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2023 Korean sexually transmitted infections guidelines by the Korean Association of Urogenital Tract Infection and Inflammation: Human papillomavirus vaccination

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The Korean Association of Urogenital Tract Infection and Inflammation (KAUTII) and the Korea Disease Control and Prevention Agency updated the guidelines for human papillomavirus (HPV) vaccine against sexually transmitted HPV infections in Korea to respond to changing epidemiologic trends, evolving scientific evidence, and advances in laboratory diagnostics and research. Main purpose and recommendation of vaccination against HPV are as follows: (1) the purpose of HPV vaccine is to reduce the risk of genital warts and HPV-related cancers including cervical and vulvar cancer, head and neck cancer, anal cancer, and penile cancer; (2) in Korea, bivalent (16, 18) vaccines, quadrivalent vaccines (6, 11, 16, 18), and 9-valent vaccines (6, 11, 16, 18, 31, 33, 45, 52, 58) are used depending on the type of HPV; (3) bivalent and quadrivalent vaccines are national immunizations targeting girls aged 11–12 years and low-income young females aged 18–26 years (age and range of inoculation: routinely administered at 11 or 12 years of age, 2 doses at 0 and 6 months for 12–14 years of age; for females aged 15–26 years, 3 doses depending on the type of vaccine; vaccination can be given to those aged up to 45 years through consultation with a clinician); (4) in the case of administering 2 doses, at least 5 months apart; in the case of administering 3 doses, it is recommended to keep 4 weeks between the 1st and 2nd doses, 12 weeks between the 2nd and 3rd doses, and 5 months between the 1st and 3rd doses; (5) immunocompromised patients such as those with HIV, malignant neoplasms, and autoimmune diseases, and those undergoing transplantation or immunosuppressive therapy should receive 3 doses. HPV vaccine is not recommended during pregnancy.

Keywords: Guideline; Human papillomavirus; Vaccination

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SUMMARY OF RECOMMENDATIONS

- Human papillomavirus (HPV) vaccines are made from recombinant L1 major proteins assembled into virus-like particles.
- The purpose of these vaccines is to reduce the risk of genital warts and HPV-related cancers including cervical and vulvar cancer, head and neck cancer, anal cancer, and penile cancer.
- In Korea, bivalent (16, 18) vaccines, quadrivalent vaccines (6, 11, 16, 18), and 9-valent vaccines (6, 11, 16, 18, 31, 33, 45, 52, 58) are used depending on the type of HPV.
- Bivalent and quadrivalent vaccines are national immunizations targeting girls aged 11–12 years and low-income young females aged 18–26 years.
- Age and range of inoculation: these vaccines are routinely administered at 11 or 12 years of age, 2 doses administered 6 months apart for 12–14 years of age in both sexes.
- For males and females aged 15–26 years, 3 doses are administered depending on the type of vaccine.
- For older ages, vaccination can be given to those aged up to 45 years through consultation with a clinician.
- In the case of 2 doses, they should be given at least 5 months apart; in the case of 3 doses, it is recommended to keep 4 weeks between the 1st and 2nd doses, 12 weeks between the 2nd and 3rd doses, and 5 months between the 1st and 3rd doses.
- Immunocompromised patients such as those with HIV, malignant neoplasms, autoimmune diseases, and those undergoing transplantation or immunosuppressive therapy should receive 3 doses.
- HPV vaccine is not recommended during pregnancy.

INTRODUCTION

Human papillomavirus (HPV) is a small, non-enveloped double-stranded DNA virus with carcinogenic potential. Most HPV infections are transient and asymptomatic without clinical consequences regardless of its risk type (low- or high-risk type). However, in a significant number of individuals, sexually transmitted HPV infection can cause anogenital warts, oropharyngeal cancer, or cancer of the urogenital tract. About 45,000 HPV-related cancers are diagnosed each year in the United States, with cervical cancer being the most common in females and oropharyngeal cancer being the most common in males. The nine-valent HPV vaccine is very effective in preventing genitourinary cancer and anogenital warts. HPV-related cervical cancer screening is an important component of cancer prevention in adult females.

HPV vaccines are based on recombinant technology to produce major L1 proteins that can self-assemble into virus-like particles [1]. Three domestic HPV vaccines (bivalent HPV, quadrivalent HPV, and nine-valent HPV) have been approved for use. A quadrivalent vaccine in 2007, a bivalent vaccine in 2008, and a nine-valent vaccine in 2016 were approved. The nine-valent HPV vaccine provides protection against seven oncogenic HPV types (16, 18, 31, 33, 45, 52, 58), which account for about 80% of cervical cancers, and two HPV types (6 and 11) that cause about 90% of condyloma acuminata [2]. Based on HPV type data from individual samples with HPV-associated cancers of the vulvovaginal, anogenital, or oropharynx, HPV types of the nine-valent HPV vaccine overlap closely with these cancer-related HPV types [3]. The nine-valent HPV vaccine has shown excellent safety in both sexes, with transient syncope being the most adverse reaction immediately after vaccination [4,5].

As for individual diseases, it has been confirmed that the number of patients with genital warts is decreased after vaccination [6-11]. For cervical cancer or precancerous lesions, it has also been confirmed that the incidence and risk of such diseases are reduced after vaccination [12-15]. In the case of anal cancer, the evidence is relatively limited, with more patients being identified in the vaccination group [16].

DEVELOPMENT OF KOREAN GUIDELINES

The Korea Centers for Disease Control and Prevention (currently the Korea Disease Control and Prevention Agency, KDCA) and the Korean Association of Urogenital Tract Infection and Inflammation (KAUTII) developed the first Korean sexually transmitted infection (STI) guidelines in 2011. Later in 2016, as the first revision, the Korean STI guidelines 2016 were published. Six years after that, in 2022, The KDCA and the KAUTII then carried out the second revision of the guidelines from July 2022 to April 2023.

The development committee consisted of a steering committee, a development committee, a writing committee, an internal review committee, and an external review committee. The writing committee included the insurance team for insurance-related review, just like the first revision of the guideline. The external review committee consisted of the Korean Urological Association, the Association of Korean Urologist, the Korean Society of Obstetrics and Gynecology, the Korean Association of Obstetricians and Gynecologists, the Korean College of Obstetrics and Gynecology, the Korean Society for Laboratory Medicine, the Korean Society

of Clinical Microbiology, the Korean Society of Infectious Diseases, and Division of HIV/AIDS Prevention and Control of KDCA. There was no conflict of interest at the beginning of the development. There was no report until the end of development either.

Following recommendation of the Korea Medical Guideline Information Center (KoMGi), we took the form of local adaptation to accommodate and develop foreign guidelines to suit the Korean situation. Therefore, various search data sources were used to search existing treatment recommendations for acceptance development. PubMed (http://www.pubmed.gov), NICE (National Institute for Health and Care Excellence; https://www.nice.org.uk), KoreaMed (http://www.koreamed.org), trials registers (http://www.clinicaltrials.gov), SciELO (https://www.scielo.org), Scopus (https://www.scopus.com), Embase (https://www.embase.com), Google Scholar (https://scholar.google.com), Cochrane Library (https://www.cochranelibrary.com), National Guideline Clearinghouse, and CMA (Canadian Medical Association) Infobase: Clinical Practice Guidelines database were used. The following search index words were used: STI index words ("sexually transmitted infection" or "sexually transmitted disease") and treatment guideline index words ("guideline", "national guideline", "practice guideline", "management guideline", "consensus", "recommendation"). The range of publication dates was limited from January 2017 to December 2022. The latest edition was selected if there was a revision. The following ten foreign STI guidelines were then searched:

- Guidelines for the management of symptomatic sexually transmitted infections, World Health Organization (WHO), 2021
- Sexually transmitted infections treatment guidelines, Centers for Disease Control and Prevention (CDC), 2021
- Sexually transmitted infections - summary of guidelines, New Zealand, 2017
- BASHH national guideline on the management of sexually transmitted infections and related conditions in children and young people, British Association for Sexual Health and HIV (BASHH), 2021
- STI treatment pocket European guidelines, International Union against Sexually Transmitted Infections (IUSTI), 2019
- Alberta treatment guidelines for sexually transmitted infections (STI) in adolescents and adults, Canada, 2018
- Reducing sexually transmitted infections, NICE, 2022
- Guidelines for the diagnosis and treatment of sexually transmitted diseases, Japanese Society for Sexually Transmitted Infections (JSSTI), 2020
- NT guidelines for the management of sexually transmitted infections in the primary health care setting, Northern Territory Government, 2019
- Australian STI management guidelines for use in primary care, Viral Hepatitis and Sexual Health Medicine (ASHM), 2021

After excluding guidelines not developed based on evidence or published without references, we evaluated five guidelines: WHO, CDC, BASHH, IUSTI, and JSSTI. For quality evaluation, the K-AGREE 2.0 (Korean version of AGREE 2.0) evaluation development scale distributed by the KoMGi was used. Four members of the development committee evaluated six areas to obtain standardized scores for each area. Calculated. After comparing scores of each area, two guidelines (WHO and CDC) were finally selected.

In order to adapt to the domestic situation, domestic data in all fields were searched and analyzed. Key questions were derived using the PICO (Population or Patient problem, Intervention, Comparison, Outcome) technique. For the search of evidence for the literature review, PubMed and KoreaMed were used. In the case of a recently published systematic review or meta-analysis, previously published literature with low level of evidence was excluded. Case reports were also excluded. The Delphi technique was applied to derive and adopt recommendations for the draft. A total of 17 panels were formed to ensure the representativeness and expertise of the recommendation development group.

The guideline development committee and the review committee for verification of recommendations adopted by consensus operated independently. Finally, it was certified by the Korean Urological Association, the Association of Korean Urologist, the Korean Society of Obstetrics and Gynecology, the Korean Association of Obstetricians and Gynecologists, the Korean college of Obstetrics and Gynecology, the Korean Society for Laboratory Medicine, the Korean Society of Clinical Microbiology, the Korean Society of Infectious Diseases, and Division of HIV/AIDS Prevention and Control of KDCA, who participated in the development.

HPV VACCINE RECOMMENDATIONS

The goal of the HPV vaccine is to reduce the risk of genital warts (quadrivalent and nine-valent) and HPV-related cancers by preventing infections caused by HPV types covered by the bivalent, quadrivalent, and nine-valent HPV vaccines. The potential role of the HPV vaccine in unvaccinated individuals diagnosed with HPV-associated lesions or precancerous conditions is unknown and research is ongoing on this topic. The following summarizes recommendations of the Advisory Committee for Immunization Practices (ACIP)

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Table 1. Domestic HPV vaccination timing and methods according to age and sex

Sex	Age of vaccination start (y)	No. of vaccine doses	Type of vaccine	Vaccination schedule (mo)
Female	9–14	2	Bivalent, quadrivalent, 9-valent	0, 6–12
		3	Bivalent	0, 1, 6
			Quadrivalent, 9-valent	0, 2, 6
	15–16	3	Bivalent	0, 1, 6
			Quadrivalent, 9-valent	0, 2, 6
	27–45	3	9-valent	0, 2, 6
Male	9–14	2	Quadrivalent	0, 6–12
		3	Quadrivalent, 9-valent	0, 2, 6
	15–26	3	Quadrivalent, 9-valent	0, 2, 6

HPV, human papillomavirus.

on the use of the nine-valent HPV vaccine to prevent HPV infections. A summary of vaccines available in Korea is also added as follows [17-19].

1. Age and age range

HPV vaccine should be routinely administered at age 11 or 12 for all girls and boys. Children who have experienced sexual abuse or sexual assault can be vaccinated as early as age 9. People who have not been vaccinated against bivalent (only indicated in girl), quadrivalent or nine-valent HPV by age 13 can be vaccinated until age 26. People between ages of 27 and 45 who have not previously received the HPV vaccine should share their decision-making with their clinicians in both sexes. This is because public health benefits of all types of HPV in the elderly are unclear because many people have already acquired multiple HPV types. Indications for domestic vaccination are listed in Table 1.

2. Schedule

A two-dose HPV vaccination schedule is recommended for healthy girls and boys (in boys, bivalent is not indicated) starting vaccination between ages of 9 years and 14 years (vaccination at 0–6 months). Persons starting vaccination after age 15 years require 3 doses (given at 0, 1–2 months, and 6 months).

3. Recommended minimum interval

For a two-dose series, ACIP recommends an interval of at least 5 months. If the second dose is too early, a repeat dose should be given (at least 5 months after the first dose). For vaccination using 3 doses, the recommended minimum interval is 4 weeks between doses 1 and 2, 12 weeks between doses 2 and 3, and 5 months between doses 1 and 3. If a vaccine dose is administered prior to the recommended minimum interval, it should be repeated after another minimum interval has elapsed since the most recent dose.

4. Vaccination in immunocompromised persons

In the case of vaccinating immunocompromised patients including those with HIV, malignant neoplasms, autoimmune disease, B lymphocyte antibody deficiencies, T lymphocyte complete or partial defects, or recipients of transplantation or immunosuppressive therapy, a 3-dose vaccination schedule should be performed.

5. Interrupted schedule

If the vaccination schedule is interrupted for longer than the dosing interval, it is recommended to complete the vaccination series without repeating the required vaccination. The total number of vaccinations is determined by the age at which the first dose was received.

6. Pregnancy

HPV vaccine is not recommended during pregnancy. However, if the vaccine is accidentally administered to a pregnant female, no intervention is required. Also, a pregnancy test is not required prior to HPV vaccination.

7. Persons previously vaccinated with a vaccine other than the 9-valent vaccine

If people have previously completed two doses of a bivalent or quadrivalent vaccine instead of a nine-valent vaccine and the vaccination was started before the age of 15, they are considered to have completed the appropriate vaccination [19]. ACIP does not provide recommendations for administering or administering the nine-valent vaccine to people who have previously received a bivalent or quadrivalent vaccine.

IMPACT OF HPV VACCINE ON HPV PREVALENCE

In Korea, there is a paucity of research examining ef-

fects of vaccines on vaccine-related diseases. However, foreign studies have revealed the impact on prevalence. In foreign studies, including those conducted in the United States, the prevalence of subtype strains covered by the vaccine is decreased significantly within 10 years after HPV immunization [20-22]. In a prevalence survey of females aged 14–34 years residing in the United States from the National Health and Nutrition Examination Survey Registry in the United States, comparing the prevalence of vaccine target strains between the pre-vaccination period (2003–2006) and 4 years after quadrivalent HPV vaccination (2009–2012), the prevalence of the quadrivalent HPV type in females was decreased by 63% in females aged 14–19 years and by 35% in females aged 20–24 years [23]. Extending the analysis of these data to 2015–2018, HPV prevalence was decreased further. It was decreased by 88% for females aged 14–19 years and by 81% for females aged 20–24 years. The decline also occurred in older females aged 25–34 years, although it was not as dramatic as that in females younger than 25 years [24]. Although HPV prevalence data in males were limited, one study showed a 59.4% reduction in persistent anal infection by HPV types 6, 11, 16, and 18 in men who have sex with men (MSM) vaccinated with 4vHPV [16]. In addition, several countries with HPV vaccination rates above 50% showed early evidence of an important role of vaccine's cross-protection and herd immunity effectiveness in males [6,13,25].

EFFECT OF HPV VACCINATION ON ANOGENITAL WART

In Korea, there are not many studies examining effects of vaccines on anogenital warts. However, one study indirectly showed that the incidence of anogenital wart in females gradually decreased starting in 2011 [26]. It could be inferred that the incidence decreased after vaccination was introduced in 2006. A study conducted in Australia from 2004 to 2011 also confirmed that HPV vaccination reduced anogenital wart by 92.6% in those under 21 years of age, by 72.6% in those aged 21–30 years, and by 21.4% in those over 30 years of age [27]. In a study performed in the United States, the first decline was confirmed in females aged 15–19 years from 2007–2010, followed by a decrease in females aged 20–24 years in 2009–2010 [7]. Meta-analysis studies of vaccine's disease suppression effects for males and females at various ages have also been conducted in developed countries [13]. Additionally, in an analysis of STD (sexually transmitted disease) surveillance in the United States, a disease reduction effect of 53.4% was confirmed not only for genital warts of females, but also for males who have sexual intercourse with the opposite sex (39%) and males homosexuals [11].

EFFECTS OF HPV VACCINATION ON CERVICAL DYSPLASIA AND CANCER

Cervical cancer and uterine dysplasia are known to occur at least 15–20 years after being infected with HPV. Since the vaccine was started in 2006, not enough time has passed to evaluate the effect of vaccine on cervical cancer or uterine dysplasia. In addition, there is still a lack of research on clear, direct results. However, some studies have mentioned the impact and effectiveness of HPV vaccine [12-15]. In one meta-analysis, at 5–9 years after vaccination, CIN (cervical intraepithelial neoplasia) 2+ was observed to be 51% lower in females aged 15–19 years and 31% lower in females aged 20–24 years. The CDC HPV-IMPACT Project reported a dramatic decline in cervical cancer between 2008 and 2012 [14]. A Swedish study conducted on a large number of patients confirmed that the incidence of cervical cancer was reduced by 88% in a group vaccinated before the age of 17 compared to a non-vaccinated group [15].

EFFECT OF HPV VACCINATION ON ANAL CANCER

Research on anal cancer is limited. In an MSM study, intraepithelial neoplasia corresponding to anus grade 2 or 3 was associated with the HPV virus of the type covered by the quadrivalent vaccine in 54.2% of cases. However, its incidence was lower than in the placebo group [16].

EFFECT OF HPV VACCINATION ON OROPHARYNGEAL CANCER

The CDC added head and neck cancer to indications for the 2021 nine-valent vaccine, although head and neck cancer has not received an indication in Korea yet for HPV vaccine. Compared to other cancers, head and neck cancer has already begun to exceed the incidence of cervical cancer in the United States. There are studies showing that head and neck cancer is also closely related to HPV. It has been shown that HPV infection through oral sex is closely related to head and neck cancer [28]. In one meta-analysis, the HPV detection rate was found to be 72%–93% lower in the vaccine group than in the non-vaccine group, proving that the HPV vaccine is also effective in preventing head and neck cancer [29]. Another study has also reported that the HPV vaccine is effective in preventing head and neck cancer, especially in males [30].

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CONCLUSIONS

HPV vaccination has a very important meaning in that it can prevent various HPV-related diseases and the occurrence of tumors. Depending on the age of start the vaccination, there is a schedule of 2 or 3 doses of vaccination. For immunocompromised or high-risk groups, vaccination is effective in preventing HPV-related diseases. Moreover, vaccination is necessary for both male and female to achieve herd immunity against HPV-related diseases and cancer.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Seung-Ju Lee and Sangrak Bae. Data acquisition: Sangrak Bae and Jin Bong Choi. Drafting of the manuscript: Chang Il Choi and Sangrak Bae. Critical revision of the manuscript: Sangrak Bae and Seung-Ju Lee. Obtaining funding: Seung-Ju Lee and Sangrak Bae. Administrative, technical, or material support: Tae-Hyoung Kim, Jeong Woo Lee, and Jun Mo Kim. Supervision: Sangrak Bae. Approval of the final manuscript: all authors.

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