Original Research

Evidence-Based Efficacy and Recommendations for HPV Vaccination in International and National Practice

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Abstract

Background: Human papillomavirus (HPV) is a major causative agent of cervical cancer and other anogenital and oropharyngeal malignancies. Prophylactic vaccination against HPV has proven effective in preventing high-risk HPV infections and their associated precancerous and cancerous lesions.

Objective: This article presents a comparative review of the immunogenicity, efficacy, and safety profiles of the quadrivalent (Gardasil 4) and nonavalent (Gardasil 9) HPV vaccines. It synthesizes current clinical guidelines from major health authorities and professional societies in the United States and Europe, and discusses updated national vaccination strategies, with a focus on recent policy changes in Georgia

Methods: A systematic literature search was conducted in PubMed, Cochrane Library, PMC, CDC, and Merck databases for publications from 2019 to 2025. Only peer-reviewed articles and official guidelines were included.

Results: Both Gardasil 4 and Gardasil 9 demonstrate equivalent protection against HPV types 6, 11, 16, and 18. Gardasil 9 induces a stronger immune response against five additional oncogenic types (31, 33, 45, 52, 58) and shows higher immunogenicity in the 9–15 age group compared to older cohorts. Network meta-analyses confirm significant reductions in CIN2+ lesions associated with HPV 16 and 18 following vaccination. Recent WHO and ECDC guidelines increasingly favor Gardasil 9 and support simplified dose regimens, including one-dose strategies for population-wide coverage. In Georgia, HPV vaccination is now freely available to females aged 10–45 and males aged 10–26 under a revised national program.

Conclusion: Gardasil 9 is the preferred vaccine for broad-spectrum HPV protection. Updated guidelines and evidence support a two-dose schedule for adolescents and a three-dose schedule for older or immunocompromised individuals. Georgia's expanded HPV vaccination program aligns with global efforts to achieve cervical cancer elimination through equitable access and optimized vaccine strategies.

Key Words: Human papillomavirus (HPV), Prophylactic vaccination, Immunogenicity, Vaccine efficacy, Vaccine safety, HPV elimination strategy, Gardasil.

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Introduction

Human papillomavirus (HPV) is a leading etiological factor in the development of cervical cancer, genital warts, and several anogenital and oropharyngeal malignancies. To date, more than 400 types of HPV have been identified. According to the World Health Organization (WHO), HPV is responsible for approximately 5% of all cancer cases. Persistent and recurrent benign lesions, such as genital and common warts, are even more prevalent. HPV is resistant to many disinfectants and relatively stable under environmental conditions. Currently, no antiviral treatment exists that can inhibit viral replication; management is based on lesion removal or stimulation of the host immune response [1].

Virtually all sexually active individuals become infected with HPV at some point in their lives, and in most cases the infection is asymptomatic. Condom use can reduce the risk of transmission but does not provide complete protection, as it does not fully cover the skin of the genital area.

In approximately 90% of cases, the human immune system is capable of clearing the infection without intervention. However, persistent infection with high-risk oncogenic HPV types is the principal cause of cervical cancer and is also associated with cancers of the vulva, vagina, oral cavity/pharynx, penis, and anus [2].

In some cases, HPV infection leads to the development of anogenital warts. In other instances, it may trigger the formation of atypical cells that can progress to cancer.

According to global statistics, HPV was responsible for 620,000 new cancer cases in women and 70,000 in men in 2019 [2]. Cervical cancer remains the fourth most common cancer among women worldwide; in 2020, there were 604,000 new cases and approximately 342,000 deaths, around 90% of which occurred in low- and middle-income countries. The highest rates of incidence and mortality are observed in sub-Saharan Africa, Central America, and Southeast Asia. Regional disparities in cervical cancer burden are linked to inequalities in access to vaccination, screening, and treatment, as well as risk factors such as HIV prevalence, gender and social biases, and poverty.

Women living with HIV have a six-fold increased risk of cervical cancer compared to the general population, and HIV is implicated in approximately 5% of all cervical cancer cases. HIV has a disproportionately large impact on younger women, and in about 20% of cases where children lose their mothers to cancer, cervical cancer is the cause.

Persistent HPV infection of the cervix (the lower part of the uterus opening into the vagina) causes approximately 95% of cervical cancer cases if left untreated. The transformation of abnormal cells into carcinoma typically takes 15–20 years, but among immunocompromised women, such as those with untreated HIV infection, this process can accelerate to 5–10 years. Risk factors for progression include HPV oncogenicity, immune status, co-existing sexually transmitted infections, high parity, early age at first pregnancy, hormonal contraceptive use, and smoking [3].

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To date, more than 400 HPV types have been identified, accounting for 5% of all cancers globally (WHO). Persistent benign lesions such as genital warts and common verrucae are even more prevalent. HPV is resilient to many disinfectants and relatively resistant to environmental conditions. There are no antiviral drugs targeting HPV replication; current treatments focus on lesion removal or enhancement of the host's immune response [4].

HPV-related cancers can be prevented via vaccination (Vaccines to Treat Human Papillomavirus Could Be a Significant Innovation in the Fight Against Cervical Cancer [10].

Three vaccines are commonly available:

- **Cervarix** – bivalent (HPV types 16 and 18),
- **Gardasil 4** – quadrivalent (HPV types 6, 11, 16, 18),
- **Gardasil 9** – nonavalent (includes additionally types 31, 33, 45, 52, 58).

Since the introduction of bivalent and quadrivalent vaccines in 2006, clinical trials and post-licensure studies have demonstrated their high effectiveness in preventing high-risk HPV infections, precancerous lesions, and invasive cancers [6]. These prophylactic vaccines are most effective when administered before exposure—typically during adolescence. They are not therapeutic for those already infected or with established HPV-related lesions; however, they may help prevent new infections with different types or re-infection with the same type [7].

Nevertheless, therapeutic vaccines based on HPV peptides show limited efficacy: only about 54% of women with advanced cervical intraepithelial neoplasia (CIN 2/3) experienced lesion regression in phase II/III trials [8].

Currently, two recombinant vaccines are in use:

Bivalent *Cervarix* (HPV 16/18) [9],

Nonavalent *Gardasil 9* (types 6, 11, 16, 18, 31, 33, 45, 52, 58) [5].

Gardasil 9 has largely replaced the earlier quadrivalent vaccine and represents a critical tool for reducing cervical cancer burden by preventing infections with oncogenic HPV types associated with disease progression.

Objective of this article: To review, analyze, and summarize current clinical recommendations for implementing population-wide HPV vaccination programs. By synthesizing guidelines from leading oncology and gynecology societies in the USA and Europe, this review aims to provide updated strategic insights into cervical cancer prevention through effective vaccination programs.

Materials and Methods

A systematic search was conducted using databases including PubMed, PMC, Cochrane and the CDC. Key search terms included "Cervarix," "Gardasil 4," "Gardasil 9," and "HPV vaccine efficacy," covering the period from 2019 to 2024. Non-peer-reviewed sources and review articles were excluded from the analysis.

Review of HPV Vaccination Guidelines

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This review article examines HPV vaccination guidelines issued between 2019 and 2025, focusing on several key parameters: the optimal age for initiating vaccination within the target population, gender inclusivity of the vaccination cohort, and the preferred vaccine regimens and dosing schedules. The review included guidelines published in English and excluded recommendations developed specifically for special populations, such as individuals with immunodeficiencies.

As a result of the search, recommendations from various scientific organizations regarding human papillomavirus (HPV) vaccination were identified. These include guidelines from the Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians, the American Cancer Society, and the American College of Obstetricians and Gynecologists. European bodies such as the European Society of Gynecologic Oncology and the European Federation for Colposcopy were also represented.

Additionally, national guidelines were considered, including those from the U.S. Centers for Disease Control and Prevention (CDC) and immunization advisory committees, as well as global recommendations from the World Health Organization (WHO), which outline international strategic approaches to HPV vaccination.

The primary rationale behind the universal recommendation for HPV vaccination is to enhance protection against HPV infections and thereby reduce the associated risk of cancer development—most notably cervical cancer—which remains a significant public health concern.

Table 1.
List of recommendations included in this study

Organization / Year	Optimal Vaccination Age	Target Sex	Upper Age Limit	Recommended Vaccine	Dosing Schedule
World Health Organization, 2022 [11]	9–14 years	F	20 years	Based on local HPV epidemiology	1 or 2 doses
American Academy of Family Physicians, 2021[12]	11–12 years	F and M	26 years	–	2 doses
Centers for Disease Control and Prevention, 2021 [13]	11–12 years	F and M	26 years	–	2 doses
National Cancer Institute, 2021 [14]	11–12 years	F and M	26 years	–	2 doses
American College of Obstetricians and Gynecologists, 2020 [15]	11–12 years	F and M	26 years	–	–
American Cancer Society, 2020 [16]	9–12 years	F and M	26 years	–	–
Advisory Committee on Immunization Practices, 2019 [17]	11–12 years	F and M	26 years	–	–
ESGO / European Federation for Colposcopy, 2019 [18]	9–13 years	F and M	25 years	–	2 doses

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Vaccination Age and Target Population

Three out of eight reviewed recommendations suggest initiating HPV vaccination at the age of 9, which is the lowest approved age according to the Summary of Product Characteristics for the available vaccines. The majority of the recommendations propose starting vaccination at age 11, and all recent guidelines from 2023 designate age 12 as the optimal point to begin HPV vaccination programs. Conversely, all reviewed recommendations emphasize that vaccination should be administered before the age of 15 to ensure immunity prior to the onset of sexual activity.

Sex of the Target Population

Most recommendations advocate for vaccinating both girls and boys. Only one guideline suggests initiating vaccination exclusively among girls, with male coverage dependent on financial feasibility and the willingness of the female population to participate in vaccination programs.

Upper Age Limit for the Target Population

Most recommendations consistently advocate administering HPV vaccination up to the age of 25–26 years. None of the guidelines reviewed recommend routine vaccination beyond age 26. Notably, all recommendations published in 2023 consistently endorsed the use of Gardasil 9 as the preferred vaccine.

Recommended Vaccination Schedule

As of 2022, all professional societies and public health organizations advised vaccination schedules in accordance with the respective Summary of Product Characteristics. Specifically, children under the age of 15 are recommended to receive a two-dose regimen, whereas those aged 15 and older should follow a three-dose schedule.

In a significant shift, the World Health Organization (WHO) became the first body in 2022 to recommend a one-dose HPV vaccine regimen. This approach, supported by public health data, is deemed to offer comparable individual protection to that of the two-dose schedule, while being simpler to implement. The WHO emphasized that this strategy could accelerate vaccination coverage among girls and lead to faster establishment of community-wide immunity [19].

In some contexts, WHO also considers it appropriate to implement a single-dose schedule regardless of prior planning. Emerging studies suggest that one dose may elicit immune responses comparable to two- and three-dose regimens among adolescents, though longer-term data are still under investigation.

Recent studies have confirmed that a single dose of the HPV vaccine can elicit an immune response comparable to that of two- or three-dose regimens in adolescent populations. However, long-term data regarding the durability of protection are still being clarified.

Comparative Efficacy of HPV Vaccines

According to the 2020 guidance from the European Centre for Disease Prevention and Control (ECDC) [20], an indirect comparison of the efficacy of available HPV vaccines was conducted.

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Analysis of the immunogenicity of the 9-valent (9vHPV, Gardasil 9) and quadrivalent (4vHPV, Gardasil 4) vaccines revealed the following [20]:

1. Both 9vHPV and 4vHPV vaccines demonstrate comparable efficacy against HPV types 6, 11, 16, and 18.
2. The 9vHPV vaccine induces a stronger immune response against additional HPV types 31, 33, 45, 52, and 58, which are not included in the 4vHPV formulation.
3. Immunogenicity of the 9vHPV vaccine is higher in boys and girls aged 9–15 years compared to women aged 16–26 years.

In the comparison of 4vHPV and bivalent (2vHPV) vaccines, the ECDC report also indicates:

1. Comparable efficacy of 4vHPV and 2vHPV vaccines in both males and females.
2. Higher immunogenicity of both vaccines in boys aged 9–15 years compared to females aged 16–26 years for the specific HPV types included in each vaccine.

Safety

All HPV vaccines have demonstrated a similar safety profile. Local reactions such as pain and redness at the injection site are the most common, while systemic effects like headache and fever are rare and generally mild. No serious adverse events have been reported.

Effectiveness in Preventing Cervical Neoplasia

In a recently published network meta-analysis by Lin et al. (2023) [21], the authors conducted a comparative assessment of the efficacy of HPV vaccination in preventing the development of cervical intraepithelial neoplasia grade 2 and above (CIN2+) associated with HPV infection.

According to the results of this analysis:

- Vaccination with the 2vHPV vaccine compared to placebo significantly reduced the risk of CIN2+ associated with HPV type 16 by 94% (RR = 0.06; 95% CI: 0.02–0.19), and with HPV type 18 by 92% (RR = 0.08; 95% CI: 0.01–0.67).
- Vaccination with the 9vHPV vaccine compared to placebo also significantly reduced the risk of CIN2+ associated with HPV type 16 by 99% (RR = 0.01; 95% CI: 0.00–0.80).

Perspectives on the Development of Therapeutic HPV Vaccines: Challenges and Strategies to Enhance Efficacy

The aforementioned vaccines are prophylactic; however, active research is currently underway to develop therapeutic vaccines against HPV, which are crucial for protecting individuals already infected with the virus and preventing the progression of HPV-associated tumors. HPV therapeutic peptide-based vaccines offer advantages in specificity and safety by targeting defined epitopes, thereby minimizing the risk of allergic or autoimmune reactions. Nevertheless, these peptide-based vaccines typically have limited immunogenicity and often fail to elicit a strong immune response. Therefore, more effective strategies are needed to enhance the immunogenicity of peptide-based HPV vaccines [22].

Specifics of HPV Vaccination in Georgia

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According to new regulations introduced in 2025 [23], HPV vaccination is provided free of charge in Georgia for the following groups:

- Girls and women aged 10 to 45 years;
- Boys and men aged 10 to 26 years.

For children aged 15 years and younger, the vaccination schedule consists of 2 doses with a minimum interval of 6 months.

For women aged 15 to 45 and men aged 15 to 26, a three-dose schedule is recommended: 0 – 2 – 6 months. The minimum interval between the first and second doses must be at least 1 month, and between the second and third doses at least 3 months.

For girls and boys aged 10–12 years, vaccination is conducted according to the National Immunization Calendar at the healthcare facility of their registration and is fully funded by the state (including the visit and physician consultation).

For women aged 13–45 and men aged 13–26, vaccination is available at any healthcare facility participating in the HPV immunization program and is fully free of charge for patients (including the vaccination visit and medical consultation).

Conclusions

The recommendations of all reviewed scientific societies unanimously emphasize the importance of vaccinating children against HPV before the onset of sexual activity. Over time, as new evidence has emerged demonstrating the efficacy of HPV vaccination in preventing cervical cancer–related infections, these recommendations have evolved. Recent guidelines increasingly advocate for the use of the 9-valent vaccine, which offers broader protection against a wider range of HPV types.

A notable innovation in recent guidelines is the endorsement of a single-dose vaccination regimen for population-based programs. This approach is aimed at simplifying program logistics, thereby making large-scale immunization efforts more feasible.

Global data confirm the pivotal role of HPV vaccination in the prevention of cervical cancer. Gardasil 9 provides protection in up to 90% of cases, and reduced-dose regimens (1 or 2 doses) maintain immunogenicity in adolescents while enabling broader population coverage. The WHO's "90–70–90" strategy outlines a practical plan for cervical cancer elimination. Key challenges remain, including unequal access in low- and middle-income countries and insufficient vaccination coverage among boys. These findings provide a foundational basis for shaping national and regional vaccination strategies.

Gardasil 9 is the vaccine of choice for the broadest HPV coverage, considering its properties and efficacy.

A two-dose regimen is sufficient for the 9–14 age group, which reduces costs and improves adherence.

A three-dose schedule is recommended for older and immunocompromised individuals.
In Georgia, HPV vaccination is administered to females aged 10 to 45 and males aged 10 to 26.

Future directions include continued surveillance to assess long-term immunity over 20 years and expansion of vaccination programs.

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მტკიცებულებებზე დაფუძნებული ეფექტურობა და რეკომენდაციები ადამიანის პაპილომავირუსის ვაქცინაციისათვის საერთაშორისო და ეროვნულ პრაქტიკაში

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აბსტრაქტი

შესავალი

ადამიანის პაპილომავირუსი (HPV) საშვილოსნოს ყელის კიბოს და სხვა ანოგენიტალური და ოროფარინგეალური ავთვისებიანი სიმსივნეების ძირითადი გამომწვევი აგენტია. HPV-ს წინააღმდეგ პროფილაქტიკური ვაქცინაცია ეფექტური აღმოჩნდა მაღალი რისკის HPV ინფექციების და მათთან დაკავშირებული კიბოსწინარე დაზიანებების პრევენციისთვის.

მიზანი: სტატია წარმოადგენს ოთხვალენტიანი (გარდასილ 4) და არავალენტური (გარდასილ 9) HPV ვაქცინების იმუნოგენურობის, ეფექტურობისა და უსაფრთხოების პროფილების შედარებით მიმოხილვას. კვლევაში სინთეზირებულია შეერთებული შტატებისა და ევროპის ძირითადი ჯანდაცვის ორგანოებისა და პროფესიული საზოგადოებების მიმდინარე კლინიკურ მითითებები და განხილულია ეროვნული ვაქცინაციის სტრატეგიები, განპირობებული თანამედროვე საქართველოში მიმდინარე მოვლენებით.

მეთოდები: 2019 წლიდან 2025 წლამდე, ჩატარდა სისტემატური ლიტერატურული კვლევა PubMed-ში, Cochrane Library-ში, PMC-ში, CDC-სა და Merck-ის მონაცემთა ბაზებში. გამოყენებულ იქნა რეცენზირებული სტატიები და ოფიციალური მითითებები.

შედეგები: როგორც „გარდასილ 4“, ასევე „გარდასილ 9“ ავლენს ექვივალენტურ დაცვას ადამიანის პაპილომავირუსის მე-6, მე-11, მე-16 და მე-18 ტიპების წინააღმდეგ. „გარდასილ 9“ იწვევს უფრო ძლიერ იმუნურ პასუხს ხუთი დამატებითი ონკოგენური ტიპის (31, 33, 45, 52, 58) წინააღმდეგ და ავლენს უფრო მაღალ იმუნოგენურობას 9-15 წლის ასაკობრივ ჯგუფში, ხანდაზმულ ჯგუფებთან შედარებით. ქსელური მეტაანალიზები ადასტურებს ვაქცინაციის შემდეგ ადამიანის პაპილომავირუსის მე-16 და მე-18 ტიპებთან დაკავშირებული CIN2+ დაზიანებების მნიშვნელოვან შემცირებას. ჯანმო-ს და ევროპის დაავადებათა კონტროლისა და პრევენციის ცენტრის ბოლოდროინდელი რეკომენდაციები სულ უფრო მეტად ემხრობა „გარდასილ 9“-ს და მხარს უჭერს გამარტივებული დოზირების რეჟიმებს, მათ შორის ერთჯერადი დოზის სტრატეგიებს მოსახლეობის ფართო მასებისთვის. საქართველოში, ადამიანის პაპილომავირუსის ვაქცინაცია ამჟამად თავისუფლად ხელმისაწვდომია 10-45 წლის

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ქალებისთვის და 10-26 წლის მამაკაცებისთვის, გადახედული ეროვნული პროგრამის ფარგლებში.

დასკვნა

„გარდასილ 9“ არის ფართო სპექტრის ადამიანის პაპილომავირუსისგან დაცვის სასურველი ვაქცინა. განახლებული რეკომენდაციები და მტკიცებულებები ადასტურებს ორდოზიან გრაფიკს მოზარდებისთვის და სამდოზიან გრაფიკს ხანდაზმული ან იმუნოკომპრომეტირებული პირებისთვის. საქართველოს გაფართოებული HPV ვაქცინაციის პროგრამა თანხვედრაშია საშვილოსნოს ყელის კიბოს ელიმინაციის გლობალურ ძალისხმევასთან, თანაბარი ხელმისაწვდომობისა და ოპტიმიზებული ვაქცინაციის სტრატეგიების გზით.

საკვანძო სიტყვები: ადამიანის პაპილომავირუსი (HPV), პროფილაქტიკური ვაქცინაცია, იმუნოგენურობა, ვაქცინის ეფექტურობა, ვაქცინის უსაფრთხოება, HPV ელიმინაციის სტრატეგია, გარდასილი.

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