“Up Close & Personal: HPV Vaccine in a Clinical Setting”

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Outline

• Definition of Genital HPV Infection
• HPV Types
• Prevalence
• Classification of Histological Findings
• Clinical Manifestations of HPV
• Clinical Diagnosis of HPV
• Natural History of HPV Infection and Potential Progression to Cervical Cancer
• Prevention of Cervical Cancer: GARDASIL Vaccine
• Common Questions By Parents
• Concluding Statements
Genital HPV infection is a sexually transmitted disease/infection (STD/STI) that is caused by human papillomavirus (HPV).

Human papillomavirus is the name of a group of viruses that includes more than 100 different strains or types.

More than 30 of these viruses are sexually transmitted.

HPV is transmitted primarily through genital contact.

Most infected persons are unaware they are infected, yet they can transmit the virus to a sex partner.

Rarely, a pregnant woman can pass HPV to her baby during vaginal delivery.

Infections with high-risk HPV types may ultimately lead to cervical cancer
Human Papillomavirus (HPV)

- >100 types identified
- 30–40 anogenital
  - 15–20 oncogenic* types, including 16, 18, 31, 33, 35, 39, 45, 51, 52, 58
  - HPV 16 (54%) and HPV 18 (13%) account for the majority of worldwide cervical cancers.
  - Nononcogenic† types include: 6, 11, 40, 42, 43, 44, 54
  - HPV 6 and 11 are most often associated with external anogenital warts.

*High risk; †Low risk

US HPV Anogenital Infection Statistics

- By 50 years of age, at least 80% of women will have acquired genital HPV infection.\(^1\)
- Estimated new infections per year: 6.2 million\(^1\)
- Estimated active infections (prevalence): 20 million\(^2\)
- In sexually active individuals 15–24 years of age, ~9.2 million are currently infected.\(^3\)
  - An estimated 74% of new HPV infections occur in this age group.\(^3\)
  - In studies of women <25 years of age, prevalence rates ranged from 28% to 46%.\(^4,5\)

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Estimated Annual Burden of HPV-Related Diagnoses in the United States

- 9,710 new cases of cervical cancer
- 330,000 new cases of high-grade cervical dysplasia (CIN 2/3)
- 1.4 million new cases of low-grade cervical dysplasia (CIN 1)
- 1 million new cases of genital warts
- 3,700 deaths estimated in 2006

CIN = cervical intraepithelial neoplasia.

References:

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Classification of Histological Findings: CIN

- Cervical Intraepithelial Neoplasia (CIN)\(^1\)
  - CIN 1: Mild dysplasia; includes condyloma (anogenital warts)
  - CIN 2: Moderate dysplasia
  - CIN 3: Severe dysplasia; includes carcinoma *in situ* (CIS)

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<tr>
<th>CIN(^1)</th>
<th>Normal</th>
<th>CIN 1 (condyloma)</th>
<th>CIN 1 (mild dysplasia)</th>
<th>CIN 2 (moderate dysplasia)</th>
<th>CIN 3 (severe dysplasia/CIS)</th>
<th>Invasive Cancer</th>
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- CIN caused by HPV can clear without treatment; however, rates of regression are dependent on grade of CIN.\(^2\)

Clinical Manifestations of HPV

• Most people who have a genital HPV infection do not know they are infected.
• The virus lives in the skin or mucous membranes and usually causes no symptoms.
• Some people get visible genital warts, or have pre-cancerous changes in the cervix, vulva, anus, or penis.
HPV and Anogenital Warts

- HPV 6 and 11 responsible for >90% of anogenital warts
- Infectivity >75%
- Up to 30% spontaneously regress within 4 months in women.
- Treatment can be painful and embarrassing.
- Topical and surgical therapies are available for genital warts.
- Recurrence rates vary greatly.
  - As low as 5% with podofilox or laser treatment
  - As high as 65% with other treatments

Clinical Diagnosis of HPV

• Most women are diagnosed with HPV on the basis of abnormal Pap tests.
• A Pap test is the primary cancer-screening tool for cervical cancer or pre-cancerous changes in the cervix.
Natural History of HPV Infection and Potential Progression to Cervical Cancer\(^1\)

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<th>0–5 Years</th>
<th>1–20 Years</th>
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<td><strong>Initial HPV Infection</strong></td>
<td><strong>Continuing Infection</strong></td>
<td><strong>CIN 2/3 AIS</strong></td>
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<tr>
<td><strong>CIN 1</strong></td>
<td><strong>Invasive Cervical Cancer</strong></td>
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CIN = cervical intraepithelial neoplasia.

AIS = adenocarcinoma *in situ*.

Prevention of Cervical Cancer: GARDASIL Vaccine

• GARDASIL is a vaccine that helps protect against the following diseases caused by HPV types 6/11/16/18
  — Cervical cancer (cancer of the lower end of the uterus)
  — Abnormal and precancerous cervical, vaginal and vulvar lesions
  — Genital warts
WHO SHOULD GET GARDASIL?
- It is indicated for girls and women as young as 9 years (but typically given at 11 years) to 26 years

PURPOSE OF GARDASIL VACCINATION:
- To prevent cervical cancer, precancerous or dysplastic lesions, and genital warts caused by HPV Types 6, 11, 16, and 18.

HOW IS GARDASIL GIVEN?
- GARDASIL is given as an intramuscular injection
- You or your child will receive 3 doses of the vaccine
  - First dose: at a date you and the health provider decide
  - Second dose: 2 months after the first dose
  - Third dose: 6 months after the first dose
Vaccine-Related Adverse Experiences

• At the Site of Injection
  — Pain
  — Swelling
  — Erythema
  — Pruritis (Itching)

• General Side Effects
  — Fever, Nausea, Dizziness
Common Questions By Parents

- Will GARDASIL help if you already have HPV?
- Does my child still have to get PAP Tests?
- Do I have to pay for the vaccine and if so, how much does it cost?
- What are the benefits of the vaccine?
- What is the vaccines duration?
• How can HPV infection be prevented?
• Does the vaccine send a message that it's okay to have sex and therefore encourage or lead to increased sexual activity?
• Why should my daughter be vaccinated at age 11 or 12? She's not sexually active. Can't we wait?
Conclusion: Important Facts About GARDASIL

- GARDASIL is contraindicated in individuals who are hypersensitive or allergic to any of the ingredients in the vaccine.

- Vaccination with GARDASIL does not substitute for routine cervical cancer screening, and people who receive GARDASIL should continue to undergo screening per standard of care.

- Vaccination with GARDASIL may not result in protection in all vaccine recipients.

- GARDASIL is not intended to be used for treatment of active genital warts; cervical cancer; CIN, VIN, or VaIN.

- GARDASIL has not been shown to protect against diseases due to non-vaccine HPV types.

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For More Information

- **CDC National Prevention Information Network**: [http://www.cdcnpin.org](http://www.cdcnpin.org)


- **Cervical Cancer Awareness**: [http://www.cdc.gov/cancer/cervical](http://www.cdc.gov/cancer/cervical)

- **American Cancer Society**: [http://www.cancer.org](http://www.cancer.org)