

1. Cervarix by GlaxoSmithKline: Bivalent (HPV2) licensed for females 10-45 years and targets HPV types 16 and 18. Currently discontinued in India.
2. Gardasil by MERCK: Quadrivalent (HPV4) licensed for females 9 - 45 years and targets HPV types 6, 11,16 and 18
3. Gardasil by MERCK: Nonavalent (HPV9) licensed for females and males 9 - 45 years. It prevents infection with HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58. Licensed in India in males of age group 9-15 years.⁶
4. Cervavac by Serum Institute of India: Quadrivalent (HPV4) indicated for females and males 9 - 26 years. India's indigenous vaccine targets HPV types 6, 11,16 and 18. The vaccine is expected to provide prevention in girls/women and boys from cervical, vulvar, vaginal, and anal cancer caused by HPV types 16 and 18, and Genital warts (condyloma acuminata) caused by HPV types 6 and 11.

In India, the Quadrivalent HPV vaccine (HPV 4) is expected to prevent ~ 83% of cervical cancers, whereas the Nonavalent vaccine (HPV 9) is expected to prevent ~ 98% of cervical cancers.

ADMINISTRATION OF VACCINE

The vaccine is given intramuscularly in the deltoid region of the upper arm as a 0.5 mL dose. The vial is to be shaken well before use to maintain suspension of the vaccine. The individual should be seated during vaccination and observed for 15 minutes after vaccination.

FPA India Medical Advisory Panel (MAP) has endorsed HPV vaccination. As per the WHO recommendations, one dose of vaccine is recommended for 9 – 20 age group girls and boys.

Target age groups	Recommended Schedule ⁵
9-14 years	One dose
15-20 years	One dose
21 years and above	Two doses: 0 and 6 months

There is no recommendation for any booster dose.

National Technical Advisory Group for Immunization (NTAGI) has recommended introduction of HPV Vaccine in the Universal Immunization Programme (UIP) with a one-time catch-up for 9 -14-year-old adolescent girls followed with routine introduction at 9 years.⁴

SIDE EFFECTS AND MANAGEMENT

Like any other vaccine, it can have minor adverse events generally mild and of short duration such as:

SIDE EFFECT	MANAGEMENT	WHEN TO GET EMERGENCY CARE
Injection site reaction(Pain, swelling, and redness)	<ol style="list-style-type: none"> 1. Lasts a day or two 2. Ice the area in case of swelling 3. Take paracetamol for redness if needed 	<ol style="list-style-type: none"> 1. Swelling of lips, face, shortness of breath 2. Redness that spreads to other parts of body
Headache	<ol style="list-style-type: none"> 1. Lasts for a couple of days 2. Take OTC pain killers 	Headache increasing and not going away
Nausea/ vomiting	<ol style="list-style-type: none"> 1. Goes away in one to two days 2. Have bland diets and avoid spicy and fried foods 3. Take OTC anti-emetics 	
Dizziness	<ol style="list-style-type: none"> 1. Happens more commonly in adolescents 2. Take vaccine sitting or lying down 3. Wait for 15 minutes after vaccination 	
Fatigue	<ol style="list-style-type: none"> 1. Lasts for a couple of days 2. Eat nutritious food and avoid strenuous activity 	
Diarrhoea	<ol style="list-style-type: none"> 1. Lasts 1-2 days 2. Keep hydrated 3. Take loperamide if very severe 	
Fever	<ol style="list-style-type: none"> 1. Rare side effect. However, some young adults may have fever 1-2 days after vaccine 2. Take OTC paracetamol 	<ol style="list-style-type: none"> 1. If fever above 104 degrees 2. If fever lasts more than 3 days

VACCINE STORAGE

Vaccines are to be stored in a refrigerator at +2° to +8°C. Do not freeze and store in an original package in order to protect from light.

IMPORTANCE OF EARLY INITIATION OF VACCINE

- Young adolescents mount a superior immune response compared to older individuals.
- Prevention of disease is better if started earlier.

CONTRAINDICATIONS

- History of severe allergic reaction (anaphylaxis) after the first dose of the vaccine or known, severe allergies to any component of the vaccine
- Pregnant women
- People with acute illness should usually wait until they recover, before getting HPV vaccine.

FOLLOW-UP SCHEDULE

The beneficiary should be followed up two weeks after vaccination to monitor for any side effects or other health concerns. A reminder should be provided for the next scheduled dose if any. Additionally, the beneficiary must be issued a vaccination card and advised to contact the clinic if any issues or concerns arise.

VACCINE SAFETY

HPV vaccines are based on virus-like particles (VLPs) that are formed by HPV surface components. VLPs are not infectious because they lack the virus's DNA. However, they closely resemble the natural virus, and antibodies against the VLPs also have activity against the natural virus.

SPECIAL SITUATIONS

- For HIV positive or immunocompromised girls, three doses are to be followed.
- HPV vaccines can be given at the same time as the Tdap vaccine. It should be ensured to use separate syringes and given at different injection sites. It should not be mixed with any other vaccine in the same syringe or vial.
- It is not recommended in pregnancy, if inadvertently given, there is no need for MTP. If the patient conceives after the first dose, it is advisable to give further doses after pregnancy.
- Lactating women can receive HPV vaccine. Available evidence does not indicate an increased risk of adverse events in either the mothers or their baby after the administration of HPV vaccine to lactating mothers.

- Efforts should be made to administer the same vaccine for all doses when using a multidose schedule. However, if the vaccine used for the prior dose(s) is unknown or unavailable, any HPV vaccine can be administered to complete the recommended schedule.
- Women aged >26 years who have been sexually active should be counselled regarding reduced efficacy in older age group and the importance of screening.
- Women with abnormal PAP/Positive HPV test/previous HPV lesions: Can be vaccinated if they desire; however, they should be counselled that it is not a therapeutic vaccine and will not treat existing pathology and there is reduced efficacy in older women.
- HPV vaccination is a primary prevention intervention and does not eliminate the need for screening, since the existing vaccines do not protect against all high-risk HPV. The screening of the cervical cancer should be done as per the guidelines.
- For any interrupted doses, continue with the remaining doses as per age-based recommendation, vaccination series need not be restarted.

ACTION TO BE TAKEN FOR PLANNING HPV VACCINATION PROGRAM AT BRANCH LEVEL

- Coordinating with schools, local community stakeholders and organising awareness/sensitization programs for them and parents/guardians to address vaccine information, stigma, myths and misconceptions.
- The programme can be planned through schools. For out of school beneficiaries, vaccination can be conducted through community outreach and mobile teams.
- Line listing for eligible beneficiaries to be prepared before planning the vaccination activity day.
- Mandatory consent form to be filled with signature by parents/guardians/beneficiary.
- Vaccine Procurement if initiated to be under prescription of Registered Medical Practitioner.
- Every beneficiary should receive the vaccine card with completed details.

CONSENT FORM TEMPLATES

HUMAN PAPILLOMA VIRUS (HPV) VACCINATION CONSENT FORM (PARENTS)

I _____ mother/father/guardian of _____ aged about _____ years (Date of birth: _____), at present residing at _____ hereby consent that my daughter/son can receive the HPV vaccine dosage schedule through _____ clinic of the Family Planning Association of India. She/He is not studying/studying in _____ class at _____ school/college in _____ area.

I have received detailed information about the HPV vaccine from the staff at FPA India. I have discussed this with my spouse and child. I agree that my child should undergo HPV vaccination.

Date: _____ Signature or thumb impression of parent/guardian: _____

Place: _____ Contact Number: _____

Thank you for completing the form

CLINIC STAFF USE

Dose	1 st Dose	2 nd Dose
Date of the vaccination		
Site of Injection (Left/Right Arm)		
Place of vaccination		
Name of the vaccine		
Batch Number of vaccine		
Expiry date of vaccine		
Signature/Thumb Impression of the parent/guardian		
Name of the immunizer		
Signature of immunizer		

This form should be translated in Hindi or local language. In case, the parent/guardian are unable to read it, it should be explained in a language they can understand, and parent/guardians thumb impression should be taken.

HUMAN PAPILLOMA VIRUS (HPV) VACCINATION CONSENT FORM (ADULTS)

I _____, the
daughter/son of _____ aged
about _____ years (Date of birth: _____), residing at _____

_____ do hereby give my consent for the complete dosage schedule of HPV
vaccination at the _____ clinic of Family Planning Association of India.

I have received detailed information about the HPV vaccine from the staff at FPA India.

Date:

Signature of beneficiary:

Place:

Contact Number:

Thank you for completing the form.

CLINIC STAFF USE

Dose	1 st Dose	2 nd Dose
Date of the vaccination		
Site of Injection (Left/Right Arm)		
Place of vaccination		
Name of the vaccine		
Batch Number of vaccine		
Expiry date of vaccine		
Signature/Thumb Impression of the beneficiary		
Name of the immunizer		
Signature of immunizer		

This form should be translated in Hindi or local language. In case, the client doesn't understand the form, it should be explained in a language they can understand, and the clients thumb impression should be taken.

VACCINATION CARD TEMPLATE

This can be printed in a card format with front side information of client and vaccine details and back side information on instructions.

VACCINATION HUMAN PAPILLOMA VIRUS (HPV) VACCINATION CARD

<i>CLIENT ID NUMBER</i>	
<i>NAME OF THE CLIENT</i>	
<i>AGE</i>	Years
<i>GENDER</i>	
<i>RESIDENTIAL ADDRESS</i>	
<i>SCHOOL/COLLEGE NAME (IF APPLICABLE)</i>	
<i>NAME OF THE CLINIC & BRANCH/PROJECT</i>	

Dose	1 st Dose	2 nd Dose
Date of the vaccination		
Site of Injection (Left/Right Arm)		
Place of vaccination		
Name of the vaccine		
Batch Number of vaccine		
Expiry date of vaccine		

Any side effects following the HPV vaccination should be reported to the clinic or your local doctor

Instructions:

- 1) After receiving the vaccination dose, please be seated for 15-20 minutes.
- 2) HPV vaccine is safe. You may experience the following, which is not harmful if for short duration:



Pain/Redness/Swelling at injection site



Fever



Dizziness/Fainting



Nausea, vomiting or abdominal pain



Headache



Joint/Muscle Pain

- 3) If above symptoms are persistent or any other symptom, please contact us on below number or visit the health facility

HPV VACCINATION FREQUENTLY ASKED QUESTIONS

1. *What is Human Papillomavirus?*

Human papillomavirus (HPV) is a common family of viruses. They can be transmitted by surface contact and also sexual contact. There are more than 200 types of HPV viruses. Some cause infection of the skin and others infect mucous membranes of various areas of the body. Different types of HPV infection affect the body in different ways. For instance, some types of HPV can lead to cancer of the tongue, tonsils, anus, cervix, vulva, and penis, and others cause warts in the genital area.

2. *How does HPV infection spread?*

Most HPV infections (70–90%) are asymptomatic and resolve spontaneously within 1–2 years, with good immunity. But when HPV infection persists, it can cause health problems including cervical cancer, which may occur many years after the initial infection. One can get HPV by having sexual contact with someone who has the virus. It also spreads through close skin-to-skin touching. A person with HPV can pass the infection to someone even when they have no signs or symptoms.

3. *What are the preventive measures against HPV infection?*

Indian Government has recommended the HPV vaccine for girls to be vaccinated between the age of 9-14 years. The HPV vaccine is safe and effective and 70% of cervical cancer in India are caused by HPV type 16 & 18. Major risk factors for persistent HPV cervical cancer include early sexual intercourse, multiple sexual partners, multiparity and poor menstrual hygiene. HIV positive patients are more likely to get cervical cancer because of lessened clearance of the vaccine from the body due to lowered immunity. Routine cervical cancer screening is also necessary from age of 30 -65 years to prevent cervical cancer.

4. *Is there a treatment for HPV?*

There is currently no treatment for the HPV itself. However, treatments are available for cancers that HPV can cause. It's important to note that the HPV vaccine is a preventive measure - it does not treat existing HPV infections or HPV-related cancers.

5. *What is cervical cancer?*

Cervical cancer occurs in the cervix (lower part of the uterus). A large majority of cervical cancer (more than 95%) is due to HPV. It is the second most common cause of cancer mortality among Indian women, therefore early protection is necessary.

6. *What are the signs and symptoms of cervical cancer?*

Cervical cancer develops slowly and in early stages may not have any symptoms. However, as the disease progresses, the following symptoms may appear:

1. Abnormal Vaginal Bleeding: This includes bleeding between periods, after sexual intercourse, or post-menopause.
2. Unusual Vaginal Discharge: A watery, pink, or foul-smelling discharge may be a sign of cervical cancer.
3. Pelvic Pain: Persistent pain in the pelvis or lower back.
4. Pain During Intercourse: Discomfort or pain during sexual intercourse can be a symptom.
5. Increased Urination: Frequent or urgent urination, sometimes accompanied by pain.

7. *Which HPV vaccines are available in India?*

Currently, there are two types of vaccines licensed against HPV in India, namely quadrivalent and nonavalent.

8. *Who should get the HPV vaccine?*

HPV vaccination can be initiated at the age of 9 years by females and males, until 45 years of age.

9. *Is it safe to get vaccinated during periods?*

Yes, you can be given HPV vaccine during menstruation. The vaccination doesn't affect menstruation and nor does menstruation cause any additional side effects of the vaccination. However, it is necessary that families are advised to make sure their daughter is well and comfortable during menstruation, if to be vaccinated.

10. *Can males be vaccinated against HPV?*

Yes, now vaccines are available for males too.

11. *If the HPV vaccine is given, does the women still need to be screened for cervical cancer?*

Yes, all women (30-65 years) are advised to undergo cervical cancer screening, irrespective of their HPV vaccination status. This is because the existing HPV vaccines do not protect against all high-risk types of HPV causing cervical cancer.

12. *What about HPV vaccine safety?*

HPV vaccine is safe, effective and is recommended by the World Health Organization (WHO). The vaccine has undergone extensive testing in clinical trials and continues to demonstrate an excellent safety profile. In India, the vaccine is manufactured by lead pharmaceutical company such as Serum Institute of India.

13. *What are the side effects of the vaccine?*

Common side effects of HPV vaccination are mild, self-limiting and resolve on their own within 2-3 days. Some examples of minor side effects are pain, redness and swelling at the injection site, fever, malaise, weakness, headache and nausea.

14. *Can HPV vaccination cause infertility?*

Various medical studies found no associations between HPV and infertility. Millions of adolescent girls across the globe have been vaccinated against HPV since 2006 and, many are mothers today.

15. *How long will the vaccine offer protection?*

The HPV vaccine provides a long-lasting protection against the strain of the virus. No booster dose recommendations have been made by the WHO or CDC.

16. *Can HPV vaccine be given to immune-compromised patients?*

The HPV vaccines do not contain live biological products or viral DNA; therefore, they are non-infectious. This characteristic makes it safer for people with weaker immune systems compared to live vaccines. Immune compromised children and adults are offered three doses of the vaccine.

References:

1. Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2024). *Global Cancer Observatory: Cancer Today*. Lyon, France: International Agency for Research on Cancer. Available from: <https://gco.iarc.who.int/today>, accessed [30 March 2024].
2. <https://www.rqcirc.org/blog/hpv-vaccination-in-india-new-progress-and-the-way-forward/>
3. FOGSI-ICOG Good Clinical Practice Recommendation GPCR Prevention and Management of Cervical Cancer. June 2023. Gynaecologic Oncology Committee
4. <https://pib.gov.in/PressReleaseDetailm.aspx?PRID=1885597>. This release can be read in: [Kannada](#), [English](#), [Urdu](#), [Hindi](#), [Punjabi](#), [Gujarati](#), [Tamil](#), [Telugu](#), [Malayalam](#)
5. Human papillomavirus vaccines: WHO position paper (2022 update). 97, 645–672. <http://www.who.int/wer>
6. <https://iapindia.org/pdf/vaccine-information/HPV-VACCINE.pdf>