

HPV VACCINE IN MALES: BREAKING THROUGH THE BARRIERS

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Abstract:

Human papillomavirus (HPV) is the most common sexually transmitted disease (STD) in the United States (Seto, Marra, Raymakers, & Marra, 2012). A literature review was conducted to investigate the barriers to vaccine uptake in the male population. Barriers were categorized into three main categories including lack of education, perceived fears, and inaccessibility. The review of literature revealed that education is critical in breaking through the barriers inhibiting the uptake of the HPV vaccine.

Introduction

As a health care provider, it is important to fully understand the ailments that frequently affect the community in which you practice. In general, members of the community have knowledge of the “larger” common diseases, such as diabetes, cardiovascular disease, and cancer. However, there is minimal public knowledge of the human papillomavirus (HPV), the risks for contracting, disease progression, treatment options, and most importantly disease prevention.

HPV is the most common sexually transmitted disease (STD) in the United States (Seto, Marra, Raymakers, & Marra, 2012). The virus has more than 100 strains that have been identified and fully sequenced, with more than forty strains being linked to genital mucosal infections. The strains are divided into oncogenic and non-oncogenic categories (Herzog, Vallerie, Smith, & Wright, 2008). Oncogenic strains have been further classified into high risk, probable high risk, and low risk subgroups. HPV genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82 have all been identified as high risk malignancy strains. Strains 26, 53, and 66 are classified as probable high risk. Low risk cancer strains include 6, 11, 40, 42, 43, 44, 54, 61, 70, 72, 81, and CP6108 (Satyprakash, Rosella, Ravanfar, & Mendoza, 2009). Further discussion of the HPV types within this article will focus on the strains contained within the quadrivalent and bivalent HPV vaccines, specifically types 6, 11, 16, and 18.

According to the Centers for Disease Control and Prevention (CDC) (2011a), nearly 50% of all sexually active people will contract HPV in their lifetime. Therefore, 100% of sexually active people are at risk for contracting HPV and developing an HPV related cancer. Cervical, vaginal, vulvar, penile, anal, and oropharyngeal cancers are all linked with HPV. Cervical

cancer is the most common HPV related cancer, with nearly all cases being attributed to HPV genotypes 16 and 18 (Garland & Smith, 2010). CDC (2011a) reports that HPV is the cause of about 50% of all vulvar, 65% of vaginal, 35% of penile, 95% of anal, and 60% of oropharyngeal cancers. Due to the severity of this worldwide health problem, Healthy People (HP) 2020 is currently developing goals to reduce the rates of HPV through raising awareness among health care providers.

Cervical cancer is the leading cause of death of women in developing countries (Satyprakash, et. al., 2009). In 2006 the Food and Drug Administration (FDA) approved a Merck manufactured quadrivalent vaccine, called Gardasil®, to be a prophylactic HPV related cancer treatment for females between 11 and 26 years of age. The quadrivalent vaccine contains two non-oncogenic (6 & 11) and two oncogenic (16 & 18) strains of HPV. The non-oncogenic strains are credited with causing approximately 90% of genital wart cases (Pomfret, Gagnon, & Gilchrist, 2010), and types 16 and 18 are responsible for more than 70% of invasive cervical cancers (Garland & Smith, 2010). Two years later, the FDA broadened its approval for the quadrivalent vaccine to include males, ages 13 to 26 (Promfret et al., 2010). The second prophylactic vaccine is Cervarix® which is manufactured and distributed by GlaxkoSmithKline. Cervarix® was approved for administration to females between ages 10 and 25 in October of 2008 (U.S. Food and Drug Administration, 2009). The bivalent vaccine only contains oncogenic types 16 and 18.

Overall, both vaccines are reported as being generally well tolerated by participants with minimal side effects. Common side effects of both vaccines include swelling, redness, and pain at the injection site (Pomfret et al., 2010). Vaccine adverse reaction data, reported by the Vaccine Adverse Event Reporting System (VAERS), was analyzed by medical professionals to

identify relationships linking the quadrivalent vaccine to seriously reported side effects such as blood clots, Guillain-Barre Syndrome (GBS), stroke, seizures, and allergic reactions. There were no common causes identified that linked the quadrivalent vaccine with central nervous system disorders, blood clots, stroke, or seizures (Pomfret et al., 2010).

Studies have shown that both the quadrivalent and the bivalent prophylactic vaccines are highly efficacious against cervical cancers caused by HPV subtypes 16 and 18; additionally the quadrivalent vaccine is 73% effective in protecting against other anogenital and vaginal lesions caused by subtypes 6 and 11 (Pomfret et al., 2010). Since HPV is the most common STD and the cost of sequelae is estimated at \$2.9 billion (Mahoney, 2006), it is extremely important to increase the uptake of the HPV vaccine in both males and females to reduce the rate of prevalence and unnecessary health care costs.

Campaigns to vaccinate against HPV have faced many barriers since the approval for girls in 2006 and for boys in 2008. Some of these barriers have been identified in the review of literature; however the topic is lacking an abundance of studies, especially in males. Research that has been conducted has shown some emerging themes related to the barriers for this particular vaccination. A systematic review of literature was performed to investigate “What are the barriers to HPV vaccine administration in males?”

Process of Discovery

A literature search was performed using CINAHL, MEDLINE, PubMed, and Proquest databases. HPV vaccine, barriers, female, costs, and boys were the keywords used to search for articles in all databases. The keywords were searched in different combinations of AND and OR

within each database to broaden the return of articles. The search was narrowed by limiting to only peer reviewed articles between 2007 and 2012. CINAHL, PubMed, and Proquest returned 33, 49, and 38 articles respectively using the following combination of key terms: HPV vaccine barriers AND boys. CINAHL returned 49 and MEDLINE returned 6 articles using the following combination of key terms: HPV vaccine AND females AND barriers. Additionally, CINAHL and MEDLINE returned 35 and 17 articles respectively using HPV vaccine AND cost as key term searches. The term HPV was used in a MeSH search in MEDLINE in which adverse effects, economics, and history were used to broaden results for barriers and 389 articles were found. Only meta-analysis and synthesis of literature articles were retained for further appraisal. Articles were selected for review based on relevance to the question “**What are the barriers to HPV vaccine administration in males?**” The review of literature revealed three common themes: lack of education, perceived fears, and inaccessibility.

Review of Literature

When reviewing the literature available, it becomes evident that lack of knowledge in most populations is a major issue regarding HPV. The research that has been conducted with males as the target population has identified lack of knowledge as being one of the primary road blocks in vaccination efforts (Brewer, Ng, McRee, & Reiter, 2010; Katz, Krieger, & Roberto, 2011; Friedman & Shepard, 2007). A survey conducted by Brewer et al. (2010) showed 41% of the participants knew that HPV caused genital warts, 24% knew it caused anal cancer, and 23% knew it caused oral cancer. Another study done by Katz et al. (2011) supported the findings of the previous study as it found that only 12.1% of the college age male participants believed they

could be at risk for contracting HPV even though 80% of those surveyed were sexually active. The same study also found a low awareness in regards to the availability of a vaccine to prevent HPV, with only 15.8% having any knowledge of the HPV vaccine for preventing cancer and 11.5% knowing of the vaccine in relation to preventing genital warts (Katz et al., 2011). A similar study cited statistics with only 16% of the male participants having any knowledge of the HPV vaccine (Hernandez, Wilkens, Thompson, Shvetsov, Goodman, Ning, & Kaopua, 2010). The available research, though not vast in quantity, clearly shows an extremely low familiarity of HPV and the risks associated in regards to the male population. In comparison to girls, the vaccination of boys in the United States lags behind significantly. The CDC states that according to the 2011 National Immunization Survey for teens only 1 percent of boys received the full 3 recommended doses to complete the series, compared to 35% of their female counterparts (“Centers”, 2011).

As stated, knowledge deficit has clearly been identified as a major barrier in acceptability of the HPV vaccine for both males and females. However, there are several other barriers identified in the literature along with lack of knowledge. Perception of low risk is one of the barriers identified in the literature directly related to males. The research conducted with male sampling has shown extremely low concern over acquiring HPV related illnesses (Katz et al., 2011; Hernandez et al., 2010). There is some deviation between males who identify as heterosexual and those that identify as bisexual/homosexual with the latter being slightly more concerned with potential risk and more likely to take preventative measures (Hernandez et al., 2010). These findings coincide with lack of knowledge. It is evident that in a population more knowledgeable of HPV there is a more realistic understanding of perceived risks.

Education of the HPV vaccine has fallen short of delivering complete information to both male and female patients, due to the FDA initially only approving the vaccine for girls. Limited studies have been done to evaluate young adults' knowledge of the HPV vaccine. Overall, studies suggest that females report a higher awareness of HPV and a greater acceptance of the HPV vaccine than males (Bynum, Brandt, Friedman, Annang, & Tanner, 2011; Friedman & Sheppard, 2007). These findings are thought to be due to the fact that marketing campaigns targeted young women as candidates for the quadrivalent vaccine. A study performed by Bynum et al. (2011) focused on HPV knowledge within in the African American young adult population and identified that educational information on the virus would be better received, especially in males, through marketing campaigns via the Internet, television, radio, and social networking sites rather than through their health care provider (Bynum et al., 2011, Friedman et al., 2007). However, compared to talking to their parents studies have shown that young people would prefer to talk with their health care provider due to the sensitive nature of this subject (Katz et al., 2011).

The HPV vaccine was added to the immunization recommendation list for females and is listed as an optional vaccine for males by the Advisory Committee on Immunizations Practices (ACIP) (Bartlett & Peterson, 2011; Slomovitz & Bodurka, 2007). However, the responsibility to educate patients and families was left up to health care providers. According to Bartlett et al (2011), parents have reported some knowledge of HPV, its link with cervical cancer, and the vaccine; however, many parents reported they were unaware of its link with genital warts or the fact that the virus is sexually transmitted. The majority of parents cited their informational sources as media marketing advertisements from sources other than their child's pediatrician. Providers report adequate education and knowledge of the HPV vaccine, but they also report

having limited accessibility to work with other providers to increase the vaccine uptake (Bartlett et al., 2011). Most studies felt that all health care providers, including pediatrics, primary care, obstetrics and gynecology, and community school nurses, need to become more involved with educating the public about the HPV vaccine (Bartlett et al., 2011; Slomovitz et al., 2007). A study done by Slomovitz et al. (2007) showed that only 55% of parents accepted the vaccine for their children, but after additional education there was a 20% increase in parents willing to vaccinate their sons and/or daughters. Furthermore, after educating parents on the link with HPV and cervical cancer an additional 84% of mothers were willing to vaccinate their daughters (Slomovitz et al., 2007).

Much like the issues with lack of knowledge and perceptions discussed previously, and of just as much importance, is that of the parental influence. Since the vaccine is recommended at a young age when the patient would still be considered a minor, the parent's decision on whether his or her child should be vaccinated plays a big role in the efforts to increase uptake. According to the available literature and studies there seems to be much hesitancy on the part of parents when it comes to vaccinating their child with the HPV vaccine. The perceived benefit of the vaccine and willingness to vaccinate among parents is moderately low, especially when it comes to vaccinating boys where it is below 50% of acceptance among parents. There were several common themes across the sources when it came to the reasoning behind the hesitancy. Some of the major barriers identified included lack of knowledge, cost, religious beliefs, fear of adverse effects, and fears of promoting promiscuity (Reiter, McRee, Gottlieb, & Brewer, 2010; Katz, Reiter, Heaner, Mack, Ruffin, Post, & Paskett, 2009; Reiter, McRee, Pepper, Chantala, & Brewer, 2011). Again, the issue of education and lack thereof becomes a theme that in order to increase vaccination rates would need serious addressing of the public.

Although education is very important for both health care providers and the public, one study done by Rothman & Rothman (2009) strongly suggests that the original educational message for the HPV vaccine emphasized the wrong information. Merck launched the original Gardasil® advertisement in a campaign to protect one less girl from losing her life to cervical cancer caused by HPV types 6, 11, 16, and 18. The national campaign maximized education that focused on cancer prevention and minimized education relating the HPV virus to sexual transmission. By minimizing the fact that the virus is sexually transmitted, the populations most at risk for contracting HPV have discounted the importance of getting vaccinated (Rothman et al., 2009). Furthermore, marketing minimized the male concerns for HPV because men perceived HPV to be less severe for themselves since it was labeled a “women’s disease” (Bynum et al., 2011, p. 300).

The second theme derived from the review of literature was perceived fears of patients and parents. The concept of fear ranged from the dread of the physical pain of the injection to the concern of promoting sexual activity at a young age. In general, adolescents are scared of pain, especially pain caused by needles, and currently both vaccines are administered on a three dose schedule, which results in three times the pain (Pomfret et al., 2010; Conroy et al., 2009). Friedman et al. (2007) showed parents reported fear of the vaccine because it could actually increase the rate of STDs due of the possibility of decreasing the rate of condom usage, and they thought it could possibly give young people the perception that they were immune to STDs. Young adult females expressed fear of receiving the vaccine because it could brand them as promiscuous since it protects against a STD (Friedman et al., 2007). Another study indicated that parents were apprehensive about administering the vaccine because they thought it might promote riskier sexual behavior earlier in adolescents (Bartlett et al. 2011).

Other fears of the vaccine include lack of efficacy and adverse effects as cited by Slomvitz et al. (2007). However, multiple studies have shown both the quadrivalent and bivalent vaccines to be well tolerated with minimal side effects (Pomfret et al., 2010; Gorin, Glenn, & Perkins, 2011). Conversely, Friedman et al. (2007) proposed that raising awareness of the vaccine itself may stimulate public fear. This was discovered in the study when there was an increase in anxiety and fear noted in participants that had received additional information linking HPV with cervical cancer. Friedman et al. (2007) strongly suggests using caution not to cause public distress when trying to promote HPV awareness. Interestingly, another fear reviled by Friedman et al. (2007) showed African Americans still distrust the government. Reasons listed for governmental cynicism were the “Tuskegee Study and... conspiracy theories about HIV/AIDS and genocide of the African American people” (Friedman et al., 2007 p. 481). These ill feelings toward the government could affect the African American population’s perception of HPV information and education.

Although fear of the vaccine and its stigma are barriers to some, others report inaccessibility as the major obstacle. Cost of the vaccine is a large barrier to inhibit access because it affects both providers and patients. Providers are concerned with expenses of purchasing the vaccine, participating in insurance plans, and HPV reimbursement rates. Furthermore, it is probably not cost effective for the provider to offer the vaccine if there is not a large adolescent population seen in the practice. Parents also report cost as an inhibitor to vaccinating their children for HPV (Bartlett et al., 2011). There are several vaccine associated costs for parents: co-pays, transportation, and possibly the full cost of the vaccine if the insurance does not reimburse the provider. Co-payments can be expensive depending on the type of insurance plan carried by the patient. The vaccine is a three part series and could require

a co-payment for each visit, but if the vaccine is not covered by insurance, the patient responsibility could cost between \$320-\$400 (Bartlett et al., 2011; Gorin et al., 2011; Reiter, et al., 2010; & Walhart, 2012). Missed vaccination opportunity is also a barrier, because providers missed the opportunity to administer the vaccine to patients seeking treatment for other minor illnesses or injuries (Conroy et al. 2009). The fact that the vaccine is a three part series is also a barrier because approximately

90% of those not vaccinated had either not returned to the physician or had not been offered the vaccine, [and] it is likely that many of those intending to receive the HPV vaccine simply did not have the opportunity to do so during the follow-up period (Conroy et al., 2009, p. 1684).

Access to health care coverage is an additional financial barrier. Since younger age groups are the target for the majority of vaccinations and insurance coverage is often suboptimal, age itself also presents a barrier to receiving the vaccine. High financial cost is a large barrier to inhibit the patient from receiving the vaccine because Walhart (2012) reported that Dahlstrom discovered parents were more willing to vaccinate both sons and daughters if the vaccine was free.

Synthesis of Related Evidence

After a thorough review of the literature, three major themes were identified when investigating barriers to HPV vaccine administration for adolescent males: lack of education (including knowledge deficits), perceived fears, and inaccessibility. Specific barriers that have been identified include lack of knowledge of both providers and the public, high cost of the

vaccines, the need for a series of 3 injections, inaccessibility to care, fear of adverse effects, parental fear related to giving their children a false sense of security when engaging in sexual activity, and the stigma that goes along with sexually transmitted diseases. It appears that most effective means of increasing the HPV vaccine uptake is to improve the providers comfort with discussing the STD and vaccine with the patient/parent and identifying all opportunities to administer the vaccine. It is equally as important for providers to refute the myths of the HVP vaccine, give sufficient education, and supply easy access to patients/parents to optimize uptake. In order to address the lack of knowledge there must be educational efforts from persons considered to be experts in the subject, which means it is important for providers to fully understand HPV and the risks/benefits of the HPV vaccine to properly educate their patients.

Essentially we found similar barriers to vaccine administration between male and female patients. Even though female patients were more aware of HPV, both sexes reported knowledge deficits, fears of the vaccine, and issues with access to care. The main difference cited by parents as a reason not to vaccinate their sons was the fact that they thought their sons were at low risk for contracting HPV, and they thought vaccine was only given to protect their son's future sexual partners.

Both males and females need to receive thorough educational interventions from multiple sources. If media advertisements are used as a trigger to stimulate HPV awareness the communication need to address the facts and promote HPV as an STD that affects both males and females alike. Media advertisements also need to refer patients to their primary care providers to discuss their risks of HPV. By doing this, it will increase the public's confidence in the source, because the health care provider is an important facet of information for the patient when it comes to choosing whether or not to vaccinate. Providing proper education will

minimize male and female patients' knowledge deficits and fears. In addition, all providers regardless of specialty should provide complete education on HPV, including where they can receive the vaccine. This is extremely important, because the provider's underperformance of educating patients on the HPV vaccine may be a major cause of the shortfall in vaccine uptake.

In order to increase the rates of HPV vaccine administration and meet the HP 2020 goal of completing the three injection series on 80% of females between the ages of 13 to 15 (Bartlett et al., 2011), recommendations need to be more clearly stated by the ACIP. The vaccine has been proven beneficial for both males and females, and therefore should be recommended for both sexes. By changing the guideline to recommend the vaccine for both sexes there would be an increase in HPV awareness across health care providers. There are only a few states that have added the HPV vaccine to the required list of vaccines to be administered prior to entering sixth grade. If the vaccination guideline was clarified, more states could standardize their school requirements.

Discussion

The barriers to HPV vaccine administration in males has been identified as: lack of education, perceived fears, and inaccessibility. Identifying the barriers inhibiting males from receiving the HPV vaccine is the first step in breaking through the obstacles to increase vaccine uptake. As stated previously, there are minimal studies available that focus on males receiving the HPV vaccine. The literature reveals more research focusing on HPV in males is necessary. Additionally, more formal research studies are required in order to influence changes on evidence based practice and to improve guidelines. Currently the Healthy People 2020 goals are

not well defined and are under development. The vague goals include: to “vaccinate 80% of girls between ages 13 and 15, reduce the proportion of females with HPV types 6 & 11, reduce proportion of females with HPV types 16 & 18, and reduce the proportion of females with other HPV types” (U.S. Department, 2012). Only one of these goals state a specific measurable outcome, and currently all of the goals exclude males.

The lack of focus on males may be related to controversial issues with opponents of the vaccine arguing that the total rate of HPV diseases in males (anal, penile, and oropharyngeal cancers) are less than the rate of cervical cancer alone in women, and they continue to argue to be cost effective that the main focus of the HPV vaccine should remain solely on females (Castle, Cox, Palefsky, 2013). Conversely, the immunization rates in females has remained low, and vaccinating only females will not protect homosexual males from contracting the virus from their partners (Castle et al., 2013) . Controversy at hand, the ACIP needs to clarify the immunization recommendations of the quadrivalent vaccine to be included as a routine administration for males. Currently the vaccine is listed as optional.

By changing the status of the vaccine from optional to recommended, barriers to vaccine uptake in males will be easily overcome. Providers will be better prepared to educate patients and parents on the vaccine with documented support from the ACIP. Furthermore, by changing the vaccine to recommended more providers will be apt to carry the vaccine and more insurance providers will broaden plan coverage. That being said, there would be a drastic improvement in access to the vaccine for patients. Consequently, perceived fears of the vaccine will be minimized as the number of adolescents vaccinated continues to rise over time.

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