

Guidelines for the clinical application of prophylactic human papillomavirus (HPV) vaccines in China (2025 edition)

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Prophylactic human papillomavirus (HPV) vaccination is a primary preventive measure aimed at preventing HPV-related lesions and cancers by preventing HPV infection. With the continuous update of global data on HPV vaccination, seven academic societies—including the Chinese Society for Colposcopy and Cervical Pathology of China Healthy Birth Science Association and Chinese Society of Gynecological oncology, Chinese Medical Association and others—have jointly developed the Guidelines for the Clinical Application of Prophylactic Human Papillomavirus (HPV) Vaccines in China (2025 Edition). This guideline was based on the previous Chinese Expert Consensus on the Clinical Application of Human Papillomavirus Vaccines¹ as well as current evidence-based medical research, China's national conditions and clinical realities. The recommended categories of this guideline are listed in [table 1](#).

HPV AND ITS EPIDEMIOLOGY

HPV genotypes and classification

HPV is a non-enveloped, double-stranded, circular DNA virus with a tropism for epithelial tissue. It consists of a viral protein capsid and a single-copy viral genomic DNA core. The capsid is composed of the major capsid protein L1 and the minor capsid protein L2.² HPV is primarily transmitted through sexual contact or skin-to-mucosa contact. Among individuals with heterosexual partners, the lifetime risk of HPV infection is estimated to be 84.6% for women and 91.3% for men.³

Genital HPV types are classified based on their carcinogenic potential into high-risk (HR-HPV) and low-risk (LR-HPV) categories. HR-HPV mainly includes 14 types: HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 (has now been reclassified as non-carcinogenic) and 68. Among them, HPV 16 poses the

highest risk and is associated with the development of HPV-related precancerous lesions and cancers of the cervix, vagina, vulva, anus, penis and head and neck. LR-HPV is primarily represented by HPV 6 and 11, which can cause anogenital warts (AGW) and recurrent respiratory papillomatosis (RRP).^{2,4}

HPV infection rates and genotype distribution

HPV infection in females: globally, the distribution of HPV genotypes varies across regions, age groups and populations.⁵ A meta-analysis including 194 studies and a total of 1 016 719 women worldwide showed that the HPV infection rate among women with normal cervical cytology was 11.7%.⁶ In mainland China, the overall HPV infection rate among women ranges from 15.5% to 24.3%, with notable differences across regions and populations.^{7–10} Data from 17 population-based cervical cancer screening studies conducted in nine provinces and municipalities in China, covering 30 207 women, showed two age-related peaks in HPV infection rates: one between ages 17–24 and another between ages 40–45.¹¹ Among Chinese women with normal cervical cytology, the five most common HPV genotypes are HPV 52 (2.8%), HPV 16 (2.7%), HPV 58 (1.7%), HPV 18 (1.1%) and HPV 33 (1.1%).¹²

The HPV positivity rate is associated with the level of cervical intraepithelial lesions. In women with cytological results showing atypical squamous cells of undetermined significance, the HPV infection rate is 52%. In low-grade squamous intraepithelial lesions (LSIL), it is 76%, and in high-grade squamous intraepithelial lesions (HSIL), it reaches 85%.¹³ The infection rates of HPV 16, 33, 58 and 52 are higher in squamous cell carcinoma (56.8%, 4.3%, 3.9%, 3.7%) than in adenocarcinoma (36.1%, 1.8%, 1.1%, 1.3%); while the infection rates of HPV 18 and 45



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Table 1 Evidence grades and recommended categories

Recommendation level	Implication
Grade 1	Based on high-quality evidence with a high level of consensus among experts
Grade 2A	Based on high-level evidence with a general consensus among experts or based on low-level evidence with a high level of consensus among experts
Grade 2B	Based on low-level evidence with a general consensus among experts or based on high-level evidence with significant expert disagreement
Grade 3	Regardless of the level of clinical evidence, there is a marked divergence of opinions among experts

are higher in adenocarcinoma (34.9%, 5.7%) than in squamous cell carcinoma (11.6%, 4.8%).⁵ In China, the overall HPV infection rate in patients with cervical intraepithelial lesions is 84.4%, with cervical intraepithelial neoplasia (CIN) 1 and CIN2/3 showing rates of 79.6% and 87%, respectively.¹⁴ The most common HPV types in LSIL patients in China are HPV 52/16/58/18/33, while in HSIL patients, they are HPV 16/52/58/33/18. In cervical cancer patients, the common HPV types are HPV 16/18/58/52/33.¹²

1. **HPV infection in males:** a meta-analysis of 65 studies from 35 countries, including a total of 44769 males aged 15 years and older, showed that the global overall HPV infection rate among men for any genotype was 31%, and the infection rate for HR-HPV was 21%. HPV-16 was the most common genotype (5%, 95% CI 4% to 7%), followed by HPV-6 (4%, 95% CI 3% to 5%).¹⁵ In the general male population in China, the overall HPV infection rate ranges from 8.0% to 16.9%, with the HR-HPV infection rate ranging from 5.5% to 9.4%.¹⁶
2. **HPV infection in special populations:** a global meta-analysis found that the HR-HPV infection rate among people living with HIV who have normal cervical cytology was 51%, with significant regional variation. The most common HR-HPV genotypes were HPV 16, 18 and 52.¹⁷

In China, the HR-HPV infection rate among HIV-positive women is 30.6%, with the most prevalent types being HPV 52, 16 and 58. The anal HR-HPV infection rate is 30.3%, with the most common types being HPV 52, 53 and 39.¹⁸ The risk of cervical cancer in HIV-positive (HIV+) women is six times higher than that in HIV-negative (HIV-) women (RR=6.07). Globally, 5.8% of new cervical cancer cases in 2018 occurred in HIV+ women, and 4.9% of all cases were attributable to HIV infection.¹⁹

Regarding men who have sex with men (MSM), a study including 64 studies and a total of 29900 men showed that the HPV infection rate among HIV+ MSM was 74.3%, higher than the 41.2% rate among HIV- MSM.²⁰ Among MSM, HPV infection rates by anatomical site from highest to lowest were anus, penis and urethra. The most common HR-HPV genotypes found in the anus were HPV 16, 51, 18, 52 and 58.²¹

The burden of HPV-related diseases

1. **Cervical cancer:** in 2022, there were 661000 new cases of cervical cancer globally, and 348200 deaths, ranking 8th and 9th, respectively, among all types of tumours.²² In 2022, there were 150700 new cases of cervical cancer and 55700 deaths in China, ranking fifth and sixth, respectively, among the newly diagnosed and deceased cases of malignant tumours in Chinese women.²³ Among Chinese women aged 15–49, cervical cancer ranks third in new cancer cases and second in deaths.²² Compared with 1990, the incidence rate of Chinese women with cervical cancer in the age group of 40–44 increased the most in 2019, accounting for as high as 73.1% of the cervical cancer cases in the 15–49 age group.²⁴
2. **Other HPV-related tumours:** it is estimated that HPV infection is associated with approximately 4.5% of new cancer cases globally.²⁵ In China, for women, the standardised incidence rates of tumours attributable to HPV infection are ranked as cervical cancer, anal cancer, vaginal cancer, vulvar cancer, oropharyngeal cancer, oral cancer and laryngeal cancer in sequence. For men, the incidence rates are ranked as penile cancer, anal cancer, oropharyngeal cancer, laryngeal cancer and oral cancer in sequence, and they show an upward trend.²⁶
3. **Diseases related to LR-HPV infection:** the estimated annual incidence rate of AGW globally is 194.5 per 100000 people.²⁷ A prospective study in China showed that the incidence rate of AGW in the general population is approximately 126 per 100000 people, and the self-reported incidence rate within 12 months is about 235 per 100000 people.²⁸ RRP is mainly caused by the infection of the upper respiratory tract by LR-HPV 6/11. It is divided into juvenile-onset RRP and adult-onset RRP. The estimated prevalence rate of RRP is 0.75 to 4 per 100000 people.²⁹ Currently, China still lacks epidemiological data on RRP.

IMMUNE MECHANISMS AND PROTECTIVE EFFECTS OF PROPHYLACTIC HPV VACCINES

Immune mechanisms of preventive HPV vaccines

1. **HPV infection and immune evasion:** following HPV infection, the body develops a specific immune response against HPV, including cellular and antibody-mediated humoral immunity.² Since HPV infection only occurs in the mucosal epithelial layer, it does not trigger a strong systemic immune response. After being infected with HPV, 70%–80% of women will experience seroconversion of neutralising antibodies, but the antibodies produced increase slowly, and their titres and affinities are not high. The median time from HPV infection to seroconversion of neutralising antibodies is 8–12 months.⁴ Because women themselves are unable to trigger an effective cellular immune response to clear the virus, patients with persistent HR-HPV infection are more likely to progress to cervical precancerous lesions.⁴
2. **Mechanism of action of prophylactic HPV vaccines:** preventive HPV vaccines use the method of genetic recombination to assemble the HPV L1 gene in different expression systems (such as *Saccharomyces cerevisiae*, Baculovirus-insect cells, *Escherichia coli* or *Pichia pastoris*, etc), enabling the expression of the HPV L1 structural protein, which is then assembled into HPV virus-like particles (VLPs). With the addition of an adjuvant, an HPV vaccine capable of inducing the body to produce specific antibodies is obtained. The antigenic activity of VLPs is almost identical to that of natural viruses. Since HPV vaccines do not contain viral DNA, they are neither infectious nor carcinogenic. HPV vaccines mainly exert their effects by inducing the body to produce

neutralising antibodies that can bind to viral particles, thereby preventing HPV infection.^{4 30}

Clinical evaluation of HPV vaccines

The clinical evaluation of HPV vaccines includes immunogenicity, protective efficacy and protective effectiveness (table 2).

Immunogenicity of HPV vaccines

1. **Bivalent HPV vaccines:** clinical studies in China have shown that 1 month after three doses of three types of bivalent HPV vaccines are administered, the seroconversion rates of serum neutralising antibodies against HPV types 16/18 are all between 97.5% and 100.0%. The geometric mean titres (GMTs) of serum neutralising antibodies against HPV types 16/18 in females aged 9–17 are numerically higher than those in females aged 18–25. After two doses of vaccination in females aged 9–14, the seroconversion rates of antibodies against HPV types 16/18 both reach 100%, and the antibody levels are not inferior to those of females aged 18–26 who receive three doses of vaccination.^{31–33} Two other follow-up studies of bivalent adsorbed HPV vaccines at 5 years and 12 years after vaccination have shown that the antibody levels against HPV 16 and HPV 18 are significant and remain stable.^{34 35}
2. **Quadrivalent HPV vaccine:** 1 month after three doses of the quadrivalent HPV vaccine are administered to females and males aged 9–45, the seroconversion rates of the HPV types covered in the vaccine reach 96.7%–99.3%. The antibody GMTs in girls and boys aged 9–15 can be 1.4–2.8 times higher than those of females aged 16–26.³⁶ The GMTs of females aged 9–13 after receiv-

Table 2 Clinical evaluation of HPV vaccines

Item	Definition and key indicators
Immunogenicity	Refers to the ability of a vaccine antigen to induce an adaptive immune response in the body, mainly including humoral immunity and cellular immunity. Key indicators for humoral immunity: ▶ Immune response rate after vaccination (including antibody seroconversion rate, etc.) ▶ Geometric mean titre (GMT)/geometric mean concentration (GMC) of antibodies ▶ Fold increase of antibodies
Protective efficacy	Refers to the protective effect induced by vaccination in the vaccinated population, which is the direct evidence and gold standard for evaluating the effectiveness of HPV vaccines. Key endpoint indicators: ▶ Cervical intraepithelial neoplasia grade 2 (CIN2)/CIN3 and adenocarcinoma in situ (AIS) (precancerous lesions, used in phase III clinical trials) ▶ Persistent HPV infection (set to shorten the approval time of iterative vaccines)¹²³
Protective effectiveness	Refers to the estimation of the protective effect generated by HPV vaccination, including both direct protection and indirect protection (ie, protection for unvaccinated populations). Measurement methods: ▶ Generally measured by monitoring vaccine-preventable diseases after routine vaccination of a specific population ▶ Monitored in real-world populations after licensing ▶ Evaluated through experimental studies or by collecting regional and national data
HPV, human papillomavirus.	

ing two doses of the vaccine are non-inferior to those of females aged 16–26 after receiving three doses (as stated in the vaccine instruction manual). Seroprevalence in males aged 16–26 years after the first dose of HPV vaccination was 97.4%–99.2% at 7 months and 57.0%–97.9% at 36 months.³⁷ Neutralising antibody positivity after quadrivalent HPV vaccination was observed in men aged 27–45 years and was similar to the immune response in young men aged 16–26 years.³⁸

3. **Nonavalent HPV vaccine:** 1 month after females aged 9–45 complete the vaccination of three doses of the nine-valent HPV vaccine, the seroconversion rates of the HPV types included in the vaccine are all >99%. Among them, the antibody GMTs of the group aged 9–19 are non-inferior to those of the group aged 20–26; the seroconversion rates of the HPV types included in the vaccine in the group aged 27–45 are non-inferior to those of the group aged 20–26.³⁹ For girls aged 9–14, the seroconversion rates and antibody GMTs after receiving two doses of the vaccine are non-inferior to those of young females aged 16–26 who receive three doses of the vaccine.⁴⁰ Neutralising antibody GMT after 3 doses of vaccine was significantly higher in boys aged 9–15 years than in adult females who received three doses of vaccine.⁴¹ The immunogenicity induced in boys who receive two doses of the vaccine is non-inferior to that in adult females who receive three doses of the vaccine.⁴⁰

Protective efficacy of HPV vaccines

1. **Domestic bivalent HPV vaccine (*E. coli*):** the protective efficacy against persistent infections in females aged 18–45 for 6 months and 12 months is 97.7% and 95.3%, respectively (as stated in the vaccine instruction manual). After 66 months of follow-up, the protective efficacy against high-grade lesions related to HPV16/18 infection in females aged 18–45 is 100.0%.^{42 43}
2. **Domestic bivalent HPV vaccine (*P. pastoris*):** in Chinese, women aged between 18 and 30 years with a follow-up of 48 months, the vaccine showed a protective efficacy of 78.6% against HPV 16/18-associated CIN2 and above (CIN2+) (as stated in the vaccine instruction manual).
3. **Bivalent HPV adsorbed vaccine:** among females aged 15–25 who have not been infected with HPV, the protective efficacy of the vaccine against CIN3 or AIS caused by HPV is 93.2%, and the protective efficacy against HPV16/18-related CIN2 and above (CIN2+) in the per-protocol population is 94.9%. The protective effects against persistent infections for 6 months and 12 months are 92.9% and 94.3%, respectively (as stated in the vaccine instruction manual).⁴⁴ The results of a 72-month follow-up of a phase III clinical trial in China show that, among the population who were HPV-negative at baseline, the protective efficacy of the bivalent HPV adsorbed vaccine against HPV 16/18-related CIN2+ is 100%, and the protective efficacies against

persistent infections for 6 months and 12 months are 96.3% and 96.7%, respectively.⁴⁵

4. **Quadrivalent HPV vaccine:** among females aged 16–24 in the per-protocol population, the protective efficacy of the vaccine against any grade of external genital and vaginal lesions related to HPV6/11/16/18 types as the endpoint is 100%.⁴⁶ The results of a 78-month follow-up of a phase III clinical trial in China show that the protective efficacies against HPV 16/18-related CIN2+ and CIN1+ are both as high as 100%.⁴⁷ In a global, multicentre, randomised, double-blind, placebo-controlled phase III clinical trial, the follow-up of males aged 16–26 for 36 months shows that the protective efficacy against the endpoint of external genital lesions related to HPV6/11/16/18 is 90.4%, and the protective efficacy against persistent infections (for 6 months and above) of HPV 6/11/16/18 in the external genital area is 85.6%.⁴⁸
5. **Nonavalent HPV vaccine:** the protective efficacy of the nonavalent HPV vaccine against HPV 6/11/16/18-related persistent infections, cervical precancerous lesions and cancer in women aged 16–26 is comparable to that of the quadrivalent HPV vaccine. Its protective efficacy against 6-month and 12-month persistent infections related to HPV types 31/33/45/52/58 is 96.0% and 96.7%, respectively, and its protective efficacy against CIN1+ is 98.2%.⁴⁹ Similar results have been observed in East Asian women aged 16–26. The protective efficacy of the nonavalent HPV vaccine against 6-month and 12-month persistent infections and CIN1+ related to HPV types 31/33/45/52/58 is 95.8%, 93.9% and 100%, respectively.⁵⁰

Protective effectiveness of HPV vaccines

Protective effectiveness from long-term follow-up studies in clinical trials

1. **Bivalent HPV vaccine:** the results of a follow-up study of up to 9.4 years after three doses of the bivalent HPV adsorbed vaccine were administered to females aged 15–25 showed that the protective effectiveness against HPV16/18-related incident infections, 6-month persistent infections, 12-month persistent infections and CIN2+ was 95.6%, 100%, 100% and 100%, respectively.⁵¹ The Costa Rica Vaccine Trial, which followed up females aged 18 to 25 for 11 years, found that the protective effectiveness of the bivalent HPV adsorbed vaccine against HPV 16/18-related CIN2+ and CIN3+ was 97.4% and 94.9%, respectively.⁵²
2. **Quadrivalent HPV vaccine:** a follow-up study of up to 14 years after females aged 16–23 in four Nordic countries received the quadrivalent HPV vaccine showed that the protective effectiveness of the vaccine was 100%.⁵³ The results of an 11-year follow-up after females aged 20–45 in China received three doses of the quadrivalent HPV vaccine showed that the protective effectiveness against HPV 16/18-related CIN2+ reached 100%.⁵⁴ For the early vaccination group of males aged 16–26, with a median follow-up of 9.5 years

after the first dose, and the catch-up vaccination group with a median follow-up of 4.7 years, no cases of external genital condyloma acuminata related to HPV 6/11 or external genital lesions related to HPV 6/11/16/18 were observed.⁵⁵

3. **Nonavalent HPV vaccine:** after 11 years of follow-up, after three doses were administered to girls aged 9–15, no cases of CIN2+ related to the nine-valent HPV types occurred.⁵⁶ After up to 12 years of follow-up, after three doses were administered to females aged 16–26, no cases of CIN2+ related to HPV types 16/18/31/33/45/52/58 occurred, and the protective effectiveness reached 100%.⁵⁷

Protective effectiveness in real-world studies after market launch

After the vaccine was launched on the market, systematic reviews and meta-analyses of real-world studies on the bivalent HPV adsorbed vaccine or quadrivalent HPV vaccine administered globally, as well as real-world studies in multiple countries, have shown good protective effectiveness.

1. **Prevention of HPV infection:** in a real-world study of HPV vaccines (bivalent HPV adsorbed vaccine or quadrivalent HPV vaccine) globally, 5–8 years after vaccination, the infection rate of HPV types 16/18 in females aged 13–19 decreased significantly by 83%, and the infection rate of HPV types 31/33/45 decreased significantly by 54%. The infection rate of HPV types 16/18 in females aged 20–24 decreased significantly by 66%.⁵⁸ The results of real-world studies in the UK, the USA and other countries also show that after HPV vaccination, the infection rate of HPV types related to the vaccine has decreased, especially significantly in young females.^{59 60}
2. **Prevention of cervical intraepithelial lesions:** the incidence of CIN2+ decreased by 51% in women aged 15–19 years and 31% in women aged 20–24 years after 5–9 years of HPV vaccination.⁵⁸ The results of a real-world study in Scotland found that after vaccination, the incidence rate of CIN2+ decreased by 88%, and the incidence rate of CIN3+ decreased by 89%.⁶¹ Real-world studies in England⁶² and other places all showed that the incidence rate of CIN2+ decreased significantly after HPV vaccination.
3. **Prevention of cervical cancer:** A real-world study in Scotland found that 11 years after females aged 12–13 received the bivalent HPV adsorbed vaccine, the protective effectiveness in preventing cervical cancer was 100%.⁶³ A real-world study of 1.67 million females aged 10–30 in Sweden showed that receiving at least one dose of the quadrivalent HPV vaccine significantly reduced the incidence rate of invasive cervical cancer by 63%. Among them, the incidence rate of cervical cancer in females who received the vaccine before the age of 17 decreased by 88%, and that in females who received the vaccine between the ages of 17 and 30 decreased by 53%.⁶⁴ Real-world studies in England, Scotland, the USA and other countries

showed that after vaccination, the incidence rate of cervical cancer decreased significantly, especially in young females.^{62–65}

4. **Prevention of AGW:** real-world studies in several countries around the world have shown that the quadrivalent and nonavalent HPV vaccines are effective in the prevention of AGW in both women and men.^{58 66–68}

HPV VACCINATION IN THE GENERAL POPULATION

HPV vaccines are available in China

As of February 2025, the National Medical Products Administration of China has approved the marketing of five types of HPV vaccines: the domestic bivalent HPV vaccine (*E. coli*), the domestic bivalent HPV vaccine (*P. pastoris*), the bivalent HPV adsorbed vaccine (baculovirus) and the quadrivalent and nonavalent HPV vaccines (*S. cerevisiae*), as shown in table 3.

Currently, the HPV vaccine in China is classified as a non-immunisation programme vaccine (category II vaccine). Vaccination institutions should comply with the Vaccine Administration Law of the People's Republic of China, the Guiding Principles for the Use of Non-Immunization Program Vaccines, and the Standards for Immunization Services. In accordance with the vaccine instructions and the principles of 'informed consent, voluntary participation and self-funded payment', recipients or their guardians should be scientifically informed and vaccination should be provided to recipients promptly.

HPV vaccination for the general population

Recommendations on HPV vaccination in international guidelines

In its updated position paper released in December 2022, the WHO recommended that HPV vaccines be included in national immunisation programmes, with girls aged 9–14 who have not initiated sexual activity as the primary target population. Females aged 15 and above, boys, older males and MSM are considered secondary target groups.⁴ The Advisory Committee on Immunization Practices (ACIP) in the USA recommends that girls and boys begin HPV vaccination at age 11 or 12, with the earliest starting age being 9.⁶⁹ The European Cancer Organization suggests including both boys and girls in routine immunisation schedules and expanding coverage to older age groups. Vaccination up to at least age 26 can help prevent new HPV infections or reinfections and interrupt transmission to new sexual partners.⁷⁰ According to WHO data on HPV vaccination coverage released in 2023, the global proportion of 15-year-old females who received the first dose and completed all doses was 20% and 15%, respectively. Among 15-year-old males, the first-dose and full-course coverage rates were 7% and 5%. In high-income countries, the first-dose coverage rate among females was 56%, with 47% completing the full vaccination course. In low-income and middle-income countries, these rates were 16% and 13%, respectively.⁷¹

Table 3 HPV vaccines approved for marketing by the National Medical Products Administration of China (as of February 2025)

Item	Bivalent HPV vaccine (<i>Escherichia coli</i>)	Bivalent HPV vaccine (<i>Pichia pastoris</i>)	Bivalent HPV adsorbed vaccine (<i>Baculovirus</i>)	Quadrivalent HPV vaccine (<i>Saccharomyces cerevisiae</i>)	Nonavalent HPV vaccine (<i>Saccharomyces cerevisiae</i>)
Global/China market launch time	2021*/2019	-/2022	2007/2016	2006/2017	2014/2018
Covered HPV types	16/18	16/18	16/18	6/11/16/18	6/11/16/18/31/33/45/52/58
Adjuvant	Aluminium hydroxide	Aluminium phosphate	AS04 adjuvant system	Amorphous aluminium Hydroxyphosphate sulphate	Amorphous aluminium Hydroxyphosphate sulphate
HPV infection - related diseases prevented (approved in China)	Cervical cancer, AIS, CIN2/3, CIN1 caused by HPV16/18 infection; persistent HPV16/18 infection	Cervical cancer, AIS and CIN2/3 caused by HPV16/18 infection	Cervical cancer, AIS, CIN2/3, CIN1 caused by HPV16/18 infection	Cervical cancer, AIS, CIN2/3, CIN1 caused by HPV16/18 infection; AIN, anal cancer caused by HPV16/18 in men; AGW and AIN caused by HPV6/11	Cervical cancer, AIS, CIN2/3, CIN1 and persistent HPV infection caused by HPV16/18/31/33/45/52/58
Vaccination targets and schedules	Females aged 9–45: three doses (0, 1, 6 months); females aged 9–14: two doses (0, 6 months)	Females aged 9–30: three doses (0, 2, 6 months); females aged 9–14: two doses (0, 6 months)	Females aged 9–45: three doses (0, 1, 6 months); females aged 9–14: two doses (0, 6 months)	Females aged 9–45, males aged 9–26: three doses (0, 2, 6 months); females aged 9–13: two doses (0, 6 months)	Females aged 9–45: three doses (0, 2, 6 months); females aged 9–14: two doses (0, 6–12 months)
The vaccination route is intramuscular injection, preferably in the deltoid muscle of the upper arm *Certified by the WHO pre-qualification (PQ) in 2021, obtained marketing authorisation in 20 countries, including Morocco, Nepal, Thailand, etc. AGW, anogenital warts; AIN, anal intraepithelial neoplasia; AIS, adenocarcinoma in situ; CIN, cervical intraepithelial neoplasia; HPV, human papillomavirus.					

Recommendations on HPV vaccination for the general population in China

Among young women in China, there is a trend towards earlier initiation of sexual activity and engagement in high-risk sexual behaviours. Surveys show that the median age of first sexual activity is 17 years in the 15–19 age group and 19 years in the 20–24 age group. The proportion of urban and rural women aged 15–19 years who are sexually active is 4.5% and 10.8%, and increases to 62.2% and 44% in the 20–24 age group, respectively.⁷² Clinical trial studies have demonstrated that females aged 9–15 generate significantly higher antibody titers after receiving the HPV vaccine compared with those aged 16–26.^{32 33 36 39 40} Real-world studies also show that receiving the HPV vaccine before age 17 reduces the incidence of invasive cervical cancer by 88%.⁶⁴ Therefore, females benefit significantly from HPV vaccination prior to their first sexual activity. Taking into account China's national conditions, cost-effectiveness, public acceptance, organisational feasibility and practical implementation, it is recommended that in regions where free HPV

vaccination can be provided, girls aged 13–14 should be prioritised as the target group for HPV vaccination.³⁰

The HR-HPV infection rate among women aged 25–45 in China is as high as 19.9%.⁸ With increasing age, declining hormone levels and weakened immunity, it becomes more difficult for HPV infections to clear naturally, increasing the likelihood of recurrent or persistent infections, which in turn raises the risk of progression to cervical precancerous lesions and cancer.¹⁰ Studies have shown that for women aged 27–45, the seroconversion rates and antibody titres induced by the bivalent, quadrivalent and nonavalent HPV vaccines are non-inferior to those in women aged 16–26.^{33 36 39 73} Therefore, women aged 27–45 can still benefit from HPV vaccination. Given the epidemiological characteristics of HR-HPV infection among Chinese women, the currently low HPV vaccination coverage, and the limited coverage of cervical cancer screening, an individualised vaccination strategy is necessary. On 2 January 2025, China's National Medical Products Administration officially approved the use of the quadrivalent HPV vaccine for males aged 9–26.

Recommendations

- ▶ HPV vaccination is strongly recommended for females aged 9–26, with a primary focus on girls aged 9–14 (recommendation category: class 1).
- ▶ Vaccination is recommended for women aged 27–45 who are eligible (recommendation category: class 2A).
- ▶ HPV vaccination is recommended for males aged 9–26 (recommendation category: class 2A).

HPV VACCINATION FOR HIGH-RISK AND SPECIAL POPULATIONS

Individuals with HPV infection or cytological abnormalities

HPV vaccines offer significant protective benefits even for women who have previously been infected with HPV, whether transiently or persistently. Studies have shown that among Chinese women aged 18–25 who were infected with non-vaccine-type HR-HPV, the bivalent HPV AS04-adjuvanted vaccine provided 100% protection against 6-month and 12-month persistent infections related to HPV 16/18.⁷⁴ Among women aged 15–25 who were seropositive for HPV 16/18, the vaccine demonstrated 67.2% efficacy in preventing HPV 16/18-related CIN1+ lesions.⁷⁵ Quadrivalent HPV vaccine provides 100% protection against CIN1+ caused by reinfection with vaccine HPV or other uninfected HPV in women 16–26 years of age who were previously infected with vaccine HPV (seropositive for HPV antibody and negative for cervical HPV DNA).⁷⁶ Among women aged 24–45 with past vaccine-type HPV infection, the quadrivalent HPV vaccine showed 66.9% efficacy in preventing HPV 16/18-related CIN1+ lesions.⁷⁷ The nonavalent HPV vaccine provided 91.1%–95.8% protection against CIN2+ caused by other non-infected vaccine-type HPV strains among women aged 16–26 currently infected with some of the vaccine-type HPV strains.⁷⁸ Additionally, HPV vaccines have shown high protective efficacy in women with cytological abnormalities. A large multicentre RCT involving approximately 14000 young women aged 16–26 found that, among those with initial cytological abnormalities, the nonavalent HPV vaccine had 94.6% efficacy in preventing 6-month persistent infections related to HPV 31/33/45/52/58.⁴⁹

Recommendation: HPV vaccination is recommended for age-eligible females regardless of whether they have an existing HPV infection or cytological abnormalities (recommendation category: class 2A)

Individuals with a history of HPV-related lesion treatment

Individuals with a history of cervical precancerous lesions/cancer treatment

Women with a history of lower genital tract HSIL may experience recurrent HPV infection, persistent infection or disease recurrence after treatment.⁷⁹ A meta-analysis of 18 studies showed that HPV vaccination reduced the risk of CIN2+ recurrence by 57%, with an even greater 74% reduction in recurrence risk for HPV 16/18-related CIN2+.⁸⁰ A post hoc analysis of the PATRICIA study revealed that among women aged 15–45, regardless

of HPV DNA status, HPV 16/18 serostatus or cervical cytology, receiving the bivalent HPV vaccine before undergoing excisional treatment significantly reduced the risk of postoperative CIN2+ recurrence by 88.2% during a 4-year follow-up.⁸¹

A prospective randomised controlled trial in Italy involving women aged 23–44 with a history of cervical squamous intraepithelial lesions found that those who received the quadrivalent HPV vaccine had a significantly lower recurrence rate of HPV-related lesions compared with unvaccinated women (3.4% vs 13.5%, $p=0.0279$).⁸² A Chinese prospective cohort study of women aged 20–45 who underwent loop electrosurgical excision procedure (LEEP) for CIN2/3 and were followed for 30 months found that the vaccinated group had a significantly lower 2-year postoperative HPV infection rate (8.11% vs 15.75%, $p=0.026$) and recurrence rate of CIN2+ (1.35% vs 10.62%, $p=0.001$), compared with the unvaccinated group. Those not vaccinated after treatment had a significantly higher risk of CIN2+ recurrence.⁸³

The optimal timing for vaccination remains unclear. Most existing studies administered the HPV vaccine either before cervical conisation or shortly after LEEP (within 1 month). Therefore, it is recommended to receive the vaccine as soon as possible, either before or after surgery, as delaying vaccination may not prevent reinfection in women at risk.⁸⁴

Recommendation: HPV vaccination is recommended for age-eligible women with a history of cervical precancerous lesions, preferably administered before or as soon as possible after treatment (recommendation category: class 2A)

Individuals with a history of precancerous lesions/cancer treatment in other HPV-related sites

Currently, there is limited evidence on HPV vaccination in individuals with a history of treatment for vulvar intraepithelial neoplasia (VIN), vaginal intraepithelial neoplasia (VaIN)/vaginal cancer, AGW and anal intraepithelial neoplasia (AIN)/anal cancer. Research has shown that in young women with HPV-related AGW, VIN or VaIN, vaccination with the quadrivalent HPV vaccine can significantly reduce the risk of developing any subsequent disease (including CIN1+, AGW, VIN1+ or VaIN1+) by up to 64.4%.⁸⁵

A prospective case-control study in women with high-grade VIN who underwent surgery showed that compared with surgery alone, receiving the quadrivalent HPV vaccine shortly after surgery reduced the incidence (19% vs 32%, $p=0.19$) and recurrence rate (4.8% vs 22.3%, $p=0.01$) of high-grade VIN.⁸⁶ Among MSM, the quadrivalent HPV vaccine significantly reduced the recurrence of AIN2+ compared with those who were not vaccinated.⁸⁷ In HIV-positive MSM over 27 years old with a history of AIN2+, receiving the quadrivalent HPV vaccine was estimated to reduce the lifetime risk of anal cancer by 60.8%.⁸⁸ Other studies have shown that children with RRP experienced disease stabilisation or

sustained remission after receiving the quadrivalent HPV vaccine.^{89 90} Adult RRP patients also benefited from a combination of surgical treatment and vaccination with the quadrivalent HPV vaccine.⁹¹

Recommendation: it is recommended that individuals with a history of vulvar or vaginal precancerous lesions/cancer, those at high risk for anal cancer (including HIV-positive individuals and MSM), and those with AGW or RRP receive the HPV vaccine as early as possible (recommendation category: 2B).

High-risk populations

Genetically susceptible individuals

Genetic susceptibility factors may influence an individual's sensitivity to HPV infection, persistence of infection and the progression rate of cervical cancer.¹

Shared genetic heritability accounts for approximately 27% of the total variation in cervical cancer susceptibility.⁹² Genome-wide association studies (GWAS) have identified several genetic susceptibility loci associated with cervical cancer, many of which are related to immune response genes. GWAS conducted in Chinese populations have identified susceptibility loci in regions such as 6p21.32, and genes like EXOC1 and GSDMB located at 4q12 and 17q12, respectively. The proteins encoded by these genes are involved in innate immunity and tumour cell proliferation.⁹³ A case-control study in a German population found that mutations at 6p21.32 (rs9357152) and 14q24.3 (rs4243652) were associated with HPV16 and HPV18-positive invasive cervical cancer. Specifically, rs9357152 may function by regulating HLA-DRB1 expression in the presence of HPV.⁹⁴

Recommendation: it is recommended that age-appropriate females with genetic susceptibility mutations (such as mutations in HLA-DPB2, EXOC1 and GSDMB) receive the HPV vaccine. Vaccination should ideally occur before the onset of sexual activity, but even after sexual exposure, vaccination is still strongly recommended as early as possible (recommendation category: 2B)

Individuals with high-risk lifestyles for cervical cancer

Early sexual activity, multiple sexual partners, multiple pregnancies and births, smoking, long-term use of oral contraceptives and history of sexually transmitted infections are all high-risk factors for cervical cancer and other HPV-related diseases.^{2 30} More than 50% of young women acquire an HPV infection within 3 years of becoming sexually active. During adolescence, the lower genital tract is still developing. Early sexual activity may lead to repeated exposure of the cervical epithelium to certain bacteria or viruses, increasing the risk of potential cellular mutations.

Recommendation: it is strongly recommended that age-appropriate females with high-risk lifestyle factors for cervical cancer receive the HPV vaccine as early as possible (recommendation category: 2A)

Immunocompromised individuals

Immunocompromised individuals include those with HIV infection, autoimmune diseases, obesity, diabetes, kidney failure requiring dialysis and those who have undergone organ or bone marrow transplants and are on long-term immunosuppressive therapy.

HIV-infected individuals

Studies show that the antibody response rate to the quadrivalent HPV vaccine ranges from 75% to 100% in HIV-infected women aged 13–45 years.⁹⁵ In HIV-infected individuals, seroconversion rates for HPV 16 and 18 after the first dose of the bivalent, quadrivalent or 9-valent HPV vaccine range from 94% to 100% at 28 weeks, and protection can last for 2–4 years.⁹⁶ A follow-up study of HIV-infected women aged 9 and older who received the quadrivalent HPV vaccine found no cases of CIN2+ after a median follow-up of 2 years.⁹⁷ The 2022 WHO position document recommended prioritising HPV vaccination for immunocompromised populations, including HIV-infected individuals, as part of public health initiatives.⁴

Recommendation: it is strongly recommended that age-appropriate HIV-infected women receive the HPV vaccine, preferably before sexual activity begins (recommendation category: 2A)

Patients with autoimmune diseases

Patients with autoimmune diseases, such as systemic lupus erythematosus, autoimmune inflammatory rheumatic diseases, rheumatoid arthritis, Sjögren's syndrome, Hashimoto's thyroiditis, etc, are at increased risk for HPV infection, with the rate being 1.6 times higher than that of the general population.⁹⁸ Studies on the HPV vaccination of patients with autoimmune diseases show that after receiving the quadrivalent HPV vaccine, the seroconversion rates for HPV serotypes 6, 11, 16 and 18 at 12 months are 76%–98%, with lower antibody titres observed in patients using immunosuppressive drugs.⁹⁹ After 5 years of follow-up, patients who seroconverted maintained persistent antibody levels, with seroconversion rates for vaccine-related types ranging from 84% to 96%.¹⁰⁰ Real-world multicentre studies have also confirmed the safety and immunogenicity of the HPV vaccine in this population.¹⁰¹ Both domestic and international guidelines recommend that autoimmune disease patients receive the HPV vaccine.^{102 103}

Recommendation: it is recommended that age-appropriate individuals with autoimmune diseases receive the HPV vaccine (recommendation category: 2A)

Diabetic patients, chronic kidney disease or haemodialysis patients

Currently, there is limited research on the HPV vaccination of diabetic patients globally. Studies in China involving HR-HPV infections and cytological diagnoses of HSIL have shown that diabetes and pre-diabetes are positively correlated with cervical cancer, and type 1 diabetes is associated with a significantly higher incidence of genital warts.¹⁰⁴

Chronic kidney disease (CKD) or end-stage renal failure patients on haemodialysis have an increased risk of HPV infections and related cancers. Among renal failure patients before transplantation, 30% of patients were found to be infected with HPV, with the highest infection rate found in cervical samples (60%).¹⁰⁵ The incidence of HPV-related cancers in patients on haemodialysis for renal failure increases annually, with the incidence being 16 times higher than that of the general population.¹⁰⁶ For CKD and renal failure haemodialysis patients, the antibody response rates to HPV 6/11/16/18 after receiving the quadrivalent HPV vaccine were 100%.¹⁰⁷ The US ACIP guidelines recommend the routine HPV vaccination for both diabetic patients and haemodialysis patients.^{108 109}

Recommendation: for age-appropriate individuals with diabetes or end-stage renal failure on haemodialysis, it is recommended that clinicians discuss with patients and, if clinically appropriate, administer the HPV vaccine. Vaccination is not recommended for patients with severe organ dysfunction or limited life expectancy (recommendation category: 2B)

Long-term immunosuppressant use after organ/bone marrow transplantation and cancer patients

In organ transplant patients, the use of long-term immunosuppressants increases the risk of HPV infections and related precancerous lesions/cancers.¹¹⁰ The antibody response rate to HPV vaccination in this population is lower than that in the general population. The seroconversion rate in kidney transplant patients is 50%–75%, while in liver transplant patients and healthy women, the seroconversion rate is 100%.¹¹¹ An investigator-initiated phase III study in solid organ transplant patients aged 18–55 years showed that the antibody seropositivity rate for the nonavalent HPV vaccine ranged from 46% to 72% at 7 months after the first dose of the vaccine. The vaccine was well tolerated with no vaccine-related serious adverse events (SAEs).¹¹² A prospective study of bone marrow transplant recipients showed that among patients receiving immunosuppressant treatment, the antibody response to all vaccine-covered types was 78.3%, while those not receiving immunosuppressants had a response rate of 95.2%.¹¹³

The 2019 guidelines of the American Society of Transplantation strongly recommend the three-dose nonavalent HPV vaccine for all 9–26-year-old transplant recipients (ideally before transplantation); for 45 years and younger individuals and 15–26-year-old transplant recipients with genital warts, HPV vaccination is also recommended (weak recommendation).¹¹⁴ The 2024 guidelines of the American Society of Clinical Oncology recommend HPV vaccination for 19–26-year-old cancer patients and suggest shared decision-making for 27–45-year-old cancer patients; ideally, vaccination should be given 2–4 weeks before cancer treatment to achieve optimal protection before the treatment affects the immune system.

Vaccination can be given 9–12 months after haematopoietic stem cell transplantation.¹¹⁵

Recommendation: for organ or bone marrow transplant recipients who are on long-term immunosuppressants or for cancer patients, it is recommended that clinicians discuss with patients and provide individualised advice based on the severity of the disease. For age-appropriate females with a long life expectancy, HPV vaccination is recommended 1 year after transplantation. For those with a limited life expectancy, vaccination is not recommended (recommendation category: 2B)

Pregnant and lactating women

Research data on HPV vaccination in pregnant women are limited. A systematic review and meta-analysis on the vaccination of pregnant women showed that receiving the HPV vaccine during pregnancy does not increase the risk of adverse pregnancy outcomes.¹¹⁶ The safety results are consistent with global clinical trials and safety monitoring studies.¹¹⁷ In women who were vaccinated with the nonavalent HPV vaccine during pregnancy, the rates of adverse pregnancy outcomes and fetal congenital abnormalities were similar to those with the quadrivalent HPV vaccine, with no adverse pregnancy outcomes related to the nine-valent vaccine.¹¹⁸

The 2019 ACIP guidelines,⁶⁹ the 2022 WHO position paper on HPV vaccination,⁴ and the 2023 China Cervical Cancer Comprehensive Prevention and Control Guidelines (second edition)³⁰ state that due to limited data on HPV vaccination during pregnancy, preventive HPV vaccination is not recommended for pregnant women, and vaccination should be postponed until after pregnancy. If pregnancy is discovered after vaccination, the uncompleted doses should be postponed until after delivery. Routine pregnancy testing before HPV vaccination is not necessary.

Based on the existing evidence, the risk of vaccine-related AEs in both the mother and infant does not increase when HPV vaccination is given during lactation. The 2022 WHO position paper concluded that HPV vaccination in lactating women does not affect the safety of breastfeeding for the mother or the infant.⁴ Although clinical trials have not yet observed the secretion of HPV antibodies into breast milk, given that many drugs are excreted in breast milk, and the lack of more safety data on HPV vaccination in lactating women, vaccination during lactation should be considered with caution.

Recommendations: HPV vaccination is not recommended for pregnant women. If pregnancy occurs after vaccination, the remaining doses should be delayed until after delivery. For women who have completed the vaccination, no intervention is needed. HPV vaccination for lactating women should be recommended cautiously.

The recommended vaccination levels for both the general and special populations are outlined in [table 4](#).

Table 4 Recommended levels for HPV vaccination in general and special populations

Different populations	Recommendation level
General population	
Females aged 9–26	Priority recommendation
Males aged 9–26	Recommendation
Females aged 27–45	Recommendation
Special populations	
Eligible females with HPV infection/cytological abnormalities	Recommendation
Pregnant females	Not recommended
Lactating females	Cautious recommendation
Eligible females with a history of treatment for HPV-related lesions	Recommendation
Genetically susceptible populations	Recommendation
Eligible females with high-risk lifestyle for cervical cancer*	Priority recommendation
Eligible females with immunocompromise†	Priority recommendation
HIV-infected individuals	Priority recommendation
Patients with autoimmune diseases: systemic lupus erythematosus, rheumatoid arthritis, connective tissue disease, Sjögren's syndrome, Hashimoto's thyroiditis, etc.	Recommendation
Diabetic patients	Recommendation
Patients with renal failure undergoing haemodialysis	To be discussed with clinicians
Patients with organ/bone marrow transplantation taking immunosuppressants long-term and patients with malignant tumours	To be discussed with clinicians

*It is recommended to vaccinate before the first sexual exposure or as early as possible;
†For those with poor function of all organs, an unfavourable condition, and a limited life expectancy, vaccination is not recommended.
HPV, human papillomavirus.

SAFETY OF HPV VACCINES

The safety evaluation data for HPV vaccines mainly come from premarket clinical trials, postmarket real-world studies and adverse reaction (AR) monitoring. In China, this monitoring is primarily conducted by the Centers for Disease Control and Prevention (CDC) and the Adverse Drug Reaction Monitoring Center.

Safety evaluation

- **Adverse reaction:** This refers to harmful reactions that occur under normal use of a qualified vaccine and have a clear causal relationship with vaccination. These reactions are generally predictable and dose-related.
- **Adverse event:** This refers to any negative event occurring during or after vaccination, but the event may not necessarily be causally related to the vaccine.
- **Serious adverse event:** This refers to events that occur after vaccination, including death, life-threatening conditions, permanent or severe disability or functional loss, hospitalisation or prolonged hospitalisation.
- **AEs following immunisation (AEFI):** This refers to medical events or reactions that occur after vaccination, which are suspected to be related to the vaccination but do not necessarily have a causal relationship with the vaccine.

Global HPV vaccine safety evaluation

Data from all sources worldwide on the use of HPV vaccines show that they have a good safety profile.⁴ The Global Advisory Committee on Vaccine Safety has conducted five periodic reviews of the safety of HPV vaccines and concluded that they are very safe.¹¹⁹ According to the WHO's updated position paper in 2022: since the vaccine was licensed in 2006, more than 500 million doses of HPV vaccines have been administered, and the vaccines have shown good safety and tolerability. Most AEs following vaccination are mild and transient. So far, apart from rare reports of allergic reactions, no serious safety issues have been identified through postmarketing surveillance.⁴ Multiple authoritative organisations and experts, including the CDC, International Federation of Gynecology and Obstetrics (FIGO) and the Women's Health Division of the Chinese Preventive Medicine Association, also recognise the safety of HPV vaccines.^{1 2 30 120}

Safety of HPV vaccines in clinical trials

In clinical trials of the bivalent vaccines in China, all ARs reported by participants were mild or moderate (≤ 3 grade). The most common local AR was pain at the injection site, followed by induration. The three most common systemic symptoms were fever, headache and fatigue (as per the vaccine's package insert). No vaccine-related SAEs were observed.⁴

In phase III clinical trials of the quadrivalent HPV vaccine conducted in China, the results showed that it was safe and well-tolerated among females aged 9–45 years, with results similar to those of global clinical trials. The most common reactions were pain and swelling at the injection site, and common systemic symptoms included fever, fatigue and headache. No vaccine-related SAEs were observed.³⁶ A phase III clinical trial of the nine-valent HPV vaccine in healthy women aged 9–45 years in China showed that most ARs were mild or moderate (<3 grade), with a local injection site AE rate of 3.1%–3.5% for grade 3, with pain and swelling being the most common.³⁹

Regarding the association between HPV vaccines and pregnancy, in the clinical trials of the quadrivalent vaccine, the frequency of pregnancy outcomes, fetal/infant SAEs and new medical conditions in the vaccine group and the placebo group was generally similar and within the normal range.¹¹⁷ Long-term follow-up of the bivalent adsorbed vaccine in premarket clinical trials in China showed no vaccine-related SAEs, immune-mediated diseases or adverse pregnancy outcomes during a 10-year follow-up period.¹²¹

Postmarket surveillance of HPV vaccine safety

Since its launch in 2006, postmarket surveillance data have shown that local and systemic ARs are generally consistent with the results from clinical trials.⁴ A study conducted by the Chinese CDC on the safety of HPV vaccines showed that between 2017 and 2020, a total of 22.74 million doses of the HPV vaccine were administered nationwide. The incidence of AEFI reports was 30.38 per 100 000 doses, indicating that HPV vaccines were well tolerated among Chinese women aged 9–45 years, with no safety concerns found.¹²² Real-world studies have reached the same conclusion, and postmarket surveillance has not reported any adverse pregnancy outcomes related to HPV vaccine exposure.¹¹⁸

PRECAUTIONS

Conditions in which HPV vaccination is not recommended

Individuals who have a hypersensitivity reaction to any of the active ingredients or excipients in the vaccine are prohibited from receiving the HPV vaccine. Those who exhibit hypersensitivity reactions after injection should not be vaccinated again. The HPV vaccine should be used with caution in the following populations: (a) Individuals with thrombocytopenia or other bleeding disorders that may contraindicate intramuscular injection should not receive the vaccine. (b) Acute diseases, which are often accompanied by fever and other systemic symptoms, may be exacerbated by vaccination, so it is recommended to wait until recovery before vaccination. (c) Since some women experience varying degrees of discomfort during menstruation, it is recommended to vaccinate outside of the menstrual period.

Cervical cancer screening after HPV vaccination

Cervical cancer screening should continue after HPV vaccination: (A) the effectiveness of the HPV vaccine is

reduced in populations with HPV infection or risk factors for HPV-related diseases (such as multiple sexual partners, previous infections with vaccine-related HPV types, immunodeficiency, etc.). (B) HPV vaccines are preventive and cannot eliminate existing HPV infections or treat HPV-related diseases, nor can they prevent the progression of lesions. (C) The HPV vaccine covers only a limited number of HPV types and cannot prevent infections from all HPV types. Even after vaccination, the body remains at risk for infections from non-vaccine HPV types. A small number of cervical cancers may not be related to HPV infection, particularly non-HPV-associated tumours. (E) Long-term follow-up studies of the earliest globally marketed quadrivalent HPV vaccine confirm its protective effect for up to 14 years, but the lifetime protection of the HPV vaccine still requires further research to be confirmed. Therefore, cervical cancer screening should still be continued after HPV vaccination.

No need for antibody testing after HPV vaccination

First, the protective efficacy of HPV vaccination is generally calculated by comparing the incidence of disease between the vaccine and placebo groups in clinical trials. This cannot be equated with the ability of antigens to stimulate the immune system to produce antibodies and sensitised lymphocytes, which refers to immunogenicity (antibody levels). There is currently no clear data on the correlation between the immunogenicity of HPV vaccines and their protective efficacy (the minimum threshold of HPV antibody levels corresponding to the prevention of CIN2/3 or sustained infection has not yet been defined). Furthermore, HPV vaccine antibody testing has not been standardised or unified, and there is no gold standard for setting the threshold for positive antibody results. Serological antibody testing is not used in clinical practice and is only employed in research. Additionally, different HPV vaccine use, different antibody testing methods and the results from these methods are not comparable. Moreover, due to the immune memory mechanism, even if antibody levels decrease years after vaccination, it has been confirmed that the vaccine's type-specific protective effects continue. The US ACIP has pointed out that there is no clinical antibody test that can determine whether an HPV vaccine recipient has acquired immune protection or is still susceptible to any specific HPV type.⁶⁹ Therefore, there is no need for HPV antibody testing after vaccination for recipients.

SUMMARY

HPV vaccination is an effective and safe method for preventing HPV infections and HPV-related diseases of the lower genital tract and other areas. Vaccination before sexual exposure provides the best immune response. HPV vaccination is primarily recommended for women aged 9–26 years, with a focus on girls aged 9–14 years. It is also recommended for men aged 9–26 years and women aged 27–45 years, advocating for prevention among both

men and women. HPV vaccination is not only suitable for the general population but also recommended for high-risk groups with behaviours that increase cervical cancer risk as well as for those with genetic susceptibility or HIV infection. HPV vaccination can be administered to women of appropriate age, whether or not they have an HPV infection or abnormal cytology. Women with a history of HPV-related lesions may benefit from vaccination to reduce recurrence. Women who are planning pregnancy, pregnant or breastfeeding should not receive the HPV vaccine. Cervical cancer screening should continue after HPV vaccination, but there is no need for HPV antibody testing.

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