

A STUDY ON HPV VACCINE MARKET TRENDS IN THE UNITED STATES

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

By

Mahak Arora

Under the Supervision and Guidance of

Dr. Sudhinder Singh Chowhan

2024

Date: 01/07/2024

TO WHOMSOEVER IT MAY CONCERN

This is to certify that, **Mahak Arora**, student of IIHMR University, Jaipur has completed her internship with **PharmaACE Analytics LLP** during the period of **April 01, 2024 to June 30, 2024**. During her internship she worked with the Forecasting department and has successfully worked on the project; **HPV Vaccine Market Trends in US**.

We wish her every success in life.



Ashima Kumar

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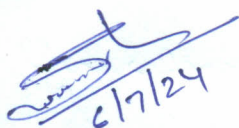
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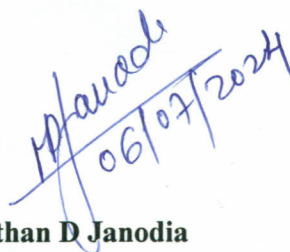
This is to certify that dissertation titled “**HPV Vaccine Market Trends in United States**” is a record of the research work undertaken by **Mahak Arora** in partial fulfilment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

A handwritten signature in blue ink, with the date '6/7/24' written below it.

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Date: 06/07/2024

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Date: 06/07/2024

Acknowledgment

I would like to extend my heartfelt gratitude to all those who have contributed to the completion of this project report. Their unwavering guidance, active participation, and invaluable support have been instrumental in its realization.

First and foremost, I am profoundly grateful to Sudhinder Singh Chowhan, **Professor** at IIHMR University. His exemplary mentorship and steadfast support have played a pivotal role in guiding me through the challenges of this project, ensuring its successful completion.

I extend my sincere gratitude to Mr. Rajan Singh, Consultant at PharmaACE, LLP, for his invaluable guidance and unwavering support throughout my dissertation journey. Mr. Singh has been a beacon of knowledge, providing me with insightful mentorship at every stage. His expertise and dedication have enriched my understanding of the pharmaceutical industry, offering me opportunities for practical learning through meaningful projects and constructive discussions.

I am deeply appreciative of Mr. Singh keen interest in my professional development during my summer training at PharmaACE. His cooperative spirit and willingness to share his expertise have been instrumental in shaping my academic pursuits and refining my research focus.

Furthermore, I extend my thanks to all those who have directly or indirectly supported me throughout this assignment. Each contribution, whether large or small, has been integral to the project's progress and achievement.

I acknowledge that any omissions in this acknowledgment do not diminish the gratitude I hold for everyone who has been a part of this journey.

Thank You

Sincerely,

Mahak Arora

Roll no. – 0399

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Abbreviations

1. CDC- Centers for Disease Control and Prevention
2. FDA- Food and Drug Administration
3. ACS- American Cancer Society
4. HSIL- High-grade squamous intraepithelial lesion
5. LSIL- Low-grade squamous intraepithelial lesion
6. CIN- Cervical Intraepithelial Neoplasia
7. VIN- Vaginal Intraepithelial Neoplasia
8. FPL- Federal poverty level
9. US- United States

Abstract

Title: A study on HPV Vaccine Market Trends in the United States

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Background: The Human Papillomavirus (HPV) vaccine is a vital tool in the fight against diseases related to HPV especially cervical cancer. Different factors such as vaccination calendars, demographics and new therapies have informed the situation of the HPV vaccine market in America.

The CDC recommends routine HPV vaccinations for kids at 11 to 12 years, with older individuals up to age 26 getting catch-up shots. This schedule aims at ensuring protection prior to potential exposure to HPV. However, different demographic groups have shown distinct vaccination rates. It has been noticed that immunization rates vary by age, sex and ethnicity. Initially it was only women who took the vaccine more than men did because they were given priority until of late when it became clear that everybody should get vaccinated.

Age, gender and ethnicity significantly affect HPV vaccination rates. It is notable that recommended preteen girls exhibit higher immunization coverage than males within the same age category. Gender discrepancies continue to arise since females report higher uptake rates compared to males.

There is evidence of racial disparities where some ethnic subgroups have lower rates of immunization due to limited access to health care, cultural beliefs and economic factors.

The United States Human Papillomavirus (HPV) vaccines market has largely been dominated by Gardasil made by Merck & Co. This vaccine provides protection against multiple strains of HPV and is supported with extensive clinical efficacy data. There is also another vaccine called Cervarix but it is a minor player in the market.

New treatments and upcoming vaccines will meet needs that the current HPV vaccine market does not cover. These advancements will offer fresh vaccines that target more HPV types and healing vaccines that might cure existing HPV infections and the diseases they cause. These developments can enhance how we prevent and handle diseases linked to human papillomaviruses (HPVs).

However, we still have important gaps to fill in the area of HPV vaccinations. These include boosting vaccination in underrepresented groups; improving public knowledge about the advantages of vaccination; and addressing myths about the vaccines that prevent people who

need them most from getting them. We need strategies to better access to vaccines and to make sure everyone has equal chances to get them.

The US market for HPV vaccines is evolving as work continues to expand immunization coverage and develop new treatment options.

Chapter 1- Introduction

HUMAN PAPILLOMA VIRUS

HPV is a varied family of small viruses with double-stranded DNA that mainly infect tissues lining the surfaces of the body. With over 200 identified types differentiated by their genetic sequences, HPV commonly causes skin warts and is associated with mucosal infections linked to cervical cancer.

Low-risk HPV types, such as 6 and 11, are responsible for benign cervical cell changes, anogenital warts, and respiratory tract papillomas, comprising the majority of anogenital wart cases.

High-risk HPV types act as carcinogens, particularly types 16 and 18, which are significant contributors to cervical cancer worldwide. While infection with high-risk HPV is a major factor in the growth of cervical cancer, other factors are usually needed as well. Even if a woman gets infected with HPV, including the high-risk types, it's important to know that most won't develop cancer as a result.

In addition to cervical cancer, high-risk HPV infections are linked to less common anogenital cancers (vulva, vagina, penis, anus) and oropharyngeal cancers.

HPV infection usually starts in the deepest layer of the skin's surface. Although HPV infections are common, they often clear up on their own within one to two years. However, a few individuals experience persistent HPV infections, which are the primary risk factor for developing cervical cancer.

In women, cervical screening detects squamous intraepithelial lesions. Low-grade lesions often regress spontaneously, whereas high-grade lesions are recognized as precursors to cancer. If left untreated, high-grade squamous intraepithelial lesions, formerly known as cervical intraepithelial neoplasia, can develop into cervical cancer over a period of years or decades.

Similar patterns may exist for other HPV-related cancers, although precursor lesions are less well understood. For example, before anal cancer develops, anal high-grade squamous intraepithelial lesions (HSIL) occur. Similarly, vulvar high-grade squamous intraepithelial lesions (HSIL) precede vulvar cancer, and vaginal high-grade squamous intraepithelial lesions (HSIL) precede vaginal cancer.

It's important to note that being infected with one type of HPV doesn't protect against other types. Among those with mucosal HPV infections, between 5% and 30% may have multiple HPV strains at the same time.

HPV is a common virus which can lead to cancer later in life. Vaccinating children with the HPV vaccine around ages 11-12 can help prevent these cancers.

- HPV infections are widespread, affecting nearly everyone at some point. Over 42 million Americans carry HPV types linked to disease, with approximately 13 million new infections annually.

- HPV spreads through intimate skin-to-skin contact, including vaginal, anal, or oral sex, even without visible symptoms.

- While most HPV infections clear up within two years (9 out of 10 cases), some persist longer and can cause:

- Cervical cancer

- Vaginal cancer

- Vulvar cancer

- Penile cancer

- Anal cancer

- Oropharyngeal cancers affecting base of the tongue and tonsils.

- HPV is responsible for about 36,000 cancer cases annually in the United States across genders.

Cancer often develops many years or even decades after someone contracts HPV. It's hard to predict who might end up with cancer or other health problems because of HPV.

People living with conditions that weaken their immune systems, such as HIV/AIDS, may struggle more to clear HPV infections from their bodies. This increases their risk of experiencing health problems related to HPV.

HPV vaccination is highly effective, preventing over 90% of cancers caused by HPV. It also protects against precancerous conditions in the anal, vaginal, cervical, and vulvar tissues, which are abnormal cells that could develop into cancer.

This is why HPV vaccines are most effective when administered at age 11-12, before exposure to the virus.

Number of Cancers Caused by HPV in the United States Each Year

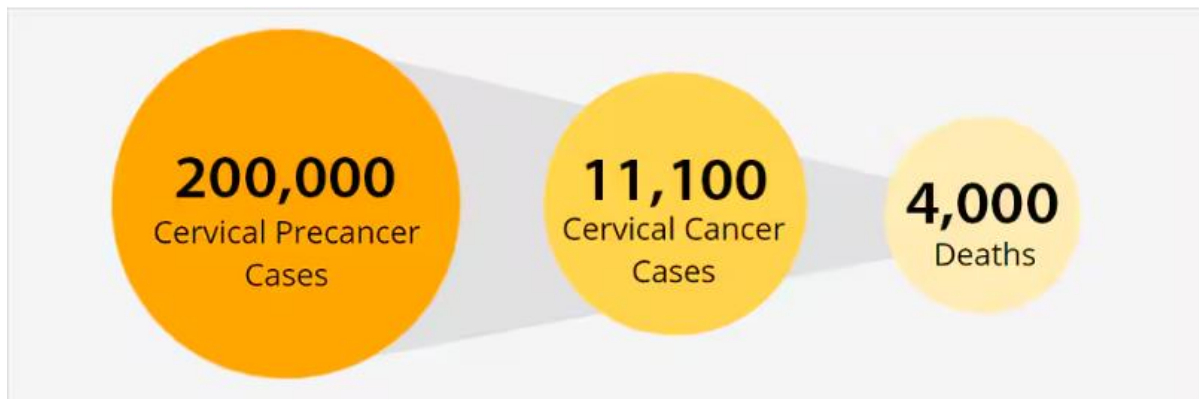
Cancer	Cases in Women	Cases in Men
Back of the Throat	2,300	12,500
Cervical	11,100	0
Anus	4,700	2,200
Vulva	2,900	0
Penis	0	900
Vagina	700	0
Total	21,700	15,600

Cervical cancer, caused by HPV infection

More than 90% of cervical cancer cases result from HPV infection. HPV vaccination has the potential to prevent nearly all cases of cervical cancer. Each year in the US:

- Each year, close to 200,000 women are diagnosed with cervical precancer.
- Each year, around 11,100 women receive a diagnosis of cervical carcinoma caused by HPV.
- Approximately 4,000 women die from cervical cancer annually.

In the past, cervical carcinoma was one of the top causes of cancer-related deaths among women in the US. Thankfully, with the availability of HPV vaccines and regular cervical cancer screenings, it has become largely preventable today.



Cervical cancer stands out among HPV-related cancers because it can be caught early through recommended screening tests. In contrast, other cancers caused by HPV often remain unnoticed until they advance. The HPV vaccine effectively prevents the infections that can lead to these cancers.

Cellular abnormalities in the cervix

Cells within the transformation zone do not undergo an immediate transformation into cancerous cells. Instead, normal cervical cells progressively undergo abnormal changes that have the potential to develop into cancer. Medical professionals use various terms to characterize these cellular changes, such as cervical intraepithelial neoplasia , squamous intraepithelial lesion, and dysplasia. These abnormalities are often referred to as precancerous or pre-cancer changes.

When doctors find these unusual changes in the cervix, they assess them using a scale from 1 to 3 depending on how much the cervical tissue is impacted:

CIN1 indicates minimal abnormality in the tissue, with a high likelihood that the cells will revert to normal on their own.

CIN2 or CIN3 (or moderate/severe dysplasia/high-grade SIL) signifies a more pronounced abnormality in the tissue. These changes carry an increased risk of progressing to cancerous cells and typically require close monitoring or treatment.

Although cervical cancers originate from cells with abnormal changes, not all women who have these cervical abnormalities will develop cancer. For many women, these abnormal cells regress spontaneously without intervention. However, sometimes these changes can develop into invasive cancer. Treating abnormal cervical cell changes promptly can effectively prevent nearly all cases of cervical cancer.

Cervical cancers and precancerous lesions are **categorized** based on their microscopic appearance in laboratory analysis. The primary types of cervical carcinoma include squamous cell carcinoma and adenocarcinoma.

1. Squamous Cell Carcinoma: Approximately 90% of cervical cancers are squamous cell carcinomas, which typically originate in the exocervix at the junction with the endocervix, known as the transformation zone.

2. Adenocarcinoma: The other types are mostly adenocarcinomas, which develop from gland cells in the mucus-secreting tissue of the inner part of the cervix.

3. Adenosquamous Carcinoma: Very rarely, cervical cancers can show features of both squamous cell carcinomas as well as adenocarcinomas, known as adenosquamous carcinomas.

While squamous cell carcinoma and adenocarcinoma account for almost all cervical cancers, there are other less common types that can also arise in the cervix, such as melanoma, sarcoma, and lymphoma. However, these types are more frequently found in other areas of the body.

How prevalent is cervical carcinoma?

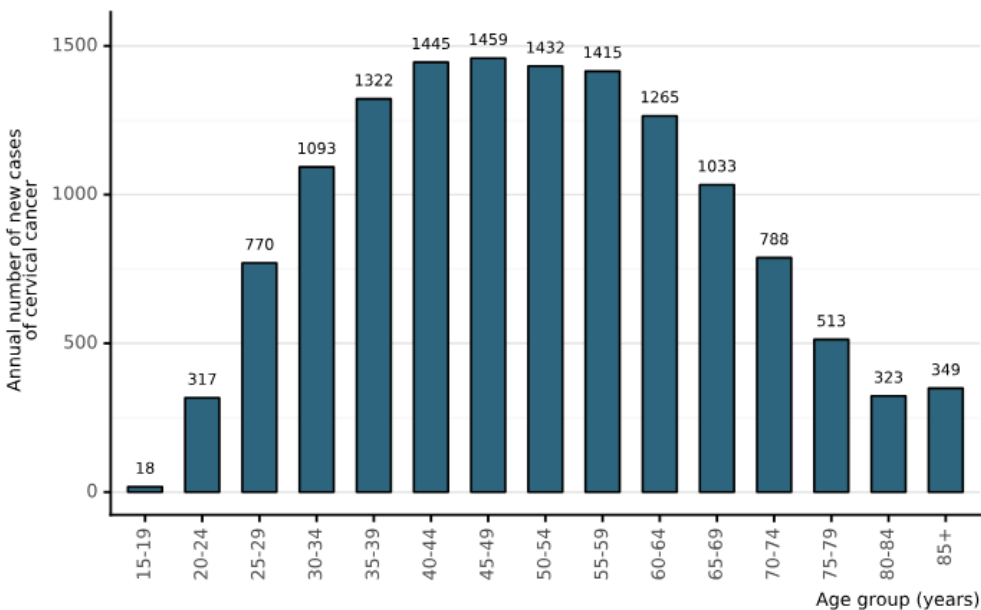
The American Cancer Society's projections for cervical carcinoma in the United States for 2024 include:

- An estimated 13,820 new cases of invasive cervical cancer are anticipated to be diagnosed
- An estimated 4,360 women are estimated to lose their lives to cervical cancer.
- Doctors diagnose cervical pre-cancers much more often than invasive cervical cancer.
- Cervical cancer mostly affects middle aged women i.e., 35 to 44, with an average age of diagnosis being 50 years. It is rare for cervical cancer to develop in women under 20 years old.
- Many women may not realize they are still at risk for cervical cancer as they get older. Surprisingly, over 20% of cervical carcinoma cases occur in women aged 65 and older. Nevertheless regular cervical cancer screening before age 65 significantly reduces the likelihood of developing these cancers.

Trends in Cervical Cancer Incidence

The number of cervical cancer cases decreased by more than half from the mid-1970s to the mid-2000s, mainly because of improvements in screening efforts. However, these rates have stabilized in recent years. Notably, from 2012 to 2019, there has been an annual increase of 1.7% in incidence rates among women aged 30-44, while rates declined by 11% annually among those aged 20-24, reflecting early signs of HPV vaccination impact.

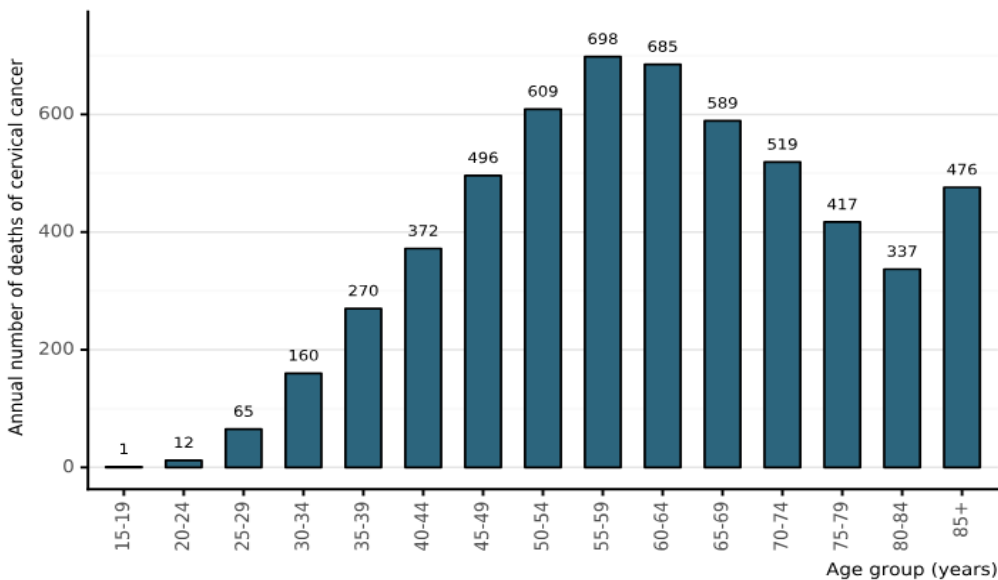
The yearly count of new cervical carcinoma cases in the US



Trends in Cervical Cancer Mortality

Historically, cervical cancer was a major contributor to cancer-related deaths among American women. However, mortality rates have dropped by over 50% since the mid-1970s, thanks to improvements in prevention and screening methods. Despite this progress, mortality rates have leveled off in recent years. Notably, mortality rates are approximately 65% higher in Black and Native American women compared to White women.

The yearly count of deaths from cervical carcinoma in the US



Risk Factors for Cervical Carcinoma

1-HPV, a family of over 150 viruses, primarily infects skin and mucous membranes through sexual contact. Some types cause benign warts, while high-risk types can lead to cancers like cervical, vulvar, vaginal, penile, anal, mouth, and throat cancers, especially if the infection persists.

While there is no cure for HPV, treatments focus on managing warts and abnormal cell growth caused by the virus. HPV vaccines are available to prevent infection by specific HPV types associated with cancers.

2-Several aspects of one's sexual history can increase the risk of cervical cancer, mainly by increasing exposure to HPV:

- Starting sexual activity at a young age, particularly before turning 18.
- Having multiple sexual partners over time.
- Being with a partner who is considered high risk, such as someone who has HPV or has had multiple sexual partners.
- Smoking and Cervical Cancer

3-Smoking significantly increases the risk of cervical cancer through separate mechanisms:

- Tobacco smoke contains carcinogenic chemicals that are absorbed into the bloodstream, affecting organs beyond the lungs.
- Women who smoke are at a greater risk of developing cervical cancer. This increased risk is linked to tobacco by-products found in cervical mucus, which can harm cervical cell DNA and weaken the immune response against HPV infections.

4-Prolonged Use of Oral Contraceptives

Research indicates that long-term use of oral contraceptives raises the likelihood of cervical carcinoma in women. However, this risk decreases after stopping the use of OCs and typically returns to normal several years later. It is advisable for a woman to discuss with her healthcare provider whether the benefits of OC use outweigh the potential risks.

5-Having multiple pregnancies that reach full term

Women who have given birth to three or more children are at a greater risk of developing cervical carcinoma. This increased risk is likely because they have had more exposure to HPV through sexual activity. Hormonal changes during pregnancy may also contribute to greater susceptibility to HPV infection or cancer progression. Additionally, pregnancy-related changes in immune function might weaken the body's defenses against HPV infection and cancer development.

6-Early Pregnancy Impact

Women who have their first child before age 20 have more chance to develop cervical cancer later in life than those who wait until they are 25 or older for their first pregnancy.

7-Economic Factors

Many women with low incomes face challenges in accessing adequate healthcare services, including screening for cervical cancer through Pap tests and HPV tests. As a result, they may not receive timely screening or treatment for cervical precancers.

8-Dietary Habits

Women who don't consume sufficient fruits and vegetables might face a higher risk of cervical cancer.

Can Cervical Cancer Be Prevented?

Detecting Cervical Pre-cancers

A highly effective method for preventing cervical carcinoma is through regular screening tests. Screening involves conducting tests to identify conditions that may progress to cancer, including pre-cancers, before they develop into invasive cancer. The Pap test, also known as a Pap smear, and the HPV test are specific screening methods used for cervical cancer.

During these tests, a healthcare professional utilizes a specialized instrument to gently collect cells from the cervix for examination. If a pre-cancerous condition is detected, appropriate treatment can prevent it from progressing into cervical carcinoma.

The **HPV test** specifically identifies infection by Hr-HPV types that are more likely to cause pre-cancers and cervical cancers. Various HPV tests are approved, some as primary tests and others as co-tests, depending on availability in different regions.

The **Pap test** involves collecting cervical cells during a pelvic exam to examine them closely in a laboratory for signs of cancer or pre-cancerous changes. It's crucial to remember that most cases of invasive cervical cancer are diagnosed in women who haven't been getting regular Pap tests. Although a Pap test is often part of a pelvic exam, not every pelvic exam includes one.

Steps to Prevent Pre-Cancers and Cancers

1.HPV Vaccination

Vaccines are available to protect kids and teens from certain HPV infections. These vaccines focus on HPV types that are frequently associated with cancer, as well as some that cause genital and anal warts.

It's crucial to administer these vaccines before potential exposure to HPV through activities like sexual intercourse, as they do not treat existing infections but rather prevent new ones.

HPV vaccines are effective in preventing cervical pre-cancers and cancers. Some vaccines also aid in preventing other cancers, genital warts, and anal warts.

The vaccines are administered through a series of shots. Common side effects include temporary discomfort, inflammation, and tenderness at the injection site. Fainting shortly after getting the shot is rare but can happen, especially among young people.

According to the ACS:

- It's recommended that children from 9 to 12 years old receive the HPV vaccine.
- Young people aged 13 to 26 who haven't received their HPV vaccine or completed the doses should get vaccinated as soon as they can.
- Vaccination at a later age in young adults is less effective in preventing cancers compared to vaccination during childhood and adolescence.
- The American Cancer Society recommends HPV vaccination for individuals under 26 years old.

It's important to note that while HPV vaccines provide substantial protection against many cancer-causing HPV types, regular cervical cancer screening remains essential.

2.Reducing Exposure to HPV

HPV spreads through touching skin that's infected. While sexual contact, like vaginal, anal, and oral sex, is a common way it spreads, HPV can also be passed through touching skin or touching genitals with hands, even without sex.

Moreover, HPV infections can spread from one area of the body to another. For example, if an infection starts in the cervix, it can potentially spread to the vagina and vulva.

Avoiding contact with the anal and genital areas of others may reduce the risk of HPV transmission, but complete prevention is challenging due to other potential transmission routes that are not fully understood.

To lower the risk of HPV exposure, it's beneficial to reduce the number of sexual partners and avoid intimate contact with individuals who have had multiple partners.

However, given the high prevalence of HPV, even sexual activity with a single partner can pose a risk. It's important to note that HPV can persist asymptomatically for years, allowing transmission without the carrier's awareness.

In summary, while certain precautions can mitigate HPV transmission risks, the widespread nature of HPV necessitates awareness and proactive measures to reduce exposure.

3.Using Condoms

Condoms often called "rubbers," give some protection against HPV but they are not perfect because they do not cover every area that might be infected such as the genital or anal skin. Condoms offer some protection against HPV and also help stop HIV and other diseases that are passed through sex.

4.Avoiding Smoking

Not smoking is a key method to reduce the risk of cervical pre-cancer and cancer. The ACS recommends that people with a cervix follow these guidelines to catch cervical cancer . These rules can also find pre-cancers , which helps in treating them to prevent cervical cancer. Remember, these guidelines do not apply to people who have already been diagnosed with cervical cancer or pre-cancer. If that describes you, it's crucial to listen to your healthcare team's guidance on necessary follow-up tests and screenings.

1. Screening for cervical cancer should commence at age 25.
2. Between ages 25 and 65, individuals should have an HPV test every 5 years as the preferred screening method. If an HPV test is not available, they can opt for a co-test every 5 years, which combines an HPV test with a Pap test. Another option is to have a Pap test alone every 3 years.
3. Regular screening is crucial regardless of the specific test chosen.
4. People over 65 who have had regular screenings with normal results in the past 10 years and no severe cervical conditions in the past 25 years should stop getting cervical cancer screenings indefinitely.

5. If you've had a complete hysterectomy, you typically do not require screening tests, unless the surgery was for treating cervical cancer or severe pre-cancer. However, if your hysterectomy did not include removing the cervix (known as a supra-cervical hysterectomy), it is important to follow guidelines for cervical cancer screening.
6. Even individuals vaccinated against HPV should adhere to these age-specific screening guidelines.

Screening Tests for Cervical Cancer

Regular screening is highly effective in detecting cervical cancer early, which significantly increases treatment success rates and prevents cervical cell abnormalities from progressing to cancer. Timely screening tests for cervical cancer include the HPV and Pap test, which can be conducted individually or simultaneously (known as a co-test) during a pelvic examination. Being vigilant about any signs or symptoms of cervical cancer also plays a crucial role in avoiding unnecessary delays in diagnosis.

THE HPV TEST

The main cause of cervical cancer is infection with human papillomavirus.

Healthcare providers detect high-risk HPV types by analyzing DNA in cervical cells through the HPV test, which can be performed alone (primary HPV test) or simultaneously with a Pap test (co-test). The procedure remains unchanged regardless of which test is conducted.

The primary HPV test is recommended by the ACS as the preferred screening method for cervical cancer in individuals aged 25-65. Certain HPV tests are only approved for use as part of a co-test, where both HPV and Pap tests are performed together. If a primary HPV test is unavailable, alternatives include a co-test every 5 years or a Pap test every 3 years.

All screening methods (primary HPV test, co-test, and Pap test) effectively detect cancer and pre-cancerous conditions. The primary HPV test is particularly effective in preventing cervical cancer compared to a standalone Pap test and minimizes unnecessary follow-up tests, which can be prompted by a co-test. Regular screening is crucial regardless of the chosen method.

The HPV test result, along with previous results, helps determine the risk of cervical cancer. A positive result may lead to additional follow-up visits, further tests to detect pre-cancerous or cancerous conditions, and sometimes treatment for identified pre-cancers.

Due to the variety of follow-up and treatment options based on individual cervical cancer risks, discussing screening results with a healthcare provider is essential for understanding personal risk and selecting the most appropriate follow-up plan.

A Pap smear, also known as a Pap test, is conducted during a pelvic exam for cervical cancer screening in asymptomatic individuals or as a follow-up to an abnormal HPV test or suspicious cervical cancer symptoms.

Pap test

What does a Pap smear test for?

A Pap test involves gathering cells from the cervix (lower part of the uterus) to examine them closely under a microscope in a lab. It identifies cell changes that could indicate pre-cancerous or cancerous conditions.

While the Pap test has been highly effective in cervical cancer prevention compared to other screening methods, it is not without limitations. One drawback is that the results require visual examination by a human, making it challenging to accurately evaluate the hundreds of thousands of cells in each sample.

POPULATION	RECOMMENDATION
Aged less than 21 years	No screening
Aged 21-29 years	Cytology (Pap test) alone every 3 years
Aged 30-65 years	Any one of the following – Cytology alone every 3 years. FDA-Approved primary hrHPV testing alone every 5 years. Cotesting (hrHPV testing and cytology) every 5 years.
Greater than 65 years	No screening after adequate negative prior screening results
Hysterectomy with removal of the cervix	No screening in individuals who do not have a history of high-grade cervical precancerous lesions or cervical cancer

Chapter 4-Literature Review

1- Cheng, Liqin, Yan Wang, and Juan Du. "Human Papillomavirus Vaccines: An Updated Review." *Vaccines*, vol. 8, no. 3, 2020.

Findings: HPV vaccines have led to a significant reduction in HPV infections and related diseases. As more people get vaccinated through inclusive programs, we expect better protection against HPV and fewer HPV-related cancers. To make this happen, it's crucial to educate people in low- and middle-income countries about HPV risks and vaccine benefits. We can also improve vaccines by exploring new additives or designs to reduce side effects and encourage more young people to get vaccinated. However, some types of HPV that current vaccines don't cover are still common among young women. Future HPV vaccines should aim to offer broad-spectrum protection through high-valent formulations. Furthermore, it's essential to conduct studies or trials to understand how HPV vaccination affects all HPV-related cancers. Therapeutic vaccines show promise in treating cancers and are vital for managing HPV infections comprehensively, from prevention to potential eradication.

2-Fokom Domgue, Joël, Robert K. Yu, and Sanjay Shete. "Trends in the Rates of Health-Care Providers' Recommendation for HPV Vaccine from 2012 to 2018: A Multi-Round Cross-Sectional Analysis of the Health Information National Trends Survey." *Human Vaccines & Immunotherapeutics*, 2021

Findings: Our research shows that healthcare providers in the U.S. are increasingly recommending the HPV vaccine to adults vary by age, with additional disparities observed based on sex, region, and ethnicity. To boost HPV vaccination rates in the U.S., it is crucial to not only raise awareness about HPV, the vaccine, and its safety but also to take immediate steps to increase provider involvement in promoting HPV vaccination, particularly among males, urban residents, and non-Hispanic Whites (NHWs).

3-Kahn, Benjamin Z., et al. "Getting Human Papillomavirus Vaccination Back on Track: A National Survey." *Journal of Adolescent Health*, 13 Mar. 2023.

Findings: Our study included a diverse group of U.S. healthcare providers: 71% physicians, 17% physician assistants and nurse practitioners, and 12% nurses. Most had over 10 years of experience (76%) and typically saw 10 or more adolescent patients weekly (73%). They primarily worked in family medicine (64%) or pediatrics (29%) clinics, mostly in suburban (50%) or urban (35%) settings, with fewer in rural areas (15%). About 56% worked in healthcare system-affiliated clinics, and 66% faced financial strain from the COVID-19 pandemic. Nearly half were women (49%), and the majority were white (68%). Providers came from all U.S. census regions.

4-Stefanos, Ruth, et al. "High Impact of Quadrivalent Human Papillomavirus Vaccine Across Racial/Ethnic Groups: National Health and Nutrition Examination Survey, 2003–2006 and 2015–2018." Human Vaccines & Immunotherapeutics, 19 Feb. 2024.

Findings: Within 12 years since the HPV vaccine was introduced, there has been a noticeable decline in the prevalence of 4vHPV types in cervicovaginal samples. This decrease underscores the vaccine's significant impact, which has been observed across all racial and ethnic groups studied. The continued decline of over 80% among young females from diverse racial and ethnic backgrounds highlights the vaccine's potential to reduce disparities in cervical cancer. Ongoing surveillance is necessary to assess the impact of the 9vHPV vaccine by race and ethnicity.

Chapter 3-Methodology

3.1 Research Approach

-Research Approach:A mixed-methods approach combining qualitative and quantitative analysis of secondary data will be employed to comprehensively analyze HPV vaccine market trends in the US. This approach allows for both statistical analysis of market data and qualitative insights from existing literature and reports.

3.2 Data Collection Methods

- Literature Review:

- Systematic review of academic literature using databases such as PubMed, Google Scholar, and specialized health databases (e.g., JAMA Network, NEJM).

- Keywords: "HPV vaccine market trends", "HPV vaccine coverage", "HPV vaccine efficacy", "HPV vaccine safety", "barriers to HPV vaccination", "HPV vaccine hesitancy".

- Review of industry reports and market analyses from reputable sources such as IMS Health, IQVIA, and CDC.

- Sources:CDC (<https://www.cdc.gov>), American Cancer Society (<https://www.cancer.org>), ASCO (<https://www.asco.org>).

3.3 Data Analysis Techniques

- Quantitative Analysis:

- Statistical analysis of market data to examine trends in HPV vaccine uptake, market size, growth rates, and market share of different vaccine brands.

- Qualitative Analysis:

- Thematic analysis of qualitative data from literature, focusing on factors influencing HPV vaccine adoption, stakeholder perspectives, and barriers to vaccination.

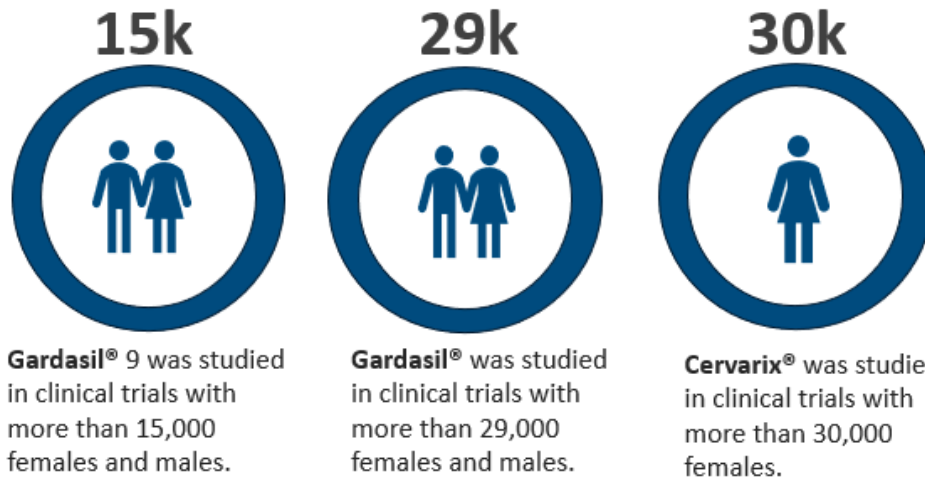
This adjusted methodology focuses solely on secondary research methods, utilizing existing literature and data sources to provide a thorough analysis of HPV vaccine market trends in the US.

HPV Vaccine

1. Since HPV vaccines were introduced in the U.S. in 2006, there has been a noticeable decrease in HPV infections and early signs of cervical cancer.
2. Among teenage girls, there has been an 88 percent reduction in infections caused by HPV types responsible for most HPV-related cancers and genital warts.
3. Among young adult women, infections from these HPV types have decreased by 81 percent since the vaccine's introduction.
4. Vaccinated women have seen a 40 percent decline in cervical precancers associated with the HPV types most commonly linked to cervical cancer.

Reasons to Get HPV Vaccine

- **High Infection Risk:** Approximately 85% of individuals will contract an HPV infection at some point in their lives. Each year, about 13 million Americans, including adolescents, acquire HPV, with most infections resolving on their own. Persistent infections can lead to various cancers.
- **Cancer Types Caused by HPV:** HPV infections can cause cancers in various parts of the body: cervix, vagina, and vulva in women; penis in men; anus in both men and women; and oropharynx (back of the throat) in both men and women..
- **Cancer Prevention:** HPV vaccination is a crucial strategy for preventing cancer. It is estimated that HPV causes nearly 36,500 cases of cancer every year in the US, but vaccination can prevent approximately 33,700 of these cases by preventing the infections that lead to cancer.
- **Preventative Benefits:** Vaccinating to prevent cancer is more effective than treating it. While screening can catch cervical cancer early, other HPV-related cancers might not be detected until they're advanced. HPV vaccination helps lower the risk of these cancers by preventing the initial infections.
- **Early Vaccination Advantages:** Most children only require two doses of the HPV vaccine if vaccinated before age 15. Routine visits to a healthcare provider, such as annual checkups or sports physicals, provide opportunities to ensure children receive recommended vaccines, including HPV.
- **Safety and Long-term Protection:** The HPV vaccine in the U.S. has proven safe with over 135 million doses administered, supported by over 15 years of extensive monitoring and research.



- **Safety and Effectiveness:** HPV vaccination offers safe, effective, and enduring protection against HPV-related cancers.
- **Monitoring and Reporting:** Both the CDC and FDA maintain close oversight of HPV vaccine safety. Any identified safety issues are promptly communicated to health authorities, healthcare providers, and the general public.
- **Distribution and Validation:** With over 135 million doses distributed since licensure, ongoing data reaffirm the vaccines' safety and effectiveness in preventing HPV-related diseases.

ACIP (Advisory Committee on Immunization Practices) Recommendations for HPV Vaccination

- **Children and adults aged 9 through 26 years.** HPV vaccination is suggested from age 9, routinely at 11-12, with catch-up vaccination up to age 26 for those not adequately vaccinated.
- **Administration.** Dosing schedules remain unchanged. No pre-vaccination testing (e.g., Pap or HPV testing) is advised.
- **Cervical cancer Screening.** Cervical cancer screening guidelines and recommendations should be followed.
- **Adults aged >26 years.** Catch-up HPV vaccination isn't for adults over 26. Shared clinical decision-making suggested for some aged 27-45. HPV vaccines not approved over 45.
- **Special populations and medical conditions.** The recommendations apply to everyone regardless of risk factors. Delay HPV vaccination during pregnancy, but no need for pregnancy testing before vaccination. Breastfeeding individuals can still get vaccinated.

Immunization Schedule

Eligibility for the HPV vaccine typically includes:

1. Age Range:

- The vaccine is recommended for adolescents and young adults.
- In the United States, it is routinely recommended for females and males starting at age 9 through age 26.

2. Catch-Up Vaccination:

- Individuals who did not receive the vaccine at the recommended age can still catch up through age 26 for females and age 21 for males.
- Catch-up vaccination typically involves a series of doses spaced over several months.

3. Special Populations:

- Certain individuals, such as those who are immunocompromised or have specific medical conditions, may need special consideration or additional doses.
- Consultation with healthcare providers is essential to determine eligibility and appropriate vaccination schedules for these populations.

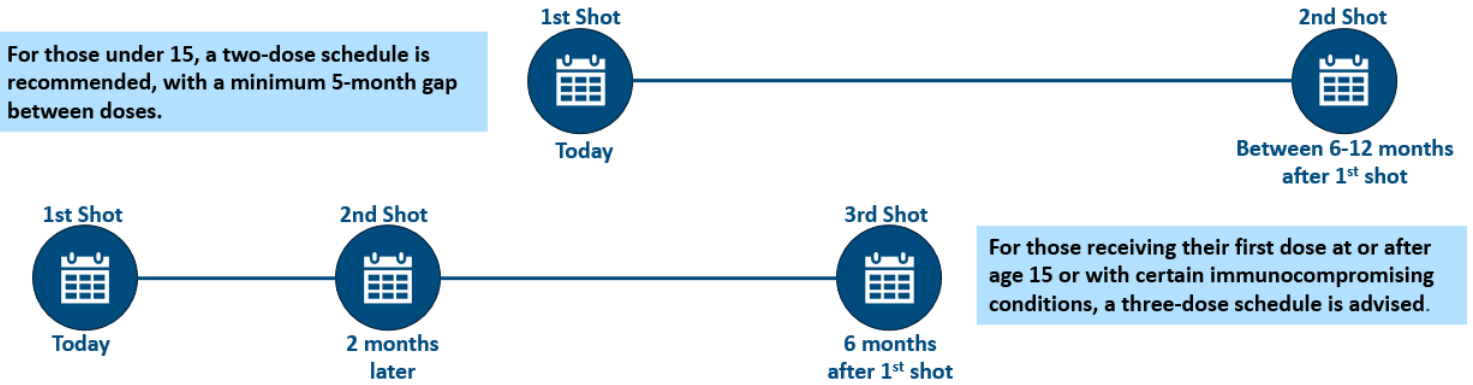
4. Pregnancy Considerations:

- The HPV vaccine is generally not recommended during pregnancy.
- However, pregnant individuals who inadvertently receive the vaccine are not considered to be at increased risk of adverse outcomes.

5. Consultation with Healthcare Providers:

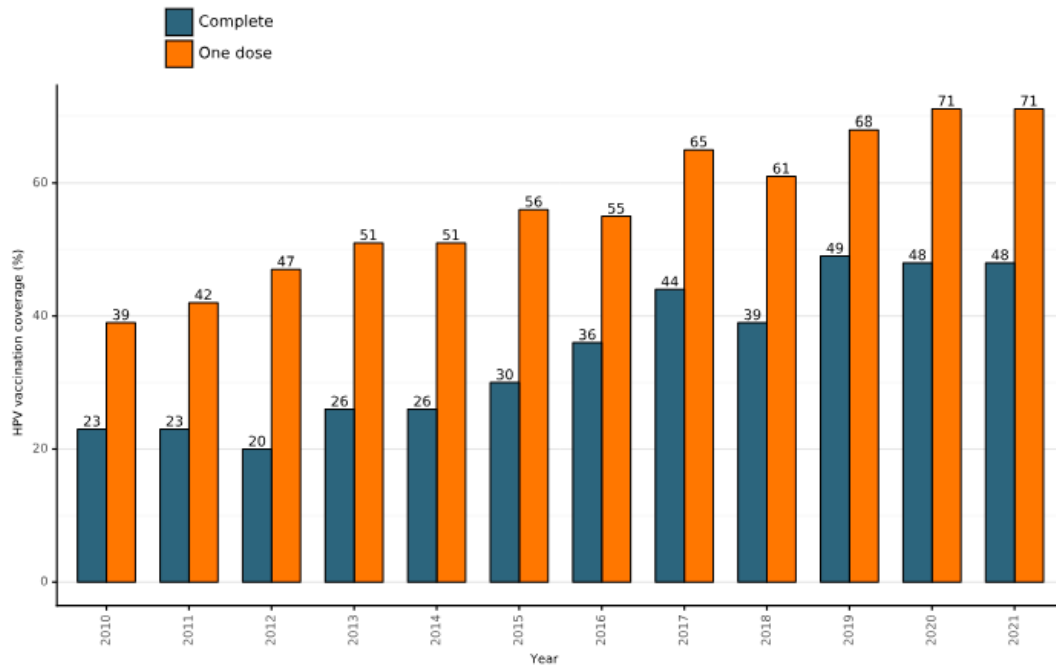
- Healthcare providers play a crucial role in assessing eligibility and recommending the HPV vaccine based on individual health histories and guidelines.
- ❖ Understanding these eligibility criteria ensures that individuals receive the vaccine at appropriate ages and stages of life, maximizing its effectiveness in preventing HPV infections and related diseases.

Routine Vaccination	Age 11-12 years: Can be started at age 9 years
Catch-up Vaccination	Age 13-26 years: If not completely vaccinated
Shared clinical decision making	Some adults age 27-45 years: If not adequately vaccinated

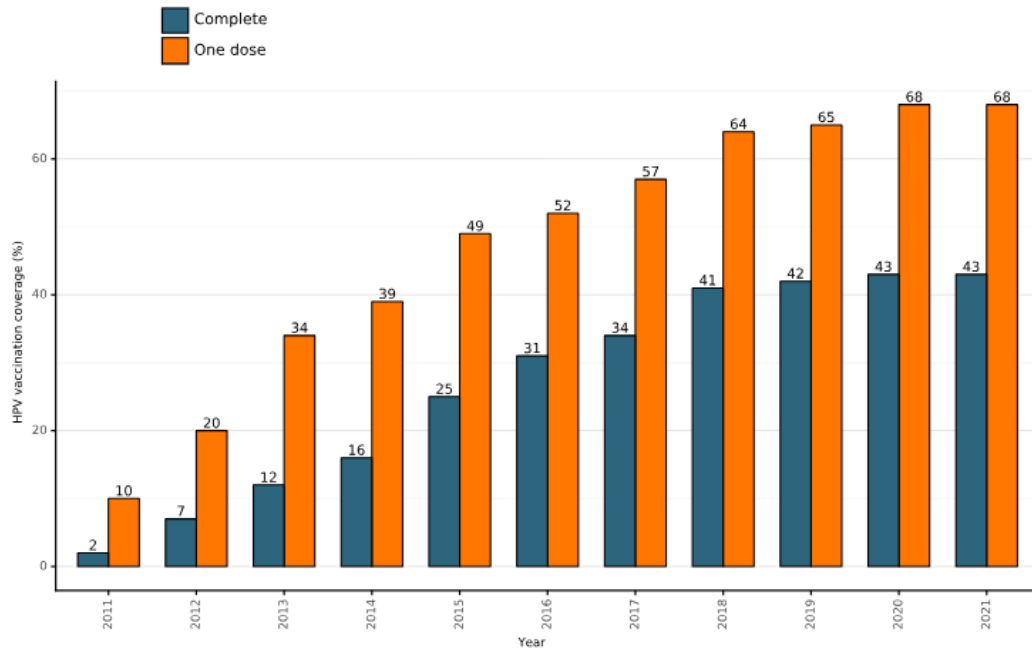


Rate Evolution for HPV Vaccination

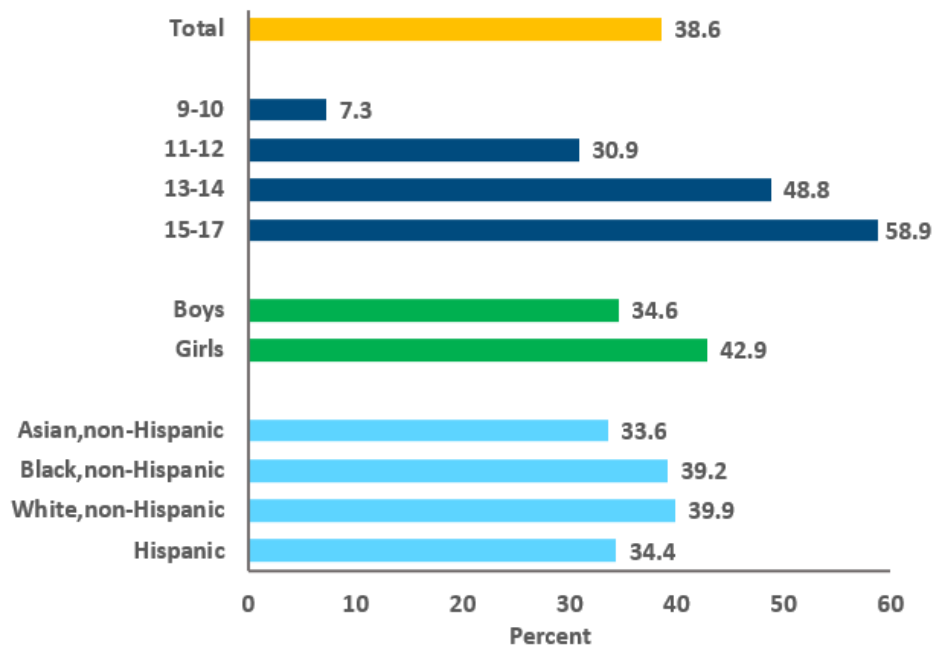
HPV Vaccination Adoption in Females by Year in the United States



HPV vaccination adoption in Males by year in United States of America

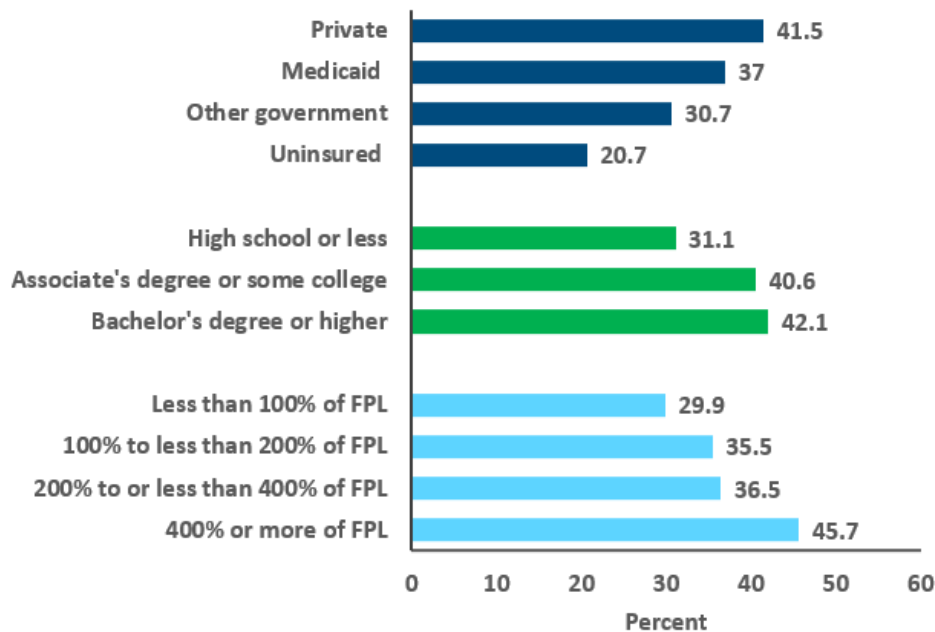


HPV Vaccination Coverage Among Children Ages 9–17 in the United States, 2022: Analyzing by Age Group, Gender, and Race/Ethnicity

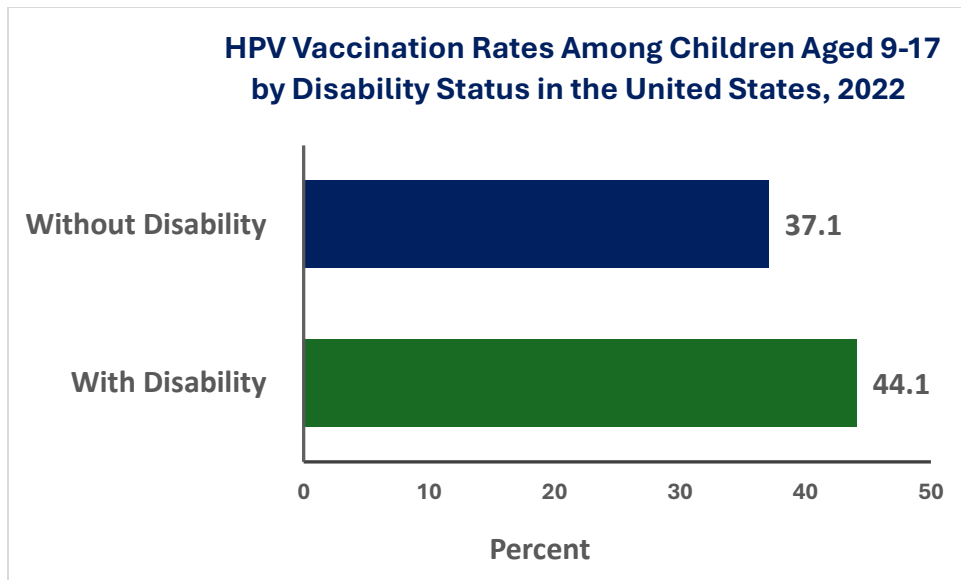


- As of 2022, about 38.6% of children aged 9 to 17 had received at least first dose of the HPV vaccine. The likelihood of getting the vaccine increased with age: only 7.3% of 9-10-year-olds had received it, compared to 30.9% of 11-12-year-olds, 48.8% of 13-14-year-olds, and 56.9% of 15-17-year-olds.
- More girls received the vaccine compared to boys, with 42.9% of girls having received at least one dose, while 34.6% of boys had received it.
- There were also differences among ethnic groups. Hispanic children were less likely to have received the vaccine, with 34.4% vaccinated, compared to 39.9% of White non-Hispanic children. However, no significant differences were found among Asian non-Hispanic, Black non-Hispanic, and other groups of children.

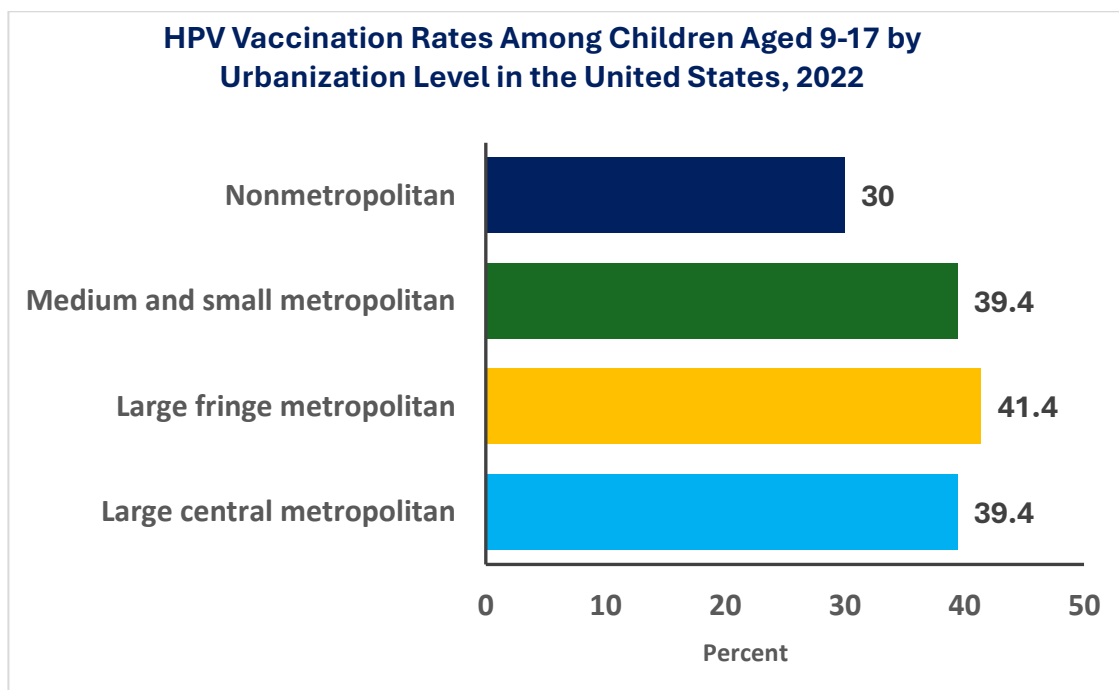
**HPV Vaccination Rates in Children Ages 9–17 in the United States,
2022: Analysis by Child's Health Insurance Coverage, Parental
Education Level, and Family Income**



- ❖ Children without health insurance had the lowest rate of getting at least the first dose of the HPV vaccine. Conversely, rates increased among children whose parents had higher education levels and household income.
- ❖ Children covered by private health insurance had the highest vaccination rates at 41.5%, compared to 37.0% for those on Medicaid, 30.2% for those with other government insurance, and only 20.7% for uninsured children. Medicaid-insured children were more likely to be vaccinated than uninsured ones, but differences between Medicaid and other government insurance were not significant.
- ❖ Vaccination rates also rose with parental education: 31.1% for parents with a high school education or less, 40.6% for parents with some college or an associate's degree, and 42.1% for parents with a bachelor's degree or higher.
- ❖ Similarly, children from higher-income families were more likely to be vaccinated. Only 29.9% of children from families below the poverty level received the vaccine, compared to 45.7% from families earning 400% or more above the poverty level.



- ❖ The rate of HPV vaccination varied depending on disability status. More often, kids with disabilities were the ones who got the vaccine, with 44.1% vaccinated compared to 37.7% of children without disabilities.



- ❖ HPV vaccination rates varied by urbanization level. Children in big city centers (39.4%), suburban areas near cities (41.1%), and medium to small cities (39.4%) were more likely to get the HPV vaccine than those living in rural areas (30.0%).

Gardasil

GARDASIL 9 is a vaccine recommended for individuals aged 9 through 45 years, designed to avert diseases and conditions caused by Human Papillomavirus (HPV) types:

Cancers: Protects against cervical, vulvar, vaginal, anal, oropharyngeal, and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58.

Genital Warts: Prevents genital warts caused by HPV types 6 and 11.

Precancerous or Dysplastic Lesions: Provides protection against HPV-related precancerous or dysplastic lesions, including:

- Mild cervical cell changes (Cervical Intraepithelial Neoplasia, or CIN, Grade 1), moderate to severe changes (CIN Grade 2/3), and early glandular cell abnormalities (Adenocarcinoma In Situ, AIS).
- Moderate to severe cell changes on the vulva (VIN, Grade 2 and Grade 3).
- Moderate to severe cell changes in the lining of the vagina (Vaginal Intraepithelial Neoplasia, VaIN, Grade 2 and Grade 3).
- Mild, moderate, and severe cell changes in the lining of the anus (AIN, Grades 1, 2, and 3).

This vaccine is indicated for both males and females to prevent HPV-related cancers, genital warts, and precancerous lesions within the specified age range.

Limitations of Use and Effectiveness:

- **Screening Recommendation:** Even if vaccinated with GARDASIL 9, it's important to follow healthcare providers' advice for regular screenings for cervical, vulvar, vaginal, anal, oropharyngeal, and other head and neck cancers.
- **Limits of Protection:** GARDASIL 9 does not prevent diseases caused by HPV types not included in the vaccine or those already acquired through sexual activity.
- **Scope of Protection:** Not all cancers of the vulva, vagina, anus, oropharynx, and other head and neck areas are caused by HPV. GARDASIL 9 specifically targets cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58.
- **Not a Treatment:** GARDASIL 9 does not cure external genital warts or cancers such as cervical, vulvar, vaginal, anal, or oropharyngeal cancers. It also does not treat pre-cancerous conditions like cervical intraepithelial neoplasia, vulvar intraepithelial neoplasia, vaginal intraepithelial neoplasia, or anal intraepithelial neoplasia.

DOSAGE AND ADMINISTRATION

Dosing Schedule 		
Patient 9-14 years	Regimen	Schedule
	2-dose	0,6,12 ,months
	3-dose	0,2,6,months
Patient 15-45 years	Regimen	Schedule
	3-dose	0,2,6,months

If the 2-dose is given less than 5 months after the 1-dose, then a 3-dose should be administered at least 4 months after the second one.

0.5 milliliters of injection suspension available in a single-dose vial and prefilled syringe.

Contraindications:

Severe allergic reactions, including those to yeast (an ingredient in the vaccine), or after a previous dose of GARDASIL 9 or GARDASIL, may occur.

Adverse Drug Reactions :

The most frequent ($\geq 10\%$) local and systemic adverse reactions reported across different age groups are as follows:

- Injection-site reactions: Common reactions include pain at the injection site, reported in:
 - Women aged 9 to 26 years: Pain (89.3% to 89.9%), swelling (40.0% to 47.8%), and erythema (16.9% to 34.1%).
 - Boys and men aged 9 through 26 years: Pain (63.4% to 71.5%), swelling (20.2% to 26.9%), and erythema (20.7% to 24.9%).
- Systemic reactions: Headache is commonly reported across all groups, with percentages ranging from 11.4% to 14.6%.

Pricing and Reimbursement Landscape

The listed price for each dose of GARDASIL 9 is \$286.78. However, the actual amount paid by individuals can vary significantly depending on factors such as insurance coverage, impacting out-of-pocket costs.

Coverage of GARDASIL 9 under Commercial or Private Insurance:

Patients with commercial insurance or private policies, such as those through employers, had no out-of-pocket costs for GARDASIL 9 in 98.7% of cases. Among those who did pay, 80% spent between \$0.01 and \$322 per shot.

Coverage of GARDASIL 9 under Medicare:

For patients with Medicare coverage, 96.1% incurred no out-of-pocket expenses for GARDASIL 9. Among those who did, 80% paid between \$0.01 and \$290.45 per shot.

Coverage of GARDASIL 9 under Medicaid:

Medicaid coverage meant that in 99.7% of cases, patients faced no out-of-pocket costs for GARDASIL 9. Among those who did have expenses, 80% paid between \$0.01 and \$345 per shot.

Without Insurance

Without insurance coverage or if insurance does not include GARDASIL 9 vaccination, individuals may be required to pay an amount closer to the listed price, along with any additional charges based on the vaccination location.

- ❖ The USFDA has approved three HPV vaccines: Gardasil 9 (9-valent HPV vaccine), Gardasil (quadrivalent HPV vaccine), and Cervarix (bivalent HPV vaccine). All three vaccines provide protection against HPV types 16 and 18, which are responsible for most HPV-related cancers.
- ❖ Since late 2016, only Gardasil-9 (9vHPV) has been available in the United States. This vaccine provides protection against nine types of HPV: 6, 11, 16, 18, 31, 33, 45, 52, and 58.

GSK Withdraws Cervarix HPV Vaccine from the US Market

Reason being - Because of "very low market demand," GlaxoSmithKline has chosen to pull its HPV vaccine Cervarix from the U.S. market, leaving Merck as the primary player in this sector. This move comes as public health officials ramp up efforts to raise vaccination rates.

Cervarix entry and exit: Cervarix, launching 3 years after Gardasil in 2009, was unable to gain significant market share due to late entry and a suboptimal label (lack of genital wart indication, approval for females only, lesser serotype coverage, and lack of cross-protection data thought to be a key differentiator by GSK. Lifecycle management activities did not adapt to the evolving needs of the market as those of Gardasil did, such as the need to vaccinate males. Therefore, Cervarix was voluntarily withdrawn from the market in 2016.

OVERCOMING UNMET NEEDS

Next Generation: Merck secured leadership in HPV market due to robust LCM strategy, well established pipeline, evolving narrative from 'STI prevention' to 'cancer prevention', 'prevention of genital warts in teens' and a strong alignment with CDC groups. Gardasil 9 entered the market with benefits such as reduced dosing, expanded sero-coverage and with its use in both male and female indications, it was quickly adopted amongst HCPs within 2 years of launch. Although HPV IZ rates have improved in recent years (1 dose reaching 75% in 2020), series completion is still an issue, with only 55% receiving 2 or 3 doses. However, with its dose reduction from 3 to 2 doses and further anticipated transition to a one dose-series in future, Merck has been focused on expanding the market by improving vaccination rates .

HPV vaccines guard against the types of viruses responsible for most cancers and genital warts. They work best when administered early, prompting the American Cancer Society to advise vaccination for children aged 9 to 12 for optimal immune defense.

While more than 60% of boys and girls in the U.S. receive atleast one dose of the vaccine, many do not complete the full recommended dosing necessary for protection against cancer. The CDC reports that vaccination rates for adolescents getting at least one dose have been steadily rising since 2012.

American Cancer Society's Goal: The HPV Cancer Free initiative aims to eradicate HPV-related cancers that can be prevented with vaccines, starting with cervical cancer, as a crucial public health objective. Our aim is to ensure that 80% of 13-year-olds in the United States receive the HPV vaccine annually by 2026.

To achieve this goal, our efforts include:

Providing training and education for healthcare providers.

Collaborating with key stakeholders and partners to enhance vaccination rates.

Advocating for the use of data-driven strategies to guide planning and effectiveness.

Taking a leadership role in HPV vaccination initiatives within healthcare systems.

Enhancing parental understanding of the vaccine through various media channels and mobilizing our ACS volunteer network to disseminate evidence-based information about HPV vaccination.

➤ **National HPV Vaccination Roundtable :**

Started in 2014 by the American Cancer Society and the CDC, the National HPV Vaccination Roundtable works to increase HPV vaccination rates and fight HPV-related cancers in the United States. Our shared vision is a future where HPV cancers are preventable, alleviating countless families from unnecessary emotional, physical, and financial hardships.

- In 2020, every country in the WHO agreed to the Global Strategy for Eliminating Cervical Cancer at the World Health Assembly. This historic endorsement marked the first-ever strategy for eliminating a type of cancer in WHO's history.

The strategy lays out three worldwide goals to prevent and treat cervical cancer:

- By 2030, ensure 90% of girls receive full HPV vaccination by age 15.
- Implement high-performance screening for 70% of women at ages 35 and 45.
- Ensure 90% of individuals diagnosed with cervical carcinoma gets appropriate treatment.

These updated recommendations provide essential guidance to countries, supporting efforts to meet screening and treatment targets of 70-90%. Increased awareness and adoption of these guidelines will promote fairness, expand access to services, and improve women's health, crucially reducing the global impact of cervical cancer.

UPCOMING THERAPIES : Future prospects

Inovio Pharmaceuticals is conducting Phase 3 trials to test VGX-3100 for treating cervical precancerous lesions and eliminating the HPV infection causing them. The REVEAL studies include women with confirmed HPV 16/18-positive cervical HSIL. REVEAL 1 is collecting one-year safety data from at least 198 patients using VGX-3100, while REVEAL 2 is enrolling participants to gather one-month safety data from at least 198 patients.

The primary goal of these Phase 3 trials is to reduce cervical HSIL and eliminate HPV 16 and/or HPV 18 from the cervix. The researchers are going to look at what happens to the tissue in the cervix around 9 months after people get three doses of VGX-3100. They'll give the doses at months 0, 1, and 3. Besides that, they also want to see if it's safe and well-tolerated, and if it can help reduce CIN 2/3 to CIN 1 or normal tissue. They're also interested in seeing if it can clear HPV infections, stop cancer from getting worse, and get rid of HPV in other areas besides the cervix.

Inovio Pharmaceuticals ran Phase 3 clinical tests REVEAL 1 and REVEAL 2, to check how well and their investigational HPV therapeutic vaccine VGX-3100 works.

REVEAL 1:

- REVEAL 1 is a Phase 3 clinical trial that learns if VGX-3100 is safe and works in treating cervical HSIL. These HSILs are the early signs of cervical cancer from HPV 16 and HPV 18.
- It involves a prospective, randomized (2:1), double-blind, placebo-controlled study design.
- REVEAL 1 aims to check if cervical HSIL goes down and if HPV 16 and HPV 18 can be removed from the cervix.
- Participants receive three doses of VGX-3100 at months 0, 1, and 3, with evaluations about 9 months after the first dose.

REVEAL 2:

- REVEAL 2 is another Phase 3 clinical trial that serves as a confirmatory study following REVEAL 1.
- It aims to provide additional safety and efficacy data for VGX-3100 in treating HPV 16 and/or HPV 18-associated cervical HSIL.
- Similar to REVEAL 1, REVEAL 2 employs a prospective, randomized (2:1), double-blind, placebo-controlled study design.
- The main goal of REVEAL 2 is to see if cervical HSIL regresses and if HPV 16 and/or HPV 18 are cleared from the cervix.
- Participants in REVEAL 2 receive the same three-dose regimen of VGX-3100 as in REVEAL 1, with assessments conducted at approximately 9 months post-treatment initiation.

These trials are crucial in evaluating the potential of VGX-3100 as a therapeutic option to treat HPV-associated cervical HSIL and reduce the risk of progression to cervical cancer.

Therapeutic Method:

We will discuss two vaccines aimed at fighting HPV infections and diseases connected to them. The first vaccine VGX-3100, serves as an experimental treatment for HPV 16 and/or HPV 18 infections that lead to high-grade squamous intraepithelial lesions in the cervix. It boosts the body's immune system to detect and destroy HPV-infected cells.

Gardasil stands as a preventive vaccine aiming at HPV types 16 18, and more. It's for people who haven't faced exposure to these HPV types aiming to block the first infection and the later rise of cervical cancer and other HPV-linked diseases.

Target Population:

Discussing the intended users, VGX-3100 addresses those already infected with HPV types 16 and 18 who have HSIL. It presents a possible treatment choice to stop developing into cervical cancer.

Gardasil aims to protect people who have not encountered HPV types 16 18, and others. It helps prevent the first occurrence of infections seeking to lower the rate of cervical cancer and other diseases linked to HPV.

Clinical Application:

The way these vaccines are used differs in some respects. VGX-3100 is a series of shots for people who already are infected with HPV and have HSIL. It strives to lessen HPV disease effects by removing infected cells and might help people avoid harsher procedures like surgery.

Gardasil gets given to young people and adolescents before they might encounter HPV. It is a part of vaccination programs that aim to stop HPV-linked cancers and diseases before they can start.

Complementary Role:

VGX-3100 and Gardavirus serve different medical purposes (therapeutic vs. preventive), but they help each other in fighting HPV-related illnesses. VGX-3100 may help those already infected with HPV and at risk for cancerous lesions. Meanwhile, Gardasil works on blocking the first infection of HPV and the further development of the disease.

VGX-3100 offers a hopeful treatment method for HPV infections and linked cancers in people already infected with HPV types such as 16 and 18. It serves a different purpose than Gardasil, a vaccine designed to lower the number of HPV-related diseases by blocking the first infection. Combined, these actions help build complete plans to fight HPV and its linked health dangers.

Future Outlook for Gardasil:

1-Merck recently spilled the beans about their upcoming clinical trials for a brand new HPV vaccine they've been working on. The goal of this vaccine is to provide a wider shield against multiple types of HPV. Not only that, but they're also planning to carry out trials with both females and males. Their aim is to evaluate how safe and effective a single-dose regimen of GARDASIL®9 is compared to the current three-dose regimen that's already approved.

2- Merck's vaccine researchers are progressing the development of GARDASIL and GARDASIL 9 by exploring new candidates aimed at providing broader protection against a wider range of HPV types. Their latest approach involves using Merck's advanced virus-like particle (VLP) technology to incorporate additional VLPs, with a focus on HPV types that are more prevalent among African and Asian populations, including those of African and Asian descent. Phase 1 clinical trials for these new candidates are set to begin in late 2024.

3- To meet increasing global demand for GARDASIL and GARDASIL 9 and ensure wider availability, Merck has made substantial investments in expanding manufacturing. Starting in 2019, the company focused on boosting production capacity by expanding current facilities and building new ones. This initiative led to nearly doubling supply from 2017 to 2020, followed by another doubling from 2020 to 2024. Merck expects to provide ample quantities of HPV vaccines to meet projected demand in 2025 and intends to continue expanding production capacity in the future.

Key Findings

Vaccination Rates and Demographics

The HPV vaccination rates in the United States have been gradually increasing, but they still haven't reached the desired levels set by public health authorities. When we look at the immunization rates, we see some significant differences based on age, gender, and ethnicity. The highest vaccination rates are among preteens and adolescents, which aligns with the recommendations from the CDC. However, there is a noticeable decline in vaccination rates among the catch-up age group of 18 to 26 years old. As for gender disparities, females have higher vaccination rates compared to males, although this gap is closing because the updated guidelines now emphasize the importance of vaccinating everyone, regardless of gender. We also see ethnic disparities, with lower vaccination rates among minority populations, especially within Hispanic and African American communities. This reflects broader issues of healthcare access and fairness.

Market Leadership and Product Dominance

When it comes to the HPV vaccine market in the USA, Gardasil, made by Merck & Co., continues to be the top choice. This is because Gardasil offers comprehensive protection against multiple HPV strains and has proven to be highly effective in clinical trials. Its ability to prevent a wide range of HPV-related diseases has made it the preferred option for both healthcare providers and patients. There is another vaccine called Cervarix, but it holds a much smaller share compared to Gardasil. Gardasil's strong position in the market is further strengthened by ongoing public health initiatives and endorsements from major health organizations.

Emerging Therapies and Future Innovations

The HPV vaccine market is set to grow with the development of new therapies, such as VGX-3100. This promising therapeutic vaccine aims to treat existing HPV infections and related conditions. It represents a significant advancement in the field, offering potential therapeutic benefits for individuals already affected by HPV. Researchers are also working on expanding the coverage of existing vaccines to protect against a wider range of HPV strains. This will enhance the overall effectiveness of the vaccines and have a greater impact on public health. These innovative approaches are expected to address some of the current limitations of HPV vaccination and provide new ways for prevention and treatment.

Addressing Unmet Needs

Despite the progress made, there are still some unmet needs in the HPV vaccination landscape. One of the main challenges is increasing vaccination rates among underserved populations, including those in rural areas, low-income groups, and certain ethnic minorities. These populations often face barriers when it comes to accessing healthcare. To overcome vaccine hesitancy, which is often fueled by misinformation, it is crucial to raise public awareness and educate people about the benefits and safety of the HPV vaccine. Additionally, improving healthcare infrastructure and implementing outreach programs are essential to ensure that the vaccine is distributed more widely and fairly. Addressing these unmet needs requires collaborative efforts from policymakers, healthcare providers, and community organizations.

Public Health and Policy Implications

The study emphasizes the significance of HPV vaccination, in preventing HPV related illnesses, such as cancer. Higher vaccination rates are linked to a decrease in the occurrence of these illnesses showcasing the vaccines effectiveness as a public health measure. The cost effectiveness of HPV vaccination initiatives is clear as they lessen the long term strain on healthcare systems by averting treatments for HPV related conditions. Recent updates to vaccination recommendations advocating for universal vaccine usage across all genders are anticipated to drive up vaccination rates and improve health outcomes. Implementing policies like offering discounted vaccinations plays a crucial role in enhancing accessibility and coverage especially for marginalized communities.

These key revelations shed light on the status and future potential of the HPV vaccine market, in the United States stressing the importance of efforts to enhance vaccination rates address unmet needs and capitalize on emerging therapies to optimize the public health advantages of HPV immunization.

Conclusion

Research on the HPV vaccine market in the US reveals a detailed picture influenced by various demographic elements, market movements, and new breakthroughs. The number of people getting the vaccine is increasing but big differences still exist among different ages, genders, and races or ethnicities. Young people and women often get vaccinated more than men. However, it's important to get more men and minority groups vaccinated for better overall protection. Gardasil leads the market because it works well and many people accept it. Yet new options like VGX-3100 could make the HPV vaccine market bigger by offering more choices for prevention or treatment. These efforts focus on closing gaps like better protection against more HPV types or even dealing with current infections.

However, the market shows gaps among those less served highlighting the need for focused efforts. Thus, there's a demand for more public awareness initiatives, improved access to healthcare, and handling vaccine refusal issues.

The future prospects of the HPV vaccine market, in the United States look bright as continuous research and advancements are anticipated to boost vaccination rates and improve health outcomes. By bridging existing gaps and utilizing treatments stakeholders can amplify the effectiveness of HPV vaccination initiatives ultimately lessening the prevalence of HPV linked illnesses among demographic groups.

References

1. Centers for Disease Control and Prevention (CDC). (2021). HPV vaccination coverage data. Retrieved from <https://www.cdc.gov/hpv/parents/vaccine.html>
2. Food and Drug Administration (FDA). (2020). Gardasil 9 (human papillomavirus 9-valent vaccine, recombinant) approval history <https://www.fda.gov/vaccines-blood-biologics/vaccines/gardasil-9>
3. American Cancer Society (ACS) HPV vaccines. <https://www.cancer.org/cancer/types/cervical-cancer/about.html>
4. Cheng, Liqin, Yan Wang, and Juan Du. "Human Papillomavirus Vaccines: An Updated Review." *Vaccines*, vol. 8, no. 3, 2020 <https://www.mdpi.com/2076-393X/8/3/391>
5. Fokom Domgue, Joël, Robert K. Yu, and Sanjay Shete. "Trends in the Rates of Health-Care Providers' Recommendation for HPV Vaccine from 2012 to 2018: A Multi-Round Cross-Sectional Analysis of the Health Information National Trends Survey." *Human Vaccines & Immunotherapeutics*, 2021 <https://pubmed.ncbi.nlm.nih.gov/34085904/>
6. Kahn, Benjamin Z., et al. "Getting Human Papillomavirus Vaccination Back on Track: A National Survey." *Journal of Adolescent Health*, 13 Mar. 2023 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10010471/>
7. Stefanos, Ruth, et al. "High Impact of Quadrivalent Human Papillomavirus Vaccine Across Racial/Ethnic Groups: National Health and Nutrition Examination Survey, 2003–2006 and 2015–2018." *Human Vaccines & Immunotherapeutics*, 19 Feb. 2024 <https://pubmed.ncbi.nlm.nih.gov/38372273/>
8. Merck & Co. (n.d.). Gardasil: Human papillomavirus quadrivalent (types 6, 11, 16, and 18) vaccine, recombinant. Retrieved June 27, 2024, from https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf
9. FiercePharma. (2020, November 20). GSK exits U.S. market with its HPV vaccine Cervarix. FiercePharma. Retrieved June 27, 2024, from <https://www.fiercepharma.com/pharma/gsk-exits-u-s-market-its-hpv-vaccine-cervarix>
10. Inovio Pharmaceuticals. (2021, April 13). INOVIO highlights key updates on Phase 3 program for VGX-3100, its DNA-based immunotherapy for the treatment of cervical HSIL caused by HPV-16 and/or HPV-18. Retrieved June 27, 2024, from <https://tinyurl.com/uamfafff>
11. Centers for Disease Control and Prevention. (n.d.). HPV vaccination: Dosage and schedule. Retrieved June 27, 2024, from <https://www.cdc.gov/vaccines/vpd/hpv/hcp/administration.html>