Review

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What Are the Barriers to Human Papillomavirus Vaccination for Male in South Korea?

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The human papillomavirus (HPV) virus causes genital warts, a sexually transmitted disease, as well as cervical and vulvar cancer in females and penile cancer in males. In addition, it this virus causes various diseases, including head and neck cancer and anal cancer. Vaccines can prevent malignant tumors caused by the HPV virus, and various projects are being conducted to eradicate HPV worldwide. The national inoculation program is a representative project among them. In Korea, only females are vaccinated; males are not included in the national mandatory vaccination list. Various reasons preventing HPV vaccination for males include cost-effectiveness, fear and misperception of side effects after vaccination, problems with the effectiveness of vaccination, and lack of social awareness about the need for vaccination, including parents, and the lack of research on male HPV disease. As female's right to health is emphasized, HPV disease, which has become more important in treatment, will never be cured if it is managed only for females. Because the disease is transmitted sexually, managing and controlling HPV in males is also essential. In that sense, males must also be included as nationally required vaccination targets.

Keywords: Human papillomavirus viruses; Vaccination; Vaccination hesitancy; Male

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INTRODUCTION

Human papillomavirus (HPV) belongs to papillomaviridae and is a non-enveloped double-stranded DNA virus [1]. There are approximately 250 species of this virus among vertebrates, and 30-40 of these cause diseases in the genital and anal areas [2]. This virus mainly invades the epithelial cells, and the mucosal layer of the epidermis has a long incubation period and remains in the human body for a long time. In most cases, the infection site is localized, with many infections asymptomatic. The virus disappears naturally after approximately 18 months without any special treatment [3]. Approximately 20 of these viruses are classified as high-risk and cause malignant tumors. Some are low-risk and cause diseases, such as genital warts. When infected with this virus, the following can result: head and neck cancer, anal cancer, genital warts in both males and females, cervical cancer and vulvar cancer in females, and penile cancer in males. This virus drew attention because of its close association with cervical cancer in females. Since then, the finding that vaccines can prevent cancer caused by this virus resulted in a Nobel Prize, and many countries are

making efforts to cure the disease to promote female's right to health. In 2018, the World Health Organization (WHO) urged the world to participate in treating HPV-related diseases and making efforts to prevent diseases using vaccines, stating the following.

> "Cervical cancer affects over half a million women each year, and kills a quarter of a million. One woman dies of cervical cancer every two minutes, making it one of the greatest threats to women's health. If we don't act, deaths from cervical cancer will rise by almost 50% by 2030.
>
> Cervical cancer strikes women in the prime of life. These women are raising children, caring for their families and contributing to the social and economic fabric of their communities.
>
> But it doesn't have to be this way. Cervical cancer is one of the most preventable and treatable forms of cancer, as long as it is detected early and managed effectively.
>
> HPV vaccines are truly wonderful inventions. The fact that the research that led to the development of vaccines against HPV won a Nobel Prize speaks for itself.
>
> That's why today I am calling for coordinated action globally to eliminate cervical cancer."

CURRENT STATUS OF HPV VACCINATION IN KOREA

In Korea, a bivalent vaccine was approved in 2007 and released in September of the same year. The quadrivalent vaccine was approved in July 2008 and launched in September. In June 2016, bivalent and quadrivalent vaccines were introduced as mandatory national vaccination targets for 12-year-old female adolescents through the national vaccination support project. In July 2016, a 9-valent vaccine was launched. In 2022, the vaccination target was expanded to 13-17 years old, only for female teenagers. In the case of the low-income class, the support target was expanded to 18-26 years old for basic livelihood security recipients and the next upper class. For females up to 45 years of age, the indications for the catch-up vaccine for the 9-valent vaccine were expanded. In addition, the United States Food and Drug Administration (US FDA) approved a vaccine for head and neck cancer in 2022, and indications for head and neck cancer are expected to expand in Korea. However, females still eligible for mandatory vaccination in Korea have yet to achieve an inoculation rate of more than 75%. If the first and second vaccinations are included, the inoculation rates across all age groups are even lower.

The national mandatory vaccination targets include only 12-year-old female adolescents, not male adolescents. The age of mandatory vaccination has recently risen to 17 years old, but males do not receive state support regardless of age. Recently, to promote female's health, the government and the legislative body enacted a policy that includes males and inoculates adolescents until 12 or 17. In addition, this policy was also supported by the President's pledge. With inclusion, there has been increasing interest in including males in the inoculation target. The vaccination age was also extended to the age at which vaccination is effective, and the indication for the catch-up vaccine was extended to 45 years of age for females, while it remained at 26 years for males. The above is not because there is no effect in males but because there needs to be more research on male diseases. Therefore, expanding the vaccination age is impossible because the basis for implementation has yet to be established. In addition, there are practical barriers to male vaccination in many areas. The following examines various factors that hinder vaccination in all aspects of politics, economy, society, and medicine.

PRACTICAL BARRIERS TO HPV VACCINATION IN MALES

1. Characteristics of the Disease – HPV-related Diseases in Males

At first, HPV was called the cervical cancer virus, and the HPV vaccine was also called the "cervical cancer vaccine." Because males do not have a uterus, the name 'cervical cancer virus' has reduced interest in the disease among males and created a false perception that it is a disease that only applies to females. On the other hand, the actual HPV virus causes various diseases according to several subtypes (Table 1). Among them are malignant tumors, including cervical

Table 1. Summary of different diseases and causative different HPV subtypes

Disease	HPV type
Common warts	2, 7, 22
Plantar warts	1, 2, 4, 63
Flat warts	3, 10, 28
Anogenital warts	6, 11, 42, 44, and others
Anal dysplasia (lesions)	6, 16, 18, 31, 53, 58
Genital cancers	・Highest risk: 16, 18, 31, 45 ・Other high-risk: 33, 35, 39, 51, 52, 56, 58, 59 ・Probably high-risk: 26, 53, 66, 68, 73, 82
Epidermodysplasia verruciformis	Over 15 forms
Focal epithelial hyperplasia (mouth)	13, 32
Mouth papillomas	6, 7, 11, 16, 32
Oropharyngeal cancer	16
Verrucous cyst	60
Laryngeal papillomatosis	6, 11

HPV: human papillomavirus.

cancer, and benign tumor diseases, such as genital warts. Genital warts are classified as a sexually transmitted disease, and the virus is transmitted through sexual intercourse between members of the opposite or same sex. Males do not have a uterus, but they play a role in transmitting the virus to females, even if there are no lesions in the male body, even if asymptomatic infection occurs. As a result, the virus can be transmitted to the woman.

In 2020, the US FDA added indications for vaccines against head and neck cancer. Head and neck malignancies are associated with HPV in many parts and have attracted much attention [4]. The association of HPV virus-associated head and neck cancers with risk factors, including oral sex, number of partners, and duration of oral sex, has been studied.

Genital warts is a disease with the highest prevalence among HPV-related diseases worldwide. This disease occurs in an estimated 30 million people annually, and the number shows an increasing trend every year. In a study conducted in Korea, genital warts showed a continuous increase in males and a decrease in females after 2012 [5]. According to data recently presented at the Korean Society of Urogenital Infection (e.g., Sang-Rak Bae), the number of male patients increased by 351% from 2007 to 2018. The prevalence increased by 334% from 132.8 to 443.6 per 100,000 people, and it occurred most frequently in the 25-29-year-old age group among the sexually active age groups. Associated health care costs have increased more than tenfold (Fig. 1). Even in the case of genital warts that do not cause malignant tumors, while not paying attention, the number of patients increased more than threefold. Recently, the age of first sexual experience has decreased, and the percentage of sexual experience is also growing. Accordingly, the risk of sexually transmitted diseases is also increasing [6].

2. Cost-effectiveness

In January 2020, a commissioned study was conducted on the cost-effectiveness of the HPV vaccine. The study announced that expanding the vaccination target age in females was more effective than expanding the vaccination target in males. As of 2018, there were 240,000 12-year-old males, and vaccinating them will cost approximately 45 billion won. On the other hand, because the cost of male HPV-related diseases is reduced by 20 billion won, it shows an effect equivalent to half of the input. On the other hand, if approximately 42 billion won worth of vaccination was administered to 220,000 12-year-old females during the same period, it would reduce the costs caused by diseases by 160 billion won. Therefore, there is an effect of four times compared to the input cost. If both males and females are vaccinated at 90 billion won, the cost of the related diseases is reduced to 180 billion won, which is twice as effective as the input cost. Therefore, it was reported that it is more efficient to focus vaccination on females than on males. Nevertheless, this conclusion does not consider the pathophysiology of HPV transmission and only considers the prevalence and incidence while excluding the relevance of sexual intercourse. In addition, because the prevalence of other diseases except for genital warts is remarkably low in males, the number of patients and treatment costs are relatively low compared to cervical cancer, a major female cancer. In addition, the contribution to the actual disease is inevitably low because it is impossible to know whether a man has the virus through a process, such as screening or examination.

Many studies have examined the cost-effectiveness for males. Studies conducted in foreign countries reported that vaccination for males is cost-effective [7-13]. In particular, there is cost-effectiveness when the vaccination of females is less than 75% [8,11,13]. On the other hand, some studies claim there is no cost-effectiveness [14-17]. In a foreign study, herd immunity occurs when the vaccination rate of one sex is 75% or higher or when the vaccination rate is 50% or higher, regardless of sex. Hence, further vaccination

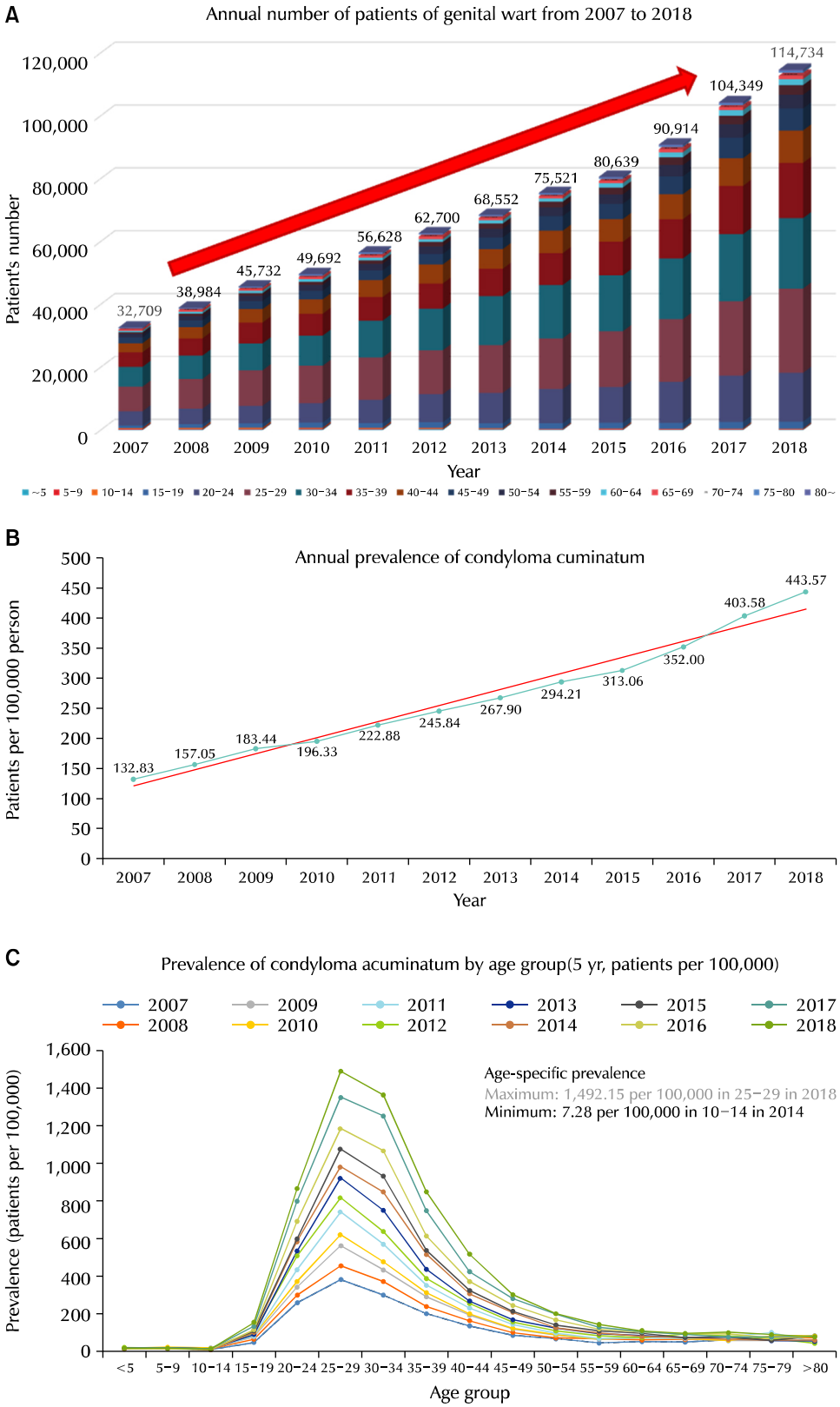

Fig. 1. Number of patients, prevalence, and related medical costs of male genital warts from 2007 to 2018. (A) Number of patients by year. (B) Prevalence by year. (C) Changes in prevalence by age.

is not cost-effective. The results of this study are also cited by WHO [18]. Medical resources are limited in all countries, but where to focus is important when determining cost-effectiveness. Factors, such as vaccine price, vaccination rate, the scale of the treatment cost for related diseases, awareness of diseases, and common opinions, are considered to determine cost-effectiveness. Unfortunately, studies on these aspects are lacking in Korea, and appropriate analysis is impossible due to the lack of research and evidence on male diseases.

3. Efficacy Problem of Male Inoculation

Viruses cause disease by infecting epithelial cells. In particular, because it is difficult to invade the mucosal layer in males, in most cases, diseases occur in the genitals, scrotum, and skin around the genitals. In addition, the HPV virus disappears naturally after approximately 18 months of infection. Thus, over time, the disease disappears without treatment. For this reason, asymptomatic infections can occur. In addition, it is difficult for males to recognize the need for vaccination because the disease rarely occurs in males. In most cases, a girlfriend or wife recommends vaccination. Therefore, more publicity and notification about the burden and risk of diseases occurring in males are needed to help them recognize and implement the need for vaccination.

In addition, a study shows that males have a lower immune response than females, even if they receive the same vaccine [19]. This study reported that the infection duration in males was shorter than in females, HPV infection in males occurred in keratinized epithelial cells, and it was difficult for the antibodies formed by the vaccine to reach the epithelial cells. As a result, they reported that the vaccine had a low effect on actual viral infections in males. In the mucosal epithelium, females showed an antibody formation rate of approximately 32.5%, while males showed a low antibody formation rate of 12.2%.

Because the HPV virus can be transmitted through sexual intercourse, it is most effective to be vaccinated before the first sexual experience and in the form of a catch-up afterward. According to a recent report on adolescent sexual health in Korea, the age of first sexual experience has decreased significantly to around 13 years of age, and the rate of sexual experience is also increasing. In the United States, a recommendation to implement the vaccination age from nine years old was announced based on a similar trend [20].

4. Vaccine-related Side Effects Issues

Recently, legislation was introduced for national vaccinations for males. This legislative proposal suggests expanding the vaccination target to include male adolescents in the mandatory vaccination target, even though the target age is different. On the other hand, there are also opinions against this proposition, citing the vaccine's side effects. Currently, according to the WHO report, 37 out of 38 OECD member countries require the HPV vaccination as a mandatory vaccination, and 20 countries also include males in the compulsory vaccination target. Among these are developed countries in North America and Europe, including the United States, the United Kingdom, France, Canada, Germany, and Italy. In Japan in 2013, there was an incident where the vaccination recommendation was withdrawn due to side effects after the HPV vaccination [21]. At that time, death, cervical cancer, and permanent paraplegia were mentioned as side effects. However, Japan's Ministry of Health and Welfare concluded in January 2014 that the adverse reaction was unrelated to the vaccine. In 2016, a study published at the University of Tokyo found that the HPV vaccine causes brain damage and paralysis. This paper was withdrawn because of overdose and inappropriate experimental processes. In addition, it was reported that complex regional pain syndrome and postural orthostatic tachycardia syndrome are side effects of the vaccines in Japan. However, the WHO and the US Centers for Disease Control and Prevention concluded that vaccination is safe and shows clear benefits. A study in Japan reported that illness and death due to HPV-related diseases occurred when vaccination was not performed for a certain period, resulting in worse outcomes than vaccination [22]. In Korea, the Korea Centers for Disease Control and Prevention vaccination assistant announces as follows.

- The HPV vaccine is considered a very safe vaccine. Severe adverse reactions related to the HPV vaccine occurred in less than 0.1% but showed a similar incidence and similar responses in both vaccine or placebo groups.
- The most common local adverse reaction is pain at the injection site; swelling, redness, and hives may also

occur. Injection site pain was reported relatively commonly (~80%). Approximately 6% of patients reported pain even when they were still or that interfered with daily activities, but most recovered within a few days without special treatment.

- Fever, nausea, headache, and myalgia have been reported as systemic adverse reactions. Severe adverse reactions, including severe allergic reactions such as anaphylaxis, may occur but are extremely rare and do not have an exceptionally high frequency compared to other infant vaccines.
- Some may temporarily lose consciousness and fall after vaccination due to extreme tension or pain at the injection site during vaccination. This can occur not only with the HPV vaccine but also with other preventive vaccinations and mainly occurs when group vaccination is performed in adolescents and young adults. Although fainting itself is temporary, it is vital to prevent injury in the event of a fall.

Adverse reactions by vaccination, https://nip.kdca.go.kr/irhp/infm/goVcntInfo.do?menuLv=1&menuCd=151

Since the national vaccination was implemented in 2016, vaccine-related adverse reactions have been reported very rarely, about 0.0075% (As of June 24, 2019, 90 adverse reactions out of 1,192,771 total reports).

5. Recognition of Members of Society

A recent study reported that parents must recognize the need for vaccination for male adolescents [23]. It was found that mothers of sons have low awareness of the need for HPV vaccination and, in many cases, show hesitation. Approximately 11.5% of mothers had already been vaccinated or were willing to be vaccinated, and approximately 61% responded that they had not decided whether to be vaccinated. The presence of a daughter as a family member, the mother's HPV-related disease, and general awareness of HPV were significant determining factors. The previous name of the HPV, 'the cervical cancer virus', was the main reason preventing males from vaccination because males mistakenly perceived it as a disease that did not apply to them.

Various advertisements and media have recently improved awareness, and the name has changed to 'human papillomavirus'. Accordingly, there is a change in perception that this disease can also occur in males and that male's participation is essential for preventing or eradicating female's diseases. Therefore, it is believed that a change in awareness of the need for vaccination is also possible.

In addition, the world is currently fighting COVID-19, a global infectious disease. To prevent infectious diseases, all citizens have learned that it is necessary to block the source of infection, avoid contact with the source of infection, and prevent penetration into the human body at the last stage. Therefore, people have been i) keeping their social distance, ii) isolating confirmed cases, and iii) wearing masks to prevent the virus from penetrating the human body. In addition, iv) vaccination was performed to increase immunity against the virus. The HPV virus is also an 'infectious disease' like COVID-19. i) Using condoms, ii) avoiding risky or indiscriminate sexual activity, and iii) similarly, boosting immunity to viruses through vaccination is helpful against disease. Hence a better response to HPV viral disease can be expected if the awareness that the HPV virus is an 'infectious disease' is more widespread.

6. Lack of Research on HPV in Males

Many studies have been conducted on HPV-related diseases in females, and many are ongoing. Valid grounds are presented based on the data and analysis, and the need for vaccination is asserted. On the other hand, studies on HPV-related diseases in Korean males are scarce [24,25]. Since females are screened for cancer through screening tests and health checkups, they can detect and treat HPV infections and related diseases relatively early compared to males. In the case of males, however, it is diagnosed only after diseases, including penile cancer, head and neck cancer, and anal cancer, have occurred. It is difficult to confirm through screening or examination of epidermal lesions, and it is impossible to confirm whether or not the virus is present. In addition, the probability of male genital malignant tumor occurrence is very low, so the related medical cost is low. A low probability of occurrence can be cited as a reason for the low associated medical costs. On the other hand, penile cancer is very invasive, with a high mortality rate and a very low 5-year survival rate, resulting in an abysmal prognosis. Some studies have investigated the presence of high-risk groups by analyzing the gene subtypes in some genital warts [26].

Penile cancer is a very rare male malignancy. In an overseas study, the probability of HPV DNA being identified in penile cancer is approximately 33.1%. In the case of high-grade prostate intraepithelial neoplasia, it is 87.1%, and HPV 16 is most commonly observed [27]. Nevertheless, no population-based study has been conducted in Korea.

Various randomized studies have also been conducted on the effects of male vaccination in foreign countries [28-30]. However, studies targeting adult males have not yet been conducted in Korea. Setting up a vaccination plan, expanding indications, and developing various indications according to the reality of Korea simply by reflecting the results of foreign countries will be challenging. In this regard, the study that the HPV vaccine increases the natural pregnancy rate in infertility or subfertility is particularly noteworthy given that Korea has entered an aging society with a low birth rate [31,32]. HPV-confirmed sperm motility decreases, resulting in a low fertility rate. Therefore, studies that showed an increase in the natural pregnancy rate after HIV vaccination in males are noteworthy. However, in Korea, the indication for vaccination is 26 years or older, and most males in infertile and sterile couples are 30 years or older. Therefore, it is difficult to verify the results of this study in Korea. Currently, the need for more research is blocking the expansion of indications. Still, it is expected that it will be able to expand to various indications if more evidence is accumulated in the future.

CONCLUSIONS

HPV-related diseases in males have received scarce attention, and few studies have been conducted on them. The need for vaccination in males has not been actively considered because of the misperception that HPV-related diseases are confined to females. In addition, with the emphasis on limited medical resources, medical costs, and cost-effectiveness within the budget, the focus has been on the vaccination of females. Projects and policies for vaccines have been promoted in the direction of expanding indications and age in females. Gender-neutral vaccination is currently being practiced in many countries, particularly in developing and lower-middle-income countries (e.g., Bhutan and Guyana). As of April 2022, more than 140 countries are running vaccination programs for females, and approximately 62 countries include males. Cervical cancer is one of the diseases that must be eradicated in Korea to secure female's right to health. However, although the disease occurs in females, the characteristics of HPV mean that both males and females can be carriers of the virus and contribute equally to the development of the disease. Therefore, attention should be paid to HPV-related diseases in males, and vaccination should also be promoted in males. Such efforts can reduce the occurrence of malignant tumors in females, reduce various other malignant tumors and sexually transmitted diseases, promote health, and prevent diseases in both males and females.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTIONS

S.B. participated in data collection and wrote the manuscript. S.B. and S.K. participated in the study design and performed the statistical analysis. S.B. participated in the study design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

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