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HPV Vaccination and the Controversy and Attitudes of Male and Female College Students

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Abstract

In recent years, the development of the Human Papillomavirus (HPV) vaccines have spurred controversy over whether or not males as well as females should obtain the vaccine against the HPV disease. HPV vaccination is an important public health issue because it prevents cancer. The HPV vaccination reduces rates of transmission of genital warts and certain HPV related cancers in males as well as reducing the incidence of cervical cancer in women. The development of the HPV vaccine has further improved opportunities for healthcare providers to effectively combat the human papillomavirus disease. Presently, there are three vaccines marketed in the United States and approved by the FDA that can protect against the sexually transmitted infection of HPV. They are Gardasil®, Gardasil 9®, Cervarix®. All three prevent infections with HPV types 16 and 18, which are the two highest risk that cause approximately 70% of cervical cancer in women and a higher percentage of other HPV-related cancers in men and women. In this article the researcher will focus on the three Human Papillomavirus vaccines, controversy over the HPV vaccine and attitudes of male and female college students regarding the HPV vaccine.

Keywords: Human papillomavirus; Vaccines; Gardasil; Cervarix

HPV Vaccination

While Pap smears once provided the most valuable protection for women against the development of HPV infection and cervical cancer, the development of the HPV vaccine has further improved opportunities for healthcare providers to effectively combat this disease [1]. Presently, there are three vaccines marketed in the United States that can protect against the sexually transmitted infection of HPV. They are Gardasil®, Cervarix®, and Gardasil 9. According to Merck & Co., Inc. [2]: Gardasil® is a vaccine indicated for females 9 through 26 years of age for the prevention of cervical, vulvar, and vaginal cancers and for males and females 9 through 26 years of age for the prevention of anal cancer, precancerous or dysplastic lesions, and genital warts caused by human papillomavirus (HPV) Types 6, 11, 16, and 18. Gardasil® is commonly referred to as HPV 4, as it is the only vaccine that protects against four types of HPV. The vaccine was first approved in 2006 by the U.S. FDA for use with girls; however, males 9-26 years of age were added in 2009 to protect them from developing genital warts. Other key dates associated with Gardasil®'s release include December 22, 2010, when the FDA expanded Gardasil® approval to preventing anal cancer in both men and women 9-26 years old. The FDA based their approval on data that showed the vaccine was effective in preventing pre-cancerous anal lesions caused by HPV types 16 and 18 [3]. On October 25, 2011, the Advisory Committee on Immunization Practices (ACIP) recommended the routine use of Gardasil® in males as young as nine years old, with boys 13-21 years old eligible for the vaccine if they had not been vaccinated or completed the three shot series. The committee also added that males 22-26 years old could elect to receive the HPV 4 vaccination [4].

Ghazal-Aswad [1] explained that Gardasil® was not an infectious vaccine, as it contained virus-like particles (VLP) rather than the actual virus. Gardasil® also contains an additive commonly used in immunizations that helps improve the body's acceptance of the vaccine [5]. The vaccinations are administered in three doses over six months, with the most protection provided to those who receive all three shots [1].

According to Merck & Co., Inc. [2], the most common side effects to Gardasil® include, (a) pain, swelling, itching, bruising, and redness at the injection site, (b) headache, (c) fever, (d) nausea, (e) dizziness, (f) vomiting, and (g) fainting. Ideally the vaccine should be administered before there is any contact with the relevant HPV types, in order to fully protect the individual against infection. What is more, Gardasil® was designed as a method of prevention, with Merck & Co., Inc. [2] reporting it was not meant to treat existing cases of "external genital lesions; cervical, vulvar, vaginal, and anal cancers; or

cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN), vaginal intraepithelial neoplasia (VaIN), or anal intraepithelial neoplasia (AIN)".

According to the CDC [6], "On October 16, 2009, the FDA licensed bivalent human papillomavirus vaccine (HPV 2; Cervarix®, GlaxoSmithKline) for use in females aged 10 through 25 years". Cervarix® is a bivalent vaccine as it protects against two HPV types (16 and 18), protecting women against CIN 1-3 as well as cervical cancer. The vaccine has been approved for use in females 9-26 years old, with the ACIP recommending a catch-up vaccination for female's ages 13 to 26 years who did not receive all three doses of the vaccine when they were younger. If a woman reaches the age of 26 years before completing the three-dose series, the ACIP noted these women were still eligible to receive the remaining [1].

In December 2014, the FDA approved Gardasil 9, for the prevention of certain diseases caused by nine types of Human Papillomavirus (HPV). Covering nine HPV types, five more HPV types than Gardasil (previously approved by the FDA), Gardasil 9 has the potential to prevent approximately 90 percent of cervical, vulvar, vaginal and anal cancers.

According to Merck & Co., Inc. [2], Gardasil 9 is a vaccine approved for use in female's ages 9 through 26 and males ages 9 through 15. It is approved for the prevention of cervical, vulvar, vaginal and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, and for the prevention of genital warts caused by HPV types 6 or 11. Gardasil 9 adds protection against five additional HPV types - 31, 33, 45, 52 and 58 - which cause approximately 20 percent of cervical cancers and are not covered by previously FDA-approved HPV vaccines [7]. The safety of Gardasil 9 was evaluated in approximately 13,000 males and females. The most commonly reported adverse reactions were injection site pain, swelling, redness, and headaches [7].

As of October 2016, CDC and ACIP also now recommend that 11 and 12 year olds receive two doses of HPV vaccine at least 6 months apart rather than the previously recommended three doses. As of December 2016, Gardasil 9 will soon be the only HPV vaccine available in the United States. The last doses of cervix expired at end of November 2016 [7]. Gardasil will expire when the last doses are administered in May of 2017 [7].

Vaccine Controversy

The advent of a vaccine for the prevention of cervical cancer in women has been viewed as a watershed event for improving women's health [7]. According to Schwartz et al. [7], the vaccine provides an important opportunity to combat HPV infection worldwide and reduce the number of cases of this disease in developing nations. Presently, 82% of all new cervical cancer cases in developing nations worldwide occur in areas without rigorous prevention programs in place, such as Pap testing. Therefore, the routine use of the HPV-vaccine in these countries would reduce unnecessary deaths and strengthen the public health system [8].

Despite the fact that some view the HPV vaccine as a watershed event for improving women's health, "controversy is grounded in moral, religious, political, economic, and sociocultural arguments" [8]. Vamos et al. [8] reported that the controversy surrounding the HPV vaccine has centered around two primary issues: (1) "vaccinating adolescent girls against a sexually transmitted virus and (2) determining whether the HPV vaccine should be mandatory for all girls of school age".

The first issue addresses the inability of young adults to fully understand that the vaccine does not protect them against all sexually transmitted infections. Vamos et al. [8] noted that:

Adolescents may not fully comprehend the utility of the HPV vaccine and may over generalize the vaccine to include "protection" against other sexually transmitted infections (STIs) such as human immunodeficiency virus/acquired immunodeficiency syndrome, as well as those with less lethal potential. In addition, a worrisome repercussion of the HPV vaccine is that it will promote premarital sex and give children tacit permission to engage in risky sexual behaviors.

The only 100% effective way to protect against STIs is abstinence, and, therefore, opponents believe a mixed message is sent to young people through the promotion of the vaccine. Vamos et al. [8] wrote that, "Advocates of this position argue that children should receive clear and consistent messages that abstinence is the only responsible, effective, and supported behavior concerning protecting one's sexual health".

The inherent right of parents to make the decisions about their children's sexual health was noted as another reason for opposing mandatory HPV vaccination [9]. Each family has a unique set of personal values and spiritual beliefs that opponents argue are not represented by the company's manufacturing the vaccines. Added to this was the fact that these large corporations funded many clinical trials run by the federal government, and lobbyists spent considerable time and money securing support for these mandates. Colgrove et al. [9] wrote that, "Although Merck's lobbying was a key catalyst in the initial push for mandates; many stakeholders came to view the company's efforts as a liability". Their involvement overshadowed the underlying health benefits intended by the legislation, resulting in the mandate viewed as a way for the company to make money [10].

Vamos et al. [8] indicated that by mandating the vaccine, a new health disparity would be created, as questions were raised on "how underserved, hard-to-reach, and uninsured women (the most vulnerable population of women with respect to cervical cancer) would receive the required 3 doses over a 6-month period and who would be responsible for incurring the cost?". Therefore, HPV vaccination would most likely be obtained by women who have routine screenings with access to health care, placing them outside of the high-risk category for developing cervical cancer. Those women who needed the vaccine the most were those who did not have the same medical access, with Vamos et al. [8] noting, "paradoxically the circumstances of the vaccine would

contribute unfavorably to existing health disparities rather than overcome them".

Another criticism against the vaccine reported by Vamos et al. [8] was "logistical uncertainties," with many unknown issues questioning the support of the vaccine in abstinence-only campaigns. These included limited data regarding the long-term effectiveness of the vaccine, and that all of the potential side effects of the vaccine have not been established. Furthermore, it is unclear if the vaccine has any long-term negative impact on fertility or plans for pregnancy in the future. The final reason noted against mandatory vaccination was the development of new vaccines that provide more protection against the virus [8]. Vamos et al. [8] concluded: "the issue of mandatory HPV vaccination was a premature action, given the range of unanswered questions and the prospect of new or divergent results from clinical trials that are not yet completed".

Proponents of mandatory HPV vaccination often refer to the "severity of cervical cancer and the efficacy of the vaccine as primary motivations for wanting to ensure that all girls were vaccinated," adding that the mandatory nature of HPV vaccination would ensure those children whose parents were against it still received the protection they deserved. Vamos et al. [8] noted that proponents of vaccination argue that the decision to be vaccinated motivates women to become more proactive in their health and health decision-making.

HPV Vaccination Attitudes of Males and Females

Despite the fact that there is considerable evidence that suggests that HPV vaccination is useful and warranted for males mandates for such vaccination have not been established by governing health bodies (eg., CDC, FDA, etc.). As a result of a lack of direct policy regarding HPV vaccination in males, the issue has not been widely examined in the literature. Would men voluntarily seek HPV vaccination? Answering this question proves challenging. However, some research has been conducted to examine male attitudes toward HPV vaccination [11]. For instance, Sandfort and Pleasant [10] examined male and female college student attitudes toward HPV vaccination. The decision not to be vaccinated was based on a lack of knowledge regarding HPV and negative stigma associated with the condition. Men in the study were less likely than women to be vaccinated against HPV. This attitude toward vaccination was associated with lower levels of HPV knowledge in men and higher levels of reported stigma associated with the disease.

Jones et al. [11] also considered the attitudes of college males and females with regard to their intent to receive HPV vaccination under specific conditions. Subjects enrolled in this study were asked to rate their willingness to receive vaccination under the following conditions: vaccine prevents the spread of all HPV; vaccine prevents cervical cancer but not genital warts; vaccine prevents genital warts but not cervical cancer; and vaccine prevents both genital warts and cervical cancer. Data collected by Cook et al. [11] demonstrated that "Men were less willing to receive a vaccine that prevents cervical cancer alone than they were to receive one that prevents cervical cancer and genital warts".

Efforts to evaluate intent to be vaccinated against HPV in males have also been examined by Crosby et al. [12]. Crosby et al. [12] evaluated the intention of 115 males between the ages of 18 and 23 years of age to acquire HPV vaccination. The sample was drawn from rural and urban populations for comparison. Overall, 35.7% of those participating in the study reported a negative intent for HPV vaccination. Variables that contributed to negative intent for males included: not having penile-vaginal intercourse in the last 12 months, lack of knowledge regarding HPV, and/or living in a rural versus urban area. Crosby et al. [12] asserted that the findings of this research should be used as a starting point for determining barriers to HPV vaccination among males.

The research reviewed here with regard to male intention for HPV vaccination represents the limited scope of research that has been undertaken on this subject. A cursory overview of the literature regarding HPV vaccination indicates that more extensive efforts have been made to evaluate female attitudes, acceptance, and intent to receive HPV vaccination [13]. For instance, Conroy et al. [14] examined predictors and barriers to HPV vaccination among women. Utilizing a sample of 189 girls between the ages of 13 and 26 years, Conroy et al. [14] evaluated the specific conditions under which young women would seek HPV vaccination. Variables identified as contributing to HPV vaccination included: endorsement of the vaccine by family, physicians or sexual partners; history of an abnormal Pap smear; and being offered the vaccine by their healthcare provider. Based on findings, Conroy et al. [14] asserted that it is possible to utilize information for the development of programs to reduce barriers to HPV vaccination and encourage increased intention to vaccinate among women.

Attitudes regarding HPV vaccination in young women have also been examined by Kahn, et al. [15]. Specifically, these authors surveyed 52 women between the ages of 18 and 30 years to determine the specific variables that contribute to positive attitudes toward HPV vaccination and intent to vaccinate. The results of this investigation suggest that knowledge regarding HPV and its health consequences, "personal beliefs about vaccination, belief that others would approve of vaccination and a higher number of sexual partners" all contributed to positive attitudes toward HPV vaccination and intention to vaccinate [15]. Kahn et al. [15] asserted that the understanding of the particular variables that contribute to positive attitudes toward HPV vaccination is important for directing public health efforts to increase the HPV vaccination rates.

Generally speaking, the research undertaken regarding women's attitudes toward and intent to receive HPV vaccination is more extensive and in-depth. While efforts have been made in the literature to evaluate HPV vaccination intention among males, extensive efforts have not been made to evaluate male attitudes toward HPV vaccination. This dearth of research is reflective of the reality for HPV vaccination.

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Although HPV vaccination for males has been recommended and supported in the literature, public health officials have not created mandates for HPV vaccination in this population.

In 2006, ACIP recommendations were for the vaccine to be routinely given to girls starting at 11 or 12 years of age, before they become sexually active. This recommendation set off an outbreak of state-level policy making [16]. Following these recommendations, within a year's time, 41 states had projected intended measures to increase vaccine uptake, including state insurance coverage requirements, educational campaigns and programs [17]. Even though these recommendations were made by the ACIP, school vaccination requirements are decided mostly by state legislators. Legislation is needed to provide funding, regardless of some state legislatures granting regulatory bodies such as the health department the power to require vaccines [17].

The most debatable proposals were those to make the vaccine requirements mandatory for school-age girls, which are determined by individual states. Presently, there are no school mandates for boys to receive the vaccine, even though Gardasil® was approved in 2009 for boy's ages 9-26 years. Bills to approve HPV vaccination requirements were introduced in 24 states, and only one state governor imposed a school mandate by executive order [10].

Policymakers argued about the HPV vaccine school mandate requirement idea from 2006 to 2008. As of February 2010, only Virginia and Washington, D.C., had enacted school HPV vaccine mandates, and Virginia's legislation included an opt-out provision so broad that it may be a misnomer to refer to the law as a mandate [18].

Most states are pushing for further discussion and debate about whether or not to require the vaccine because of the cost of the drug, safety, parents' rights to refuse, moral objections, coverage by insurance plans, and financing for the uninsured [19]. The CDC announced that the HPV vaccine is available through the federal Vaccines for Children (VFC) program in all 50 states. VFC provides vaccines for children ages nine to 18 years who are covered by Medicaid, or who are Alaska-Native or Native American.

Daley et al. [18] found that women were confused about the true meaning of an HPV diagnosis. The main causes of cervical cancer are from specific types of HPV, which has posed a serious public health concern for women [20-23].

A group of CDC scientists and physicians looked at 40 different publications regarding the prevalence of HPV infections in men, in order to better understand the high prevalence rate of HPV infections in the male population [23]. They concluded that more than half of American men would be infected with HPV at some point in their lives.

Conclusion

HPV and the HPV vaccine continue to be a significant public health issue. The research undertaken regarding women's attitudes toward HPV and intent to receive HPV vaccination is more extensive and in-depth compared to men. While efforts have been made in the literature to evaluate HPV and the HPV vaccination intention among males, extensive efforts have not been made to evaluate male attitudes toward HPV and the HPV vaccination. This dearth of research is reflective of the reality for HPV and the HPV vaccination. It is very important to know about the HPV vaccines, HPV screening guidelines, and HPV vaccination recommendations because these three very important things can mean the difference between life and death.

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