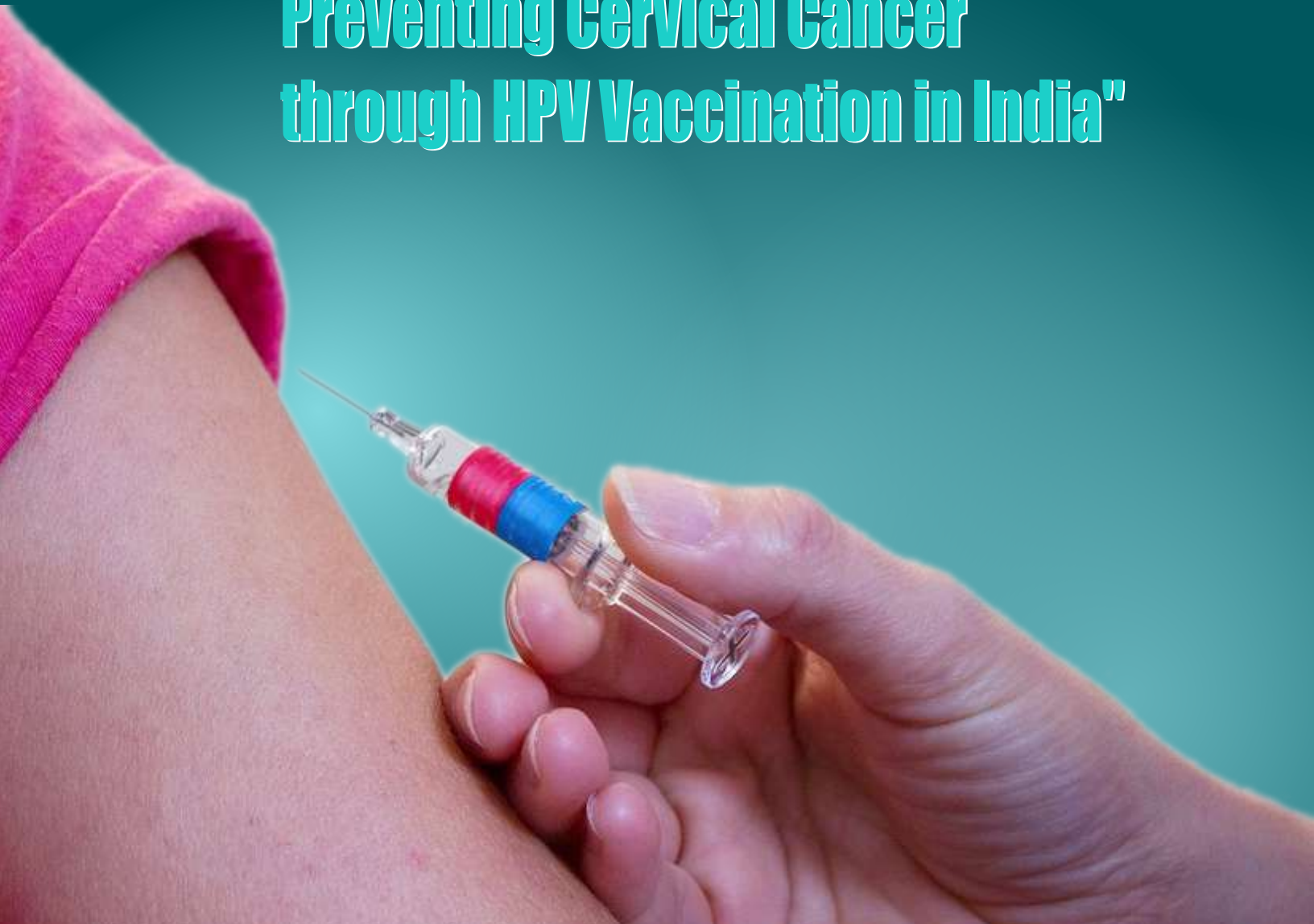


FOGSI- UNICEF presents

# "A Guide Book for Master Trainers: Preventing Cervical Cancer through HPV Vaccination in India"



**FOGSI 360**  
Coordinate Communicate Community  
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**unicef**   
for every child



*For every child*



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# Foreword

**Luigi D' Aquino**  
Chief of Health, UNICEF India



Cervical cancer is a pressing public health concern, with India accounting for highest number of cases and highest number of deaths globally, representing 70% of the nation's cervical cancer cases and a fifth of the global burden. The 2024 Health Budget of the Government of India, prioritized the Human Papillomavirus (HPV) vaccination for girls aged 9-14, aligning with the WHO's recommendation as a cost-effective measure against cervical cancer.

Like any new vaccine introduction, key concerns among the stakeholders include vaccine effectiveness and efficacy, lack of knowledge, misinformation, parental concerns about safety or potential vaccine side effects, moral and cultural issues combined with lack of strong vaccine endorsement by the health care professionals, and complacency because cervical cancer rates are falling in the country. Strong HPV vaccine recommendation by the health care providers (HCPs) remains a crucial strategy for successful vaccine implementation program. Patient-physician communication is a modifiable factor impacting HPV vaccination uptake. How the provider announces the vaccine, including message clarity, comprehension, and focus on patient-centeredness, as well as their ability to address questions, can impact vaccine uptake.

The master trainer's module developed by the Federation of Obstetrics and Gynecological Society of India (FOGSI) in collaboration with UNICEF will serve as a guide for the medical fraternity for spreading uniform messages and advocacy for improving knowledge and managing hesitancy for HPV vaccination. This effort will certainly contribute to the roll out and scale up the HPV vaccination to achieve the desired target of 90% vaccination for girls by the age of 15 years.

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Luigi D' Aquino



# Message

## Dr. Jaydeep Tank President FOGSI 2024



The fight against cervical cancer has reached a pivotal moment in India. With the recommendation to include HPV vaccination in the Universal Immunization Program, we have an unprecedented opportunity to significantly reduce the incidence of this devastating disease. Cervical cancer remains a major public health challenge, causing immense personal suffering and socio-economic burdens. The need for comprehensive and effective preventive strategies has never been more urgent.

The "Trainers Guide for HPV Vaccination for the Prevention of Cervical Cancer" is designed to equip trainers with the knowledge, skills, and tools necessary to effectively disseminate HPV vaccination education across India. This action guide is not just a manual; it is a blueprint for a nationwide effort to protect future generations from cervical cancer.

Our aim is to empower trainers with a thorough understanding of HPV, its link to cervical cancer, and the critical role that vaccination plays in prevention. By fostering a cadre of well-informed and passionate trainers, we can ensure that accurate and impactful information reaches every corner of our diverse country. This guide provides detailed content on the scientific basis of HPV vaccination, practical approaches to community engagement, and strategies for addressing common myths and concerns surrounding the vaccine.

The Federation of Obstetrics and Gynecological Society of India (FOGSI) in collaboration with UNICEF has developed this guide, to spread uniform messages and foster advocacy for promoting HPV vaccination. We acknowledge the contributions of healthcare professionals and experts whose dedication has shaped this guide. Their insights and experiences have been invaluable in creating a resource that is both comprehensive and practical. I would especially like to congratulate Dr Hrishikesh Pai, Immediate Past President, FOGSI, Dr Madhuri Patel, Hon. Secretary General, FOGSI, and Dr Surekha Tayade Chair Clinical Research Committee FOGSI and the UNICEF team for their hard work on this project.

As we embark on this journey, it is essential to remember that the success of this initiative depends on our collective efforts. By working together, we can create a wave of awareness and acceptance that will lead to the widespread uptake of HPV vaccination. Our ultimate goal is to save lives, reduce the burden of cervical cancer, and pave the way for a healthier future for all women in India.

We are confident that this guide will serve as an essential resource for trainers and healthcare professionals across the country. Let us unite in our mission to eradicate cervical cancer through education, vaccination, and unwavering commitment to public health.

A handwritten signature in black ink, appearing to read 'Dr. Jaydeep Tank'. The signature is stylized and written in a cursive-like font.

**Dr. Jaydeep Tank**  
President FOGSI



# Message

**Prof. Hrishikesh D Pai,**  
Trustee FIGO Asia-Oceania 2023-25  
President FOGSI 2023



The Federation of Obstetric and Gynecological Societies of India (FOGSI) And UNICEF are deeply committed to prioritizing the health and lives of women through the prevention of cervical cancer. This Trainers Guide developed for the Training of Trainers (ToT) to create awareness among Gynecologists and Physicians of India compiles the essential resources, evidence, and messaging that can be easily implemented.

FOGSI serves as the global voice for women's health, addressing health concerns across a woman's lifespan from adolescence to maturity. Cervical cancer is a pressing public health concern, with India accounting for approximately 124,000 cases and 75,000 deaths annually, representing 70% of the nation's cervical cancer cases and a fifth of the global burden. The 2024 Health Budget prioritizes Human Papillomavirus (HPV) vaccination for girls aged 9-14, aligning with the WHO's recommendation as a cost-effective measure against cervical cancer.

HPV vaccination is effective, safe, and provides long-lasting protection. Since its introduction in 2006, hundreds of millions of girls and boys in over 100 countries have received the HPV vaccine safely. In 2020, the World Health Organization (WHO) set a target to fully vaccinate 90% of all eligible girls before their 15th birthday as part of its Strategy for Cervical Cancer Elimination. We can significantly reduce the incidence of this disease with effective vaccination programs, screening initiatives, and treatment protocols. Primary prevention through HPV vaccination and secondary prevention via screening and treating precancerous lesions can prevent most cervical cancer cases.

Physicians must educate their peers, patients, and the community throughout the country. They must be the leaders who will end cervical cancer by effectively advocating for HPV vaccination of early adolescents, universal screening, and treatment. As respected leaders, physicians need to spearhead global efforts to eradicate cervical cancer.

This Training of Trainers Guide is designed to empower you with the knowledge and tools necessary to lead the charge in HPV awareness and prevention within your communities. The formulation of this guide has been a collaborative effort, bringing together the collective wisdom and expertise of some of the brightest minds in our field. As President of FOGSI 2023, I have the honor of overseeing this ambitious project, and I am deeply grateful for the dedication and hard work of everyone involved.

Together, we can make a difference and save countless lives.

Sincerely,



**Prof. Hrishikesh D Pai,**

MD FRCOG MSc FCPS FICOG  
Trustee FIGO Asia-Oceania 2023-25  
President – FOGSI 2023





# Message

**Dr Madhuri Patel**  
Hon. Secretary General, FOGSI



Cervical cancer remains one of the leading causes of cancer-related deaths among women in India. Yet, with the advent of the HPV vaccine, we have the potential to drastically reduce the incidence of this preventable disease. The importance of widespread vaccination cannot be overstated, and the need for informed, skilled trainers to lead this effort is critical.

The "Trainers Guide for HPV Vaccination for the Prevention of Cervical Cancer", is crafted to support the Training of Trainers (ToT) program in India. This guide is an essential tool designed to empower trainers with the necessary knowledge, techniques, and resources to effectively educate and advocate for HPV vaccination in their communities.

Our mission is to build a robust network of trainers who are well-versed in the science of HPV, the benefits of vaccination, and the strategies to overcome barriers to vaccine acceptance. This guide provides comprehensive information on HPV and cervical cancer, detailed instructions on vaccination protocols, and practical advice on engaging with communities and addressing vaccine hesitancy.

This guide is a result of the collective efforts of FOGSI and UNICEF, India with the help of healthcare professionals and experts who have dedicated their expertise to this cause. I congratulate Dr Jaydeep Tank President, FOGSI and Dr Hrishikesh Pai, Immediate Past President, FOGSI for this mammoth task. I applaud Dr Surekha Tayade, Chairperson, Clinical Research Committee, FOGSI for coordinating the development of this guide

We believe that through effective training and education, we can create a ripple effect of awareness and acceptance, ultimately leading to the eradication of cervical cancer in India. By equipping trainers with this guide, we are taking a significant step towards a future where cervical cancer is no longer a threat to women's health.

We invite all trainers to embrace this guide with dedication and passion, knowing that your efforts will have a profound impact on the health and well-being of women across India. Together, we can make a difference and move closer to a world free of cervical cancer.

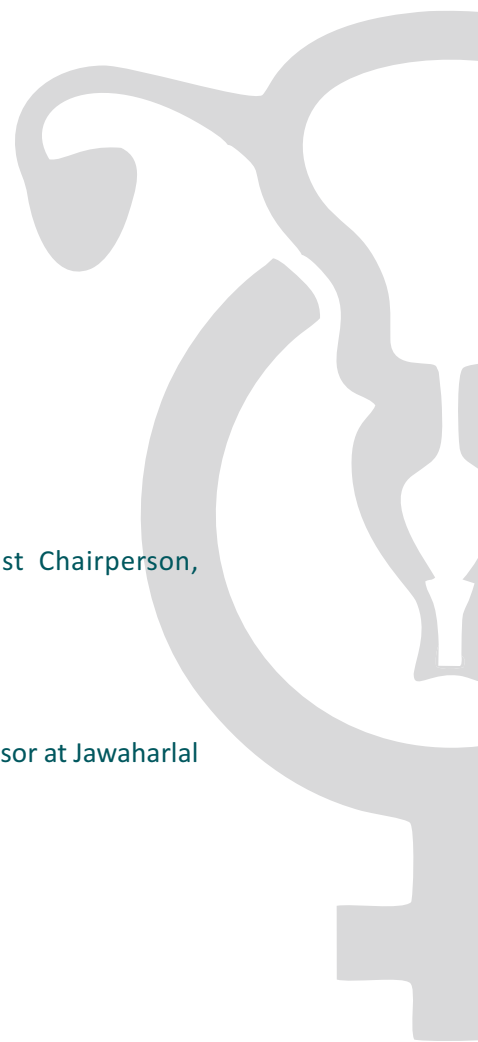
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**Dr Madhuri Patel**  
Hon. Secretary General, FOGSI



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# Sessions For Training of Trainers

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- ▶ **1. Introduction to Cervical Cancer** **1-7**
  - Overview of cervical cancer
  - Epidemiology and Global Burden
  - Risk factors
  
- ▶ **2. Human Papillomavirus (HPV)** **8-14**
  - Biology and types of HPV
  - HPV transmission and risk factors
  - High-risk vs. low-risk HPV strains
  - HPV infection and its progression to cervical cancer
  
- ▶ **3. Screening and Early Detection** **15-24**
  - Importance of screening and early detection
  - Screening methods (Pap smear, HPV DNA test)
  - Screening guidelines and recommendations
  
- ▶ **4. HPV Vaccination** **25-30**
  - Vaccination schedules and recommendations
  - Efficacy and safety of HPV vaccines
  
- ▶ **5. Prevention and Public Health Strategies** **31-41**
  - Primary, Secondary and Tertiary prevention
  - Barriers to vaccination and strategies to increase uptake
  
- ▶ **6. The Role of Doctors** **42-52**
  - Boosting HPV Vaccine Uptake using Social and Behaviour Change Communication (SBCC)





## Chapter 1 –

# INTRODUCTION TO CERVICAL CANCER

Overview, Epidemiology Global Burden & Risk factors



## GLOBAL Burden -

Globally, there are an estimated 20 million new cases of cancer and 9.7 million deaths attributed to cancer. Among women worldwide, cervical cancer ranks as the fourth most common cancer, following breast, lung, and colorectal cancers. However, in India, cervical cancer is the second most common cancer affecting women, trailing only breast cancer<sup>1</sup> (Globocon,2022). This significant prevalence underscores the critical public health challenge posed by cervical cancer in the country.



Each year, there are about 660,000 new cases of cervical cancer diagnosed and 350,000 deaths, with over 90% of these cases occurring in developing countries. By 2050, it is projected that there will be one million new cases annually, with 90% still concentrated in developing countries<sup>2</sup> (WHO fact sheets,2024). This high prevalence underscores the urgent need for effective prevention and control measures.

## The INDIAN Scenario

India accounts for approximately one-sixth of the global burden of cervical cancer and one-fifth of the global deaths from the disease.

Cervical cancer is the second most common cancer among women aged 15 to 44 years in the country. India reported approximately 123,907 new cases of cervical cancer, with around 77,348 deaths attributed to the disease<sup>3</sup>.

With a population of 511.4 million women aged 15 years and older who are at risk<sup>3</sup>, there is a critical need for comprehensive cervical cancer prevention strategies, including improved screening, vaccination programs, and public awareness campaigns to address this significant health challenge.





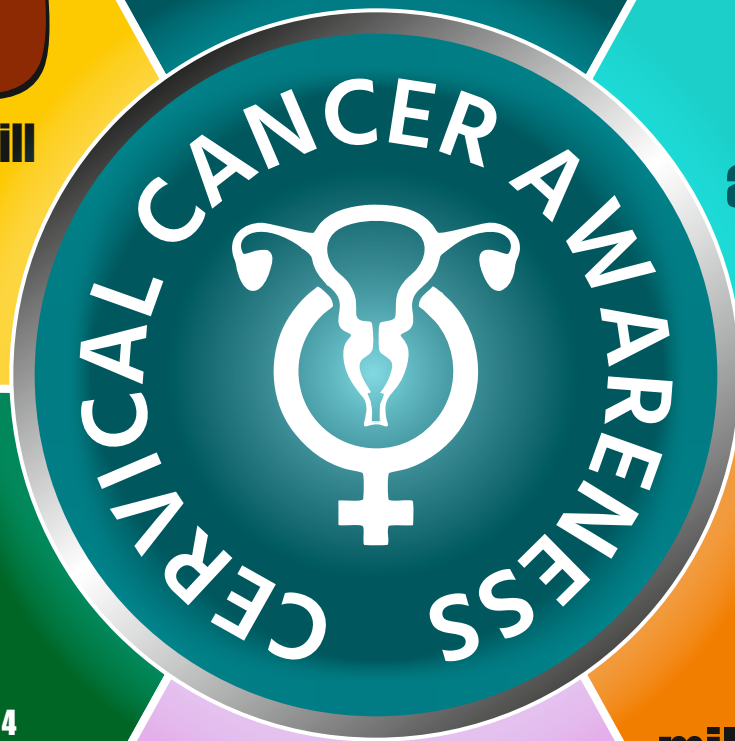
# Second Leading cause of cancer deaths in women

An estimated

**1 in 53**

women in India will  
develop cervical  
cancer in their  
lifetime<sup>5</sup>

**123,907**  
new cases  
est. **77,348**  
annual deaths<sup>3</sup>



**A Woman  
in India Dies  
Every**

**8** Minutes<sup>4</sup>

**from  
cervical  
cancer**

**More than  
480  
million women  
in India are  
at risk<sup>3</sup>**

**8 out of 10**  
women Globally will  
get infected with HPV  
at some point in their lifetime<sup>6</sup>



## GLOBAL STRATEGY TO ELIMINATE CERVICAL CANCER

World Health Organization (WHO) calls for 'A World Free of Cervical Cancer'. The Global Strategy for the Elimination of Cervical Cancer, spearheaded by the WHO presents a comprehensive framework to eradicate cervical cancer as a public health issue. The strategy emphasizes the need for widespread HPV vaccination, aiming to immunize 90% of girls aged 9-14 years by 2030. It also targets screening 70% of women aged 35-45 years with high-performance tests and ensuring that 90% of women with invasive cervical cancer receive effective treatment<sup>7</sup>.

### World Health Organization Achieving Elimination

A World free of  
**Cervical  
Cancer**



coverage of  
HPV Vaccination  
of girls (age 9 -14 Years)



coverage of  
screening (70% of women are  
screened with high-performance  
tests by the ages of 35 and 45 years)



of women identified with  
cervical disease receive  
treatment for precancerous  
lesions or invasive cancer



Every country must introduce and scale-up HPV screening for women between 30 and 49 years old, and ensure appropriate treatment and follow-up

*Dr. Tedros Adhanom Ghebreyesus, WHO Director-General 24 September 2018*

Overview of

# HPV VACCINATION INITIATIVE IN INDIA

HPV vaccination in India was initiated in Delhi in 2010, marking the beginning of a national effort to combat cervical cancer. By 2017, vaccination programs expanded to Bathinda and Mansa in Punjab, and in 2018, Sikkim launched a state-wide HPV vaccination campaign across 1,166 schools. Despite the vaccine being available in the private sector, its high cost remains a significant barrier. In 2022, the National Technical Advisory Group on Immunization (NTAGI) recommended including the HPV vaccine in the Universal Immunization Program (UIP), and the government allocated a budget for this initiative in 2024<sup>8</sup>. Nonetheless, achieving the 2030 target of vaccinating 90% of girls remains challenging, with less than 1% of girls currently vaccinated and fewer than 2% of Indian women having undergone cervical cancer screening according to NFHS-5 data<sup>9</sup>.



## Take Action

Prioritising  
HPV Vaccination  
in Practice

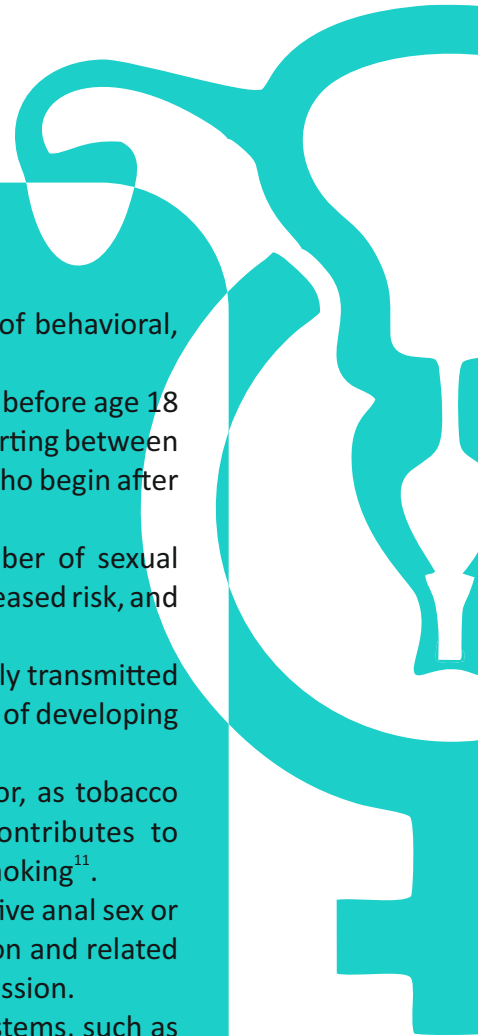




# RISK FACTORS

Cervical cancer risk factors are influenced by a combination of behavioral, environmental, and biological factors:

1. **Early Age of Sexual Activity:** Women who start sexual activity before age 18 have a twofold increased risk of cervical cancer, while those starting between ages 18 and 20 face a 1.5-fold higher risk compared to those who begin after age 21.
2. **Multiple Sexual Partners:** The risk increases with the number of sexual partners. Women with two sexual partners have a twofold increased risk, and those with six or more partners have a threefold increased risk.
3. **High-Risk Sexual Partners:** Having sexual partners with sexually transmitted diseases (STDs) or a history of HPV infection heightens the risk of developing cervical cancer.
4. **Smoking and Alcohol Use:** Smoking is a significant risk factor, as tobacco chemicals can damage cervical cells. Alcohol use also contributes to increased risk, although its impact is less direct compared to smoking<sup>11</sup>.
5. **Receptive Anal Sex and Homosexual Men:** Engaging in receptive anal sex or being a homosexual man can increase the risk of HPV infection and related cancers, including cervical cancer, due to potential HPV transmission.
6. **Immunosuppression:** Individuals with weakened immune systems, such as those with HIV/AIDS or on immunosuppressive treatments, are at higher risk.
7. **Chronic Cervicitis:** Persistent inflammation or infection of the cervix can contribute to the development of cervical cancer.
8. **Family History:** A family history of cervical cancer or other HPV-related cancers may increase an individual's risk.
9. **Socioeconomic Factors:** Limited access to healthcare services, including screening and vaccination, can contribute to a higher risk of cervical cancer.
10. **Early Childbearing:** Women who give birth at a young age may have a higher risk of developing cervical cancer.





# COMPREHENSIVE CERVICAL CANCER CONTROL (CCCC)

CCCC involves a multi-faceted approach to prevent, detect, and treat cervical cancer effectively.

Key components include:

## 1. Primary Prevention:

- o **HPV Vaccination:** Implement widespread HPV vaccination programs targeting pre-adolescent girls (9-14 years old) to prevent the onset of HPV infection. Extend vaccination to boys where feasible, as it can reduce the overall prevalence of HPV.
- o **Education and Awareness:** Promote public education about the importance of HPV vaccine and its role in preventing cervical cancer. Increase awareness of risk factors and preventive measures.

## 2. Secondary Prevention:

- o **Screening Programs:** Establish and enhance regular screening programs for cervical cancer using high-performance tests like Pap smears or HPV testing. Aim to screen 70% of women aged 35-45 years.
- o **Early Detection:** Facilitate easy access to screening services, especially in underserved areas. Encourage women to participate in routine screenings and follow-up care.

## 3. Tertiary Prevention:

- o **Treatment of Precancerous Lesions:** Ensure timely treatment for women with precancerous lesions detected through screening to prevent progression to invasive cancer.
- o **Cancer Treatment:** Provide comprehensive care for women diagnosed with cervical cancer, including surgery, radiation therapy, and chemotherapy. Ensure access to effective treatment options and support services.

## 4. Health System Strengthening:

- o **Infrastructure and Resources:** Improve healthcare infrastructure to support the delivery of cervical cancer prevention, screening, and treatment services. This includes training healthcare providers and ensuring the availability of necessary medical equipment and supplies.
- o **Integration of Services:** Integrate cervical cancer control efforts with other health services to improve efficiency and accessibility.



## 5. Equity and Access:

- o **Address Disparities:** Focus on reducing disparities in access to cervical cancer prevention and treatment services, particularly for marginalized and low-resource populations.
- o **Community Engagement:** Involve community leaders and organizations to promote cervical cancer awareness and encourage participation in prevention and screening programs.

## 6. Policy and Advocacy:

- o **Supportive Policies:** Advocate for and implement policies that support cervical cancer prevention and control, such as funding for vaccination programs and screening initiatives.
- o **Global Collaboration:** Collaborate with international organizations and stakeholders to share knowledge, resources, and best practices in cervical cancer control.

By addressing cervical cancer through these comprehensive strategies, it is possible to significantly reduce its incidence and mortality, ultimately working towards the goal of elimination as a public health problem.

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## BIOLOGY OF HPV

Human papillomavirus (HPV) infection represents a major global health challenge, contributing significantly to cancer morbidity and mortality. HPV is associated with approximately 4.8% of all human cancers. This virus is a small, non-enveloped entity with a diameter of 52-55 nm. It comprises a single double-stranded DNA molecule (Figure 1) of about 8,000 base pairs, which is encapsulated within a protein capsid made up of 72 pentameric capsomeres<sup>1</sup>. The structure of HPV enables it to effectively infect epithelial cells, leading to a range of outcomes from benign warts to malignant cancers, including cervical, anal, and oropharyngeal cancers.

### HUMAN PAPILOMAVIRUS

HPV

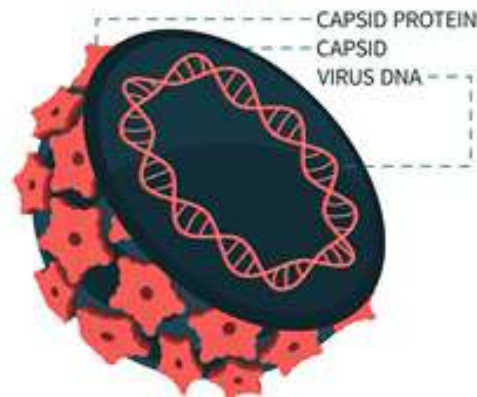


Figure1: Structure of HPV

Jalil AT, Karevskiy A. The Cervical Cancer (CC) Epidemiology and Human Papillomavirus (HPV) in the Middle East. International Journal of Environment, Engineering and Education. 2020 Aug 5;2(2):7–12.

## HPV GENOME

The circular genome of human papillomavirus (HPV) is divided into three functional regions (Figure 2):

- 1. Early Region (E1-E7):** This segment encodes proteins essential for viral replication, transcription, and immune evasion<sup>2</sup>.
- 2. Late Region (L1-L2):** This region encodes the structural proteins L1 and L2, which are responsible for the assembly and formation of the viral capsid and are critical for the virus's ability to form a stable virion and facilitate its transmission<sup>3</sup>.
- 3. Upstream Regulatory Region (URR) / Long Control Region (LCR):** This largely non-coding segment regulates the transcription and replication of the viral genome<sup>4</sup>.

The E6 and E7 oncoproteins play a central role in the development of cancer by interfering with the host's tumor suppressor proteins<sup>5,6</sup>.

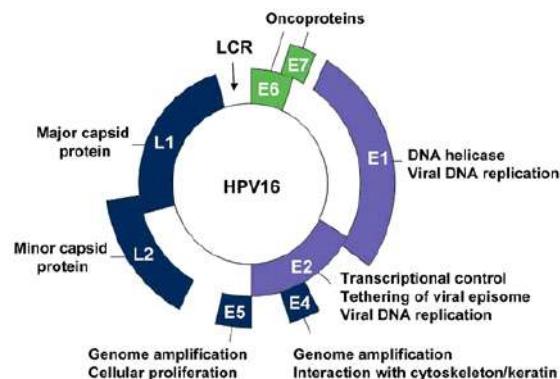


Figure 2 : HPV genome and their functions

D'Abramo CM. Small Molecule Inhibitors of Human Papillomavirus Protein - Protein Interactions. The Open Virology Journal. 2011 Jul 4;5(1):80–95

### Classification

HPV viruses are categorized based on their oncogenic potential into low-risk and high-risk types:

- **High-Risk HPV Types:** These are associated with various cancers, including cervical, anal, and oropharyngeal cancers. Notably, HPV types 16 and 18 are responsible for the majority of HPV-related cancers. Other high-risk types include HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, and 59.
- **Low-Risk HPV Types:** These are primarily associated with benign conditions such as warts and respiratory papillomatosis. Low-risk types include HPV 6, 11, 42, 43, 44, 54, 61, 70, 72, and 81 (Burd et al,2003).

Disorders	HPV TYPES
Cutaneous(Common Warts, Plantar Warts, Butcher's Wart)	
Common And Plantar Warts	1,2,4
Flat Warts	3,10
Butcher's Warts	2,7
Anogenital Epithelium	40 Subtypes
Genital Warts /Condyloma Accuminatum	6,11
Squamous Intraepithelial Lesions/ Carcinoma Cervix, Vagina, Vulva, Anus, Penis	15 Subtypes HPV 16 (Most Common, HPV 18
Other Mucosal Surfaces	
Oral Mucosa	16
Respiratory Mucosa –Respiratory Papillomatosis (benign laryngeal tumour of children-transmission from infected mother)	6,11

CANCER TYPE	Percentage Linked to High-Risk HPV
Cervical Cancer	99-100%
Anal Cancer	90%
Vulvar Cancer	69%
Viginal Cancer	75%
Orpharyngeal Cancer	70%

## HPV and Cancers –

High-risk HPV types are closely linked to cervical dysplasia and cervical cancer. They are responsible for the majority of these cancers, with the following key statistics:

Table 2 - Association of high-risk HPV types with various cancers:



## TRANSMISSION

HPV transmission primarily occurs through unprotected penetrative sexual intercourse. This includes vaginal, oral, or anal sex with an infected individual. Even intimate skin-to-skin contact involving an infected area can lead to HPV infection.

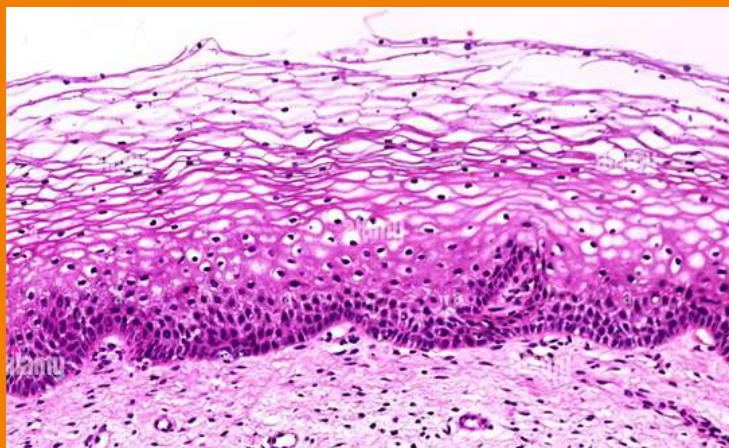
Infected individuals may not exhibit signs or symptoms for years, which complicates detection and emphasizes the importance of having an effective screening program to identify and manage HPV infections<sup>8</sup>.

### Normal Differentiation of Cervical Epithelium

Normal Differentiation of Cervical Epithelium involves a series of stages as cells progress from the basal layer to the superficial layer:

- 1. Basal Cells:** These cells are located in the basal layer of the cervical epithelium. They are characterized by their small, round nuclei and basophilic (dark-staining) cytoplasm. Basal cells actively divide and differentiate as they move upward.
- 2. Parabasal Cells:** As basal cells divide and move away from the basement membrane, they mature into parabasal cells. These cells have larger, more rounded nuclei and basophilic cytoplasm compared to basal cells.
- 3. Intermediate Cells:** With further differentiation, parabasal cells become intermediate cells. These polygonal cells feature abundant cytoplasm and smaller, round nuclei. As cells progress through this stage, they begin to exhibit a more flattened shape.
- 4. Superficial Cells:** In the final stage of differentiation, cells become large and markedly flattened. The nuclei of these superficial cells become small, dense, and pyknotic (shrunken). The cytoplasm of these cells becomes more transparent as they approach the surface.

Overall, as cells mature from the basal to the superficial layer, there is a noticeable increase in cell size and a reduction in nuclear size. Cells exiting the cell cycle typically do so as they leave the basal layer, resulting in a loss of nuclei in the suprabasal cells. This orderly process of differentiation ensures the proper function and renewal of the cervical epithelium<sup>9</sup>.



# LIFECYCLE OF HPV

HPV targets cutaneous and mucosal squamous epithelium composed of basal layer of undifferentiated cells. HPV can only establish in actively dividing cells. The virus relies on host cell for its genome replication. HPV itself does not encode for any enzymes or polymerases. E6, E7 are critical for growth, persistence and transformation of host genome, persistence of high-risk HPV being the major risk factor for the development of ano-genital cancers.

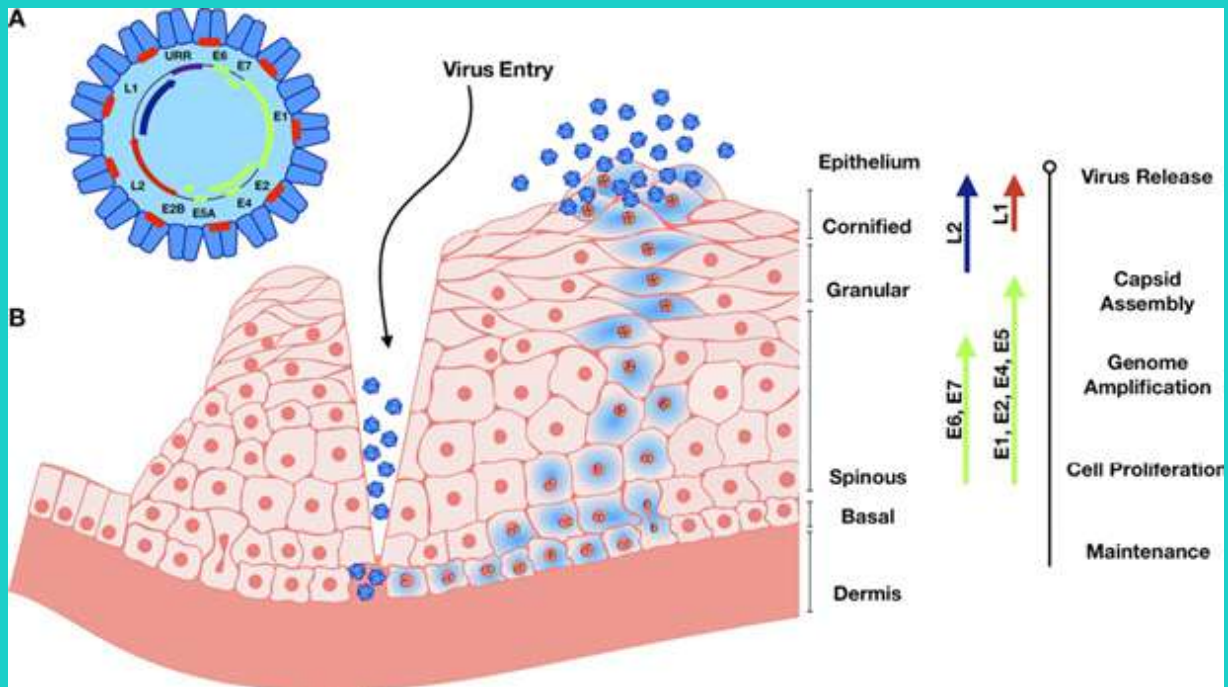


Figure 4: Lifecycle of HPV

O'Leary JJ, White C, Spillane C, Naik P, O'Brien R, Reynolds S, et al. Cervical screening: A new way forward (tests of risk and tests of disease). HRB Open Research [Internet]. 2018 Feb 28;1:3

HPV enters the host basal layer through micro abrasions in the epithelium. Basal layer is composed of stem cells which act as reservoir for new layers of suprabasal cells. Viral replication is encoded by E1 & E2. This initiates a low-level amplification of the HPV episome, to a copy number of ~100/cell. As HPV infected basal cells divide, viral genome are partitioned into daughter cells. As infected cells leave the basal layer- they remain active due to activation of E7 and re-enter S phase. They detach from the basal layer, migrate towards stratum granulosum and undergo differentiation. Presence of E7 causes retention of nuclei throughout the layers. After assembly of virions, they are released from superficial layers<sup>10</sup>.

# NATURAL HISTORY OF HPV

HPV is considered ubiquitous with nearly 90% of sexually active men and women being infected with it. In spite of infecting a large majority of people, the virus does not cause cancer in a large majority of cases. Most infections are inapparent and are cleared by the host immune system within 12-18 months. However, approximately 10–15% of women have persistent HPV infection with immunosuppressed state, smoking, multiple sexual partners being predisposing factors<sup>11</sup>.



## HPV – CLINICAL PROGRESSION

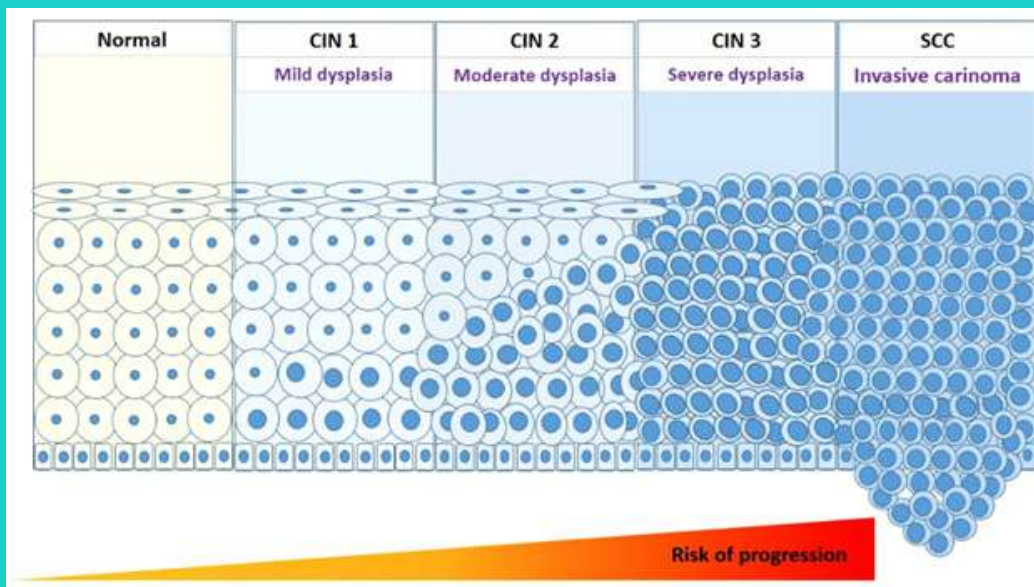


Figure 5: Clinical progression of HPV infection

Sudenga SL, Shrestha S. Key considerations and current perspectives of epidemiological studies on human papillomavirus persistence, the intermediate phenotype to cervical cancer. *International Journal of Infectious Diseases*. 2013 Apr;17(4):e216–20.

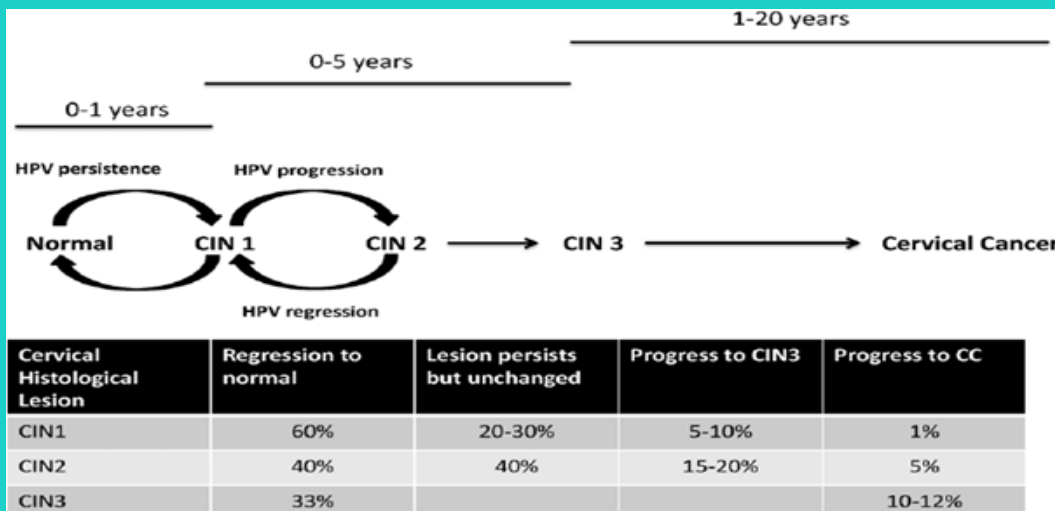
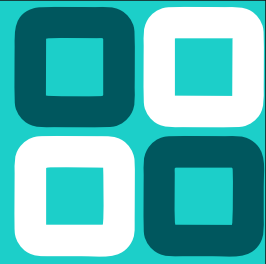


Figure 6



HPV Clinical Progression involves several stages, from initial infection to potential cancer development:

### 1) Initial Infection:

- **Transmission:** HPV infection typically occurs through unprotected sexual contact. The virus enters epithelial cells at the site of contact.
- **Asymptomatic Phase:** The majority of HPV infections are asymptomatic and can resolve spontaneously. This phase generally lasts from a few months to 2 years, with most infections clearing within this timeframe without causing symptoms.

### 2) Viral Replication:

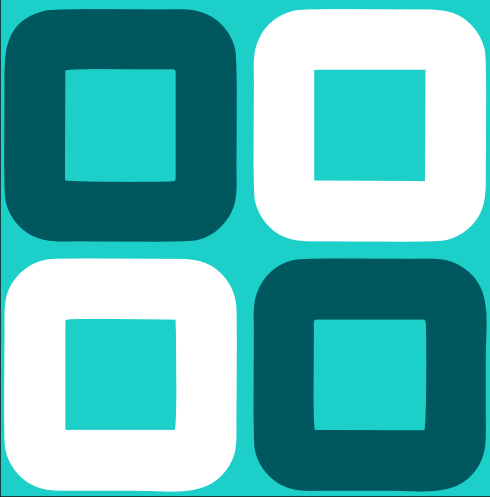
- **Early Stage:** During this period, HPV replicates within the basal layer of the epithelium. E6 and E7 proteins are expressed, leading to cellular changes. This stage often lasts several months to years.

### 3) Clinical Manifestations:

- **Benign Lesions:** For some individuals, HPV infections lead to the development of benign warts or condylomas. Low-risk HPV types typically cause these lesions, which can appear within a few months to years after initial infection.
- **Precancerous Lesions:** High-risk HPV types can cause precancerous lesions such as cervical intraepithelial neoplasia (CIN). The progression from HPV infection to CIN can take several years. **CIN stages are:**
  - o **CIN 1:** Mild dysplasia or low-grade squamous intraepithelial lesion (LSIL). This can develop within 1-2 years after initial infection.
  - o **CIN 2:** Moderate dysplasia or high-grade squamous intraepithelial lesion (HSIL). This may develop 2-3 years after initial infection.
  - o **CIN 3:** Severe dysplasia or carcinoma in situ (CIS). This can take 3-5 years or more to develop from CIN 1 or CIN 2 if left untreated.

### 4) Progression to Cancer:

- **Invasive Cancer:** If CIN lesions are not treated, they may progress to invasive cervical cancer. This progression can occur over a period of 5-10 years or more, depending on the individual's immune response and other factors. HPV-related cancers in other sites, such as anal or oropharyngeal cancers, may follow similar timelines (de Sanjose,2017).





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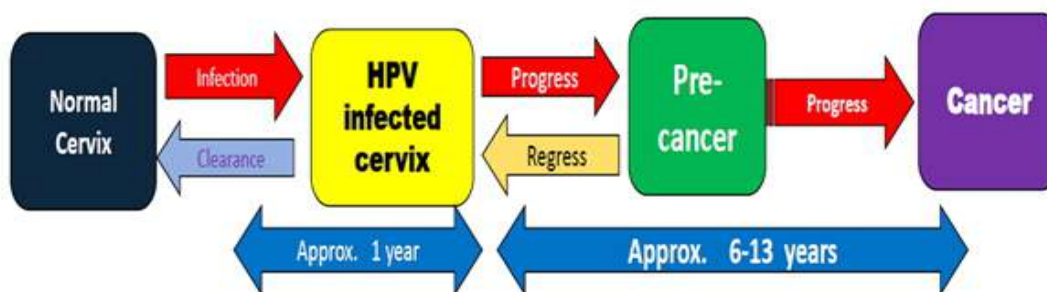
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## Importance Of Cervical Cancer Screening

Nearly all cervical cancers are caused by HPV, which often develops without early symptoms. While most HPV infections regress naturally, persistent infections can cause pre-malignant changes. Cervical cancer screening through Pap smears and HPV tests is crucial for early detection and prevention. These tests identify abnormal cells before they become cancerous, improving outcomes and survival rates. Treating precancerous lesions prevents invasive cancer and complements HPV vaccination efforts. Early detection also reduces long-term healthcare costs and improves patients' quality of life by allowing for less invasive treatments.

Temporal progression of HPV infections :



## Goals of Screening

**Early Detection:** Identifying precancerous lesions, enabling timely intervention.

**Prevention:** of invasive cancer by treating precancerous lesions & reducing individual risk.

**Reducing Mortality:** and improving survival rates through early detection and treatment.

**Enhancing Quality of Life:** Minimizing treatment burden with less invasive procedures

**Cost-Effectiveness:** Reducing healthcare costs by preventing advanced cancer.

## SCREENING MODALITIES

Cytologic:	HPV Testing:	Visual Inspection:	Molecular:
<ul style="list-style-type: none"> <li>• Conventional Pap smear</li> <li>• Liquid-based cytology (LBC)</li> <li>• Automated Cytology</li> <li>• Dual staining to identify p16 and Ki-67</li> </ul>	<ul style="list-style-type: none"> <li>• HPV alone</li> <li>• Co-testing (HPV + Cytology)</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection with acetic acid or with Lugol's iodine (VIA/VILI)                             <ul style="list-style-type: none"> <li>• Naked eye</li> <li>• Magnified by colposcope or camera</li> </ul> </li> <li>• Automated visual evaluation of digital images</li> </ul>	<ul style="list-style-type: none"> <li>• Nucleic acid amplification tests (NAAT):                             <ul style="list-style-type: none"> <li>• High-risk HPV DNA/NAAT</li> <li>• mRNA</li> </ul> </li> <li>• DNA methylation</li> <li>• Protein biomarkers                             <ul style="list-style-type: none"> <li>• HPV antibodies</li> <li>• Oncoproteins</li> </ul> </li> <li>• Markers of proliferation (Ki-67, MYC, telomerase, MCM2, TOP2A)</li> </ul>

## Optimizing the Pap Test

Pap smear involves collecting cells from the cervix and examining them under a microscope to identify any abnormalities that may require further investigation or treatment. Regular cervical cytology screening is important for early detection and prevention of cervical cancer.

**Avoid Menstruation:** Schedule the test when the patient is not menstruating to avoid interference with the sample.

**Abstain from Vaginal Intercourse/Douching /Vaginal Tampons** for 24-48 hours before the test to prevent contamination or irritation.

**Optimum Cervical Visualization:** Use speculums to ensure clear visualization of the cervix during the test.

**Avoid Touching the Cervix** with speculum prior to the test to prevent removing any dysplastic epithelium.

## Methods for Obtaining a Cervical Smear



**Spatula (wood or plastic):** Cells from the ectocervix



**Endocervical brush:** Cells from the endocervix



**Cervical sampler broom:** Cells from the endocervix and ectocervix

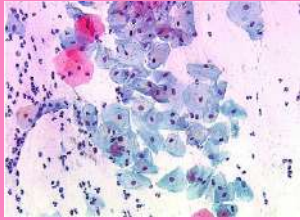


**Cervex-Brush® Combi:** Cells from the endocervix and ectocervix



## Specimen Adequacy

**Satisfactory Specimen** - *Conventional smear*: 8000 to 12000 squamous cells

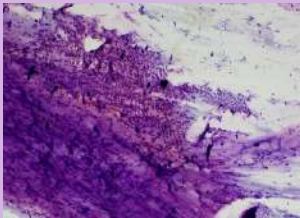


- *Liquid-based cytology*: >5000 squamous cells

- *Endocervical zone component*: >10 endocervical or squamous metaplastic cells

- If high-grade cancer is detected, it is not necessary to report the transformation zone component

### Unsatisfactory Specimen



- *Rejected specimen*: Improper label or patient information

- *Unsatisfactory specimen*: Obscuring blood, inflammatory cells, etc.

- *Completely obscured*: >75% of squamous cells obscured

- *Partially obscured*: 50-75% of cells are obscured

Incidence: 6.1%

## Liquid Based Cytology (LBC)

LBC is a method wherein the sample is collected by a brush and is deposited into a small bottle with preservative liquid. A brush or spatula is used to collect cells from the cervix. Instead of spreading the sample directly onto a microscope slide, the cells are rinsed into a vial containing a liquid preservative. The liquid sample is processed to separate the cells from mucus and other debris in the laboratory. The cells are then evenly distributed onto a slide. The prepared slides are examined under a microscope for abnormal cells.

## Automated Cytology

### 1. Auto -cyte (semi-automated):

- Scans the slides & records images of 128 of the most abnormal fields found on the slide (most significant abnormality found in the center).
- When the findings of both the reviewer and the computer match then, a diagnosis of "within normal limits" is given.
- Sensitivity: 97.2%

### 2. Auto - Pap:

- The material on the slide is reviewed and scored based on an algorithm, as to the likelihood of an abnormality is given.
- 97% sensitivity



## Bethesda System for Reporting Cervical Cytology

NEGATIVE FOR INTRAEPITHELIAL LESIONS OR MALIGNANCY	EPITHELIAL CELL ABNORMALITY		NON-NEOPLASTIC FINDINGS	ORGANISMS
	SQUAMOUS CELL	GLANDULAR CELL		
	<ul style="list-style-type: none"> <li>- ASC-US</li> <li>- ASC-H</li> <li>- LSIL</li> <li>- HSIL</li> <li>- SCC</li> </ul>	<ul style="list-style-type: none"> <li>-Atypia</li> <li>-Favoring Neoplasia</li> <li>-AIS</li> <li>-Adeno Carcinoma</li> </ul>	<ul style="list-style-type: none"> <li>-Atrophy</li> <li>-Keratinosis</li> <li>-Metaplasia</li> <li>-Inflamed</li> </ul>	<ul style="list-style-type: none"> <li>-Trichomonas</li> <li>-Fungus</li> <li>- Bacterial Vaginosis</li> <li>- Herpes</li> <li>- CMV</li> </ul>

## Conventional Versus Liquid Based Cytology

Feature	Conventional Cytology (Pap Smear)	Liquid-Based Cytology (LBC)
<b>Sample Collection</b>	Cells collected with a brush or spatula and spread directly onto a slide.	Cells collected with a brush or spatula and rinsed into a liquid preservative vial.
<b>Sample Preparation</b>	Fixed with a spray fixative and stained on a slide.	Processed in the lab to separate cells from debris; cells are then evenly spread onto a slide.
<b>Slide Clarity</b>	Often obscured by mucus, blood, and artifacts.	Cleaner slides with fewer artifacts and better cell preservation.
<b>Inadequate Sample Rate</b>	Higher chance due to cellular overlap or clumping.	Reduced chance due to liquid preservation and processing.
<b>Additional Testing</b>	Not typically performed on the same sample.	Allows for additional tests (e.g., HPV testing) on the same sample.
<b>Diagnostic Accuracy</b>	May have more false negatives due to sample quality and artifacts.	Generally higher diagnostic accuracy and fewer false negatives.
<b>Unsatisfactory</b>	6.1 %	2.1%
<b>Cost</b>	Generally lower cost.	Slightly higher cost due to processing and preservation.

## HPV TESTING

### Non-Amplification Techniques

- **Nucleic Acid Probe Tests:** use probes to detect specific HPV DNA or RNA sequences. They do not involve amplification of the target DNA.

### Amplification Techniques



1. **Target Amplification (PCR-Based)** - PCR (Polymerase Chain Reaction) amplifies specific HPV DNA sequences to detect the presence of the virus. This technique is highly sensitive and can detect low levels of HPV (eg Cobas 4800).
2. **Signal Amplification** - amplifies the signal generated by the hybridization of HPV DNA with specific probes. It enhances the detection of HPV by increasing the signal without amplifying the DNA itself ( eg Hybrid Capture (HC2), HCT II, Cervista HPV HR, Cervista HPV 16/18)
3. **Probe Amplification** - LCR amplifies the target DNA through a series of ligation and amplification steps, which increases the sensitivity of the test. It detects specific HPV types by amplifying the DNA. (eg **Ligase Chain Reaction (LCR)**).

## PRIMARY HPV TESTING

Primary HPV Testing refers to the use of HPV testing as the initial or primary method for cervical cancer screening, rather than as a follow-up to cytology (Pap smear).

### Key Aspects

#### 1. Testing Method:

- o HPV DNA Tests: Detect the presence of high-risk HPV types by amplifying and identifying viral DNA.
- o HPV RNA Tests: Detect the presence of high-risk HPV types by identifying viral RNA.

#### 2. Advantages:

- o Increased Sensitivity: HPV testing can detect infections that might not yet show cytological changes, leading to earlier intervention.
- o Longer Screening Intervals: HPV testing generally allows for longer intervals between screenings compared to Pap smears due to its higher sensitivity<sup>[15]</sup>

# HPV Self testing

## Self Testing Devices

Evalyn Brush



Delphi Screener



Self-HPV sampling is as effective and reliable as physician-collected samples and cytology. With a 98% satisfaction rate, 93.8% agreement between sample types, and similar positivity rates (12.3% for self-sampling vs. 13.0% for physician-collected), it is a reliable and acceptable alternative to traditional methods.

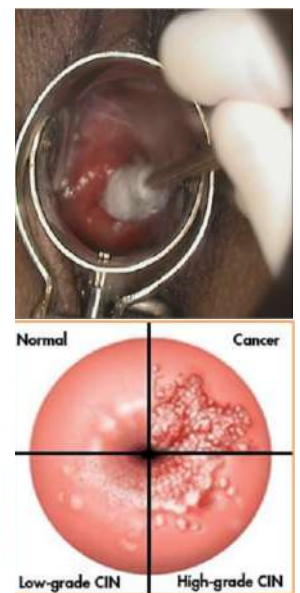
### Co-Testing

Co-testing combines HPV testing and cytology (Pap smear) for cervical cancer screening, enhancing accuracy and reliability. It offers nearly 100% sensitivity while maintaining cytology's specificity. Recommended for women aged 30-65, co-testing has a high negative predictive value, providing strong reassurance when both tests are negative

### VIA (Visual Inspection Under Acetic Acid)

VIA is a cost-effective test useful in low-resource settings, offering immediate diagnosis and treatment. Mix 3-5 ml glacial acetic acid with 95-97 ml distilled water to prepare the acetic acid solution and apply 3-5% solution to the cervix. The acetic acid coagulates cellular proteins, causes epithelial and columnar cell swelling and dehydrates cells, revealing abnormal areas.

**Advantages are low cost and immediate results**



## Interpretation of VIA test results

Parameters of aceto white lesion	VIA positive	VIA negative
<b>Speed of appearance</b>	Appears rapidly and may last 1-2 minutes	Appears late and quickly disappears
<b>Colour intensity</b>	Shiny and cloudy white, more dense, thick and opaque	Pale or dull white, less dense, thin, often translucent
<b>Borders and demarcation</b>	Well demarcated, regular, raised from surrounding epithelium	Patchy with ill-defined, diffuse margins
<b>Location</b>	Restricted to transformation zone (TZ) , lesion close or abutting squamocolumnar junction	Distributed widely in the cervix, not restricted to TZ
<b>Colour uniformity</b>	Uniformly white	Colour intensity varies across the lesion

### Visual Inspection with Lugol's Iodine (VILI)

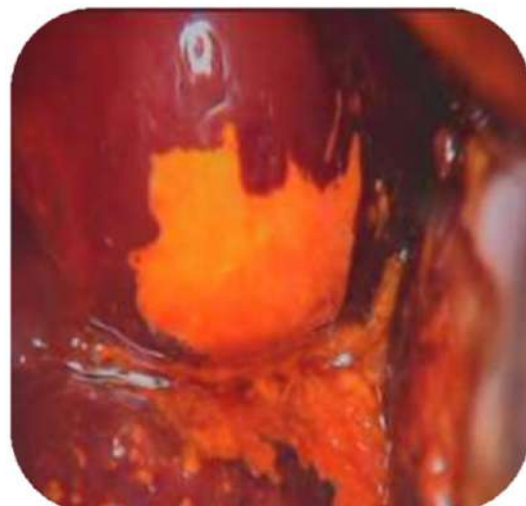
VILI uses Lugol's iodine to detect cervical precancerous lesions and cancer. Normal epithelium turns mahogany brown due to glycogen. Lesions/Cancer appear yellow due to lack of glycogen. It is cost effective and gives immediate results

#### Appearance:

- Test-Negative: Mahogany brown
- Test-Positive: Bright yellow
- Suspicious for Cancer: Ulcerative or cauliflower-like growths

#### Implication:

- Test-Negative: Normal
- Test-Positive: Precancerous lesions or cancer
- Suspicious for Cancer: Suggestive of invasive cancer



## Screening Guidelines by Various Organisation

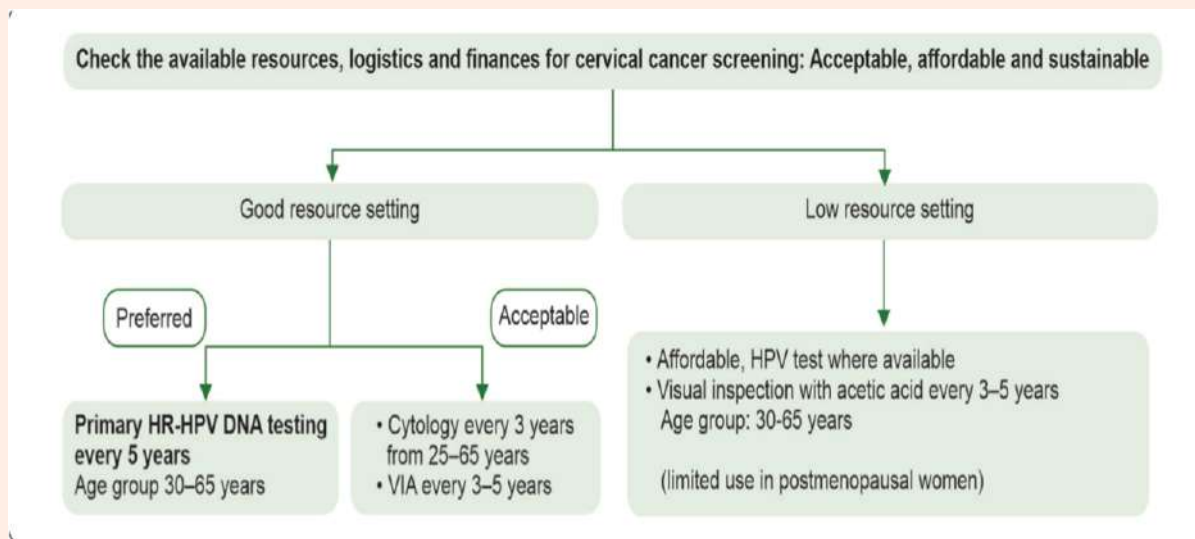
Organisation	Recommended screening measures	Age of screening	Additional considerations
<p>USPSTF (United State preventive Services Task Force) August 2018</p> <p>ACOG endorses USPSTF ( April 2021)</p>	<p>In women aged 21-29 years, screen every 3 years with cytology alone.</p> <p>In women aged 30-65 years, screen every 3 years with HR-HPV alone or every 5 years with Co-testing (HR-HPV+cytology)</p>	21-65 years	Currently under review as of March 2022
<p>ACS (American Cancer Society) July 2020</p>	Screen with HR-HPV testing every 5 years , if not available screen with cytology every 3 years	25- 65 years	
<p>ASCO (American Society for Clinical Oncology) September 2022</p>	<p>Screen with HR-HPV DNA testing wherever available in all resource settings.</p> <p>VIA for use in basic setting.</p> <p>Screen every 5 years from age 25-65 in maximal resource setting.</p> <p>Screen every 10 years from age 30-49 in low resource setting.</p>	Varies based on resource setting	<p>In HIV + individuals perform HR-HPV soon after HIV diagnosis and perform screening twice as frequently as in the general population.</p> <p>&amp; 6 months postpartum in all resource setting.</p>
<p>ASCCP (American Society for Colposcopy and Cervical Pathology) July 2021</p>	Endorses 2018 USPSTS recommendations and the 2020 ACS recommendations		Endorses any screening method for secondary prevention & interventions that improve screening for underscreened/ unscreened individuals
<p>European Commission November 2022</p>	Screen with HR-HPV testing every 5 years or more	30-65 years	Consider offering HPV cervical self-sampling to those declining routine screening.
<p>WHO July 2021</p>	<p>Screen with HR-HPV DNA testing every 5-10 years.</p> <p>If not available, screen with cytology or VIA every 3 years</p>	30-50 years	<p>For HIV + screen every 3-5 years with HR HPV DNA testing, starting at 25 years.</p> <p>For all individuals, may stop screening after two consecutive negative tests of the appropriate intervals after the age of 50.</p>
FIGO	Approach screening guidelines on a national or regional basis based on resource available		<p>Recommended that at a minimum vaccination be provided to young females in the population 11-18 years and followed with atleast a single HR-HPV screen at age 35-39 years, or atleast a VIA.</p> <p>If resources are available, repeat HR-HPV testing at 10 year- interval or at 5-year interval.</p>

## FOGSI Resource Based Screening Recommendations 2023

	Good Resource Setting	Limited Resource Setting
Modalities	HPV testing <ul style="list-style-type: none"> <li>• Primary HPV testing</li> <li>• Co-testing (HPV and cytology)</li> </ul> Cytology and VIA	VIA (Affordable HPV testing may be introduced if feasible)
Target Age Group (years)	25-65	30-65 (In postmenopausal women, screening with VIA may not be effective)
Age to start (years)	<ul style="list-style-type: none"> <li>• Cytology at 25</li> <li>• Primary HPV testing/ Co-testing at 30</li> </ul>	VIA at 30
Frequency	<ul style="list-style-type: none"> <li>• Primary HPV testing or Co-testing every 5 years</li> <li>• Cytology every 3 years</li> </ul>	Every 5 years (at least 1-3 times in a lifetime)
Age to stop	<ul style="list-style-type: none"> <li>• 65 with consistent negative results in last 15 years</li> <li>• Women with no prior screening should undergo test once at 65 years , and, if negative they should exit screening</li> </ul>	-do-
Follow-up method after treatment	HPV testing preferred or cytology	VIA
Interval	12 months	12 months
Screening following abnormal reports, CIN2 & above, irrespective of mode of treatment	For 20 years	20 years
Screening in hysterectomized women	<ul style="list-style-type: none"> <li>- Hysterectomized for benign cause with no prior history of CIN- No need for screening</li> <li>- Absence of cervix must be confirmed by clinical records or examination</li> <li>- If indication is unclear, screening may be performed at clinicians discretion</li> </ul>	-do-
Follow up of women with CIN in hysterectomy with no HPE report	Need to be screened with HPV testing at 6 months and 18 months	
Screening of immunocompromised women	<ul style="list-style-type: none"> <li>- Start within one year of initiation of sexual activity</li> <li>- HPV testing/Co-testing/Cytology/ VIA</li> <li>- Every 2-3 years</li> </ul>	VIA/ (Affordable HPV testing if available) Every 3 years (at least twice as often as general population)



# Resource based screening algorithm (FOGSI GCPR 2023)



For Algorithms on Screen and Treat and Screen Traige and Treat visit FOGSI GCPR  
<https://www.fogsi.org/fogsi-gcpr-on-prevention-and-management-of-cervical-cancer-june-2024>

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## Chapter 4 – HPV Vaccination



Human papillomavirus (HPV), is a common virus that is transmitted primarily sexually through skin-to-skin or skin-to-mucosa contact. Persistent infection can lead to cervical, vulval, vaginal, anal, penile and oropharyngeal cancers, as well as genital warts<sup>1</sup>. HPV vaccination stands at the forefront of modern preventive medicine and is one of the most important discoveries of modern medicine and offers significant protection against genital and oropharyngeal cancer and genital warts. The introduction of vaccines against the most oncogenic HPV types has revolutionized the landscape of public health, providing a powerful tool to reduce the burden of these diseases.



### Understanding HPV

HPV is widely prevalent and ubiquitous. The average lifetime probability of acquiring this infection varies from 85% for women to 91% for men. Most infections resolve on their own without causing any symptoms or long-term health issues. However, persistent infection with certain high-risk strains of HPV leads to carcinogenic changes in cells over time, particularly affecting the cervix, anus, and oropharynx.



### The Role of HPV Vaccines

Prophylactic HPV vaccines are composed of virus-like particles that stimulate the immune system to produce antibodies against the virus. Preventing infection and subsequent development of HPV-related cancers. The vaccines are most effective when administered before exposure to the virus, and this is why they are recommended for preteens and young adults before they become sexually active<sup>2</sup>. Currently, there are several HPV vaccines approved for use in India, which protect against the most prevalent cancer-causing strains of the virus. These vaccines have been extensively studied and have been shown to be safe and effective in preventing HPV infections and related cancers.



### HPV vaccines marketed in India\*

- Quadrivalent (MSD, SII)
- Nonavalent (MSD)
- \* Globally HPV Vaccines have been approved for use across countries for various age groups and genders with specific dose schedules, Please refer the package insert of each HPV vaccine for detailed information.





## Vaccine Safety

- No serious safety issues to date except rare reports of anaphylaxis.
- The Global Advisory Committee for Vaccine Safety (GACVS) is constantly monitoring and has not identified any safety concerns.
- Among males and females of all ages receiving HPV vaccine, injection site reactions included pain (35–88%), redness (5–40%), and swelling (4–35%).
- Adverse events following HPV vaccination are generally mild and of short duration<sup>3</sup>.
- Mild systemic adverse events included headache, dizziness, myalgia, arthralgia, and gastrointestinal symptoms (nausea, vomiting, and abdominal pain).
- HPV vaccines are safe and well tolerated and can be used in persons who are immunocompromised or human immunodeficiency virus (HIV) infected.



## Storage

All HPV vaccines are stored at 2–8°C, not frozen but protected from light. They should be administered immediately after removal from the refrigerator<sup>4</sup>.



## Dosage

The vaccine is available as 0.5ml dose. It should be given intramuscularly in the deltoid region. The individual should be seated during vaccination and observed in a separate room for 15 minutes after vaccination<sup>5</sup>.

### HPV vaccination Schedule :

	Schedule	Level of Evidence
<b>Females</b>	<ul style="list-style-type: none"> <li>• <b>Two doses</b> (9–14 years, at least 6 months apart (qHPV))</li> <li>• <b>Three doses</b> (9-14 years; 0,2,6 months, (9vHPV))</li> <li>• <b>Three doses</b> (15–26 years: 0, 2, 6 months) (qHPV, 9vHPV)</li> <li>• <b>Three doses</b> (Older women up to 45 years, aHPV(MSD))</li> </ul>	<b>Level 1 Grade A</b>
<b>Males</b>	<ul style="list-style-type: none"> <li>• <b>Two doses</b> (9-14 years, 0,6 months) (qHPV SII)</li> <li>• <b>Three doses</b> (15-26 years; 0,2,6 months) (qHPV SII)</li> <li>• <b>Three doses</b> (9 to 15 years; 0,2,6 months) (9vHPV)</li> </ul>	Level 2, Grade C
<b>Reduced Dose* as per FOGSI GCPR 2023</b>		
Two doses (WHO SAGE Recommendation)	<ul style="list-style-type: none"> <li>• One or two doses (9–14 years)</li> <li>• One or two doses (15–20 years)</li> <li>• Two doses (21 years and above)</li> </ul>	Level II, Grade B
Alternative Single Dose (Off-label)	- Single dose for girls and boys (9–20 years)	Level II, Grade B

\*The reduced dose schedule of the HPV vaccine is not yet approved by the Drug Controller General of India (DCGI).

## Special Mentions

- Based on fresh evidence on disease burden and a review of international data as well as HPV vaccine trials in India including the India IARC trial of Gardasil vaccine and the Cervavac vaccine trial, the National Technical Advisory Group on immunization (NTAGI) recommended the 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 of age”.
- Based on the preclinical and clinical trial data of safety & immunogenicity and recommendations of Subject Experts Committee (SEC), the Indian regulator, Central Drugs Standard Control Organization (CDSCO) has approved one indigenously manufactured and three imported HPV vaccines.
- As for Gardasil and Cervarix, NTAGI has recommended single dose HPV vaccine for introduction in UIP (campaign or routine). Gardasil-9 has not been recommended for UIP due to additional cost but dosing recommendation is the same.
- However, for Cervavac, NTAGI recommended two dose vaccine for campaign as well as routine till it fulfils the WHO criteria of demonstration of stable antibody levels at two years post introduction.
- The Costa Rica vaccine trial, India IARC trial, KENSHE trial and DORIS trial support the validity of single dose of HPV vaccine.
- WHO has included an off-label recommendation of single dose HPV vaccination and now recommends one or two doses of HPV vaccine for the primary target group aged 9- 14 years, as well as for the older age group 15-20 years. It recommends two doses for individuals over 21 years. However 3 doses are recommended for immunocompromised individuals, including those living with HIV.



## Primary and Secondary Target Groups

- To prevent cervical cancer, the World Health Organization (WHO) recommends vaccinating girls aged 9–14 years before they become sexually active.
- Vaccinating over 80% of girls in this age group also helps protect boys from HPV infection.

Vaccinating other groups, such as older girls, boys, men, or men who have sex with men (MSM), is recommended only if it is possible and affordable, and does not take resources away from vaccinating the primary target group, which is girls aged 9-14 years.

## Benefits and Impact

- The benefits of HPV vaccination extend beyond individual protection to broader public health outcomes.
- By reducing the prevalence of HPV infections in communities, vaccination contributes to herd immunity, indirectly protecting those who may not be vaccinated.
- This collective immunity is crucial in controlling the spread of HPV and reducing the incidence of associated cancers over time.
- In countries with high vaccination coverage, significant declines have been observed in HPV infections due to vaccine-contained types, genital warts, precancerous lesions and cancer, demonstrating the real-world impact of vaccination programs.
- Cervical cancer rates have been declining in populations where HPV vaccination is widespread, offering hope for future generations.

## Co-administration and Interchangeability

- As per licensing indications, specific HPV vaccine may be administered concomitantly with other routine vaccines containing diphtheria (d), tetanus (T), and acellular pertussis (pa), with no clinically relevant interference with antibody response to any of the components of either vaccine.
- 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 may be administered to complete the recommended schedule.

## Special Situations

- HPV vaccine can be safely co-administered with other age-appropriate vaccines.
- It is not recommended for use in pregnancy. If the patient conceives after the first dose, it is advisable to give further doses after pregnancy.
- If inadvertent vaccination occurs during pregnancy, there is no need for the medical termination of pregnancy.
- Lactating women can receive HPV vaccine. Available evidence does not indicate an increased risk of adverse events in either the mothers or their babies after the administration of HPV vaccine to lactating mothers.

- Sexual assault survivors should be given age-appropriate HPV vaccination, with the first dose at the time of initial examination.
- 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 that 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. Screening for cervical cancer should be done as per the guidelines.
- Women/girls with immunocompromised or immunosuppressed state should be administered a 3-dose schedule, or a minimum of 2 doses.<sup>7</sup>

## Important points

Despite its proven benefits, the HPV vaccine faces challenges due to misinformation and vaccine hesitancy. Common concerns include its safety, potential side effects, and the appropriate age for vaccination.

Healthcare providers and public health authorities must understand the value and benefits of the HPV vaccine. They must address public concerns with accurate, consistent information and education to support informed decision-making by individuals and families.

Ongoing efforts are crucial to improving access to HPV vaccination in India, where high cervical cancer rates are due to limited screening and prevention resources. Key steps include integrating HPV vaccination into routine immunization programs, regularly screening women over 30, and raising awareness among healthcare providers, parents, and adolescents. These actions are essential for achieving higher vaccination coverage and reducing the global burden of HPV-related cancers.

## Conclusion

HPV vaccination is a major milestone in preventive medicine, providing strong protection against HPV infections and related cancers. By expanding access to vaccination and addressing barriers to uptake, we can move towards a future where HPV-related diseases are rare rather than common health issues.

Remember, vaccination is not just a personal choice but a community responsibility, protecting the health of future generations and advancing public health goals globally.

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## Chapter 5 –

# Public Health Strategies for HPV Prevention

On May 2018, the WHO Director-General announced a global call for cervical cancer elimination as it is considered preventable and curable. In 2006, Austria had introduced HPV vaccination in its national immunization schedule. Till 2019, WHO recorded that 100 countries have adapted it too. In India, however, the recommendation for HPV vaccine to include in national immunization program is yet to materialize except in Punjab and Sikkim, where there were reports of successful vaccination<sup>1,2</sup>.

### Australian Success Story for HPV vaccination<sup>3</sup>

A documented success story of HPV vaccination in Australia highlights significant public health achievements. Notably, the vaccination program covers both males and females, resulting in a 34% decrease in precancerous abnormalities and a 77% reduction in HPV infections included in the vaccine. In 2007, Australia became the first country to implement a national HPV vaccination program. Initially targeting girls, the program expanded in 2013 to include boys. This initiative has distributed 200 million doses across 130 countries to date. The current vaccines provide substantial protection, covering approximately 70% of cervical cancers, 90% of genital warts, 70% of vaginal cancer cases, and up to 50% of vulvar cancer cases.

## Impact of HPV Vaccination in Australia

- **HPV Infections:** Within the first four to five years of the program, HPV infections of the types included in the vaccine decreased by 77% among 18-24-year-olds.
- **Precancerous Abnormalities:** There was a 34% reduction in precancerous abnormalities among 20-24-year-olds.

## Prevention of Cervical Cancer

Over the years, the incidence and related morbidity and mortality of cervical cancer have reduced. This can be attributed to the understanding of natural history of cervical cancer, which have been made possible with the discovery of Human Papilloma virus as an important cause for its occurrence. This led to establishment of effective primary prevention with HPV vaccination and secondary prevention with screening for precancerous lesion strategies. Early diagnosis and treatment of cancer cervix carries a good 5-years survival rate. Effective implementation and follow through are required for good outcome.

The role of HPV in primary and secondary prevention is indisputable. However, India still accounts for a fifth of the global burden and HPV related incidence and mortality still looms large. In India, awareness on cervical cancer and its prevention is poor<sup>4</sup>. Screening uptake is still below par and HPV vaccination uptake is subpar too.

# Barriers to poor HPV Vaccination uptake

A systematic review on barriers and facilitators of HPV vaccination identified several factors responsible for poor vaccine uptake, including lack of knowledge about HPV and the vaccine, fears about safety and efficacy, discrimination, and cost. Trust in the vaccine's safety and efficacy, understanding the risks of HPV infection and the benefits of vaccination, positive recommendations, and reduced costs can help improve vaccine uptake. A critical appraisal of HPV vaccination in India highlighted similar barriers, noting that misinformation about safety and efficacy, along with costs and lack of awareness, significantly contribute to vaccine hesitancy and low uptake.

## ▶ Facilitators of HPV Vaccination

A systematic review identified several key factors that can help facilitate vaccine uptake<sup>5</sup>. By focusing on these facilitators, public health initiatives can enhance HPV vaccination rates. Building trust, providing education, securing healthcare provider support, reducing costs, implementing supportive policies, and engaging communities are all essential strategies to improve vaccine uptake<sup>7</sup>

## ▶ Trust in Vaccine Safety and Efficacy:

- **Public Confidence:** Building trust in the vaccine's safety and effectiveness is crucial. This can be achieved through transparent communication and endorsement from reputable health organizations and professionals.
- **Clinical Evidence:** Sharing robust clinical trial data and real-world evidence demonstrating the vaccine's safety and effectiveness can help alleviate concerns.

## ▶ Understanding Risks and Benefits:

- **Educational Campaigns:** Implementing comprehensive education campaigns to inform the public about the risks of HPV infection and the benefits of vaccination can significantly increase acceptance.
- **Clear Information:** Providing clear, accessible information about how the vaccine works, its benefits, and the potential risks of not getting vaccinated can help people make informed decisions.

## ▶ Positive Recommendations:

- **Healthcare Provider Endorsement:** Strong recommendations from healthcare providers, such as doctors and nurses, are critical. When trusted healthcare professionals actively encourage vaccination, it greatly influences patients' decisions.
- **Counseling and Communication:** Training healthcare providers to effectively communicate the importance of the vaccine and address any concerns parents or patients may have.

## ▶ Reduced Cost:

- **Subsidized Vaccines:** Making the vaccine affordable through government subsidies or inclusion in national immunization programs can remove financial barriers and increase access.
- **Insurance Coverage:** Ensuring that the vaccine is covered by health insurance can also help alleviate the cost burden on families.

## ▶ Public Health Policies:

- **Government Support:** Strong support and advocacy from government bodies can drive public health initiatives and funding for widespread vaccination programs.
- **School-Based Programs:** Implementing vaccination programs in schools can increase uptake by making it convenient for adolescents to receive the vaccine.



### ▶ **Community Engagement:**

- **Local Leaders and Influencers:** Engaging community leaders and influencers to advocate for vaccination can help change public perception and increase acceptance.
- **Cultural Sensitivity:** Developing culturally sensitive messaging and outreach programs to address specific concerns and beliefs within different communities.

### ▶ **How to overcome the barriers and challenges?**

- Education and awareness campaigns
- Policies and programs to promote vaccination and screening
- Role of healthcare providers in prevention

A multi-pronged approach is necessary to overcome these barriers. An important factor is to promote the role of physicians in understanding about HPV and vaccine, engaging them for awareness campaigns and educating masses; these factors when supported by policies/programs promoting vaccination and screening can help overcome vaccine hesitancy and promote its uptake.

### ▶ **Role of Healthcare Providers:**

- **General Physicians:** As the first point of contact for healthcare needs, general physicians can create awareness about HPV infection, its morbidity and mortality, and the benefits of prevention through vaccination.
- **Pediatricians:** Pediatricians cater to the target population and are closely associated with vaccination programs for children and adolescents, playing a crucial role in creating awareness and promoting vaccine uptake.
- **Gynecologists:** Gynecologists, involved in the screening and treatment of cervical cancer, play a pivotal role. They interact with women at various reproductive phases, including ante- and post-natal clinics, cervical cancer screening clinics, and STI clinics. Routine history taking in these clinics provides an opportunity for counseling about HPV vaccination.



## **Role of Gynecologist**

- ✓ Educate caregivers and recipients about HPV and cervical cancer
- ✓ Address myths and concerns
- ✓ Advocate for vaccination during consultations



## ► Effective Endorsement Strategies by Healthcare Providers

- **Healthcare Provider Endorsement:** Strong recommendations from healthcare providers, such as doctors and nurses, are critical. When trusted healthcare professionals actively encourage vaccination, it greatly influences patients' decisions.
- **Counseling and Communication:** Training healthcare providers to effectively communicate the importance of the vaccine and address any concerns parents or patients may have.
- **Support from Medical Societies:** Support and motivation by medical societies can help promote physicians to recommend the HPV vaccine routinely and confidently. Medical societies can alert physicians of their pivotal role in preventing cervical cancer and cultivate champions who will advocate for increased administration of the HPV vaccine among peers and parents.



## GATHER Method for HPV Vaccination Counselling

**Greet:** "Hello, it's great to see you today. How are you doing?"

**Ask:** "Could you tell me a bit about your health and any concerns you might have?"

**Tell:** "Today, I'd like to talk to you about the HPV vaccine, which helps protect against the human papillomavirus, a common infection linked to several types of cancers. The vaccine is very effective in preventing infections that can lead to cervical, vaginal, vulvar, anal, and oropharyngeal cancers, as well as genital warts."

**Help Decide:** "Do you have any questions or concerns about the HPV vaccine that I can help address? It's important to know that the vaccine has been thoroughly tested and is considered very safe and effective. Would you like to discuss how the vaccine can benefit you or your child?"

**Explain:** "The HPV vaccine works by stimulating your immune system to fight the virus, reducing the risk of HPV-related cancers and genital warts. By getting vaccinated, you're not only protecting yourself but also helping to reduce the spread of HPV in the community."

**Return:** "If you decide to get the vaccine today, we will schedule follow-up appointments to ensure you receive all the required doses for full protection. I'm here to support you throughout this process. If you have any questions after today's visit, feel free to reach out."



## Important Tips

- ❖ **Start discussions on HPV by asking questions**
  - Listen to what people know about HPV, and cervical cancer.
- ❖ **Offer reassurance and feedback**
  - Adapt your approach based on cultural norms (e.g., eye contact).
  - Show acknowledgment through nodding or paraphrasing to ensure understanding.
- ❖ **Convey Knowledge and Experience**
  - Share ideas, experiences, and information.
  - Interaction and trust are foundational to effective communication

HPV vaccine promotion should be advanced through various initiatives to enhance awareness and increase uptake. Key strategies include:

### 1. Educational Platforms for Physicians

- **Regular Updates:** Keeping physicians informed about the dangers and risks associated with HPV infection and the burden of cervical cancer is crucial. Highlighting the ease of prevention through vaccination is also essential.
- **Multiple Platforms:** Utilize social media, posters, billboards, and other platforms to disseminate information.
- **Regular Reminders:** Frequent reminders help reinforce the importance of the HPV vaccine, maintaining the momentum of the promotion efforts.

### 2. Ongoing Training for Physicians

- **Refresher Trainings:** Conduct regular refresher trainings covering updated guidelines. This ensures that physicians remain confident and knowledgeable about promoting the HPV vaccine.

### 3. Public Advocacy Campaigns

- **Consistent Advocacy:** Launch consistent and regular advocacy campaigns that emphasize the risks of cervical cancer and the benefits of prevention through vaccination.
- **Diverse Media:** Use a variety of platforms, including social media, traditional media, and community outreach, to reach a broad audience and create public awareness.

### 4. Local Physician Champions

- **Trusted Endorsements:** Campaigning with endorsements from trusted, well-known medical professionals helps build trust in the HPV vaccine.
- **Community Impact:** Local physician champions can address uncertainties about vaccination and encourage its usage within their communities.

### 5. Effective Communication

- **Responsibility Emphasis:** Emphasize the responsibility to protect against the risks of cervical cancer in a clear and accessible language. This approach facilitates productive communication, helping to overcome vaccine hesitancy and highlight the need for vaccination.

#### Build Trust on HPV Vaccine

- ❖ Engage with known medical professionals
- Engage with local physicians to confidently encourage vaccine usage
- Engage with local physician champions to endorse the vaccine

#### Build Trust on HPV Vaccine

- Engage with patients from the risks of cervical cancer
- Engage with communication around Cervical Cancer and HPV vaccine shared with doctors



## Behaviour Change Study

A project was undertaken “Using Behavioural Insights to improve uptake of the HPV vaccine among Adolescent girls(9-14years)” to understand and address factors that influence decision making around physicians' recommendation of the vaccine and parents' uptake of the vaccine.

### Partners:

- Centre for Social and Behaviour Change
- American Cancer Society
- Cancer Foundation India

### Key Findings:

#### 1. Interventions Identified:

- Refreshing the Dangers of Cervical Cancer: Emphasizing the severity of cervical cancer and the ease of prevention through vaccination was found to be effective.
- Endorsement by a Trusted Medical Champion: Having the vaccine endorsed by a respected and well-known medical professional significantly influenced physicians' willingness to recommend the vaccine.

#### 2. Impact on Physician Recommendations:

- Both interventions led to a significant increase in the likelihood of physicians expressing an intention to recommend the HPV vaccine, with about a 100% increase observed.

## The Four Step Approach<sup>8</sup>



**Be prepared**

**Listen**



**Use appropriate messages**

**Plan with the patient**



**Tailored counseling strategies for specific hesitancy**



### **Policies and programme to promote vaccination**

The National Technical Advisory Group for Immunization (NTAGI) has recommended incorporating HPV vaccination for girls into the Universal Immunization Program. The 2024 Health Budget has prioritized this initiative for girls aged 9-14. However, to effectively counter barriers and facilitate widespread vaccine uptake, comprehensive interventions are necessary at multiple levels.

### **Recommendations for HPV Vaccination Rollout<sup>7</sup>:**

#### **1. Interpersonal Interventions**

- Training and Workshops:
  - For Physicians: Regular training sessions to update physicians on the importance of HPV vaccination, address misconceptions, and enhance their ability to recommend the vaccine confidently.
  - For Recipients/Parents: Educational workshops to increase awareness about HPV infection, vaccine benefits, and address concerns.

#### **2. Sociocultural Interventions**

- Targeted Education: Develop culturally relevant educational programs tailored to different communities to address specific barriers and promote vaccine uptake.
- Nationwide Awareness Campaigns: Implement comprehensive campaigns using various media channels to raise public awareness and educate the general population about HPV and the vaccine.



### 3. Community Engagement and Social Mobilization Tactics for Engaging Community Leaders and Local Influencers

- **Identify Key Community Leaders and Influencers:**
  - **Mapping Exercise:** Conduct a community mapping exercise to identify influential leaders, including religious leaders, educators, local politicians, media personalities, and respected elders.
  - **Stakeholder Analysis:** Assess the influence and reach of various potential influencers to prioritize engagement strategies.
- **Relationship Building:**
  - **Personal Meetings:** Schedule individual meetings with key influencers to discuss the importance of HPV vaccination, address any concerns, and highlight their potential role in influencing public opinion.
  - **Cultural Sensitivity:** Show respect for local customs, beliefs, and values during interactions to build rapport and trust.
  - **Involvement in Planning:** Actively involve community leaders in the planning and implementation process to foster ownership and commitment.
- **Capacity Building:**
  - **Training Workshops:** Organize training sessions for community leaders to ensure they have accurate information about HPV, cervical cancer, and the vaccine. Equip them with the skills to effectively communicate this information.
  - **Resource Provision:** Supply community leaders with educational materials, such as brochures, posters, and FAQs, tailored to the local language and context.
- **Community Mobilization:**
  - **Local Events:** Host community events such as health fairs, workshops, and town hall meetings with community leaders as featured speakers to raise awareness and promote vaccination.
  - **Peer Education Programs:** Encourage community leaders to identify and train peer educators who can further disseminate accurate information within their networks.
- **Leveraging Existing Platforms:**
  - **Religious Gatherings:** Utilize platforms such as church services, mosque gatherings, and temple events, religious festivals to disseminate information about HPV vaccination.
  - **School and Parent-Teacher Meetings:** Collaborate with school authorities and involve community influencers in school events to reach out to parents and adolescents.
- **Public Endorsements:**
  - **Media Campaigns:** Feature community leaders and influencers in media campaigns, including radio, TV, and social media, endorsing HPV vaccination and sharing personal testimonials about its importance.
  - **Local Success Stories:** Highlight local success stories and testimonials from community members who have benefited from vaccination, with influencers endorsing these stories.



- **Feedback Mechanisms:**
- **Community Feedback Forums:** Establish forums where community members can express their concerns and receive timely, accurate responses from trusted leaders and health professionals.
- **Regular Engagement:** Schedule regular follow-up meetings and check-ins with community leaders to update them on progress, address new concerns, and adjust strategies as needed.
- **Incentive Programs:**
- **Recognition and Rewards:** Create recognition programs to publicly acknowledge the efforts of community leaders in promoting HPV vaccination. This could include certificates of appreciation, awards, and public mentions in local media.
- **Material Support:** Provide material support, such as transportation stipends or communication tools (e.g., mobile phones or internet access), to community leaders involved in outreach activities.
- **Collaboration with Local NGOs and CBOs:**
- **Partnerships:** Partner with local non-governmental organizations (NGOs) and community-based organizations (CBOs) that have established trust and credibility in the community.
- **Joint Initiatives:** Develop joint initiatives with these organizations to leverage their networks and resources for broader community engagement.
- **Monitoring and Evaluation:**
- **Track Progress:** Implement monitoring systems to track the engagement activities of community leaders and influencers, measuring their impact on vaccination rates and community attitudes.
- **Iterative Improvement:** Use collected data to refine engagement strategies and address any gaps or challenges identified during the implementation process.

By employing these tactics, public health initiatives can effectively build trust and engage community leaders and local influencers, significantly enhancing the acceptance and uptake of HPV vaccination at the community level.



### 1. Institutional Interventions

- Multisectoral Partnerships: Collaborate with various sectors, including health, education, and community organizations, to support vaccine rollout and integration into existing programs.
- Training Programs and Curriculum Integration: Incorporate HPV vaccination education into medical and nursing school curricula to ensure future healthcare professionals are well-informed and prepared to advocate for the vaccine.

### 2. Media Engagements

- Public Campaigns: Utilize traditional and digital media platforms to disseminate information about the HPV vaccine, share success stories, and address common myths and concerns.
- Engage Influencers: Partner with celebrities and public figures to endorse the vaccine and enhance its visibility and acceptance.

### 3. Structural Aid

- Access and Availability: Ensure that vaccines are widely available and accessible, particularly in underserved and remote areas. Establish vaccination clinics and mobile units where needed.

### 4. Public Policy

- Standard Operating Guidelines: Develop and implement comprehensive guidelines for the HPV vaccination program, including procedures for vaccine administration, monitoring, and evaluation.
- Make Vaccination Mandatory: Policy makers should consider making the HPV vaccine mandatory as part of the national immunization schedule to ensure widespread uptake.

**"Satisfaction lies in the effort, not in the attainment. Full effort is full victory"**



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## Chapter 6 - The Role of Doctors: Boosting HPV Vaccine Uptake Using Social and behaviour Change Communication (SBCC)



### Understanding Barriers to HPV Vaccine Uptake

At the caregiver and recipient level, several barriers hinder the uptake of the HPV vaccine. A significant obstacle is the limited knowledge and awareness among families regarding HPV, cervical cancer, and the benefits of vaccination. This lack of adequate information makes families vulnerable to misinformation and fosters concerns about the vaccine's safety, potential side effects, and pain associated with it. Furthermore, social stigma and taboos play a crucial role in vaccine hesitancy. The association of HPV with sexual activity often results in the vaccine being perceived as an endorsement of early sexual activity. This perception leads to reluctance in discussing the vaccine openly, particularly among fathers who may be uncomfortable acknowledging their daughters' potential sexual activity.

Affordability and accessibility are additional challenges that impede vaccine uptake. The high cost of the HPV vaccine and its limited availability in private healthcare settings are significant barriers, especially for socioeconomically disadvantaged populations. Families who cannot afford the vaccine or who do not have easy access to vaccination services are less likely to get their daughters vaccinated. Moreover, factors such as age, gender, and education level influence knowledge and attitudes toward the vaccine. Parental literacy plays a crucial role in disseminating information about HPV and its risks to children. Educational efforts that exclude adolescent boys contribute to their negligible understanding of HPV, thereby limiting the overall awareness within families. Medical practitioners also face barriers that affect the promotion and administration of the HPV vaccine. Knowledge gaps and limited resources are prevalent, particularly among physicians in rural areas. Many doctors lack adequate awareness about HPV

#### Knowledge and awareness related

- Lack of awareness about HPV diseases among both men and women and cervical cancer, its severity and burden
- Lack of awareness of regular screening for early diagnosis and HPV vaccination to prevent cervical cancer, their effectiveness and safety
- Lack of awareness about HPV vaccination program, eligibility, dose schedule, logistics etc.

#### Perceptions related

- Perceived low-risk and low prevalence of cervical cancer
- Bias among health workers associating higher incidence of cervical among specific population groups
- Misplaced beliefs about vaccine to prevent cervical cancer as a sterilization method
- Association of HPV with HIV and other sexually transmitted infections
- Concerns about vaccines being unavailable to boys and men

#### Hesitancy related

- Fear of injections among adolescents
- Lack of trust among parents for vaccinations targeting girls and requiring written or explicit consent, vis-à-vis routine childhood vaccinations
- Institutional (human rights groups) and religious refusal of vaccination

#### Service delivery related communication challenges

- Reluctance of health-workers and medical practitioners to recommend vaccination
- Reluctance of health-workers to initiate a conversation about cervical cancer and the vaccine because of norms and biases around conversations about sexually transmitted diseases
- Reluctance to initiate conversation and advocate the vaccine by health care-workers, teachers, faith-based influencers, community leader, etc.



and the vaccine due to insufficient training and resources, which hampers their ability to effectively address patient concerns. Time constraints and communication challenges further exacerbate the situation. Limited consultation time during patient visits restricts the opportunity for in-depth discussions about the benefits and importance of the HPV vaccine, leading to inadequate patient education. Supply and demand issues present another significant challenge for medical practitioners. Low demand for the vaccine complicates storage and access, making it difficult for healthcare providers to maintain an adequate supply. These combined factors create a complex environment where both caregivers and medical practitioners face significant hurdles in promoting and administering the HPV vaccine effectively. Addressing these barriers requires a multifaceted approach that includes increasing awareness, improving accessibility, enhancing medical training, and fostering open communication between patients and healthcare providers.

## Recommendations for Doctors

Organizing interactive sessions with healthcare professionals, students and caregivers is essential to address their questions in a safe and informative environment. These sessions provide an opportunity for doctors, girls and parents to engage directly with experts, dispelling their myths and misconceptions about the HPV vaccine. Additionally, implementing peer education programs can be highly effective; by training student leaders to provide accurate information, we can foster a supportive community where peers can learn from each other and feel more comfortable discussing sensitive topics like HPV and cervical cancer.

Furthermore, information meetings for parents are crucial in ensuring comprehensive understanding and support for HPV vaccination. Utilizing parent-teacher meetings to discuss cervical cancer and HPV vaccination allows healthcare professionals to directly address

- **Active Involvement:** As key champions for HPV vaccine uptake.
- **Regular Reminders:** Utilize online and offline platforms for consistent communication.
- **Awareness Campaigns:** Organize campaigns to highlight cervical cancer risks.
- **Refresher Trainings:** Provide ongoing education and training for physicians.
- **Continuous Engagement:** Maintain your active participation to build trust in

### For Girls :

- **Protect Your Health:** Protect you from Cervical Cancer
- **Safe and Effective:** Thoroughly tested, already protecting millions of people globally

### For Parents :

- **Powerful tool in preventing Cervical Cancer**
- **Proven Safety Record:** Recommended by GoI.
- **Optimal Age for Vaccination:** Best time to vaccinate 9-14 years
- **Long-term Protection:** Vaccine provides long-lasting protection
- **Easy Access:** Available at nearest healthcare facility and in schools
- **IAP, FOGSI and IMA recommends the HPV vaccine**
- **More than 300 million doses of HPV vaccine have been safely given worldwide**

parents

' concerns and questions, ensuring they have the necessary information to make informed decisions for their children. This approach not only educates parents but also reinforces the importance of vaccination through trusted and familiar channels, thereby enhancing vaccine acceptance and uptake.

To promote the key messages about the HPV vaccine among girls, it is essential to emphasize the critical health benefits and the robust safety record of the vaccine.

# Promoting Key messages among girls and parents

The foremost message is that the HPV vaccine protects their health by preventing cervical cancer, a significant concern for women in India. Highlighting that the vaccine is safe and effective, having been thoroughly tested and already protecting millions globally, can build trust and confidence in the vaccine. This reassurance can help overcome fears and misconceptions, encouraging more girls to get vaccinated and take a proactive step in safeguarding their health.

Similarly, for parents, it is important to communicate the vaccine's effectiveness as a powerful tool in preventing cervical cancer. Emphasizing that the vaccine significantly reduces the risk of developing cervical cancer can help parents understand its importance in protecting their daughters' future health. Additionally, pointing out that the vaccine has a proven safety record and is recommended by the Government of India can further reassure parents about its safety and efficacy. Highlighting the optimal age for vaccination, which is 9-14 years, can help parents make timely decisions to ensure their daughters receive the vaccine when it is most effective.



Moreover, stressing the long-term protection provided by the HPV vaccine can reassure parents that their daughters will be safeguarded against cervical cancer for many years. The ease of access to the vaccine, available at the nearest healthcare facility and in schools, makes it convenient for parents to get their children vaccinated. Highlighting endorsements from reputable organizations such as the Indian Academy of Pediatrics (IAP), the Federation of Obstetric and Gynecological Societies of India (FOGSI), and the Indian Medical Association (IMA) can further build trust in the vaccine's credibility and importance.

Lastly, showcasing the global success of the HPV vaccine, with over 300 million doses safely administered worldwide, can reinforce its reliability and effectiveness. This widespread use and positive track record can alleviate any remaining concerns parents might have about the vaccine. By addressing these key messages in a comprehensive and reassuring manner, we can significantly enhance the acceptance and uptake of the HPV vaccine, ultimately reducing the burden of cervical cancer in India.



## Effective use of Interpersonal Communication

Doctors play a crucial role in promoting the HPV vaccine through effective interpersonal communication. Establishing a connection with patients and their families is the first step in building rapport. This initial bond creates a foundation of trust, making it easier for patients to feel comfortable and open during consultations. Engaging in meaningful dialogue is essential; doctors should not only educate but also listen and respect the opinions of their patients. By fostering an environment where patients feel heard and valued, doctors can address concerns and misconceptions more effectively.

Respectful interaction is key to successful communication. Understanding what the patient already knows about HPV and cervical cancer allows doctors to tailor their conversations appropriately, engaging with patients as equals. This mutual respect is the cornerstone of meaningful conversations, ensuring that patients do not feel talked down to or dismissed. Initiating discussions by asking questions about what people know about HPV and cervical cancer can uncover gaps in knowledge and areas of concern. This approach not only informs the doctor about the patient's understanding but also shows the patient that their knowledge and experiences are valued.

Offering reassurance and feedback is another vital aspect of effective communication. Doctors should adapt their approach based on cultural norms, showing acknowledgment through nodding or paraphrasing to ensure understanding. This technique helps in creating a supportive environment where patients feel reassured and confident in the information provided. Conveying knowledge and sharing personal experiences can further enhance the communication process. By sharing ideas, experiences, and information, doctors can build a foundation of trust and interaction, which is essential for effective communication. This holistic approach ensures that patients receive accurate information and feel supported in their decision-making process regarding the HPV vaccine.



### **BUILD RAPPORT:**

- Establish a connection

### **ENGAGE IN DIALOGUE:**

- Discuss, listening and respect opinions, don't just educate

### **RESPECTFUL INTERACTION:**

- Begin dialogue as an interaction between equals.
- Mutual respect is key to meaningful conversations.
- Understand existing knowledge

## Use of GATHER Approach for Counseling GATHER Approach

**Greet:** Welcome the client and make her feel comfortable. Build rapport.

**Ask:** Ask questions effectively in a friendly manner using words that the client understands. Listen patiently and without judgment. Identify client needs by asking relevant questions about personal, social, family, medical, and reproductive health.

**Tell:** Provide relevant information to help her make an informed choice regarding vaccinating herself or her daughter against cervical cancer.

**Help:** Assist the client in reaching a decision and provide related information, such as how to protect herself from cervical cancer.

**Explain:** Detail the vaccination process, its benefits in preventing cervical cancer, potential side effects, and how to overcome them.

**Return:** Emphasize the need for follow-up and ongoing HPV vaccination, if required.

The GATHER approach is a structured method that can significantly enhance the counseling process for HPV vaccination. The first step, "Greet," involves welcoming the client warmly and making her feel comfortable. Building rapport at this initial stage is crucial as it sets the tone for a trusting and open conversation. A friendly and respectful greeting helps to ease any anxiety the client may have, fostering a positive environment for the discussion ahead.

Next, the "Ask" step requires you to ask questions effectively in a friendly manner, using language that the client can easily understand. It is important to listen patiently and without judgment, creating a safe space for the client to express her concerns and thoughts. By asking relevant questions about her personal, social, family, medical, and reproductive health, you can identify the patient's specific needs and tailor your conversation accordingly. This personalized approach ensures that the client feels heard and valued.

In the "Tell" phase, you provide the client with relevant information to help her make an informed choice regarding HPV vaccination. This involves explaining the benefits of the vaccine in preventing cervical cancer, addressing any misconceptions, and offering clear, evidence-based facts. The goal is to empower the patient with the knowledge she needs to make a confident decision about her health or the health of her daughter.

The "Help" step focuses on assisting the patient in reaching a decision. You offer support by providing additional information, such as ways to protect herself from cervical cancer beyond vaccination. This guidance is crucial in helping the client feel supported and understood, ultimately aiding her in making a well-informed decision.

### GATHER Approach

**Greet:** Welcome the client and make her feel comfortable. Build rapport.

**Ask:** Ask questions effectively in a friendly manner using words that the client understands. Listen patiently and without judgment. Identify client needs by asking relevant questions about personal, social, family, medical, and reproductive health.

**Tell:** Provide relevant information to help her make an informed choice regarding vaccinating herself or her daughter against cervical cancer.

**Help:** Assist the client in reaching a decision and provide related information, such as how to protect herself from cervical cancer.

**Explain:** Detail the vaccination process, its benefits in preventing cervical cancer, potential side effects, and how to overcome them.

**Return:** Emphasize the need for follow-up and ongoing HPV vaccination, if required.

During the "Explain" phase, you describe the vaccination process, including its benefits in preventing cervical cancer, potential side effects, and how to manage them. This comprehensive explanation helps demystify the vaccination process, making it more approachable and less intimidating for the client.

Finally, in the "Return" step, you emphasize the importance of follow-up and ongoing HPV vaccination, if required. This ensures that the patient understands the need for continued care and monitoring, reinforcing the commitment to her long-term health. By following the GATHER approach, you can provide thorough, empathetic, and effective support, ultimately enhancing the uptake and success of the HPV vaccination program.

As a doctor, your role is vital in increasing HPV vaccine uptake and reducing cervical cancer rates. You are responsible for educating patients and their families about HPV and the vaccine, addressing myths and safety concerns with clear, evidence-based information. It's essential to tackle social stigma by focusing on the vaccine's role in preventing cancer rather than its connection to sexual activity. Advocate for improved vaccine access and affordability and stay informed to address knowledge gaps among your peers. Through effective communication, including building rapport and actively listening, you can significantly influence vaccine acceptance and help lower cervical cancer incidence. Your proactive involvement and advocacy are key to making a meaningful impact in public health.



## Frequently Asked Questions. For the Medical Community.

### ▶ **What is Human papillomavirus (HPV)? What are the symptoms of HPV infection?**

Most people infected with HPV do not show any signs or symptoms, and most infections are naturally eliminated by the body within the first couple of years. However, infections that are not eliminated can become persistent and lead to serious health problems, including:

**Cervical cancer:** Virtually all cases of cervical cancer are caused by persistent HPV infection.

**Other cancers:** HPV can also cause cancers of the oropharynx (throat), anus, penis, vagina, and vulva.

Cervical cancer often develops slowly and may not cause any symptoms in its early stages. 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.

It's important to note that HPV can affect both men and women. While cervical cancer is a significant concern for women, men can also develop cancers caused by HPV, especially those who engage in male-to-male sexual contact (MSM). Hence, HPV vaccination can help prevent future infections that can lead to cancers of the penis, anus, and back of the throat in men

### ▶ **How serious is HPV infection and how is it spread.**

Most HPV infections (70–90%) are asymptomatic and resolve spontaneously within 1–2 years. But when HPV infection does not go away, it can cause health problems including cervical cancer, which may manifest after decades. 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.

### ▶ **What are the preventive measures against HPV infection?**

To protect your patients from HPV infection, it is recommended by the Indian Government for girls to be vaccinated between the age of 9-14 years. The HPV vaccine is safe and effective, protecting against diseases caused by HPV, including cervical cancer, when given at the recommended age as per WHO guidelines.



70% of cervical cancer in India are caused by HPV type 16 & 18. Major risk factors for persistent HPV cervical cancer include early sexual debut, multiple sexual partners, multi parity and poor menstrual hygiene. Women living with HIV are 6 times more likely to develop cervical cancer compared to the general population, and an estimated 5% of all cervical cancer cases are attributable to HIV.

▶ **What is cervical cancer?**

Cervical cancer as the name suggests, appears in the cervix (lower end of the uterus). It is curable if detected early and treated adequately. A large majority of cervical cancer (more than 95%) is due to HPV.

▶ **How many shots of HPV vaccine will be given to my patients?**

Currently, there are four types of vaccines licensed against HPV in India. The vaccination schedule depends on the type of vaccine used, either two doses or a single dose. Both schedules provide the protection needed to prevent HPV infection. The plan as of July 2024 is to vaccinate with two doses. Please refer to your local health authorities advisory about which schedule is being used. It is crucial to inform families with young girls about the vaccination plans, so that they are fully prepared and able to ask questions and learn about the vaccine benefits.

▶ **What is the recommended age for the HPV vaccine?**

The WHO recommends the HPV vaccine for all girls aged 9-14 years i.e., well before they are exposed to the infection. Hence, any girl who has celebrated her 9th birthday and has not celebrated her 15th birthday is eligible for the HPV vaccination.

Why are girls being vaccinated against HPV and not boys? Why is important for girls to be vaccinated against HPV?

HPV can affect girls, boys, women, and men of reproductive age, but cervical cancer is by far the most common HPV-related disease. Hence, for the prevention of this cancer, HPV vaccination for girls aged 9–14 years is recommended. Furthermore, achieving over 80% coverage in girls also reduces the risk of HPV infection for boys. It is important that vaccine is given to girls at an early age before exposure to the virus, it can protect them from the most harmful types of HPV, which cause cervical cancer.

▶ **Is it safe to get my patients vaccinated during menstruation?**

Yes, your patients can be given HPV vaccine during menstruation. Menstruation has no correlation with or impact of menstruation on the HPV vaccination. However, it is necessary that families are advised to make sure their daughter is well and comfortable during menstruation, if to be vaccinated. Also, after any immunization it is advisable to wait at the session site for 30 minutes.

▶ **Why do girls have to be vaccinated against HPV at such an early age?**

As per current evidence available, HPV vaccines work best when they are given in the recommended age group (9-14 years). Studies have shown that the production of protective antibodies is highest in young children.

▶ **Even if the HPV vaccine is given, will my patient still require screening for cervical cancer when they get older?**

Yes, all women (30-65 years) are advised to undergo HPV 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.

▶ **Does the HPV vaccine protect my patient against sexually transmitted infections other than HPV?**

The HPV vaccine does not protect against other STIs such as Chlamydia, gonorrhoea, or HIV. It only protects against certain strains of HPV virus (16 & 18). It is important for your patient to use other form of protections to prevent the spread of STIs.

▶ **How about the HPV Vaccine safety?**

HPV vaccine is safe, effective and is recommended by the World Health Organization (WHO). As of December 2022, over 126 countries have already introduced the HPV vaccine including some of our neighbouring nations- Myanmar, Sri-Lanka, Maldives and Thailand. 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 companies such as Serum Institute India.

▶ **Does the vaccine have any side effects and, if so, what are they?**

Vaccines, like any medicine, may have side effects. Most of the people who are administered HPV vaccine may not have any side effects at all. Common side effects, which are mild are 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.

▶ **Some parents may ask about fainting in relation to the vaccine administration. What should I advise them?**

People faint for many reasons. Some pre-teens and school-age children may faint before vaccination, due to anxiety. Fainting may happen after any medical procedure, including receiving vaccines. Sitting or lying down for about 15-30 minutes after a vaccination can help prevent fainting and fainting-related injuries. Hence, as a vaccination process, it is recommended that the beneficiaries wait at the vaccination site for 30 minutes post vaccination.

▶ **Can HPV vaccine cause infertility in my patient?**

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.



Is it mandatory to get the HPV vaccine for my patients? No, it is not mandatory to get the HPV vaccine for your patients. However, it is recommended with the aim to protect the future of the girls against cervical cancer, which is the second most common cancer for women in India.

▶ **How long will the vaccine provide protection to my patient?**

The HPV vaccine provides a long-lasting protection against the strain of the virus.

▶ **Is it safe to get the HPV vaccine if my patient has a weakened immune system?**

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. Studies have shown that there is high sero / serum-conversion in people who are immuno-compromised, and it remains high if they are given three doses. Therefore, HPV vaccines are safe in patients that have weakened immune system.

▶ **Can girls receive HPV vaccine doses at various places, like schools and clinics?**

Yes, girls can receive HPV vaccine doses at various locations, such as schools and clinics, as long as the vaccination schedule is followed, and proof of vaccination is maintained.











*For every child*



**FOGSI 360**  
Coordinate Communicate Community  
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