Concerns, knowledge, and beliefs of northwestern Ohio patients regarding human papillomavirus vaccine and acceptability for themselves and for their children

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Dedication

First and foremost I would like to thank my husband, Brian, for all of his patience, encouragement, and expert advice along every step of the way of this project. I could not have done this without him. Also I would like to thank my family for understanding when my time was precious and giving me the time that I needed. Lastly, thanks to my classmates. Without them, I could not have gotten through it all.
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Introduction

The U. S. Centers for Disease Control and Prevention estimates that about 20 million Americans are diagnosed with human papillomavirus (HPV) infection currently, and about 6.2 million Americans become newly infected every year (U. S. Centers for Disease Control and Prevention [CDC], 2008). Infection with HPV is the most common sexually transmitted infection (STI) in the United States (US), and by age 50, an estimated 4 out of every 5 women will be infected at some point in their lifetime. A reported 50% of sexually active Americans will contract HPV at some point in their lifetime (CDC, 2008).

Human papillomavirus can affect genital areas including the vagina, vulva, cervix, anus, rectum, and penis, with certain infections becoming cancerous. The virus can also affect the respiratory tract if spread from mother to baby during vaginal deliveries (CDC, 2008b). Cervical cancer is the most common cancer associated with HPV infection and the second leading cause of cancer in women worldwide. There are about 12,000 women diagnosed with cervical cancer each year, and roughly 4,000 die from the disease (U.S. Food and Drug Administration [FDA], 2009).

Human Papillomavirus Virus

Human papillomaviruses are double-stranded DNA viruses that cause benign and malignant tumors (Duensing & Munger, 2004). Of the more than 100 types that have been identified, there are 40 types that affect the genitals (CDC, 2008a). Genital warts develop from HPV types considered to be low-risk for infection (types 6 and 11), and cervical and anogenital cancers develop from the types that are high-risk, acting as carcinogens, including the most common cancer-related types 16 and 18, (Munoz et al., 2003).
Each of the viruses has a circular genome enclosed in a capsid shell formed by late genes (L1 and L2) as well as many early genes (E1-E7). Late genes encode for viral capsid shells and will self-assemble to appear as viruses (virus-like particles). The genome has an area that is composed of DNA elements that act as binding sites for cellular and viral proteins which oversee transcription and replication of the virus, although HPVs do not have all the enzymes needed for replication. The early genes encode for proteins dealing with viral replication and the viral life cycle, and it is the E6 and E7 types that are found in high-risk HPV types. These proteins infect the host cells by re-programming the host DNA (Duensing & Munger, 2004). It is this step that allows HPVs to replicate their own genomes (Knipe & Howley, 2001) if they can overcome the host’s natural immune response, cellular apoptosis, and replicative senescence (zur Hausen, 1999).

If infection occurs, it is usually cleared by the host within two years regardless of HPV type (CDC, 2008a) because it is located in the epithelium only (Stanley, 2006). If not cleared, basal epithelial cells are infected by viral replication in the differentiating cells by the HPVs using the cellular replication machinery. Once infection occurs, cells that are normally nondividing remain in the active cell cycle. This forms thickened lesions that exfoliate to further shed the virus (Duensing & Munger, 2004) and genome replication continues to occur, incorporating into host chromosomes (Markowitz et al., 2007).

There is no test for HPV infection available to the general population. Also, there is no test for men to see if they are infected, although infection can be inferred in men by testing women prior to sexual activity and after, as men can be the vectors for the infection. Additionally, the virus cannot be cultured. Therefore, detection of the virus requires identifying its genetic information by using a liquid nucleic acid hybridization test. Testing for HPV is
indicated in those women with abnormal Papanicolaou (Pap) smears or to use as a cervical cancer screening tool (Markowitz et al., 2007).

**HPV Vaccine**

In 2006, a vaccine was approved by the Food and Drug Administration (FDA) to prevent human papillomavirus (HPV) infection in adolescent girls by administering the vaccine before sexual contact. Gardasil, manufactured by the pharmaceutical company Merck, is the first approved vaccine for HPV in the US and the second vaccine demonstrated to prevent cancer (FDA, 2008); the first vaccine to prevent a cancer was the hepatitis B vaccine which can prevent liver cancer (Slade et al., 2009). Indications for Gardasil are prevention of cervical, vulvar, and vaginal cancer as well as genital warts and other precancerous lesions caused by HPV (Merck, 2008).

Vaccination with HPV has received much press coverage lately due to the concern about side effects and the widespread advertising of Gardasil. A recent CDC press release reported about 25,000 cases of cervical cancer caused by HPV occurred in the US from 1998-2003 (Watson et al., 2008). Estimates have shown that half of precancerous lesions, two-thirds of invasive cancers, and most genital warts could be prevented with the HPV vaccine (Frazer et al., 2006).

*Intended Population.*

In March 2007, recommendations were provided to the CDC’s Advisory Committee on Immunization Practices (ACIP) from physicians working for the CDC, using information gathered about the virus and the vaccine using the most up to date studies. They recommend that all girls aged 11-12 should be vaccinated with Gardasil as a routine immunization, although girls
as young as 9 and women as old as 26 should receive the vaccine if they have not already. This vaccine is ideally given to those girls who have not yet had sexual contact, under the assumption that they have not yet been exposed to HPV and thus would benefit the most from vaccination. The ACIP extends the age to 26 to include those already sexually active in hopes of preventing infection by any of the four types of HPV that are provided in the vaccine (Markowitz et al., 2007).

Components and Schedule.

The vaccine is composed of a purified L1 protein that resembles the late genes on the outer coating of the virus, and is thus called a virus-like particle (VLP) vaccine (Duensing & Munger, 2004). It protects against HPV types 6, 11, 16, and 18, which cause the majority of precancerous and cancerous changes in the cervix, vagina, and vulva, as well as genital warts (FDA, 2008). Three intramuscular injections of 0.5mL in the deltoid muscle are needed to be immunized, with the second dose two months after the first, and the third dose six months after the first (Markowitz et al., 2007).

Safety.

Currently, the FDA has established that the HPV vaccine is safe, based on studies conducted in over 11,000 girls worldwide (2009). It contains the late gene major capsid protein (L1) for each of the HPV types included in the vaccination. These are expressed in yeast and have proteins that allow it to assemble itself into the non-infectious virus like particles that are conformationally intact to the actual HPV. It is each L1 protein that is used as the antigen for the injection (Stanley et al., 2006). Administration of the vaccine to both animals and humans creates an antibody response that will bind to natural HPV particles if it comes in contact with them, forbidding their entry into host cells. Because the vaccine is composed of virus-like protein
recombinant particles manufactured in benign biological systems, it has no infectious genetic material, and therefore, it has no oncogenic potential (Frazer et al., 2006). The most common side effect is mild soreness at the injection site, with 94% judging their side effect to be mild to moderate (Merck, 2008), and of all the reports of adverse effects as of the end of December 2008, 94% of the roughly 12,400 reports were either non-serious fainting, soreness at site, headache, nausea, or fever (FDA, 2009). Out of the Gardasil study population of 25,274, a total of 0.05% reported serious systemic adverse reactions including appendicitis, urinary tract infections, and pneumonia among others. There have been 24 reported deaths, with the most common cause being motor vehicle accidents (MVA) (Merck), which coincides with unintentional accidents (including MVAs) ranking as the number one cause of death in this population (CDC, 2007). Of the seven deaths from MVAs in the population study, four participants received the Gardasil vaccine and three were in the control group. Other causes of death include overdose/suicide seen in two participants that received the vaccine and two in the control group, and pulmonary embolism/deep vein thrombosis seen in one participant that received Gardasil and one participant in the control group. In addition, some cases of a rare neurologic disorder, Guillain-Barre, has been reported, causing muscle weakness and some thromboembolic disorders or blood clots. Because the vaccine has been distributed to over 16 million women worldwide, these serious side effects are likely not related to the vaccine and are no higher than expected for the population (FDA).

Gardasil is reported as safe for concomitant use with the vaccine for Hepatitis B, as long as it is given in a different injection site. Administration of the HPV vaccine with other vaccines has not been studied. It is unknown if the vaccine is excreted in breast milk, and safety data has not been reported in girls under 9 years old, women over 45 years old, or males (Merck, 2008).
Efficacy.

The FDA has concluded the HPV vaccine as effective for girls and women aged 9-26 years old. It has been established to prevent precancerous lesions of the cervix, vagina, and vulva as well as prevent genital warts (FDA, 2008). Villa and colleagues (2005) conducted a randomized double-blind placebo-controlled phase II study to conclude 100% efficacy in preventing cervical pre-cancers from the targeted HPV types and nearly 100% efficacy in preventing vulvar and vaginal pre-cancers as well as genital warts in those who were naïve to HPV vaccine types. It has not been determined how long the vaccine will prevent against infection, although effectiveness has been shown for at least five years. The Gardasil vaccine is efficacious when administered concomitantly with the Hepatitis B vaccine if given at a separate injection site. At this time, there is no information regarding the administration of Gardasil with other vaccines (Merck, 2008).

Cost-effectiveness.

Four studies were conducted prior to the approval of the vaccine and were used to demonstrate to the ACIP that the HPV vaccination is cost effective (Markowitz et al., 2007). The studies are divided in the models used to estimate quality-adjusted life-years (QALY) and to determine cost-effectiveness by calculating a dollar amount per QALY. QALY is a measure of the health of a population that combines an assessment of both mortality and disability (Taber's cyclopedic medical dictionary, 2005). Two studies based their research on Markov models excluding herd immunity, and two based their research on dynamic transmission models including herd immunity. Herd immunity is the ability of a community to resist epidemic disease, which may develop naturally in a society as a result of widespread exposure to disease, or it may be stimulated artificially by mass vaccination programs, such as the HPV vaccine.
Of the Markov model studies, a study reported that if assumptions included 100% vaccine coverage of the 12-year-old female cohort, 90% efficacy of reducing HPV types 16 and 18 infections, long-term immunity, and a cost of $377 for the vaccine series, there would be an estimated 50% reduction in lifetime risk of cervical cancer at a cost-effectiveness ratio of $24,300 for 2002 US dollars per QALY as compared to current practice of no vaccination (Goldie et al., 2004). Another study assumed 70% vaccine coverage in 12-year-old females, 75% efficacy against all high risk HPV types, immunity for 10 years with an additional 10 years after a booster, and a cost of $300 for the series and $100 for the booster for 2001 US dollars. Results showed a decrease in lifetime cervical cancer of about 20% at a cost of $22,755 QALY as compared to no vaccination (Sanders & Taira, 2003). For both of these studies, the researchers based cost-effectiveness on a value less than $75,000 US as a cost-effective intervention cut off (Gold, Siegel, Russell, & Weinstein, 1996).

Using dynamic transmission models to include herd immunity, one study assumed 70% coverage of vaccinating 12-year-old females, 90% efficacy for reducing HPV types 16 and 18 infections, 10 year protection with an additional 10 years following a booster, and a cost of $300 for the series and $100 for each booster. Results showed a decrease in lifetime cervical cancer of 61.8% at $14,583 per QALY in 2001 US dollars compared to no vaccination. Additionally, this study concluded that vaccinating boys and men would have a QALY of $442,039 (Taira, Neukermans, & Sanders, 2004). The second study also assumed 70% coverage of 12-year-old females and 90% efficacy for HPV infections by types 6, 11, 16, and/or 18, but assumed 100% efficacy in HPV associated diseases and lifelong protections as well as a $360 series at 2005 US dollars. It was determined that vaccination in the population’s cohort would decrease the incidence of cervical cancer by 78% at $2964 per QALY. Results also showed that including
boys and men in the vaccination cohort was the most effective by reducing cervical cancer incidence by 91% at $45,056 per QALY (Elbasha, Dasbach, & Insinga, 2007). This study assumed $75,000 per QALY as a threshold for cost effectiveness (Gold, et al., 1996).

More recently, another study has evaluated the cost-effectiveness of HPV vaccination using the dynamic model including herd immunity. Assumptions were vaccination of 12-year-old females with 75% coverage at 100% efficacy with lifelong duration at the current cost of $360 for the series. Conclusions for this study demonstrated a cost-effectiveness ratio of $34,600 per QALY in 2006 US dollars as compared to current screening guidelines (Kim & Goldie, 2008). Limits for cost-effectiveness for this study were $50,000 per QALY gained with an upper threshold of $100,000 per QALY gained (Eichler, Kong, Gerth, Mavros, & Jonsson, 2004).

Each of the previous studies has demonstrated the cost-effectiveness of the HPV vaccination for females aged 12 years old. Although one study proved cost-effectiveness for males (Elbasha et al., 2007), another study did not (Taira et al., 2004). Perhaps these findings or the lack of HPV testing practices in males have contributed to the lack of approval for usage of the HPV vaccine in males.

Since approximately 4 out of 5 American women will be infected with HPV by age 50 (CDC, 2008a), it is imperative that health care providers supply female patients and parents of adolescent girls with the most current medical information available to help women decide if they should be vaccinated and to help parents make wise decisions about HPV vaccination use in their daughters. With the recent FDA approval of Gardasil, immunization guidelines for adolescent girls now include this vaccine (FDA, 2009) in the immunization schedule. Also, due to the large number of research studies recently completed that researched the risks, benefits, and acceptability of Gardasil, the narrow population recommended to receive it, and the widespread
marketing of Gardasil, it is easy to understand that patients and parents may be confused about HPV vaccination and may question it as a routine immunization. As with all health matters, health care providers should interpret this new information for patients and parents, answer their questions and concerns, and help them make the best possible decisions regarding use of the HPV vaccine for themselves or their children.

Patients and parents of patients are often unaware of HPV and its consequences. They also may be lacking information about the Gardasil vaccine, its benefits, and its risks. Due to this lack of knowledge and information, patients and parents may be unable to make an informed decision regarding vaccination for themselves or for their children. Therefore, the purpose of this research study was to determine northwestern Ohio patient and parent concerns, beliefs, and knowledge of HPV vaccination, to determine where they received this information, and to determine their acceptance to allow vaccination of themselves and of their children.

Questionnaires were given to all patients of a family practice and to all parents of patients a pediatric practice in Norwalk, Ohio and to all patients of a family practice or to all parents of patients a pediatric practice in Toledo, Ohio who fulfilled the inclusion criteria. The questionnaires were distributed from February 2009- April 2009 and were constructed after viewing numerous surveys from other HPV vaccine publications and after a test group composed of 10 colleagues ensured necessary changes before distribution.
Literature Review

There are numerous studies published regarding the HPV vaccine prior to approval of the Gardasil vaccine and many post-approval. Although a vast amount of information is currently known about this relatively new addition to the standard childhood immunizations, patients and parents have concerns about it. Even with the best recommendations published in the literature about HPV vaccination, it serves no purpose if there are barriers to vaccination such as skepticism by patients and parents.

Many studies have been conducted to determine if parents will vaccinate their daughters and their reasons for or against vaccination. Thirty-six studies published in English from 2001 through 2009 were found using the PubMed database and researched parental acceptance of the HPV vaccine. Each of these 36 studies concluded that parents are accepting of their daughters receiving HPV vaccination, with approximately 28 of them being conducted worldwide before the vaccine was approved in each country, and another 8 more having been conducted since vaccine approval. Ranges of acceptance for daughters to be vaccinated in pre-approval studies ranged from 52% (Chan, Cheung, Lo, & Chung, 2007) to 100% (Gerend, Lee, & Shepherd, 2007). Of the 28 pre-approval studies, parents raised concerns about vaccine safety in 13 of them, efficacy in 1, cost in 6, and the fear it would lead to promiscuity in 9 studies. Post-approval studies have showed acceptance of daughters to receive the vaccine ranging from 69.9% (Watts et al., 2009) to 93% (Stretch et al., 2008) but identified the same concerns as the pre-approval studies; 9 identified safety concerns, 2 for efficacy, 4 for cost, and 3 for promiscuity. Six pre-approval studies and 4 post-approval studies found these concerns were the reason to not accept vaccination for their daughters. Besides the concerns of safety, efficacy, cost, and influence on sexual behavior, some parents refused vaccination altogether because they denied their children
were at risk for contracting infection by HPV (Constantine & Jerman, 2007; Rosenthal et al., 2008; Watts et al.); one study concluded that patient’s perceived risk of HPV infection was low for most patients (Gerend & Magloire, 2008). Regarding patients’ or parents’ acceptance of Gardasil for themselves, 13 studies have been completed worldwide before the vaccine was approved that found that acceptance of the vaccine for patients themselves ranged from 66% (Fazekas, Brewer, & Smith, 2008) to 86% (Woodhall et al., 2007). Nine more studies have been completed since vaccine approval that indicated vaccine acceptance for themselves as patients ranged from 50% (Donders et al., 2008) to 88% (Walsh et al., 2008).

Concerns about Vaccine Safety

Parents, physicians, and patients often question the safety of all vaccines (FDA, 2009), and fears of adverse reactions due to the HPV vaccine are commonly reported reasons to not vaccinate or be hesitant to vaccinate. In one study, 65% of mothers worried about side effects of HPV vaccine (Marlow, Waller, & Wardle, 2007), while 63% of mothers who disagreed with HPV vaccination listed concerns of potential side effects as their primary reason (Chan et al., 2007). Issues of side effects that might affect external appearance, fertility, or health were major considerations for vaccine acceptance (Lee et al., 2007), and the most common reason to decide against vaccination was the belief it was dangerous (Di Giuseppe, Abbate, Liguori, Albano, & Angelillo, 2008). In terms of specific safety concerns, one study found the fear of experiencing discomfort or pain when receiving the vaccine as the only safety concern (Dempsey, Zimet, Davis, & Koutsky, 2006). Also, in regards to government reassurance of HPV vaccine safety, a United Kingdom (UK) study showed that only 61% of parents would trust these reassurances, but 78% would trust scientific evidence of the vaccine’s safety (Brabin, Roberts, Farzaneh, &
Kitchener, 2006). While no reason was given for this finding, it should be noted that a Dutch study published shortly before the UK study showed a negative outlook of highly educated parents and healthcare workers on vaccine safety policies (Hak, Schonbeck, De Melker, Van Essen, & Sanders, 2005). Similar results concluding safety as a concern were found in additional publications (Davis, Dickman, Ferris, & Dias, 2004; Kahn et al., 2008; Lenselink et al., 2008; Marlow et al. 2007; Noakes, Yarwood, & Salsbury, 2006; Olshen, Woods, Austin, Luskin, & Bauchner, 2005; Slomovitz et al. 2006; Waller, Marlow, & Wardle, 2006; Woodhall et al., 2007).

Other authors have found that perceived safety of the HPV vaccine as a positive predictor for intent to vaccinate. One study found that perceived safety of the vaccine was an independent predictor of acceptability to vaccinate (Gerend et al., 2007), and another concluded perceived benefits to safety as a reason for vaccination in the 66% who approved of it (Kahn et al., 2008). Likewise, in a study of Vietnamese mothers, 95% of those surveyed agreed or strongly agreed that vaccines in general are safe (Dinh et al., 2007).

Regarding physician’s attitudes toward safety, of the 12% of those surveyed who would not recommend the vaccine, 25% reported that concerns with safety was the primary reason for not recommending it (Ishibashi, Koopmans, Curlin, Alexander, & Ross, 2008). Also, lack of knowledge of potential long-term side effects was an important characteristic as to whether or not to recommend vaccination (Riedesel et al., 2005). There is no definition for the length of long-term, and since the vaccine has only been in FDA approved use since June 2006, it is too early to see long-term side effects. To identify these long-term side effects as expediently as possible, the FDA has established a reporting system for unconfirmed vaccine adverse effects
called the Vaccine Adverse Event Reporting System that monitors the safety of all vaccines (FDA, 2009).

Although the FDA has established Gardasil as safe for the indicated population, many parents and physicians have differing opinions. It is unknown what is needed to change the beliefs of those who disagree with the FDA. Perhaps more information about the vaccine would ease these fears.

 Concerns about Vaccine Effectiveness

Some parents who do not accept HPV vaccination for their daughters believe the vaccine is not efficacious, though the reasons for this belief are unknown. All physicians surveyed in a study of American Academy of Pediatrics members concluded HPV vaccine efficacy as an important characteristic in terms of recommendation of the vaccine (Riedesel et al., 2005), and efficacy was determined to have the strongest influence on parental acceptability of vaccination for their daughters (Zimet et al., 2005). Results such as this were found in several other studies (Davis et al., 2004; Korfage, Essink-Bot, Daamen, Mols, & van Ballegooijen, 2008; Stewart & O'Mahony, 2007; Stretch et al., 2008). Currently, the FDA has established that Gardasil® is effective in preventing genital warts and cervical cancer when given to girls and women aged 9-26 (FDA, 2009).

Studies have found a positive prediction in HPV vaccine acceptability and vaccine effectiveness (Brabin et al., 2006; Di Giuseppe et al., 2008; Kahn et al., 2008; Sauvageau, Duval, Gilca, Lavoie, & Ouakki, 2007). Ninety-four percent of mothers surveyed in a Vietnamese study agreed or strongly agreed that HPV vaccination would be effective in protecting their daughter from cervical cancer (Dinh et al., 2007). In regards to US patients, one study concluded that
perceived effectiveness of HPV vaccination correlated with intentions of getting the vaccination themselves, although it was not determined to be an independent predictor (Gerend et al., 2007).

Beliefs of the HPV vaccine being efficacious are important to vaccine acceptance because of the cost, time, and transportations factors with getting children to the doctor to receive the vaccine series. It is no surprise that parents are concerned about the vaccine doing what it says it will, given those factors involved with getting the vaccine.

Concerns about Vaccine Cost

Vaccination against HPV is the most expensive childhood immunization, costing $360 for the 3-dose series. It is covered by most insurance if given to girls and women between the ages of 9 and 26. If not covered by insurance, there is a Vaccine for Children program that allows those children under 19 years old to receive the recommended vaccinations for free (National Center for Immunization and Respiratory Diseases [NCIRD], 2008).

Twenty-five percent of women believed the vaccine would be very likely or extremely likely to cost a lot of money (Kahn, Rosenthal, Hamann, & Bernstein, 2003), although the study did not define “a lot of money”, and cost was found to be a barrier to vaccination in 38% of parents (Hausdorf, Newman, Whiteman, Aitken, & Frazer, 2007). More people would accept the vaccine if it was free (Friedman & Shepeard, 2007), having to pay $50 for the vaccine was a cause of not accepting it (Jones & Cook, 2008), and having to pay $100 was a barrier to vaccine acceptance (Sauvageau et al., 2007). Furthermore, a recent study by Walsh and colleagues (2008) showed that 70.5% of parents wanted the vaccine to be free. Regarding insurance status, those without insurance were less likely to accept the vaccine (Kahn et al., 2008) although another study in Appalachian Kentucky found those without insurance would more likely to
accept the vaccine for themselves and their daughters than those with insurance; 88.9% without insurance who wanted the vaccine as compared to 84.5% with insurance who wanted the vaccine for themselves, and 75.8% who wanted the vaccine for their daughters but did not have health insurance as compared to 66.2% who wanted the vaccine for their daughters but did have insurance (Hopenhayn, Christian, Christian, & Schoenberg, 2007). In this same study, those reporting higher income were less likely to accept vaccination for themselves and their daughters in addition to those with higher education levels although the published study did not expound upon why.

In contrast, one study showed 50% were willing to accept the vaccine no matter what the cost (Donders et al., 2008). Fazekas and colleagues (2008) determined that of the 84% that would accept vaccination for their daughters, the average cost they would pay for the vaccine was $178. Additionally, this study showed those from a public clinic versus a private clinic and those with greater perceived likelihood or severity of either HPV infection or cervical cancer were willing to pay more money for the vaccine. Furthermore, those with a greater belief of the negative consequences of cervical cancer, and those that believed vaccination was effective for cervical cancer were willing to pay more money for the vaccine.

In a 2005 study, 95% of physicians believed the vaccine needed to be offered at a reasonable cost, 97% believed it should be affordable to those without insurance or those whose policies do not cover it, and 94% believed it should be covered by most insurance (Riedesel et al.). More so, a study showed that of the 9.3% of physicians who would not recommend the vaccine, 52.5% stated cost as their reason (Ishibashi et al., 2008). Several studies found no association between income or health insurance and vaccine acceptability (Kahn et al., 2003; Lazcano-Ponce et al., 2001; Slomovitz et al., 2006; Stretch et al., 2008; Zimet et al., 2005).
Due to the high cost of this vaccine, most are concerned with being able to buy it for their children. Also, they want to make sure that if they do buy it, they will be protecting their children from cervical cancer and will not be causing them any unnecessary harm.

Concerns about Sexual Behavior

The social stigma of promiscuity has been associated with HPV vaccination, specifically among parents who believe that the vaccine will lead to riskier sexual behavior or an earlier sexual debut. Multiple studies concluded this as a concern (Brabin et al., 2006; Constantine & Jerman, 2007; Davis et al., 2004; Kahn et al., 2008; Lee et al., 2007; Lenselink et al., 2008; Marlow et al., 2007; Sauvageau et al., 2007; Stewart & O'Mahony 2007; Waller et al., 2006; Woodhall et al., 2007). Another concern is that others would think of those who got the vaccine as being promiscuous (Friedman & Shepeard, 2007). In a study of physicians 12.5% of the total 9.3% that did not recommend vaccination believed it would encourage promiscuity (Ishibashi, et al., 2008). Contrastingly, another physician study found the belief that vaccination would provide an opportunity to discuss other health-related issues (Riedesel et al., 2005).

One study found different results regarding promiscuity, showing that 90% of parents did not think vaccination would encourage earlier sexual behavior (Dinh et al., 2007). A study concluded that none of the women surveyed would decline vaccination because it would prevent a STI (Donders et al., 2008), and the majority of women who would accept vaccination themselves would not feel safe having more sexual partners or not using condoms because of vaccination (Kahn et al., 2003). Furthermore, Stretch and colleagues (2008) found that 77% of parents thought vaccination would not encourage sex.
Concerns, beliefs, and knowledge about the vaccine can lead parents to hesitate or to prevent their daughters from receiving the HPV vaccine. Even those who accept vaccination have concerns. Based on recent publications, the CDC and FDA recommend HPV vaccination for all adolescent girls aged 11-12 as a routine immunization (NCIRD, 2008). The purpose of the current research project was to determine northwestern Ohio patient and parental concerns, beliefs, and knowledge of HPV vaccination, and to determine their acceptance to allow vaccination for themselves and for their children.

Northwestern Ohio is a diverse area of differences in population within close proximity. Since changes in location can result in changes of beliefs, concerns, and knowledge, areas may have vastly differing views on issues. Approximately 80% of the US population resides in urban areas and roughly 20% resides in rural areas (U.S. Department of Transportation [USDOT], 2004), coinciding approximately with the current population distribution of the northwestern Ohio town of Norwalk; 75% of the roughly 22,000 people live in an urban area and 25% live in a rural area (Onboard Informatics, 2008a). A city such as Norwalk is considered to be an urban cluster, based on its populations of less than 49,999 people (USDOT), although it can be considered rural according to which definition of rural is used (U.S. Department of Agriculture Economic Research Service, 2007). Residents of Huron County, Ohio, where Norwalk is located are qualified to receive rural health care grants (U.S Department of Health and Human Services), thus by this definition, Norwalk, Ohio, is considered a rural location. Toledo is a northwestern Ohio city that consists of an urban area because the population of Lucas County where Toledo is located is greater than 50,000 people (U.S. Department of Agriculture Economic Research Service); an estimated 295,000 people reside in Toledo (Onboard Informatics, 2008b).
Approximately 55 miles separate Norwalk and Toledo geographically, and a difference in location such as this may have an effect on a population’s concerns, knowledge, and beliefs about healthcare because their access to healthcare may be very different. Rural as well as inner city urban populations often experience a lack of healthcare providers or have transportation costs that may contribute to a lack of access to healthcare services (Council on Graduate Medical Education, 2007), which is one of the many deterrents to healthcare (National Center for Health Statistics, 2007). Locations that have different access to healthcare may have different concerns regarding preventative services such as vaccinations as cervical cancer screening. With regard to HPV vaccination, the differing locations of Norwalk and Toledo, Ohio, may have an impact on acceptability for patients and parents to have themselves and their children vaccinated.

Research Questions
Are urban Toledo and rural Norwalk different in their concerns, knowledge, and beliefs regarding HPV and the HPV vaccine? How does their knowledge, their beliefs, and their concerns relate to their reported willingness to have themselves or their child vaccinated? Are there differences in concerns, knowledge, and beliefs between family practice offices and pediatric offices? If there are differences, how do they affect their acceptance of the vaccine?
Methodology

Cover letters and questionnaires were distributed to a family practice and a pediatric practice in both Norwalk, Ohio and Toledo, Ohio, for a total of four locations. A power analysis was calculated for the planned Chi-square analyses. Using a confidence level of 95% and a confidence interval of 6.93%, the desired sample size calculated was 200. The total sample size was divided among the four office locations for a goal of 50 questionnaires from each location. Using a calculated response rate of 38%, 130 questionnaires were given for distribution at each location.

The cover letter included introductory information regarding who conducted the research and where they are from. The purpose of the project was explained as determining patient and parent concerns, knowledge, and beliefs regarding HPV vaccination and acceptability of allowing themselves and their children to receive vaccination in northwestern Ohio. An explanation was given as to why those receiving the questionnaire were selected. For example, being a patient of one of the four clinics and being 18 years or older were inclusion criteria for the study. Participants were clearly provided with what their role was in the project (complete the survey and leave it in the closed box before they leave) and they were provided with a description of how their privacy will be assured (no questions will be asked that could link participants with their responses, and surveys are to be left in a sealed box that only the researcher will have access to). Patients and parents were informed that their participation in the research study was optional and they could have declined or stopped participation at any time. No compensation was provided. Finally, patients and parents were provided with information regarding who to contact if questions arose regarding the questionnaire.
A one-page, double-sided questionnaire with the cover letter was distributed at the medical offices (included in appendix). Questions were directed at concluding information regarding demographics, knowledge, beliefs, and concerns such as safety, efficacy, cost, and promiscuity regarding the HPV vaccine. Perceived risk of HPV infection was also assessed regarding children. To ensure those patients approached about the study had their HPV infection and vaccine questions answered, an informational brochure published by the CDC was provided to all who were invited to participate in the study, whether they completed the questionnaire or not. If participants had other concerns, they were advised to contact their health care provider.

Results were gathered after the 3-month survey time. Survey data was coded using Microsoft Excel 2003 and imported into SPSS version 16.0. Descriptive statistics were obtained via SPSS. Differences in responses due to town location or practice setting were analyzed using the chi square test in SPSS version 16.0. Tables and figures were constructed from the data using Microsoft Excel 2003. Location of the results was assessed to conclude any differences between the urban population of Toledo and the rural population of Norwalk. Knowledge level and concern level of the HPV vaccine were assessed to determine if more knowledge was linked to greater willingness to be vaccinated and more concern was linked to fewer acceptances to be vaccinated. Statistical hypotheses were as follows:

**Concerns**

- There will be a difference in concerns regarding HPV vaccination between patients and parents utilizing family practitioners and those utilizing pediatricians.
- There will be a difference in concerns regarding HPV vaccination between patients and parents utilizing healthcare practitioners in rural Norwalk and those using healthcare practitioners in urban Toledo.
• There will be a difference between those who were concerned about HPV vaccination versus those who reported not being concerns in terms of acceptance of vaccination for themselves and/or for their children.

• Respondents with concerns about the vaccine will want additional information about it.

Knowledge

• There will be a difference in knowledge levels regarding HPV vaccination between patients and parents utilizing healthcare practitioners in rural Norwalk and those using healthcare practitioners in urban Toledo.

• There will be a difference in knowledge levels of HPV and the HPV vaccine between people utilizing family practitioners and those utilizing pediatricians.

• There will be a difference between respondents who are knowledgeable about HPV and the HPV vaccine in terms of acceptance of vaccination for themselves and/or for their children.

• Respondents who are not knowledgeable will want additional information about HPV and the HPV vaccine.

• Respondents who are knowledgeable about HPV and the vaccine have fewer concerns that those respondents who are not knowledgeable.

Sources of Information about HPV and the Vaccine

• Main source of information about HPV will differ between respondents who would accept the vaccine for themselves or their children and those who would not accept the vaccine.
Results

Descriptive Statistics

Response rates at the four sites from 0.069-63%. A total of 225 participants completed the survey with ages ranging from 18 to 59 years old with a mean age of 32 years old. Females composed 96% of the respondents. Eighty-five percent of the respondents were married or in a monogamous relationship; the remainder reported they were unmarried. Respondents with children made up 92% of the population. The majority of respondents, 51%, had both daughters and sons. Twenty-four percent had only daughters and 25% had only sons. Those with health insurance themselves were 89%, while 97% of those respondents who had children had health insurance for their children (see Table 1).

Acceptance of the HPV vaccine

Questions were asked regarding of acceptance of vaccination for patients and for their children (Table 2). Almost the entire population (99.1%) surveyed had not gotten the HPV vaccine themselves, and neither had their children (91.0%). Most respondents would consider getting the vaccine themselves (59.1%) and their children (77.0%) if insurance paid for it. When asked directly if the participants wanted the vaccine for themselves, 62.9% did not want the vaccine. Regarding parents views for their children, the majority (64.1%) wanted them to get the vaccine and 83.3% planned on them returning within 6 months for all three doses. The most commonly reported reason respondents gave for wanting the vaccine was to be safe and protected from HPV infection. This was the most common response for both themselves (64.8%) and for their children (74.1%). See Table 3. The most commonly reported reason for not wanting the vaccine for themselves was that they believed they had no need for the vaccine
(29.3%); for not wanting the vaccine for their children, the most commonly reported reason was side effects (21.4%). Table 4 provides more information.

Concerns about HPV and the Vaccine

To assess concern regarding HPV and the vaccine, eleven specific questions were asked that were gathered from data in previous studies as to what the common concerns were: cost, safety, efficacy, and promiscuity. Results concluded that the majority, 68.8%, of the respondents do not believe cost of the vaccine is an issue, and most would get the vaccine for themselves and their children if insurance covered it. In terms of safety, both the common and the rare-but-serious side effects of the HPV vaccine were not identified as concerns to the majority of patients and parents for themselves (82.0%, 78.8%) or for their children (71.0%, 59.6%). Concerns about their children’s future fertility after getting a vaccine for an STI was an issue for the majority of parents (53.1%). For efficacy, patients and parents were not concerned, with 87.2% of respondents answering “no” to being upset at the possibility of needing a 4th dose of the HPV vaccine later in life. For patients themselves, the majority of respondents (94.1%) would not change their sexual behavior after receiving the vaccine. The same was true regarding the respondent’s children’s current or future sexual behavior. See Table 5 for a summary of concerns.

To view concerns as a whole, participants who answered “yes” to at least 8 out of the 11 questions were described as concerned about the HPV vaccine. Results showed that 92.9% of participants were not concerned about the HPV vaccine. Respondents who were concerned were more likely to be seen in pediatric offices (68.8%) than in family medicine offices, though this difference was not shown to be statistically significant ($\chi^2 = 0.113, df = 1, p=0.737; \alpha = 0.05$). In
terms of location, concerned respondents were more likely to be completing the survey in Norwalk (62.5%); again, this difference was not shown to be statistically significant ($\chi^2 = 0.201$, $df = 1$, $p=0.654$; $\alpha = 0.05$). Table 6 provides additional details.

It was hypothesized that there would be a difference between those who were concerned about HPV vaccination versus those who reported not being concerned in terms of acceptance of vaccination for themselves and/or for their children. The study found that there was no statistically significant difference among the groups for themselves ($\chi^2 = 3.671$, $df = 1$, $p=0.055$; $\alpha = 0.05$) or for their children ($\chi^2 = 3.692$, $df = 1$, $p=0.055$; $\alpha = 0.05$). Those with concerns who wanted to receive the shot for themselves composed 5.1%, with 3.4% not wanting to receive the shot. Thirty-two percent of those without concerns want to get the shot for themselves, and 59.4% did not want the shot. The study also found that there was no statistically significant difference among those who were concerned about the vaccine and those who would accept vaccination for their children. Nine percent of those with concerns wanted their child to get the shot, 55.2% of those without concerns wanted their child to get the shot, 34.5% of those without concerns do not want their child to get the shot, 1.4% of those with concerns do not want their child to get the shot. See Table 7 for results.

Only 31.8% of respondents indicated that they would like additional information about HPV or the vaccine. It was hypothesized that respondents who were concerned about the vaccine would want more information. The study concluded that there is a statistically significant difference between the concerned and not-concerned groups in terms of wanting additional information ($\chi^2 = 19.555$, $df = 1$, $p=0.000$; $\alpha = 0.05$). Those that had concerns and wanted more information composed 6.5% compared to 1.5% of those that without concerns that wanted more information. See Table 8 for all results.
Knowledge of HPV and the Vaccine

To determine respondents’ level of knowledge of HPV and the HPV vaccine, nine questions were asked. The majority of participants had heard of HPV before the day they were surveyed (91.6%), knew that being sexually active was a risk for catching HPV (73.9%), and had heard of a shot that could prevent catching HPV (81.3%). Far fewer respondents knew that their healthcare providers (38.3%) or their children’s healthcare providers (34.9%) offered the HPV shot in their clinics. Most did not know the dosing schedule for the vaccine (58.6%), the cost (77.8%), or the common (53.2%) and serious side effects (69.4%). To determine knowledge as a whole, if respondents answered at least 6 out of the 9 questions correctly, they were categorized as knowledgeable. Only 33.8% of respondents were identified as knowledgeable. Of these, 71.1% were from Norwalk, and 63.2% were seen in a pediatrics clinic. See Table 9 for all results.

It was hypothesized that there would be a difference in knowledge of HPV and the HPV vaccine between patients and parents utilizing rural health care providers and those utilizing urban health care providers. The study found that there was no statistically significant difference among the groups ($\chi^2 = 0.640$, $df = 1$, $p=0.424$; $\alpha = 0.05$). In Norwalk, 24.0% was knowledgeable, and in Toledo, 9.8% was knowledgeable. See Table 6 for all results.

It was also hypothesized that there would be a difference in those that were knowledgeable about HPV and the HPV vaccine between those utilizing family practitioners and those utilizing pediatricians. While respondents being seen in pediatrics clinics were more likely to be knowledgeable (21.3%) versus those being seen in family medicine clinics (12.4%), this
difference was not found to be statistically significant ($x^2 = 0.151, df = 1, p = 0.698; \alpha = 0.05$). See Table 6 for all results.

It was hypothesized that those who were knowledgeable about the HPV vaccine would report a greater willingness to have themselves and their children vaccinated against HPV. Those who were knowledgeable and wanted the vaccine composed 13.7\% for themselves, though this was not statistically significant ($x^2 = 0.476, df = 1, p = 0.490; \alpha = 0.05$). For their children, 23.4\% who were knowledgeable wanted the vaccine although no statistical significance was found here either ($x^2 = 2.034, df = 1, p = 0.154; \alpha = 0.05$). See Table 7 for all results.

It was hypothesized that there would be a difference in those that are knowledgeable and those that would want more information. Seven percent of those that were knowledgeable wanted more information compared to 24.9\% of those that were not knowledgeable that wanted more information, though no statistical significance was found ($x^2 = 0.433, df = 1, p = 0.006; \alpha = 0.05$). See Table 8 for all results.

**Sources of Information about HPV and the Vaccine**

Several questions were asked to assess participants’ beliefs about health, HPV risk, and the HPV vaccine. Where patients and parents get their information can influence their beliefs, therefore questions were asked regarding where the participants receive their health information. The majority, 76.4\%, of patients and parents get their health information from their doctors, followed by 51.6\% from the media (including television, newspapers, magazines, radio, Internet, etc.) and 35.6\% from nurses. When respondents were asked where they got specifically their HPV information from, the responses differed in majority. Most (65.3\%) get their HPV
information from the media, followed by 40.9% from doctors and 13.8% from nurses (see Table 10).

It was hypothesized that the main source of information about HPV will differ between respondents who would accept the vaccine for themselves or their children and those who would not accept the vaccine. The study found that there is a statistically significant difference between the groups ($x^2 = 3.920, df = 1, p=0.048; \alpha = 0.05$). Those who got their HPV information from the media and accepted the vaccine for themselves composed 20.1%; 43.1% of those who got their information from the media rejected the vaccine for themselves; 17.2% of those who accepted the vaccine for themselves did not get their information from the media, and 19.5% of those that rejected the vaccine for themselves did not get their information from the media. In terms of their children, the study concluded that there is not a statistically significant difference among the groups ($x^2 = 1.169, df = 1, p=0.280; \alpha = 0.05$). Those who got their HPV information from the media and accepted the vaccine for their children composed 38.6%, 24.8% of those who got their information from the media rejected the vaccine for their children, 25.5% of those who accepted the vaccine for their children did not get their information from the media, and 11.0% of those that rejected the vaccine for their children did not get their information from the media (see Table 11).

With regard to those who received their HPV information from doctors, it was hypothesized that there would be a difference in rejection of the vaccine based on HPV information obtained from doctors. The study concluded that there is a statistically significant difference between groups for themselves groups ($x^2 = 6.260, df = 1, p=0.012; \alpha = 0.05$). Twenty percent of those who got their HPV information from doctors accepted the vaccine for themselves, 21.7% of those who got their information from doctors rejected the vaccine for themselves, 25.5% of those who got their information from doctors accepted the vaccine for their children, and 30.0% of those who rejected the vaccine for their children did not get their information from the doctors.
themselves, 17.1% of those who accepted the vaccine for themselves did not get their information from doctors, and 41.1% of those that rejected the vaccine for themselves did not get their information from doctors. For their children, the study concluded that there is no statistically significant difference between the groups ($x^2 = 0.067, df = 1, p=0.796; \alpha = 0.05$).

Those who got their HPV information from doctors and accepted the vaccine for their children made up 24.8%, 13.1% of those who got their information from doctors rejected the vaccine for their children, 39.3% of those who accepted the vaccine for their children did not get their information from doctors, and 22.8% of those that rejected the vaccine for their children did not get their information from doctors. See Table 11 for all results.
Discussion

This is the first study that has dealt with concerns, knowledge, and beliefs about HPV and the HPV vaccine, and how they relate to acceptance of the vaccine for patients themselves and for their children in Northwest Ohio. For the issue of concern about the HPV vaccine, results showed that 92.9% of the surveyed population is not concerned about the vaccine. This result differs greatly from the research showing that the majority of studies reviewed (32 out of 36) showed that respondents did have concerns such as safety, efficacy, cost, and promiscuity.

Concerns about the Vaccine

Safety. Specifically for safety, most patients (82.9%) were not concerned about the common side effects of soreness, redness, or itching at the injection site for themselves and most parents (71.0%) were not concerned about these for their child. Results were the same when participants were asked about serious side effects such as fever, nausea or vomiting, and dizziness (78.8% for themselves, 59.6% for their children). These results differ from Marlow, Waller, & Wardle (2007) who concluded that 65% of mothers surveyed worried about side effects, and Dempsey, Zimet, Davis, & Koutsky (2006) who found the fear of experiencing discomfort or pain when receiving the vaccine was a safety concern. Many other studies found differing results as well (Davis et al., 2004; Kahn et al., 2008; Lenselink et al., 2008; Noakes et al., 2006; Olshen et al., 2005; Slomovitz et al., 2006; Woodhall et al., 2007).

Efficacy. Most (87.2%) patients and parents would not be upset if another dose of the HPV injection was needed later in life if the vaccine was determined not to be efficacious. This conclusion differs from a 2008 study that concluded efficacy as a major concern for many participants (Wong).
Cost. The majority (68.8%) of patients and parents did not believe cost was a concern. The is similar to results from Lee et al. (2007) that found cost was a minor concern of acceptability of HPV vaccination.

Sexual behavior. The issue of promiscuity turned out to be not a concern for this population. The majority of patients (91.8%) did not believe that getting the HPV vaccine would encourage more risky sexual behavior. This coincided with what parents thought about their children; the majority (89.8%) is not concerned of encouragement of more risky sexual behavior after receiving the HPV vaccine. Two studies agreed with these results (Dinh et al., 2007; Stretch et al., 2008). Many other studies disagreed with these results (Brabinet al., 2006; Constantine & Jerman, 2007; Davis et al., 2004; Kahn et al., 2008; Lee et al., 2007; Marlow et al., 2007; Sauvageau et al, 2007; Stewart & O'Mahony, 2007; Waller et al., 2006; Woodhall et al., 2007).

For Northwest Ohio patients and parents, the conclusions drawn from this study clear up many misconceptions that patients and parents are concerned about the safety, efficacy, cost, and issue of promiscuity in terms of Gardasil. In regard to each of these issues, the majority of patients and parents in the survey population did not report concern for the issues.

Knowledge of Vaccine

For knowledge, this is the first study that investigated what parents and patients in Northwest Ohio know about HPV and the HPV vaccine. Results prove that most (66.2%) patients and parents were not knowledgeable. Although most (91.6% and 81.3%) had heard of HPV and the HPV vaccine before the date of the survey, the majority (61.7% and 65.1%) did not know that their healthcare provider or their children’s healthcare provider offered the vaccine in their clinic. Also, the majority (73.9%) of respondents did know that being sexually active was a
risk for catching HPV. Most of the patients and parents did not know the dosing schedule for the vaccine (58.6%), the cost (77.8%), or the common (53.2%) and serious side effects (69.4%). These results conclude that most of those surveyed had only known it was an STI.

_Beliefs about the HPV Vaccine_

This was also the first study to assess where Northwest Ohio patients and parents get information about the HPV vaccine. Most (76.4%) patients and parents obtain their health information from their doctors while most (65.3%) obtain their HPV information from the media. This is an interesting find because it shows a discrepancy between general health and HPV information, perhaps resulting in the media overexposure of the HPV vaccine or the lack of healthcare providers sharing their knowledge with their patients. Either way, it is important to note. Other studies agree that participants often obtained their information both from doctors and from the media (Di Giuseppe et al., 2008; Dinh et al., 2007; Hopenhayn et al., 2007; Noakes et al., 2006). Most (89.5%) participants believed adult women should be allowed to get the vaccine if they wanted to although it is not currently intended for them. These results were found in other studies (Baykal et al., 2008; Fazekas et al., 2008; Kahn et al., 2003; Marshall, Ryan, Roberton, & Baghurst, 2007; Sauvageau et al., 2007; Slomovitz et al., 2006). Most (79.3%) participants believed boys and men should be allowed to get the vaccine if they wanted to although it is not currently intended for them. Similar results were found in other studies (Lenehan et al., 2008; Lenselink et al., 2008; Noakes et al., 2006; Olshen et al., 2005; Walsh et al., 2008). It is interesting to note that while 95% percent of participants believed that children today are more sexually active at earlier ages than they were in the past, only 39.3% believed their child is at risk or will be at risk in the future for catching HPV. This discrepancy is understandable because
parents often believe that their children do not apply to common generalization. Fifty-five percent believed the vaccine should be given before the teen years, 42.9% believed it should be given during the teen years, and 2.1% believed it should be given after the teen years.

Constantine and Jerman (2007), Lenselink et al. (2008), Marlow et al. (2007), Sauvageau (2007), Waller et al. (2006), and Walsh et al. (2008) agreed that most should be vaccinated before age 13 and Marshall et al. (2007) and Riedesel (2005) concluded that most believed the vaccine should be given by age 13. Dempsey et al. (2006) disagreed by concluding that acceptance increases as age for vaccination increases along with Stewart and O’Mahoney (2007) who concluded most should be vaccinated between ages 11 and 15. The majority (94.1%) of patients and parents thought children should be up to date on their recommended shots during school. Most (92.1%) respondents believed talking about the HPV vaccine would provide an opportunity to counsel their children on safe sex which may address the issue of riskier sexual behavior that is sometimes thought of with the HPV vaccine.

Acceptance of the HPV Vaccine

Trends regarding knowledge and concerns versus acceptance of the vaccine for patients and parents themselves and for their children were a major conclusion to be drawn in this study. The majority of the population surveyed would consider getting the vaccine themselves and their children if insurance paid for it; 59.1% and 77.0%. Of note is the result that most (77.8%) did not know that most insurances covers the cost for all three doses. This response differs from when participants were asked directly if they wanted the vaccine for themselves, where the majority (62.9%) did not. This result differs from 22 studies found that most patients were accepting of the vaccine for themselves (Fazekas et al., 2008; Gerend et al., 2007; Kahn et al., 2003;
Slomovitz et al., 2006; Stewart & O'Mahony, 2007; Woodhall et al., 2007), etc. It is unclear as to why most patients and parents would consider the vaccine for their children but do not want it for themselves, especially since most stated that cost was not a concern (68.8%). Contrastingly, most parents (64.1%) wanted their children to get the vaccine, which coincided with results found in 36 studies. This makes sense considering the response that 94.1% of patients and parents believed that children should be up to date on their recommended shots during school, especially since the HPV vaccine is on the FDA list of recommended shots as well as the CDC’s. Of those that wanted the vaccine for themselves and their children, the majority (64.8% and 83.3%) planned on returning within 6 months for all three doses, concluding that the dosing schedule is not a concern. Similar results were found in other studies (Fazekas et al., 2008; Kahn et al., 2008). The main reasons for wanting the vaccine for themselves and for their children was to be safe and protected (64.8% and 74.1%) and the main reason for not wanting the vaccine was lack of need (29.3%) for patients themselves and side effects for children (21.4%). This is interesting because side effects were the fourth most frequent response among patients themselves at 9.8% behind being too old at 17.4%, being married or in a monogamous relationship at 25.0%, and not having a need at 29.3% that did not compare to order of responses for their children. Additionally, the majority of patients and parents were not concerned about the side effects either common or serious for themselves (82.0% and 78.8%) or for their children (71.0% and 59.6%), which differed from 22 studies found that side effects were a concern.

Differences in location of Norwalk and Toledo and practice of family practice and pediatrics were analyzed to see if there were statistically significant differences between responses or not. For concerns about the HPV vaccine, there is not a statistically significant
difference between concerns of those in rural and urban populations or between concerns of those in pediatric offices and those in family practices.

Regarding knowledge of HPV and the HPV vaccine, there is not a statistically significant difference between knowledge of those in rural and urban populations or between knowledge of those in pediatric offices and those in family practices. These results conclude that concerns about the vaccine and knowledge about the infection and the vaccine do not differ based on location or practice setting.

In terms of how concerns affect acceptance of the HPV vaccine, results showed no statistically significant differences between those who are concerned about the vaccine and those who are not concerned, in terms of accepting the vaccine for themselves or for their children. While there appears to be a relationship between concern and acceptance, this was not statistically significant.

With regard to how knowledge affects acceptance of the HPV vaccine, the study found no statistically significant difference between those who are knowledgeable versus those who are not in terms of vaccine accept for themselves or for their children. Because there was no statistically significant difference among either group, as with concern, the amount of knowledge did not appear to affect acceptance of the vaccine for themselves or their children.

While descriptive statistics have identified that over half of patients would consider receiving the vaccine and over three-fourths of parents would consider getting their children vaccinated, the data do not support that this willingness to be related to knowledge or concerns about the vaccine or to the type of practice or location of practice, at least not at the level of statistical significance. It is likely however that at least some of these variables, particularly concern about the vaccine, could have practical significance in clinical practice.
Sources of Information and their Relationship to Vaccine Acceptance

Analyses were conducted to determine how information from the media and information from doctors affect acceptance of the vaccine. The results conclude there is a statistically significant difference between source of information (physician or popular media) and the decision to reject or accept of the vaccine for themselves; for respondents’ children, no statistically significant difference was found between the groups. Those who get their HPV vaccine information from doctors were more likely to accept the vaccine for themselves than those who do not get their information from doctors. This reinforces the important role that healthcare providers play in patient education with regard to the HPV vaccine (as with other healthcare decisions).

Knowledge and Concerns about the Vaccine

Concerns and knowledge were compared to see if the responses were statistically significant. The results conclude that there is a statistically significant difference between those respondents that are knowledgeable and those that are concerned. This concludes that those who are knowledgeable about HPV and the HPV vaccine have fewer concerns. Statistics were also calculated to determine if those who are concerned wanted more information. The results conclude that there is a statistically significant difference between those respondents that are concerned and those that want more information. This shows that those with concerns about the HPV vaccine would like more information about it. Finally, statistics were calculated to determine if those who were knowledgeable wanted more information about the HPV vaccine. The results conclude that there is a statistically significant difference between those respondents
that are knowledgeable and those that want more information showing that those who are less knowledgeable want more information about the HPV vaccine.

**HPV in the News**

Prior to February 2009 when the survey began, there were news briefs regarding HPV and Gardasil both nationally and locally than may have impacted the participants’ outlooks. Reports against Gardasil have been published, with one story in July 2008 being featured at the CNN website. This report focused on the adverse events of Gardasil, including that it may cause death and that two girls were in court because the vaccine made them sick (CNN, 2008). On a local level, a publication titled *Toledo Area Parent* published a story about Gardasil featured on the cover of its January 2009 edition. This publication is free in the Toledo area (but not in Norwalk) and can be purchased for further delivery. The theme of the article was that parents and even some physicians should be cautious about Gardasil and parents should not rush into having their daughters vaccinated (Schrader, 2009).

At the same time, there had also been press releases from the FDA and other stories about the ongoing development of new information about Gardasil that may have had an impact on participants in a positive way. In September 2008, Gardasil was expanded to include indication for the prevention of vulvar and vaginal cancers in addition to cervical cancers (FDA, 2008). Also, a news report posted at the *New York Daily News* web site in November 2008 reported that Gardasil prevents genital warts in men (Associated Press, 2008).

Neither directly for nor against Gardasil, there have been other reports in 2008 and 2009 that have included Gardasil. Merck, the company that makes Gardasil, was in the news in April 2008. The FDA issued a warning letter regarding Merck’s deviation from current good
manufacturing practice for the manufacturing of its vaccines including Gardasil in a Pennsylvania location (Elder, 2008). More recently in January 2009, Merck reported on its own website that the FDA will not approve Gardasil for use in women aged 27-45 currently, and request that the company submit additional safety data when its 48-month study has concluded (Merck, 2009b). Also, in October 2008, the New York Daily News web site reported that immigrants will now be required to get the Gardasil vaccine, although it is unknown who will pay for it (Black, 2008). Furthermore, Merck’s commercials on Gardasil have been marketed heavily on televisions since November 2006 (Medical News Today, 2006). For this study, there is no way to tell if these media stories directly impacted patient’s decisions of rejection of the vaccine for themselves.

Limitations of the Study

There are limitations to this study. The response rate for the Toledo family practice was extremely low at 0.069%. A response such as this when compared to other response rates that were above the goal of 50 surveys for each location had a direct effect on the research hypotheses. Due to this response rate, the total surveying time had to be extended to 3 times the normal timeline of 1 month in an attempt to gather more information. Even after several attempts to aid the situation, it was continually difficult to ensure that the office staff was distributing the questionnaires as previously agreed upon. Perhaps if the author of the study and survey was present to distribute the questionnaires to the participants, there would have been a better result. Also, there were many questionnaires that were not complete. This data was left out of the statistics which created different totals for the questions. This may be due to the long length of the survey and/or that each question asked to respond by a “yes” or a “no.” Many patients may
have preferred a “don’t know” option due to a lack of information about HPV and the vaccine or about their child’s behavior. The questionnaire was two total pages in length and was designed this way to gather the most information possible after viewing many other surveys on this topic. If the survey was narrowed down to just concerns, knowledge, and beliefs about the participants’ children instead of for themselves as well, there may have been less incomplete surveys. In addition, the questionnaire was distributed in waiting rooms of the offices where participants may have felt rushed to complete the survey before seeing their healthcare provider or where they may have had no interest in completing a survey because they had a medical concern that was more important. Another venue for surveying may have provided better results by allowing each participant more time to complete the questionnaire such as a mail in survey. Finally, this study did not address all concerns, knowledge, and beliefs versus acceptance of the vaccine specifically. Frequencies were totaled for concerns (including safety, efficacy, cost, and sexual behavior), knowledge, and beliefs as well as acceptance but only concerns, knowledge, media information and doctor information were calculated in terms of acceptance. There was too much information collected and too little time to interpret each issue with acceptance directly, which are other limitations to this study.

Recommendations for Future Research

This study concluded a lack of knowledge for patients and parents in Northwestern Ohio, and only a few facts were shared about HPV with participants at the top of the survey, although information brochures were supplied to each participant after the survey for them to read. Several studies have determined if patients and parents responses to questions asked about HPV and the HPV vaccine changed once information regarding these topics was taught or shared with
them. This would be an interesting research topic for this area that could study the knowledge gained and how it influenced their decisions to vaccinate themselves or their children once this population is informed about the vaccine. Also, several previous studies gathered additional demographic information about their sample such as race, income, and religion. Authors of these studies concluded no differences between these groups, therefore this information was not asked as part of demographics for this survey. This would be an interesting direction to go in for Northwest Ohio to see if there would be any differences between these groups in terms of acceptance for the vaccine for themselves or their children. Furthermore, as more information is collected regarding Gardasil and passed on to patients and parents, further studies should be completed in the same populations to see if there are any changes in responses once more information about the vaccine is determined.

**Implications for Practice**

This research is important to the physician assistant profession to determine where to focus regarding patient and parent education. If the beliefs, knowledge, and concerns are known, a positive impact can be made on patients and parents who need more information before they can make a decision on HPV vaccination. By providing the most reliable, most current information, patients and parents can make informed decisions about whether to get the vaccine for themselves and/or their children. Information gathered in specific locations can also be useful to other health care providers in the area as well as schools who are responsible for addressing sex education.

This study found that most patients and parents surveyed did not know about the HPV vaccine and that they did not have concerns, which may be due to the fact that they knew little
about the virus or vaccine (not knowing enough to know the issues about which to be concerned). Information such as this will help all healthcare providers in the Northwest Ohio area realize the need to share more information about this topic with their patients. Additionally, the response rates of three of the four locations were enough to make some of the research hypotheses statistically significant, though additional responses would have strengthened the study. Each of the physicians in the survey locations will be able to use this information as well as the frequency statistics to determine how they should adjust their practice style to their patient population. Furthermore, having four survey locations has brought more awareness about HPV and the vaccine to those locations, which may encourage patients and parents to get more information about the topic either from their doctors or own their own. Finally, this study has added to the literature of HPV vaccine concerns, knowledge, and beliefs. Conclusions from this study may lead future research to look at other differences between rural and urban populations or family and pediatric practices.

Recently Published Research

In August 2009, several journal articles were published in *JAMA* about Gardasil that resulted in discussion through common news sources from the media. The main article that was commented on was a study coauthored by the FDA and the CDC that looked into post licensure safety data from June 2006 through December 31, 2008, when over 23 million doses of Gardasil had been distributed in the US (Slade et al, 2009). This report studied adverse events following immunization (AEFI) for the first 2.5 years post licensure of Gardasil using the Vaccine Adverse Event Reporting System (VAERS) which reports the safety of all vaccines. Outcomes measured in this study were numbers of reported AEFI, reporting rates as reports per 100,000 doses of
distributed vaccine or per person-years at risk, and comparisons with expected background rates. Adverse events that were reported totaled 12,424 with 772 (6.2%) being serious, including 32 reports of death among others such as anaphylaxis (1%), pulmonary embolism (1.8%), deep vein thrombosis (1.2%), convulsions (8.8%) or Guillain-Barre Syndrome (GBS) (4%) which occur on the Gardasil label. These AEFIs were studied further and determined that a higher number of venous thromboembolic events (VTEs) (including deep venous thrombosis and pulmonary embolism) and syncope occurred with Gardasil than with other vaccines, with reporting rates (RR) of 0.2 per 100,000 doses for VTE and 8.2 per 100,000 doses for syncope. In addition, the reporting rate for GBS was 0.2. Although adolescents have a higher background rate for syncope than other age groups, the ACIP published guidelines that recommend a 15-minute waiting period after vaccination that has been updated on the Gardasil package insert (Merck, 2009a). With regard to the reported VTEs, it was found that 90% of those with VTEs had risk factors such as taking estrogen-containing birth-control pills, positive family history, a history of smoking, or were overweight. Furthermore, the RR for GBS revealed a lower value than the background incidence rate of 1.57 (Slade et al.). The FDA and CDC state that due to the large distribution of Gardasil post licensure, AEFIs can report safety data that is too rare to be detected in prelicensure trials and that the information found in this study is consistent with prelicensure trials safety data. Furthermore, they state that Gardasil continues to be safe and effective and that the benefits of vaccination still outweigh the risks. Additionally, the FDA will continue to monitor safety data for Gardasil (FDA, 2009).

The other articles in this edition of the *JAMA* about Gardasil were an editorial discussing the risks and benefits of HPV vaccination (Haug, 2009), which provided no new information about the vaccine, and a special communication article discussing the marketing strategies for the
vaccine and how medical professionals should interpret this information regarding adolescent health (Rothman & Rothman, 2009). The main article regarding Gardasil in this edition of *JAMA* was about the postlicensure safety.

Research studies that were conducted after Gardasil received FDA approval regarding the same topics or outcomes as this study have been published in 2009. Specifically, two studies occurred in roughly the same Midwestern area as the current study. A publication by Katz et al. (2009) assessed barriers of accepting the HPV vaccine for participants. This study was completed in Ohio Appalachia during the summer of 2007, where there is an increased incidence of cervical cancer compared to other geographic regions. As with this current study, an overall lack of knowledge was found regarding cervical cancer, HPV, and the HPV vaccine. Similar concerns to the current study such as safety, efficacy, cost, and promiscuity were found to be barriers to vaccination. Furthermore, most HPV information was obtained from the media such as in a television commercial, coinciding with results found here as well. Dempsey et al. (2009) conducted a study from January to March 2007 through the University of Michigan’s family and pediatric health care clinics such as this study did. The objective was to determine reasons for or against HPV vaccination for adolescent daughters. For those who rejected the vaccine, safety concerns were commonly the number one reason for decline, specifically related to mothers not feeling they knew enough about the vaccine. This was an issue for mothers accepting the vaccine also, although they felt the benefits of vaccination were greater.

A North Carolina study by Reiter et al. (2009) conducted in 2007 determined parents’ beliefs about HPV vaccination for their daughters through correlates to vaccine initiation. Conclusions found in this area of high cervical cancer rates were that a doctor’s recommendation, perceived barriers, and perceived potential vaccine harms were the strongest
correlates to initiation of the vaccine. Additionally, they determined that many beliefs of vaccine initiation are consistent between racial group and with urban and rural parents.

Since about 20 million Americans are diagnosed with human papillomavirus (HPV) infection currently (CDC, 2008b) and about 6.2 million Americans become newly infected every year (CDC, 2008a), infection with HPV is a health concern for all Americans. The newness of the HPV vaccine, Gardasil, has caused many questions from both healthcare providers on how they educate their patients and from patients and parents on how to make the decision to accept vaccination or not for themselves and their children. This study has helped to ease the patient-provider-parent relationship by determining the concerns, knowledge, and beliefs of HPV and the vaccine as well as determining acceptance of the vaccine by patients and parents. It was determined that there is a lack of knowledge as well as a lack of concern in the Northwest Ohio population. Now that results such as this are known, healthcare providers can focus their teaching on more information about HPV and the vaccine without having to worry that patient and parent concerns may overshadow the facts. More so, this study has increased awareness of the second vaccine that can prevent cancer. Hopefully this information will lead to decreased HPV infections and cervical cancer rates in Northwest Ohio as well as nationally.
References


mothers of adolescents in Cuernavaca, Mexico. *Archives of Medical Research, 32*(3), 243-247.

Lee, P. W., Kwan, T. T., Tam, K. F., Chan, K. K., Young, P. M., Lo, S. S., et al. (2007). Beliefs about cervical cancer and human papillomavirus (HPV) and acceptability of HPV vaccination among Chinese women in Hong Kong. *Preventive Medicine, 45*(2-3), 130-134.


Table 1

*Characteristics of Survey Respondents*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>96%</td>
</tr>
<tr>
<td>Male</td>
<td>4%</td>
</tr>
<tr>
<td>Married or Monogamous</td>
<td>85%</td>
</tr>
<tr>
<td>Not Married or Monogamous</td>
<td>15%</td>
</tr>
<tr>
<td>Have Health Insurance Themselves</td>
<td>89%</td>
</tr>
<tr>
<td>Do Not Have Health Insurance Themselves</td>
<td>11%</td>
</tr>
<tr>
<td>Have Children</td>
<td>92%</td>
</tr>
<tr>
<td>Do Not Have Children</td>
<td>8%</td>
</tr>
<tr>
<td>Have Daughters Only</td>
<td>24%</td>
</tr>
<tr>
<td>Have Sons Only</td>
<td>25%</td>
</tr>
<tr>
<td>Have Both Daughters and Sons</td>
<td>51%</td>
</tr>
<tr>
<td>Have Health Insurance for Children</td>
<td>97%</td>
</tr>
<tr>
<td>Do Not Have Health Insurance for Children</td>
<td>3%</td>
</tr>
</tbody>
</table>

*Note.* $n = 225$
Table 2

Acceptance the HPV Vaccine

<table>
<thead>
<tr>
<th>Have you gotten at least 1 HPV shot?</th>
<th>Yes, For Themselves</th>
<th>Yes, For Their Children</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.9%</td>
<td>9.0%</td>
</tr>
<tr>
<td>If you have gotten at least 1 shot, will you return for all 3 doses within 6 months?</td>
<td>40.0%</td>
<td>92.9%</td>
</tr>
<tr>
<td>Do you want to get the HPV shot?</td>
<td>37.1%</td>
<td>64.1%</td>
</tr>
<tr>
<td>If so, do you plan on returning for all 3 doses within 6 months?</td>
<td>55.9%</td>
<td>83.3%</td>
</tr>
</tbody>
</table>

Note. $n = 225$
Table 3

*Reasoning for wanting the vaccine for themselves and their children*

<table>
<thead>
<tr>
<th>Reasons for Wanting the Vaccine</th>
<th>For Themselves</th>
<th>For Their Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>To Be Safe and Protected</td>
<td>64.8%</td>
<td>74.1%</td>
</tr>
<tr>
<td>Curiosity</td>
<td>3.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Prevention of Infection/Cancer</td>
<td>29.6%</td>
<td>21.2%</td>
</tr>
<tr>
<td>Previous HPV Infection</td>
<td>1.9%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Too Old</td>
<td>17.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td>No Need</td>
<td>29.3%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Hate Needles</td>
<td>3.3%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Need More Information</td>
<td>5.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Don’t Take Meds or Get Shots</td>
<td>1.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Prevent the Spread of Infection</td>
<td>0.0%</td>
<td>4.7%</td>
</tr>
</tbody>
</table>

*Note.* $n = 225.$
Table 4

*Reasoning for not wanting the vaccine for themselves and their children*

<table>
<thead>
<tr>
<th>Reasons for Not Wanting the Vaccine</th>
<th>For Themselves</th>
<th>For Their Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side Effects</td>
<td>9.8%</td>
<td>21.4%</td>
</tr>
<tr>
<td>Previous HPV Infection</td>
<td>8.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Married/Monogamous Relationship</td>
<td>25%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Too Old</td>
<td>17.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td>No Need</td>
<td>29.3%</td>
<td>7.1%</td>
</tr>
<tr>
<td>Hate Needles</td>
<td>3.3%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Need More Information</td>
<td>5.4%</td>
<td>16.7%</td>
</tr>
<tr>
<td>Don’t Take Meds or Get Shots</td>
<td>1.1%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Not for Boys</td>
<td>0.0%</td>
<td>14.3%</td>
</tr>
<tr>
<td>Too Young</td>
<td>0.0%</td>
<td>14.3%</td>
</tr>
<tr>
<td>Need More Protection Besides the Shot</td>
<td>0.0%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Not Sexually Active</td>
<td>0.0%</td>
<td>11.9%</td>
</tr>
<tr>
<td>Concern of Other Conditions</td>
<td>0.0%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Afraid of Encouraging Sex</td>
<td>0.0%</td>
<td>4.8%</td>
</tr>
</tbody>
</table>

*Note. n = 225.*
Table 5

*Concerns Regarding HPV and the Vaccine*

<table>
<thead>
<tr>
<th></th>
<th>Yes (neither specifically for themselves nor for their children)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you concerned with the cost of the shot?</td>
<td>31.2%</td>
</tr>
<tr>
<td>Would it upset you to find out those that who get the shot may need a 4&lt;sup&gt;th&lt;/sup&gt; dose later in life?</td>
<td>12.8%</td>
</tr>
<tr>
<td>Would you like more information about HPV and the vaccine?</td>
<td>31.8%</td>
</tr>
<tr>
<td>Overall Concerned</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Yes, for themselves</th>
<th>Yes, for their children</th>
</tr>
</thead>
<tbody>
<tr>
<td>If your insurance covered the HPV shot, would you consider getting it?</td>
<td>59.1%</td>
<td>77.0%</td>
</tr>
<tr>
<td>Are you concerned about the common side effects of the HPV shot?</td>
<td>18.0%</td>
<td>29.0%</td>
</tr>
<tr>
<td>Are you concerned about rare but serious side effects of the HPV shot?</td>
<td>21.1%</td>
<td>40.4%</td>
</tr>
<tr>
<td>Are you concerned about being able to have children after getting a shot for an STI?</td>
<td>17.4%</td>
<td>53.1%</td>
</tr>
<tr>
<td>Would getting the HPV shot encourage more risky sexual behavior such as unprotected sex?</td>
<td>5.9%</td>
<td>10.2%</td>
</tr>
<tr>
<td>If people did get the HPV shot, should they be embarrassed to tell others?</td>
<td>8.2%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Do you think your child is at risk or will be at future risk for catching HPV?</td>
<td>-</td>
<td>39.3%</td>
</tr>
<tr>
<td>If your child got the vaccine already, will you talk about this survey with them?</td>
<td>-</td>
<td>83.3%</td>
</tr>
<tr>
<td>If your child will get the vaccine already, will you talk about this survey with them?</td>
<td>-</td>
<td>57.0%</td>
</tr>
</tbody>
</table>

*Note. n = 225*
Table 6

*Knowledge and Concerns of the HPV Vaccine, Locations, and Practices*

<table>
<thead>
<tr>
<th>Location</th>
<th>Practice</th>
<th>Chi Square Statistics</th>
<th>Family</th>
<th>Pediatrics</th>
<th>Chi Square Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toledo</td>
<td>Concerned</td>
<td>2.7%</td>
<td>2.2%</td>
<td>4.9%</td>
<td>0.201, df = 1, p=0.654</td>
</tr>
<tr>
<td></td>
<td>Not Concerned</td>
<td>29.8%</td>
<td>32.9%</td>
<td>60.0%</td>
<td>0.113, df = 1, p=0.737</td>
</tr>
<tr>
<td>Norwalk</td>
<td>Concerned</td>
<td>4.4%</td>
<td>12.4%</td>
<td>21.3%</td>
<td>0.640, df = 1, p=0.424</td>
</tr>
<tr>
<td></td>
<td>Not Concerned</td>
<td>63.1%</td>
<td>22.7%</td>
<td>43.6%</td>
<td>0.151, df = 1, p=0.698</td>
</tr>
</tbody>
</table>

*Note.* \( n = 225 \). None were statistically significant.
Table 7

Knowledge and Concerns of Acceptance of the HPV Vaccine

<table>
<thead>
<tr>
<th></th>
<th>Themselves</th>
<th></th>
<th>Their Children</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accept</td>
<td>Not Accept</td>
<td>Chi Square</td>
<td>Accept</td>
</tr>
<tr>
<td>Concerned</td>
<td>5.1%</td>
<td>3.4%</td>
<td>$x^2 = 3.671$, df = 1, p=0.055</td>
<td>9.0%</td>
</tr>
<tr>
<td>Not Concerned</td>
<td>32.0%</td>
<td>59.4%</td>
<td></td>
<td>55.2%</td>
</tr>
<tr>
<td>Knowledgeable</td>
<td>13.7%</td>
<td>20.0%</td>
<td>$x^2 = 0.476$, df = 1, p=0.490*</td>
<td>23.4%</td>
</tr>
<tr>
<td>Not Knowledgeable</td>
<td>23.4%</td>
<td>42.9%</td>
<td></td>
<td>40.7%</td>
</tr>
</tbody>
</table>

Note. n = 225. *p < .05
Table 8

Knowledge and Concerns of the HPV Vaccine and Wanting for Information About it

<table>
<thead>
<tr>
<th></th>
<th>Knowledgeable</th>
<th>Not Knowledgeable</th>
<th>Chi Square Statistics</th>
<th>Want Information</th>
<th>Do Not Want Information</th>
<th>Chi Square Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerned</td>
<td>0.4%</td>
<td>6.7%</td>
<td>( x^2 = 5.835, ) df = 1, ( p=0.016^* )</td>
<td>6.5%</td>
<td>1.5%</td>
<td>( x^2 =19.555, ) df =1 , ( p=0.000^{**} )</td>
</tr>
<tr>
<td>Not Concerned</td>
<td>33.3%</td>
<td>59.6%</td>
<td></td>
<td>25.4%</td>
<td>66.7%</td>
<td></td>
</tr>
<tr>
<td>Knowledgeable</td>
<td>-</td>
<td>-</td>
<td></td>
<td>7.0%</td>
<td>28.4%</td>
<td>( x^2 =7.433, ) df = 1, ( p=0.006^{**} )</td>
</tr>
<tr>
<td>Not Knowledgeable</td>
<td>-</td>
<td>-</td>
<td></td>
<td>24.9%</td>
<td>39.8%</td>
<td></td>
</tr>
</tbody>
</table>

Note. \( n = 225. \) \( ^*p < .05. \) \( ^{**}p < .01 \)
Table 9

**Knowledge of HPV and the Vaccine**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had you heard of HPV before today?</td>
<td>91.6%</td>
</tr>
<tr>
<td>Had you heard of the HPV shot before today?</td>
<td>81.3%</td>
</tr>
<tr>
<td>Does your healthcare provider offer the shot?</td>
<td>38.3%</td>
</tr>
<tr>
<td>Did you know the shot requires 3 doses over 6 months?</td>
<td>41.4%</td>
</tr>
<tr>
<td>Did you know most insurance covers the $360 cost for all 3 doses?</td>
<td>22.2%</td>
</tr>
<tr>
<td>Did you know the most common side effects are soreness, redness, and itching of the arm where the shot is given?</td>
<td>46.8%</td>
</tr>
<tr>
<td>Did you know the more serious side effects of the shot are fever, nausea or vomiting, and dizziness?</td>
<td>30.6%</td>
</tr>
<tr>
<td>Did you know that being sexually active was a risk for catching HPV?</td>
<td>73.9%</td>
</tr>
<tr>
<td>Does your child’s healthcare provider offer the shot?</td>
<td>34.9%</td>
</tr>
<tr>
<td>Overall Knowledgeable</td>
<td>33.8%</td>
</tr>
</tbody>
</table>

*Note. n = 225*
Table 10

*Resources for Health and HPV Information*

<table>
<thead>
<tr>
<th>Source for Information</th>
<th>Health Total</th>
<th>HPV Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spouse/Partner</td>
<td>16.4%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Friend</td>
<td>12.9%</td>
<td>9.8%</td>
</tr>
<tr>
<td>Media</td>
<td>51.6%</td>
<td>65.3%</td>
</tr>
<tr>
<td>Children</td>
<td>0.4%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Religious Leader/Church</td>
<td>1.3%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Parents</td>
<td>25.3%</td>
<td>4.9%</td>
</tr>
<tr>
<td>Doctor</td>
<td>76.4%</td>
<td>40.9%</td>
</tr>
<tr>
<td>Teacher</td>
<td>2.7%</td>
<td>6.2%</td>
</tr>
<tr>
<td>Other Family Members</td>
<td>20.4%</td>
<td>5.8%</td>
</tr>
<tr>
<td>Nurse</td>
<td>35.6%</td>
<td>13.8%</td>
</tr>
<tr>
<td>School</td>
<td>0.4%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Books</td>
<td>1.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Work</td>
<td>6.2%</td>
<td>5.8%</td>
</tr>
<tr>
<td>Research/Internet</td>
<td>1.8%</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

*Note. n = 225*
Table 11

*Information Sources and Acceptance of the HPV Vaccine*

<table>
<thead>
<tr>
<th></th>
<th>Themselves</th>
<th>Accept</th>
<th>Reject</th>
<th>Chi Square Statistics</th>
<th>Their Children</th>
<th>Accept</th>
<th>Reject</th>
<th>Chi Square Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Media</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>20.1%</td>
<td>43.1%</td>
<td>$x^2 = 3.920, df = 1, p=0.048*$</td>
<td></td>
<td>38.6%</td>
<td>24.8%</td>
<td>$x^2 = 1.169, df=1, p=0.280$</td>
</tr>
<tr>
<td>Not Media</td>
<td></td>
<td>17.2%</td>
<td>19.5%</td>
<td></td>
<td></td>
<td>25.5%</td>
<td>11.0%</td>
<td></td>
</tr>
<tr>
<td>Doctor</td>
<td></td>
<td>20.0%</td>
<td>21.7%</td>
<td>$x^2 = 6.260, df =1, p=0.012*$</td>
<td></td>
<td>24.8%</td>
<td>13.1%</td>
<td>$x^2 = 0.067, df=1, p=0.796$</td>
</tr>
<tr>
<td>Not Doctor</td>
<td></td>
<td>17.1%</td>
<td>41.1%</td>
<td></td>
<td></td>
<td>39.3%</td>
<td>22.8%</td>
<td></td>
</tr>
</tbody>
</table>

*Note. n = 225. *$p < .05$
Appendix: Cover Letter and Questionnaire

I am a physician assistant student at the University of Toledo. I am conducting a research study to determine what patients and parents in the northwestern Ohio area know about the human papillomavirus (HPV) vaccine. The purpose of my research is to determine what the current level of knowledge is regarding the risks and benefits, to determine where this information is coming from and to determine if parents are willing to have themselves and their children vaccinated. This study will also examine general vaccine beliefs for participants’ children. I am inviting you to participate in this study because you are 18 years old or older. Results from this study will help health care providers to better understand the needs of their patients and parents in northwestern Ohio regarding the HPV vaccine.

This survey is anonymous so that no one will be able to connect you and your survey responses. Your participation is voluntary, so you do not have to complete the survey if you do not want to. If you choose to participate, you may leave questions blank. You can also complete the survey but decide not to submit it. There are no foreseeable risks or discomforts associated with completing this survey, and you will not be compensated in any way for this survey.

If you decide to participate, complete the survey stapled to this letter. It should take about 10 minutes to complete. After you complete the survey, please return it to the reception desk and place it in the return box. Next to the box, there is an educational brochure from the Center for Disease Control and Prevention about HPV. Please take a brochure; even if you do not complete the survey, you are welcome to take a brochure.

If you have questions regarding this study, please contact me at (269) 876-1476 or my major advisor on this project, Jolene Miller, MLS, at (419) 383-4959. You can also leave a message with the receptionist for me or email me at erin.palecek@utoledo.edu. If you have questions about HPV or the HPV vaccine, ask your health care provider.

Thank you for participating in this research study.

Erin Palecek, PA-S II
Human papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the US, with about 50% of sexually active Americans being infected at some point in their lifetimes by either vaginal, anal, or oral sex. Infection with the virus can cause genital warts or cancer although most people who get the infection will recover without treatment. Currently, there is a vaccine for HPV that is intended ONLY for girls aged 9-26. For best results, the vaccine is given before sexual activity.

First, please tell a bit about yourself and your children if you have any.

1. What is your age? _____
2. What is your sex/gender?  □ Female  □ Male
3. Are you in a monogamous relationship or married?  □ Yes  □ No
4. Do you have health insurance?  □ Yes  □ No
5. Do you have children?  □ Yes  □ No
   a. If yes, check all that apply.  □ Daughter(s)  □ Son(s)  □ Both daughter(s) and son(s)
   b. If yes, does your child (children) have health insurance?  □ Yes  □ No

The following questions deal with your beliefs.

6. Where do you get most of your health information?  (check all that apply)
   □ Spouse/Partner  □ Friend  □ Media- TV, newspaper, magazine, radio, Internet, etc.
   □ Children  □ Religious leader/church  □ Teacher
   □ Parents  □ Doctor  □ Nurse
   □ Other________________________

7. Before today, had you heard of HPV?  □ Yes  □ No
   a. If yes, where did you get your information about HPV?  (check all that apply)
      □ Spouse/Partner  □ Friend  □ Media- TV, newspaper, magazine, radio, Internet, etc.
      □ Children  □ Religious leader/church  □ Teacher
      □ Parents  □ Doctor  □ Nurse
      □ Other________________________

8. Before today, had you heard of a shot that can prevent you from catching HPV?  □ Yes  □ No
9. Do you know if your health care provider offers the HPV shot in their clinic?  □ Yes  □ No
10. Did you know that the HPV shot requires three doses over 6 months?  □ Yes  □ No
11. Did you know that most insurance covers the $360 cost for all three doses?  □ Yes  □ No
12. Are you concerned with the cost of the shot?  □ Yes  □ No
13. If your insurance covered the HPV shot, would you consider getting it for yourself?  □ Yes  □ No
14. Would it upset you to find out that those who get the shot may need a 4th dose later in life?  □ Yes  □ No
15. Did you know the most common side effects are soreness, redness, and itching of the arm where the shot is given?  □ Yes  □ No
16. Are you concerned about these side effects of the HPV shot?  □ Yes  □ No
17. Did you know the more serious side effects of the HPV shot are fever, nausea or vomiting, and dizziness?  □ Yes  □ No
18. Are you concerned about these side effects of the HPV shot?  □ Yes  □ No
19. For yourself, are you concerned about being able to have children after getting a shot for a STI?  □ Yes  □ No
20. Before today, did you know that being sexually active vaginally, orally, or anally was a risk for catching HPV?  □ Yes  □ No
21. For yourself, would getting the HPV shot encourage more risky sexual behavior such as unprotected sex?  □ Yes  □ No
22. Although the HPV shot isn’t currently intended for adult women, do you think they should be able to get the shot if wanted?  □ Yes  □ No
23. Although the HPV shot isn’t currently intended for boys and men, do you think they should be able to get the shot if wanted?

Yes No

24. Have you gotten at least 1 HPV shot?
   a. If yes, do you plan on returning for all three doses within 6 months?
   b. If no, would you like to get the HPV shot?
   c. If yes to question 24b, do you plan on returning for all three doses within 6 months?

25. If you did get the HPV shot, would you be embarrassed to tell people?

26. For yourself, what is your main reason for either wanting the shot or not?
   DO want the shot: _______________________________________________________________________
   DON’T want the shot: ______________________________________________________________________

27. Would you like more information about HPV and the vaccine?
   Yes No

The following questions deal with your beliefs about children whether or not you have any.

28. Are children today more sexually active at earlier ages than they were in the past?
   Yes No

29. The ideal recommended age for the HPV shot is 11-12 years old. Should children this age and older be involved in deciding to get the HPV shot?
   Yes No

30. When is the best time to give the shot?
   Before teen years During teen years After teen years

31. Do you think children should be up to date on their recommended shots during school?
   Yes No

If you don’t have children, you’re finished. Thank you for your time!

If you have a child (children), please answer the following questions that deal with your beliefs.

32. Would talking about the HPV shot with children provide an opportunity to counsel them on safe sex?
   Yes No

33. Do you know if your child’s healthcare provider offers the HPV shot in their clinic?
   Yes No

34. If insurance covered the HPV shot for your child would you consider having them get it?
   Yes No

35. Are you concerned about side effects of the shot such as soreness, redness, or itching at the injection site?
   Yes No

36. Are you concerned about side effects of the shot such as fever, nausea or vomiting, and dizziness?
   Yes No

37. For your child, are you concerned about him or her being able to have children after getting a shot for a STI?
   Yes No

38. For your child, would getting the HPV shot lead them to more risky sexual behavior such as unprotected sex?
   Yes No

39. Do you think your child is at risk or will be at future risk for catching HPV?
   Yes No

40. Has your child gotten at least 1 HPV shot?
   a. If yes, do you plan on your child returning for all three doses within 6 months?
   b. If yes, will you talk about this survey with them?
   c. If no to question 40, do you want your child or future children to get the HPV shot?
   d. If yes to question 40c, do you plan on your child returning for all three doses within 6 months?
   e. If yes to question 40d, will you talk about this survey with them?

41. If your child did get the HPV shot, would you be embarrassed to tell people?
   Yes No

42. For your child, what is your main reason for either wanting him or her to get the shot or not?
   DO want the shot: _______________________________________________________________________
   DON’T want the shot: ______________________________________________________________________

Thank you very much for taking this survey!

If you have any questions about HPV or the vaccine, talk with your health care provider!
Abstract

**Objective:** To determine northwestern Ohio patient and parent concerns, beliefs, and knowledge of HPV vaccination, where they received this information, acceptance of vaccination for themselves and their children, and whether there are differences in location (rural vs. urban)

**Method:** Paper questionnaire distributed in pediatric and family medicine offices in Norwalk and Toledo, Ohio, from February-April 2009.  **Results:** There is a lack of knowledge in this area regarding Gardasil, although there were no concerns in 92.9% of participants about cost, safety, efficacy, or effect on sexual behavior. This did not differ based on location or practice setting. Most (62.9%) did not want the vaccine for themselves, but 64.1% did for their children. Also, 65.3% received their HPV information from the media.  **Conclusions:** Respondents are neither informed nor concerned about Gardasil. The majority do not want the vaccine for themselves although they do want the vaccine for their children.