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### AN ASSESSMENT OF HPV VACCINATION BY GEORGIA PHYSICIANS: KNOWLEDGE, BARRIERS, SUPPORTS, PRACTICES, AND ADHERENCE TO ACIP GUIDELINES AND RECOMMENDATIONS

by

### ELIZABETH DIXON

(Under the Direction of John Luque)

### ABSTRACT

The purpose of this study was to examine Georgia physicians' administration of the quadrivalent human papillomavirus (HPV) vaccine to 11-12 year old females according to the Advisory Council Immunization Practices (ACIP) guidelines, their intention to recommend HPV vaccine to 11-12 year old males, and their perceived knowledge and barriers associated with HPV vaccination. A distinction between urban and rural was examined to determine if there were differences in HPV vaccination recommendation. A stratified sample was created from the Georgia Vaccine For Children (VFC) provider list. The final sampling frame included 264 (n = 264) providers. Of these, 218 physicians were contacted yielding a response rate of 82.6%. Forty-two were located in rural counties and 176 were located in urban counties. Examination of perceived barriers, perceived knowledge and administration practices revealed no differences between urban and rural physicians. Approximately one in ten Georgia physicians (12%) who responded reported they always vaccinate 11-12 year old females. The number increased to one in five (22.9%) who always vaccinate females age 13-17 years, suggesting parents or physicians may be delaying vaccination until females are older than 12 years.

Approximately one quarter (23.7%) recommend the vaccine to their male patients. More than half (59.4%) reported insufficient insurance coverage for the vaccine as a barrier to vaccinating males and females. In multivariate logistic regression models, variables independently associated with not recommending to 11-12 year old females included: female gender of the physician (OR, 3.07; 95% CI, 1.02-9.29) and parental barriers (OR 1.15; CI, 1.04-1.29). There were no associated findings with not recommending male vaccination. Findings from this study may serve as a helpful resource for further assessment of HPV vaccination in Georgia and targeting educational and policy interventions.

INDEX WORDS: HPV, Adolescents, Physician, Knowledge, Barriers, Vaccination, ACIP guidelines

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by

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A Dissertation Submitted to the Graduate Faculty of Georgia Southern University in Partial Fulfillment of the Requirements for the Degree

### DOCTOR OF PUBLIC HEALTH

STATESBORO, GEORGIA

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## RECOMMENDATIONS

by

### ELIZABETH DIXON

Major Professor: John Luque Committee: John Luque Robert Vogel Stuart Tedders

Electronic Version Approved: May 2011

### DEDICATION

This dissertation is dedicated to my husband, Donnie Dixon, to my children, Kelly and Harry Dixon; and to the memory of Robert W. Tonning Jr. and Anne J. Tonning. Because of their love, encouragement, personal example, and sacrifice on my behalf, this achievement was possible.

#### ACKNOWLEDGMENTS

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#### **CHAPTER 1**

# BACKGROUND SIGNIFICANCE AND LITERATURE REVIEW Introduction

The human papillomavirus (HPV) is the most common sexually transmitted virus in the United States and it is estimated that 70% of sexually active men and women acquire an infection at some point during their lifetime (CDC, 2010). In total numbers, approximately 20 million people in the United States are currently infected with 6.2 million new infections annually (Dunne & Markowitz, 2006). Using census figures (Census Bureau 2010) for Georgia (n= 9,829,211), approximately 633,000 people in are Georgia currently infected with genital HPV, and approximately 20,000 people in Georgia will acquire a new genital HPV infection each year.

In the majority of people, HPV infections are not serious. Most infections are asymptomatic, transient, and resolve without medical intervention. While an HPV infection is necessary for the development of precursor lesions and cervical cancer, it is not always sufficient to cause cervical abnormalities (CDC, 2010). However, continuous infection of one or more high-risk HPV types, particularly subtypes 16 and 18, can result in precursor lesions and cervical cancer (Muñoz et al., 2003). Approximately 11,000 cases of cervical cancer occur in the United States annually. Of these 11,000 cases, approximately 36.4% will result in death (NCI, 2010). Cervical cancer also causes and economic burden and it is estimated that over \$2 billion dollars is spent annually on the treatment of cervical cancer in the United States (CDC, 2010).

Estimates for the incidence and prevalence of genital warts caused by low-risk HPV types 6 and 11 are inexact. However, it is estimated that 5.6% of sexually active adults age 18 to 59 years living in the United States report ever being diagnosed with genital warts (Dinh, Dunne, & Markowitz, 2008). According to the Centers for Disease Control and Prevention (CDC), there are approximately one million new cases of genital warts each year in the United States (CDC, 2010).

Although genital warts are commonly perceived as a non-serious condition, treatment is often lengthy with 25% of cases reoccurring within three months (Mandell, Bennett, & Dolin, 2009). Men and women who participated in a study by Mortensen (2010) considered quality of life to be significantly lowered because of genital warts, and participants expressed negative psychological and social effects. They also believed genital warts were associated with adverse consequences of daily life and affect the ability to develop new relationships. Women who took part in a study by McCaffery et al. (2006) described feeling stigmatized, anxious and stressed. They were concerned about new relationships and worried about disclosing their condition to others. This was also true regarding the psychological burden of the HPV infection and the woman's relationship status and history, their social and cultural norms and practices around sex and relationships, as well as their understanding of key features of HPV (McCaffery, Waller, Nazroo, & Wardle, 2006).

The burden of HPV infection and cervical cancer can be eliminated now that a vaccine targeting the HPV virus has been developed. On June 8th, 2006, the U.S. Food and Drug Administration (FDA) approved Gardasil® by Merck Pharmaceuticals as the first quadrivalent HPV vaccine to protect women from HPV infection of subtypes 6, 11, 16, and 18 (Markowitz et al., 2007). Less than one year later, in 2007, the Advisory Council on Immunization Practices (ACIP) of the CDC recommended all girls aged 11 and 12 years be vaccinated against HPV, with the indication that girls as young as 9 years of age, and older females between the ages of 13 and 26 may receive the vaccine at their providers' discretion (Markowitz et al., 2007).

In order for the HPV vaccine to be most effective, it must be administered prior to onset of sexual activity and the exposure to the HPV virus, which requires administering to preadolescents and young adolescents (Markowitz et al., 2007). Dempsey, Koutsky, and Golden (2007) indicate HPV is "nearly ubiquitous among sexually active individuals...." (p.506) and further note "... individuals do not need to engage in high-risk sexual behavior to become infected...." (p. 506) thus indicating the vaccine must be administered early rather than later if it is to be effective.

In another study involving 60 adolescent women, 27% of a group of females were infected with HPV. This increased to 45% for females aged 14 to 24, leading researchers to conclude that the "cumulative prevalence of HPV infection in sexually active adolescent women is extremely high" (Brown et al., 2005). Research by Hopenhayn, Christian, Christian, and Schoenberg (2007), report one-third of Kentucky ninth graders admit to having sexual intercourse and two-thirds report doing so by the time they are seniors in high school. Charo (2007) noted youth dropout rates from school begin to increase after age 13 and youth who leave school are more likely to engage in sexual activity earlier.

As we learn more about the early onset of sexual activity of adolescents and their increased risk for HPV infection, it becomes apparent a vaccine protective of both males and females would be beneficial if the virus is to be defeated. This is further noted as there is a high rate of transmission of HPV in female partners of men with pre-existing genital warts, and HPV infection in men has been shown to contribute to HPV infection and subsequent cervical disease and cancer in women (MMWR, May, 2010). On October 16, 2009, the FDA approved the same quadrivalent HPV vaccine, Gardasil®, for use in boys and men 9 through 26 years of age for the prevention of genital warts caused by HPV subtypes 6 and 11. In addition, this vaccine offers

protection to their female partners against subtypes 6 and 11, making it the only HPV vaccine approved for use in males (FDA, 2009).

Presently, there is debate on the cost effectiveness of the HPV vaccine and the potential for herd immunity given that it has been recommended to both females and males. In a presentation to the ACIP on October 21, 2009, a CDC Health Economist, Dr. Harrell Chesson, stated factors associated with HPV vaccination cost effectiveness include protection against HPV subtypes 6, 11, 16, and 18, duration of protection, degree of cross protection, and vaccine price (Chesson, 2009). According to Chesson's research, the possible reduction in the fifty million annual cervical cytology (Pap) screens to detect cervical disease is an important benefit of HPV vaccination (Chesson, 2009). In a 2011 report to the ACIP, Dr. Chesson noted 12 year old girls who received the vaccine had a cost per quality-adjusted life year ranging from \$3,000 to \$45,000 (CDC, 2011).

A national study of physicians' intentions regarding the impact of HPV vaccine on cervical cancer screening further indicates a reduced number of future Pap screens for women who have had the HPV vaccine (Wong, Berkowitz, Saraiya, Wideroff, & Bernard, 2010). Internal medicine physicians who responded to the survey agreed that vaccination would affect Pap screening frequency by reducing the number of Pap screens needed over the lifetime of the woman.

According to the annual report of cancer statistics, cervical cancer caused by the HPV virus occurs most often in women aged 30 years and older (Jemal, 2009). In 2009, 11,270 women in the United States were diagnosed with cervical cancer and 4,070 died from the disease (Jemal et al., 2009). Healthy People 2010 created a focus on cervical cancer with Cancer Goal 3-4, "Reduce the death rate from cancer of the uterine cervix to a target of 2.0 deaths per 100,000

females" (USDHHS, 2000). The rate of cervical cancer in the United States is 2.5 per 100,000 and the rate for Georgia is 2.7 per 100,000 (State Cancer Profiles, 2010). In 2006, the U.S. rate was reported to be 2.5. Counties in Georgia with the highest mortality for cervical cancer include Chatham, Fulton, Richmond, Gwinnett, and Cobb Counties (NCI, 2010). The National Cancer Institute's State Cancer Profile reported that Georgia had an estimated 364 new cases of cervical cancer in 2006, resulting in 122 deaths from the disease (State Cancer Profiles, 2010). However, despite having this vaccine available, only 38% of female teens in Georgia have been vaccinated with at least one of the three doses that are necessary for HPV immunity (MMWR, 2010).

Health disparities among certain groups with higher rates of cervical cancer are noted. Smith, Christopher and McCormick (2004) and suggest African Americans are currently 1.5 times more likely to experience an incidence of cervical cancer and two times more likely to experience mortality than Caucasian women. Incidence rates for Hispanic and some Asian subpopulations are also reported to be higher than Caucasian rates. Moreover, women of Mexican descent typically receive the least preventative care services within Latina populations (Scarinci et al., 2010). Data also suggest immigrants from Southeast Asia have the lowest levels of Pap screens of all racial/ethnic populations in the United States (Jackson et al., 2000). Finally, southern states, including Georgia, have a higher incidence of cervical cancer (Markowitz et al., 2007).

While the economic impact of cervical cancer can have ill effects upon the local economy, a more insidious economic impact is the cost of testing for cervical cancer by obtaining numerous Pap screenings throughout the life span. The National Health Interview Survey notes that fifty million tests for cervical cancer through Pap screens are performed annually in the United States

(Hiatt, Klabunde, Breen, Swan, & Ballard-Barbash, 2002). Women who follow the American College of Gynecology guidelines will obtain multiple Pap screens during their lifetime (ACOG Practice Bulletin, 2006). Having immunity against four of the HPV subtypes will not entirely protect against all cervical cancers, but this protective factor may decrease the number and need for many Pap screens during a women's lifetime.

The FDA-approved quadrivalent HPV vaccine Gardasil® targets the HPV strains responsible for approximately 70% of cervical cancers and 90% of genital warts making it a very effective vaccine if given at the proper stage (Bratten & Laufer, 2008, MMWR, 2010). Yet, despite the availability of this vaccine, it is estimated that 44.3% of eligible girls nationally and 38% in Georgia have been vaccinated with at least one of the three doses required for HPV immunity (MMWR, 2010). There is a clear need for a better understanding of the benefits of this vaccine.

### **Purpose of the Study**

The purpose of this study was to examine the prevalence of Georgia physician intention and administration of the HPV vaccine to 11-12 year-old girls, as well as the intention to recommend the HPV vaccine to 11-12 year old boys. The study examined the attitudes and beliefs of Georgia physicians toward administering the HPV vaccine and assessed perceived knowledge, barriers, practices, and adherence to ACIP guidelines and recommendations regarding HPV vaccination. A survey was administered to a random sample of 264 Georgia physicians yielding a response rate of 82.6% (n= 218). Respondents to the survey were asked to describe their intention and prevalence of administering the HPV vaccine to their female and male patient population. Respondents were then asked about their knowledge of the HPV vaccine and if they administered the vaccine according to ACIP guidelines by offering it to females at 11-12 years of

age. They were also asked if they recommended it according to ACIP guidelines of "permissive use" to 11-12 year old males. Respondents were asked to respond to barriers they perceive to be associated with this vaccine. A distinction between urban and rural was examined to determine if there were differences. The Health Belief Model (Becker, 1974, Champion & Skinner, 2008; Glanz, Rimer, & Viswanath, 2008) was use to inform this study of Georgia physicians.

### Significance of the Study

At present, less than half the eligible girls in Georgia receive the HPV vaccine (MMWR, 2010). The body of knowledge obtained through this study, indicating how and to whom Georgia physicians are administering the vaccine, will be beneficial in planning future immunization actions and interventions. The current study, as designed, provided the first comprehensive examination of HPV vaccination of physician practices in Georgia. By addressing issues related to physician endorsement and recommendation of this vaccine, the study will serve as an important and necessary step toward realizing the public health benefits of HPV vaccination. This study will contribute information to the body of knowledge of HPV vaccination in general and in particular, for the state of Georgia.

The study examined Georgia physician recommendations and prevalence of immunization of the HPV vaccine to 11-12 year-old girls and intention to recommend the HPV vaccine to 11-12 year old boys. The study examined the attitudes and beliefs of Georgia physicians toward administering the HPV vaccine and assessed perceived knowledge, barriers, practices, and adherence to ACIP guidelines and recommendations regarding HPV vaccination.

### **Literature Review**

### Human Papillomavirus

According to the CDC (2010) there are more than 40 HPV types that can infect the genital areas of males and females although subtypes 6, 11, 16 and 18 are the most prevalent. HPV is passed on through genital contact, most often during vaginal and anal sex. HPV can be passed on even when the infected partner has no signs or symptoms. A person can have HPV even if years have passed since he or she had sexual contact with an infected person. Most infected persons do not realize they are infected or that they are passing the virus to a sex partner. It is also possible to be infected with more than one type of HPV.

HPV can cause normal cells to turn abnormal. The infected person cannot see or feel these cell changes. In most cases, the body fights off HPV naturally and in 90% of cases, the body's immune system clears HPV naturally within two years (CDC, 2010). But in cases when the body does not fight off HPV, it can cause visible changes in the form of genital warts or cancer. Warts can appear within weeks or months after getting HPV. Cancer often takes years to develop after getting HPV.

Genital warts usually appear as a small bump or groups of bumps in the genital area. They can be small or large, raised or flat, or shaped like a cauliflower. If left untreated, genital warts may resolve, remain unchanged, or increase in size or number. They will not turn into cancer. Cervical cancer usually does not cause symptoms until it is quite advanced and difficult to treat (Rock & Jones, 2008).

### **Cervical Cancer**

Cervical cancer is a malignant and excessive growth of abnormal tissue of the cervical area that left untreated may be fatal (Young, O'Dowd, & Stewart, 2010). In 2009, 11,270 women in

the United States were diagnosed with cervical cancer and 4,070 died from the disease (Jemal et al., 2009). The HPV infection is a necessary factor in the development of nearly 70% of all cases of cervical cancer (Young et al., 2010). The two subtypes of HPV are types 16 and 18, and these subtypes are the cause of over 70% of cervical cancer cases and are included in the HPV vaccine (CDC, 2008; Markowitz et al., 2007).

TeLinde's operative gynecology (2008) notes presentation of cervical cancer may be absent until the cancer is in an advanced stage making it difficult for women to seek early treatment. Cervical cancer is comprised of five stages to determine the amount of cancer in the body. In the initial Stage, or Stage 0, abnormal cells are found in the deepest lining of the cervix. Stage 0 is called carcinoma in situ and is found in the cervix. Stage 0 is followed by Stage I which includes growth of the cancer. The five year survival rate for Stage I range from 80-99%. Common treatments include surgery, chemotherapy and radiation (NCI, 2010).

In Stage II, cancer has spread beyond the cervix but not into the pelvic wall or to the lower third of the vagina. Five-year survival is 65-69%. Common treatments for Stage II cervical cancer include surgery, radiation and chemotherapy (NCI, 2010).

In Stage III, cancer has spread to the lower third of the vagina and may have spread to the pelvic wall. With advanced cervical cancer, the woman has symptoms of weight loss, a vague feeling of fatigue, pelvic pain, back pain, leg pain, a single swollen leg, heavy bleeding from the vagina, possible leaking of urine or feces from the vagina, or bone fractures (Rock & Jones III, 2007). Five-year survival at this state is 40-43 %. Common treatments include chemotherapy and radiation (NCI, 2010).

In Stage IV, the cancer has left the pelvis and spread to the bladder, rectum, or other parts of the body such as the abdomen, liver, intestinal tract, or lungs. The five-year survival rate for this stage of cancer is 15-20 %. Types of treatment include chemotherapy and radiation (NCI, 2010).

Each year the American Cancer Society (ACS) publishes a summary of recommendations for early cancer detection and a report on data and trends in cancer screening rates. The ACS reviews current guidelines by the US Preventive Services Task Force and from the American College of Obstetricians and Gynecologists (ACOG). The ACS screening guidelines for cervical cancer recommend different surveillance strategies and options based on the woman's age, screening history, other risk factors, and the choice of screening tests (Smith, Cokkinides, Brooks, Saslow, & Brawley, 2010). The ACS guidelines for cervical cancer screening were updated in 2009 to include best practices since the changes made in the 2002 update. The 2009 ACS guidelines recommend screening for cervical cancers begin at age 21 years. Until age 30, and according to the guidelines, women at average risk receive biannual Pap screening using liquid-based cytology. After age 30 years, women with normal or negative Pap screens may choose either to undergo screening every three years using either conventional or liquid-based cytology, or undergo screening every three years with the combination of HPV-DNA testing and conventional or liquid-based cytology (Smith et al., 2010; Waxman, 2009).

The current guidelines recommend women who have an intact cervix and who are in good health continue screening until age 70 years, and afterward may choose to stop screening if they have had no abnormal or positive cytology tests within the 10-year period prior to age 70 years, and if there is documentation that the three most recent Pap screens were technically satisfactory and interpreted as normal. However, screening after age 70 years is recommended for women in good health who have not been previously screened, women for whom information about previous screening is unavailable, and women for whom there is a low likelihood of past screening (Smith et al., 2010; Waxman, 2009).

The US Public Health Service and Infectious Disease Society of America also have recommendations for cervical cancer screening. The US Public Health Service and Infectious Disease Society of America recommend women with a history of cervical cancer or in utero exposure to diethylstilbestrol (DES) follow the same screening guidelines as average-risk women before age 30 years, and continue with that protocol after age 30 years. Women who are immunocompromised by organ transplantation, chemotherapy, chronic corticosteroid treatment, or who are human immunodeficiency virus (HIV) positive should be tested twice during the first year after diagnosis, and annually thereafter. There is no specific age to stop screening for women with a history of cervical cancer, with in utero exposure to DES, and who are immunocompromised. Women in these risk groups should continue cervical cancer screening for as long as they are in reasonably good health and would benefit from early detection and treatment (Smith et al., 2010).

In November 2009, ACOG presented their updated guidelines for cervical cancer screening that recommended screening beginning at an older age and longer screening intervals for women in all age groups. According to ACOG's Cervical Cytology Screening (2009) the significant changes in the new guidelines include a set age to begin screening regardless of age of onset of vaginal intercourse, a lengthening of the screening interval by one year, and the establishment of an age to stop screening if there is a 10-year history of normal screening tests.

### **History of Vaccines**

All humans have some amount of natural immunity to disease and infection. Immunization is the process of artificially creating immunity by deliberately infecting a person so the body learns to protect itself (Waterson, 1978). A vaccine causes the body's immune system to produce antibodies to fight a modified form of the virus that is not harmful. Then, if the person encounters the real and dangerous virus, the body is able to protect itself (Waterson, 1978).

The concept of immunization, or how to artificially induce the body to resist infection, received widespread recognition in 1796, when British physician Edward Jenner inoculated a young boy in England and successfully prevented him from getting smallpox. Jenner used a lancet to scratch infected material from a woman with cowpox which is very similar to smallpox, under the boy's skin (Riedel, 2005).

Vaccines work in the same manner and deliver minute amounts of substances that provoke antibody responses called antigens. Antigens multiply more slowly and for a shorter period of time than their disease-producing counterparts. As a result, the body recognizes just enough antigens to develop protective antibodies (CDC, 2009). Today there are 15 different vaccines children may receive prior to their 21<sup>st</sup> birthday (Immunization Action Coalition, 2010)

### **HPV Vaccine**

The quadrivalent human papillomavirus vaccine Gardasil® developed by Merck Pharmaceuticals for females prevents infection from serotypes 6, 11, 16, and 18, which are the four most common serotypes of human papillomavirus associated with the development of cervical cancer, genital warts, and some less common cancers (CDC, 2008). The HPV vaccine Gardasil® protects against two of the HPV types 16 and 18 that cause approximately 70% of all cervical cancer. In addition, the quadrivalent HPV vaccine also protects against two additional HPV types 6 and 11 that cause most genital warts (CDC, 2008). It is the only vaccine which prevents against these four HPV types (CDC, 2008).

The safety and efficacy of the vaccine continues to be studied and documented. In females, a four year evaluation of the prophylactic efficacy of the HPV vaccine in preventing low grade cervical, vulvar, and vaginal intraepithelial neoplasias and anogenital warts, indicated sustained protection against low grade lesions attributable to vaccine HPV subtypes 6, 11, 16, and 18 and a substantial reduction in the burden of these diseases through 42 months of follow-up (Dillner et al., 2011). In addition, researchers from the University of Massachusetts conducted an extended literature search on the safety and efficacy of the HPV quadrivalent vaccine. These researchers reviewed multiple bibliographic databases and concluded the vaccine was effective in the management of HPV by preventing vaccine subtype-related persistent infection and precancerous lesions.

Research by Giuliano et al. (2011) on 4,065 healthy males 16-26 years of age from 18 countries in a double-blind trail examined safety of the HPV vaccine against active HPV types 6, 11, 16, and 18 and efficacy in preventing the development of external genital lesions and anogenital HPV infection in boys and men. The primary efficacy objective was to show that the quadrivalent HPV vaccine reduced the incidence of external genital lesions related to HPV-6, 11, 16, or 18. The conclusion of this study was quadrivalent HPV vaccine prevents infection with HPV-6, 11, 16, and 18 and the development of related external genital lesions in males 16 to 26 years of age.

The vaccine was also regarded as generally safe and well-tolerated, based on an assessment of reported adverse events submitted through governmental databases and analyzed by independent researchers (Pomfret, Gagnon, Jr., & Gilchrist, 2011).

On October 16, 2009, the FDA licensed bivalent HPV Cervarix® manufactured by GlaxoSmithKline pharmaceuticals for use in females aged 10 through 25 years. Cervarix® is the

second HPV vaccine licensed for use in females in the United States and contains two HPV types rather than four types like the Gardasil® vaccine. It is not licensed for males. It protects against HPV types 16 and 18, the causes of most cervical cancers (MMWR, 2010). Cervarix will not be included in this research because it is not covered by the VFC program.

Public health officials in the United States recommend vaccination of young women against HPV noting that as many as 80% of American women will have contracted at least one strain of HPV by age fifty (Dunne et al., 2007). In 2000, genital HPV cost the nation \$2.9 billion in direct medical costs (Chesson, Blandford, Gift, Tao, & Irwin, 2004). Since neither vaccine covers all high-risk types of HPV, experts continue to recommend regular Pap smear screening even after vaccination (NCI, 2010; Markowitz et al., 2007).

The ACIP recommends the HPV vaccine be administered to females by intramuscular injection in the upper arm. The recommended schedule is a three-dose series with the second dose administered two months after the first dose. The third and last dose is given six months after the first dose. The recommended age for vaccination of females is 11-12 years. The vaccine can be administered to girls as young as 9 years old. Catch-up vaccination is recommended for females aged 13-26 years who have not been previously vaccinated (Immunization Action Coalition, 2010).

A recommendation from the American Academy of Pediatrics was made in 2007 (AAP, 2007) recommending the vaccine to the pediatrician's female patients. The American Academy of Family Physicians followed and recommended the vaccine to their female patients in 2007 (Goeser, 2007).

Until this time, the HPV vaccine was licensed only for young females. It was not until October 16, 2009, that the FDA licensed quadrivalent human papillomavirus vaccine, Gardasil®

as the only HPV vaccine for use in males 9 to 26 years for prevention of genital warts caused by human papillomavirus types 6 and 11. (MMWR, May 28, 2010). Efficacy and safety of the vaccine for males in preventing the development of external genital lesions and anogenital HPV infection was performed on male's age 16 to 26 years (Giuliano et al., 2011). Their research indicated the quadrivalent HPV vaccine reduced the incidence of external genital lesions related to HPV subtypes 6, 11, 16, or 18, and reduced the development of related external genital lesions in males 16 to 26 years of age.

After FDA approval, and on October 21, 2009, the ACIP provided guidance stating the HPV vaccine may be given to males aged 9 through 26 years to reduce their likelihood of acquiring genital warts. The ACIP did not recommend the HPV vaccine for routine use among males. Instead, the committee voted to support the "permissive use" of the HPV vaccine among males, leaving decisions on whether to immunize males ages 9-26 years who request the vaccine to the discretion of their health care professional (MMWR, May 28, 2010). In December 2010, The FDA also approved the HPV vaccine Gardasil® for the prevention of anal cancer and associated precancerous lesions due HPV sub types 6, 11, 16, and 18 in both males and females age 9 through 26 years (FDA, 2010).

The ACIP recommends the HPV vaccine be administered to males by intramuscular injection in the upper arm. The recommended schedule is a three-dose series with the second dose administered two months after the first dose. The third and last dose is given six months after the first dose. The recommended age for vaccination of males is 11-12 years. The ACIP allows the vaccine to be administered to those as young as age 9 years and through age 26 (MMWR, May 28, 2010).

### **Barriers Related to HPV Vaccine Administration**

Research shows many important links between barriers and intention to vaccinate and how it affects vaccination rates. The causal relationship between HPV and cervical cancer is a relatively recent discovery with clinical trials for the vaccine beginning in the 1990's (Markowitz et al., 2007). Since its discovery in 1956, HPV has been intensely studied. Physician and scientist Harald zur Hausen first postulated in 1983 that HPV caused cancer in women (zur Hausen, 1996). Zur Hausen (1996) was able to unveil HPV's novel properties and proved that two HPV subtypes (16 and 18) could cause as much as 70% of cervical cancer cases. In 2008, zur Hausen received the Nobel Prize for his work on HPV (Nobel Prize, 2008).

As detailed in a systematic review by Allen et al. (2010), most research on this topic was conducted prior to vaccine licensure in 2006. In their review, it was noted that at least two-thirds of existing U.S. studies and 36% of non-U.S. studies were conducted prior to HPV vaccine licensure. With this consideration, barriers to HPV vaccination will be summarized below.

### **Informational Barriers**

Lack of information and education is identified by many researchers as a barrier to HPV vaccination. Information and education barriers for young women, parents of adolescent girls, and physicians are well documented (Chan, Cheung, Lo, & Chung, 2007; Mays, Sturm & Zimet, 2004; Olshen, Woods, Austin, Luskin, & Bauchner, 2005; Woodhall, 2007). Multiple studies suggest parents and young women often are not aware of the risks of contracting HPV or its direct association to cervical cancer (Chan, Cheung, Lo, & Chung, 2007; Dempsey & Davis, 2006; Gerend, Lee, & Shepherd, 2007; Hoover, Carfioli, & Moench, 2000). Lack of information may also impede physicians from recommending the vaccine if they are not aware of the benefits of vaccination, or how to educate about the benefits of the vaccine. In a New Mexico study

involving 37 primary care providers, researchers revealed barriers to counseling parents on HPV vaccination included limited knowledge of HPV and low levels of knowledge by adolescents (Sussman et al., 2007). Throughout the literature, researchers recommended continued educational outreach and interventions for parents, women, and physician healthcare providers.

### **Safety and Efficacy Barriers**

There are concerns by physicians, parents, and young women, about vaccine safety and efficacy. According to published research, there have been more than 26 million doses of the HPV vaccine distributed in the United States with 12,424 reports of adverse reactions. Most adverse events rates were no greater than background rates compared with other vaccines, but there was disproportional reporting of syncope and venous thromboembolic events with the HPV vaccine (Slade et al., 2009).

In a study of 513 pediatricians using a traditional mail survey, pediatricians reported concerns about the safety of the vaccine and uncertainty regarding the efficacy of the vaccine in terms of lifetime protection for individuals (Kahn et al., 2005). In an editorial in the Journal of American Medicine, Gostin and DeAngelis (2007) caution physicians to consider the lack of adequate efficacy trials for girls aged 9 to 15 and recommend more trials be completed before mandating the vaccine for school enrollment. Other concerns by parents and young women focus on potential harmful side effects from the vaccine and the general safety of the vaccine (Gerend et al., 2007; Marshall, Ryan, Roberton, & Baghurst, 2007; Woodhall et al., 2007).

### **Cultural Barriers**

Cultural barriers in the literature focus on race, ethnicity, socioeconomic status, education level and health insurance status (Sussman et al., 2007). According to the American Cancer Society (2009), Latinas have higher cervical cancer age-adjusted incidence and mortality rates, and present with more advanced disease compared to non-Latino whites. Research to determine HPV awareness among Latina immigrants and Anglo women in the southern United States suggested Mexican and Honduran women were less likely to be aware of HPV and the HPV vaccine, and more likely to be uninsured and without a regular health care provider than Anglo women (Luque et al., 2010).

In a study of Hispanic women in New Mexico that included a series of focus groups, participants indicated physicians should consider relevant cultural issues (Vanslyke et al., 2008). The researchers noted Hispanic men may put their sexual partners at heightened risk for HPV due to cultural tolerance of refusing to wear condoms and engaging in sexual activities outside of a committed relationship. In another qualitative research study with Hispanics conducted in south Georgia for the purpose of developing cervical cancer education curriculum for lay health worker outreach, study participants reported cultural barriers for cervical cancer screening, primarily regarding feelings of embarrassment, and not having permission from their husbands to go to the clinic (Luque, et al., In Press).

In a qualitative study, Tissot et al. (2007) found pediatricians had concerns about parents' anti-vaccination beliefs, particularly parents who have strong religious beliefs or who believe in holistic approaches to healing. This study noted African Americans were less trusting of physicians and vaccines. The study also reviewed socioeconomic factors and suggested lower education and income may decrease parental ability for those who seek vaccination. However, the study also suggested those with higher income and education may not consider their children vulnerable and so would be less willing to seek vaccination. Issues of higher income and lower education status were found to be barriers to intentions in other studies as well, regardless of race (Hopenhayn et al., 2007; Woodhall et al., 2007).

### **Psychological Barriers**

Psychological barriers are barriers associated with personal concerns with HPV vaccination. These barriers are placed in two broad categories. The first category is concerns by the vaccinating physicians regarding attitudes of parents toward the vaccine that prevents an STD, and obtaining parental consent (Dempsey & Davis, 2006; Kahn et al., 2005; Sussman et al., 2007). The second category is by parents of young women. The parental concern is that HPV vaccination encourages promiscuity. Another concern in the parental category is the perception of there being little personal risk of HPV infection for their children (Brewer & Fazekas, 2007; Marshall et al 2007; Woodhall, et al., 2007).

### **Financial Barriers**

The HPV vaccine, Gardasil®, is the most expensive vaccine recommended for children and adolescent with a reimbursement cost of \$360, compared with other recommended vaccines that are less than \$50.00 (Gudeman, 2007). Women with health insurance report this does not necessarily make the HPV vaccine affordable if their health insurance plan does not cover the cost (Hopenhayn et al., 2007). As a result, some physicians report keeping their vaccine inventory low and will only offer it to those patients whose coverage will provide reimbursement (Daley, 2006; Gudeman, 2007).

This upfront or initial cost of purchasing HPV vaccine places a significant financial burden on physicians who must purchase it for their patients with insurance or otherwise do not qualify for the federal and state Vaccine for Children (VFC) immunization program. The VFC program provides free vaccines to qualifying children based upon income (Dempsey & Davis, 2006). Indeed, Gudeman (2007) notes that while the VFC program offers vaccine at no cost to underinsured adolescents, there is limited access to VFC discounts if the physician is not part of the VFC program. There is further limited access if there is a lack of presence of Federally Qualified Health Centers or a Rural Health Clinics in the geographic area.

### **Religious Barriers**

Cultural considerations which include religious beliefs and implication toward vaccination have been studied by many (Askelson, 2010; Borrayo & Jenkins, 2003; Chan et al., 2007; Charo, 2007; Daley et al., 2006; Katz et al., 2009; Hoover et al., 2000; Tissot et al., 2007). Their research suggests strong religious beliefs lead to a delay of vaccine administration until an older age or omitting the vaccine altogether. According to qualitative review of the relevant literature by Zimet (2005), religious conservatives voiced concern that allowing their daughters to receive the vaccine undermines abstinence teaching. This argument is similar to that used against school-based sex education programs and condom distribution (Zimet, Shew, & Kahn, 2008).

### **Compliance Barriers**

The HPV vaccine is the only vaccine offered to older children and requiring a three-dose series (McIntosh, Sturpe, & Khanna, 2008). This may present a compliance challenge for some female patients. Patients particularly vulnerable are those populations with limited access to transportation or who must take off work repeatedly to complete the three dose series (Herzog, Huh, Downs, Smith, & Monk, 2008). In addition, this older age group does not have as much routine contact with physicians as when they were younger and receiving medical visits for growth and development monitoring. In Georgia, and according to the Medicaid periodicity schedule of visits, physicians are reimbursed for one annual health check visit during adolescence. Other visits to the physician must be a problem focus visit to qualify for reimbursement ("Health check services", 2007; McIntosh et al., 2008). Most insurance companies follow this guideline and limit the number of routine office visits. Requiring three

visits for the vaccine series can place an added burden on both patient and physician in terms of scheduling, vaccine availability, and the above noted limits placed on the number of visits covered for adolescent well-visits by insurance and other third party reimbursement programs.

Reimbursement and getting to the physician's office are not the only compliance barriers. Other researchers found completing the vaccine three dose series to be a barrier even when the vaccine was provided within a school setting, as students missed their scheduled appointments (Brabin et al., 2008). This same study also found uptake was significantly lower in schools with a higher proportion of ethnic minority girls or if there was a higher proportion of girls entitled to free school meals (Brabin et al., 2008).

### **Supports Related to HPV Vaccination**

Similar to barriers, there are supports noted in the literature that encourage HPV vaccination. Financial supports and health behavior were reported most often as supports (Kahn et al., 2008; Spereber, Brewer, & Smith, 2008). Other common supports included in the literature comprise physician recommendations and organizational supports (Kahn et al., 2009; McCave, 2010). Supports to HPV vaccination will be discussed in greater detail in the following sections.

### **Financial Supports**

The financial burden of the HPV vaccine has been a concern for patients of lower socioeconomic status and providing financial support to physicians and patients is important. Physicians, women, and parents indicate that having the vaccine covered fully by insurance is necessary, as is making it affordable for those without insurance (Kahn, et al., 2005; Hoover et al., 2000).

The most significant financial support is the inclusion of the HPV vaccine in the VFC) list of federally covered vaccines. The CDC's Section 317 Grants Program is the main source of

funding for state immunization programs. States use these federal funds to pay for underinsured patients to cover their vaccine costs under Section 317 of the Vaccination Assistance Act of 1962 (Rein, Honeycutt, Rojas-Smith, & Hersey, 2006; Institute of Medicine, 2003).

The VFC program is a federal entitlement program established in 1994. Research published in the Journal of American Medical Association, notes that VFC funds account for approximately 43% of vaccine expenditures (Lee et al., 2007). The VFC program provides free immunization services to uninsured and underinsured children up to age 19 to participating physicians, Federally Qualified Health Centers and Rural Health Clinics (Institute of Medicine, 2004). Once the ACIP adds a vaccine to the recommended childhood/adolescent immunization schedule and votes to include the vaccine for use under the VFC program, the vaccine must be subsidized under VFC for qualified children (Orenstein, Rodewald, Hinman, 2004). Parents who support a mandatory HPV vaccination are aware of the VFC program and how it could improve coverage for those with limited financial resources (Ferris, Horn, & Waller, 2010).

The Georgia VFC program, which began October 1994, is coordinated by the Georgia Immunization Program within the Division of Public Health through the Department of Community Health (Georgia Department of Community Health, 2010). Georgia's VFC Program provides free vaccines to private and public providers including physicians, for children up to 18 years old who are Medicaid-eligible, American Indian/Alaska Native, uninsured, and underinsured (Immunization in Georgia, 2009). As of December 2004, 3,062 private physicians at 1,025 locations participate in the VFC program in Georgia (Immunization in Georgia, 2009). A study of adosescent girls enrolled in the Florida Medicaid VFC Program, which offers the HPV vaccine, indicated girls in this program were more likely to have initiated the HPV vaccine series if the financial barrier of cost was removed (Staras, Vadparampil, Haderxhanai, & Shenkman, 2010).

### **Organizational Supports**

Organizational supports provided by primary care settings such as clinics and private practices have been discussed in the literature (Bhatla et al., 2010; Chao, Velicer, Slezak, & Jacobsen, 2010; Humiston et al., 2009). Creating physician office supports, such as decreasing time constraints and providing information to parents, was found to be effective (Chan et al., 2007).

In a qualitative study of 31 pediatricians by Tissot et al. (2007), potential supports for improving HPV vaccination were considered. The findings for supports included a number of strategies that pediatricians believed were critical for effective future implementation of HPV vaccination. These included: 1) maximizing ease of vaccine administration; 2) implementing office-based procedures and policies to optimize vaccine uptake; 3) ensuring broad access to vaccines; 4) ensuring endorsement of vaccination by influential organizations; and 5) addressing the educational needs of providers, parents, and patients (Tissot et al., 2007, p. 124). Supports included providing lectures and written materials, such as information sheets and professional organization policy materials. Other supports included hosting local expert guest speakers, directing patients to informational web sites and providing data on HPV prevalence and susceptibility, HPV-related diseases, and health impact and devising strategies for talking with parents and youth in a culturally sensitive way were also incorporated (Tissot et al., 2007).

In Georgia, a statewide web portal internet system is able to assist providers who administer vaccine by allowing them to access vaccine information on any individual who has received a vaccine in Georgia. The Georgia Immunization Registry law was passed in 1996 and the

Georgia Registry of Immunization Transactions and Services (GRITS) were introduced statewide to include vaccination history on childhood vaccines in May 2003. It was expanded by House Bill 1526 in 2004 to require reporting by any person who administers a vaccine or vaccines licensed for use by the FDA, to a person from birth to death, be recorded in the GRITS statewide vaccine registry (Georgia General Assembly, 2004).

Among other benefits, the internet based GRITS immunization registry allows enrolled physicians and other providers, both public and private, to input and access any individual's complete immunization record. This access decreases over and under immunization, and provides a current picture of the immunization status of all Georgians including that of the HPV vaccine. The benefits are beginning to be realized as the GRITS registry is used in population-based research for children behind schedule in receiving immunizations and provides a reminder to those who require the second and third dose of a series immunization such as the HPV vaccine (DHR - Immunization in Georgia, 2006).

#### **Physician Recommendation as a Support**

HPV vaccine acceptability by parents and young women is greater when they perceive that their health provider recommends the vaccine (Gerend et al., 2007; Tedeschi et al., 2006). Indeed Sussman et al. (2007) listed four factors important in the counseling process: 1) the importance of rapport building with adolescents; 2) the assumption that adolescents will engage in high-risk behaviors; 3) the difficulty and complexity of counseling about the HPV vaccine; and 4) the attitudes of primary care providers, nurse practitioners, and community acceptance of the HPV vaccine. In a national survey of pediatricians by Daley et al. (2006), respondents were more likely to recommend HPV vaccination to older compared to younger adolescents. They

further noted respondents were more likely to recommend vaccine to female versus male patients (Daley et al., 2006, p. 2284).

McCave (2010) noted supports necessary for improving HPV vaccination rates include a personal belief in the positive impact of the HPV vaccine. This was followed by providers feeling comfortable talking with parents about the sexual nature of diseases prevented by the vaccine, and the importance of adhering to the CDC's recommendations on HPV vaccination. McCave further noted age of the patient likely influenced the providers' HPV vaccination behaviors, particularly if parents have concerns about vaccinating their pre-adolescent child. She concluded her finding by stating providers can best serve their patients when they are aware of the potential barriers and supports that may influence their HPV vaccination behaviors.

In a study of physicians currently administering the vaccine to females, findings suggest physicians supported the concept of vaccinating males for the benefits it imparts on both sexes. The physicians in the study agreed a gender-neutral HPV vaccination recommendation would be appropriate with regard to public health but were less sure that such a recommendation would change patient or parental attitudes toward HPV vaccination or improve current HPV vaccination efforts (Weiss, Zimet, Rosenthal, Brenneman, & Klein, 2010).

### State Law and the HPV Vaccine Mandate for School Admission

In a report by the Institute of Medicine, state immunization programs, including Georgia, have seen an increase in the number of new and expensive vaccines (Institute of Medicine, 2003). The newer vaccines improve the health of the child immunized and prevent many diseases that were once common to childhood. However, according to the latest price lists published by the CDC, the total cost dose to fully vaccinate a child in Georgia at a physician's office has risen from \$155.00 in 1995 to over \$1,200.00 in 2010 (CDC Pediatric/VFC Pricelist, 2010).

Historically, the preservation of the public's health has been the responsibility of state and local governments, and the authority to enact laws relevant to the protection of the public health derives from the state's general police powers (Gostin, 2008). All states in the United States have mandated various types of vaccines for school-aged children. The most persuasive case for a mandate is when the vaccine prevents a serious infectious disease spread by casual contact in the age group for which it is mandated. Examples of mandated vaccines in this category are those that protect against polio, measles, mumps, rubella, diphtheria, and pertussis. Exemptions to vaccinations are available in cases of religious convictions. However, widely used vaccine exemptions result in a lowering of what epidemiologists refer to as "herd immunity," and result in an increase in disease (CDC, 2006).

In February 2007, Texas became the first state to mandate the HPV vaccine for girls entering sixth grade. Texas legislators were not supportive and by May 2007 passed a bill reversing the governor's order for the mandate and instead mandated that no HPV vaccine could be ordered for schoolchildren over the next four years (Javitt, Berkowitz, & Gostin, 2008). During this same time, a cross-sectional, web-based survey of Texas physicians was conducted to determine three outcome variables pertaining to HPV vaccination. These were: HPV vaccine recommendations to 11-to-12-year-old girls, probability of recommending the vaccine to 11-to-12-year-old boys, and agreement with the mandated vaccination of 11-to-12-year-old girls. Of the 1,122 respondents to the survey, over half of physician respondents did not follow current recommendations for universal HPV vaccination of 11-to-12-year-old girls (Kahn et al., 2009). In Georgia, lawmakers determined the HPV vaccine does not meet the high threshold necessary for school entry. Namely, HPV is spread by sexual or very close contact and therefore is not an epidemic infectious disease among school-aged children requiring it to be a mandated vaccine (National Conference of State Legislatures, 2010). Therefore the state of Georgia does not mandate the HPV vaccine as a required vaccine for school admission (Georgia Department of Education, 2010).

#### **Georgia Public Health Districts**

Georgia Department of Community Health, Division of Public Health is the lead division entrusted by the people of the State of Georgia with the ultimate responsibility for the health of communities and the entire population. At the state level, the Division of Public Health is divided into numerous branches, sections, programs and offices (Georgia Department of Community Health, 2010). At the local level, the Division of Public Health functions through 18 health districts which contain the 159 county health departments (Appendix A).

The Immunization Section of the Division of Public Health works collaboratively with public and private providers, advocacy groups, and other stakeholders, to increase immunization rates for all Georgians and decrease the incidence of vaccine-preventable diseases. Each of the 159 counties has some public health presence and the ability to administer the HPV vaccine.

According to Dr. Anil T. Mangla, Director of the Immunization Section of the Division of Public Health, a population-based study conducted in Georgia in 2004 showed most childhood immunizations (70%) were administered in the private sector at the physician office, while 14% were administered by county health departments. The sources for 16% were unknown though some were expected to be Federally Qualified Health Centers located in low income areas (A. T. Mangla, personal communication, October, 2010). A Georgia immunization study conducted in 2007 revealed that most childhood immunizations (81%) were administered in the private sector at the physician office, while county health departments immunized 9.8%, and the sources for 9% were unknown, indicating more children are receiving vaccines at physician offices (Georgia Department of Community Health, 2010). The Georgia Division of Public Health does not record information on physician HPV vaccination administration rates. However, according to a CDC report, Georgia physicians vaccinate one in three females eligible for HPV (MMWR, 2009). As the Mission and Vision of the Immunization Section of the Division of Public Health is to "... work to increase immunization rates for all Georgians and decrease the incidence of vaccine-preventable diseases," it is important that the Immunization Section of the Division of Public Health have information about the attitudes and beliefs of Georgia physicians toward administering the HPV vaccine and assess perceived knowledge, barriers, practices, and adherence to ACIP guidelines and recommendations regarding HPV vaccination.

### **Urban and Rural Classification of Georgia Counties**

This research sought to determine differences between urban and rural physicians' administration and recommendation of HPV vaccine. According to a health care workforce report commissioned by the U.S. Department of Health and Human Services, it was noted Georgia's rural population lacked adequate geographical access to basic health care services (Bureau of Health Professions, 2011). According to their report, the percent of Georgia's population residing in primary care federally-designated health professional shortage areas (HPSAs) exceeds the national proportion. Rural areas continue to have difficulty recruiting primary care physicians and Georgia's community health centers in underserved areas voice growing concerns about their difficulty recruiting and retaining physicians (Bureau of Health Professions, 2011). As this present research sought to determine differences between urban and rural physicians' administration and recommendation of HPV vaccine, the terms urban and rural had to be defined to determine if differences emerged between vaccination rates in rural or urban defined areas. Rural is an imprecise term that can mean different things to different researchers. For example, what is considered rural in one state with low population density may not be considered rural in another state with a much higher density. However, for the purposes of this proposed research, there is a need for exact definitions of what is meant by "rural."

Government agencies considered whose definitions of what is rural or urban include: 1) the U.S. Census Bureau; 2) the Office of Management and Budget; 3) the Economic Research Service of the U.S. Department of Agriculture (USDA); and 4) the Georgia Office of Rural Health.

According to the U.S. Census Bureau, specific urban entities are defined as an urbanized area and include an urban nucleus of 50,000 or more people. Individual cities with a population of 50,000 may or may not be contained in an urbanized area. Urbanized areas have a core with a total land area less than two square miles and a population density of 1,000 persons per square mile. They may contain adjoining territory with at minimum 500 persons per square mile and encompass a population of at least 50,000 people. An urban cluster also has a core as identified above with a total land area of less than two square miles and a population density of 1,000 persons per square square mile. They may contain adjoining territory with at minimum 500 persons per square mile and encompass a population of at least 50,000 people. An urban cluster also has a core as identified above with a total land area of less than two square miles and a population density of 1,000 persons per square mile. They may contain adjoining territory with at minimum 500 persons per square square mile. They may contain adjoining territory with at minimum 500 persons (United States Census Bureau, 2010).

A second definition of rural is offered by the Office of Management and Budget, which defines metropolitan statistical areas - or metro areas - as central or core counties with one or

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more urbanized areas, and outlying counties that are economically tied to the core counties as measured by work commuting (Office of Management and Budget, 2010). They include outlying counties if 25% of workers living in the county commute to the central counties, or if 25% of the employment in the county consists of workers coming out from the central counties-the so-called "reverse" commuting pattern. Non-metro counties are outside the boundaries of metro areas and are further subdivided into two types.

The Office of Management and Budget use the term "Micropolitan statistical areas "or "micro areas" to denote non urban areas. These are non-metro counties with an urban cluster of at least 10,000 persons or more (Office of Management and Budget, 2010). The last type is the noncore county. Researchers and others who discuss conditions in rural America often refer to nonmetropolitan areas that include both micropolitan and noncore counties as rural areas (Office of Management and Budget, 2010).

A third definition is through the offices of The Economic Research Service. This includes the United States Department of Agriculture (USDA), the Department of Health and Human Services, Health Resources and Service Administration's Office of Rural Health Policy along with Rural Health Research Center, and the University of Washington which collaborated to develop the Rural-Urban Commuting Area system. Their definition is a census tract-based classification that utilizes the Bureau of Census urbanized area standard and place definitions in combination with commuting information to characterize rural and urban status of census tracts (United States Department of Agriculture Economic Research Center, 2010).

The fourth and final definition is used by the Georgia Office of Rural Health. The Georgia Office of Rural Health defines a Georgia rural county as any county having a population of less than 35,000 according to the U.S. Census of 2000 (Rural Assistance Center, 2010). Since this

study involved research pertaining to possible differences between urban and rural HPV vaccine administration of Georgia physicians by county, this study will use the Georgia Office of Rural Health Classification for rural counties. Therefore, those counties with less than 35,000 will be classified as rural and those with greater than or equal to 35,000 will be classified as urban.

#### **Use of Theory**

This study relied upon theory to inform the development of the research questions and interpret the findings. Health improvements, such as providing HPV vaccination to one's patients, cannot be completed by simply providing the physician with information and raising his or her awareness to the need to educate parents about HPV.

Indeed, ecological models suggest that multiple levels must be in place for change to occur. Stokols (1996) notes successful health improvement and promotion programs must link behavioral strategies with efforts to strengthen environmental supports within the broader community that are conducive to well being. Using the social ecological approach, there are alternative yet complementary perspectives. The social ecological model considers the complex interplay between individual, relationship, community, and societal factors by allowing us to address the four factors, or levels that put people at risk (Stokols, 1996).

The first level looks at the broad societal factors that help create a climate in which HPV vaccination is encouraged or inhibited. These factors include social and cultural norms. Other large societal factors include the health, economic, educational and social policies that help to maintain economic or social inequalities between groups in society (Stokols, 1996).

The second level explores settings such as the physician workplace, and organizations in which social relationships occur. It also seeks to persuade or dissuade providing HPV vaccination.

The third level encompasses relationships with peers, professional partners, and family members. Factors include whether or not other trusted physicians are providing the vaccine, and if valued sources of information such as professional journals and associations, encourage vaccination.

The first level, or individual level, identifies biological and personal history factors. In this research, factors associated with the first level include age, education, and personal feelings toward HPV vaccination. In this level, the Precaution Adoption Process Model was explored to determine if it would inform the research undertaken.

The Precaution Adoption Process Model was first suggested by Weinstein (1988) as a model used to describe and explain the process by which people adopt precautions against a new risk. For example, a risk that they have recently learned about rather than a risk they have been aware of for some time. It is applicable in the situation where a new precaution against an "old" risk becomes available such as the introduction of the HPV vaccine to prevent cervical cancers and genital warts.

The Precaution Adoption Process Model specifies seven discrete stages. It defines the stages without reference to arbitrary time periods and, between having never thought about adopting a particular precaution and having thought about it and decided not to act. In each stage the types of information and interventions needed to move people closer to action varies (Weinstein, 1988). One advantage of such a stage theory is that it useful when the same population is being surveyed over time or targeting interventions to move people through stages. It was not used in this research as the survey was administered once and follow up surveys to the sample were not part of this research. Next, the health belief model was explored to inform this research.

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### **Health Belief Model**

The central premise that a primary care provider's perceived barriers and benefits of providing HPV vaccine to her clients, which stem from the physician's personal or normative beliefs as well as perceived severity and susceptibility of diseases associated with the human papillomavirus, and her recommendation and administration of the vaccine is the foundation for this study.

The Health Belief Model was created to provide a framework to better understand why some people take actions to avoid illness, whereas others do not (Becker, 1974). This model was developed by social psychologist researchers with the U.S. Public Health Service in the early 1950s (Becker, 1974; Champion & Skinner 2008; Rosenstock, 1974). The U.S. Public Health Service researchers were motivated to study why people sought radiographic examinations for tuberculosis and why others did not. They created a theory that attempted to explain and predict given health-related behavior from certain patterns of belief about the recommended health behavior and health problems that the behavior was intended to prevent or control. The model postulates that the following conditions both explain and predict a health-related behavior:

- A person believes their health is at risk or their chances of getting a condition. For the behavior of seeking screening or treatment, the person must believe that he/she can have the disease yet not feel symptoms. This collection of beliefs is referred to as "perceived susceptibility."
- The person perceives the potential seriousness of the condition in terms of pain or discomfort, time lost from work, economic difficulties, or other negative outcomes. This belief is referred to as "perceived severity."

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- 3. On assessing the circumstances, the person believes that benefits derived from the recommended behavior (such as obtaining an immunization) outweigh the costs and inconvenience and that they are indeed possible and within her ability to acquire. These perceived or anticipated benefits and costs are referred to as "perceived benefits."
- 4. Before taking action, the person must determine the tangible and psychological costs of the action and barriers. Then the barriers must be reduced through reassurance, incentives and/or assistance. This is referred to "perceived barriers."
- 5. The person receives strategies to act or a precipitating force that makes the person feel the need to take action. This is referred to "cues to action."
- Finally, the person must have confidence is their own ability to take action. This final step is referred to as "self-efficacy."

The model soon changed shape when applied to other health problems such as seeking immunization and attempted to more broadly define people's different responses to public health measures and their use of health services. In these wider applications, the model substituted a belief in susceptibility to a disease or health problem for the more specific belief that one could have a disease and not know it, which had been featured in Godfrey Hochbaum's original study as the most important belief accounting for seeking screening examinations (Breslow & Cengage, 2002; Champion & Skinner, 2008). The Health Belief Model was selected to inform the development of the research questions and interpretation of results. See Table 1 for Health Belief Model constructs and it application to this research of the HPV vaccination.

#### Table 1:

Health Belief Model and HPV

Health Belief Model Component	HPV vaccination counterpart
Perceived susceptibility	Knowledge that the patient is at risk for HPV infection.
Perceived severity	Knowledge that HPV can become a serious illness leading to genital warts, cervical and other cancer.
Perceived benefits	Knowledge that the vaccine reduces risk of HPV
Perceived barriers	Fear of inadequate reimbursement, inability to complete series, and parental barriers surrounding the vaccine
Cues to action	Scheduling healthcare visits for the patient to obtain the HPV vaccine through telephone call back, reminders, and parental education.
Self-efficacy	Confidence in belief that the physician is capable of administering the HPV vaccine

#### Summary

The human papillomavirus is the single most common sexually transmitted disease in the United States (Trottier, 2006). On June 8th, 2006, the FDA approved Gardasil® by Merck Pharmaceuticals as the first HPV vaccine to protect women between the ages of 9 and 26 (Markowitz et al., 2007). Less than one year later, in 2007, the ACIP of the CDC recommended that all girls aged 11 and 12 be vaccinated against HPV, with the indication that girls as young as 9 years of age, and older females between the ages of 13 and 26 may receive the vaccine.

On October 16, 2009 the FDA approved the same HPV vaccine, for use in boys and men 9 through 26 years of age for the prevention of genital warts caused by HPV types 6 and 11 and for offering protection to their partners, making it the only HPV vaccine approved for use in males at this time. The approved HPV vaccine protects against HPV types 6 and 11 which cause

approximately 90% of all genital warts cases (MMWR, May 28, 2010). Since there is a high rate of transmission of HPV in female partners of men with pre-existing warts, and HPV infection in men has been shown to contribute to HPV infection and subsequent cervical disease and cancer in women, it is necessary to vaccinate both males and females to prevent the spread of the virus (Giuliano, 2007).

The National Cancer Institute's State Cancer Profile reveals Georgia with an estimated 364 new cases of cervical cancer in 2006, with 122 deaths from the disease (State Cancer Profiles, 2010). Despite having this vaccine available, only 38% in Georgia have been vaccinated with at least one of the three doses that are necessary for HPV immunity (MMWR, 2010). This study examined the prevalence of Georgia physician intention and administration of the HPV vaccine, to 11-12 year-old girls and intention to recommend the HPV vaccine, to 11-12 year old boys. For the purposes of this research, the quadrivalent human papillomavirus vaccine, Gardasil® was used as it is the only quadrivalent HPV vaccine currently available for commercial use and it is the only HPV vaccine approved by the VFC program for use in Georgia.

# **CHAPTER 2**

# HYPOTHESES AND RESEARCH QUESTIONS

## **Research Questions**

The following research questions were explored:

## Research Question #1:

What barriers do Georgia physicians enrolled in the Vaccine for Children (VFC) program perceive when providing the Human Papillomavirus Virus (HPV) vaccine to their female patients?

### Research Question #2:

What knowledge do the Georgia physicians enrolled in the VFC program have when providing the HPV vaccine to their female patients?

## Research Question #3:

What percentage of Georgia physicians enrolled in the VFC program administers the HPV vaccine to their female patients according to Advisory Committee on Immunization Practices (ACIP) published guidelines by providing the vaccine to their 11 - 12 year old patients?

# Research Question #4:

What percentage of Georgia physicians enrolled in the VFC program indicates they will recommend the HPV vaccine to their male patients?

### Research Question #5:

What differences will emerge when the data are analyzed by urban vs. rural characteristics?

## Hypotheses

In addition, the following hypotheses were tested:

### Hypothesis #1:

No statistical differences will be detected between the perceived barriers by physicians enrolled in the VFC program who provide the HPV vaccine to females, and geographic setting (urban vs. rural).

### Hypothesis #2:

No statistical differences will be detected between the perceived knowledge of physicians enrolled in the VFC program who provide the HPV vaccine to females, and geographic setting (urban vs. rural).

### Hypothesis #3:

No statistical differences will be detected between the percentage of Georgia physicians enrolled in the VFC program who administer the HPV vaccine according to ACIP published guidelines by providing the vaccine to their 11 - 12 year old patients and geographic setting (urban vs. rural).

### Hypothesis #4:

No statistical differences will be detected between the percentage of Georgia physicians enrolled in the VFC program who indicate they recommend the HPV vaccine to male patients, and geographic setting (urban vs. rural).

#### **CHAPTER 3**

### METHODS AND MATERIALS

### **Purpose of the Study**

The purpose of this study was to survey Georgia physicians enrolled in the VFC program to assess their perceived knowledge, barriers, practices and adherence to ACIP guidelines and recommendations of immunization of the quadrivalent HPV vaccine. The Health Belief Model (Becker, 1974; Champion & Skinner, 2008; Glanz, Rimer, & Viswanath, 2008; Rosenstock, 1974) was used to inform this study of Georgia vaccine administration in urban and rural locations.

#### **Design of the Study**

The study was approved by the Georgia Southern University Institutional Review Board prior to data collection in October 2010 (Appendix B). The variables under study, perceived knowledge, barriers, practices, and adherence to ACIP guidelines were assessed via a crosssectional research design (Campbell & Stanley, 1966). The intent was to provide researchers, Georgia Department of Community Health and Georgia Public Health with a comprehensive examination of the *status quo* with regard to compliance with recommended ACIP guidelines for vaccine administration in urban and rural locations.

### **Sampling Plan**

The Georgia Immunization Section of the Division of Public Health located within the Department of Community Health was contacted in January 2010 and a request for a list of VFC providers who administer the HPV vaccine was submitted. The request was granted by the acting program director in February 2010. The VFC list included 1,807 providers throughout the state. Upon examination of the list, it was determined that a physician provider on the list could be a single provider practicing at one location or multiple providers practicing at one location. In addition, it was determined not all provider locations were up to date, and others should be excluded. Examples of those considered for exclusion included chain grocery stores which had clinics located within the grocery store and provided influenza vaccines to the general public. The list was updated in March 2010 with the assistance of the Georgia Immunization Section within the Division of Public Health to contain only providers who administered vaccine at a physician setting. The updated list contained 1,307 (N= 1,307) provider practice locations in each of the 159 counties in Georgia. From this, a stratified sample where type of county was the strata was created from the VFC provider list. The primary sampling unit was the county. Counties were selected via probability proportional to size (PPS) sampling. Probabilities for each county were constructed based on the number of providers within a county, thus counties with more VFC providers had a higher probability of being selected for inclusion. The secondary unit of sampling was the provider and all providers within a county were sampled. As some providers represented more than one physician at a practice location, a question was included to determine how many physicians were located at that practice location (Appendix C). The final sampling frame included 389 (n = 389) provider locations. Of these, 305 were located in six urban counties and 84 were in 18 rural counties. An attempt to contact the 389 provider locations was made. Ninety five responded that they did not give the HPV vaccine in their office, 30 could not be contacted by telephone or email and 264 responded that they administered the HPV vaccine in their office yielding a final sampling frame of 264 (n=264).

#### Instrumentation

The survey of physician perceived knowledge, barriers, practices and adherence to ACIP guidelines and recommendations of immunization of the HPV vaccine was designed based upon

previous research. A modification of a previously validated survey tool developed by researchers from the H. Lee Moffitt Cancer Center and Research Institute (Moffitt) was used. The Moffitt survey was developed and tested by Vadaparampil and Kahn as part of review of US physicians and was part of a NIH funded four year project examining physician recommendations for the quadrivalent human papillomavirus vaccine in 11-12 year old girls, intention to recommend HPV vaccines to 11-12 year old boys, and attitudes about mandated HPV vaccination for 11-12 year old girls (Vadaparampil, 2009; Kahn et al., 2009). That survey was structured to assess constructs identified as being important in predicting physician intention to recommend HPV vaccines.

The outcome or dependant variables selected for inclusion in the final survey tool pertained to recommending and administering the HPV vaccine. The first outcome variable was HPV vaccine recommendation to 9-10 year olds, 11-12 year olds, 13-17 year olds, and 18-26 year olds. The second outcome variable is likelihood of recommending the HPV vaccine to 11-12 year old boys and the third outcome variable was agreement with mandated ACIP guidelines of vaccinating 11-12 year old girls.

The final survey tool developed for this research included 23 questions that were Yes/No, True/False, and Likert-type responses (Appendix D). The final survey question was open ended. This question allowed respondents the opportunity to share any information or valuable lessons learned about adopting a new vaccine into their practice. Participants were asked to identify responses that best match with their perceived knowledge, barriers, practices, and adherence to the ACIP guidelines and recommendations. All questions pertained to the quadrivalent HPV vaccine Gardasil® and did not include questions on other vaccines. This decision was made because Gardasil® is the only vaccine allowed under the VFC program at this time. The first section of the survey tool accessed physician HPV knowledge, valued sources of information about HPV vaccines, educational needs related to HPV vaccines, barriers to HPV vaccination, frequency of HPV vaccine recommendation and administration to girls in four age groups (9-10, 11-12, 13-17, and 18-26 years) and intention to recommend the HPV vaccine to boys in the same four age groups.

Physician knowledge about the HPV vaccine was measured with the use of seven items. These were: assessing HPV medical intervention, treatment of HPV, causes of genital warts and cervical cancer, FDA approval, and if a previous diagnosis of HPV precluded immunization. Physician and parental barriers to HPV vaccination were assessed through 12 Likert-type scale items.

Practice characteristics included whether the physician cared for women in different age groups, patient demographic characteristics, patients' insurance coverage, primary physician specialty, type of practice (Pediatric, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Academic or other), and practice location (urban or rural). Two questions explored physician vaccination adoption style.

The remaining section of the survey contained demographic questions on the physician's age, gender, and ethnicity. All questions were quantitative in nature except the final question which was open-ended. This question allowed respondents the opportunity to share any information or valuable lessons learned about adopting a new vaccine into their practice. The qualitative data did not receive in-depth analysis, but was used to enhance findings and to be of use to others who wish to offer a new vaccine or increase their rates of immunization. The variables included in this research are described in Table 2.

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# Table 2:

VARIABLE	DESCRIPTION	VARIABLE TYPE
Administration of HPV vaccine to girls	Intramuscular injection of the HPV vaccine to a female between the ages of 9 and 26 years	Outcome Variable
Recommendation of HPV vaccine to boys	Recommending the HPV vaccine to male patients between the ages of 11 and 12 years.	Outcome Variable
Administration of HPV vaccine according ACIP guidelines	Intramuscular injection of HPV vaccine to female between the ages of 11 and 12 years	Outcome Variable
Georgia County – Urban	County with > or = 35,000 population	Independent Variable
Georgia County – Rural	County with < 35,000 population	Independent Variable
Sources of Information	Professional Organization ACIP guidelines State and local immunization programs Colleagues Pharmaceutical representatives Internet websites Media Medial conference Grand rounds Local institutional lectures	Independent Variables

Study Variables Description and Variable Type - HPV

# Table 2.

(Continued) Study Variables Description and Variable Type - HPV

VARIABLE	DESCRIPTION	VARIABLE TYPE
Barriers to HPV vaccination	<ul> <li>Vaccine safety to the patient</li> <li>Vaccine efficacy against HPV</li> <li>Discussing sexuality/sexually transmitted infections with child or parent by physician</li> <li>Administering a new vaccine with limited track record of safety</li> <li>Adding another vaccine to vaccine schedule</li> <li>Lack of information about the Quadrivalent HPV vaccine by child or parent</li> <li>Cost of purchasing the vaccine (upfront cost to physician)</li> <li>Cost of stocking HPV vaccine to the physician</li> <li>Lack of adequate reimbursement for HPV vaccine to physician</li> <li>Failure of some insurance companies to cover the cost of HPV vaccine</li> <li>Time to discuss HPV vaccination with patients and/or parents by physician</li> <li>Difficulty ensuring patient will complete the 3 dose HPV vaccination series</li> <li>HPV vaccination is not required for school attendance in Georgia</li> </ul>	Independent Variable

# Table 2.

(Continued)	Study	Variables	Description	and Variable	Type - HPV
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VARIABLE	DESCRIPTION	VARIABLE TYPE
Knowledge about HPV	<ul> <li>Physician knowledge that most HPV infections resolve without medical intervention</li> <li>Physician knowledge that HPV is a relatively common sexually transmitted infection</li> <li>Physician knowledge that HPV causes genital warts in males and females</li> <li>Physician knowledge that almost all cervical cancers are caused by HPV infection</li> <li>Physician knowledge that FDA approved the quadrivalent HPV vaccine for use in females ages 9-26</li> <li>Physician knowledge that females who have been diagnosed with an HPV infection may still receive the vaccine</li> <li>Physician knowledge that the FDA approved the quadrivalent HPV vaccine for use 29-26</li> </ul>	Independent Variable
Clinic specialty	Categorical variable of Pediatrics Family Medicine Internal Medicine Obstetrics/Gynecology Academic Other	Independent Categorical Variable
Practice characteristics	Categorical variable of <ul> <li>Single Specialty</li> <li>Multispecialty</li> <li>Other</li> </ul>	Independent Categorical Variable

### Table 2.

VARIABLE	DESCRIPTION	VARIABLE TYPE
Number of physicians in practice	Categorical variable of • 1 • 2-5 • 6-9 • 10-14 • 15-25 • > 25	Independent Categorical Variable
Race/Ethnicity of physician	Categorical variable of • White/Caucasian • Asian • Native Hawaiian/Pacific Islander • Black/African-American, American • Indian/Alaska Native • Mixed Race • Other,	Independent Categorical Variable
Years in practice since Residency	Categorical variable classifying number of years since medical residency training	Independent Categorical Variable
Type of insurance	<ul> <li>Categorical variable of</li> <li>Private insurance</li> <li>Medicaid,</li> <li>PeachCare (state insurance for low income children)</li> <li>Uninsured/Self pay</li> <li>Medicare</li> <li>Other</li> </ul>	Independent Categorical Variable
Age of Physician	Categorical variable of the physician's age at the time of survey	Independent Categorical Variable
Gender of Physician	Categorical variable of • Male • Female	Independent Categorical Variable

(Continued) Study Variables Description and Variable Type - HPV

## **Collection and Treatment of Data**

Data collection occurred between December 2010 and February 2011. Three steps were used to collect data (Table 3). In step one, key informants such as physicians, immunization nurses or office managers at each physician location were identified to determine the size of the practice

and who would complete the survey. At this stage, an electronic format for respondents (i.e., Survey Monkey) was created and uploaded onto a dedicated webpage. In step two, the physician or key informant who would respond to the survey for the physician was contacted to obtain his/her agreement to participate in the study. This was to inform participants about the internet survey site and to verify that all contact information (i.e., electronic/postal mail addresses and phone numbers) was correct. The third step involved second, third, and fourth survey mailing, postal mailing and follow-up phone calls (Appendices E, F, G, and H). An offer to complete a telephone survey with non-responders to maximize response rate was initiated during the month of January and occurred after the third phone call (Appendix I). Phone calls continued until all participants responded, or until the scheduled date for survey completion arrived – February 7, 2011.

#### Table 3:

Date	Activity
August/September 2010	Key information on Georgia physicians participating in VFC program
	identified
October 20 – 30, 2010	Survey Monkey format created for key informant survey
November 1, 2010	Survey posted to internet link
November 8, 2010	Phone calls and mail to physician responders begins
January 3 – January 31 2011	Follow-up phone calls and mail to non-responders
Week of February 7, 2011	Deadline for survey completion
Week of February 14, 2011	Data entry begins

#### Analysis and Interpretation of the Data

A survey instrument was administered to a sample of Georgia physicians in 14 public health districts in six urban and 18 rural counties. The survey was sent to the sample of 264 providers. Respondents were asked about their knowledge of the vaccine and if they administered the vaccine according to ACIP guidelines by offering it to females at 11-12 years of age and if they recommend it to males according to ACIP guidelines of "permissive use." Respondents were also asked to respond to barriers they perceived to be associated with this vaccine.

A final qualitative question was open-ended and allowed respondents to comment on their experience with the vaccine. Prevalence data were created for all dependent measures to determine the percentage of perceived knowledge, barriers, practices, and adherence to ACIP guidelines where appropriate. The qualitative data did not receive an in-depth analysis, but were used to augment findings and to record what may be useful to other providers and others who wish to offer a new vaccine or increase rates of immunization.

Quantitative data analysis was performed using SAS. Data came from a complex probability sample, and was summarized and analyzed using the SAS procedures, SurveyFreq, SurveyMeans, SurveyReg and SurveyLogistic. SAS procedure SurveySelect was used to help select the sample using a PPS without replacement design. As the data were the result of a complex probability based survey, results for strata and domains were generally presented in terms of confidence intervals which provide the most meaningful analysis. A logistic regression analysis was performed to determine what may influence a physician's decision to not recommend (dependent variable) HPV vaccine while payer type, physician barriers, and parental barriers served as the independent variables.

### **CHAPTER 4**

#### RESULTS

The purpose of this study was to examine the prevalence of Georgia physician intention and administration of the HPV vaccine to 11-12 year-old girls and intention to recommend the HPV vaccine to 11-12 year old boys. The study accessed perceived knowledge, barriers, practices, and adherence to ACIP guidelines and recommendations regarding HPV vaccination. The Health Belief Model (Champion & Skinner, 2008; Glantz, et al., 2008) was used to guide this study of Georgia physicians.

This chapter is organized into the following sections to present study results: (1) sample characteristics; (2) descriptive analysis of survey questions; (3) descriptive analysis for variables; (4) analysis of the research questions and hypotheses and analysis of variables associated with not recommending the HPV vaccine.

#### **Sample Characteristics**

A stratified single stage 100% cluster sample with counties being the cluster was performed. Two strata were formed, urban and rural. Sampling weights for the clusters were computed based on the number of providers within the county. The number of providers within a county divided by the number of providers in the state was the probability of a county being selected. The sampling weight is the inverse of the probability of selection. Once a cluster was selected then all providers within that county were included in the survey (hence 100% cluster sample). All computations were performed using SAS Proc SurveyMeans, Proc SurveyFreq and Proc SurveyLogistic.

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The initial sampling frame included 389 (N = 389) provider locations. Of these, 305 were located in six urban counties and 84 were in18 rural counties. Of the 389 physicians, 264 (67.9%) responded to telephone contact and stated they administered the HPV vaccine, 95 (24.4%) stated they did not administer the HPV vaccine and 30 (7.7%) were unable to be contacted by telephone or postal mail.

Of the 264 who administered the HPV vaccine, 62 (23.5%) were in 18 rural counties located in ten public health districts and 202 (76.5%) were in six urban counties located in ten public health districts. These 264 providers served as the study's population for HPV survey administration (n=264).

There were 42 physician locations (17.4%) that did not respond to the request to take part in the survey. Thirty eight (14.4%) of the 42 stated their refusal to participate when contacted and the remaining eight (3%) could not be contacted by telephone or postal mail. There were 218 physicians or key informants who could represent the physician in the Georgia study population who positively responded to the survey questionnaire yielding a response rate of 82.6%. Of the 218 respondents, 15 (6.8%) responded through Survey Monkey, 72 (33%) responded though the postal mail and 131 (60.1%) responded by telephone survey. Table 4 displays the method by which the 214 physicians responded to the survey questionnaire.

Table 4:

Variable	п	Percent
Survey Monkey	15	5.7
Postal Mail survey	72	33
Telephone survey	131	60.1
Responded to survey	218	100

Method by Which Physicians Responded to Survey

Demographic variables of the respondents were obtained; however, not all respondents answered all questions in the survey. The variables of race, ethnicity, gender, and years in practice were included in the survey. Respondents were predominantly white (109 or 51.4%) followed by Asian respondents (48 or 22.6%) followed by African American (39 or 18.4%). There were 10 (7.3%) who preferred not to answer and seven (3.3%) who listed their race as *other*. Six of the 218 did not respond to this question.

Most respondents (190 or 90.5%) self identified as non Hispanic or Latino. Two hundred ten (96.3%) responded to the question of gender with slightly more male's (107 or 51%) than female's (103 or 49%). Forty four physicians (25%) had been in practice 0-9 years, followed by 65 (36.9%) in practice from 10-19 years. Forty-one physicians (23.3%) had been in practice 20 – 29 years and 26 (18.8%) had been in practice for 30 years or more. Table 5 displays the demographic characteristics.

Table 5:

Physician	<i>Demographic</i>	<i>Characteristics</i>

Variable	n	Percent
Race		
White	109	51.4
Asian	48	22.6
Black or African American	39	18.4
Prefer not to answer	10	4.7
Other	7	3.3
Responded to question (one responded in two categories)	212	100%
Hispanic/Latino		
Identified as Hispanic or Latino	20	9.5
Did not identify as Hispanic or Latino	190	90.5
Responded to question	210	100%
Years in Practice		
0-9 years	44	25
10-19 years	65	36.9
20-29 years	41	23.3

Variable	n	Percent
>30 years	26	18.8
Responded to question	176	100%
Physician Gender		
Male	107	51%
Female	103	49%
Responded to question	210	100%

Information on physician practice variables was obtained. The majority of respondents (182 or 85%) were in a single practice specialty, followed by 27 (12.7%) in multi-specialty practices. Three (1.4%) respondents listed *other* for practice characteristics. These were Federally Qualified Health Clinics or medical clinics associated with a teaching hospital with physician oversight.

Two hundred thirteen responded to the question on primary clinical practice specialty. Sixty eight (31.9%) identified their specialty as Family Medicine, seven (3.3%) identified as Internal Medicine, and seven (3.3%) identified as Obstetricians/Gynecologists. The majority (126 or 59%) identified as pediatricians. Approximately 2.3% self identified as *other*.

Most physicians (102 or 47.9%) were in a solo practice, meaning they were the only physician in their respective practices. Ninety-two (43.2%) were in practice with as many as four other physicians. Ten (4.7%) respondents practiced with six to nine other physicians. Five (1.4%) were in practice with as many as 25 other physicians and one practice (0.5%) reported over 26 physicians. For the purposes of this research, resident physicians, nurse practitioners and physician assistants working with the physician were excluded.

Reimbursement in various forms was accepted by most physicians. Of the 206 who responded to this question, private insurance and Medicaid was accepted by all physicians at practice locations. The Georgia Children's Health Insurance or PeachCare was accepted by 202 physicians (98%). Uninsured or patients paying for services themselves were accepted by 204 physicians (99%) and Medicare was accepted by 195 physicians (94.6%). Other forms of payment (such as military reimbursement) were accepted by 81.5% of physicians.

Urban or rural classification was coded by the researcher after all surveys were submitted. Using the definition from by the Georgia Office of Rural Health (2002), 176 physicians (80.7%) practiced in an urban county and 42 (19.3%) practiced in a rural county. If the physician or key informant completing the survey questionnaire for the physician had a practice in more than one location, the respondent was asked to complete the survey by answering questions as if it pertained only to that practice location. For example, if the physician gave HPV vaccine to males at one location but did not administer the vaccine at the location that received the survey, the physician or key informant was asked to answer survey questions at it pertained to the location that received the survey. Table 6 displays demographic variables of the physician's practice.

Table 6:

Variable	n	Percent
Practice Characteristics		
Single specialty	182	85.8
Multi specialty	27	12.7
Other	3	1.4
Responded to question	212	100%
Practice Classification		
Family Medicine	68	31.9
Internal Medicine	7	3.3
Obstetrics/Gynecology	7	3.3
Pediatrics	126	59.2
Other	5	2.3
Responded to question	213	100

Physician Practice Demographic Characteristics

Variable	п	Percent
Physicians at Location		
1	102	47.9
2-5	92	43.2
6-9	10	4.7
10-14	3	1.4
15-25	5	2.3
> 26	1	0.5
Responded to question	213	100
Reimbursement Accepted by Practice	206	100
Private insurance	206	100
Medicaid	202	98
PeachCare of Georgia	204	99
Uninsured/Self-pay	195	94.6
Medicare	168	81.5
Other (example: Military)		
	206	100
Responded to question		
County classification		
Urban	176	80.7
Rural	42	19.3
Coded by researcher	218	100%

### **Descriptive Analysis of Survey Questions**

Nine items assessing valued sources of information about HPV vaccine are shown in Table 7. Most of the 215 respondents (94.4%) indicated professional organization was a source of information on HPV vaccine. The ACIP as a source was reported by 92.1%). State and local immunization programs were noted by 197 respondents (92.5%) and information from the HPV pharmaceutical representatives (92.5%) was a reported source of HPV information. Going to colleagues (86.4%), internet websites (81.5%), and medical conferences (77.9%) were not as valued. Least valued were media sources (44.1%) and grand rounds or location institution lectures (27.2%) by respondents.

Table 7:

Sources of Information

Variable	n	Percent
Valuable sources of information about HPV vaccination		
Professional Organizations (e.g., AAFP, ACOG, AAP, SGIM)	203	94.4
Advisory Council of Immunization Practice (ACIP)	198	92.1
State and local immunization programs	197	92.5
Colleagues	184	86.4
Pharmaceutical representative	197	92.5
Internet websites	174	81.5
Media	94	44.1
Medical conferences	166	77.9
Grand rounds/local institutional lectures	58	27.2
Responded to question	215	100%

Seven items assessing knowledge about HPV vaccine were determined. Of the 214 respondents, 164 (76.7%) knew HPV infections resolved without medical intervention, 184 (86.4%) knew HPV was a common sexually transmitted disease, and 192 (90.6%) knew HPV caused genital warts in males and females. The FDA approval of the vaccine for use in females ages 9-26 was known by 208 (97.2%) while 169 (79.3%) knew that a previous HPV infection did not preclude a female from being vaccinated. Lastly, the FDA approval of the vaccine for males for permissive use for ages 9-26 years was known by 200 (94.8%) of the respondents. The seven items assessing knowledge about HPV vaccine are shown in Table 8.

Table 8:

Knowledge About HPV

Variable	п	Percent
Knowledge items (correct)		
Most HPV infections resolve without medical interventions	164	76.7
HPV is a relatively common sexually transmitted disease	184	86.4
HPV causes genital warts in males and females	192	90.6
Almost all cervical cancers are caused by HPV infection	195	91.1
The FDA approved the quadrivalent HPV vaccine for use in females ages 9-26	208	97.2
Females diagnosed with HPV infection can be given the vaccine	169	79.3
The FDA approved the quadrivalent HPV vaccine for use in males ages 9-26	200	94.8
Responded to question	214	100%

Barriers to vaccination attributed to the physician were assessed through 12 items. The responses of *sometimes*, *often* and *always* were summed to achieve the number of physicians who perceived these as barriers to administering the HPV vaccine. A total of 212 responded as illustrated in Table 9. Of those who responded, 21 (9.9%) were concerned about vaccine safety and 22 (10.3%) were concerned about the efficacy of the HPV vaccine. Administering a new vaccine with a limited track record of safety was a barrier to 32 physicians (15.1%) and 22 physicians (10.3%) believed adding another vaccine to the vaccine schedule was a barrier. Lack of information about the vaccine was perceived as a barrier by 12.7% of the respondents.

The initial cost, or upfront cost of purchasing the vaccine was considered a barrier among 129 respondents (60.8%) and 134 respondents (63.2%) believed cost of stocking the vaccine to be a barrier to their practice. Lack of adequate reimbursement for the vaccine was considered a barrier among 136 respondents (64.2%) and failure of some insurance companies to cover the cost of vaccination was a barrier among 126 respondents (59.4%). Only 40 respondents (18.7%)

considered the time it takes to discuss the vaccine with parents or patients to be a barrier.

Moreover 90 respondents (42.5%) believed that ensuring the completion of the 3-dose series to

be a barrier. HPV vaccination not being a requirement for school attendance was perceived to be

a barrier among 15.1% of those responding.

Table 9:

Barriers to	> HPV	Vaccination	– Physician
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Variable	n	Percent
Barriers related to immunizing against HPV		
Concerns about vaccine safety	21	9.9
Concerns about vaccine efficacy	22	10.3
Administering a new vaccine with a limited track record of safety	32	15.1
Adding another vaccine to the vaccine schedule	22	10.3
Lack of information about the vaccine	27	12.7
Up front cost of purchasing private stock vaccine	129	60.8
Cost of stocking the vaccine	134	63.2
Lack of adequate reimbursement for the vaccine	136	64.2
Failure of some insurance companies to reimburse the vaccine	126	59.4
Time to discuss the vaccine with parents and/or patients	40	18.7
Difficulty ensuring 3-dose vaccine compliance	90	42.5
Vaccine is not required for school attendance	34	15.1
Responded to the question	212	100

Twelve barriers to vaccination attributed to the parent were assessed. The responses of *sometimes, often,* and *always* were summed to achieve the number of physicians who perceived these to be barriers recognized by the parent as not allowing the male or female child to be vaccinated. A total of 208 physicians, or key informants, who responded as the physician, completed this section. Of those who responded, 137 (65%) believed the parent had concerns about vaccine safety and 78 respondents (37.5%) believed the parent had concerns about vaccine efficacy. A larger group (77.9%) believed parents were reluctant to discuss sexuality or sexually transmitted infections, while 145 respondents (69.7%) indicated parental concerns that their child would assume approval of premarital sex if the parent agreed to vaccination. Lack of parental

education or understanding about the vaccine was given by 173 respondents (84.3%) and 168 respondents (80.8%) believed the parent thought their child was not at risk for HPV infection. Parental consent to vaccination was not considered a significant barrier and was given by 121 respondents (58.2%). Parent opposition to HPV vaccination for moral or religious reasons appeared to be the least important barrier as indicated by 53 respondents (25.5%). Physicians who believed parents thought their child was too young for vaccination numbered 168 (80.8%) and parental concern about negative media reports related to the HPV vaccine was low (40.4%). Table 10 displays parental barrier variables to HPV vaccine.

Table 10:

Variable	n	Percent
Barriers related to immunizing against HPV		
Concerns about vaccine safety	137	65
Concerns about vaccine efficacy	78	37.5
Reluctance to discuss sexuality/sexually transmitted infections	162	77.9
Concern adolescent will assume that parent who agrees to	145	69.7
vaccination condones premarital sex		
Concern vaccinated child will practice riskier sexual behaviors	144	69.2
Lack of education/understanding of HPV infection	173	83.2
Request that vaccination be deferred	187	89.9
Belief that adolescent is not a risk for HPV infection	168	80.8
Will not consent to vaccination	121	58.2
Opposition to vaccination for moral or religious reasons	53	25.5
Belief that adolescent is too young for vaccination	168	80.8
Concern about negative media reports related to vaccine	84	40.4
Responded to the question	208	100

Respondents were asked if they recommended the HPV vaccine, as well as the patient's age when the recommendation was made. Responses are profiled in Table 11. Of the 209 who responded for 9-10 year old females, 58 (27.8%) reported they never offer the vaccine at this age, 57 (27.3%) offered it rarely and 30 (14.4%) indicated they sometimes offered the vaccine.

Twenty-three (11.0%) reported they offered the vaccine often and 34 (16.3%) reported they always offered the HPV vaccine to female patients in this age group. Seven (3.3%) responded they did not see patients in this age group.

Of the 210 who responded regarding their 11-12 year old female patients, 10 (4.8%) reported they never offer the vaccine at this age, 30 respondents (14.3%) offered it rarely and 19 respondents (9.0%) sometimes offered the vaccine. Forty respondents (19.0%) reported they offered the vaccine often and 106 (50.5%) reported they always offered the HPV vaccine to female patients in this age group. Five respondents (2.4%) indicated they did not see patients in this age group.

Of the 209 who responded regarding their 13-17 year old females, none (0%) reported they never offer the vaccine at this age indicating they offer the vaccine to females at this age. Only 2 (1%) did so rarely and 17 (8.1%) responded they sometimes offered the vaccine. Forty-four respondents (21.1%) reported they offered the vaccine often and 50.5% of respondents reported they always offered the HPV vaccine to female patients in this age group. Five (2.4%) responded they did not see patients in this age group.

Of the 207 who responded for 18-26 year old females, none (0%) reported they never offer the vaccine indicating they offer to all females at this age. Only 4 (1.9%) did so rarely and 15 (7.2%) responded they offered the vaccine sometimes. Thirty-three (15.9%) reported they offered the vaccine often and 53.6% physicians reported they always offered the HPV vaccine to female patients in this age group. Forty-four (21.3%) responded they did not see patients in this age group.

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### Table 11:

	9-10 y	11-12 у	13-17 y	18-26 y
	n (%)	n (%)	n (%)	n (%)
Never (never recommend)	58 (27.8)	10 (4.8)	0 (0.0)	0 (0.0)
Rarely (recommend 1-25%)	57 (27.3)	30 (14.3)	2 (1.0)	4 (1.9)
Sometimes (recommend 26-50%)	30 (14.4)	19 (9.0)	17 (8.1)	15 (7.2)
Often (recommend 51-75%)	23 (11.0)	40 (19.0)	44 (21.1)	33 (15.9)
Always (recommend >76%)	34 (16.3)	106 (50.5)	146 (69.9)	111 (53.6)
Do not see patients in this age group	7 (3.3)	5 (2.4)	0 (0.0)	44 (21.3)
Responded to question	209	210	209	207

#### Recommend HPV Vaccine to Girls by Age Group

Respondents were then asked at what age they administered at least one dose of HPV vaccine to their female patients. Responses to this question are illustrated in Table 12. Of the 210 who responded for 9-10 year old females, 79 (37.6%) reported they never administer the vaccine at this age, approximately one-third (33.8%) did so only rarely and 31 (14.8%) responded they offered the vaccine sometimes. Sixteen (7.6%) reported they offered the vaccine often and 34 (16.3%) reported they always administered the HPV vaccine to female patients in this age group. Seven (3.3%) responded they did not see patients in this age group.

Of the 209 who responded for 11-12 year old females, 17 (8.1%) reported they never administered the vaccine to female patients at this age, 48 respondents (23%) did so only rarely and 51 respondents (24.4%) indicated they administered the vaccine sometimes. Approximately one-third (30.1%) reported they administered the vaccine often and 25 respondents (12%) indicated they always administered the HPV vaccine to female patients in this age group. Five respondents (2.4%) indicated they did not see patients in this age group. Of the 210 who responded for 13-17 year old females, none (0%) reported they never administered the vaccine at this age indicating all respondents administer to females at this age. Although 10 respondents (4.8%) indicated they offered it rarely and approximately one-third (31.9%) responded they administered the vaccine sometimes. Eighty-five (40.5%) reported they administered the vaccine often and 106 (50.5%) reported they always administered the HPV vaccine to female patients in this age group. Five (2.4%) responded they did not see patients in this age group.

Of the 208 who responded for 18-26 year old females, none of the physicians (0%) reported they never administered the vaccine indicating all administer the vaccine to all females at this age. Fourteen (6.7%) did so rarely and approximately one-fourth (24%) responded they offered the vaccine sometimes. Approximately one-third (32.7%) reported they offered the vaccine often and 34 physicians (16.3%) reported they always offered the HPV vaccine to female patients in this age group. Forty-two (20.2%) responded they did not see patients in this age group.

#### Table 12:

	9-10 y	11-12 у	13-17 y	18-26 y
	n (%)	n (%)	n (%)	n (%)
Never (never administered)	79 (37.6)	17 (8.1)	0 (0.0)	0 (0.0)
Rarely (administered 1-25%)	71 (33.8)	48 (23.0)	10 (4.8)	14 (6.7)
Sometimes (administered 26-50%)	31 (14.8)	51 (24.4)	67 (31.9)	50 (24.0)
Often (administered 51-75%)	16 (7.6)	63 (30.1)	85 (40.5)	68 (32.7)
Always (administered >76%)	6 (2.9)	25 (12.0)	48 (22.9)	34 (16.3)
Do not see patients in this age group	7 (3.3)	5 (2.4)	0 (0.0)	42 (20.2)
Responded to question	210	209	210	208

#### Administer HPV to Girls by Age Group

Parental refusal to allow their daughters to be vaccinated is a barrier. Respondents were then asked if parents refused to allow their daughters to be vaccinated when the physician offered or recommended the HPV vaccine, and at what age did refusal occur. Responses are illustrated in Table 13. Of the 202 who responded for 9-10 year old females, seven physicians (3.5%) reported they never experienced a parent who refused to have their daughter vaccinated with the HPV vaccine once it was offered. Twelve (5.9%) indicated this occurred only rarely and 41 (20.3%) responded this sometimes. Over one-fourth (25.7%) reported they experienced this often and 83 (41.1%) reported they always experienced refusal with this age group. Seven (3.3%) responded they did not see patients in this age group.

Of the 205 who responded for 11-12 year old females, three physicians (1.5%) reported they never experienced a parent who refused to have their daughter vaccinated with the HPV vaccine once it was offered. Thirty-eight (18.5%) indicated this occurred only rarely and 88 (42.9%) responded this occurred sometimes. Over one-fourth (25.4%) reported they experienced this often and only 19 physicians (9.3%) reported they always experienced refusal with this age group. Five (2.4%) responded they did not see patients in this age group. Of the 208 who responded for 13-17 year old females, seven physicians (3.4%) reported they never experienced a parent who refused to have their daughter vaccinated with the HPV vaccine once it was offered. Approximately one-third (34.1%) indicated vaccine refusal occurred only rarely and over half (55.8%) responded this occurred sometimes. Twelve respondents (5.8%) reported they and over half (55.8%) reported often and few (1.0%) reported they always experienced refusal with this age group.

Of the 207 who responded for 18-26 year old females, eight physicians (3.9%) reported they never experienced a parent who refused to have their daughter vaccinated with the HPV vaccine

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once it was offered. Approximately one-third (30%) indicated this occurred only rarely and 86 (41.5%) responded this occurred sometimes. Seven (3.4%) reported they experienced this often and few (1.0%) reported they always experienced refusal with this age group. Forty-two physicians (20.3%) did not see female patients in this age group.

#### Table 13:

	9-10 y  n (%)	11-12 y  n (%)	13-17 y  n (%)	18-26 y  n (%)
Never (never refused)	7 (3.5)	3 (1.5)	0 (0.0)	0 (0.0)
Rarely (refused 1-25%)	12 (5.9)	38 (18.5)	10 (4.8)	14 (6.7)
Sometimes (refused 26-50%)	41 (20.3)	88 (42.9)	67 (31.9)	50 (24.0)
Often (refused 51-75%)	52 (25.7)	52 (25.4)	85 (40.5)	68 (32.7)
Always (refused >76%)	83 (41.1)	19 (9.3)	48 (22.9)	34 (16.3)
Do not see patients in this age group	7 (3.5)	5 (2.4)	0 (0.0)	42 (20.2)
Responded to question	202	205	208	207

Parental Refusal of HPV Vaccine to Girls by Age Group

The ACIP recommends optional HPV vaccination for males to protect them from genital warts, although the ACIP stopped short of recommending routine use in males. Of the 211 who responded for 9-10 year old males, 86 physicians (40.8%) reported they never recommend their male patients receive the HPV vaccine. Forty-nine (23.2%) did so only rarely and 23 (10.9%) responded they offered the vaccine sometimes. Twenty-two (10.4%) reported they offered the vaccine often and 23 (10.9%) reported they always offered the HPV vaccine to male patients in this age group. Eight (3.4%) responded they did not see patients in this age group.

Of the 211 who responded regarding their 11-12 year old male patients, 49 respondents (23.2%) reported they never offer the vaccine at this age, 34 respondents (16.1%) did so only rarely and 29 respondents (13.7%) indicated they offered the vaccine sometimes. Forty-one (19.4%) reported they offered the vaccine often and 50 (23.7%) reported they always offered the

HPV vaccine to male patients in this age group. Eight (3.8%) responded they did not see patients in this age group.

Of the 208 who responded regarding their 13-17 year old males, 37 (17.8%) reported they never offer the vaccine at this age. Thirty-two (15.4%) did so rarely and 34 (16.3%) responded they offered the vaccine sometimes. Forty-two (20.2%) reported they offered the vaccine often and slightly over one-fourth (26.9%) reported they always offered the HPV vaccine to male patients in this age group. Seven (3.4%) responded they did not see patients in this age group.

Of the 210 who responded for 18-26 year old males, 29 physicians (13.8%) reported they never offer the vaccine to all males at this age. Thirty-three physicians (15.7%) did so rarely and 25 (11.9%) responded they offered the vaccine sometimes. Thirty (14.3%) reported they offered the vaccine often and 47 physicians (22.4%) reported they always offered the HPV vaccine to male patients in this age group. Forty-six (21.9%) responded they did not see patients in this age group. Responses are profiled in Table 14.

### Table 14:

	9-10 y	11-12 y	13-17 y	18-26 y
	n (%)	n (%)	n (%)	n (%)
Never (never recommend)	86 (40.8)	49 (23.2)	37 (17.8)	29 (13.8)
Rarely (recommend 1-25%)	49 (23.2)	34 (16.1)	32 (15.4)	33 (15.7)
Sometimes (recommend 26-50%)	23 (10.9)	29 (13.7)	34 (16.3)	25 (11.9)
Often (recommend 51-75%)	22 (10.4)	41 (19.4)	42 (20.2)	30 (14.3)
Always (recommend >76%)	23 (10.9)	50 (23.7)	56 (26.9)	47 (22.4)
Do not see patients in this age group	8 (3.8)	8 (3.8)	7 (3.4)	46 (21.9)
Responded to question	211	211	208	210

Recommend HPV Vaccine to Boys by Age Group

## **Analysis of Research Questions and Hypotheses**

## **Research Question #1**

What barriers do Georgia physicians enrolled in the Vaccine for Children (VFC) program perceive when providing the Human Papillomavirus Virus (HPV) vaccine to their female patients?

For those physicians that responded, 64.2% believed the most important barrier for not vaccinating was lack of adequate reimbursement for HPV vaccination. This was followed by 63.2% citing the cost of stocking the HPV vaccine, 60.8% believed the upfront or initial cost of purchasing the private stock HPV vaccine, and 59.4% believed the failure of some insurance companies to cover the cost of the vaccine was a barrier. Difficulty ensuring that patients will complete the 3-dose HPV vaccination series was cited as a barrier by 42.5% of respondents. Barriers dropped sharply with 18.7% indicating the time it takes to discuss HPV vaccination with patients and or parents as a barrier. Administering a new vaccine with a limited track record of safety was a barrier to only 15.1% of respondents and lack of information was a barrier to 12.7% of respondents. Adding another vaccine to the vaccine schedule and concerns about efficacy of the HPV vaccine was a barrier to 10.3% respectively. Only 9.9% had concerns about the safety of the HPV vaccine.

The most significant parental barrier to vaccination according to physicians was the request that HPV vaccine be deferred until the female patient was older. This barrier was noted by 89.9% of respondents followed by lack of education/understanding of the HPV vaccine (83.2%). Physicians noted parental belief that the daughter was too young and the barrier that they believed the daughter was not at risk for HPV infection were 80.8% respectively. Reluctance to discuss sexuality or sexually transmitted infections by the parent was 77.9%. This was followed by 69.7% believing parental concern that the adolescent assumed parents who agree to HPV vaccination condone premarital sex. Slightly more than two-thirds or 69.2% believed parent has concerns that the vaccinated adolescent would practice riskier sexual behaviors. Parental concern about vaccine safety was noted by 65% of the respondents. Refusal to consent to have the adolescent vaccinated was a barrier of 58.2% respondents. Parental concerns about negative media reports related to the HPV vaccine was a barrier to only 40.4% and parental concern about vaccine efficacy was a concern to 37.5%.

In summary, barriers to HPV vaccination for physicians focused on the cost of purchasing and storing the vaccine by the physician and lack of adequate reimbursement. The physician time it takes to talk about or educate about the vaccine was viewed as less of a barrier. The least mentioned barrier was parental opposition to HPV vaccination for moral or religious reasons.

The most important barrier for parents toward HPV vaccination was the parental request that vaccination be deferred. This barrier was followed by lack of education or understanding of the vaccine. Many physicians cited as a common barrier the parents' belief that their female child was not a risk for HPV infection.

#### **Research Question #5:**

What differences will emerge when the data are analyzed by urban vs. rural characteristics?

To answer research question #5, Hypothesis #1 was tested.

# **Hypothesis #1:**

No statistical differences will be detected between perceived barriers by physicians enrolled in the VFC program who provide the HPV vaccine to females and geographic setting (urban vs. rural). Due to missing cells in the response categories, tests of hypothesis could not be performed, however estimates of proportions and their standard errors were calculated and no statistical significance was detected between perceived barriers by physicians enrolled in the VFC program that provide the HPV vaccine to females, and geographic setting. Estimates of proportions and their standard errors to physician perceived barriers are listed in Table 15 and estimates of proportions and their standard error to parental barriers are listed in Table 16. Since confidence intervals were overlapping across response categories between urban and rural practice setting, no statistical differences were detected

Table 15:

Responses to	Question	#3
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	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
Concern about vaccine safety Q3A Rural Q3A Urban	.4 (.317, .484) .442 (.326, .558)	.4 (.316, .483) .255 (.17, .341)	.18 (.103, .257) .19 (.096, .284)	.02 (0, .053) .109 (.042, .176)	0 - .003 (.0, .007)
Concern about vaccine efficacy Q3B Rural Q3B Urban	.381 (.297, .464) .407 (.292, .521)	.4 (.33, .47) .289 (.196, .381)	.18 (.11, .25) .191 (.098, .285)	.04 (0, .087) .109 (.042, .177)	0 .003 (.0, .007)
Administering a new vaccine with limited safety track record Q3C Rural Q3C Urban	.262 (.186, .337) .162 (.091, .233)	.478 (.396, .561) .371 (.264, .478)	.18 (.103, .257) .291 (.197, .384)	.08 (.014, .146) .177 (.09, .263)	0 - 0 -
Adding another vaccine to schedule Q3D Rural Q3D Urban	.302 (.228, .375) .188 (.104, .272)	.395 (.325, .464) .333 (.227, .440)	.244 (.163, .324) .347 (247, .446)	.06 (.013, .107) .117 (.04, .195)	0 .015 (.002, .028)
Lack of information about the vaccine Q3E Rural Q3E Urban	.162 (.085, .239) 298	.524 (.44, .607) .373	.264 (.174, .354) .175	.051 (.001, .101) .154	0 - 0

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
	(.193, .402)	(.262, .484)	(.11, .241)	(.074, .234)	-
Upfront cost of purchasing vaccine Q3F Rural Q3F Urban	0 - .044 (0, .091)	.119 (.072, .166) .035 (.018, .051)	.319 (.232, .406) .18 (.096, .263)	.411 (.325, .497) .601 (.492, .711)	.151 (.076, .226) .14 (.06, .221)
Cost of stocking vaccine Q3G Rural Q3G Urban	0 - .046 (0, .092)	.099 (.066, .132) .036 (.0175, .054)	.279 (.201, .356) .13 (.064, .196)	.471 (.385, .557) .643 (.543, .744)	.151 (.071, .23) .145 (.061, .23)
Lack of reimbursement Q3H Rural Q3H Urban	0 .043 (0, .089)	.105 (.07, .14) .033 (.002, .064)	.318 (.228, .407) .167 (.094, .241)	.306 (.203, .409) .511 (.395, .626)	.271 (.17, .372) .246 (.146, .347)
Failure of some insurance to pay Q3I Rural Q3I Urban	0 .035 (0, .080)	.163 (.097, .228) .044 (.011, .078)	.330 (.251, .408) .217 (.131, .304)	.336 (253, .42) .467 (.354, 581)	.171 (.085, .257) .236 (.136, .336)
Time it takes to talk about the vaccine Q3J Rural Q3J Urban	0 .036 (.018, .054)	.384 (.297, .47) .357 (.245, .469)	.426 (.35, .501) .448 (.342, .553)	.191 (.108, .274) .158 (.078, .237)	0 - .002 (0, .004)
Difficulty ensuring patient completes 3- dose series Q3K Rural Q3K Urban	.020 (0, .054) .072 (.015, .130)	.174 (.108, .24) .260 (.154, .365)	.261 (.183, .339) .258 (.158, .358)	.524 (.424, .624) .362 (.253, .472)	.020 (0, .054) .048 (0, .095)
Not required for school attendance Q3L Rural Q3L Urban	.060 (.003, .117) .075 (.019, .132)	.043 (.347, .512) .205 (.121, .288)	.202 (.145, .258) .451 (.342, .56)	.265 (.188, .341) .201 (.129, .273)	.044 (0, .096) .068 (.007, .129)

## Table 16:

# Responses to Question #4

	Never 0%	Rarely 1-25%	Sometimes 26-29%	Often 51-75%	Always >75%
Concern about vaccine safety Q4A Rural Q4A Urban	.011 (0, .029) .030 (0, .081)	.359 (.277, .442) .340 (.228, .451)	.474 (.386, .563) .537 (.422, .652)	.135 (.06, .209) .088 (.049, .127)	.020 (0, .054) 0 -
Concern about vaccine efficacy Q4B Rural Q4B Urban	.052 (.009, .094) .078 (.016, .141)	.476 (.386, .566) .570 (.456, .684)	.400 (.323, .477) .308 (.2, 417)	.052 (.001, .103) .043 (.009, .078)	.020 (0, .054) 0 -
Reluctance to discuss sexuality/STI Q4C Rural Q4C Urban	.020 (.02, .02) .003 (0, .007)	.217 (.137, .298) .223 (.128, .318)	.574 (.466, .682) .457 (.353, .562)	.168 (.084, .253) .314 (.208, .421)	.020 (0, .054) .002 (0, .004)
Concern adolescent will assume parent condones premarital sex Q4D Rural	0-	.247 (.162, .332)	.692 (.598, .787)	.061 (.014, .108)	0-
Q4D Urban	.030 (0, .08)	.341 (.232, .45)	.428 (.321, .535)	.198 (.104, 292)	.001 (0, .004)
Concern adolescent will practice riskier sexual behavior Q4E Rural	0	.267 (.176, .359)	.539 (.437, .641)	.194 (.143, 245)	0-
Q4E Urban	.035 (0, .081)	.352 (.243, .462)	.417 (.31, .524)	.196 (.111, .281)	0
Lack of parental education Q4F Rural	0	.182 (.107, .257)	.361 (.265, .457)	.364 (.268, .461)	.092 (.031, .153)
Q4F Urban	0-	.183 (.091, .275)	.345 (.247, .442)	.346 (.238, .454)	.126 (.048, .205)
Request vaccine be deferred Q4G Rural Q4G Urban	0	.112 (.073, .15) .161 (.071, .251)	.472 (.382, .562) .469 (.36, .579)	.416 (.328, .504) .331 (.24, .423)	0 .038 (0, .084)
Belief adolescent not at risk Q4H Rural Q4H Urban	0 - 0	.162 (.103, .22) .221	.398 (.303, .492) .348	.441 (.352, .529) .395,	0 .037

	Never 0%	<b>Rarely</b> 1-25% (.123, .318)	Sometimes 26-29% (.255, .44)	Often 51-75% (.285, .505)	Always >75% (0, .083)
Parent won't consent to vaccine Q4I Rural Q4I Urban	0 .028 (0, .073)	.374 (.246, .502) .401 (.286, .516)	.539 (.404, .673) .485 (.377, .594)	.087 (.015, .159) .054 (.006, .101)	0 - .033 (0, .078)
Opposition for moral or	.278	.479	.222	.020	0
religious reasons	(.191, .365)	(.385, .574)	(.155, .29)	(0, .054)	-
Q4J Rural	.319	.415	.194	.071	.002
Q4J Urban	(.211, .426)	(.305, .525)	(.107, .28)	(.006, .136)	(0, .004)
Belief adolescent is too	0	.296	.581	.124	0
young	-	(.235, .356)	(.493, .668)	(.053, .194)	-
Q4K Rural	.007	.182	.329	.472	.009
Q4K Urban	(0, .018)	(.089, .276)	(227, .43)	(.355, .589)	(0, .02)
Concern about negative	.122	.487	.371	.02	0
media reports	(.122, .122)	(.418, .556)	(.304, .437)	(0, .054)	-
Q4L Rural	.024	.585	.371	.018	.002
Q4L Urban	(0, .054)	(.474, .696)	(.259, .484)	(.005, 030)	(0, .004)

## **Research Question #2:**

What knowledge do Georgia physicians enrolled in the VFC program have when providing the HPV vaccine to their female patients?

To answer this research question, seven items assessing knowledge about HPV vaccine were asked of the respondents. The majority of respondents answered the seven questions correctly. Most physicians (97.2%) answered correctly that the FDA approved the quadrivalent HPV vaccine for use in females aged 9-26 years of age. This was followed by 94.8% who knew the FDA has approved the quadrivalent HPV vaccine for use in males for the same age group. Also receiving a high correct response (91.1%) were those who knew almost all cervical cancers are cause by HPV infections and 90.6% were correct that HPV causes genital warts in males and females. The fact that HPV was a relatively common sexually transmitted disease was known

by 86.4%. Seventy-nine point three percent of respondents were aware that females with a diagnosis of HPV infection can still receive the HPV vaccine. The question receiving the lowest correct score of 76.7% asked if respondents were aware that most HPV infections resolve without medical intervention. The findings from this survey suggest knowledge of HPV and HPV vaccine were well known by the majority of respondents.

## **Research Question #5:**

What differences will emerge when the data are analyzed by urban vs. rural characteristics?

To answer research question #5, Hypothesis #2 was tested.

## **Hypothesis #2:**

No statistical differences will be detected between perceived knowledge of physicians enrolled in VFC program who provide the HPV vaccine to females and geographic setting (urban vs. rural).

Due to missing cells in the response categories, tests of hypothesis could not be performed. However estimates of proportions and their standard errors were calculated and no statistical significance was detected between perceived knowledge of physicians enrolled in VFC program who provide the HPV vaccine to females and geographic setting. Since confidence intervals were overlapping across response categories between urban and rural practice settings, no statistical differences were detected.

Estimates of proportions and their standard errors to physician perceived barriers are listed in Table 17.

# Table 17:

# Responses to Question #2

Question	True	False	Unsure
Most HPV infections resolve w/out medical intervention (TRUE) Q2A Rural	.818 (746, .890)	.067 (.010, .125)	.114 (.069, .159)
Q2A Urban	.790	.101	108
	(.703, .878)	(.043, .159)	(.036, .180)
HPV is a relatively uncommon sexually transmitted infection (FALSE) Q2B Rural	.190 (.124, .258)	.771 (.704, .838)	.038 (0, .083)
Q2B Urban	.082	.896	.021
	(.019, .145)	(.832, .960)	(.007, .036)
HPV causes genital warts in males and	.881	.042	.077
females (TRUE)	(.822, .940)	(0, .091)	(.045, .108)
Q2C Rural	.898	.065	.036
Q2C Urban	(.834, .963)	(.009, .120)	(.002, .070)
Almost all cervical cancers are caused by HPV infections (TRUE) Q2D Rural	.874 (.805, .943)	.038 (0, . 083)	.087 (.034, .140)
Q2D Urban	.929	.039	.031
	(.873, .986)	(0, .085)	(0, .064)
FDA approved HPV vaccine for use in females age 9-26 (TRUE) Q2E Rural	.943 (.892, .993)	.019 (0, .050)	.038 (0, .077)
Q2E Urban	.978	.020	.001
	(.946, 1.0)	(0, .052)	(0, .004)
<i>Females diagnosed with HPV infection</i> <i>should not be given the vaccine (FALSE)</i> Q2F Rural	.019 0, .050)	.817 (.748, .886)	.164 (.102, .225)
Q2F Urban	.066	.776	.158
	(.002, .128)	(.679, .874)	(.077, .240)
FDA approved HPV vaccine for use in males for permissive use for ages 9-26 (TRUE) Q2G Rural	.943 (.893, .993)	0-	.057 .007, .107
Q2G Urban	.951	.036	.013,
	(.903, 1)	(0, .083)	(.002, .024)

## **Research Question #3:**

What percentage of Georgia physicians enrolled in the VFC program administers the HPV vaccine to their female patients according to Advisory Committee on Immunization Practices (ACIP) published guidelines by providing the vaccine to their 11 - 12 year old patients?

ACIP guidelines recommend administering the vaccine to females between the ages of 11-12 years of age (CDC, 2008). To answer this research question, respondents were asked if they administered the vaccine to 11-12 year olds in their practice. Of those who responded, only 12% said they always administer the vaccine to this age group. A response of always indicated the vaccine was given to more than 75% of female patients between the ages of 11-12 years. Approximately 31.1% of respondents state they often administer the vaccine to this age group. A response of often indicated the vaccine was given to 51-75% of female patients between the ages of 11-12 years. One quarter of respondents (24.4%) administered the vaccine sometimes to this age group. A response of *sometimes* indicated the vaccine was given to 26 -50% of female patients between the ages of 11-12 years. Respondents who rarely administer the vaccine to this age group were 23%. A response of *rarely* indicated the vaccine was given to 1 - 25% of female patients between the ages of 11-12 years. Physicians who never administer the vaccine to any females in this age group were 8.1% indicating approximately one in ten Georgia physicians do not administer the vaccine according to ACIP guidelines. Patterns for this analysis can be viewed in Table 18.

Table 18:

Administer HPV According to ACIP Guidelines

	11-12 y
Never (administers the vaccine to 0% of girls in this age group)	<i>n</i> (%) 17 (8.1)
Rarely (administers the vaccine to 1-25% of girls in this age group)	48 (23.0)
Sometimes (administers the vaccine to 26 - 50% of girls in this age group)	51 (24.4)
Often (administers the vaccine to 26 - 50% of girls in this age group)	63 (30.1)
Always (administers the vaccine to 76-100% of girls in this age group)	25 (12.0)

# **Research Question #5:**

# What differences will emerge when the data are analyzed by urban vs. rural characteristics?

To answer research question #5, Hypothesis #3 was tested.

# Hypothesis #3:

No statistical differences will be detected between percentage of Georgia physicians enrolled in VFC program who indicate they recommend the HPV vaccine to male patients, and geographic setting (urban vs. rural).

Estimates of proportions and their standard errors were calculated and no statistical

significance was detected between administering HPV vaccine to female patients according to

ACIP guidelines of administering the vaccine to 11-12 year old females and geographic setting.

Since confidence intervals were overlapping across response categories between urban and rural

practice setting, no statistical differences were detected.

Table 19 depicts estimates of proportions and their standard errors.

#### Table 19:

Administer HPV According to ACIP Guidelines with Mean and CIs

	11-12 y Urban	11-12 y Rural
Never (administers the vaccine to 0% of girls in this age group)	.123 (.046, .2)	.061 (.003, .119)
Rarely (administers the vaccine to 1-25% of girls in this age group)	.246 (.159, .334)	.273 (.204, .343)
Sometimes (administers the vaccine to 26- 50% of girls in this age group)	.214 (.133, .296)	.175 (.113, .238)
Often (administers the vaccine to 51-75% of girls in this age group)	.286 (.182, .39)	.354 (.219, .488)
Always (administers the vaccine to 76- 100% of girls in this age group)	.094 (.032, .156)	.113 (0, .225)

### **Research Question #4:**

What percentage of Georgia physicians enrolled in the VFC program, indicate they will recommend the HPV vaccine to their male patients?

The ACIP recommends "permissive use" of the HPV vaccine among males age 9-26 years (MMWR, May 28, 2010). To answer this research question, respondents were asked if they recommended the vaccine to males in their practice and if so at what age was it recommended. Age grouping of male patients was broken down into categories of 9-10 years old, 11-12 years old, 13-17 years old and 18 – 26 years old. Responses are listed in Table 20. Of those who responded, only 10.9% said they always recommend the vaccine to 9-10 year old males. A response of *always* indicated the vaccine was recommended to more than 75% of male patients between the ages of 9-10 years. Respondents who often recommend the vaccine to this age group were 10.4%. A response of *often* indicated the vaccine was recommended to 51-75% of

male patients between the ages of 9-10 years. Respondents who sometimes recommend the vaccine to this age group were 10.9%. A response of *sometimes* indicated the vaccine was recommended to 26 -50% of male patients between the ages of 9-10 years. Respondents who rarely recommend the vaccine to this age group were 23.2%. A response of *rarely* indicated the vaccine was recommended to 1 - 25% of male patients between the ages of 9-10 years. Physicians who never recommend the vaccine to any males in this age group were 40.8%. A response of *never* indicated the vaccine was not given to anyone in this age group,

Of those who responded to recommending the vaccine to 11-12 year old males, 23.7% said they always recommend the vaccine to 11-12 year old males. A response of *always* indicated the vaccine was recommended to more than 75% of male patients in this age group. Respondents who often recommend the vaccine to this age group were 19.4%. A response of *often* indicated the vaccine was recommended to 51-75% of male patients between the ages of 9-10 years. Respondents who sometimes recommend the vaccine to this age group were 13.7%. A response of *sometimes* indicated the vaccine was recommended to 26 -50% of male patients between the ages of 11-12 years. Respondents who rarely recommend the vaccine to this age group were 16.1%. A response of *rarely* indicated the vaccine was recommended to 1 - 25% of male patients between the ages of 11-12 years. Physicians who *never* recommend the vaccine to any males in this age group were 23.8%. A response of *never*, indicated the physician did not vaccinate anyone in this age group, indicating approximately one fourth of Georgia physicians do not recommend the vaccine according to ACIP guidelines to males age 11-12 years.

Of those who responded recommending the vaccine to 13-17 year old males, 26.9% said they *always* recommend the vaccine to 13-17 year old males. A response of *always* indicated the vaccine was recommended to more than 75% of male patients in this age group. Respondents who often recommend the vaccine to this age group were 20.2%. A response of *often* indicated the vaccine was recommended to 51-75% of male patients between the ages of 13-17 years. Respondents who sometimes recommend the vaccine to this age group were 13.7%. A response of *sometimes* indicated the vaccine was recommended to 26-50% of male patients between the ages of 13-17 years. Respondents who rarely recommend the vaccine to this age group were 15.4%. A response of *rarely* indicated the vaccine was recommended to 1 - 25% of male patients between the ages of 13-17 years. Physicians who never recommend the vaccine to any males in this age group were 17.8%. A response of *never* indicated the physician did not vaccinate anyone in this age group suggesting approximately one of five Georgia physicians do not recommend the vaccine according to ACIP guidelines to 13-17 year old males. Responses are summarized in Table 20.

Of those who responded to recommending the vaccine to 18-26 year old males, 22.4% said they always recommend the vaccine to 18-26 year old males. A response of *always* indicated the vaccine was recommended to more than 75% of male patients in this age group. Respondents who often recommend the vaccine to this age group were 14.3%. A response of *often* indicated the vaccine was recommended to 51- 75% of male patients between the ages of 13-17 years. Respondents who sometimes recommend the vaccine to this age group were 11.9%. A response of *sometimes* indicated the vaccine was recommended to 25 - 50% of male patients between the ages of 18-26 years. Respondents who rarely recommend the vaccine to this age group were 15.7%. A response of *rarely* indicated the vaccine was recommended to 1 - 25% of male patients between the ages of 18-26 years. Physicians who never recommend the vaccine to any males in this age group were 13.8%. A response of *never* indicated the physician did not vaccine anyone in this age group suggesting approximately one of five Georgia physicians do not recommend the vaccine according to ACIP guidelines to 18-26 year old males. Responses are summarized in Table 20.

Table 20:

Recommend HPV to Boys by Age Group

	9-10 y	11-12 y	13-17 y	18-26 y
	(%)	(%)	(%)	(%)
Never (administers the vaccine to 0% of boys in this age group)	40.8%	23.2%	17.8%	13.8%
Rarely (administers the vaccine to 25% of boys in this age group)	23.2%	16.1%	15.4%	15.7%
Sometimes (administers the vaccine to 26-50% of boys in this age group)	10.9%	13.7%	16.3%	11.9%
Often(administers the vaccine to 51-75% of boys in this age group)	10.4%	19.4%	20.2%	14.3%
Always (administers the vaccine to 76- 100% of boys in this age group)	10.9%	23.7%	26.9%	22.4%

# **Research Question #5:**

What differences will emerge when the data are analyzed by urban vs. rural characteristics?

To answer research question 5, Hypothesis #4 was tested.

# **Hypothesis #4:**

No statistical differences will be detected between percentage of Georgia physicians enrolled in VFC program who indicate they recommend the HPV vaccine to male patients, and geographic setting (urban vs. rural).

Estimates of proportions and their standard errors were calculated and no statistical

significance was detected between recommending HPV vaccine to male patients, and geographic

setting. Since confidence intervals were overlapping across response categories between urban

and rural practice setting, no statistical differences were detected.

Estimates of proportions and their standard errors to physician perceived barriers are listed

in Table 21

## Table 21:

	Never	Rarely	Sometimes	Often	Always
Q8A Rural	.304	.288	.163	.081	.139
9-10 yr old	(.213, .396)	(.216, .36)	(.124, .203)	(.03, .133)	(.106, .172
Q8A Urban	.394	.225	.118	.095	.076
9-10 yr old	(.288, .501)	(.129, .321)	(.045, .19)	(.031, .158)	(.02, .131)
Q8B Rural 11-12 yr old	.163 (.074, .253)	118 (.072, .165)	.190 (.118, .262)	145 (.07, .22)	.360 (.278, .44)
Q8B Urban	.171	.159	.17	.221	.186
11-12 yr old	(.103, .24)	(.078, .24)	(.088, .253)	(.124, .319)	(.096, .276)
Q8C Rural	.143	.118	.159	.196	.359
13-17 yr old	(.06, .227)	(.072, .165)	(.094, .225)	(.111, .281)	(.278, .44)
Q8C Urban 13-17 yr old	126 (.066, 186).	.122 (.049, .196)	.244 (.142, .346)	.215 (.117, .313)	.2 (.108, .292)
Q8D Rural	.090	.141	.102	.113	265
18-26 yr old	(.015, .156)	(.083, .199)	(.054, .149)	(.041, .185)	(181, .349)
Q8D Urban	.099	.145	.178	.139	.132
18-26 yr old	(.048, .15).	(.062, .228)	(.095, .261)	(.063, .216)	(.059, .204)

Recommend HPV to Boys According to ACIP Guidelines

After completing all descriptive statistics and reviewing all data, a combination of three new variables were created. The three new variables are: knowscore, barriers, and parental barriers. Knowscore measured the physician's knowledge as ascertained through question 2 on the survey. Question 2 contained seven sub-questions and for each correct response the physician was awarded one point. The scores range from 0 to seven.

The second new variable, barriers, measured the physician's perception of barriers as ascertained from question 3 on the survey. For each barrier the physicians agreed with (agree or

strongly agree) the physician was awarded one point. There are 12 listed barriers, with score range from 0 to 12.

The third and final variable, parental barriers, measured the physician's perception of parental barriers as ascertained from question 4 on the survey. For each parental barrier the physicians agreed with (agree or strongly agree) the physician was awarded one point. There are 12 listed barriers, so the scores ranged from 0 to 12.

As each of these three new variables represents a new summative scale, Cronbach's alpha was calculated to assess the reliability of scales. For the Knowscore scale consisting of seven items, Cronbach's Alpha = 0.744, which can be consisted moderately good. For the Barrier Scale with 12 items, Cronbach's Alpha = 0.808, again, a moderately good reliability. Finally, for the Parental Barrier Scale, consisting of 12 items, Cronbach's Alpha = 0.822, and provides moderately good reliability.

Since the three new variables were created, summary statistics that incorporate the sample design (calculated with SAS Proc Surveymeans) are illustrated in Table 22.

#### Table 22:

Variable	Mean(SE)	Lower 95% limit	Upper 95% limit
Barrier	4.18(0.25)	3.76	4.60
Parental Barrier	2.47(0.24)	2.06	2.88
Knowscore	6.16(0.10)	5.98	6.33

Summary Statistics Across Counties

Since the three new variables were created, summary statistics that incorporate the sample design (calculated with SAS Proc Surveymeans) are given in Table 23.

### Table 23:

Variable	Mean(SE)	Lower 95% limit	Upper 95% limit
Rural			
Barrier	3.77 (0.48)	2.98	4.61
Parental Barrier	2.42 (0.49)	1.58	3.23
Knowscore	6.16 (0.25)	5.73	6.59
Urban			
Barrier	4.33 (0.28)	3.85	4.81
Parental Barrier	2.49 (0.27)	2.02	2.96
Knowscore	6.16 (0.10)	5.98	6.34

Summary Statistics Rural and Urban

After summary statistics incorporating the sample design were established, logistic regression analysis was performed to determine variables that may influence a physician's decision to not recommend the HPV vaccine to their patients. There were two dependent variables of interest: females' age 11-12 years and males age 11-12 years. Table 24 refers to females not getting an HPV vaccine recommendation.

#### Table 24:

Females Age 11-12 Not Getting HPV Vaccine Recommendation

Effect	Df	Wald statistic	P-value
%Medicaid	4	191.63	<0.001***
Physician gender	1	3.946	0.047***
Knowscore	1	0.216	0.641
Barrier	1	0.057	0.812
Parental barrier	1	6.721	<0.001***

% Medicaid is most likely a spurious result due to only 2 providers not accepting Medicaid.

The significant effect (p < 0.001) detected by having Medicaid as a payer sources is most likely a spurious result due to only two providers not accepting Medicaid. A significant effect (p=0.047) was detected between physician gender and a female patient not getting a recommendation for HPV vaccine. A second significant effect (p<0.001) was detected between parental barrier and a female not getting an HPV vaccine recommendation.

Next, confidence limits on odds ratio was performed to further determine variables that may influence a physician's decision to not recommend HPV vaccine to their patients. Refer to Table 25 for estimated odds ratio and 95% confidence intervals.

Table 25:

Confidence Limits on Odds Ratios for Not Getting HPV Recommendation

Effect	Estimated OR	95% C.I. for Odds Ratio
Medicaid 1 vs. 5 (0% vs. 76-100%)	<0.001	(<0.001, <0.001) ***\$\$\$
Medicaid 2 vs. 5 (1-25% vs. 76-100%)	3.762	(0.268, 52.709) NS

Effect	Estimated OR	95% C.I. for Odds Ratio
Medicaid 3 vs. 5 (26-50% vs. 76-100%)	2.960	(0.772, 11.347) NS
Medicaid 4 vs. 5 (51-75% vs. 76%-100%)	1.439	(0.315, 6.573) NS
Gender (female vs. male)	3.071	(1.015, 9.293) ***
Knowscore	0.895	(0.562, 1.427) NS
Parental Barrier	0.986	(0.881, 1.104) NS
Barrier	1.154	(1.035, 1.285) ***

\*\*\* indicates statistical significance at alpha=0.05, \$\$\$- spurious result (there are only 2 providers for less than 1% who state 0% Medicaid)

Parental barrier was significant with an estimated odds ratio of 1.154. Of interest was the estimated odds ratio for female physicians to not recommend the HPV vaccine to their female patients of 3.071 indicating physician gender has an impact on the likelihood of vaccination. Other variables were not considered significant.

The likelihood of physicians to *not* recommend the HPV vaccine to males' ages 11-12 years was explored. Logistic regression analysis was performed to determine variables that may influence a physician's decision to not recommend HPV vaccine to their male patients as shown in Table 26 for estimated odds ratio and 95% confidence intervals.

Table 26:

Effect	Df	Wald statistic	P-value
%Medicaid	4	3.545	0.471
Physician gender	1	3.171	0.075
Knowscore	1	2.394	0.122
Barrier	1	0.156	0.693

Males 11-12 Years Not Getting HPV Recommendation

Effect	Df	Wald statistic	P-value
Parental barrier	1	2.592	0.108

No significant effect (p < 0.05) was detected with any variable. Confidence limits on odds ratio was performed to further determine variables that may influence a physician's decision to not recommend HPV vaccine to their male patients. No significant effects were detected. Refer to Table 27.

# Table 27:

Confidence Limits on Odds Ratios for Not Getting HPV Recommendation

Effect	Estimated OR	95% C.I. for Odds Ratio
Medicaid 1 vs. 5 (0% vs. 76-100%	0.791	(0.173, 3.624) NS
Medicaid 2 vs. 5 (1-25% vs. 76- 100%)	2.780	(0.218, 35.459) NS
Medicaid 3 vs. 5 (26-50% vs. 76- 100%)	1.022	(0.256, 4.082) NS
Medicaid 4 vs. 5 (51-75% vs. 76%- 100%)	0.740	(0.175, 3.121) NS
Gender (female vs. male)	2.529	(0.911, 7.021) NS
Knowscore	0.662	(0.392, 1.116) NS
Parental Barrier	1.039	(0.860, 1.256) NS
Barrier	1.132	(0.973, 1.317) NS

\*\*\* indicates statistical significance at alpha=0.05.

### Chapter 5

## SUMMARY, DISCUSSION, AND CONCLUSIONS

The purpose of this study was to examine the prevalence of Georgia physician intention and administration of HPV vaccine to 11-12 year-old girls and intention to recommend the quadrivalent HPV vaccine to 11-12 year old boys. The study examined the attitudes and beliefs of Georgia physicians toward administering HPV vaccine and assessed perceived knowledge, barriers, practices, and adherence to ACIP guidelines and recommendations regarding HPV vaccination. A distinction between urban and rural counties was examined to determine if there were differences.

#### **Summary of Findings**

The response rate for this study was 82.6%, with physicians and key informants representing Georgia physicians in the VFC program who administer HPV vaccine to their male and female patients. The diverse representation of the respondents included 51.4% White, 22.6% Asian and 18.4% African American. Latino's were noted to be 9.5% of respondents. Males accounted for 51% and females were 49% of respondents. Respondents practicing in rural counties represented 18.8% and urban county respondents were 81.2%. Practice size ranged from single physician practices to one practice with more than 26 physician providers.

<u>Research Question #1:</u> Descriptive analysis of data showed 64.2% believed the most important barrier for not vaccinating was lack of adequate reimbursement for HPV vaccination. The barrier of inadequate reimbursement was followed by 63.2% citing the cost of stocking the HPV vaccine and 60.8% believing the upfront or initial cost of purchasing the private stock HPV vaccine was a barrier. Only 9.9% had concerns about the safety of the HPV vaccine. Many physicians commented on the lack of reimbursement by private insurance companies. Research by Kahn et al. (2009) with Texas physicians yielded nearly identical findings as it pertains to barriers of cost and reimbursement. In the Texas study, 67.1% noted lack of payment by some insurance companies as a barrier compared with 64.2% in this research (Kahn et al., 2009). This is especially important for those physicians with practices that do not contain many VFC patients where cost of the vaccine is covered. Gudeman (2007) had similar findings and observed that while VFC programs work for those who qualify; those who do not qualify for the VFC program do not benefit from vaccination and reimbursement remains an issue. As one physician noted:

"I would give more vaccine if insurance paid for it. It is difficult to ask a mother to pay \$350.00 for a vaccine not required for school and not covered by her insurance."

The most significant parental barrier to vaccination according to Georgia physicians was the request that HPV vaccine be deferred until the female patient was older. This barrier was noted by 89.9% of respondents followed by lack of education/understanding of the HPV vaccine at 83.2%. Parental opposition to HPV vaccination for moral or religious reasons was a barrier to less than one in four physicians. Previous research (Charo, 2007; Daley et al., 2006; Katz et al., 2009; Tissot et al., 2007) suggested strong religious beliefs lead to a delay or refusal of vaccine was not found in this research. One Georgia physician summed what others stated by observing:

"I have never had a mother tell me it was against her religious belief to not vaccinate with this vaccine. I think the press made a big deal in the beginning when the vaccine was new, but it is not true."

<u>Research Question #2:</u> The overall knowledge about HPV and who could receive the HPV vaccine was well known by most respondents. Over 90% of respondents were aware that the FDA approved the quadrivalent HPV vaccine for males and females, that almost all cervical cancers are caused by HPV, and that HPV also causes genital warts in both sexes. The

remaining survey questions were answered correctly by over 75% of respondents and pertained to knowledge that HPV is a sexually transmitted disease which usually resolves without medical intervention and that females with an HPV may still receive the vaccine. These combined scores indicate an overall high rate of knowledge among respondents. These findings of Georgia physicians are similar to finding by Daley et al. (2010) in a national survey of physician knowledge.

<u>Research Question #3:</u> Vaccinating females according to ACIP guidelines at age 11-12 years was performed by 12% who stated they always administer the vaccine to this age group. Many providers who administer the vaccine stated they use reminders to assist with vaccination and use a positive, professional approach:

"I tell the mom I am going to vaccinate at the next visit, then at that visit I have a matter of fact approach about it, no big deal, I vaccinate and talk about how this vaccine protects against cervical cancer and that I wish there were more vaccines that protected against other types of cancer. I tell the mother there are two more shots and that my office will remind her when to bring her daughter back."

Other physicians were less compliant when vaccinating 11-12 year old females. Indeed, 30.1% stated they were successful with 51-75% of their patients, and about one-quarter of respondents was successful with 26 - 50% of their female patients in this age group. Multiple physicians stated parental concern about the age of the child as a barrier, noting:

"I recommend the vaccine beginning at age 10 but moms have different reasons why they want to wait to have their daughters vaccinated. Some wait until their daughter goes to high school in case she talks about it with her friends and I've had some moms that wait until their daughter start their menstrual cycle. If insurance does not cover it, moms will often refuse the vaccine." Physicians who never vaccinate females at 11-12 years of age were 8.1%. One physician summed what others who did not vaccinate at this age noted:

*"Most women wait until their daughter is at least 13 years old and then they bring her in for the vaccine. It is less of a concern to the mom at that age."* These findings of Georgia physicians are similar to finding by Daley et al. (2010) in a

national survey of physician vaccination. Other researchers (Kahn et al., 2008; Katz et al., 200; Ko et al., 2010 & Shan et al., 2007) has similar findings indicating physicians appear to be delaying vaccinating until the adolescent is past of age of 12 and not vaccinating according to ACIP guidelines.

<u>Research Question #4:</u> Analysis of the data revealed less than one-quarter of physicians always recommend the HPV vaccine to male patients at any age. The fewest physicians recommend it to males 9-10 years with only 10.9% recommending. In addition, the physicians who stated they never recommended the vaccine was surprising with 40.8% stating they never recommend HPV vaccination to 9-10 year olds. The data were slightly better for 11-12 year old males with 23.7% stating they always recommend the vaccine and 23.2 % stating they never recommend the vaccine to 11 -12 year old males. Other researchers (Weiss et al., 2010) who studied physicians currently administering HPV vaccine to females suggest physicians supported the concept of vaccinating males for the benefits it imparts on both sexes. Recommending the vaccine early and to both sexes was seen as important. By doing so, patient and parent can be educated about the HPV vaccine and vaccination may occur at the next annual visit. As one physician commented:

"It is difficult enough to get girls vaccinated, I am just now starting with the boys. I tell them I think they should have it but they don't see it as important or something they need right now."

<u>Research Question #5:</u> No difference emerged when the data were analyzed by urban or rural geographic location. This may be attributed to sample size but the response rate for this study was 82.6%. Data reveals that geographic location of physician practice does not appear to impact HPV vaccine administration.

After completing analysis for the research questions with no significant findings, three new variables were created to reveal what may cause physicians not to recommend HPV vaccination. From these three new variables, logistic regression was used to determine that female physicians and parental barriers made it more likely that female patients 11-12 years of age would not receive a recommendation for HPV vaccination. There was no effect on not recommending the HPV vaccine to male patient's age 11-12 years.

The findings that method of payment, such as having a low percentage of patients with Medicaid as a payer source, appears to be a spurious result because less than 1% of respondents were in this category.

To summarize the findings, none of the original variables (administering the HPV vaccine to 11-12 year old females according to ACIP guidelines, recommending the HPV vaccine to males, barriers, or knowledge) impacted differences among urban and rural physician providers in Georgia although female physicians and parental barriers appear to be make it more likely that 11-12 year of female patients will not receive a recommendation for vaccination.

### **Health Belief Model and Research Findings**

HPV vaccination by physicians within the framework of the Health Belief Model was used to inform this research. The Health Belief Model views key determinants of health and illness to be individual health behavior (Becker, 1974; Glanz, et al., 2008; Rosenstock, 1974). Using the Health Belief Model, perceived susceptibility manifested by physician knowledge that patients are at risk for HPV infection was evident by the correct responses to the survey. Physicians correctly answered survey questions pertaining to HPV infection and the immense prevalence of the virus within the population.

## **Perceived susceptibility**

As previously noted by Brown (2005), the cumulative prevalence of HPV infection in sexually active adolescent females is high, and physicians must educate parents and adolescents about the risks if improved vaccination rates are to be achieved. Physician education of parents can increase the parent's understanding of adolescent susceptibility. The knowledge could lead to increased HPV vaccination. This is vital because 80.8% of respondents to this survey indicated parents do not believe their adolescent to be at risk for HPV. These finding suggests low perceived susceptibility to the human papillomavirus when in fact over 70% of sexually active men and women will acquire a genital HPV infection during their lifetime (CDC 2010).

## **Perceived severity**

Perceived severity of HPV infection leading to problems of genital warts and possible cervical cancer were known by the majority of physicians in this survey. Most HPV infections are asymptomatic, transient, and resolve without medical intervention (CDC 2010). Most physicians were aware of this fact as was noted in this research and studies by Daley et al. (2010) and Kahn et al. (2009). These studies also showed a high adoption rate of vaccination by physicians with most physicians aware of several key aspects of HPV epidemiology. While not all adolescents will go on to have genital warts or develop cervical cancer, submitting accurate information to physicians will allow them to make informed decisions about vaccination and could prevent many future cases.

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# **Perceived benefits**

Keeping within the framework of the Health Belief Model, perceived benefits of vaccinating which reduces the risk of HPV infections was known by most respondents in this survey. Nevertheless, for the benefits of vaccination to be realized, the vaccine must be administered before the onset of sexual activity and exposure to HPV virus (Markowitz et al., 2007) if it is to be most effective. Research by Daley et al. (2010) note physicians are well aware of HPV and HPV vaccine but at least 25% of physicians in that study do not follow ACIP guidelines of vaccinating 11-12 year olds and often wait until after 13 years of age. Their findings were similar to findings in this research of Georgia physicians which noted 8.1% never vaccinate and 23% rarely vaccinate 11-12 year olds.

When placed in the framework of the Health Belief Model, there are opportunities to increase HPV vaccination rates of this age group. For example, school entry laws create a perceived benefit of vaccination, yet HPV vaccination is not mandated in Georgia or most other states (Charo, 2007). Currently in Georgia, students must receive or show proof of having tetanus, diphtheria, pertussis, hepatitis B, polio, measles, mumps, rubella and varicella vaccinations or have a religious exemption before attending school (Georgia Department of Education, 2010). This is not the case for HPV vaccine. By mandating HPV vaccine for middle school entry, a perceived benefit is implied, particularly if physicians support the school mandate. However, the American Academy of Family Physicians note in their 2007 policy statement that they would recommend the vaccine as a mandate for school admission only after "long term safety with widespread use, stability of supply, and economic issues have been clarified" (AAFP 2007). The position of the AAFP has not changed and there is still no recommendation to include HPV vaccine as part of school mandated vaccines (AAFP, 2011).

In one survey by Horn, Howard, Waller, and Ferris, (2010), most parents supported mandatory vaccination programs in general, but less than half who responded to the survey felt the HPV vaccine should be mandated. The main reasons for nonsupport were that it would infringe on their rights, that the vaccine had not been well studied, and had too many adverse effects.

## **Perceived barriers**

Within the framework of the Health Belief Model, barriers identified by this research are viewed as components that converge to yield the final decision to vaccinate or not to vaccinate. For example, cost of the vaccine was cited as just one barrier by many physicians who took part in this research. Brewer and Fazeka (2007) noted variables associated with HPV vaccine initiation in multivariate analyses included the barrier of the physician's ability to store HPV vaccine and perceived barriers to obtaining HPV vaccine.

For parents, cost of missed working hours and transportation costs must also be considered. Many adolescents do not have private health insurance that covers the cost of the vaccine. Those that may be eligible may not take advantage of public programs such as Medicaid or VFC.

Another barrier within the framework of the Health Belief Model is under-utilization of health care services by male and female adolescents. If HPV vaccine education is to occur during the physician visit, then the visit must first occur. Then the physician can impart his beliefs regarding perceived susceptibility and severity of disease, and perceived benefits of vaccination. The AMA (2011) recommends three visits from age 11 -21 years. The first visit is recommended between the ages of 11-14, one visit for ages 15-17 and the last visit before the 21<sup>st</sup> birthday. Within the framework of the Health Belief Model, if the physician perceives the severity of HPV and the adolescent's lifetime susceptibility of the disease, and if the physician

has the self-efficacy to administer the vaccine, then the physician will use this visit as a cue to action to recommend and administer the vaccine provided the adolescent makes the visit.

### Cues to action to vaccinate and self-efficacy

Cues to action to vaccinate and self-efficacy were not explored in depth in this research but should be the subject of future research. McCave (2010) noted vaccination rates improved when the physician had a personal belief in the positive impact of the HPV vaccine and office strategies which supported vaccination. Effective physician strategies for HPV vaccine delivery (Tissot, et al., 2007) indicated multiple office approaches improved vaccination rates. Implementing office-based procedures and policies, providing education and information opportunities to physicians and parents, and ensuring endorsement of HPV vaccination by influential organizations, were noted to be effective.

Although the main purpose of this research was to provide a quantitative assessment of Georgia physician intention and administration of the HPV vaccine to 11-12 year-old girls and intention to recommend the HPV vaccine to 11-12 year old boys, a rich compilation of qualitative information accompanies the data set. This will provide the basis for future analysis and reporting and further contribute to the knowledge base in this area of public health.

#### **Discussion of Findings**

Despite national recommendations for universal vaccination of 11-12 year old females, approximately one in ten Georgia physicians (12%) who responded to this survey reported they always vaccinate females in this age group. The number increases to one in five (22.9%) who reported they always vaccinate females age 13-17 years, suggesting parents or physicians may be delaying vaccination until females are older than 12 years. This study was conducted five years after the ACIP recommendation to vaccinate females at 11-12 years (Markowitz et al.,

2007) suggesting additional efforts are needed to improve physician awareness of and adherence to national recommendations.

This study found 50.5% of Georgia physicians always recommended HPV vaccine to 11-12 year old females which was similar to the findings of a Texas study (Kahn et al., 2009) where 48.5% reported they always recommend HPV vaccination at this age. A national internet and standard mail survey of physicians by Daley et al. (2010) also indicated 56% of physicians strongly recommend the vaccine to this age group. As the girls become older, this study indicated 69.9% always recommend the vaccine to 13-17 year olds which is very similar to Texas physicians (Kahn et al., 2009) where 64.4% always recommend. However the national study by Daley et al. (2010) had a higher recommendation rate of 82%.

These findings suggest more physicians strongly recommended HPV vaccination to patients 13 years and older and was the finding in this research of Georgia physicians. Research by Daley et al. (2010) to a national group of pediatricians and family practice physicians indicated fewer respondents strongly recommended HPV vaccination for 11-to 12-year old girls than for older female patients. Among pediatricians, 57% said they recommended the vaccine for that age group, but 90% recommended the vaccine for their 13- to 15-year old patients. Findings from the national study were similar to findings of Georgia physicians from this research.

Perceived barriers to HPV vaccination indicated financial barriers and parent opposition as reasons for not vaccinating. Financial constraints were found to be a barrier in this research by the majority of physicians. This was also found to be a barrier in research by Kahn et al (2009) statewide survey of Texas physicians, research by Daley et al. (2010), in a national survey of physicians. The national survey of physicians found that vaccine costs and insurance coverage were the main financial barriers to strongly recommending HPV vaccination.

More than half (59.4%) Georgia physicians reported insufficient insurance coverage for the vaccine as a barrier to their practice when offering the vaccine. HPV vaccination coverage by both public and private health care plans remains an important issue if Georgia vaccination rates are to increase. Physicians had experienced parental barriers to HPV vaccination, and most of these had been anticipated by physicians in studies conducted before HPV vaccine licensing (Daley et al., 2006; Dempsey & Davis, 2006). Findings suggest that providing physicians with information about HPV vaccines and with strategies to educate parents while addressing specific parental concerns will be important in overcoming barriers. State and local immunization coalitions that focus on regaining public trust in vaccines and that encourage accurate and responsible journalism will be essential in efforts to increase HPV vaccination rates.

The physician perceived parental barrier that the vaccinated child would practice riskier sexual behavior was noted by 69.7% in this research. However, research published in the American Society for Colposcopy and Cervical Pathology had a different finding and noted "most parents do not think the HPV vaccine would actually encourage sexual activity in their children" (Ferris, Cromwell, Waller, & Horn, 2010, p. 179). In their study, most parents thought the HPV vaccine would not alter their children's reproductive behavior. Their research indicated only a very small minority of parents believed it might lead to riskier sexual behavior. Older parents and parents with older adolescents were the ones more likely to think that HPV vaccine encourages riskier sexual behavior. In addition, parents with a greater number of daughters were concerned about risky sexual behavior. Their study found that these children became sexually active shortly after receiving the vaccine by coincidence, and as a result, the vaccine was blamed for this action. However, research by Daley et al. (2010) indicated parental concern about HPV vaccination was also a barrier; with 39% of pediatricians and 43% of family physicians reporting that parents worried that vaccination against a sexually transmitted infection may encourage earlier or riskier sexual behavior. The survey also found that 22% of pediatricians and 23% of family physicians reported that parents of their 11- to 12-year-old patients were upset that they were offering the vaccine to that age group. Eighteen percent of pediatricians and 29% of family physicians reported that at least one fourth of parents of 11- to 12-year-old patients refused HPV vaccine (P < .01). Common reasons for parent refusals were that the vaccine was too new, the child was too young, and lack of health insurance for HPV vaccination.

Georgia physician's attitudes about vaccinating males indicate approximately one quarter Georgia physicians always recommend HPV vaccine to male patients. However, findings were different when compared to recommendations for vaccinating males, with 42% of Texas physicians (Kahn et al., 2009) indicating they were extremely likely to recommend the vaccine to 11-12 year old males.

Most physicians stated lack of payment as a barrier to vaccinating males. While the number of physicians who always recommend the vaccine is less than those who always vaccinate female patients, physicians may be more likely to recommend HPV vaccine as more information becomes available about HPV related diseases in men. Nevertheless, male HPV vaccination raises unique issues and specific educational messages for physicians, parents, and males will need to be developed if vaccination rates are to increase.

In Georgia, female physicians and parental barriers are factors associated with not recommending the HPV vaccine to 11-12 year old females. In a national study by Daley (2006) surveying pediatrician's knowledge and attitudes regarding HPV vaccination, 97% of female pediatricians versus 81% of male pediatricians reported feeling comfortable discussing sexuality with female patients. In a follow up study by Daley et al. (2010) female family physicians were

more likely to give the vaccine than male family physicians. Ko et al (2010) findings suggested female, primary care, and community and private practice physicians were associated with increased vaccination. Physicians who took part in this research also noted the greatest barrier to vaccination was reimbursement concerns. Reimbursement was also a barrier for Georgia physicians.

#### **Study Strengths and Limitations**

This study provides researchers and immunization professionals with a comprehensive examination of the prevalence of Georgia physician intention and administration of HPV vaccine to 11-12 year-old girls, and their intention to recommend HPV vaccine to 11-12 year old boys. The study examined the attitudes and beliefs of Georgia physicians toward administering HPV vaccine and assessed perceived knowledge, barriers, practices, and adherence to ACIP guidelines and recommendations regarding HPV vaccination.

The major strength of the study is its response rate of 82.6% from the sampling plan (n=264) of Georgia physicians who administer the HPV vaccine. The researcher drew the sample from a database maintained by the Immunization Section of the Division of Public Health within the Department of Community Health and the database is updated annually. A second strength of the study was the survey tool itself. We adopted a previously validated survey tool developed by researchers from the Moffitt Cancer Center and tested by Vadaparampil (2009) from a nationwide survey.

A limitation to this study is the possible difference in physician response in larger practices from those who were smaller practices or practiced alone. For example, in an office practice with two or more physicians, only one physician was asked to complete the survey. It is not known if asking all physicians in a practice would yield the same results as asking one physician and this could be the basis for further research. However, researchers of physician surveys suggest bias may be of less concern in physician surveys than in surveys of the general public and physicians tend to be fairly homogeneous with respect to knowledge, training, attitudes, and behaviors (Kellerman & Herold, 2001). It is also possible that some survey respondents, while authorized by the physician to respond, might not have been the correct key informant with appropriate knowledge and could have reported inaccurate responses. The database obtained by the Immunization Section of the Division of Public Health within the Department of Community Health may not have included all physicians who are on the VFC list and who administer the HPV vaccine. Lastly, the study assessed physician-reported behavior but did not observe actual vaccination practices.

#### **Implication for Public Health Programs, Policies, and Allocation of Resources**

In Georgia, most childhood immunizations (81%) are administered in the private sector at physician offices (Georgia Department of Community Health, 2010). Public health must have a firm understanding of who is recommending and administering vaccines in order to target messages and action. As the Mission and Vision of the Immunization Section of the Georgia Division of Public Health is to "... work to increase immunization rates for all Georgians and decrease the incidence of vaccine-preventable diseases" (DCH, 2010), it is important to have information about the attitudes and beliefs of Georgia physicians toward administering the HPV vaccine and assess perceived knowledge, barriers, practices, and adherence to ACIP guidelines and recommendations. Future efforts may focus on female gender of physician and parental barriers with regards to recommendation of the vaccine to 11-12 year old girls, to guide strategies.

The Immunization Section of the Georgia Division of Public Health will be informed of findings to assist with future immunization program outreach. As noted by Daley et al. (2010) physicians appear more likely to recommend the HPV vaccine at older ages and vaccination may not occur at the age recommended by national guidelines. Therefore, educational materials should highlight ACIP guidelines and recommendations of HPV vaccination. The finding that financial barriers exist will assist the Immunization Section target the release of VFC vaccine and information to areas where providers may have experienced difficulty in vaccinating uninsured and under-insured children. The finding of female physicians being less likely to recommend the HPV vaccine to 11-12 year old female patients will be shared with local medical organizations to determine best approaches for addressing this finding and encouraging vaccination.

According to *Healthy People 2010* (USDHHS, 2000), programs that employ social ecological model approaches for immunization are becoming more prevalent, with policy intervention at the societal level being one strategy to impact change. Policy that includes the option of creating a state mandate in Georgia would improve overall HPV vaccination rates among the target population. However, it is not certain that physicians and other key stakeholders are prepared to endorse a state mandate in Georgia.

Engaging physicians in the policy debate of a future state mandate will be necessary if higher rates of HPV vaccine uptake among the population are to be realized and if policy is to change. Although only 15.1% of physicians surveyed believed not requiring a school mandate to be a barrier, the fact remains that overall vaccination rates according to ACIP guidelines is 38% in Georgia (MMWR 2010).

This study provides the first comprehensive examination of the prevalence of Georgia physician intention and administration of the HPV vaccine to 11-12 year-old girls, and their intention to recommend the HPV vaccine to 11-12 year old boys. While the findings are similar to other studies completed nationally and in different states, this is the first such study to be conducted in Georgia. As such, its contribution to Georgia's public health's promoting comprehensive adolescent immunization is important. It serves as a snapshot of what is happening in Georgia and as baseline data for future studies.

The Office of Immunization within the Georgia Division of Public Health will be able to use data from this and future studies to create a baseline for vaccine outreach, marketing campaigns, grant activities, and legislative education. Having baseline immunization data can be the first step in creating policy that targets those who provide the majority of immunization. It can only do this by engaging the physicians who administer the most vaccine. Having a better understanding of physician knowledge, attitude and vaccination practice is the first of many steps toward improved immunization rates. By sharing and following examples of others, physicians can customize messages and parent education to better meet the needs of their distinctive patient population. As one physician noted:

# "I have no idea what others do (in their office), I could be leading the pack or bringing up the rear."

Public health practitioners should strive to increase the number and percentage of males and females who receive HPV vaccine to comply with ACIP guidelines and to promote overall health and wellness among the population. One local activity "Tea and HPV" that appears to have met with moderate success will be shared across the state and may also prove useful in other states to increase HPV vaccination rates. "Tea and HPV" utilized the school setting as a place to bring

young girls together with their mothers to learn more about the virus and vaccine. The middle school was opened after school hours to female students in the fifth and six grade and their mothers. The lunchroom was decorated and parents were served light refreshments by their daughters. Public Health nurses provided a brief presentation on HPV and remained to answer any questions. A similar venue can be done with boys and their fathers.

#### **Suggestions for Future Research**

Although the main purpose of the current study was to provide a quantitative assessment of Georgia physician intention and administration of the HPV vaccine to 11-12 year-old girls and their intention to recommend the HPV vaccine to 11-12 year old boys, a rich compilation of qualitative information accompanies the data set. Future efforts may focus on female gender of the physician and parental barriers with regards to recommendation of the vaccine to 11-12 year old girls, to guide strategies. Focus groups of female physicians with public health professionals facilitating may lead to an expansion of reasons given for not recommending the vaccine. This will be beneficial if efforts to increase rates are to be realized in Georgia. It may also be useful to include parents in separate focus groups to allow them freedom to express their concerns and barriers to vaccinating their younger daughters. Efforts to explore barriers of physicians and parents may lead to modifications in social media and actions that could be applied to other states.

Other areas of focus for researchers may include examining how the HPV vaccine is supplied to determine if providing the vaccine in smaller unit packages has an impact on the physician barrier of cost of stocking the vaccine. Finally, another focus may be exploring how public health communicates vaccine information and education to physician offices. While 92.5% of respondents indicated they received vaccine information from state and location

immunizations programs, a knowledge gap remains. Educating the physician about the VFC program and which patients may qualify for this program is another area for future research.

Most physicians in this study indicated financial barriers kept them from recommending and administering the HPV vaccine more often to their patients. The VFC program is available to reimburse the physician for providing the vaccine to children who do not have insurance or who have insurance that does not cover the cost of HPV vaccine. As all physicians in this study were VFC providers and may not be aware of how this program could help their patients who do not have insurance. Further research to explain why physicians are not utilizing this program to cover the cost of vaccine for their uninsured and underinsured patients, should be explored. The VFC program is a federal program and findings may be applicable to other states.

The current practice in the Georgia Immunization Sections is to provide new vaccine information and communications through telephone fax and email to the physician office. However, it is not known if all physician locations receive this information or if the telephone fax or email address is current. Indeed, when physicians change office location, retire, or move to another practice, this information may not be available to the Georgia Immunization Section. In this case, current information on vaccine changes will not be known to the physician. An annual review of the VFC provider list to verify telephone fax and email information is necessary to ensure all physicians have access to the most current vaccine information and can apply the information at their practice.

#### Conclusion

This study was intended to provide an assessment of HPV vaccination by Georgia physicians to assess perceived knowledge, barriers, supports, practices, and adherence to ACIP guidelines and recommendations. A proportionate stratified random selection method was utilized to survey pediatricians, family physicians, gynecologists, and internal medicine physicians in Georgia. The final sampling frame included 264 (n=264) physicians who administered the HPV vaccine, 62 in rural counties and 202 in six urban counties. Response rate to the survey was 82.6% yielding a high degree of reliability.

As a result of this study, 64.2% believed the most important barrier for not vaccinating their female patients was lack of adequate reimbursement. The most significant parental barrier to vaccination according to 89.9% was the request that HPV vaccine be deferred until the female patient was older, confirming female adolescents ages 13 to 17 are getting vaccinated in higher proportions than their pre-adolescent counterparts.

Knowledge about HPV and who could receive the vaccine was correctly known by >90% of respondents. Vaccinating females according to ACIP guidelines at age 11-12 years was performed consistently by only 12% of respondents. Less than one quarter of physicians consistently recommend HPV vaccine to male patients at 11-12 years of age.

No difference emerged when the data were analyzed by urban or rural geographic location. Three new variables created revealed through logistic regression that female physicians and parental barriers made it more likely that female patients 11-12 years of age would not receive a recommendation for HPV vaccination.

This study adds to existing research highlighting the importance of considering barriers and supports, particularly the influence of financial barriers. It also points to the significance of personal beliefs, specifically having a belief that the HPV vaccine will have a positive impact on young men and women's lives. Future efforts may focus on female gender of the physician and parental barriers with regards to recommendation of the vaccine. Scholars from public health

will be at the research table and join others as part of the creation of a new body of literature with state-wide implications.

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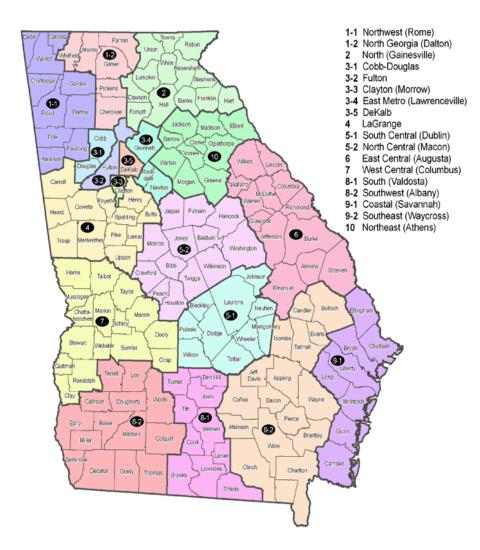
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#### **APPENDICES**

#### A. MAP OF GEORGIA BY PUBLIC HEALTH DISTRICTS



#### **B. IRB Approval Letter**

	Georgia Southern University Office of Research Services & Sponsored Programs							
	Institutional Review Board (IRB)							
Phone: 912-478-	Phone: 912-478-0843 Veazey Hall 2021							
	P. O. Box 8005							
Fax: 912-478-07	719IRB@GeorgiaSouthern.eduStatesboro, GA. 30460							
То:	Betty Dixon, 103 Gloucester Road, Savannah, GA. 31410 John S. Luque, Robert Vogel, Stuart Tedders							
CC:	Charles E. Patterson, Vice President for Research and Dean of the Graduate College							
From:	From: Office of Research Services and Sponsored Programs Administrative Support Office for Research Oversight Committees, (IACUC/IBC/IRB							
Date:	October 4, 2010							
Expiration	May 1, 2011							
Date:								
Subject:	Status of Application for Approval to Utilize Human Subjects in Research							

After a review of your proposed research project number H11059 and titled <u>"An Assessment of HPV Vaccination</u> by Georgia Physicians: Perceived Knowledge, Barriers, Supports, Practices, and Adherence to ACIP Guidelines AND Recommendations," it appears that (1) the research subjects are at minimal risk, (2) appropriate safeguards are planned, and (3) the research activities involve only procedures which are allowable. You are authorized to enroll up to <u>349</u> subjects.

Therefore, as authorized in the Federal Policy for the Protection of Human Subjects, I am pleased to notify you that the Institutional Review Board has approved your proposed research.

This IRB approval is in effect for until May 1 2011. If at the end of that time, there have been no changes to the research protocol; you may request an extension of the approval period for an additional year. In the interim, please provide the IRB with any information concerning any significant adverse event, whether or not it is believed to be related to the study, within five working days of the event. In addition if a change or modification of the approved methodology becomes necessary, you must notify the IRB Coordinator prior to initiating any such changes or modifications. At that time, an amended application for IRB approval may be submitted. Upon completion of your data collection, you are required to complete a Research Study Termination form to notify the IRB Coordinator, so your file may be closed.

Sincerely,

**Eleanor Haynes** 

Eleanor Haynes Compliance Officer

# C. Sampling Frame

# Selection method: PPS without replacement – Original Sampling Frame

Obs	County type	County name	Pop 2000	Pop 2009	Public Health District	Number prov	Selection Prob	Sampling Weight
1	Rural	Wilkinson County	10220	10076	5-2 North Central (Macon)			23.5000
2	Rural	Berrien County	16235	17044	8-1 Valdosta	2	0.08511	11.7500
3	Rural	Hancock County	10074	9219	5-2 North Central (Macon)	2	0.08511	11.7500
4	Rural	Jeff Davis County	12685	13659	9-2 Waycross	2	0.08511	11.7500
5	Rural	Mitchell County	23934	23800	8 -2 Southwest	B -2 Southwest 4 0.17021		5.8750
6	Rural	Franklin County	20287	21748	North (Gainesville) 5 0.21277		4.7000	
7	Rural	Appling County	17419	18011	9-2 Waycross	0-2 Waycross 6 0.25532		3.9167
8	Rural	Jefferson County	17263	16478	6 East Central (Augusta)	6	0.25532	3.9167
9	Rural	Lumpkin County	20979	27528	2 North (Gainesville)	6	0.25532	3.9167
10	Rural	Toombs County	26067	27959	9-2 Waycross	6	0.25532	3.9167
11	Rural	Wayne County	26565	29407	9-2 Waycross	6	0.25532	3.9167
12	Rural	Sumter County	33200	32084	7 West Central	11	0.46809	2.1364
13	Urban	Spalding County	58417	64708	4 LaGrange	7	0.04110	24.3333
14	Urban	Gordon County	44104	53292	1-1 Rome	10	0.05871	17.0333
15	Urban	Houston County	110765	135715	5-2 North Central (Macon)	11	0.06458	15.4848
16	Urban	Clayton County	236520	275772	3-3	33	0.19374	5.1616
17	Urban	Fulton County	815827	1033756	3-2 Fulton	113	0.66341	1.5074
18	Urban	Gwinnett County	588450	808167	3 – 4 Gwinnett	118	0.69276	1.4435

#### **D** HPV Survey of Physicians

#### **HPV Survey**

The survey is an assessment of HPV vaccination knowledge, barriers, and practice guidelines. Questions are designed to match up with the most current guidelines and recommendations published by the Advisory Committee on Immunization Practice (ACIP). The answers you give will play a part in understanding more about the overall health of Georgia citizens. The information will contribute valuable information to research.

The survey is private and your participation is voluntary; taking the survey means you consent to take part in the study. The answers will not be traced to you, so please give honest answers to each question. Thank you.

For the purposes of this survey, we are asking about the quadrivalent HPV vaccine (Gardasil®).

	Never	Rarely	Sometimes	Often	Always
Professional Organizations (e.g., AAFP, ACOG, AAP, SGIM)					
Advisory Council on Immunization Practices (ACIP)					
State and local immunization Programs					
Colleagues					
Pharmaceutical representative					
Internet websites					
Media					
Medical conferences					
Grand rounds/local institutional lectures					

#### 1. How often do you use the following sources to obtain information about the HPV vaccine?

2. Please answer the following true/false questions and base your answers on your current understanding of HPV and HPV vaccine, without looking at other sources of information. Feel free to check "Unsure" when you do not know the answer. (*Please check box that applies for each statement*.

	True	False	Unsure
Most HPV infections resolve without medical intervention.			
HPV is a relatively uncommon sexually transmitted infection.			
HPV causes genital warts in males and females.			
Almost all cervical cancers are caused by HPV infection.			
The FDA approved the quadrivalent HPV vaccine for use in females ages 9-26.			
Females who have been diagnosed with HPV infection should not be given the HPV vaccine.			
The FDA approved the quadrivalent HPV vaccine for use in males for permissive use for ages 9-26.			

3. How strongly would you agree or disagree that the following are <u>barriers</u> related to immunizing your patients against HPV?

DisagreeDisagreeNeutralAgreeAgreeMy concerns about the safety of HPV vaccine
safety of HPV vaccine
My concerns about the efficacy of HPV vaccine       Image: Concerns about the efficacy of HPV vaccine         Administering a new vaccine with a limited track record of safety       Image: Concerns about the efficiency of the vaccine schedule         Adding another vaccine to the vaccine schedule       Image: Concerns about the efficiency of the vaccine schedule       Image: Concerns about the efficiency of the vaccine schedule         Lack of information about the quadrivalent HPV vaccine       Image: Concerns about the efficiency of the vaccine schedule       Image: Concerns about the efficiency of the vaccine schedule         The upfront cost of purchasing private stock       Image: Concerns about the efficiency of the vaccine schedule       Image: Concerns about the efficiency of the vaccine schedule
efficacy of HPV vaccine
Administering a new       vaccine with a limited       Image: Constraint of the second of the
vaccine with a limited track record of safety       Image: Constraint of the safety       Image: Constraint of the safety         Adding another vaccine to the vaccine schedule       Image: Constraint of the safety       Image: Constraint of the safety       Image: Constraint of the safety         Lack of information about the quadrivalent HPV vaccine       Image: Constraint of the safety       Image: Constraint of the safety       Image: Constraint of the safety         The upfront cost of purchasing private stock       Image: Constraint of the safety       Image: Constraint of the safety       Image: Constraint of the safety
track record of safety
Adding another vaccine       Image: Constraint of the vaccine schedule       Image: Constraint of the vaccine schedule         Lack of information       Image: Constraint of the vaccine       Image: Constraint of the vaccine         Lack of information       Image: Constraint of the vaccine       Image: Constraint of the vaccine         The upfront cost of       Image: Constraint of the vaccine       Image: Constraint of the vaccine         The upfront cost of       Image: Constraint of the vaccine       Image: Constraint of the vaccine
to the vaccine schedule
Lack of information         about the quadrivalent         HPV vaccine         The upfront cost of         purchasing private stock
about the quadrivalent HPV vaccine     Image: Constant of the upfront cost of purchasing private stock     Image: Constant of the upfront cost of the u
HPV vaccine    The upfront cost of    purchasing private stock
The upfront cost of purchasing private stock
purchasing private stock
HPV vaccine to my
practice
The cost of stocking HPV
Lack of adequate
reimbursement for HPV
Failure of some insurance
companies to cover the
cost of vaccination
discuss HPV vaccination
with patients and /or
parents
Difficulty ensuring that
patients will complete the
3-dose HPV vaccination
series
HPV vaccination is not
required for school
attendance

# 4. How often have you experienced the following <u>parental</u> barriers to immunizing female patients against HPV?

	Never 0%	<b>Rarely</b> 1-25%	Sometimes 26-50%	Often 51-75%	Always >75%
Parent concern about vaccine Safety					
Parent concern about vaccine efficacy					
Parent reluctance to discuss sexuality/sexually					
transmitted infections Parent concern that adolescent will assume					
that a parent who agrees to HPV vaccination condones premarital sex					
Parent concern vaccinated child will practice riskier sexual behaviors					
Lack of parent education/understanding about HPV infection					
Parent requests that HPV vaccination be deferred					
Parent believes child is not at risk for HPV infection					
Parent won't consent to vaccination					
Parent opposition to HPV vaccination for moral or religious reasons					
Parent believes child is too young for the HPV vaccine					
Parent concern about negative media reports related to the HPV vaccine					

Check here if you don't recommend HPV vaccine in your clinic practice and skip to Question 9

# 5. In the <u>past 12 months</u>, how often did you <u>recommend</u> the HPV vaccine to your female patients, in the following age groups:

	Never 0%	Rarely 1-25%	Sometimes 26-50%	Often 51-75%	Always >75%	Do not see patients in this age group
Ages 9-10						
Ages 11-12						
Ages 13-17						
Ages 18-26						

6. In the <u>past 12 months</u>, how often did you <u>administer</u> at least one does of the HPV vaccine to your female patients, in the following age groups:

	Never 0%	Rarely 1-25%	Sometimes 26-50%	Often 51-75%	Always >75%	Do not see patients in this age group
Ages 9-10						
Ages 11-12						
Ages 13-17						
Ages 18-26						

7. In the <u>past 12 months</u>, how often did your female patients or parents of your female patients in the following age groups <u>refuse</u> HPV vaccination (i.e., did not agree to vaccination currently or at a later date)?

	Never 0%	Rarely 1-25%	Sometimes 26-50%	Often 51-75%	Always >75%	Do not see patients in this age group
Ages 9-10						
Ages 11-12						
Ages 13-17						
Ages 18-26						

8. The ACIP has recommended optional HPV vaccination for boys and young men to protect them from genital warts, although the ACIP stopped short of recommending its routine use in boys. How often would you recommend vaccination to males in the following age groups:

	Never 0%	<b>Rarely</b> 1-25%	Sometime 26-50%	•	
Ages 9-10					
Ages 11-12					
Ages 13-17					
Ages 18-26					

The remaining questions are included so that we will know about the physicians reached by this survey and the characteristics of their practices.

9. Are you a Vaccine for Children (VFC) provider? Yes No Don't know

10. Which of the following describes your primary	clinical specialty? (choose one)
Pediatrics	Obstetrics/Gynecology
☐ Family Medicine	Other (Specify):
Internal Medicine	Academic
<b>11. Including you, how many physicians are in you</b> 1       2-5       6-9       10-14       1	
12. Which of the following best characterizes your      Single Specialty      Multispecialty	

# 13. About what percent of your patients use the following primary payment methods? (Please approximate; groups may not sum up to 100%)

	0%	1-25%	26-50%	51-75%	76-100%
Private insurance					
Medicaid					
PeachCare (Georgia's Children's Health Insurance Program (CHIP)					
Uninsured/self-pay					
Medicare					
Other					

14. Compared to my clinical peers, I am often among the first to use a newly recommended vaccine.

	ongly agree	Somewhat Disagree	Neutral	Some Agr		Strongly Agree		
15. I tend to wait to adopt new medications, vaccines, or procedures until I hear about them from several trusted colleagues.								
	ongly Agree	Somewhat Disagree	Neutral	Some Agro		Strongly Agree		
<b>16. Which of the following best describes the geographic location of your clinical practice?</b>								
□ Suburban				Other (Specify):				
17. Wh 18. Ar	at is your re you:		years Female					
19. Which term best describes your race/ethnic group?								
	White/Ca	ucasian			Black/A	frican-Ame	rican	
	Asian				America	n Indian/Al	laska Native	
	Native H	lawaiian/Pacifi	c Islander		Mixed ra	ace		
	Other				Prefer no	ot to answer	r	

<b>20. Are you Hispanic or Latino?</b> Yes No
21. In what year did you complete residency training?
22. In what zip code is your primary practice located?
23. Date survey completed: mm/dd/yyyy

Do you have and additional comments or suggestions that apply to the HPV vaccine from your perspective that you are willing to share?

This is the end of the survey. Thank you for your time

End of Survey

## E. First Email to Physicians

(First email sent to MD offices informing MD of upcoming survey)

Good Afternoon! I am a public health nurse and a doctoral candidate at Georgia Southern University in the College of Public Health. Your medical practice was selected as part of a statistical sample of physician practices in Georgia to take part in a survey pertaining to the quadrivalent HPV vaccine, Gardasil®.

I hope you will find the time to complete the survey when it is sent to this office. The entire process will take less than 10 minutes. The 23 item survey is to obtain information on Georgia physician knowledge, barriers, and ACIP practice as it pertains to the HPV vaccine, Gardasil®. The information will add to the current knowledge of immunization practice in Georgia. A similar survey was conducted in Texas and Florida. This study has been approved by the Georgia Southern University Institutional Review Board. To decrease the amount of time this takes, only one physician (or his/her representative) is requested to complete the survey regardless of how many physicians practice at this location.

I will send a second e-mail instructing you how to access the survey online. If there is someone else in this office who should receive this e-mail, please let me know by return e-mail and I will make the correction. If you request, I can send the survey by postal mail with a return postage paid envelope. As you can see, I am doing what I can to decrease the amount of time you spend on the survey. Please know all responses will be held confidential. For every survey completed, \$1 will be donated to the American Cancer Society.

Thank you very much for your time, I know it is valuable.

Elizabeth Dixon, RN, BSN

### F. Second Email with Internet Link

Good Day,

I am a public health nurse and a doctoral student at Georgia Southern University in Statesboro Georgia in the college of Public Health. Your medical practice has been selected to take part in a survey pertaining to the quadrivalent HPV vaccine, Gardasil®. The survey is confidential and has been approved by the Georgia Southern University Institutional Review Board.

#### Here is a link to the survey.

This link is uniquely tied to this survey and your email address. Please do not forward this message. Only one physician (or his/her representative or nurse) is requested to complete the online survey regardless of how many physicians practice at this location. If a nurse or physician representative completes the survey on behalf of the physician, please respond as if you are the physician. For example, there is a question "in what year did you complete residency training?" Please respond with the answer that represents the year the physician completed his/her residency, rather than the year you completed your training.

I hope you will find the time to complete the enclosed survey. The entire process will take less than 10 minutes. The 23 item survey is to obtain information on Georgia physician knowledge, barriers, and ACIP practice as it pertains to the HPV vaccine, Gardasil® . The information will add to the current knowledge of immunization practice in Georgia. A similar survey was conducted in Texas and Florida.

Thank you very much for your time. If you have any questions or concerns, I may be reached by phone at 912-898-1222 or by email at <u>ed00027@georgiasouthern.edu</u>. Please know all responses will be held confidential. For every survey completed, \$1 will be donated to the American Cancer Society.

Sincerely,

Elizabeth T. Dixon, RN, BSN

Please note: If you do not wish to receive further emails from us, please click <u>here</u>, and you will be automatically removed from our mailing list.

## G. Postal Mail Survey

(For those who did not have email address or who had not responded to email survey)

Good Morning,

I am a public health nurse and a doctoral student at Georgia Southern University in Statesboro Georgia. Your medical practice has been selected to take part in a survey pertaining to the quadrivalent HPV vaccine, Gardasil®. The survey is confidential and has been approved by the Georgia Southern University Institutional Review Board.

Only one physician (or his/her representative) is requested to complete the enclosed survey regardless of how many physicians practice at this location. If a nurse or physician representative completes the survey on behalf of the physician, please respond as if you are the physician. For example, there is a question "in what year did you complete residency training?" Please respond with the answer that represents the year the physician completed his/her residency, rather than the year you completed your training.

I hope you will find the time to complete the enclosed survey. The entire process will take less than 10 minutes. The 23 item survey is to obtain information on Georgia physician knowledge, barriers, and ACIP practice as it pertains to the HPV vaccine, Gardasil®. The information will add to the current knowledge of immunization practice in Georgia. A similar survey was conducted in Texas and Florida.

Thank you very much for your time. If you have any questions or concerns, I may be reached by phone at 912-898-1222 or by email at ed00027@georgiasouthern.edu. Please know all responses will be held confidential. For every survey completed, \$1 will be donated to the American Cancer Society.

Sincerely,

Elizabeth J. Dijon

Elizabeth T. Dixon, RN, BSN

# H. Follow Up Phone Call

(left on voice mail or with physician answering service)

Hello, [KEY INFORMANT NAME]!

My name is Elizabeth Dixon I am doing my dissertation research at Georgia Southern University on the quadrivalent HPV vaccine - Gardasil.

I am calling because this Medical Practice was selected from a random sample of all Georgia practices that provide immunizations to their patients.

Your help is needed as a participant in this study. By now this office should have received a (MAIL OR EMAIL) survey. The survey is an assessment of HPV vaccination knowledge, barriers, and practice guidelines.

Questions on this survey have been used in Texas, Florida and other states and are designed to match up with the most current guidelines and recommendations published by the Advisory Committee of Immunization Practice.

The 23-item survey should take no more than 10 minutes to complete. All responses will be held confidential; for your information, this study has been approved by the IRB at GSU and will contribute valuable information to research on immunization practice in Georgia.

Your participation is very much appreciated and I hope you will take the time to complete the survey.

If you have not received the survey or would like to have it resent to your office, please call 912-898-1222 or you may request by email at ed00027@georgisouthern.edu.

Thank you.

# I. Follow up Phone Call (during office hours)

Hello, [KEY INFORMANT NAME]!

My name is Elizabeth Dixon I am doing my dissertation research at Georgia Southern University on the quadrivalent HPV vaccine - Gardasil.

I am calling you again because your Medical Practice was selected from a random sample of all Georgia practices that provide immunizations to their patients.

Your help is needed as a participant in this study. By now your office has received two or three (MAIL OR EMAIL) surveys. The survey is an assessment of HPV vaccination knowledge, barriers, and practice guidelines.

The 23-item survey should take no more than 10 minutes to complete. All responses are confidential. This study has been approved by the IRB at GSU and will contribute valuable information to research on immunization practice in Georgia.

Do you have the time now, or should I call back? When is a good time for me to call back?

(survey by phone) If you have a few minutes, we can do the survey now!

That's it. Your participation is very much appreciated! Thank you again for the time you took away from your practice and with me to answer these questions.