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# Is Increasing HPV Infection Awareness Promoting Increased Vaccine Compliance?

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## Abstract

Human papilloma virus (HPV) is recognized as the most common sexually transmitted infection in the United States. The infection is virtually asymptomatic and if gone undetected, may contribute to the development of pre-cancerous and cancerous changes of the cervix. Certain strains of the virus are also responsible for the development of external genital warts. The recent development and the Food and Drug Administration (FDA) approval of two preventive vaccines against HPV show promise for preventing the infection in adolescent and young females between the ages of 11-26 years. However, the importance of patient and parental education on the risks and benefits of the vaccines is crucial. The dispelling of myths that the vaccine will promote sexual promiscuity among eligible females is a challenge faced by all healthcare providers. This paper will discuss the impact of HPV infection, and examine the role of increasing patient and provider awareness and the part it plays in increasing vaccine compliance.

## BACKGROUND

According to the Centers for Disease Control (CDC), human papilloma virus (HPV) is the most common sexually transmitted infection (STI) in the United States (U.S.) with 25 being the average age for infection.<sup>3</sup> A study recently performed by the CDC revealed that one in four women in the U.S., between the ages of 14-59, have HPV.<sup>15</sup> HPV infections are usually asymptomatic with certain strains responsible for the development of cervical cancers and external genital warts. Approximately 11,000 new cases of cervical cancer are diagnosed each year in the U.S. with 4,000 resulting in death.<sup>3</sup> In 2005, U.S. healthcare expenditures of HPV-related conditions were between \$2.5-4.6 billion dollars, making early detection and treatment an important part of preventive healthcare.<sup>12</sup>

Two vaccines have been developed for the prevention of HPV infection. These vaccines have been approved by the FDA for use in females between the ages of 9-26 and most recently, males 9-18 years of age. The two vaccines are Gardasil and Cervarix. The age recommendations are intended to promote vaccination before sexual debut, when the vaccine is proved to be most effective.<sup>15</sup> Barriers to compliance includes vaccine financing, knowledge, and awareness of HPV infection. Increased knowledge and the available vaccines, play an important role in achieving

increased vaccination compliance rates for adolescents and young females.

Recommendation and state mandate administration of the vaccines are two separate issues. The importance of parental education on the risks and benefits of the vaccines is crucial. The dispelling of myths that the vaccine will promote sexual promiscuity among adolescent females who get the vaccine, is a treatment challenge faced by all healthcare providers. The clinical question is whether increasing HPV awareness promotes increased HPV vaccine compliance. Successful vaccine compliance is dependent on parental, patient and provider awareness and attitudes towards the vaccine. Immunization compliance is based on whether or not parents are abiding by healthcare provider recommendations to vaccinate patients eligible to receive the vaccine.<sup>18</sup>

## SCOPE OF THE PROBLEM

Human papilloma virus (HPV) is associated with the development of cervical cancer. According to the CDC, approximately 20 million individuals are infected with HPV.<sup>4</sup> Over 40 known strains of the virus. Individuals, who become infected, are usually asymptomatic. Specific strains are also responsible for the development of genital warts. A person can contract HPV by vaginal and anal intercourse. Transmission of the virus to an uninfected person can occur without the infected person knowing. Ninety-percent (90%)

of infections can be cleared by the body's immune system successfully.<sup>4</sup>

A research study performed by the CDC from 1998-2003 reported that approximately 24,900 HPV-associated cancers occur annually with more than 17,300 of HPV related cancers occurring in women.<sup>4</sup> The percentage of HPV related cancers may be underreported and the statistics may not be an accurate representation of the number of actual cases.

Two (2) HPV vaccines are available for use and prophylaxis against HPV infection. Despite their availability and reasonable safety, suboptimal vaccination rates are reported, major concerns about the acceptability and adoption of the vaccines by adolescents, parents and healthcare providers exist. A study performed by Ferris, Horn and Waller, reported minimal vaccine coverage for adolescent girls ages 9-12.<sup>9</sup> This number is concerning because it represents the ideal age for immunization with the vaccine. The lack of knowledge and the sexual nature of HPV infection transmission have been major barriers to the advancement of HPV immunization programs. Healthcare providers that include physicians, nurse practitioners (NPs), certified nurse midwives (CNM), and physician assistants (PAs) must be ready to dismiss myths and discuss the risks and complications associated with HPV infection. These providers should be prepared to discuss the benefits of the HPV vaccines and the role played in the prevention of HPV and its related complications.

### **VACCINE EFFICACIES**

Currently two vaccines are available for the prevention of oncogenic human papilloma viruses. The vaccines have the potential of reducing the incidence of cervical cancer, cervical intraepithelial neoplasia (CIN) grades 2 and 3, low-grade squamous intraepithelial lesions (LSIL), and genital warts. The two vaccines are the quadrivalent vaccine (Gardasil) and bivalent vaccine (Cervarix). Gardasil protects against four (4) strains of HPV that include: HPV 6, 11, 16, and 18. Cervarix protects against only HPV-16 and HPV-18.<sup>15</sup> The strains, HPV-16 and HPV-18 are responsible for approximately 70% of invasive cervical cancers.<sup>13</sup> A randomized observer-blinded study was performed comparing the efficacy of both vaccines in a population of women between the ages of 18-45 years of age. The vaccines were administered according to the recommended three (3) dose schedules. Antibodies for HPV were measured and compared. The results of the study demonstrated that

both Cervarix and Gardasil demonstrated high levels of immunogenicity against HPV-16 and HPV-18 respectively, 7 months after completion of the vaccination series.<sup>13</sup> Side effects of the vaccines were limited to injection site reaction and pain.

A double-blind randomized placebo controlled trial performed by Harper and colleagues was performed to assess the long term immunogenicity, efficacy and safety of the bivalent HPV 16/18 vaccine and its protection against HPV infection. The study population included women who were eligible for the vaccine, who reported receiving all three (3) of the scheduled vaccinations. The average age of the participants was 24 (n=776). The study was conducted from November 2003 through July 2004. The study divided the groups into those participating in the vaccine group (n=373), and the placebo group (n=371).<sup>11</sup> The results of the study demonstrated vaccine efficacy against HPV 16/18 with the virus like particle vaccine adjuvanted with AS04 4-5 years after initial vaccination (CI95%).<sup>11</sup>

### **BARRIERS TO COMPLIANCE**

According to the CDC, randomized controlled studies (RCTs) were performed before the vaccines for prevention of HPV infection could be licensed for clinical use. The studies were performed in adolescents and young women between the ages of 9-26. Clinical trials for the vaccine Cervarix were performed in England and Europe prior to approval by the Food and Drug Administration.<sup>3</sup> Despite the performance of these studies, many parents continue to voice concerns about the general safety of these vaccines

According to Lehman and Benson, high rates of HPV infection among adolescent females is frequently detected with 24% of adolescent females between the ages of 14-19 years testing positive for the HPV infection. Ninety-three percent of adolescents in the U.S have suboptimal vaccine compliance.<sup>14</sup> Adolescents were less likely to seek preventive healthcare and in most instances, required visits for catch-up immunizations. The CDC and the Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination for all adolescent girls ages 11-12 years of age. At the present time, vaccine efficacy trials are being performed to study vaccine efficacy in specific populations.<sup>14</sup>

According to Herzog, educational awareness of HPV infection is important for patients, parents and providers. The increase in knowledge promotes successful vaccination initiatives. The study demonstrated that 25% of females

knew what HPV infection is and approximately 70% knew that HPV was transmitted sexually, and this lack of awareness was considered a major barrier to compliance.<sup>13</sup>

According to a systematic review performed by Brewer and Fazekas, predictors that influence HPV vaccine acceptability are related to perceived safety issues associated to the vaccines. These issues are considered a major barrier to acceptance.<sup>2</sup> In study performed by Deckker, 14.5% of parents (n=1768) with children 0-6 years of age felt unsure about the safety of the vaccines and most were uncomfortable vaccinating their children.<sup>7</sup> The study revealed that parents of low socioeconomic and educational backgrounds are less likely to have their children vaccinated and more likely to question the safety of the vaccine.<sup>7</sup>

Acceptance in diverse ethnic and religious groups continues to be a barrier for acceptance and adherence to vaccine compliance. According to Herzog, Hispanic ethnicity, low socioeconomic status and religious beliefs were viewed as major barriers to vaccine compliance and acceptance. Parents that complied with vaccinating their daughters cited the main reason was disease prevention. The parents of girls, younger than 9 years of age, were primarily concerned with vaccine safety.<sup>7</sup>

According to Gostin and DeAngelis, concerns about the long-term efficacy and safety of the vaccines were major issues related to compliance.<sup>10</sup> The authors cited a low prevalence of HPV infection in young adolescent girls between the ages of 9-12, who had not yet reached sexual debut. Given this fact, healthcare providers voiced serious concerns about the potential for making parents feel coerced or pressured to vaccinate their child.<sup>10</sup> Gostin and DeAngelis concluded that until further studies are performed on vaccine efficacy and safety, the vaccine should be used as a strategy for prevention of HPV infection and cervical cancer.<sup>10</sup>

The high cost of vaccines and lack of insurance coverage for immunizations are considered two major barriers to compliance.<sup>5</sup> The average cost of a three dose regimen of HPV vaccine is approximately \$375 dollars.<sup>3</sup> Some physicians do not offer the vaccines because of cost and most refuse to purchase them due to the uncertainty of reimbursement.<sup>10</sup> Uninsured families that fall under low socioeconomic or poverty levels for income are unable to afford the vaccine. Vaccine programs, such as the CDC's Vaccines for Children Program (VCP) provide vaccine funding for adolescents and children 18 years of age or younger who are uninsured or eligible for Medicaid

services.<sup>4</sup> Agencies such as local county health departments and rural clinics throughout the U.S. provide HPV vaccines at little to no cost for populations that are eligible to receive the vaccine. Healthcare providers should be informed on community resources available for uninsured families who cannot afford the vaccine. Primary healthcare provider (PCP) awareness of the various insurance coverage plans that assist with HPV vaccines is important in compliance. Although more insurance carriers are providing coverage for the vaccines, at the present time, the numbers remain few.<sup>5</sup>

### **PARENTAL ATTITUDES AND BELIEFS**

Parental attitudes and beliefs are a major factor in vaccine compliance. Eighteen-percent of parents with daughters between the ages of 13-16 were less likely to vaccinate because of concerns with the vaccine's potential effect on their sexual behavior.<sup>13</sup> Their concerns include encouragement of sexual behavior in adolescents who might otherwise remain abstinent.<sup>6</sup> Approximately 55-100% of parents in the U.S. reported were most likely to vaccinate their children.<sup>13</sup> Women who were educated on the risks and complications of HPV infection were more likely to comply with vaccinating their daughters. Some parents reported minimal concerns about their children contracting HPV and therefore, were less likely to have their child vaccinated.<sup>6</sup>

A qualitative study performed by Brabin, Roberts, Farzaneh and Kitchener, revealed that parental compliance in vaccinating their adolescent daughters was based on their perceptions of vaccine efficacy and safety.<sup>1</sup> The study was performed in the United Kingdom (UK), with a sample consisting of the parents of 1300-1900 students enrolled in schools in Manchester, England. A Likert-like questionnaire was distributed, and questions were designed around vaccine policy and the decision to vaccinate or not vaccinate.<sup>1</sup> Approximately 61% of parents reported serious concerns related to vaccine safety.<sup>1</sup> Parents also voiced concerns that the vaccines may promote a false sense of protection against HPV, thus encouraging promiscuity.<sup>1</sup> The results of the study suggested that education and good communication between the healthcare provider, parents, and patients is essential for vaccine compliance.<sup>1</sup> The discussion of HPV vaccinations provides a good starting point for parents who find it hard to engage in conversation with their children about sexually transmitted infections.<sup>1</sup>

Parental attitudes and past experiences with children's immunizations contributed to their perception of the vaccines. If a parent perceives their young child at low risk

for sexual activity, they will demonstrate a decreased urgency to vaccinate their child.<sup>17</sup> Studies revealed that implementation of an educational intervention on HPV infection for parents and patients, increased their compliance to vaccinate.<sup>17</sup>

### **HEALTHCARE PROVIDER AWARENESS**

A survey conducted by Duvall and colleagues was performed to study nurse's knowledge and attitudes towards HPV infection and its association with vaccine compliance. The basis for the study was to research nurse's willingness to recommend the HPV vaccine and reasons that affect the decision to do so. Approximately 1,799 self-administered questionnaires were distributed to nurses who were randomly selected to participate in the study. Nine-hundred forty six (946) questionnaires were analyzed and the statistics demonstrated that 97% of the nurses recognized the vaccine as useful in the prevention of HPV infection, and 93% would support its use if the vaccine was publicly funded.<sup>8</sup> Eighty-six percent were in favor of the vaccine being given at school.<sup>8</sup> Nurses who participated in administering the vaccine in their place of employment were more likely to recommend the vaccine, whereas nurses who did not, were less likely to recommend its use.<sup>8</sup> The knowledge reported by the participating nurses revealed that 74-77% answered the questions pertaining to HPV and its association with cervical cancer and anogenital wart development correctly.<sup>8</sup> Lastly, 59% of the participants answered not knowing sufficient information on the HPV vaccines.<sup>8</sup> All of the participants were in agreement that more educational information and training sessions on HPV and the HPV vaccines was necessary in helping parents and patients make informed decisions about whether or not to get vaccinated. The study was limited in that the sample size was not a true representation of all nurses involved in immunization activities and more studies that included different nursing populations was recommended.

According to Miller, Wilson, and Waldrop, 43% of physicians treating pediatric patients were unaware of the HPV vaccine and approximately 11% were not likely to recommend the vaccine due to their concerns of promoting unsafe sexual activity among adolescents receiving the vaccine.<sup>17</sup> A study performed on a random sample size of 1,000 family physician members of the American Academy of Family Physicians (AAFP) was conducted to examine their attitudes about HPV vaccinations and their intent to vaccinate. An 84-item survey to assess knowledge about HPV, attitudes about vaccination, and intention to vaccinate

were used. One-hundred and fifty-five surveys were successfully returned. Ninety-nine percent of the physicians cited availability of the vaccine at an affordable cost was an important factor associated with ordering of the vaccine.<sup>17</sup> Family physicians were more likely to vaccinate girls than boys, and the intent to vaccinate was higher for older adolescent girls than younger adolescent girls.<sup>18</sup> The researchers concluded that successful vaccine compliance is associated with efforts to educate providers about HPV infection and its complications. Healthcare providers should be given information on the safety and efficacy of the available vaccines as well as emphasizing the importance of vaccinating eligible adolescents, both male and female, before they acquire the infection.

### **STRATEGIES TO PROMOTE AWARENESS AND ACCEPTANCE**

Theoretical frameworks, such as the Health Care Belief Model (HCBM), have been used to help understand parental decisions concerning their child's healthcare. The model is based on an individual's perception of perceived benefits from a specific health action.<sup>16</sup> The model is also based on the premise that an individual's response to the severity of a health threat motivates them to participate in a preventive health behavior.

According to Miller, Wilson, and Waldrop, theoretical frameworks have been used to understand parental decisions regarding their children's healthcare. The HCBM focuses on behavior as a determining factor for disease prevention. The components of the model, which best describe the reasons why parents do not participate in health prevention activities are as follows: the perceived threat of the condition, the perceived severity of the acquired condition, the perceived benefits of the health action, and lastly, the perceived barriers, or in this case, expense of the recommended behavior.<sup>17</sup> The components of the HCBM can best be integrated by educating parents and adolescents about sexually transmitted infections and their consequences. The link between HPV infection and the development of cervical cancer should be clearly established and understood. Parents who are unable to afford the vaccine should be referred to health departments and community clinics that provide the vaccine at a reduced cost. Parents usually look to healthcare providers for prevention and treatment recommendations. Parents will usually accept and comply with treatment recommendations when concise information is delivered.

### **MANDATORY VACCINE PROGRAMS**

In 2007, Governor Rick Perry initiated an executive order for all adolescent girls in Texas to receive the HPV vaccine prior to entering sixth grade. This initiative was blocked by lawmakers who voiced concerns about vaccine safety and the violation of parent's right to choose whether or not to vaccinate their child. The issue of the HPV vaccine raised concerns by legislators and parents alike that the issue of the vaccine promoted teenage promiscuity.<sup>6</sup> A federal law, House Bill 1098, was later initiated to prohibit HPV vaccines from becoming an integral part of mandatory school vaccines. This initiative provided parents of adolescents the opportunity to refuse the immunization. The opposition was based on issues related to teenage sexuality and an intrusion on family privacy.<sup>6</sup>

The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination with three doses of HPV vaccine for females 11-12 years of age with the first dose beginning at age 9.<sup>4</sup> A survey conducted by the CDC reported that only 25% of adolescent females between the ages of 13-17 have received one dose of the HPV vaccine.<sup>9</sup> During the 2007-2008 school year, compliance for varicella and hepatitis B vaccines were 94% and 96% respectively. The success in vaccination rates was based on the fact that varicella and hepatitis B vaccines are mandatory for school entry and HPV vaccine is not. According to Duval and colleagues, implementation of HPV immunizations should be included as part of the mandatory school vaccines.<sup>8</sup> The fact that these vaccines are not yet recognized as required for school entrance, makes compliance and vaccination efforts difficult. Efforts to increase parental acceptance of the HPV vaccines should include vaccine comparison with other successful adolescent vaccines like hepatitis B and the meningococcal vaccine.<sup>17</sup>

### **CONCLUSION**

The integration of strategies to increase HPV awareness is vital for vaccine compliance. Increasing parent's awareness on the safety and efficacy of the vaccines is necessary for vaccination promotion. The major reason for increasing HPV immunization compliance is to prevent the risks and complications associated with HPV infection. Increased parental, provider, and patient awareness about HPV infection, as well as efforts to replace concerns with facts on the safety and preventive benefits of the vaccine, have been proven to increase compliance. Controversy still exists among parents and providers because of the moral and sexual implications associated with the infection. The

establishment of mandatory school based vaccination programs is one solution to the problem of compliance, however, time for implementation will be required and the success of the program will depend on public acceptance.<sup>10</sup>

The role of the advanced practice nurse (APN) in increasing HPV awareness should be based on the best evidence in the treatment and prevention of HPV infection and its complications. The APN's role as educator and healthcare policy advocate is essential for making the changes needed to improve compliance and increase awareness.

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