REVIEW ARTICLES

The Efficacy, Effectiveness, and Safety of Human Papillomavirus (HPV) Vaccines

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ABSTRACT

Objective: This review aims to (1) synthesize and evaluate the available scientific evidence on the efficacy, effectiveness, and safety of HPV vaccines in both clinical trials and real-world settings; (2) compare the differences in outcomes between vaccines, age groups, and deployment contexts; and (3) discuss public health implications and applicability in the Vietnamese context.

Methods: This narrative review was conducted through a comprehensive search and analysis of published literature in major medical databases, including PubMed, Scopus, Google Scholar, and official reports from the WHO and CDC. Evidence from clinical trials, long-term follow-up studies, and real-world data was compiled thematically using the SANRA scale.

Results: HPV vaccines have shown high efficacy and effectiveness in preventing HPV infection and precancerous cervical lesions. Bivalent HPV vaccines are 93–98% effective against moderate to severe cervical lesions caused by HPV-16/18. The quadrivalent HPV vaccine showed 100% protection against grade 2 or higher cervical lesions during 24,099 person-years of follow-up, reducing HPV-6, 11, 16, and 18 infections by approximately 90% and maintaining a sustained immune response for at least 12 years. The nine-valent HPV vaccine offered protection against five additional high-risk HPV types, achieving ≥90% efficacy for 10–12 years with seropositivity rates of ≥81–90% for the covered types. Real-world data also confirms high preventive effectiveness among children and adolescents. The safety profile of HPV vaccines has been well established in both clinical trials and post-licensure surveillance, with most post-vaccination reactions being mild and transient (pain, swelling, fatigue, headache), while serious adverse events were rare and comparable to placebo.

Conclusion: HPV vaccines are safe and highly effective in preventing HPV infection and precancerous cervical lesions, offering superior preventative benefits compared to minimal risks. Early vaccination, a single-dose regimen, expanded coverage, and increased public awareness are key strategies to optimize the effectiveness and coverage of HPV vaccination programs.

Keywords: *cervical cancer, HPV vaccine, Efficacy, Effectiveness, Safety.*

INTRODUCTION

Human papillomavirus (HPV) is one of the most common sexually transmitted infections worldwide that poses a significant public health challenge (1). Persistent infection with high-risk HPV genotypes is the primary cause of cervical cancer and several other anogenital and oropharyngeal malignancies. In 2022, approximately 660,000 new cervical cancer cases and 350,000 related deaths were reported globally, including more than 4,612 incident cases and 2,571 deaths in Vietnam(2,3). In addition to cervical cancer, HPV is a major etiologic agent responsible for the majority of anal, oropharyngeal, vulvar, vaginal, and penile cancers (4). Low-risk HPV types cause most cases of genital warts.

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For several decades, cervical cancer prevention strategies have relied primarily on regular screening programs, such as the PAP test, to detect and treat precancerous cervical lesions (cervical intraepithelial neoplasia, CIN) at an early stage. While this approach has been proven effective in settings with well-developed health systems, it entails substantial costs, requires complex infrastructure and sustained long-term adherence, and does not prevent other HPV-related cancers (6). The advent of HPV vaccines, based on safe and non-infectious virus-like particle (VLP) technology, has marked a major turning point by enabling a primary prevention strategy with strong and durable immune responses (7). In practice, a robust body of evidence—from randomized clinical trials to real-world implementation—has demonstrated the efficacy, effectiveness, and safety of HPV vaccines (8–10). In this context, synthesizing and critically appraising the available evidence is essential. Therefore, this narrative review aims to: (1) summarize and evaluate existing scientific evidence on the efficacy, effectiveness, and safety of prophylactic HPV vaccines from both clinical trials and real-world settings; (2) compare differences in outcomes across vaccine types, age groups, and implementation contexts; and (3) discuss public health implications and potential applications in the Vietnamese context.

Although numerous systematic reviews and meta-analyses on HPV vaccines have been conducted globally, most have focused on individual aspects (efficacy, effectiveness, or safety), specific vaccine types, or have relied predominantly on data from high-income countries. As evidence on HPV vaccines continues to expand and diversify in terms of study design, duration of follow-up, and implementation settings, a structured narrative synthesis is warranted to integrate and interpret these findings. Such an approach can provide a comprehensive, up-to-date, and accessible overview for the public health field, particularly to inform policy-making and vaccination program implementation in middle-income countries such as Vietnam.

METHODS

Study design: This study was conducted as a narrative review, aiming to provide an overarching perspective and contextual interpretation of existing evidence on the efficacy, effectiveness, and safety of HPV vaccines.

Study scope, setting, and timeframe: This review focused on both international and domestic studies examining the efficacy, effectiveness, and safety of licensed HPV vaccines (bivalent, quadrivalent, and nonavalent). Eligible publications included peer-reviewed articles and reports published in English or Vietnamese between 2005 and September 2025. The types of studies considered comprised randomized controlled trials, observational studies, and post-licensure surveillance data, involving female and male populations within the recommended age range for HPV vaccination.

Search strategy and data sources: This review was guided by the SANRA (Scale for the Assessment of Narrative Review Articles) checklist for conducting narrative reviews (11). A comprehensive and systematic search strategy using Medical Subject Headings (MeSH) and relevant keywords was employed. Searches were conducted across major international databases, including PubMed, Scopus, and Google Scholar, as well as official reports from the World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (CDC). Search terms were used both independently and in combination and included “HPV vaccine,” “Human Papillomavirus vaccine,” “efficacy,” “effectiveness,” “safety,” and their equivalent

terms in Vietnamese. Study selection was based on relevance to the review objectives and adherence to the SANRA-guided principles for narrative reviews (11).

Data analysis: Data were stored and managed using Microsoft Excel, and synthesis was conducted following a thematic analysis approach (12). Extracted data were categorized into three main domains for analysis: (1) HPV vaccine efficacy, (2) real-world vaccine effectiveness, and (3) vaccine safety. This approach emphasized consistency and variability across studies rather than quantitative synthesis.

RESULTS

3.1. Types of HPV vaccines and mechanisms of action

At present, three types of HPV vaccines have been licensed and are globally used (13): (1) the **bivalent vaccine (2vHPV, *Cervarix* – GSK),** approved by the European Medicines Agency (EMA) in 2007 and by the U.S. Food and Drug Administration (FDA) in 2009, which protects against HPV types 16 and 18; (2) the **quadrivalent vaccine (4vHPV, *Gardasil*)**, which protects against HPV types 6, 11, 16, and 18; and (3) the **nonavalent vaccine (9vHPV, *Gardasil 9*)**, approved by the FDA in 2014 for use in both females and males as prophylaxis against cervical cancer, other anogenital cancers, cervical intraepithelial neoplasia (CIN), and genital warts. Since 2016, *Gardasil 9* has been the only HPV vaccine distributed in the United States, protecting against nine HPV types (6, 11, 16, 18, 31, 33, 45, 52, and 58).

Table 1. Comparison of bivalent, quadrivalent, and nonavalent HPV vaccines (13)

HPV vaccine (brand name)	Cervarix	Gardasil	Gardasil 9
Year of FDA approval	2009	2006	2014
Name of company/Manufacturer	GSK	Merck & Co	Merck & Co
HPV types covered	16 & 18	6, 11, 16, 18	6,11,16,18,31,33,45,52, 58
Dosage	0.5 mL/dose × 3 doses	0.5 mL/dose × 3 doses	0.5 mL/dose × 2 or 3 doses
Vaccination timeline (months)	0, 1, 6	0, 2, 6	0, 6 -12 or 0, 2, 6

Note: 0 indicates the month of the first dose; 1, 2, 6, and 12 indicate the number of months after the first dose.

Efficacy and effectiveness of HPV vaccines

Efficacy from randomized controlled trials

● Efficacy of 2vHPV

The bivalent HPV vaccine has demonstrated very high efficacy (91–100%) among young women with no prior HPV exposure. In adult women aged 26–45 years, protective efficacy was lower, largely due to prior HPV exposure (14).

● Efficacy of 4vHPV

Long-term follow-up data in both sexes have consistently confirmed the durable protective efficacy of the quadrivalent HPV vaccine against HPV-related diseases and cancers. A phase III randomized controlled trial conducted in 2007 among 12,167 women aged 15–26 years showed that 4vHPV achieved 98% efficacy in preventing high-grade cervical precancerous lesions (CIN2+) caused by HPV-16/18 in

HPV-naïve participants, and 44% efficacy in the intention-to-treat population (15). Other large-scale randomized trials in young women further confirmed high efficacy (96–100%) in preventing CIN, vulvar and vaginal lesions, and genital warts associated with vaccine-covered HPV types, with protection maintained for at least five years post-vaccination. Immune responses in adolescents were superior to those observed in adult women (16). A multinational phase III trial involving 4,065 males aged 16–26 years demonstrated a 60.2% reduction in the risk of external genital lesions and an 85.6% reduction in persistent HPV infection (17).

● Efficacy of 9vHPV

The nonavalent HPV vaccine has been developed and evaluated internationally. A randomized trial involving 14,215 women aged 16–26 years showed that 9vHPV achieved 96.7% efficacy in preventing high-grade cervical, vulvar, and vaginal lesions related to HPV types 31, 33, 45, 52, and 58, while eliciting immune responses non-inferior to 4vHPV against HPV types 6, 11, 16, and 18 (16). According to a 2017 review, 9vHPV has the potential to prevent approximately 90% of cervical cancers, 70–85% of CIN2+, 85–95% of vulvar, vaginal, and anal cancers, and about 90% of genital warts. Evidence also suggests that vaccine efficacy can be extrapolated to males and adolescents, with immune responses comparable to or higher than those observed in young women (18,19). However, 9vHPV does not provide protection against non-vaccine HPV types or in individuals previously exposed through sexual activity (20).

Real-world effectiveness

● Effectiveness of 2vHPV

In real-world settings, the bivalent HPV vaccine has demonstrated high effectiveness against HPV types 16 and 18. Epidemiological data from England and Scotland reported a reduction in HPV-16/18 prevalence among young women from 15–30% to below 1–5% (21,22). A study in Japan confirmed that vaccine-induced protection was maintained for at least six years post-vaccination, with effectiveness ranging from 93.9–95.5% against HPV-16/18 and 67.7–71.9% against HPV-31/45/52 (23).

● Effectiveness of 4vHPV

In the FUTURE II trial, no cases of HPV-16/18–related CIN2+ were observed over 24,099 person-years of follow-up, corresponding to 100% effectiveness sustained for at least 12 years, with stable immune responses to all four HPV types (6/11/16/18) (24). Global analyses have shown approximately a 90% reduction in HPV-6/11/16/18 infections and an 85% reduction in CIN2+ among women vaccinated before HPV exposure, alongside decreased viral transmission and herd protection (25). In China, 13-year follow-up data from the V501–041 trial showed no CIN2+ cases among early vaccine recipients over 5,513.6 person-years, compared with one case in the unvaccinated group, corresponding to a 100% risk reduction. Similarly, no CIN2+ cases were observed in the catch-up vaccination group, whereas the pre-vaccination incidence was 22.3 per 10,000 person-years. Seropositivity rates remained above 92% for HPV-6/11/16 and 84% for HPV-18 after 13 years, indicating durable immune responses (26).

● Effectiveness of 9vHPV

Evidence also supports the long-term protective effectiveness of 9vHPV against infections and lesions associated with the nine targeted HPV types (HPV-6/11/16/18/31/33/45/52/58). In a phase III study involving 2,029 women aged 16–26 years in Denmark, Norway, and Sweden, no cases of HPV-type–related CIN2+ were reported after 12 years of follow-up in the per-protocol population, indicating sustained vaccine effectiveness above 90% throughout the study period (27). Among male and female

adolescents aged 9–15 years participating in extension studies, no cases of persistent HPV infection or external genital lesions related to vaccine-covered types were observed after 7–8 years of follow-up, with low rates of persistent infection (52–54.6 per 10,000 person-years). Seropositivity rates remained ≥90% for most HPV types and ≥81% across different assay methods up to 10 years after the final dose. Data from pediatric and adolescent populations consistently demonstrate high preventive effectiveness without significant waning over time, including protection against persistent infection, CIN, and genital warts.

Factors influencing vaccine effectiveness

Age is one of the most important factors influencing HPV vaccine effectiveness. A study by Ellingson et al. showed that the youngest age group achieved the highest effectiveness, highlighting the importance of vaccination before HPV exposure through sexual activity. Among individuals aged 9–14 years, vaccine effectiveness ranged from 74% to 93%, whereas among those aged 15–18 years, it ranged from 12% to 90%. Although individuals vaccinated before 18 years of age remained substantially protected, optimal effectiveness was achieved with earlier vaccination. Studies from Scotland and Japan similarly reported a 2–3-fold higher risk of HPV-related disease among individuals vaccinated after the age of 16 compared with those vaccinated earlier.

Previously, evidence suggested that the **number of doses** administered could influence HPV vaccine effectiveness, with the highest effectiveness observed among individuals completing the three-dose schedule. However, analyses published after 2019 indicate that a single-dose regimen can still confer high protective effectiveness, particularly when administered at younger ages (28).

Safety of HPV vaccines

Safety is a critical determinant of HPV vaccine injection acceptance. Systematic reviews and meta-analyses of phase II and III randomized controlled trials conducted between 2007 and 2022 have shown that HPV vaccines are generally safe, with most adverse events being mild and transient, such as injection-site pain, swelling, erythema, fatigue, myalgia, low-grade fever, or headache. Serious adverse events were rare and comparable to placebo (29). Post-licensure surveillance data from the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink in the United States, as well as studies conducted in Europe and Asia, consistently confirmed vaccine safety, with no increased risk of autoimmune diseases, pregnancy-related complications, severe allergic reactions, or cardiovascular events (30–34). VAERS data from 2006 to 2024 further demonstrated a declining proportion of serious adverse events across vaccine generations, from 33.4% for *Cervarix* to 7.8% for *Gardasil* 9, while the majority of reported events were mild and self-limited, reinforcing the strong safety profile of HPV vaccines (35).

In Vietnam, both the quadrivalent and nonavalent HPV vaccines have been licensed by the Drug Administration of Vietnam under the Ministry of Health following rigorous evaluation (36–38). Common post-vaccination reactions include pain, swelling, redness, pruritus, or induration at the injection site, as well as mild systemic symptoms such as low-grade fever, headache, fatigue, myalgia, dizziness, or nausea; most events are mild and self-resolving (39,40). A clinical study of *Gardasil 9* reported local reactions including pain (44.5%), swelling (5.5%), and erythema (2.0%), with over 81% classified as mild. Common systemic reactions included headache (3.5%), dizziness (2.5%), and nasopharyngitis (2.5%). No deaths or vaccine-related serious adverse events were reported. One case of subcutaneous abscess

was documented, which resolved completely and was assessed as unrelated to vaccination. Notably, no cases of fever ≥37.8°C were observed following vaccination (41).

DISCUSSION

Efficacy, effectiveness, and safety of HPV vaccines

Based on the reviewed literature, all three licensed HPV vaccines demonstrate high levels of efficacy, effectiveness, and safety. Existing evidence consistently supports the preventive benefits of HPV vaccination in reducing HPV infection and related diseases. In particular, the broader type coverage of the nonavalent HPV vaccine (9vHPV), compared with the quadrivalent vaccine, suggests its potential added value in comprehensive prevention strategies targeting HPV-related diseases and cancers. Long-term follow-up studies have not identified serious vaccine-related adverse effects, further supporting the favorable safety profile of HPV vaccines (42,43). Overall, available evidence indicates that 9vHPV maintains high efficacy and sustained immune responses for at least 10 years after vaccination. These findings suggest that 9vHPV may contribute meaningfully to long-term reduction of HPV-related disease burden at the population level, particularly when integrated into well-designed vaccination programs.

In addition, the literature consistently highlights the importance of administering HPV vaccination before puberty or before sexual debut. Vaccination in the 9–12-year age group is considered the most effective preventive approach, in line with recommendations from the World Health Organization (WHO) and the Advisory Committee on Immunization Practices (ACIP) (33). Since 2019, emerging evidence has suggested that a single-dose vaccination schedule may still provide substantial protection, which has important implications for vaccination policy and program implementation, particularly in resource-constrained settings (28).

Challenges and future directions

- **Key challenges**

A major challenge in HPV prevention remains **the inequitable access to and coverage of HPV vaccination** across the globe. Vaccine cost continues to be a substantial barrier in many low- and middle-income countries, where the burden of HPV-related disease is high but financial resources and health system capacity are limited (44). In several sub-Saharan African countries, HPV vaccines have not yet been incorporated into national immunization programs due to high procurement and delivery costs (45). In Vietnam, vaccine cost similarly affects HPV vaccination coverage. Studies conducted in Can Tho reported a vaccination uptake of 4%. A vast majority of previously untreated females (91.4% in the countryside and 84.4% in urban areas) expressed the want for vaccination free of charge (46). According to a report in 2024, in Can Tho, 25.8% of mothers refused to take their children to get vaccinated due to high costs, while 49.5% of mothers agreed to have their children vaccinated if there were no costs involved (47). Aside from the financial barrier, there exists a hesitance to receive vaccination due to misinformation on safety, especially when it comes to reproduction and autoimmune disease, which has reduced coverage rates even in high-income countries (48). In addition, ensuring a stable and sufficient global vaccine supply remains an ongoing challenge, requiring coordination among manufacturers, governments, and international organizations.

- **Future directions**

The WHO global strategy to accelerate the elimination of cervical cancer is a promising one, with an ambitious 90-90 target set for 2023:

90% of girls to be fully vaccinated against HPV before the age of 15; **70%** of women to be screened with high efficacy testing; and **90%** of women with the disease to be treated (49). Based on scientific evidence, the WHO Strategic Advisory Group of Experts on Immunization (SAGE) has recommended a single-dose HPV vaccination schedule, expected to reduce the cost and logistical barriers of HPV vaccination, thereby helping rapidly increase the global vaccine coverage (50). Future research and development efforts may focus on next-generation prophylactic vaccines with broader coverage and fewer doses, as well as therapeutic vaccines targeting HPV-infected cells (51).

In Vietnam, the integration of HPV vaccination into the National Expanded Programme on Immunization (NEPI) has the potential to reduce financial barriers, increase vaccination coverage, and promote equity across regions. According to Government Resolution No. 104/NQ-CP (August 15, 2022), Vietnam plans to introduce free HPV vaccination for 11-year-old girls starting in 2026 as a part of the TCMR program (52). The Ministry of Health has also approved expanded indications for Gardasil 9 for both females and males aged 9-45 years (53). Effective implementation will require a clear policy roadmap, sustainable financing, cost-effectiveness evaluation, consideration of reduced-dose schedules, and strengthened vaccine supply and distribution systems, particularly in remote and underserved areas (50). Additionally, it is necessary to strengthen community communication, such as the *"Vì một Việt Nam không gánh nặng bởi HPV"* (For a Vietnam free from the burden of HPV) of the Ministry of Health to raise people's awareness and encourage HPV vaccination to effectively prevent cervical cancer (54).

Limitations of the review

This narrative review has several limitations. First, although multiple major databases were searched, the possibility of missing unpublished studies or studies published in languages other than English and Vietnamese cannot be excluded. Second, this review did not include a quantitative synthesis or formal risk-of-bias assessment of individual studies; therefore, it does not allow for a precise comparison of the strength of evidence across studies. Third, heterogeneity in study design, study populations, and implementation contexts may affect the generalizability of the findings. Consequently, the conclusions should be interpreted within the context of a qualitative synthesis.

CONCLUSION

This narrative review synthesizes global evidence indicating that HPV vaccines are highly efficacious, effective, and safe, with preventive benefits against cervical cancer and other HPV-related diseases that outweigh the minimal associated risks. The HPV vaccination represents one of the most important achievements of 21st-century public health as a key public health intervention, playing an important role in efforts to reduce the burden of cervical cancer and other HPV-related conditions. Current evidence suggests that early-age vaccination, adoption of reduced-dose schedules, and expansion of vaccine coverage are promising strategies for enhancing the public health impact of HPV vaccination programs. However, additional high-quality studies conducted in Vietnam are needed to generate context-specific evidence to support policy development and optimize implementation of HPV vaccination strategies within the national health system.

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