

SYNOPSIS

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“HPV Vaccine Market Trends in United States”

Introduction

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.

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. With increased vaccine coverage and the implementation of pan-gender vaccination programs, enhanced protection against HPV and a decrease in HPV-related cancer cases are anticipated. Achieving this goal requires educational efforts to highlight the risks of HPV and the benefits of vaccination, particularly in low- and middle-income countries. Reducing side effects through alternative adjuvants or new vaccine designs will help increase acceptance and vaccination rates among young people. However, HPV types not covered by current vaccines remain prevalent among young females. Future HPV vaccines should aim to offer broad-spectrum protection through high-valent formulations. Additionally, it is important to conduct studies or clinical trials to assess the impact of HPV vaccination on all HPV-related cancers. Therapeutic vaccines hold great promise for treating cancers and are crucial for comprehensive HPV infection management, from prevention to 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 findings indicate that trends in healthcare providers' recommendations for the HPV vaccine among U.S. 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 sample comprised 71% physicians, 17% physician assistants and nurse practitioners, and 12% nurses. The majority had been practicing for 10 or more years (76%) and typically saw

10 or more adolescent patients per week (73%). Primary care providers mainly worked in clinics specializing in family medicine (64%) or pediatrics (29%). Most served urban (35%) or suburban (50%) areas, with a smaller portion working in rural areas (15%). Over half of the participants were employed in clinics that were part of a healthcare system (56%), and two-thirds (66%) reported that their clinics faced moderate to high financial strain due to the COVID-19 pandemic. Demographically, nearly half of the respondents were women (49%) and the majority were white (68%); primary care providers from all four U.S. census regions were included in the sample.

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 of the HPV vaccine's introduction, there has been a significant decrease in cervicovaginal 4vHPV-type prevalence, demonstrating the vaccine's substantial impact across all evaluated racial and ethnic groups. 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.

Research Questions

- 1.What are the current trends in HPV vaccine immunization rates and schedules in the United States, and how effective are these in preventing HPV infections, considering ACIP recommendations and the existing unmet needs around vaccination?
2. What are the key challenges and future outlook for the HPV vaccine market in the United States, including the impact of current trends, immunization rates, and schedules on HPV infection prevention, as well as potential strategies to address unmet needs and improve vaccine uptake?

Objectives

1. Analyze current HPV vaccine immunization rates across different demographics and regions in the United States.
2. Evaluate adherence to recommended HPV vaccination schedules and their effectiveness in preventing HPV infections.
3. Review ACIP recommendations for HPV vaccination and their impact on immunization practices.

4. Identify unmet needs and barriers to HPV vaccination, including socio-economic, cultural, and logistical challenges.
5. Evaluate the overall impact of HPV vaccination programs on public health, particularly in reducing HPV-related infections and cancers.
6. Predict future trends and opportunities in the HPV vaccine market, considering potential advancements in vaccine technology and policy changes.
7. Propose strategies to enhance HPV vaccine uptake and address identified gaps in vaccination coverage and public awareness.

Research Methodology

1. Research Design

- Descriptive Research: To analyze current immunization rates, vaccination schedules, and market trends related to HPV vaccines.
- Exploratory Research: To investigate Advisory Committee on Immunization Practices (ACIP) recommendations, unmet needs, and future outlook in the HPV vaccine market.

2. Inclusion Criteria

- Healthcare providers, vaccine manufacturers, policymakers, and public health officials involved in HPV vaccination programs in the United States.
- Studies and reports published in the last 10 years (2014-2024) to ensure relevance and timeliness.

3. Exclusion Criteria

- Studies not conducted in the United States.
- Studies focused solely on non-human subjects or non-HPV related vaccines.
- Studies lacking sufficient data or clear methodology.

4. Data Collection

- Secondary Data Collection Methods:
 - Review of literature, reports, and statistical data from credible sources such as:
 - Centers for Disease Control and Prevention (CDC)

- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- World Health Organization (WHO)
- Peer-reviewed journals and academic publications.
- Keyword searches: "HPV vaccine market trends," "HPV vaccination rates," "ACIP recommendations HPV vaccine," "HPV vaccine effectiveness," "HPV-related cancers prevention," etc.

5. 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.

6. Ethical Considerations

- Ensuring confidentiality and anonymity of participants.
- Obtaining informed consent from all participants involved in primary data collection.

Implications of Research

This research will provide policymakers with evidence-based strategies to enhance vaccination uptake and shape national health policies. Healthcare providers can optimize vaccination schedules and improve patient education to boost vaccination rates and reduce HPV-related disease burden. Public health officials can use these strategies to overcome barriers to vaccination and improve access, especially in underserved communities. Educational initiatives aimed at healthcare professionals and the public can increase awareness about HPV vaccination benefits. Identifying research gaps can guide future studies on vaccine effectiveness, economic impact, and global health implications, ensuring effective strategies to combat HPV-related diseases worldwide through collaborative efforts among stakeholders.

Ethical Considerations

1. Ensuring the confidentiality and anonymity of data sources to protect privacy.
2. Adhering to ethical guidelines and avoiding biases in data interpretation.
3. Acknowledging and addressing potential conflicts of interest in the selection and analysis of secondary sources.
4. Respecting cultural sensitivities and ensuring accurate representation of diverse perspectives in the findings.

References

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