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# To Vaccinate, or Not? Health Care Providers and the HPV Controversy

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**To Vaccinate, or Not? Health Care Providers and the HPV Controversy**

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Undergraduate Honors Thesis

Thesis Advisor: Thomas Blank, Ph.D.

Submitted to the University of Connecticut Honors Program  
in Partial Fulfillment of the Requirements to Graduate as an Honors Scholar  
with a Bachelor of Science in Human Development and Family Studies  
from the College of Liberal Arts and Sciences

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## Abstract

Gardasil® – the vaccine was first thought to be a medical breakthrough in the fight against cancer, but it quickly became plagued with controversy. Despite wide media coverage, little attention has been paid to today's health care professionals who are ultimately responsible for prescribing the vaccine, and who may be the most knowledgeable about it. The present study seeks to expand on previous literature by investigating health care providers' current beliefs and practices with the human papillomavirus (HPV) immunization. It is essential that more recent research be performed in order to encompass current views of the vaccine, post FDA-approval.

Data was collected through open-ended interviews with nine health care providers, including MDs and APRNs, and family practice, obstetrics-gynecology, and pediatrics. The interview guide included major topics such as demographics, personal practices and opinions, perceptions of patients and guardians, and opinions on important controversial issues. Major themes and ideas were then found among their responses through qualitative analysis.

Results from the data show that providers' attitudes and behaviors are relatively uniform. Every provider currently administers and strongly supports the vaccine. Although many expressed that beginning immunization at age nine seemed young, none opposed administering it at that age. It was completely dependent upon the patients' sexual history and the overall demographics of their patient population. Some providers even expressed a desire to vaccinate outside of the FDA recommendations, to include boys and older females. Evidence-based research and experience with treating cervical cancer were cited as the main reasons for supporting the vaccine. When asked about the controversial topics, no providers felt that motives of pharmaceutical profit were relevant, and none believed that the vaccine would promote sexual activity. Mandates were the only topic to receive varying opinions.

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## LITERATURE REVIEW

### **Introduction**

The focus of this thesis is on the attitudes, opinions, and practices of physicians (MDs) and nurse practitioners (APRNs) with Gardasil®. Gardasil® is a newly approved immunization which has recently received a great deal of attention in the media. The vaccine protects recipients from four strains of the most common sexually transmitted infection; human papillomavirus (HPV). I will first give a brief history of immunization and vaccines, followed by a description of HPV and other STDs. Finally, I will review the literature as it relates to the controversies surrounding Gardasil® and the attitudes and opinions of the major groups involved in HPV vaccination.

#### *Immunization and Vaccines*

Infectious and parasitic diseases have affected humanity for as long as anyone can remember. The significant burden and devastation caused by this seemingly endless number of illnesses is combated by the medical community through the use of therapies, medications, and other forms of treatment. However, the astronomical health care costs associated with both curing and treating medical conditions, combined with the severe emotional and psychological impact of said diseases (Aneshensel, Frerichs & Huba, 1984), present society with an even greater battle.

Enter; preventive medicines – rather than focusing on the acute or chronic treatment of disease, work to prevent it from occurring in the first place. Immunizations are a prime example of this concept. According to Payette and Davis (2001), “The goal of a vaccine is to induce immunity to an infectious disease without having to suffer the pathogenesis associated with natural infection” (p. 241). The majority of licensed human vaccines contain a weakened or

dead form of the invading virus or bacteria. Even though these forms cannot typically induce the illness, the body still recognizes the disease germ and is able to make antibodies against it, without having to actually fight it off. If and when the real disease germs enter the body, the pre-made antibodies will immediately know how to destroy them without risk of infection (Center for Disease Control and Prevention, 2001).

With that being said, vaccines have been responsible for the reduction, and in some cases complete elimination of infectious diseases all over the world (Bloom & Lambert, 2003). Stern and Markel (2005) poetically describe the grim reality of certain illnesses that were once unchecked by immunization, “The gasping breath and distinctive sounds of whooping cough; the iron lungs and braces designed for children paralyzed by polio; and the devastating birth defects caused by rubella...” (p. 611). These are only a few of the diseases that once plagued society. Smallpox, measles, tetanus, and diphtheria are also diseases which are now successfully vaccinated against. Greg Zimet, professor of pediatrics and clinical psychology at Indiana University School of Medicine, states “When you consider that only a century ago infant mortality in the United States was 20 percent and another 20 percent of kids died before the age of 5...the critical role that compulsory vaccination plays is clear; the infant mortality rate today is less than 1 percent” (Houppert, 2007, p. 18).

However, such an overwhelming statistic seems to be slowly forgotten, as more and more parents are refusing to vaccinate their children. Zimet goes on to explain, “Vaccines are their own worst enemy. When they work, they reduce the element of risk to almost negligible. Who knows anyone who has ever had diphtheria or polio today? Take the deadly diseases so far out of the equation, and these parents will focus on what the vaccine’s side effects may be” (Houppert, 2007, p. 18). Despite the fact that no scientific evidence has found truth in the

severe, debilitating, and sometimes lethal claims being made about immunizations (Omer, Salmon, Orenstein, deHart, & Halsey, 2009), more and more U.S. children are no longer being vaccinated, and there are already signs of increasing illnesses because of it.

Among all of this controversy, researchers continued pressing to find novel vaccines that would have important and positive impacts on public health. They began investigating a whole new category of illness which might be prevented through immunization; sexually transmitted infections.

### *Sexually Transmitted Infections*

Sexually transmitted infections (STIs), also known as sexually transmitted diseases, are currently a huge issue, not only in the United States, but worldwide. According to the American Social Health Organization (1998), the estimated total number of people living in the U.S. with a viral STI is over 65 million, and every year there are at least 19 million new cases of STIs. More recently, the Centers for Disease Control and Prevention (CDC) (2007) found that in 2007 alone, over 1 million cases of chlamydia were reported; this is the largest number of cases ever reported to the CDC for any condition. There was also a reported 355,991 cases of gonorrhea and 11,466 cases of syphilis; a number that was once on the decline, yet has been increasing every year since 2001.

These STIs are the only ones actually required to be reported to the CDC. There are countless other sexual diseases invading the population that go undocumented. It is estimated that the most common sexually transmitted disease currently affects an astounding 20 million Americans, and another 6.2 million become infected each year (Centers for Disease Control and Prevention, 2008). This virus is known as human papillomavirus (HPV).



### *Human Papillomavirus, Cancer, Vaccination*

According to Zimet, Shew, and Khan (2008), HPV consists of more than 100 different types. Of those 100, about 40 are passed on through sexual contact, affecting the anogenital areas. It is estimated that HPV causes about 90% of genital warts (types 6 and 11), and 70% of cervical cancers (types 16 and 18). Despite a high HPV prevalence rate, most women will not go on to develop cervical cancer. Regardless, the National Cancer Institute estimates that in 2009, there will be 11, 090 new cases of cervical cancer, and over 4,000 deaths from the disease caused by HPV.

In terms of prevention, the wide spread use of Pap smears has allowed healthcare providers to find abnormal cell formations in the cervix, which can then be treated before turning into cervical cancer. However, false-negatives can be common due to a variety of possible errors (Roberts, Gurley, Thurloe, Bowditch, & Laverty, 1997). So how can abnormal cells be prevented in the first place? Immunization.

Gardasil® is a vaccine which protects against the four types of human papillomavirus most commonly linked to genital warts and cervical cancer. It is given in three doses, over a six month period. Gardasil® was FDA-approved in June of 2006, and is currently recommended for females between the ages of 9 and 26.

### **Previous Literature**

#### *The Gardasil® Controversy*

Coming about in an age when immunizations are being questioned by some, Gardasil® has only added fuel to the debate. What initially was considered a wave of hope in the ongoing fight against cancer quickly became plagued with controversy. According to Karen Houppert (2007), "Today, as thirty-one state legislatures consider mandating the vaccine for middle school

girls, skepticism about the wisdom of embarking on this swift and widespread inoculation program has bubbled up from critics who span the political spectrum” (p. 17). Such arguments stem from some abstinence-only believers who claim that the disease is a result of lifestyle decisions, and therefore cannot be mandated, as opposed to say, a chicken pox or measles, mumps, rubella vaccine. Also, there is a debate that the vaccine will lead to sexual promiscuity, in which the common idea that ‘talking about sex, leads to sex’ again arises. There are also many critics of Merck & Co. who claim that the company is pushing the vaccine only on the grounds that they stand to make \$4 billion a year from this particular pharmaceutical, and are in no way considering women’s health and safety. From this stems other beliefs that it is too soon to tell whether or not the drug has any serious side effects or is even truly effective.

Although the media have extensively covered these debates, there is far less scientific research available to determine how prevalent such arguments are, or how they are impacting acceptance of the vaccine. When the FDA came out with recommendations for girls as young as 9, there was an immediate questioning of the implications. As far as sexuality, nothing has been published thus far looking at whether or not the vaccine has caused recipients in the last three years to have sex earlier than they normally would have, or if it had any impact whatsoever on their views of sexual activity. There has, however, been previous research on other forms of STI prevention (Kirby, 2002; Raine, Harper, Leon, & Darney, 2005; Zelnik & Kim, 1982). All studies found no evidence to support the idea that these programs led to earlier or riskier sexual intercourse. More extensively, a literature review by Baldo, Aggleton, and Slutkin (1993) looked at 19 studies which examined sexual behavior of high school and/or college students who have received sexual education across multiple countries. Not only did none of the studies indicate that the education led to an earlier onset, or more frequent sexual activity, but a number

of studies found just the opposite – that sexual education in fact caused a delay in the onset of sex or a reduction in sexual activity overall. Based on these findings, it seems that STI prevention through the use of an HPV vaccination would not lead to sexual promiscuity.

There have also been arguments claiming that the vaccine is neither safe nor effective. However, there has been a multitude of research suggesting otherwise. The vaccine demonstrated 100% efficacy in preventing warts and vaginal dysplastic lesions, and was 98% effective in preventing high-grade cervical lesions (e.g., Villa, Costa, Petta, Andrade, Ault, Giuliano, et al., 2005; Koutsky, & Harper, 2006; Future II Study Group, 2007; Garland, Hernandez-Avila, Wheeler, Perez, Harper, Leodolter, et al., 2007). These same studies also found the vaccine to be safe. In clinical use, any serious adverse effects that were reported were analyzed by the FDA and CDC and later found to be inaccurate. These agencies issued a statement in July of 2008, “Based on ongoing assessments of vaccine safety information, the FDA and CDC continue to find that Gardasil is a safe and effective vaccine. The benefits continue to outweigh the risks... This vaccine is an important cervical cancer prevention tool.”

However, there is still an issue regarding the actual length of efficacy. The vaccine has only been FDA-approved for about three years, with research dating back to clinical trials before approval as well. Studies have demonstrated a sustained efficacy for at least five years (Harper, Franco, Wheeler, Moscicki, Romanowski, Roteli-Martins, et al., 2006; Villa, Costa, & Peta, Andrade, Paavonen, Iverson, et al., 2006; Ault, 2007), which is how long research on the vaccine has been underway. There have been other studies as well which demonstrated an estimated efficacy of 12 years or more (Fraser & Tomassini, 2007), and another which discovered an immune response normally found in vaccines with a long lasting efficacy (Olsson, Villa, Costa, Petta, Andrade, Malm, et al., 2007). Regardless of what goes on in the media, evidence-based

research has found that Gardasil® is both safe and effective in preventing genital warts and cervical cancer in females age 9-26.

Populations outside these FDA guidelines are also being studied to see if they might be included. Males are carriers of HPV, and they pass it on to their partners during sexual interaction (Dunne, Nielson, Stone, Markowitz, & Giuliano, 2006). While they cannot develop cervical cancer, anogenital warts are frequently presented. Nielson, Flores, Harris, Abrahamsen, Papenfuss, Dunne, Markowitz, and Giuliano (2007) examined 463 men age 18 to 40, and found that 51.2% were positive for at least one oncogenic or nononcogenic HPV type based on samples from multiple anogenital areas. Furthermore, studies have also found that HPV type 16 may lead to penile, anal, and head and neck cancers. It was found that among a small sample of males with penile carcinoma, 77.5% had HPV (Pascual, Pariente, Godinez, Sánchez-Prieto, Atienzar & Segura, 2007). Studies are currently underway to determine the safety and efficacy of Gardasil® among males, in the hopes that they too will be approved for vaccination. Thus far, research indicates that the vaccine stimulates a strong immunogenic response and has no significant safety issues in men (Block, Nolan, & Sattler, 2006).

Women over age 26 are another population that might benefit from HPV vaccination. In January of 2009, Gardasil® was again denied approval for this population. However, the issue is based on cost-effectiveness. The vaccine's efficacy drops greatly once females have already been exposed to HPV, so the point is to catch females before they engage in any sexual activity (Krauskopf & Pierson, 2009). Regardless, if a female is virginal at any age, or has not gotten HPV yet, the vaccine can still be effective. Long-term clinical studies are again underway to provide evidence-based research supporting this age group.

### *Attitudes and Opinions of Gardasil®*

Based on the vast amount of information being presented, whether evidence-based or not, it is clear that there are many different opinions surrounding the HPV vaccine. This has important implications for how the vaccine is being accepted and administered. Research is needed to examine the attitudes and opinions of the major stake holders in Gardasil®. This includes the children, adolescents and young adults being vaccinated, the parents of those patients who are underage, and the healthcare providers prescribing the vaccine.

Previous research investigating the attitudes of adolescents and young adults found that they had a great interest in HPV vaccination, especially an immunization that prevents both cervical cancer and genital warts (Zimet, Perkins, Sturm, Bair, Juliar, & Mays, 2005; Zimet, Mays, Winston, Kee, Dickes, & Su, 2000; Hoover, Carfioli, & Moench, 2005; Kahn, Rosenthal, Hamann, & Bernstein, 2003; Boehner, Howe, Bernstein, & Rosenthal, 2003). For instance, one of the studies examined both female and male acceptance of STD vaccinations among college students using hypothetical immunizations for genital herpes and HPV. Researchers found an overall endorsement rate of 74% (Boehner et al., 2003). Khan et al. (2003) also performed quantitative research, though focused on only females and the human papillomavirus. Ultimately, 85% indicated that they would be very or extremely likely to receive an HPV vaccine once it was approved. Such research refutes earlier discussion that because Gardasil® is based on a sexually transmitted disease, the stigma and taboo attached to it may prevent young patients from wanting to receive it (Zimet, Mays, Fortenberry; 2000).

Parents are another important group involved in the vaccination process, especially those who will be making the decision for children who are not yet old enough to do so themselves. Despite concerns that parental refusal would be a major barrier to Gardasil® administration,

previous research, reviewed by Zimet et al. (2006), all found that parents expressed a moderate to strong interest in vaccinating their preadolescent and adolescent children against STIs (Mays, Sturm, & Zimet, 2004; Davis, Dickman, Ferris, & Dias, 2004; Zimet, Mays, Sturm, Ravert, Perkins, & Juliar, 2005; Zimet, Perkins, Sturm, Blair, Juliar, & Mays, 2005; Liddon, Pulley, Cockerham, Lueschen, Vermund, & Hook, 2005; Olshen, Woods, Austin, Lushkin, & Bauchner, 2005; Dempsey, Zimet, Davis, & Koutsky, 2006; Brabin, Roberts, Farzaneh, & Kitchener, 2006). More research has been published since the Gardasil® FDA-approval in 2006. Most studies continued to find that the majority of parents wanted to have their children vaccinated against HPV specifically (Constantine & Jerman, 2007; Brabin, Roberts, & Kitchener, 2007; Woodhall, Lehtinen, & Verho, 2007). A common theme among the minority of parents who opposed the vaccination concerned issues previously discussed above; sexual promiscuity, feeling their child would not be infected, and worries about efficacy and safety. Perhaps providing parents with evidence-based research regarding these concerns would lead to an even greater acceptance rate. Overall, this wide mixture of studies ranged from pre- to post- FDA-approval, was performed in various countries and across multiple samples, and included both quantitative and qualitative research.

The next major group is an essential part of the immunization process. Healthcare providers are an important population to study because they must decide if they are going to discuss, recommend, prescribe, and administer Gardasil® to incoming patients. Regardless of whether or not the children, young adults and guardians want it, healthcare providers ultimately determine if they can have it. In addition, Smith, Kennedy, Wooten, Gust, & Pickering (2006) and Gonik (2006) found that healthcare providers have a large influence on a parent's choice to vaccinate their children, including those who believe that vaccines are unsafe.

The majority of previous published research looking at provider attitudes and opinions was performed prior to Gardasil's® FDA approval. It was quantitative survey analysis, and most studies only focused on one healthcare profession at a time. Of the endless number of healthcare providers available, nurse practitioners and physicians specializing in pediatrics, family/internal medicine, and obstetrics-gynecology are the ones most involved in the actual prescription and vaccination of Gardasil®.

One of the first studies performed with regards to healthcare providers and general STI vaccination was also the only study to look at the attitudes and beliefs of nurse practitioners. Mays and Zimet (2004) explained that, "Future successful sexually transmitted infection (STI) vaccine programs will depend on health professionals' readiness to vaccinate adolescents" (p. 428) – a purpose that will be echoed throughout the rest of the research on medical professionals. Participants in the study rated 13 hypothetical vaccine scenarios which varied according to the type of STI infection, the age and gender of the patient, and endorsement of the vaccine by a major organization. The researchers concluded that nurse practitioners would be willing to recommend STI vaccinations when they became available. Medical organization endorsement was one of the main factors mediating vaccine uptake. Interestingly, gender of the patient did not influence whether or not providers would recommend the vaccine. Also, there was a preference to vaccinate 17 year olds, as opposed to 11 year olds.

This study laid the groundwork for all future research regarding the upcoming HPV vaccine. It is important to note, however, that HPV was not included in this particular study; rather genital herpes and HIV. Regardless, the finding that older adolescents were preferred over younger ones will continue to be a common finding. This has important implications for the

future, considering the rate of sexual activity and STI prevalence among a younger population (Centers for Disease Control and Prevention, 2002; Burnstien, Gaydos, & Diener-West, 1998).

Gynecologists' were the next group of healthcare professionals to be studied. Again, only one study was performed on this particular medical practice. Raley, Followwill, Zimet, & Ault (2004) looked directly at HPV vaccine scenarios, and they found similar results. Organizational endorsement was considered the most important factor in determining predisposition to provide the vaccine, followed by vaccine efficacy, and age of the patient. Once again, there was a preference to vaccinate at age 17 and a strong disinclination to vaccinate at 13.

The only study to specifically focus on family physicians was performed by Riesdesel, Rosenthal, Zimet, Bernstein, Huang, Lan, and Kahn (2005). This study went a step further in assessing the issue of gender. They found that these physicians had a higher intention to recommend to girls over boys, a finding that differs from the STI recommendations of nurse practitioners. HPV vaccination may be perceived differently from other STIs included in their study. Despite this difference, other findings remained consistent with previous research. There was an overall willingness to vaccinate against HPV; however, older adolescents were preferred over younger ones.

The final group of healthcare providers involved in the immunization process is pediatricians. This profession, unlike the others, was studied much more extensively as opposed to just a single research study. Of the quantitative studies taking place before FDA-approval, all found the common theme that the majority of pediatricians strongly endorsed the vaccine. Again, they were most likely to recommend the HPV vaccine to older patients rather than younger, and more often to girls over boys (Kahn, Zimet, Bernstein, Riesdesel, Lan, Huang, & Rosenthal, 2005; Daley, Liddon, Crane, Beaty, Barrow, Babbel, Markowitz, Dunne, Stokley,



Dickinson, Berman, & Kempe, 2006). These studies also found that providers felt parents may be a significant barrier in vaccination.

Similar quantitative studies were performed directly after the June 2006 FDA approval; however, they still mainly measured intent to prescribe rather than actual practices and behaviors (Feemster, Winters, Fiks, Kinsman, & Kahn, 2008; Ishibashi, Koopmans, Curlin, Alexander, & Ross; 2008). Interestingly, Feemster et al. (2008) found that 78% of respondents reported being extremely likely to recommend the vaccine to 11-12 year old girls, and 18% were somewhat likely. These findings vary greatly from the pediatric studies performed a year or more before FDA-approval.

The only qualitative study found was also based on pediatricians. Kahn, Rosenthal, Tissot, Bernstein, Wetzel, and Zimet (2007) utilized semistructured individual interviews to assess attitudes and intentions regarding HPV immunization for 31 pediatricians in three Midwest states. Again, physicians felt that parents might be a large barrier to vaccination, despite previously mentioned research that found a relatively high rate of acceptance from guardians. Also, this study, which was performed closer to the FDA-approval time period, found that only half preferred vaccinating patients over age 15.

Based on all the preceding research, it appears that as time elapsed, healthcare providers became more likely to administer the vaccine to a younger population. Finally, there was also only one qualitative pre-FDA approval study that looked across physicians from all three different backgrounds; obstetrics-gynecology, family physicians, and pediatricians (Duval, Gilca, McNeil, Dobson, Money, Gemmill, Sauvageau, Lavoie, & Ouakki, 2007). Researchers found some similarities, but also interesting differences. Overall, 95% of physicians thought the vaccine should be given before first sexual encounter. When asked if they ultimately will

prescribe HPV vaccines, 93.6% of gynecologists, 90.8% of family physicians, and only 77.1% of pediatricians said they would – percentages which correlated with the amount of correct HPV knowledge known. It is also important to note that this study was performed in Canada; there are no published studies to date that compare different providers in the United States. Such findings will be important to expand upon in future research.

It is clear that more research is needed to investigate the attitudes and behaviors among healthcare providers about HPV vaccination as it is adopted into the medical community. The present research expands on previous literature by performing a study almost three years into the clinical usage of Gardasil®, after its FDA-approval in 2006. It will be important to see if practitioners are continuing to become more accepting of the vaccine and whether or not they are actually administering it in their practice. Also, changes in the gender and age accepted for immunization may be changing as well, presenting an entirely new phenomenon in the Gardasil® debate. The present study will also be based on qualitative methodology rather than the overwhelming amount of survey analysis done in the previous studies. Similar to the previous research by Duval et al. (2007), an open-ended interview guide will allow providers to expand on their thoughts without being limited to a pre-determined set of answers. This may allow for interesting findings about provider attitudes and beliefs that were not able to be captured in surveys and questionnaires. Finally, the present study will be looking across the three major healthcare providers involved in the Gardasil® immunization process, while also expanding to include nurse practitioners – a population that was only studied once, and not specifically with regards to the HPV vaccine (Mays et al., 2004). It is essential that we obtain a more current view of healthcare providers and their thoughts and behaviors regarding their patients and Gardasil®.

## METHODS

### Sample Criteria

Although many medical professionals can *give* medications or injections, only physicians and nurse practitioners can prescribe them, and therefore they were the only providers included in the criteria. Inclusion criteria for the study stated that participants are currently practicing in the state of Connecticut, English-speaking, and certified to prescribe medications, specifically the HPV vaccine, Gardasil®. Of the physicians and nurse practitioners, only those specializing in pediatrics, internal/family medicine, and obstetrics-gynecology were included. These three specialties deal most directly with counseling and administering Gardasil® to patients. Any respondents who did not fit these criteria were to be excluded, though no one outside of these restrictions contacted the principal investigator to be interviewed. Age, gender, sexual orientation and ethnicity were not limited in this study.

### Participants

Participants for this study included nine healthcare providers practicing in the state of Connecticut. Three were located near the Waterbury area, and six others worked in the towns and cities surrounding Mansfield, Connecticut. Three were nurse practitioners and six were physicians. By specialty, two were in pediatrics, three in obstetrics gynecology, and four in internal/family medicine. Ages ranged between 35 and 71, with three males and six females. Table One, below, summarizes the demographic characteristics and also includes the typical patient age range each provider sees. One internal/family provider treats patients in the pediatric age range along with those over age 20.

Table One: Participant Characteristics

Participant	Gender	Age	Profession	Practice	Patient Ages
1	Male	63	M.D.	Pediatrics	0-22
4	Male	71	M.D.	Pediatrics	0-20's
6	Male	45	M.D.	Obstetrics Gynecology	Preteen-90's
3	Female	43	A.P.R.N.	Obstetrics Gynecology	11-82
5	Female	35	A.P.R.N.	Obstetrics Gynecology	Teen-90's
7	Female	49	A.P.R.N.	Family/Internal	16-70
2	Female	66	M.D.	Family/Internal	14-97
8	Female	49	M.D.	Family/Internal	18-24
9	Female	53	M.D.	Family/Internal	0-90's

### Procedure

To recruit participants for this study approximately 200 letters and flyers, approved by the University of Connecticut IRB (#H08-308), were mailed out to practices in and around the areas of Mansfield and Waterbury. Based on business listings in the Connecticut Yellow Pages, only those providers meeting the designated criteria were specifically contacted. The letter outlined the current controversies over Gardasil®, the purpose and qualitative nature of the study, as well as how to get in touch with the primary investigator. It was then up to the providers to contact the researcher if they wanted to participate. Providers were not paid for their participation in the study.

Once a line of contact was established, using telephone or email, the provider specified whether he or she would like to meet in person or over the phone. She or he then designated a

date, time, and place which was most convenient to conduct the interview, based on estimation that it would take between 15-25 minutes depending on how in-depth the provider wanted to be in his or her responses. For those interviews which took place in person, a consent form was given at the meeting for the provider to read and sign. Those who wished to discuss the study over the phone were faxed a copy of the consent form and asked to fax it back before the interview.

Immediately prior to the interview participants were re-informed that the study was going to be audio-taped with a digital recorder, their participation was completely confidential, and that they did not have to answer any questions with which they felt uncomfortable. During the interview, all participants were given as much time as they needed, and could address any concerns or questions about the study.

During the interview process, the researcher asked all questions in the order that they appeared on the guide. Due to the open-ended nature of the study, some providers provided an answer to another question while answering an earlier one. When a question was reached that had already been partially or fully answered, the researcher indicated so, and then proceeded to read the question and ask if they wanted to expand more, or were comfortable with what they had said previously.

### **Measure**

A qualitative interview guide was used to collect information; it was approved by the University of Connecticut IRB before the recruitment process. Questions were open-ended to ensure that providers were able to explore all different aspects of the HPV vaccine. Due to the qualitative nature of the research, and because it was being performed approximately two years into actual clinical usage of Gardasil®, there were no specific interview guides in the published

research that could be used. Based on what has been done, the principal investigator prepared a list of possible questions which were reviewed by peers and professors at the university. The final interview guide consisted of 22 main questions, some of which also included sub questions. They were then examined for common themes in order to categorize them more efficiently. The following description contains two examples for each main group of questions asked. Appendix A contains a full copy of the interview guide.

The first was demographics and general information about the providers' medical practice, such as:

*General Information:*

- Age and gender?
- Medical certification/specialize in?

The next segment focused on the healthcare provider's own personal opinions and practices regarding Gardasil®, for example:

*The Healthcare Provider:*

- Do you currently administer the HPV vaccine to your female patients? What has led you to this decision? (Probe; religion, personal experience, companies, peers, research).
- Do you bring up the vaccine with female patients/their guardians on your own, or do you wait for them to ask about it before voicing your opinion? Why?

The third section covered their experiences with patients, such as:

*The Patients:*

- Why do you think some patients and/or guardians choose not to get the vaccine? Or have you experienced any who did not want it? Do you agree with any of these reasons or do you have any of your own?

- Have your patients ever experienced any negative side effects which they believe occurred because of taking the vaccine?

The final questions attended to more controversial issues that have come about in the media, e.g.:

*Controversial Issues:*

- If you do administer the vaccine, at what age or age range do you think females should start getting Gardasil®? What led you to choose this age (range)? Do you agree with the FDA beginning the age range at 9? Why or why not?
- Do you believe administering the vaccine to females, who are not yet sexually active, will cause them to have sexual intercourse before they normally would have, had they not had the vaccine? Does your opinion change depending on the age of the female?

### **Data Analysis**

All interviews were kept on the student researcher's digital recorder until the last interview was obtained to ensure confidentiality. Once the interviews were ready for analysis, they were uploaded onto the investigator's computer and transcribed verbatim. For qualitative analysis, the transcripts were read and examined to find main themes among the providers' responses. Similarities and differences were uncovered regarding healthcare provider practices, opinions, and experiences with Gardasil®, and then these ideas were categorized into the major themes. These topics were different from the four interview sections since the provider responses were much more specific, and information consistently came about that had not initially been accounted for. Anita Garey, honors advisor, communicated with the principal investigator about qualitative analysis. Also, a previous study on provider HPV vaccine attitudes was used as a guide for investigation, as it was the only study to use a qualitative interview approach (Kahn et al., 2007).

## RESULTS

After conducting and analyzing the interviews of nine different healthcare providers, major themes surfaced with regards to their attitudes, practices, and experiences with the Gardasil® vaccine. It is important to remember that providers varied by profession, area of specialization, and gender. Yet, the first major finding was that provider responses were rather uniform across most topics, with a few exceptions. That is, being a physician or an APRN in a particular specialty, or being male or female, did not consistently affect reported attitudes and behaviors.

Beyond that major point, in order to describe these results efficiently, I will present them within six major categories or themes; (1) provider attitudes and opinions, (2) provider practices, (3) thoughts on the FDA guidelines of 9-26 year old females, (4) experiences and beliefs surrounding patient/guardian refusal, (5) providers' own reasoning for vaccination, and (6) controversial topics. These thematic categories are further broken down into sub-themes where appropriate. Quotes are also used to better illustrate how the providers (1-9) felt about specific issues throughout the interview, and the providers' profession and specialization will be provided for further comparative study.

### **1) Providers' General Attitudes and Opinions Regarding Gardasil®**

#### *Initial Introduction of the Vaccine*

Gardasil® was approved for prescription by the Federal Drug Administration in July of 2006. When asked how providers initially felt about the HPV vaccine around this time, answers were mainly positive. Two providers who did not go into much detail for this particular question mentioned that they felt the vaccine was a great advancement for the medical community. Others expanded on this point as follows:



“I think that it was definitely something that I thought was a pretty incredible break through, it was certainly something that was very compelling.” (5 – APRN, ObGyn)

“I knew about its development. I was very excited about it being released. And, like I said, I think it has great clinical potential.” (6 – MD, ObGyn)

One of the respondents was particularly prompt to respond to the FDA approval, mentioning a more personal experience with the following quote:

“Well, let’s put it this way; the first person who I gave it too was my own daughter. And that was, I believe September 20<sup>th</sup> ’06!” (9 – MD, Family/Internal)

Alternatively, a pediatrician expressed a somewhat different opinion:

“As a physician who deals with this all the time, you have to start from a skeptical point of view. And then you leave it out there. I won’t be the first to adopt, I won’t be the last. It has to be out there about a year maybe two to get an idea.” (4 – MD, Pediatrics)

This difference in initial uptake of the vaccine is an interesting finding. Several non-pediatric providers mentioned at points in their own interviews that they felt pediatricians were much slower on accepting and administering the vaccine at first. These two providers explain:

“First they [pediatricians] weren’t giving it out, and I was giving it out, and they weren’t too quick on the uptake. The GYNs were, we were, but the pediatricians took a little while before they started to do it. I think they all do it now, but they were a little hesitant at first.” (9 – MD, Family/Internal)

“Many times now I bring it up and the patients will say ‘Oh I already got that!’ This for me is fairly new in the last year or so, that I think the pediatricians have become much more active in getting their patients vaccinated.” (3 – APRN, ObGyn)

The other pediatrician in the study unfortunately did not mention when he began vaccinating his patients. Pediatrics aside, this slight sense of skepticism was voiced by a couple of the other providers as well, though none stated exactly when they adopted the vaccine into their clinical practice. One of the nurse practitioners mentioned it in a different light:

“I think a little bit of wait-and-see attitude. I think that I was hopeful that it would be a good thing for patients, because I do a lot of women’s health, so skepticism in the sense that I always wait to see what the downstream effect of it will be.” (5 – APRN, Family/Internal)

Similar beliefs were mentioned by another APRN in obstetrics gynecology who claimed to have some reservations. Overall, none of the providers had any explicitly negative comments or opinions of the vaccine during its FDA approval.

*Current Feelings; Approximately Two and a Half Years since Approval*

When asked if their views have changed at all in the short time since its introduction, most of the providers who had initially expressed support and praise for the vaccine stated that they still felt the same way. All those who had mentioned any kind of skepticism claimed that they now fully support the vaccine in their practice. A female provider was very adamant about the efficacy and safety shown in the research particularly and also mentioned that she felt Gardasil® should be considered along the same lines as any other vaccination. She explains in the following quote:

“I had my reservations, as I do whenever there’s a vaccine, same thing with chicken pox, and meningitis, and so forth... Until I got a chance to read the research, and recognized that it was a fully tested and FDA approved medication. My views have changed not because I didn’t recognize that HPV was an issue, because HPV has always been an issue. My views changed once I saw the data of the ability of the HPV vaccine in preventing HPV, which is almost 100%!” (3 – APRN, ObGyn)

The pediatrician (4) went on to explain how his practice has changed quite a bit:

“It took a good 18-20 months for me to adopt. Now we go through about 3-4000\$ worth of vaccine on about a 6-10 week basis, so it’s a lot!” (4 – MD, Pediatrics)

Another provider mentioned that she now felt like a stronger advocate for the vaccine since the initial release, and stated that she has even just gotten used to it in her everyday practice (8 – MD, Family/Internal). So although there were some differences among the providers as far as their initial feelings, all participants currently believe the vaccine is a great medicinal development for their patients.

### *Beliefs about Vaccine Safety and Efficacy*

When asked about Gardasil's® safety, every participant in the study was quick to state that they felt it was safe to give to patients. Responses included everything from “Yes” and “Absolutely,” to more in-depth responses, such as:

“After all these years and the thousands of patients who have received it, it is safe to administer.” (4 – MD, Pediatrics)

All providers also felt that the vaccine was effective in preventing cervical cancer, with similar responses to those listed above. There was some variation, however, when discussing the long term efficacy. Many providers mentioned within their interviews that they were still unsure about how long the vaccine would be useful, and this was based on the fact that the vaccine just has not been out long enough to see if it will last a lifetime, or if booster shots will be needed.

One provider explained:

“Well, as much as the data shows it's effective. What are we, at seven or eight years, at 2006 there had been about five years of data. So, you know, here we are, and it still looks effective at this point, so to that extent, yes. There's still a question of the long term efficacy, but you know, that's to be known.” (5 – APRN, ObGyn)

The issue of long term efficacy is brought up in more depth later on when discussing patient and guardians' attitudes towards the vaccine. To date, however, all the providers expressed a similar belief that the vaccine was both safe to give to patients, and effective in preventing cervical cancer linked to HPV.

## **2) Providers' General Clinical Practices**

### *Administration of the Vaccine*

As foreshadowed by the above discussion of current opinions and attitudes, all participants stated that they currently administer Gardasil® to their female patients on a regular basis.

Expanding on the idea of safety, none of the providers experienced any severe side effects in their patients when the vaccine was administered correctly, that is, one shot to start, another shot two months later, and a final shot six months after the first. There was an instance mentioned by one participant when the vaccine was not given correctly by a fellow nurse practitioner:

“We had one, and it was actually not my patient, it was one of the other nurse practitioners in the office, and it was when we first started giving the vaccine and she initially made an error and told the patient she needed to come back one month instead of two months, so the patient got her second Gardasil® injection only like 35 days after her first one and she broke out with a terrible case of shingles... Which, I think certainly that her immune system was compromised beforehand; it would make sense that she might have a shingles outbreak – Did it cause her to have shingles? You know, who knows. So, when the vaccine is given appropriately I have not seen anybody have any adverse effects.” (3 – APRN, ObGyn)

Although this event is a serious condition, the dose was not given correctly, and the provider believed that there may have been an issue beforehand with the patient’s immune system for it to cause such a severe reaction. All other providers either claimed that they had experienced no negative side effects at all, or reported some of the common side effects listed on the vaccine’s website. These include feeling faint, pain, and headache. For example, one APRN noted:

“It’s been really consistent with the research! Which is local, the site of the injection, like very small welts or some pain.” (5 – APRN, ObGyn)

Some providers attributed the fainting to be more of a needle-phobia reaction, or typical reaction to any immunization. One such example:

“We’ve really not had any, we’ve had a couple of people that have had one of the normal reactions afterwards where they’ve felt faint, and lots of people feel that that has nothing to do with the vaccine, that that’s just a-um, teenage response.” (2 – MD, Pediatrics)

One provider also mentioned that there were some small allergic reactions to the vaccine which then caused the patient to stop the series. This too is listed on the Gardasil® website as a

possible reaction to a type of yeast in the vaccine. Overall, the majority of providers claimed no side effects whatsoever.

### *Recommendation of the Vaccine*

When asked if they *actively* recommend the HPV vaccine to patients, the majority of providers, eight out of nine, said that they did. Only one provider stated that he did not, saying,

“I um, ehh not really... Most of the time we wait for them, but, I, you know what... That’s not fair; our room assistants often will mention it.” (1 – MD, Pediatrics)

He seemed hesitant and unsure of his answer and when asked if he wanted to explain further, he seemed to get somewhat defensive and immediately mentioned that there were other providers in the office who brought it up. This physician was one of only two pediatricians in the study, which may again link back to the idea that pediatricians could be somewhat different in their approach to Gardasil®. The other pediatrician, who had mentioned waiting about a year and a half before vaccinating, does actively recommend the vaccine at present and was very adamant about doing so.

Other providers, all of whom took an active role in recommending, mentioned some of the ways in which they did so. These examples included simply bringing up the vaccine, as one physician explained:

“Well, I ask them if they’re aware that there’s a vaccine available that could prevent HPV infection and subsequent possibility of cancer. And then I inform them and I give them the choice of if they would like to do that or not, and sometimes I’ll say, ‘You know, you don’t have to decide now, but the next time you come back let’s talk about it again.’”  
(2 – MD, Family/Internal)

Others reported using specific tactics which aimed to convince the patients that Gardasil® was a good investment, which was demonstrated by a gynecological physician who brought up the trouble cervical cancer can cause (a concept that is addressed again later on when discussing why providers choose to vaccinate):

“I do so by saying that the HPV vaccination and it’s infection are endemic at this time, and that it can lead to not only cancer of the cervix, but a whole bunch of other slew of things that lead to more visits to me, that lead to more procedures by me, that are not fun, so!” (6 – MD, ObGyn)

Another provider tactic was information. This provider describes how she tries to influence guardians to have their daughters vaccinated:

“I try to tell parents that the whole point is to catch them before they’re sexually active, not *when* they become sexually active, and actually I try to even influence them a little bit more by saying... Somewhere in the literature I think there’s evidence that it actually works a little bit better in the younger age group. So I try to influence some of those parents who think their kid is too young, when they’re really 13, 14, or 15, that there’s evidence to show that the vaccine works even better the younger you get it. I don’t know, I mean 1-2%, but even so, you know sometimes with someone who has got some negative ideas you have to use whatever you can.” (9 – MD, Family/Internal)

This same provider cited the use of pamphlets and informational sheets around her office:

“Oh, I have lots of literature in the office, from the company first of all, that’s all over the office. Second of all, when there’s a patient who I know hasn’t had it, and is at an age where they can get it, I talk it over with them and the mother.” (9 – MD, Family/Internal)

The second half of her statement brings up another important idea that came up in the interviews. When asked if they brought up the vaccine on their own, or waited for patients and/or guardians to ask about it first, the majority of providers cited a patient’s age and sexual history as being the deciding factor in whether or not they even recommended it.

#### *Recommendation with Regards to Patient Age and Sexual History*

A common theme that arose under the major topic of “Provider Practices” was that providers based their recommendation of the vaccine on the patient’s age, and to a higher degree, sexual history. The importance of vaccinating children before they are sexually active was a huge factor that many of the providers mentioned across all disciplines. One pediatrician noted that:

“It’d be very unusual to see cervical cancer in the age group that we deal with [pediatrics], but I mean, you’ve got to get them immunized early enough so that they can have the vaccine before getting HPV.” (1 – MD, Pediatrics)

This doctor seemed hesitant to mention sexual activity specifically. Other providers went into more detail. The following quotes demonstrate the commonality of this particular response:

“You know, if it’s a young girl who’s sexually active, I strongly encourage her to get the HPV vaccine. If I’m lucky enough to see them before they’re sexually active or I can talk to their moms, I strongly encourage them to have their children get the HPV vaccine. If, you know, I have a patient who is maybe young, 23, 24, but is either married or in a monogamous relationship and really considers themselves not at risk any longer, you know I still mention it but I may not push as hard, because I think really the people we want to vaccinate are the sexually innocent.” (3 – APRN, ObGyn)

“I actively recommend it for virginal women and girls. And that’s based on the data that the efficacy is cut in half in women who are sexually active... It’s an incredible benefit to especially a girl who is virginal... It depends on the demographics. If they’re 40 and married it’s not important at all. If they’re virginal it’s pretty important.” (5 – APRN, ObGyn)

“I bring it up. Any patient who is in the range, hopefully before their sexual debut, so that’s the ideal patient to find... It depends on their age and where they’re at. I mean if somebody is 30 and showing up after 3 kids it’s not terribly important, and they’re not the ones that are most recommended for it right now. Whereas the other patient I just mentioned is right.” (6 – MD, ObGyn)

“It’s just part of the routine things that I discuss at preventive health visits, so, women in their 40’s I would discuss mammography, women in the 9-26 range I would recommend the HPV vaccine.” (7 – APRN, Family/Internal)

Many of the providers above cited the FDA age range in their responses. This leads directly to the next major theme.

### **3) Provider Thoughts on the FDA Approval of 9-26 Year Old Females**

This particular section links intricately with provider practices. However, the FDA recommendation brought up specific opinions and evoked certain experiences which are better categorized as a separate theme. The first subject involved beginning the age range at nine.

Here, providers explained how they felt about it, as well as the age at which they typically started

vaccinating, and why. A major finding was that most providers in this study started administered in the early teens, though none disapproved of vaccinating at nine. Some did express feelings that it was young, yet agreed that there are certain patient populations which should be getting the vaccine at that age.

### *Age Nine and Patient Population*

Many providers started out by stating when they felt females should start getting Gardasil®, which for all was somewhere between about 10 to 13. These comments are illustrative of that belief:

“I um, I think that they can, the easiest way to remember is to say starting with double digits, when they start to be 10, and then they can get it.” (1 – MD, Pediatrics)

“Well I don’t treat them, but I would certainly start at puberty, just before puberty... Because you never know when a child’s going to become sexually active and be exposed to HPV, it’s unknown!” (2 – MD, Internal/Family)

“I tend to think that the early teen years, before, again I commented on my daughter age, I think that by you know 11 or 12... I know they can start as early as 9, but I think that’s a little early.” (7 – APRN, Family/Internal)

When probed about the FDA starting their age range approval at nine, participants all expanded on the importance of a provider’s patient population, as demonstrated in the following quotes:

“You know, I suspect in certain populations by starting early you’re trying to capture people, but I certainly think 11 or 12. Though I’ve had patients who’ve been sexually active as early as that, so I think that it’s an individual decision hopefully for parents and/or guardians to make.” (7 – APRN, Family/Internal)

“Oh I think middle school. Like 12ish? Hopefully that is before onset of any sexual activity. You have to know your patient population! You may work at a poor inner-city clinic and you may want to get those kids going at age eight, I don’t know. It’s just sad to think.” (8 – MD, Family/Internal)



Other providers jumped right into a discussion of population without being asked specifically about the FDA, and some mentioned possible rape or young pregnancies as a factor. A nurse practitioner talked about molestation in the following quote:

“I think 9 is young, I do... However, I have said to mothers, you know, god forbid your child is molested at 10, you know, not that they’re going to become sexually active, but don’t you want to protect them from everything?” (3 – APRN, ObGyn)

This particular response can also be tied back to some of the tactics that providers use to convince patients and/or guardians about the benefits of Gardasil®. Continuing with the issue of early pregnancies and population, some providers said:

“It depends on where you’re at. Like with my kids, mainly we start administering about 11. I have one mother who is a nurse who works at a low-income type clinic and they give their stuff starting at exactly 9 and a half. I asked her why, and she said she’s got 11 and a half year olds who are delivering babies. So, she knows they’re active, she wants to protect them.” (4 – MD, Pediatrics)

“Umm, well, 9 I agree with for certain populations where there are kids who are pregnant at 11 or 12, and I think that’s why they did it. I hope for some of the inner city population who, when they’re 9, they’re really like another person’s 18! It’s really crazy. But for those people, yes I think they even need it more, because they’re starting so young.” (9 – MD, Family/Internal)

One nurse practitioner explained how she actually had experienced young pregnancies in her own practice:

“You know, you have to believe the public health research in terms of the age range for sexual activity, and sort of maybe tailor it to your population... You know, I’ve had pregnant 11 year olds. And I see that if you’re a pediatrician or you’re looking at it from a public health perspective to have a standardized time for the vaccination is probably a good thing.” (5 – APRN, ObGyn)

This provider also brings up other reasoning for having a young age range in the second half of her comment. She mentions taking a public health perspective and seeing how a set range could be a good thing. Continuing with this idea, other providers went into more detail about the

efficiency of having the HPV vaccine available at nine. Two physicians explained in the following quotes:

“You know, it seems young to me when I first hear that age, I go ‘Gosh..’, and maybe there’s a small cadre of the population who is nearing their sexual debut at 9. It’s also though a very effective way to get to people that are still seeing their pediatricians on a regular basis, and they have to get their school physicals. So, in terms of the public health means of administering an effective treatment, you’re catching a lot more of the population doing it that way than waiting until they’re teenagers and neglecting their health for better or worse.” (6 – MD, ObGyn)

“Yeah I don’t really usually give it at 11, so much as around 12, 13. Um, I think most kids aren’t sexually active by that time. It depends on your population obviously, but, you know I mention it when, usually there’s a 6<sup>th</sup> grade physical in Connecticut, so that’s 11. I mention it at that time so that they can be primed on it and some of them say, ‘Yeah let’s get a start on it!’ 6<sup>th</sup> grade and high school sophomores must come in for physicals.” (9 – MD, Family/Internal)

Again, the concept of focusing on one’s patient population brings up the common theme that providers felt patients needed to be vaccinated before any onset of sexual activity. A couple of the participants even brought up their own children as examples, which adds a very personal aspect to their beliefs and practices. As previously quoted, one had mentioned giving it to her daughter almost as soon as the vaccine was approved (9 – MD, Family/Internal). Another provider mentioned waiting to get the added benefit of having a longer effect because she was confident that her child was not yet sexually active, as shown in the following quote:

“You know, I have to admit I’m a parent myself; I have a 10 year old daughter, but I probably will wait until she’s probably 12, you know another two years, that’ll give another two years of data...” (7 – APRN, Family/Internal)

Another nurse practitioner, who doesn’t have children of her own, spoke similarly:

“But, you know, if I was the parent of a child who I was fairly certain was not going to be sexually active in the next few years I might delay it to get the added benefit of, you know, if it’s only good for ten years you might delay it for that reason.” (5 – APRN, ObGyn)

Finally, one of the physicians spoke of his daughter:

“I think it’s something you give. You know, when my daughter reaches an appropriate age, and right now she’s nine, so very soon, she’ll be getting it!” (6 – MD, ObGyn)

These quotes in particular overlap with a major theme that will be discussed later: providers’ feelings and experiences with patients and/or guardians who may or do refuse the vaccine.

Before exploring more on that issue, I’ll note other concerns that came up with regards to the FDA recommendations of females, 9-26. These included the vaccination of older women, as well as boys. One gynecologist explained:

“You know, I think the recommendations that have come out are useful. I don’t feel that they should be written in stone, because I think that there are opportunities to use them outside of those recommendations wisely and effectively.” (6 – MD, ObGyn)

#### *Women over Age 26*

A comment that came up relatively often, without any specific questioning from the researcher, was the topic of older women and the HPV vaccine. One nurse practitioner described a relevant experience she recently encountered that made her more aware of wanting to advocate for an older female population:

“You know, I have a hard time with that because I know that the FDA chose 9-26 because that’s the age range when we mostly can get these young girls without... But I just was going over a case with the doctor on a patient who is 57 years old, she was married for 20-odd years, got divorced, and then was alone with herself for about 10 years. Never had an abnormal Pap, completely normal. She gets a new boyfriend, now she’s 57, she starts having intercourse with a new person who obviously has HPV, she shows up 6 months later with a high-grade lesion. Now, you know, when she came in and she said “I’m divorced, I’m going to be sexually active again with a new partner,” she would have been your perfect person to give Gardasil® to! But because she falls outside of that FDA range, not to say that we don’t prescribe drugs all the time outside of the FDA, you know off-label, but right now they’re sort of hitting us up with, ‘Well that’s the age range, we really don’t have enough to give it to everybody.’ I really think you have to look at an individual case by case basis. There are many women like this who have been in monogamous relationships for many years and now they’re going to be back out in the dating scene, ya know?” (3 – APRN, ObGyn)

Another nurse practitioner also experienced it in her practice, and expressed her own feelings on the matter while also explaining that she was even apart of some of the data soon to come out on the older female population:

“I wish it was offered for patients later. I think the 26, I know they’re looking at it, because I’ve actually been apart of some preliminary data coming out on Gardasil® for older women. It doesn’t stop at 26!” She goes on later to explain, “Hopefully it will be offered for older women. Women who are HPV negative who are older, because I think that’s a population that would benefit from the vaccine. I see that population, that’s sort of my point, is that there is a populace that you know... people get married young, enter a monogamous relationship, and then split-up; that would be a population that I think would be... And I have seen that in my own practice, so I think that’s an unaddressed segment of the population.” (7 – APRN, Family/Internal)

Another provider brought up the issue of recommending vaccination to females over age 26 even despite the FDA range:

“And of course the adolescent cervix is much more prone to transfer of HPV than the 40 year old cervix. But still, if I had a 40 year old virginal patient who was becoming sexually active I’d definitely recommend it!” She goes on to state later, “I actively recommend it for virginal women and girls. I offer it to everybody. And that’s based on the data that the efficacy is cut in half in women who are active.” (5 – APRN, ObGyn)

It is interesting to note that one of the providers stated she would recommend the vaccine outside the FDA recommendations. Unfortunately, it is unknown whether or not she has actually administered the vaccine to a female over the age of 26; or if any of the providers in this study have.

#### *Young Males and the HPV Vaccine*

Another population that was brought up, which falls outside the FDA’s guidelines, is that of young boys. This group was brought up less often than the older women, but it is still a significant issue gaining media attention. Although males cannot get cervical cancer from HPV, they pass it on to their female partners, who can then be affected by it. Also, some studies are investigating whether males may benefit from prevention of genital warts, and in very rare cases,

penile cancer. One provider brought up the idea of vaccinating boys when asked if he had any other comments at the end of the interview:

“You know what, there’s one other thing you didn’t ask about, that I don’t know if you want to include this, but, what about the idea, about how people feel about giving it to males? I mean I think there’s no reason why it shouldn’t be offered to males as well! Because obviously, that is how the females are mainly getting it!” (1 – MD, Pediatrics)

Another provider also mentioned males, along with some interesting speculations about gender differences. She explained:

“I think every kid should have it quite frankly. And this means the boys too! Which is in the works. What would be a really interesting study is once the boys come out with being approved, how many of the parents are resistant to having the boys vaccinated as opposed to the girls vaccinated. That would be a very interesting gender discordant opinion. I bet a lot of the mothers would rather have their boys vaccinated sooner than their girls, because they think of their little girls as angels, and the boys they know are not [laughs].” (9 – MD, Family/Internal)

It is interesting that she would speculate boys being vaccinated sooner, and perhaps implying more often, than girls. The final provider to bring up male HPV immunization initiated the topic when asked how he felt about federal mandates, which will be discussed in more detail during the main controversial issues theme. He notes:

“Fine, as long as I can give it to the guys too! I don’t think it should be mandated just for girls. You can’t mandate until you’ve got universal coverage.” (4 – MD, Pediatrics)

From his response, it can be assumed that this provider would approve of male HPV vaccination using Gardasil® and would administer it in his practice.

Another interesting point to note is that all the respondents who brought up male vaccination worked with a pediatric population. Two of the participants specifically specialize in pediatrics, and the other is certified in family medicine, but stated that she saw patients as young as infancy. As previously mentioned, the internal/family provider was one of the respondents who stated that she felt actual pediatricians were slow on the uptake of the vaccine (9 – MD,

Family/Internal). Of the two pediatricians, one mentioned that he did not take an active part in recommending the vaccine to patients, though he did administer it (1 – MD, Pediatrics), and the other mentioned waiting about 18-20 months after FDA approval before administering (4 – MD, Pediatrics). However, according to these findings, they were both more than willing to vaccinate males if and when the time comes and brought the issue up of their own accord during the interviews.

Shifting focus from the FDA guidelines, I mentioned above how some providers brought up the issue of being parents themselves, and having to make the vaccination decision. A main theme that arose from the questions was why these providers felt patients and/or guardians might refuse the vaccine, or what experiences they have had when patients do decline to get it or seem not to want it.

#### **4) Provider Feelings about Patients'/Guardians' Attitudes towards Gardasil®**

When it comes to healthcare, the opinion of the provider is extremely important. As we have seen, all the providers in this study administer Gardasil® to their patients. However, it is not always that simple. Patients may have their own feelings on the vaccine that do not necessarily coincide with the healthcare professional. In this section, providers' feelings and experiences with refusal or skepticism of the vaccine are discussed.

With Gardasil®, an important dynamic is created unlike that of most other vaccines. In this case, the age group recommended for vaccination runs from an age at which parental consent is required to one at which female patients are old enough to obtain the vaccine on their own. So the providers are commenting on why they believe either patients *and/or* guardians refuse or question the HPV vaccine.

### *Knowledge and Information*

One of the first issues mentioned involved patient information or knowledge about Gardasil® and HPV in general. One of the nurse practitioners commented on the sheer lack of knowledge she experienced with her patients which only recently began to turn around:

“Thank God Gardasil® has come out as far as being able to teach people about HPV! Before Gardasil® nobody had any idea and the first thing when you call them up and told them they had an abnormal pap and it might be a sexually transmitted disease, they like went berserk on you. At least now they’ve heard about it and they understand it and it’s a little bit easier to discuss.” (3 – APRN, ObGyn)

Although knowledge of the actual existence of HPV may be improving, other providers mentioned lack of knowledge and information with regards to Gardasil® research in the following quotes:

“Because they’ve only recently heard of it, and they’re assuming that it’s a new untested vaccine, which is not the case!” (1 – MD, Pediatrics)

“Patients come in and talk about them [commercials], and it’s really not productive, it doesn’t help inform them it just... You know, there might be a good drug and the television will have them scared about side effects that really are not consequential.” (2 – MD, Family/Internal)

The above provider brought up the issue of patient fear in her response, which emerged as another main sub-theme to be discussed shortly. She also mentioned the media, a common form of information for potential patients. There are multiple media through which patients can obtain Gardasil® information, but providers worried that these modes were not founded in research or evidence-based. One pediatrician explained:

“Keep in mind if it bleeds it leads. And that is how newspapers, etc. get your attention. ‘Cause they’ll give you a blurb and then that’s it. It’s not in the best light obviously... You know, it really depends on the source. You go on the web, God knows what opinion you’re gonna get.” (4 – MD, Pediatrics)

Another provider explained that she felt alternative sources of information were acceptable, and even important in forming ones’ opinion, but again, evidence-based was key:

“Well, you know, I really think that people should be able to get as much information as they can and from a lot of different sources, and I don’t want to be the sole source of information for people. So I think the discussion is valid, but the sort of alarmist stuff about people dying from Gardasil®, I think that’s a little hard to sift through.” (5 – APRN, ObGyn)

A physician implied a similar response:

“Sometimes you need to look at a number of sites to get where all those points of light intersect, and then make your best assessment of those. So, people that are way out there you can throw away. Unfortunately, many patients don’t do that.” (6 – MD, ObGyn)

He specifically mentioned the feeling that patients may not be getting adequate or accurate information. Another nurse practitioner expanded on the kind of information that can be out there, and the importance, again, of research and evidence:

“I find across the board the information is only as good as the source. So you can find good information out there and bad information. It’s like the vaccines for, you know, people saying that it’s linked to autism. That the MMRs [measles, mumps, and rubella immunization] are related to autism, if you can find a site out there that will tell you it is, and it’s been shown in study and study *and study* that it hasn’t been! So you can find that kind of thing with the HPV vaccine too. I just think that I want to caution people about being very careful about where they get their information.” (7 – APRN, ObGyn)

Overall, it seems that providers believe many patients and/or guardians who refuse the vaccine, or raise questions about it, may not have an adequate amount of information, or information that providers would consider valid. The issue of research is brought up later on when discussion of “Why Provider’s Choose to Vaccinate” is investigated.

### *Fear*

Fear was the most commonly cited reason for refusal or skepticism of HPV vaccination. There were many different kinds of fear explored by the providers, many of which link back to the sense of misinformation or inadequate resources. One provider broadly stated:

“I think that there are some people who are reserved, there are a lot of people who are very afraid of the medical community, and they hear a lot of things about drug companies just want to make money, and they have some un-informed un-realistic fears, and sometimes that overrides any information you can give them.” (2 – MD, Family/Internal)



More specific fears ranged from sexual promiscuity, to side effects and safety, as well as just needle phobias. It is interesting to see the wide variety of possible fears that providers felt might be at the root of some patients' or parents' negative attitudes toward Gardasil® and/or decisions not to be vaccinated or have their daughters vaccinated. With regards to sexual promiscuity specifically, the following quotes illustrate the providers' views of parental concerns:

“The other reason is because they all say, well, the parents will say, ‘Well my daughter isn’t promiscuous so why does she need it?!’” (1 – MD, Pediatrics)

“I had a patient the other day who told me that her husband really did not want the daughter vaccinated, more I think out of that whole idea of he really didn’t want to think about his daughter being sexually active.” (3 – APRN, ObGyn)

“I think a lot of them kind of hope that their child isn’t going to become sexually active, and if they don’t give them the vaccine then it won’t happen.” (9 – MD, Family/Internal)

“And then sort of, all the religious right concern that it’s going to make people promiscuous, which I think is false.” (5 – APRN, ObGyn)

“I think there are a subset of parents that feel as though by administering a vaccine for a sexually transmitted disease, that that will somehow open up the flood gates for sexual promiscuity. I think that that’s been marketed to some parts of the population.” She later says, “I think that there’s a subset of the media, sort of the really conservative that’s portrayed it as sexually promiscuous; I find fault with that.”(7 – APRN, Family/Internal)

Many of these beliefs seem to be speculation. It is unknown if any parents or patients actually expressed such feelings.

Fear of duration, or more so concern that the vaccine might not last long enough, was also an issue. As previously quoted, one provider (7 – APRN, Family/Internal) was withholding vaccination for her daughter to get the added benefit of more years on efficacy data. With regard to patients in particular, these providers explain:

“I think that some of the parents just want to wait and see, kind of what the long term efficacy will be.” (7 – APRN, Family/Internal)

“They have questions about it. The biggest one is duration. We don’t know how long it’s going to last. Then I tell them, this is good for at least 10-12 years, but I can’t tell you beyond that yet.” (4 – MD, Pediatrics)

To an even lesser extent, one provider mentioned just a fear of needles:

“Some people, this is just shots, but I’ve had someone mention just say they can’t... They’re so needle-phobic that they couldn’t get the concept of getting a shot voluntarily.” (8 – MD, Family/Internal)

Aside from these reasons, the main fear seemed to lie with safety and side effects. This was the most commonly mentioned among providers, as the following quotes show:

“I have experienced it, I have. I think that some of it is fear. I think that there is always that fear of unknown, it’s new, and they want to wait.” (3 – APRN, ObGyn)

“Some people are worried about side effects and safety, things like that. You get tons of stuff about peoples’ safety concerns and safety issues.” (5 – APRN, ObGyn)

“A lot of the parents think their kid is too young, you know, the vaccine hasn’t been out as long as they would like to see it.” (9 – MD, Family/Internal)

Other providers were more specific, again referring back to a lack of scientifically-based information, demonstrated by their responses:

“I think that there are some misconceptions about the risks associated with any immunization. And they are frequently construed to this one. So, the risks of autism for instance, or other learning disabilities, or other issues that are not well scientifically documented, but out there in the lay media and popular books are frightening to some people. I’ve heard people ask about it, you know, they’re not hook line and sinker sold on those particular opinions, but it’s something, it’s a hurdle to cross.” (6 – MD, ObGyn)

“I mean, I think a lot of it is the same fear people have of any vaccine. I mean I think it’s the same reason that some parents choose not to vaccinate their children against mumps, measles, and rubella; is that people have a fear that there’s some untoward reaction.” (7 – APRN, Family/Internal)

The third and final sub-theme found with regards to provider feelings on patients’/guardians’ attitudes, was that of patient lifestyle, and not thinking they needed it. For one, common misconceptions, such as the belief that because they were not yet sexually active they should not get the vaccine, were discussed previously in the results. Patients or guardians

may not be aware that that is in fact the best time to get the vaccine. One of the physicians commented:

“Well, women who are not sexually active yet, a lot of times don’t want to get it because they don’t feel they need to. They can’t think preventative.” (8 – MD, Family/Internal)

Also, going back to parents, a nurse practitioner explained:

“You know, they think, why give a vaccine if their child’s not sexually active, or they actually believe will never become sexually active?” (7 – APRN, Family/Internal)

Other specific lifestyle beliefs were mentioned as well. Another nurse practitioner stated:

“I mean some girls say, ‘I’m gonna marry somebody whose virginal, I’m virginal, it’s never going to be an issue for me.’ Some girls are pretty adamant about that. I suppose I’m more of a realist, or maybe a cynic [laughs], you know? When somebody tells me, ‘I’m going to marry somebody who’s never had sex’ I sort of think, well, even in a perfect world, even if that’s for religious reasons, what if you marry somebody who’s been married before and their wife died... You never really know what you’re going to be exposed to.” (5 – APRN, ObGyn)

Taken together, patients’ information and knowledge of HPV and Gardasil®, along with varied fears and lifestyle beliefs, were the three main reasons providers felt patients may choose to delay or not get the vaccine. To offset these attitudes, whether perceived or actually experienced with patients/guardians, the next theme instead demonstrates why providers themselves feel compelled to use Gardasil®.

### **5) Providers’ Choice to Vaccinate Against HPV**

Again, all nine providers in this study stated that they administered the vaccine to their patients. Two main themes repeatedly came up among provider responses, as to why they choose Gardasil®: research, and prevention of cervical cancer.

#### *Research*

As demonstrated throughout much of the previous results discussion, research and evidence-based literature was a huge factor with a majority of providers. Across specialties and

roles, most providers expressed belief in the importance of an evidence base, as the following quotes illustrate:

“I’d say peer-reviewed articles have led me to this decision.” (1 – MD, Pediatrics)

“I believe my peers, the research people, that’s about it, reading the literature is important.” (4 – MD, Pediatrics)

“Overall opinion, I mean I went to a couple of seminars before on HPV and the vaccine, and the statistics were wonderful and I thought it was something that we should be doing... The FDA approved it, so, they have statistics to show that it helps number one, and that it doesn’t harm.” (9 – MD, Family/Internal)

“The research, the evidence... Initially the reporting of the adverse events was just a question, there was no concrete evidence that they were valid reports... Now the most recent data shows that there are not any adverse effects.” (5 – APRN, ObGyn)

Some quotes that stood out in particular include:

“Well, I like to practice evidence-based medicine, so I think that my decision is based on evidence-based research that shows that the vaccine is safe and effective... It’s also FDA regulated so you know they can’t make claims that they don’t have the research to make!” (3 – APRN, ObGyn)

“Research! Research, it’s all evidence-based, and if you go to *good* clinicians that’s what they’re driving themselves by. And the data are overwhelmingly supportive at this time.” (6 – MD, ObGyn)

The next reasoning was on a much more personal level. Especially within obstetrics gynecology and family/internal medicine, they have experienced the hardships, both emotional and physical, with regards to HPV and cervical cancer.

### *Prevention of Cervical Cancer*

One physician abruptly stated:

“I think that if we have a chance to prevent cancer we should!” (2 – MD, Family/Internal)

Many providers also drew upon their own personal experiences with patients who had abnormal cells found in their cervix, and then had to face treatment to stop cervical cancer from developing. A particularly illustrative quote explained:

“I think that from a more personal stand point is that as a provider who has been doing this for so many years I’ve seen the devastating effect of HPV in young girls who have gotten cervical dysplasia and then had to go on and have LEEPs or Cons [treatment for abnormal cell growth in the cervix] and then have become what our industry calls, you know, obstetrical cripples because they can’t maintain a pregnancy because they don’t have enough cervix left to hold onto a pregnancy because people have been hacking away at their cervix to prevent them from getting cervical cancer.” (3 – APRN, ObGyn)

Another provider spoke of her own experiences with patients, and the importance of following a preventative healthcare model:

“I think just from, as a healthcare provider I see so many women who have suffered the effects of HPV, so if there’s a vaccine or anything that as a healthcare provider I can provide my patients with that could prevent a long term sequel of HPV, with minimal consequences, I would be happy to provide that. And I think as a nurse practitioner, I think the medical model, or the nursing model is to be a steward of preventive care, and that [the vaccine] would be part of a preventive care model.” She goes on to say later, “I have seen the consequences of HPV, and I think that if you have ever taken care of a woman who has succumbed to cervical cancer, or has had to have repeated colposcopys, or has had to have a hysterectomy, or the cost both emotionally and physically is huge, and if there’s something that can be done to prevent that...” (7 – APRN, Family/Internal)

One of the family/internal providers, who works specifically with college students, also brought up her experiences:

“Seeing so many effects from HPV, and anything that might decrease incidence of HPV is great in my book... Since I do colposcopy exams where I examine the cervix and have to do biopsies, it’s painful to put these young people through this. And I don’t like putting them through this. Any anything that might... getting chunks of your cervix biopsied is not a fun thing.” (8 – MD, Family/Internal)

The healthcare provider mentioned earlier who works with patients from age 0-death, explained seeing all types of spectrums because of this, and added to what previous providers have said in even greater detail:

“I think that we would eliminate a lot of the angst, because you know, even if it’s not cervical cancer, there’s anxiety and inconvenience in terms of having to have other cervical surgical procedures, or more frequent pap testing, and more worry about, “Well, is it ok!?” And all this kind of thing. And I think that’s the beauty of the vaccine too; it will eliminate in the future generation [most] of that garbage... so that we’re not, you know, making women crazy about an abnormal Pap that really doesn’t have to happen. And you know, honestly I have not diagnosed cervical cancer in my practice, but I’ve

seen a lot of CIN, cervical intraepithelial neoplasia, which is dysplastic changes in the cervix, precancerous changes of different levels and all that sort of thing. And that I think is what I hope to see eliminated in the future, so that women don't have to be put through as much of that kind of, 'Oh, no, do I have cancer?!' or, 'Is it precancerous and I have to have this procedure done?'... So I think that kind of stuff, the vaccine should in the future eliminate a great deal of. Which is a good thing!" (9 – MD, Family/Internal)

These explanations were some of the most descriptive and personal accounts throughout the interviews. Providers made it clear that evidence-based research and clinical experience with the virus were huge factors in their decision to administer Gardasil®.

### **6) Provider Opinions on Other Controversial Issues**

An article by Karen Houppert (2007) outlined some of the major controversies currently plaguing Gardasil®. The providers were asked how they felt about some of these issues. We have already covered the young age range, with the FDA guidelines stating providers could start immunization as young as nine. Other concerns stem from sexual activity, something that was touched upon under parental attitudes, as well as pharmaceutical motives and possible mandating of the vaccine in the United States.

#### *Sexual Activity*

Providers were asked if they believe administering the vaccine to females, who are not yet sexually active, will cause them to have sexual intercourse before they normally would have. The overwhelming response from all participants was that it did not. Some were short and brief in their answer, as the following quotes show:

“No, absolutely not.” (1 – MD, Pediatrics)

“Absolutely *not!* That’s another myth.” (4 – MD, Pediatrics)

“That would be no.” (7 – APRN, Family/Internal)

“No!” (8 – MD, Family/Internal)

Another provider took on a more sarcastic, joking tone:

“No. And it probably won’t lead them to getting a pilot’s license either, I mean, come on.” (2 – MD, Family/Internal)

Other providers went more in-depth about why they felt it was not an issue. Sex education and contraception was a common theme, as shown in these gynecologists’ quotes:

“No, I don’t. That has been the argument since birth control pills came out in the 1960s. It is the same reason why we do sex education the way we do. I mean you have Sarah Palin, she was a perfect example of how not teaching sex education in high school does not stop your daughter from getting pregnant! I mean, that, you know, [laughs] the right wingers really want to make it out like... people who feel that that’s really a political religious choice really they have not had good outcomes for their, ‘Let’s bury our head in the sand’ kind of, ‘Oh it’s not gonna happen if we don’t talk about it,’ and I think that’s where that sort of theory comes from. It doesn’t work!” (3 – APRN, ObGyn)

“No, not at all. None of the evidence supports that. It doesn’t support that giving out condoms makes people sexually active earlier, so, or birth control! It really shows that when you prescribe birth control pills, it does not make people more likely to be sexually active.” (5 – APRN, ObGyn)

“I don’t... And you know what, if discussion about sex leads to sex, you know, it probably leads to more responsible sex, because it should include all of the discussion about things that are onerous about it. And in fact it may delay sex as much as people say it encourages it.” (6 – MD, ObGyn)

A family/internal physician brought up an interesting argument, going back to age range:

“No! Most of them don’t even know what it is or about, and they just think it’s another shot, something good to do. I mean, ask a kid when they had their last tetanus or pertussis vaccine... They’ll say ‘What? Did I ever have that?’ and they’ve had it a zillion times, so, you know, most of the time they just know they have a shot and it’s gonna hurt and they have to do it, but they don’t necessarily, usually know what it is, or inquire or care. Unless they have a specific interest. I could see some populations where older girls would come in and ask without their guardians, but I haven’t seen that in my own practice.” (9 – MD, Family/Internal)

She also brings up an interesting idea around older females. The provider working with a college population expanded on her previous “No” answer:

“I don’t. But then I have a very narrow range of patients that I see. In some patients it may, they may be asking for it because they’re thinking of becoming sexually active. But it and of itself, no I don’t think so.” (8 – MD, Family/Internal)

Going back to the comment that children are not even aware of what they are getting immunized for, another provider agreed:

“If you don’t want to give it as sort of a “It’s okay for you to have sex” kind of thing, then it’s better off giving it to your nine year old who really doesn’t quite understand the concept of what it is they’re getting... They’re used to it, at 10 they get their tetanus booster anyways, so if you did the tetanus booster and the Gardasil®, I think that that would be a perfect time for them to get it!” (3 – APRN, ObGyn)

*Pharmaceutical Profit; Merck*

Much of the outcry over the vaccine has stemmed from concerns that Merck & Co. are not concerned with girls’ safety, but rather just making profits. Some providers felt that there was more of a concern for profit, but didn’t seem to think it was much of an issue, as the quotes show:

“Come on [laughs], I don’t live in a fairy tale world. Of course they’re out to make money, everybody wants to make money. Is there some altruism there? I’d like to believe that there is, but you know, if they had figured out how to make Viagra back when Viagra came out, I’m sure they would be just as happy. Are they able to get people to believe and fund things more for them because there’s some issue of altruism? Perhaps, and I’m sure that they will be forced in some way either through social pressures or so forth to give back some to the community.” (3 – APRN, ObGyn)

“Well obviously they’re primarily concerned with money. And after that comes safety, etc. They’re in business to make money...” (4 – MD, Pediatrics)

“I certainly believe they have a concern for profit [laughs]. But you know, hopefully they have some concern for women’s health as well.” (7 – APRN, Family/Internal)

A majority did outwardly state that they felt this was not an issue as far as they were concerned, or it was an issue that had nothing to do with their own clinical use of Gardasil®. Their responses explain:

“Oh I think that they’re concerned with profits. You know, but I mean they happened to hit upon a vaccine that is safe and useful.” (1 – MD, Pediatrics)

“I would hope they’re concerned with safety, and I’m sure that they want to get the money back that they did in research, but I don’t know that that’s their primary goal for



doing this... It's unrelated to the individual who would benefit from it!" (2 – MD, Internal/Family)

"Well, it depends on who's they? It's a corporation. So, of course they're concerned about profits and that's the bottom line, and I think that's what drives corporations. But I don't really care either! If it's an effective, safe vaccine, that's great. I don't care what Merck, as a corporation, what their motivation is." (5 – APRN, ObGyn)

Several other providers explained how safety and profits were intertwined, so patients and guardians should find comfort in the fact that Merck© is essentially obligated to worry about safety regardless, stating as follows:

"I think they're obligated to be concerned with all of those. They are a for-profit company, and they make no bones about it, and neither should we. We know that they're out to make money or otherwise they'd be giving it away, and they're not. I don't have any confusion about that... They're worried about girls' safety because you know the people that sit around a board table are concerned about the populace as individuals, but they're more concerned that those individuals might raise a class action lawsuit against Merck and put them under. That would be my inclination, and that's not to suggest that they are bad individuals or bad people, but that their job is to run a business, and to run it as safely as possible and liability is one of the things that will sink a business extremely quickly!" (6 – MD, ObGyn)

"They're definitely concerned with profit, but you can't say that they're not concerned with safety because it's gonna look bad on their profit margin if it's a bad vaccine!" (8 – MD, Family/Internal)

When asked if the drug was being pushed too hard or too soon by the company, every single participant said no, that it wasn't an issue. Some felt it should be pushed, or perhaps the pace of introduction was even helping.

### *A Federal Mandate*

A federal mandate is an order from the central government that requires all state and local government to comply. Once the overwhelming research came out about the efficacy of the vaccine, many people felt that it could be mandated in the interest of the public health. However, many other people felt that mandates were completely out of the question. With that being said,

this particular section was the most varied in terms of provider responses; they fell on both sides of the spectrum. Some flat out felt it should not be mandated:

“I don’t think any, I don’t think it should be mandated.” (1 – MD, Pediatrics)

“I guess I’m not a fan of mandates. You know, I think that you should just... Yeah, that just rubs me the wrong way. And so I think that if you, you can’t force people to get vaccines you know.” (5 – APRN, ObGyn)

Others were against a full-out mandate, but willing to accept an opt-out requirement, in which patients would be administered the vaccine unless a parent states otherwise. Two providers clarify:

“I like the opt-out option a lot more than, you know, a federal mandate that you will be vaccinated if you plan on surviving, or something, punishable by what? Deportation? I don’t think that that’s a good idea. We live in a country where we uphold ourselves as people who value individual judgment and individual freedoms. So, for that reason alone you can’t mandate these kind of things. Having said that, we mandate helmet use. We mandate seatbelt use. We mandate things for people’s safety on a regular basis. Should we be doing that? I would argue no. Live free or die – I’m a New Hampshire guy [laughs] so I don’t think it should be mandated that they go before school. I don’t think it should be included among the ones that are communicable diseases that affect the population much more readily, respiratory born diseases for instance, so I don’t agree with that.” (6 – MD, ObGyn)

I don’t think it should be mandated. I think opt-out maybe. I think it should just be offered. I mean I think it’s... I think mandated from a societal stand point is pretty... ‘Cause it’s not, I mean it would be... Oh gosh that’s tough... I mean I think it should be opt-out I guess.” (7 – APRN, Family/Internal)

The above nurse practitioner is a good example of how hesitant and unsure many of the participants were when answering this particular question. Another standpoint that fell somewhat in between was pro-mandate, yet still hesitant to flat out say so:

“You know if you compare it to other vaccines, the reason that other vaccines are mandated is because these diseases are contagious in a way that a person can get them without doing anything, without having sexual intercourse or without. So, that’s a difficult question. I suppose if push came to shove I would lean towards having it mandated.” (2 – MD, Family/Internal)

“As a public health minded person, I can easily rationalize doing that [mandating it] considering the association with cervical cancer and the health costs to the population and health care system. So I can see doing it. On a political basis, I can see that being difficult. You’d have to have people be able to opt-out without penalty, because of the religious objections of, it’s making them more sexually active – It’s hard to, I would like, I could easily see backing it being mandated, unless you opt-out because of religious objections for example. I know, we’ve added so many vaccines to childhood vaccines, gosh, my kids if they were just being born now would be like, pin cushions!” (8 – MD, Family/Internal)

One provider raised an excellent point with regards to gender. He was certainly pro-mandate, but only if it was universal:

“Fine, as long as I can give it to guys too. You can’t make it mandatory unless you make it universal, and that means giving it to males too. I don’t think it should be mandated just for girls. You can’t just pick out this one and that one and say they all should have it – it’s everybody or nobody.” (4 – MD, Pediatrics)

Another pro-mandate physician explained her reasoning in a different light, which was not brought up by any of the other participants. She explains:

“That’s a good question. It’s the question of when do you decide as a society that this is a public health issue. You know, we do have requirements for school age children for measles, mumps, rubella, and for chicken pox and for other sorts of things which on some level may actually cause less of an issue. HPV is not as obvious a disease, it takes *time* to develop cervical cancer, it takes time, it’s over time that you see changes. And it’s also over other exposures that people are exposing other people to it as well, which, you know is a subtle issue there. You know, it’s not like you’re contagious, you give someone chicken pox in 2 weeks. You can give someone HPV and they have that around, and then maybe 10 years later they start to have some changes on their Pap tests. So, I think it would be a good idea. I think every kid should have it quite frankly.” (9 – MD, Family/Internal)

Finally, the most illustrative and descriptive quote came from a provider who vehemently supports the idea of a mandate, citing many important reasons for doing so:

“It would be perfect. I think it would take away the parental issues with it. I mean, there are still, and you know it’s funny because as a midwife I try to be very respectful of people and their choices of what they want, especially in their childbearing years and through their labor and delivery and birth... and toward that end there are many of my patients, I wouldn’t say many, there used to be more, that really didn’t want to have their children vaccinated with anything. And you know you try to be respectful of those people, but some of their, when you really listen to their reasons for not wanting it,

they're not based in fact. They're based in fairy tale, and they're based in fear. And again, you know, I think if it was just, age 10 you got your tetanus and your Gardasil – There it is, it will go away!

It's the same issue as to when about, 10-12 years ago, the state of CT mandated that we had to test every woman in pregnancy for HIV. And if they refused to be tested, then we would test the baby when the baby was born. And so, you know, I remember doing prenatal visits with these women and you'd have to spend 20 minutes going through, that you had to sign this consent, we're going to test you for HIV, and blah blah blah, and now, you know, you check it off on the lab slip and nobody even questions it anymore! So I think that a tenure of time will definitely make this better. But, I also think that mandating it just sort of takes away the... It's in the best interest of the public health, which is what the HIV test does, it's what, you know all of those things. It's the same thing with the chicken pox, I didn't want my kids to get the chicken pox vaccine when it first came out, but you know what, I'd rather have them get the chicken pox vaccine now than have the risk of getting it later on in life when it can actually be fatal.

As much as we don't want to look at it because we're so myopic in a sense, we have to look at the best interest of public health. You have to at some degree look at that because you know you can't say that this doesn't effect... It's just like the woman who just had the 8 babies. You can't see that in a vacuum, it will affect all of us ultimately in one way or another, and if you don't believe it does you're naïve. They're already saying, from the impact of the insurance companies, and the costs to take care of these babies, we will all eventually pay for that because the rates of insurance are going to go up because there are cases like this. So you know you can't just say, 'oh, that was her personal decision to do that,' because her personal decision has a huge impact on everything else! None of us live within a vacuum, we're a society and we live together and we impact each other, and so, you know, doing the best that we can to prevent something like this [HPV, cervical cancer] from becoming epidemic, which it is in other countries..." (3 – APRN, Family/Internal)

As the quotes demonstrate, views differed quite dramatically from provider to provider on this issue. This is clearly different from the previous themes and ideas discussed. Mandating continues to be a controversial issue, not just in the media.

## DISCUSSION

The following chapter will summarize the main themes and explain various patterns, or lack thereof, found among participants. Previous research will also be included where necessary, with possible implications from these findings and future research recommendations.

### **General Discussion**

The healthcare professionals participating in the study varied tremendously with regards to their profession and area of specialization. There were three nurse practitioners and six physicians, of whom two practiced pediatrics, three were in obstetrics-gynecology, and four were in family/internal medicine. Despite this variation the findings show a relatively uniform set of overall practices and opinions. Previous research has shown some differences among these various professions with regards to the vaccine (Duval et al., 2007). However, due to the qualitative nature of the present study, providers were able to offer both similar and different reasoning behind those initial thoughts and behaviors. Also, it is possible the results found in previous studies were due to the timing of those studies, which were completed prior to FDA approval. As noted by a number of this study's participants, a slower acceptance by pediatricians, and differences by profession appear to have dissipated over time. There were also a minority of ideas which instead elicited very diverse responses among the participants.

Using an open-ended interview approach allowed participants to expand on their opinions, without being limited to predetermined answers. Since previous published research was performed before or during FDA approval, and was mainly quantitative surveys, these results give a more current picture of provider practices and experiences while also explaining *why* providers choose to vaccinate, and how they feel about the more controversial issues regarding Gardasil®.

*General Attitudes, Opinions, and Practices*

As providers discussed their initial feelings about the HPV vaccine during its approval in 2006, many felt it was a great medical breakthrough. Some did voice skepticism, but none of the participants expressed any outright negative opinions. There was some difference in when providers actually incorporated the vaccine into their clinical practice, but when asked about their current views, all providers believed that Gardasil® was an important vaccine for patients.

With that being said, all providers stated that they currently administer the HPV vaccine to their patients on a regular basis, and all believed that it was both safe and effective in preventing cervical cancer linked to the four HPV strains immunized against, as much as the research showed. However, although the current study found that 100% of this varied group of providers supported vaccination, the sample size does not support a generalization across all professionals. Previous research examining intent to administer found a high number of participants stating they would vaccinate when the vaccine became available, but it was not across the board. Presently, there may certainly still be providers who do not support the vaccine even after its FDA approval, though they were not included in this particular sample. Future research will benefit from a larger sample size.

When meeting with patients, only one provider said that he did not actively bring up and recommend the vaccine when patients did not address it first. When asked to expand, he became somewhat defensive and hesitated before stating that other medical assistants will often bring it up with his patients. This reaction to the question might show that providers feel pressure from outside sources or feel they are expected to actively immunize their patients. Future research exploring this further would be an interesting topic. This pediatrician was a strong proponent of the vaccine, so it was somewhat unexpected that he did not actively bring it up. Some of the

earlier previous research has shown that pediatricians anticipated giving the human papillomavirus vaccine to older patients rather than younger ones, usually around age 13 or higher (Kahn et al., 2005, Daley et al., 2006). Also, seeing children from age zero to early 20's leaves a large number of patients who come in that are much younger than the FDA guidelines. This may make it harder for the pediatrician to adopt an active recommendation schedule. However, the other pediatrician in the study did say he brought it up when appropriate. Future research would benefit from looking more closely at the exact processes pediatricians, as well as other healthcare professionals, go through when meeting with patients, and why. Some of the participants in this study had even devised certain tactics or routines when discussing Gardasil® with patients and/or their guardians in order to explain their beliefs about its benefits, safety, and efficacy.

#### *FDA Recommendations for Females Ages 9-26*

Many interesting findings emerged with regards to the particular theme concerning FDA age range. As mentioned before with the pediatricians, previous literature has consistently found that providers across all medical disciplines would prefer to vaccinate, or were intending to vaccinate, against sexually transmitted infections more often as the age of the female patient increased. These studies looked at nurse practitioners, gynecologists, family physicians, and a majority of pediatricians (Mays et al., 2004; Raley et al., 2004; Riedesel et al., 2005; Kahn et al., 2005; Daley et al., 2006; Duval et al., 2006). The current study found a very different pattern. Although some of the participants expressed that nine seemed young, and most did not frequently vaccinate at that age, none would oppose administering it at that age. Those few providers who did see a more high-risk population did administer around nine, and the rest stated they had no problem with starting at that age when appropriate. It was completely dependent

upon the patients' sexual history and the demographics of their patient population. Two very common themes among the providers were that patients should absolutely try to receive HPV vaccination before any onset of sexual activity, and secondly, again, the importance of knowing one's patient population.

It is important to note that all previous literature was performed before or during FDA-approval; this may be responsible for the noted difference in accepted age for administration. After over two years of clinical use, Gardasil® may be better understood and accepted in the medical community. Several providers even mentioned feeling that it was more of a routine now than anything, and that all the "hullabaloo" from the beginning seemed to be dying down.

Another interesting finding was the desire to vaccinate outside the FDA guidelines, both for boys and for women over age 26. More providers mentioned the issue of vaccinating older females. Although the vaccine has not yet been FDA-approved for this population, providers told stories of their experiences with such patients and expressed a longing to give them Gardasil®. One provider even expressed an inclination to give it anyway, and stated that she would actively recommend the vaccine to a virginal patient regardless of age. These findings are not consistent with previous research which claims organizational endorsement of the administration of the vaccine is one of the most important factors in guiding healthcare providers' intentions (Mays et al., 2004; Raley et al., 2004; Riedesel et al., 2005; Kahn et al., 2005). The previous research focused on actual Gardasil® endorsement rather than guidelines, but it would be interesting to see in future research if there are many providers who are already vaccinating boys and older women before actual approval. Providers may be well aware that the FDA is not approving these populations mainly due to cost-effectiveness issues, not on actual



concerns of safety. The above mentioned research also showed that providers were more willing to vaccinate females over males, another finding that may be changing with time.

### *Perceptions of Patient/Guardian Attitudes*

Providers discussed their experiences with guardian or patient refusal/skepticism of the vaccine, as well as possible reasons that might not be outwardly stated to them. These findings were relatively consistent with previous research reviewed by Zimet et al. (2008) which found that, “Across all studies, opposition to HPV vaccine was associated with concern about vaccination leading to sexual disinhibition, viewing one’s child as being at low risk for infection, and worries about vaccine safety” (p. 227). It is unknown how often the providers in this study encountered opposition to the vaccine, whether it was daily, every week, or even less often, and, indeed, whether the opposition is real or was just perceived or assumed by the provider.

Previous research found that most parents find HPV vaccines to be acceptable and want their children to be vaccinated (Olshen et al., 2005; Dempsey et al., 2006; Constantine & Jerman, 2007). Future research should examine this phenomenon of perceived or real parental opposition to gain better insight into what providers are experiencing with patients and their guardians now that the vaccine has been in clinical usage for over two years. Post-FDA approval studies will continue to be important in order to see if any changes are taking place as time progresses.

### *Why Providers are Vaccinating*

There have been no published studies to date which explore why providers are choosing to vaccinate. Again, the open-ended nature of the interviews allowed providers to explain their experiences and feelings in greater detail, especially after actually being able to give the vaccine within the last few years.

The two main findings that came up were a firm belief in the research, and provider experiences with HPV and cervical cancer patients. The literature was a constant factor for all providers, whether it was for their own practices, or with regards to the information being obtained by patients. They felt that evidence-based research was one of the most important aspects of accepting and administering an immunization; information that many patients may not obtain, or not realize is available. Future research could look at how often patients are in fact receiving valid research data for Gardasil®, as well as possible initiatives to increase the availability of articles and journals outside the healthcare office. The degree of reliance on evidence underscores the need for developing and widely distributing clear, unbiased information about medical treatment and applications of new prevention options.

The provider discussion of experiences treating females who have gotten HPV, which later developed into abnormal cell growth, was very eye-opening. It is not often in the research that one sees such personal accounts of the actual physical and emotional tolls cervical cancer can have on patients and on the people who treat them. The gynecologists and family/internal medicine providers all wanted to eliminate the devastation of telling women they needed an invasive procedure to prevent them from progressing into a more serious phase, as well as the sadness and pain associated with the direct procedures themselves. The previous quantitative literature was not able to capture this illustrative side of the research which clearly pervades many of the providers' experiences. It may also be speculated that a possible explanation for the slower uptake of the vaccine by pediatricians mentioned by other providers, as well as the pediatric physician in the study who was not actively recommending, may be due to the fact that they do not often see or deal with the effects of cervical cancer and HPV in their patients. Providers who do experience this side of the illness may be more passionate about the

vaccination process. Future qualitative research could examine this phenomenon further to gain a better idea of why certain medical professions are faster on immunization uptake, or more accepting of novel vaccines and medications based on their healthcare specialties.

#### *Other Controversial Issues*

Sexual promiscuity, pharmaceutical profit, and a federal mandate are all debates currently surrounding Gardasil®. The first issue, which maintained that the HPV vaccine could open the door to sexual activity for children, was overwhelmingly condemned by the participants in this study. Each provider felt very strongly that the vaccine does not lead children to engage in sexual intercourse any earlier than they normally would have. An interesting dynamic is created because many of these same providers felt that this was one of the issues parents had with the vaccine, though it is not known how often. Upcoming research topics could investigate whether or not there truly is a major gap between parental and provider opinions. To date, no studies have compared these two groups, despite the fact that they both have a large part in the HPV vaccination process.

Pharmaceutical profit was another topic of controversy in the media, though none of the providers in this study felt the orientation or motive of Merck© was of any real concern. They all stated a similar belief that the company was out for profit, like any other business, but that should not be an issue. They again pointed to the fact that the vaccine has proven itself to be both safe and effective, and therefore, any arguments about the pharmaceutical company are irrelevant. When discussing whether Merck's© previous arthritis drug, Vioxx®, which was pulled from the market after possibly causing multiple illnesses and deaths, would raise a similar possibility related to Gardasil®, one of the providers made an interesting point. Rather than a fear of history repeating itself, it would make more sense to think that because of the previous

incident the company would work that much harder to make a safe and effective vaccine. After all, if they are only concerned with profits, they surely would not want to make the same mistake twice.

The final issue, which elicited the most diverse responses, was that of federally mandating the vaccine. All the providers made very good points as to why the vaccine should or should not be mandated for a specific age range, including children. When asked if they felt the vaccine should be mandated, many of the providers seemed caught off-guard, as though they had not really given much thought to their own opinions beforehand; this may have influenced their responses. Regardless, previous research has shown that the mandate issue *is* one of complex and varying opinions (Haber, Malow, & Zimet, 2007). As time progresses, and as more research comes out on the vaccine's safety and efficacy, perhaps the issue of mandating will no longer be as controversial. Due to the conflicting responses found among the providers in this study, this political issue will be a rich area for future research. Such investigations could lead to important policy recommendations as more information becomes available about not only safety and efficacy, but also possible universal approval of all genders and ages. Healthcare providers are a huge part of the immunization process; therefore their practices and opinions will be important in the discussion of a future mandate. As many of the providers stated, almost three years into clinical use, they have noticed greater acceptance of Gardasil®, a trend that may continue. If this is the case, ongoing research will also be important in examining how opinions and administration of the HPV vaccine are changing, and why.

## **Conclusions**

There is no question that Gardasil® has risen to be among the list of society's modern healthcare controversies. Houppert (2007) stated it best when she explained, "How a medical

breakthrough for women set off a political firestorm” (p. 17). Despite the wide range of opinions available to the general population, healthcare providers are the ones ultimately responsible for prescribing and administering the vaccine. Thus, they are often the first people patients and guardians will go to, to ask questions about such immunizations or to get help sifting through all the information. Smith et al. (2006) found that health care providers have a positive influence on parents to vaccinate their children, including parents who believe that vaccinations are unsafe. Therefore, it is essential to study opinions and experiences with Gardasil® among all healthcare providers who influence patient and parental decisions.

This study has certain limitations that can be improved upon in future research. As previously mentioned, nine providers is a small sample size to work with, especially when broken down into a specific combination of training and specialty. Future research would benefit greatly by including many more health care providers while utilizing the same diverse criteria and qualitative methodology. Also, recruitment could be performed at a national level rather than just Connecticut in order to obtain a more inclusive view of the rest of the country’s medical practices and beliefs. Such improvements would allow for greater generalization strength, and could also lead to new and important findings that were not captured in the current research.

Also, there is an issue of selection bias based on who was included. Participants were health care providers who were willing to be interviewed by an undergraduate student without remuneration for the interview. Thus, they may have more well-formed, consistent, and/or positive attitudes about Gardasil® and sought out the opportunity to express their opinion. Future research, again benefiting from a larger sample size, should use recruitment methods

which might increase the likelihood of participation from those providers who may not administer the vaccine.

Finally, the interview guide was relatively structured with regards to the questions and how they were asked. Interview sessions were also relatively brief, as opposed to a multi-hour, very open discussion which can be an important part of qualitative research. Future studies may need to offer a gift or monetary compensation to have longer, less structured interviews with providers. The question guide could also be improved by including more in-depth questions about some of the themes that arose that were not previously accounted for. Discussion focusing more on actual practices and experiences with patients and guardians would be beneficial in broadening the framework of a more current view of Gardasil® use in today's society.

Despite these limitations, the study provides some important information not available in other sources. The current study expanded on previous research by performing a more in-depth qualitative interview study. This allowed participants to expand on their beliefs and explain their current experiences with the vaccine now that it has been approved for almost three years. Earlier research, as previously mentioned, was all performed before or during FDA approval so provider responses were based on their intentions rather than their actual thoughts and behaviors using Gardasil®. Looking across more than just one medical profession and specialization also allowed for some interesting findings which may not have been discovered otherwise, or were not compared in other studies. The fact that this group of providers had such noticeable uniformity across their responses will have significant implications for coming research on HPV vaccination.

It is hoped that the current findings might lend important information to those people who have not yet seen their healthcare provider about Gardasil®, are financially unable to, or are too

uncomfortable bringing up the issue with them. Knowledge about how providers feel, how they make their decisions, and what they have experienced thus far with the vaccine could be disseminated to other provider offices, health agencies, schools, and programs which provide preventive services to a range of clients, including those who are less informed and/or unable to access certain resources.

Also, as more immunizations are in the works for other sexually transmitted infections, including HIV/AIDS and genital herpes, current research on provider opinions and practices with Gardasil® will be important in determining the possible uptake of such vaccines in the future. A recent Center for Disease Control and Prevention study found that one in four female adolescents in the United States has at least one of the most common STIs (Forhan, Gottlieb, Sternberg, Xu, Datta, Berman, & Markowitz, 2008). This is a huge issue that society will no longer be able to ignore, and more research on healthcare providers will be essential in tracking the fight against such illnesses.

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### Appendix A: Interview Guide

<b>General Information:</b>	
	Age?
	Gender?
	Number of years in practice?
	Medical certification/title?
	Specialize in?
	Typical age range of patients?
<b>The Provider:</b>	
	What did you initially think about the HPV vaccine, Gardasil®, when it was first introduced in 2006? Have your views changed at all?
	Do you currently administer the HPV vaccine to your female patients? What has led you to this decision? (Probe; religion, personal experience, drug companies, peers, research)
	Do you feel the vaccine is effective in preventing cervical cancer?
	Do you think the vaccine is safe to administer?
	Do you actively recommend the HPV vaccine to your female patients and/or their guardians? If so, how?
	Do you bring up the vaccine with female patients/their guardians on your own, or do you wait for them to ask about it before voicing your opinion? Why?
	When meeting with female patients, how important is the issue of Gardasil® among other topics?
<b>The Patients:</b>	
	Why do you think some patients and/or guardians choose not to get the vaccine? Or have you experienced any who did not want it? Do you agree with any of these reasons; or do you have any of your own?
	How do you think the media has portrayed the vaccine in a negative or positive way? How accurate do you think such outside information is for patients?
	Have your patients ever experienced any negative side effects which they believe occurred because of taking the vaccine?
<b>Controversial Issues:</b>	
	If you do administer the vaccine, at what age or age range do you think females should start getting Gardasil®? What led you to choose this age (range)? Do you agree with the FDA beginning the age range at 9? Why or why not?
	Do you believe administering the vaccine to females, who are not yet sexually active, will cause them to have sexual intercourse before they

	normally would have, had they not had the vaccine? Does your opinion change depending on the age of the female?
	Do you believe that Merck, the drug company responsible for creating Gardasil®, is concerned with profits, or girls' safety?
	Is the drug being pushed too hard and too soon? (Probe; some have voiced concern that the pace of the vaccine's introduction is jeopardizing its ultimate success)
	How would you feel about the HPV vaccine being mandated for girls before they enter middle school? Or an opt-out option?
	Overall, any other comments?