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Final DNP Capstone Report: Improving Adolescent HPV Vaccination Rates

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Final DNP Capstone Report: Improving Adolescent HPV Vaccination Rates

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Dedication

To my daughters, Nola and Maya, both of whom were born during my graduate work and have given me endless inspiration to better myself.

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Table of Contents

List of Tables and Figures

Chapter 1

Capstone Report Introduction

Introduction

The CDC's Advisory Committee on Immunization Practices (ACIP) currently recommends that all 11-12 year old males and females be vaccinated with the three-dose human papillomavirus (HPV) vaccine (CDC, 2011a; Markowitz et al., 2006). Research has indicated that the vaccine is safe and effective against cervical, anal, and oral HPV infections; however, vaccination rates in the United States (U.S.) have remained low (CDC, 2013b). National data for 2012 indicate that roughly 54% of females and 21% of males initiated the HPV vaccine, and only 33% of females and 7% of males completed the three-dose series (CDC, 2013b). These rates are a stark contrast to vaccination rates for other vaccinations recommended for the same 11-12 year old age group including Tdap (84.6%) and meningococcal (74.0%; CDC, 2013b).

Because HPV related cancers are largely vaccine preventable, continued low HPV vaccination rates in the U.S. have prompted concern within the medical community. Indeed, the U.S. Department of Health and Human Services Healthy People 2020 includes an objective to increase the number of females ages 13-15 who have received all three doses of the HPV vaccine to 80% (HHS, 2013). Additionally, the President's Cancer Panel (PCP) issued a report in February 2014 addressing the low vaccination rates and urging the President and the nation to take steps to accelerate HPV vaccine uptake (PCP, 2014).

This capstone project will present three manuscripts that explore the HPV vaccine and strategies to increase vaccination rates. The first manuscript is an integrative review of HPV vaccine efficacy in both males and females. It discusses studies that evaluated vaccine efficacy against cervical cancer, anal HPV infection in women, oral HPV

infection in women, and HPV infection in men. The second manuscript analyzes a healthcare policy proposed in Kentucky in 2013 that would require the HPV vaccine for all adolescent males and females prior to sixth grade entry in the state. Ultimately this policy was unsuccessful, but the introduction of healthcare policy is one proposed approach to increasing HPV vaccination rates. Finally, the third manuscript is a report of a quality improvement project with three aims: 1) to describe primary care providers' practices related to HPV vaccine recommendations, 2) to identify primary care providers' facilitators and barriers to recommending the HPV vaccine, and 3) to determine the HPV vaccination rate among 11-12 year old patients within an urban primary care clinic. The combined information gathered from these manuscripts will be used to offer evidence based practice recommendations for primary care providers to increase HPV vaccination rates within their practices.

Chapter 2

Manuscript #1:

HPV Vaccine Efficacy in Males and Females: An Integrative Review

Abstract

Purpose: The purpose of this literature review is to describe the current research regarding the efficacy of human papillomavirus (HPV) vaccines for both males and females. This review will investigate vaccine efficacy against cervical, anal, and oral HPV infection and vaccine safety.

Data Sources: The data was gathered from ten studies that focused on HPV vaccine efficacy and safety. A literature search was conducted using CINAHL, PubMed, the Cochrane Database, Google Scholar, and hand searching for randomized controlled trials (RCTs) and systematic reviews related to HPV vaccine efficacy.

Findings: Short-term studies indicate that both the bivalent (protecting against HPV 16 and 18) and quadrivalent (protecting against HPV 6, 11, 16, and 18) vaccines were 94.5-100% effective against cervical lesions caused by their respective HPV types in women. Additionally, the bivalent vaccine has been shown to be 83.6% effective against anal HPV 16/18 infection in women, and 93.3% effective against oral HPV 16/18 infection in women. In men, the quadrivalent vaccine was 90.4% effective against genital lesions and 77.5% effective against anal intraepithelial neoplasias caused by HPV types 6, 11, 16, or 18. The most commonly reported adverse event related to the vaccine is pain at the injection site, and the number of serious adverse events was similar in the vaccine and control groups in all studies that reported on vaccine safety.

Implications for Practice: Providers should continue to follow the Advisory Committee for Immunization Practices (ACIP) recommendations for HPV vaccination of males with the quadrivalent vaccine and females with either the bivalent or quadrivalent vaccine, as studies continue to support vaccine efficacy and safety.

HPV Vaccine Efficacy in Males and Females: An Integrative Review

Background and Significance

Human papillomavirus (HPV) causes a significant disease burden for men and women worldwide. By age 50, 80% of sexually active women and 60-70% of sexually active men will have been infected with genital HPV at some point in their lifetime (Garnock-Jones & Giuliano, 2011). There are approximately 14 million new HPV infections annually in the United States, making it the most common sexually transmitted infection (CDC, 2013a). The incidence of infection is highest between ages 15-24 for both men and women (Fernandez, Allen, Mistry, & Kahn, 2010), with nearly half of the new infections in the U.S. occurring in this age group (CDC, 2013a). HPV is spread via skin to skin contact; penetrative sexual intercourse is not necessary for transmission (Fernandez et al., 2010). Currently, 130 types of HPV have been discovered, while 30-40 types are known to infect the anogenital tract (Haupt & Sings, 2011). Of these, there are 15 types that are oncogenic, or cancer causing (De Carvalho et al., 2010). Nationally, the overall prevalence of infection with these high-risk HPV types is 23% in men and women ages 14-65 (CDC, 2012a). HPV is known to cause genital warts, respiratory papillomatosis, and cervical, vulvar, vaginal, penile, anal, and orophayngeal cancers (CDC, 2010b; CDC, 2011a; Markowitz et al., 2007).

Healthcare providers and patients are increasingly aware of the link between HPV and cervical cancer. HPV DNA is found in 99.7% of cervical cancers (Garnock-Jones & Giuliano, 2011), with 70% of those caused by HPV 16 or 18 (Beibei, Kumar, Castellsague, & Guiliano, 2011). Worldwide, cervical cancer is still the second most common cancer affecting women (De Carvalho et al., 2010). Approximately $1.5 billion

was spent on cervical cancer treatment in the U.S. in 2010. The net cost for the initial care of cervical cancer in 2010 was $54,209 for women under 65 years old (Mariotto, Yabroff, Shao, Feuer, & Brown, 2011). Additionally, there are an estimated 10 million cases of cervical intraepithelial neoplasias (CIN) II or III worldwide annually (The Future I/II Study Group, 2010), which can develop into cervical cancer if not treated. However, treating high-grade CIN is costly and can lead to complications, including problems with fertility.

While anal and oropharyngeal cancers are less common than cervical cancer, their incidence is on the rise (Chaturvedi et al., 2011; Kreimer et al., 2011). It has been estimated that 70% of oropharyngeal cancers in the U.S. are now associated with HPV infection (Herrero et al., 2013). Oropharyngeal cancer occurs three times more often in men than women, and is primarily caused by HPV 16 (CDC, 2013b). Rates of anal cancer are increasing in both women and men (Palefsky et al., 2011), although it is most common in men who have sex with men (Kreimer et al., 2011). Similar to cervical cancer, anal cancers are primarily caused by HPV types 16 or 18 (Palefsky et al., 2011).

HPV is also responsible for anogenital warts. Annually, approximately 30 million men and women develop low-grade CIN or anogenital warts worldwide (The Future I/II Study Group, 2010), with an excess of 500,000 new cases of anogenital warts yearly in the U.S. (Garnock-Jones & Giuliano, 2011). Approximately 90% of anogenital warts are caused by HPV 6 or 11 (CDC, 2012b). While anogenital warts are not directly associated with cancer, there are related psychological burdens and costs of treatment (Giuliano et al., 2011).

A quadrivalent HPV vaccine (HPV4) that protects against HPV types 6, 11, 16,

and 18 was developed and approved by the U.S. Food and Drug Administration (FDA) in 2006. Later that same year, recommendations for the administration of the vaccine to females ages 9-26 were released by the CDC's Advisory Committee on Immunization Practices [ACIP] (Markowitz et al., 2007). The quadrivalent vaccine is now approved for use in 121 countries (Haupt & Sings, 2011). In 2009, a bivalent vaccine (HPV2) that protects against oncogenic HPV types 16 and 18 was introduced, and the ACIP released recommendations regarding its administration to females ages 9-26 (CDC, 2010). In 2011, the ACIP updated their recommendations again to include vaccination of males ages 9-21 (and up to age 26 for special populations, including men who have sex with men) with the quadrivalent (HPV4) vaccine (CDC, 2011a). Both the quadrivalent and bivalent vaccines are a three-dose series. The ACIP recommends the routine vaccination of 11-12 year old females with either the bivalent or quadrivalent vaccine, and the routine vaccination of males ages 11-12 with the quadrivalent vaccine (CDC, 2010a; CDC, 2011a; Markowitz et al., 2006).

Purpose

The purpose of this critical review of the literature is to describe efficacy and safety of the HPV vaccine for males and females. Additionally, recommendations will be offered to guide practice regarding administration of the HPV vaccine to patients. While the vaccine has had several years of research in women for the prevention of CIN and cervical cancer, newer research has been conducted to determine its efficacy in males, its efficacy in females against anal and oral HPV infection, and longer term efficacy against CIN and cervical cancer.

Methods

The literature search for this review was conducted using several databases including CINAHL, PubMed, the Cochrane Library, and Google Scholar. Hand searching was also employed. Search terms included *HPV vaccine efficacy, quadrivalent HPV vaccine efficacy, bivalent HPV vaccine efficacy, human papillomavirus vaccine efficacy, HPV vaccine efficacy and men, HPV vaccine randomized controlled trials, and HPV vaccine systematic reviews*. Initially, articles were searched from 2006, the original date of licensure of the quadrivalent vaccine for use in females. However, this search yielded many duplicate articles, and several of the randomized controlled trials had concluded more recent study endpoints. Additionally, several new studies have been conducted since 2010 that investigated vaccine efficacy in men, and against oral and anal HPV infections. Articles were included if they focused on vaccine efficacy of either the bivalent or quadrivalent vaccine in women, men, or both, ages 9-26. Studies were excluded if they were conducted on patients older than 26 and/or were not either a randomized controlled trials or a systematic reviews of randomized controlled trials. Duplicate studies were also eliminated. Twenty-two studies published since 2010 were identified, and 10 met the final criteria for review, which was current research examining the efficacy of HPV vaccines for males and females against cervical, anal, and/or oral HPV infections.

Findings

Women: Cervical Lesions

The majority of studies reviewed focused on vaccine efficacy related to anogenital warts, cervical intraepithelial neoplasia (CIN), and/or cervical cancer in

women. While most studies focused on either the bivalent or quadrivalent vaccine, one systematic review combined studies of the monovalent (for HPV 16), the bivalent, and the quadrivalent vaccines and found that in the per protocol population (PPP), all vaccine types were highly effective against CIN 1+ (Beibei et al, 2011). Also, while long-term data showing vaccine efficacy for greater than 5 years is not yet available, both the bivalent (Lehtinen et al., 2012) and the quadrivalent vaccines (The Future I/II Study Group, 2010) have been found very efficacious against their respective HPV types up to four years after initial vaccination. Another smaller study found the bivalent vaccine highly effective for up to 7.3 years (De Carvalho et al., 2010). Other, shorter term studies of the bivalent and quadrivalent vaccines found them effective against genital lesions, CIN, and cervical cancer associated with vaccine HPV types (Szarewski et al., 2012; Yoshikawa et al., 2013). In summary, both the bivalent and quadrivalent vaccines have demonstrated high efficacy against CIN and cervical cancer in women.

Women: Anal HPV Infection

Although anal cancer is uncommon in women, it is on the rise in both sexes. Most anal cancers can be attributed to HPV types 16 or 18 (Kreimer et al., 2011). Only one study specifically investigated the efficacy of the bivalent vaccine against anal HPV 16/18 infection in women. In women who were negative for both HPV 16 and 18 at the start of the study, the vaccine showed 83.6% efficacy. This was measured one time, four years after the initial vaccination, and was similar to the efficacy of the vaccine against cervical HPV 16 and 18 (Kreimer et al., 2011).

Women: Oral HPV Infection

While it is known that many orophayngeal cancers are caused by oral HPV

infection, research has been lacking to determine vaccine efficacy against oral HPV. In July 2013, Herrero et al. reported findings on the efficacy of the bivalent HPV vaccine against oral infections with HPV 16 and 18. This randomized controlled trial of 5834 women ages 18-25 provided some of the first data available regarding HPV vaccine efficacy against oral HPV. The women in the study were given either the bivalent HPV vaccine or a hepatitis A vaccine as a control. An oral specimen was collected once, at the study endpoint after 4 years. At that time, they were tested for multiple types of HPV, including HPV 16 and 18 (Herrero et al., 2013). The study found the vaccine to be 93.3% effective against oral infection with HPV 16 and 18. Oral HPV 16/18 was detected in one participant in the vaccine group compared to 15 HPV 16/18 infections detected in the control group (Herrero et al., 2013). These findings show promise that the implementation of the HPV vaccine can reduce the incidence of oral HPV infection and consequently orophayngeal cancer.

Men

Many of the vaccine efficacy studies have been focused on cervical cancer in women; however, men are also affected by HPV infection. The rate of HPV infection among males is similar to that of the female population. In addition to genital warts, men are also susceptible to penile, anal, and oropharyngeal cancers associated with HPV infection (Giuliano et al., 2011). Two studies reviewed examined the male population and focused on the efficacy of the quadrivalent vaccine against HPV infection in males (Giuliano et al., 2011), and more specifically against anal intraepithelial neoplasia caused by HPV 6, 11, 16, or 18 (Palefsky et al., 2011). The outcomes of these studies support the continuation of routine vaccination of males for the primary prevention of HPV

infection. In the per protocol groups, the vaccine was 90.4% effective against any lesions caused by HPV 6, 11, 16, or 18; 85.6% effective against persistent HPV infection with these types (Giuliano et al., 2011); and 77.5% effective against anal intraepithelial neoplasias (Palefsky et al., 2011).

Vaccine Safety

Of the six studies that looked at vaccine safety, all concluded that the HPV vaccine has a favorable safety profile. The most commonly reported adverse events were pain at the injection site (Beibei, Kumar, Castellsague, & Giuliano, 2011; Giuliano et al., 2011; Yoshikawa, Ebihara, Tanaka, & Noda, 2013), vaccine site reaction (Palefsky et al., 2011), and headache (Beibei, et al., 2011; Yoshikawa, et al., 2013). Two studies found that pain at the injection site was more commonly reported in the vaccine group than the control group (Giuliano et al., 2011; Yoshikawa, et al., 2013). All studies found the risk of serious adverse events to be similar in the vaccine and control groups (Beibei, et al., 2011; De Carvalho et al., 2010; Giuliano et al., 2011; Lehtinen et al., 2012; Palefsky et al., 2011; Yoshikawa, et al., 2013).

	Table 1			
Source	Sample	Method	Purpose	Findings
Beibei et al. (2011)	7 RCTs	Systematic Review	To determine efficacy of the monovalent, bivalent, and quadrivalent HPV vaccines against cervical HPV infection in women, and to explore vaccine safety.	**Efficacy**: Studies showed reduction of CIN 1+ and CIN 2+ caused by HPV 16 and 18 and persistent (> 6 mo) HPV infection with 16/18 in both PPP and ITT groups. **Safety**: AE did not differ significantly in

				vaccine and control groups
De Carvalho et al. (2010)	433 women	RCT	To verify long-term efficacy (up to 7.3 years after vaccination) of the bivalent HPV vaccine in young adult women.	**Efficacy:** Vaccine efficacy was high (94.5%) in the vaccine group up to 7.3 years post vaccination. **Safety**: Safety profiles were comparable in the vaccine and placebo groups.
The Future I/II Study Group (2010)	17,622 women	2 RCTs (Future I and Future II)	To determine quadrivalent vaccine efficacy against low grade cervical, vulvar, and vaginal intraepithelial neoplasias and condyloma acuminate.	**Efficacy**: Efficacy against lesions caused by HPV 6, 11, 16, 18 were 96% for CIN 1, 100% for vulvar and vaginal intraepithelial neoplasia grade 1, 99% for condyloma over 42 months. **Safety:** Not addressed in this report.
Giuliano et al. (2011)	4065 males	RCT	To evaluate the efficacy of the quadrivalent HPV vaccine against genital lesions caused by HPV 6, 11, 16, and 18 in boys and men	**Efficacy**: Efficacy in PPP against HPV 6, 11, 16, 18 lesions was 90.4%. Efficacy in ITT for HPV 6, 11, 16, 18 lesions was 65.5%. **Safety**: Most common AE was

			ages 16 to 26.	pain at the injection site with both vaccine and placebo. No serious AE were related to vaccination.
Herrero et al. (2013)	7466 women	RCT	To determine efficacy of bivalent HPV vaccine against oral HPV infection in women.	**Efficacy:** The vaccine was 93.3% effective against oral infection with HPV 16 and/or 18. **Safety:** Not addressed in this report.
Kreimer et al. (2011)	4210 women	RCT	To evaluate the efficacy of the bivalent HPV vaccine against anal infection with HPV 16/18 in women ages 18-25.	**Efficacy**: Efficacy against anal infection with HPV 16/18 was 62% measured 4 years post-vaccination. Efficacy in the restricted cohort (1989 women who tested neg for HPV 16/18 at the start of the study) was 83.6%. **Safety**: Not addressed in this report.
Lehtinen et al. (2012)	TVC group: vaccine=9319 women, control=9325 women TVC naïve group: vaccine=5824 women, control=5820 women	RCT	To establish vaccine efficacy of the bivalent HPV vaccine against grade 3 or greater CIN caused by HPV 16/18.	**Efficacy**: Four years after vaccination, efficacy against CIN 3+ caused by HPV 16/18 was 100% in TVC naïve group, and 45.7% in the TVC. Efficacy against AIS was 100% in TVC naïve and 76.9% in TVC.

				Safety: The number of women reporting AE were similar in vaccine and control groups.
Palefsky et al. (2011)	602 males	RCT	To verify the efficacy of the quadrivalent HPV vaccine against anal intraepithelial neoplasm in men who have sex with men, ages 16-26.	**Efficacy**: Against HPV 6, 11, 16, 18 associated anal intraepithelial neoplasia was 50.3% in ITT and 77.5% in PPP. **Safety**: No serious AE reported in this study.
Szarewski et al. (2012)	18,644 women	RCT	To determine the efficacy of the bivalent HPV vaccine against HPV 16/18 infection in women ages 15-25 without prior exposure to HPV 16/18 infection.	**Efficacy**: The vaccine was efficacious against HPV 16/18 in women who were HPV 16/18 DNA negative and seronegative and women who were HPV 16/18 DNA negative but had serological evidence of previous HPV 16/18 infection. If women were HPV DNA positive for one type, the vaccine was still effective against the other type. **Safety**: Not addressed in this report.
Yoshikawa et al. (2013)	Vaccine=509 women Placebo=512 women	RCT	To establish the efficacy of the quadrivalent HPV vaccine	**Efficacy**: Infection with HPV 6, 11, 16, 18 reduced by 87.6% in vaccine group.

			against HPV 6, 11, 16, & 18 in Japanese women ages 18-26.	**Safety**: Pain and headache most common AE. No serious AE related to vaccination.

Discussion

Critique of Studies

This review of the current literature investigating safety and efficacy of the bivalent and quadrivalent HPV vaccines for males and females demonstrates that both vaccines are safe and effective. This paper adds to the body of evidence by providing an updated review of the latest research related to HPV vaccine efficacy and safety regarding cervical lesions in women and genital lesions in men, as well as new research exploring vaccine efficacy against anal and oral HPV infections. Additionally, it reports some longer-term data, including vaccine efficacy of the quadrivalent vaccine against CIN 1, vulvar and vaginal intraepithelial neoplasias grade 1, and condyloma up to 42 months and efficacy of the bivalent vaccine in women up to 7.3 years (De Carvalho et al., 2010; The Future I/II Study Group, 2010).

While efficacy of the HPV vaccine against cervical lesions in women (particularly those caused by HPV 16 or 18) is high, studies examining vaccine efficacy and safety for longer than five years are still in progress. Additionally, there are many areas where research is only in the beginning stages. Routine vaccination with the quadrivalent vaccine has only been recommended for males since 2011, and the majority of research is focused on genital and anal lesions. Investigations are still in progress to evaluate its effectiveness against penile, anal, and oropharyngeal cancers in men. Furthermore, new

studies support that the vaccine can prevent anal and oral HPV infection in women, but additional research is needed in this area.

Emerging evidence has the potential to change current practice. Recent studies suggest that two doses of the vaccine are possibly as effective as the traditional three-dose series (Kreimer et al., 2011b; Romanowski et al., 2011). Similarly, research has been conducted to determine vaccine efficacy against non-vaccine HPV types (Wheeler et al., 2012) and the effect of vaccinating women who are known to have HPV related cervical and vulvar disease (Joura et al., 2012). Lastly, despite lower than desired vaccination rates in the United States, the incidence of HPV in females ages 14-19 with HPV 6, 11, 16, and 18 has decreased by 56% since the implementation of routine vaccination (Markowitz et al., 2013). These are areas for further research, but have the potential to alter vaccine recommendations.

Limitations in these studies include potential conflicts of interest. For example, several of the larger studies in this review were funded by pharmaceutical companies and the researchers were employed by the pharmaceutical companies (The Future I/II Study Group, 2010; Lehitenen et al., 2012; Palefsky et al., 2011; Szarewski et al., 2011). While the studies were well-conducted, with large samples sizes in various sites (including North America, Latin America, Europe, and Asia), their funding represents potential bias. Other limitations include the smaller sample sizes of some studies. While most were large, multi-site studies, a few had a sample size fewer than 1000 (De Carvalho et al., 2010; Palefsky et al., 2010), or were conducted at only one site (De Carvalho et al., 2010; Herrero et al., 2013; Kreimer et al., 2011; Yoshikawa et al., 2013). Lastly, the fact that the majority of research is still concentrated on vaccine efficacy in women against CIN or

cervical cancer represents a potential limitation. Only two of the included studies evaluated HPV infection in men (Giuliano et al., 2011; Palefsky et al., 2011). Research in other areas, including vaccine efficacy in men and vaccine efficacy against anal and oral HPV infections, is lacking.

Recommendations for Practice

Providers should know that, to date, both the bivalent and quadrivalent vaccines have shown high efficacy against their respective HPV types. Additionally, in nearly all studies reviewed, reported adverse events were similar in the vaccine and control groups. Providers should continue to follow the ACIP recommendations for routine and catch-up administration to both male and female patients. The quadrivalent vaccine is recommended for males, but it is not specified whether the bivalent or quadrivalent vaccine is preferable for females and thus the decision is left up to providers. A compelling rationale for recommending the quadrivalent vaccine is that it also protects against anogenital warts caused by HPV types 6 and 11. Additionally, it is important for providers to note their patients' sexual history, as in some cases this may affect vaccination (for example, ACIP recommends vaccination up to 26 years old in men who have sex with men).

Given the decline in HPV 6, 11, 16, and 18 infections in adolescent girls since the implementation of vaccination, there is promise that continued vaccination could greatly reduce HPV infection and therefore lessen the incidence of associated cancers. Two of the Healthy People 2020 objectives are to reduce the number of females with HPV 6, 11, 16, and 18 infections, and to increase the number of females ages 13-15 who have received 3 doses of the HPV vaccine to 80% (HHS, 2013). Potential recommendations to

improve vaccination rates include strong provider recommendation to patients, patient (and parent) education, and focusing on health policy that would mandate the vaccine for adolescents entering the sixth grade.

Conclusion

Short-term data supports the efficacy and safety of the HPV vaccine, but long-term data is yet to be determined. Recent research has shown promise that the vaccine is effective in women for the prevention of cervical, oral, and anal HPV infections and in men for the prevention of genital lesions and anal HPV infections. Since infection with oncogenic HPV types has been linked to cervical, vaginal, penile, anal, and orophayngeal cancers, a reduction in high-risk HPV infections should correlate with a reduction in associated cancers. Additionally, research continues to demonstrate a positive safety profile for the vaccines. Providers should continue to recommend the HPV vaccine to male and female patients per the ACIP recommendations as a primary prevention method for the reduction of HPV infection. If vaccination rates can meet the Healthy People 2020 objectives, morbidity, mortality, and healthcare costs associated with HPV infection could be greatly reduced.

Chapter 3

Manuscript #2:

Policy Analysis: Requiring the HPV Vaccine for Adolescents in Kentucky

Abstract

Infection with certain strains of human papillomavirus (HPV) has been associated with the development of cervical, vulvar, vaginal, penile, anal, and orophayngeal cancers. Both the bivalent and quadrivalent HPV vaccines protect against these oncogenic strains. Despite an ACIP recommendation that all 11-12 year old males and females should be routinely vaccinated against HPV in the United States, initiation and completion of the three-dose series are low. One proposed intervention to increase vaccination rates is to introduce policy that requires HPV vaccination for school entry. Kentucky legislators introduced House Bill 358 during the 2013 session that would require the vaccine for all males and females in the state prior to entering sixth grade. This paper will discuss the social, financial, and political implications of the proposed bill, as well as alternative measures to increase HPV vaccination rates.

Policy Analysis: Requiring the HPV Vaccine for Adolescents in Kentucky

The Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) in 2006 released recommendations to routinely vaccinate 11-12 year old females (Markowitz et al., 2007), and in 2011 that 11-12 year old males be vaccinated (CDC, 2011a) with a three-dose human papillomavirus (HPV) vaccine. The bivalent vaccine (HPV2) that protects against types 16 and 18 is recommended for use in females; the quadrivalent vaccine (HPV4) that protects against HPV types 6, 11, 16, and 18 is recommended for use in males and females. However, vaccination rates have remained low. In 2012, only 33.4% of adolescent females and 6.4% of adolescent males had completed the three-dose vaccine series (CDC, 2013d). Implementing policy that would require the HPV vaccine for school entry is one proposed solution to low vaccination rates. In 2013, Kentucky legislators proposed House Bill 358 that would require the HPV vaccine for both males and females prior to sixth grade entry. The bill passed the Kentucky House of Representatives, but it was ultimately unsuccessful after being stalled in Senate committee. This paper will explore the stakeholders that are involved and affected by a vaccine mandate, the factors that influence the development and acceptance of a bill, and possible alternative solutions that would facilitate an increase in HPV vaccination rates.

Background and Significance

Human papillomavirus is a sexually transmitted disease that is extremely widespread. It is estimated that 75% of sexually active people will become infected between the ages of 15 and 50 (La Torre, de Waure, Chiaradia, Mannocci, & Ricciardi, 2007). According to estimates from the CDC (2013a), there are more than 14 million

new infections yearly, and 79 million active infections in the United States currently. This makes it by far the most prevalent sexually transmitted infection (STI) in the U.S. Incidence of infection peaks between ages 15-24 for both men and women (Fernandez, Allen, Mistry, & Kahn, 2010). Approximately 90% of HPV infections are cleared by the body's immune system within one to two years. However, infection with high-risk types can lead to cancerous changes and is linked to the development of cervical, vulvar, vaginal, penile, anal, and oropharyngeal cancers (CDC, 2011a; Markowitz et al., 2007).

HPV DNA was discovered in cervical cancer cells approximately 30 years ago. It was later determined that over 99% of cervical cancers are caused by oncogenic strains of HPV; 70% of these are caused by HPV 16 and 18 (HHS, 2012). While cervical cancer rates have declined in the past 50 years due to the implementation of routine screening, the CDC estimates that in 2010, 11,818 women were diagnosed with and 3,939 women died from cervical cancer in the United States (CDC, 2012c). Kentucky is one of the twelve states with the highest rates of cervical cancer with an incidence of 8.1-11.2 per 100,000 (CDC, 2012d).

Evidence supports a strong link between HPV infection and both oropharyngeal and anal cancers. Approximately 95% of anal cancers (CDC, 2013e) and nearly 70% of newly diagnosed oropharyngeal cancers in the U.S. are caused by human papillomavirus (Herrero et al., 2013). While HPV-related anal cancer is most common in men who have sex with men (Kreimer et al., 2011), the incidence of both oropharyngeal and anal cancers are on the rise in men and women (Herrero et al., 2013; Palefsky et al., 2011). Similar to cervical cancer, HPV related anal cancers are primarily caused by oncogenic HPV types 16 and 18 (Palefsky et al., 2011), while oral cancers are largely caused by

HPV 16 (Herrero et al., 2013). Approximately 1 % of the U.S. population is infected with oral HPV 16, and men are three times more likely than women to be infected with oral HPV (CDC, 2013b).

HPV is also responsible for anogenital warts. Annually, approximately 30 million men and women worldwide develop low-grade intraepithelial neoplasias and/or anogenital warts (The Future I/II Study Group, 2010), with an excess of 500,000 new cases of anogenital warts yearly in the U.S. (Garnock-Jones & Giuliano, 2011). Approximately 90% of anogenital warts are caused by HPV 6 or 11. Conjunctival, nasal, oral, and laryngeal warts can also be caused by HPV 6 or 11 (CDC, 2012b). While these lesions are not directly associated with cancer, there are related psychological burdens and costs of treatment (Giuliano et al., 2011).

In 2006, the United States Food and Drug Administration (FDA) approved the three-dose quadrivalent vaccine (HPV4) that protects against HPV types 6, 11, 16, and 18. In June 2006, the ACIP released recommendations regarding the administration of the vaccine to females (Markowitz et al., 2007). This included recommendations to vaccinate females ages 9-26, with routine vaccination at ages 11-12. Additionally, a bivalent vaccine (HPV2) was introduced in 2009 that protects against HPV types 16 and 18 (CDC, 2010a). In 2011, the ACIP updated their recommendations again to include the routine vaccination of males ages 11-12, and all males ages 9-21 (and up to age 26 for special populations including men who have sex with men and those who are immunocompromised) with the quadrivalent vaccine (CDC, 2011a).

While long-term studies are still in progress, the HPV vaccines have had positive reports for safety and efficacy to date (Beibei, Kumar, Castellague, & Giuliano, 2011; De

Carvalho et al., 2010; The Future I/II Study Group; Giuliano et al., 2011; Herrero et al., 2013; Palefsky et al., 2011; Yoshikawa, Ebihara, Tanaka, & Noda, et al., 2013) . Studies have suggested that the vaccine is highly effective at preventing cervical intraepithelial neoplasias (CIN) grades 1 and 2 caused by HPV 16 and 18 (Beibei, et al., 2011) and lesions caused by HPV 6, 11, 16, and 18 in both women (The Future I/II Study Group, 2010; Yoshikawa, et al., 2013) and men (Giuliano et al., 2011). The vaccine has shown high efficacy for up to 7.3 years post vaccination (De Carvalho et al, 2010). Additionally, research suggests that the vaccine is effective against oral (Herrero et al., 2013) and anal HPV infections (Kreimer et al., 2011; Palefsky et al., 2011). The vaccine also has a favorable safety profile with the most common adverse events being pain at the injection site (Beibei, et al., 2011; Giuliano et al., 2011; Yoshikawa, et al., 2013), vaccine site reaction (Palefsky et al., 2011), and headache (Beibei, et al., 2011; Yoshikawa, et al., 2013). Additionally, the CDC maintains that the vaccine is safe, effective, and long-lasting according to study results thus far, with nearly 46 million doses given in the U.S. as of June 2012 (CDC, 2012h).

Statement of Problem

Despite evidence of both safety and efficacy, HPV vaccination rates in the U.S. remain low (CDC 2013d; Markowitz et al, 2007). The 2007 National Immunization Survey-Adult (NIS-Adult) showed that a few months after initiation of the ACIP recommendations, although patient knowledge of HPV infection was high, only 10% of women 18-26 initiated the vaccine series (Jain et al., 2009). By 2012, 53.8% of adolescent females ages 13-17 in the U.S. had received the initial dose of the HPV vaccine, and 33.4% had completed the three-dose series. In Kentucky in 2012, 51.2% of

adolescent females had initiated the HPV vaccine series, and 34.9% had completed the three-dose series (CDC, 2013d). This remains significantly lower than the compliance rate of other immunizations initiated during the same time period including meningococcal (70%) and Tdap (85%; CDC, 2012g). National rates of HPV vaccination among females actually decreased slightly from 2011 to 2012 (CDC, 2013d). One of the Healthy People 2020 objectives includes increasing the number of females ages 13-15 who have completed the three-dose HPV vaccine series to 80% (HHS, 2013). In order to reach this goal, providers will have to educate patients and their families, and strongly advocate for vaccination of all adolescents.

One proposed way to increase HPV vaccination rates is to introduce policy that mandates vaccination of all adolescents prior to sixth grade entry. There is currently no federal law that dictates vaccinations; each state has different laws regarding which vaccines are required for school entry. In nearly every legislative session since 2006, Kentucky has had proposed legislation that would require the HPV vaccine for students entering the sixth grade. In the 2013 session, lawmakers proposed HB 358, a bill that would mandate the HPV vaccine for all adolescents entering sixth grade in Kentucky. While the legislation passed the House, it was stalled in Senate committee.

Kentucky is not the only state that has proposed legislation to require HPV vaccination. Virginia and Washington D.C. have passed bills mandating that girls entering sixth grade receive the HPV vaccine. Both pieces of legislature provided an 'opt out' for parents who do not desire to vaccinate their daughters. The governor of Texas similarly mandated that girls entering sixth grade would be required to receive the vaccine, with an opportunity for parents to opt out. This mandate was eventually

overruled by the Texas legislature (Chen, 2012). Similar to Kentucky, New York and Virginia proposed unsuccessful legislation in 2013-2014 that would mandate the vaccine for males and females entering sixth grade. Other states have proposed comparable legislation in previous years without success (NCSL, 2013).

Conceptual Framework

The use of a guiding framework when introducing legislative agenda is important to increase the chance of success. John Kingdon (2003) describes three processes, or "streams" that are involved when setting legislative agendas. These processes are problems, policies, and politics. *Problems* are the issues that are either brought to the attention of politicians by discussion with someone within the government, or by looking at different indicators that politicians use to monitor incidents and occurrences. Some examples of monitoring are monetary (i.e., examining expenditures and budgets) and surveys (can be conducted by governmental or non-governmental groups, and sometimes required by a statute). An issue may be identified as a problem, but may eventually fade from the agenda if appropriate action is not taken. *Policies* describes the process of creating policy proposals. There are many specialists in and around the government who are involved in the formation of policy. Depending on the issue, the group of specialists involved in writing a proposal can vary widely and may include academics, researchers, and others close to the topic. Again, some policy proposals move on to develop legislation while others do not. Finally, *politics* depicts the overall political mood and sentiments of the public. This stream functions independently of the other two, yet can have a strong impact on the agenda (Kingdon, 2003).

The problem in Kentucky (as in the rest of the United States) is that HPV vaccine completion rates are subpar, and far below the Healthy People 2020 goal for adolescent females of 80%. Data from the National Immunization Survey Teen (NIS-Teen) 2012 can be used to support the need for action (CDC, 2013d). This could be considered an indicator of a national problem. In response to this problem, a proposal, or HB 358 (2013), was created. Kentucky had proposed similar bills in the past; the main difference with HB 358 is that it mandates vaccination of both male and female adolescents. However, due to politics, the bill was stalled in Senate committee and did not pass. The HPV vaccine is not widely accepted by the general public, and this undoubtedly affected some politicians' decisions regarding a vaccine mandate. Currently, only Virginia and Washington D.C. have been successful in passing similar legislation.

Analysis of Issue

Key Stakeholders

There are several key stakeholders in the development of Kentucky House Bill 358 (2013). The first are the legislators who sponsored the bill including Representatives David Watkins, Tom Burch, Joni L. Jenkins, and Mary Lou Marzian. Representatives Burch, Jenkins, and Marzian are all of the Democratic Party representing Jefferson County. Representative Watkins is also from the Democratic Party representing Henderson County. Representatives Watkins and Marzian are a physician and a nurse, respectively. All four representatives have been previously involved in the sponsorship of HPV vaccine related legislation in Kentucky, and all have sponsored previous attempts to require the HPV vaccine for school entry in the state.

The Kentucky Medical Association (KMA) is fully supportive of HB 358 (2013). One of the public health goals the KMA House of Delegates announced in 2012 was to include the HPV vaccine as one of the required vaccines for males and females in Kentucky (KMA, 2012). The group reiterated this stance in a report about HB 358 in the May 2013 issue of the *KMA Communicator*. The House of Delegates is the legislative body of the KMA, and is responsible for developing policy (KMA, 2013b). The American Nurses Association's (ANA) official stance is that they are supportive of the CDC/ACIP recommendations and also of all policies that would improve child and adolescent health. They do recommend that parents have a choice to "opt out" of HPV vaccination once they are fully educated about the risks and benefits, and they support continued research regarding HPV vaccine efficacy (ANA, 2012).

Another key stakeholder in this issue is the pharmaceutical companies that manufacture the HPV vaccine. While it is unclear to what extent the pharmaceutical companies were involved in this particular piece of legislation, it is known that they have lobbied in other states for similar legislation (Mello, Abiola, & Colgrove, 2012). Pharmaceutical companies, especially Merck that manufactures Gardasil (the quadrivalent HPV vaccine) stand to gain great financial benefits from the passage of HB 358 and other comparable legislation that would mandate that adolescents receive the HPV vaccine.

Finally, The Family Research Council (FRC) and Focus on the Family are two conservative Christian groups that oppose HPV vaccine mandates. Both groups take a similar stance in that they support the development of the HPV vaccine and continued research regarding its efficacy, but they oppose mandating the vaccine for school entry

(Focus on the Family, 2012; Gaul, 2013). Focus on the Family states that abstinence until marriage should be the primary prevention strategy for HPV infection, and that decision to vaccinate should be left up to parents. FRC states that vaccination should be choice of the parent after they have discussed the risks and benefits with their healthcare provider (Gaul, 2013).

Individuals affected

Kentucky adolescents and their parents would be directly affected by a mandate to require HPV vaccination for school entry, particularly those who were not previously vaccinated. While most adolescents and their parents should be educated about and offered the vaccine per ACIP recommendations at their 11-12 year old well-child exam, the vaccine is not currently required for school attendance. If HB 358 were passed, parents would still be permitted an "opt out" if they did not want their child to receive the vaccine. Although parents would be free to decline vaccination for any reason, a written letter of refusal would be required to be kept on file with the child's immunization records. Additionally, although the Vaccines for Children (VFC) program covers most children that are uninsured or underinsured, parents would potentially be responsible for out of pocket vaccine expenses.

Schools and primary care providers, including family practice providers and pediatricians, would also be affected. Schools would be responsible for instituting policies regarding the vaccine mandate and enforcing that students have documentation of all required vaccines. Generally, students cannot attend school without a record of required vaccinations. In the case of the HPV vaccine, the student would either need to have received the vaccine, or have an "opt out" letter written by a parent or guardian on

file. It would also be the responsibility of primary care providers to stay up to date on the vaccination requirements if new legislation were passed. This would ensure that they could educate parents and adolescents accordingly, and make sure their patient populations were up to date on all required vaccines.

Political Factors

According to one study, the pharmaceutical company Merck was heavily involved in all areas of legislation regarding mandatory HPV vaccination. These political activities included lobbying, writing proposals, and rallying interest groups (Mello, Abiola, & Colgrove, 2012). California, Indiana, New Hampshire, New York, Texas, and Virginia were included in the study. Kentucky was not included in this particular study, and it is unclear how extensively pharmaceutical companies are involved in Kentucky's proposed legislation. Merck has also provided substantial financial support to Women in Government, an organization of female legislators in the U.S. (Colgrove, Abiola, & Mello, 2010). Even if obvious political activities were not present, there could be potential contributions to campaign funds by pharmaceutical companies and other actions that could affect political outcomes.

While HB 358 passed the Kentucky House of Representatives with a vote of 54/40, this topic appears to have divided the legislators by political party. Of the 54 'yea' votes, only four came from Republicans. Similarly, only three of the 40 votes to oppose the bill were from the Democratic Party. This is not surprising since the primary sponsors of the bill are all from the Democratic Party, and the HPV vaccine mandate has been controversial, particularly among conservatives. However, a previous piece of legislation (HR 80, 2012) that urged all eligible males and females in Kentucky to

become more knowledgeable about the HPV vaccine was passed nearly unanimously by the House in 2012. This suggests that the majority of legislators are not opposed to the HPV vaccine itself, but to the mandate.

Social Factors

While many patients and providers see the vaccine as a great tool for cancer prevention, the vaccine has received a stigma among some because it prevents cancer by immunizing against a virus that is sexually transmitted. There has been open debate that mandating the vaccine will give adolescents permission to engage in premarital sex or sexual promiscuity (Chen, 2012). Since the vaccine is given to 11 and 12 year olds prior to sixth grade entry, parents (and providers) may be uncomfortable engaging in frank discussion about sexuality and sexual behavior. There are also conservative groups that advocate delaying sexual activity until after marriage as a way to prevent the spread of HPV (Focus on the Family, 2012).

A general concern with some parents about vaccines is the potential link to adverse health outcomes. This has lead to a more lenient exemption process in some states. The rate of unvaccinated children in the U.S. rose from 1% in 2006 to 2% in 2011 (Blank, Caplan & Constable, 2013), and there is currently a movement of parents who opt out of vaccination due to safety concerns (Colgrove, 2006). This general distrust of vaccines has carried over for the HPV vaccine, as well. Additionally, the HPV vaccine has been targeted because of the lack of very long-term safety and efficacy studies.

Economic Issues

There are numerous economic issues related to this topic because the HPV vaccine is very expensive. Out of pocket cost for the vaccine averages $130 per

injection, or $390 for the vaccine series (American Cancer Society, 2013). This makes it one of the most costly ACIP recommended vaccines. Additionally, $390 includes just the cost of the vaccine series, and does not include any fees that may be charged for vaccine administration. The HPV vaccine is currently covered by the VFC program, along with the other ACIP recommended vaccines. However, not all providers are VFC approved. This means they would have to order the vaccine to have on hand, with the potential that it would not be used before its expiration date. Due to the high cost of the vaccine, this is most likely a risk that some providers are not willing to take.

According to the fiscal note attached to HB 358 (2013), there would be no fiscal impact, as the Commonwealth of Kentucky is not responsible for providing the vaccine under the legislation. This may be misleading, however, because the HPV vaccine is part of the VFC program. VFC uses federal funds to provide ACIP recommended vaccines to children younger than 19. Children that are qualified for VFC are those that are Medicaid-eligible, uninsured, underinsured, or American Indian or Alaskan Native (CDC, 2012e). So while Kentucky would not directly be responsible for cost, much of Kentucky's adolescent population qualifies for VFC. This means that federal spending for this program would be greatly increased in a short time span. If all states were to institute similar legislation at the same time, it would be a tremendous strain to the system. Additionally, there would also be potential for increased financial burden to private insurers as all eligible children who were previously unvaccinated would be receiving the vaccine.

Practical Considerations

While attempting to improve HPV vaccination rates by requiring the vaccine for school entry is a reasonable approach, this is still a controversial topic. Although Virginia and Washington D.C. have been successful in implementing a policy that requires the vaccine for adolescent girls with a choice for parental opt out, most states have been unsuccessful in instituting HPV vaccine mandates. There are also many questions regarding whether legislators should be involved in deciding what vaccines should be required, or whether it should be left up to public health officials (Colgrove, Abiola, & Mello, 2010).

Policy Options

In 2013, states chose to approach the need to improve HPV vaccination rates in a variety of ways using health policy. States including Florida, Georgia, and New York proposed legislation that would either require that all parents and adolescents receive education about the HPV vaccine, or encouraged voluntary vaccination. Virginia, New York, and Kentucky proposed that all adolescents receive the HPV vaccine prior to entry into sixth grade (with all states allowing exemptions to vaccination). There has been similar legislation proposed in previous years that would require vaccination of all females entering sixth grade. Instead of proposing vaccine mandates, New Hampshire and South Dakota use state funds to offer the vaccine at no cost to any female state resident under 18 (NCSL, 2013; Savage, 2007). Including the states mentioned above, there has been proposed legislation to either require HPV vaccination or to require education to the public or adolescents regarding HPV vaccination in 42 states since 2006 (NCSL, 2013).

Best Policy Option/Alternative Approaches

Because the list of state required vaccines is often based directly on the ACIP recommendations, and ACIP recommends the vaccine for all 11-12 year olds, it would seem only natural that the HPV vaccine should be added to the list of vaccinations required for school entry. However, as previously discussed, the vaccine has had many unique controversies. Specifically, it is a vaccine that prevents a virus that is spread only by sexual contact. Currently, the ACIP has not provided any recommendations regarding HPV vaccine policy or requirements for school entry. Policy requiring that all adolescents and parents of adolescents receive education from their healthcare provider regarding the HPV vaccine would be prudent given the low rates of vaccination. At this time, policy requiring a vaccine mandate may be premature due to political, social, and economic concerns surrounding this issue.

Description of Strategies for Moving Forward

The CDC already has strategies in place to increase HPV vaccination rates. The Preteen and Teen Vaccine Communication Campaign focuses on education for adolescents (ages 9-18), parents of adolescents, and health care providers who treat adolescents. Its focus is to improve vaccination rates for Tdap, meningococcal (MCV4), HPV, and influenza vaccines in this age group. The focus also includes encouraging adolescents to get their vaccines on time and/or make up any missed vaccines. On the CDC website, this campaign includes posters, flyers, and fact sheets that can be printed, posted and given out as patient education materials. It also includes information on the Healthy People 2020 objectives for all included vaccines (CDC, 2011b).

Moving forward, providers should not only use the CDC provided information to educate themselves, but also provide information for their patients with an included strong recommendation to get all ACIP suggested vaccines for their age group. Providers should also use sick visits to make up missed vaccines if possible, since adolescents are often not seen by their primary care providers frequently. Additionally, it is essential to stress the importance of receiving all three doses of the HPV vaccine prior to sexual debut in order to receive adequate protection.

Potential Unintended Consequences of Recommended Policy

Potential inadvertent outcomes include increases in VFC spending, as currently 41% of vaccines given to children and adolescents in the United States are paid for by VFC (Kaiser Family Foundation, 2013). There is also potential for increased spending by private insurers. Because of the policy language that allows parents to exempt their children from vaccination, there is also a possibility that there would be no change in vaccination rates despite policy implementation. Additionally, students would not be allowed to attend Kentucky schools without either receiving the vaccine or providing an exemption letter, which poses a potential for truancy issues related to the policy.

Implementation/Enforcement Issues

If a policy mandating HPV vaccination is passed in the future, implementation will be similar to that of other required vaccines in Kentucky. Schools will be responsible for enforcing that students have immunization records on file with current and required vaccinations, or they will not be allowed to attend school. If the "opt out" language stays in the bill, parents would also have the option to have a written letter on file with the child's immunization records if they choose to decline the HPV vaccine.

There could be possible implementation issues until all schools and providers are aware that an additional vaccine is required. Another possible issue could occur if many unvaccinated adolescents need to receive the vaccine at the same time, and there are not enough VFC vaccinations available, as this could lead to potential delays in vaccinations or missed doses. Finally, as with other vaccinations, requirements will differ by state. Students transferring to Kentucky schools may be unvaccinated and will have to either become vaccinated or present a letter of exemption prior to starting school.

Conclusion

Providers should continue to follow the ACIP recommendations that all 11-12 year old males and females receive one dose of Tdap, one dose of meningococcal, and three doses of HPV vaccine separated by appropriate intervals (CDC, 2013d). Providers should offer patient and parent education coupled with a strong recommendation that all eligible adolescents receive the HPV vaccine. Large scale studies have shown, and continue to show, that the vaccine is safe and effective against cervical, orophayngeal, and anal HPV infections. Long-term efficacy studies are currently in progress. At this time, a vaccine mandate may be premature due to social, financial, and political barriers, but providers can still work to increase vaccine acceptance and HPV vaccination rates in their patient population. An important recommendation is to reduce missed opportunities to vaccinate by considering every visit with adolescent patients as a chance to review immunization records and check for missed vaccines/doses.

Chapter 4

Manuscript #3:

Assessing Providers' Facilitators and Barriers to Recommending the HPV Vaccine

Abstract

Background: Human papillomavirus (HPV) vaccines have been shown to be effective against HPV types that are linked to cervical, vaginal, vulvar, penile, anal, and oropharyngeal cancers. Despite Advisory Committee on Immunization Practices (ACIP) recommendations that all 11-12 year old males and females in the U.S. should be vaccinated with the three-dose HPV vaccine series, vaccination rates remain low. In 2012, only 34.9% of adolescent females and 6.8% of adolescent males completed the series. Efforts to increase vaccination rates are needed, and healthcare providers have been shown to be an important part of the solution.

Purpose: This investigation was conducted to determine providers' current practices regarding HPV vaccine recommendation, consistency with following ACIP guidelines, and perceived facilitators and barriers to recommending the HPV vaccine.

Methods: This descriptive study utilized a retrospective chart review of all 11-12 year old adolescents presenting to a primary care clinic for a well-child exam between April 23, 2013 and September 30, 2013. Charts were audited for patient demographics, whether HPV vaccination counseling was offered and by whom, patient response (accepted/declined/deferred), if the vaccine was initiated, and if it was completed. Additionally, an anonymous provider survey was administered via REDCap and a provider focus group was conducted to elicit perceived facilitators and barriers to recommending the vaccine.

Results: Chart audits (N= 60) revealed that 42% of the adolescents initiated the vaccine, and only 14% completed the series within the CDC recommended interval. Review of provider documentation revealed that counseling and/or provider recommendation was

documented in only 11 of 60 charts. Barriers to vaccine initiation included recommending the vaccine more often to female than male patients, language barriers, low medical literacy, time constraints, inconsistent patient follow-up, and patient/parent concerns about long-term safety.

Recommendations: Based on focus group discussion, suggestions to improve HPV vaccination rates included offering a strong provider recommendation for HPV vaccination to all adolescent patients, standardizing documentation of HPV vaccine recommendation, and using the EMR to improve return rates for second and third vaccine dose.

Assessing Providers' Facilitators and Barriers to Recommending the HPV Vaccine

Introduction

Human papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the United States with 79 million existing cases in 2008, and 14 million new cases annually (CDC, 2013a). Currently, over $8 billion is spent each year on the prevention and treatment of HPV infection in the U.S. (Chesson, Ekwueme, Saraiya, Lowry, & Markowitz, 2012), and HPV is the second most costly STI after HIV (CDC, 2013a). Infection with certain cancer causing strains of HPV has been linked to the development of cervical, vaginal, vulvar, penile, anal, and oropharyngeal cancers (CDC, 2011a; Markowitz, 2007). Over 99% of cervical cancers (HHS, 2012), 95% of anal cancers (CDC, 2013e), and approximately 70% of newly diagnosed oropharyngeal cancers in the U.S. (Herrero et al, 2013) are caused by HPV. The majority of these cancers are caused by oncogenic HPV types 16 or 18 (Herrero et al., 2013; HHS, 2012; Palefsky et al., 2011). Additionally, HPV types 6 and 11 are responsible for over 90% of anogenital warts, and are also linked to conjunctival, nasal, oral, and laryngeal warts (CDC, 2012a).

Currently, two HPV vaccines are approved for use by the United States Food and Drug Administration (FDA). The bivalent (HPV2) vaccine protects against HPV types 16 and 18; the quadrivalent (HPV4) vaccine protects against types 6, 11, 16, and 18. Both vaccines are recommended for use in females, while only the quadrivalent vaccine is recommended for use in males. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) currently recommends routine vaccination of all 11-12 year old females with either the bivalent or quadrivalent three-dose vaccine series, and all 11-12 year old males with the quadrivalent vaccine

series. Females ages 13-26 and males ages 13-21 (and up to age 26 in special populations including men who have sex with men) should receive catch-up vaccination (CDC, 2011a; Markowitz, 2007).

Despite the ACIP recommendation to vaccinate all adolescents, rates of vaccination have remained low. In 2012, according to data from the National Immunization Survey (NIS) Teen, 53.8% of girls ages 13-17 in the United States initiated the HPV vaccine and only 33.4% completed the three-dose series (CDC, 2013c). HPV coverage in female adolescents dropped from 2011 to 2012 in the U.S. (CDC, 2013d). In Kentucky, 51.2% of females initiated vaccination in 2012, while 34.9% completed the series. In males ages 13-17 in the U.S., 20.8% initiated vaccination and 6.8% completed the series in 2012 (CDC, 2013d). Healthy People 2020 objectives include increasing vaccine coverage amongst adolescents, and more specifically, increasing the number of females ages 13-15 who have completed the three-dose HPV vaccine series to 80% (HHS, 2013).

While the U.S. and Kentucky vaccination rates are similar, there is undeniably a need to increase vaccination rates. Input from providers could provide valuable information about barriers to vaccination of children often faced in clinical practice. The purpose of this investigation is to 1) determine providers' current practices related to HPV vaccine recommendations and their consistency with following the ACIP guidelines and 2) to identify providers' perceived facilitators and barriers to recommending the HPV vaccine. Provider suggestions to decrease barriers to recommending the HPV vaccine and improve vaccination rates are also described.

Methods

This descriptive study consisted of three parts: a retrospective chart review (phase 1), a provider survey (phase 2), and a provider focus group (phase 3). All phases were conducted by the principal investigator (PI) within the primary care clinic.

Retrospective Chart Review

Objective. Phase 1 consisted of a retrospective chart review to: 1.) determine the rate of HPV vaccination among 11-12 year old adolescents presenting to the clinic for well-child exams between April 23, 2013 and September 30, 2013; and 2.) assess whether providers at the primary care clinic were recommending and offering the HPV vaccine to their adolescent patients according to ACIP guidelines. Additionally, patient demographics, including gender, age, race, and insurance type were recorded.

Methods and Design. This descriptive, retrospective chart review included all male and female, 11-12 year old patients that presented to a primary care clinic for their well-child exams between April 23, 2013 and September 30, 2013. After approval from the Institutional Review Board (IRB) was received, a patient list was obtained that included medical record numbers of all patients meeting inclusion criteria that were coded with the ICD-9 for a well-child exam (V20.2). This list contained a total of 68 medical record numbers. A chart audit tool (Appendix A) was used to review the patient charts to determine if vaccine counseling was provided and by whom, whether the vaccine was offered by the provider, whether the vaccine was accepted/declined/deferred by the patient, if the vaccine series was initiated, and if it was completed. Gender, age at time of visit, race, and type of insurance were recorded. The principal investigator (PI) entered the de-identified data into the chart audit tool in Research Electonic Data Capture

(REDCap). REDCap is a secure online data collection tool hosted by the University of Kentucky (Harris et al., 2009). Data was then stored under password protection on the PI's personal mobile electronic device.

All male and female patients, ages 11-12, that presented to an outpatient, primary care clinic in an urban setting between April 23, 2013 and September 30, 2013 for a well-child exam (ICD-9 code V20.2) were included in the study. This timeframe was chosen because April 23, 2013 was the date that electronic medical record (EMR) use started in this clinic, and this interval was intended capture all adolescents presenting for their well-child exams prior to entry into sixth grade. Once the data was analyzed, patients that had initiated or completed the HPV vaccine series prior to their well-child exam were excluded from the study. This excluded eight patients, making the final number of participants 60.

Provider Survey

Objectives. The intention of the provider survey was to examine the providers' current practices related to recommending the HPV vaccine, their current knowledge of the ACIP recommendations regarding the HPV vaccine, and their perceived facilitators and barriers to recommending the vaccine to their adolescent patients.

Methods. An anonymous survey was administered to the providers email address using REDCap (Harris et al., 2009) [Appendix B]. The survey was administered to all providers (physicians and advanced practice nurses) that practice within the primary care clinic where the project took place. The survey asked providers how often they offer the HPV vaccine to both male and female patients, and how often patients accept the vaccine when offered. It also inquired about potential facilitators and barriers to recommending

the HPV vaccine that the providers might experience in practice. Finally, it asked a series of questions to determine the providers' knowledge of the ACIP recommendations regarding the HPV vaccine.

Provider Focus Group

Objectives. The focus group was held in order to identify and discuss providers' perceived facilitators and barriers to recommending the HPV vaccine series to their adolescent patients. In addition, a brief presentation was given by the PI that reviewed the ACIP recommendations regarding administration of the HPV vaccine, and discussed the results of the retrospective chart review. An open forum was used to provide an opportunity for providers to discuss facilitators and barriers to recommending the HPV vaccine and to offer suggestions on how to improve related practice within the clinic.

Focus Group Procedures/Process. All providers at the primary care clinic were invited via email to attend the focus group, which was held at the clinic during regular operating hours. Informed consent was collected prior to the initiation of the discussion. Risks and benefits as well as contact information for the Office of Research Integrity (ORI) were discussed prior to commencing the focus group. The PI gave a brief Power Point presentation that discussed background and incidence of HPV infection in the United States, current ACIP recommendations for HPV vaccination, and rates of HPV vaccination in the U.S. and Kentucky. The results of the retrospective chart review were also presented at this time. The discussion was informal, and all providers were encouraged to ask questions and express opinions and concerns freely during the presentation. At the conclusion of the presentation, providers were asked:

- What factors within your practice facilitate the recommendation of the HPV vaccine according to ACIP guidelines?
- What barriers do you experience in your practice that makes recommending the HPV vaccine difficult?
- Do you have any suggestions that would make recommending the HPV vaccine easier within your practice?

Results

Retrospective Chart Review

Patient Demographics. In the final sample of 60 patients, 25 were female (42%) and 35 were male (58%). The majority of the patients (58%) were African American, with 13% white, 12% both Hispanic and biracial, 3% Middle Eastern, 2% Asian, and 2% undocumented. The vast majority of the patients were covered by government insurance (85%), with 10% being uninsured and 5% having private insurance.

Counseling on HPV vaccine provided during visit. Of the 60 patient charts reviewed, 11 (18%) had documentation of counseling on the HPV vaccine during the well-child visit. Currently there is not a specific place in the clinic's EMR to document any type of counseling, but several providers notated in the discussion section regarding HPV vaccine counseling. However, documentation of counseling was not consistent, and was more likely to be documented if the patient or parent declined or deferred vaccination.

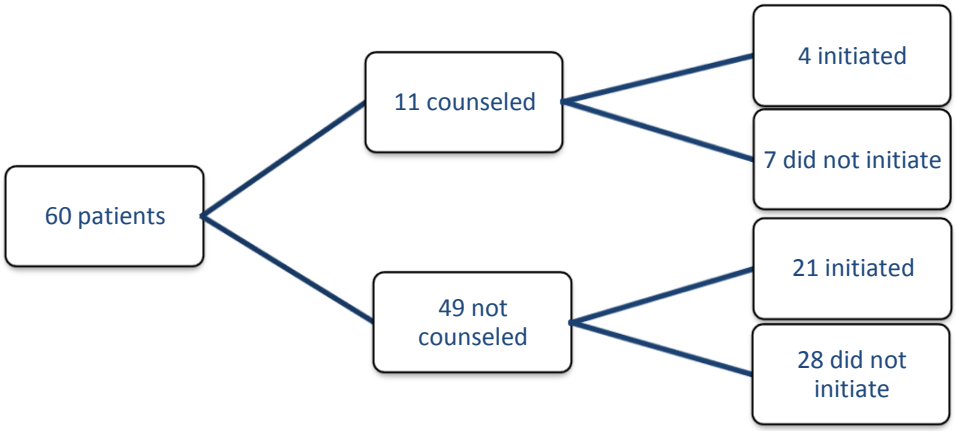

Figure 1: Describing if HPV vaccine counseling was offered and if so, did patient initiate or not initiate vaccination.

Initiation of the HPV vaccine. At this primary care clinic during the given time frame (April 23, 2013 to September 30, 2013), 25 patients or 42% of the sample, received their first dose of the HPV vaccine. In 2012 in the United States, 53.8% of adolescent females and 20.8% of adolescent males initiated the HPV vaccine series. Similarly, 51.2% of adolescent females in Kentucky received at least one dose of the HPV vaccine in 2012 (CDC, 2013f). There is not currently data for Kentucky male vaccination rates.

Table 1
Total Patients Initiating HPV Vaccine by Gender

	Study total	**Number initiated**	**Percentage initiated**
Males	35	15	43%
Females	25	10	40%

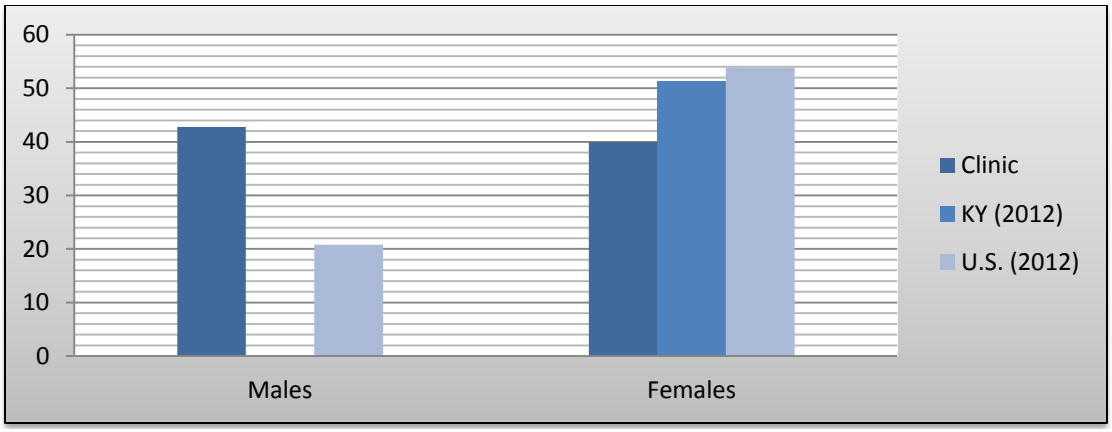

Figure 2. Clinic HPV Vaccine Initiation Rates compared to 2012 U.S. and Kentucky Data

Second and/or Third Dose of Vaccine Administered on Time. The CDC recommends that the second dose of HPV vaccine be given one to two months after the first dose, and the third dose be given six months after the first dose. According to these guidelines, all 25 patients that initiated vaccination would have been eligible for the second dose of the vaccine at the time of the chart review. However, only 32% (8/25 patients) had completed the second dose of the vaccine. Additionally, there was at least a six month interval since the first dose in seven patients, making them eligible for the third vaccine dose. Only 14% (1/7 patients) of those eligible to receive the third dose of vaccine had done so. Nationally, 33.4% of adolescent females and 6.8% of adolescent males completed all three doses of the HPV vaccine in 2012 (CDC, 2013f).

Provider Survey

Two of the four providers that practice at the primary care clinic responded to the REDCap (Harris et al., 2009) survey. One provider responded that they offered the HPV vaccine to all (100%) 11-12 year old male and female patients, and that 50-74% of females and 25-49% of males initiate vaccination. The second provider reported offering the vaccine to 50-74% of male patients and 75-99% of female patients, with a 50-74%

acceptance rate for females and 1-25% acceptance rate for males. The providers agreed facilitators to HPV vaccination within their clinic included the fact that the clinic participates in the Vaccines for Children Program (VFC) and that their patient population believed in primary prevention. The barriers included: patients had long-term safety concerns about the vaccine, patients were unlikely to return for the second and third dose, and that the vaccine was not required for school. Other facilitators and barriers discussed in the provider survey are presented in Table 2. The providers reported that they were both aware of the current ACIP recommendations. Both respondents answered questions correctly regarding their knowledge of the ACIP recommendations for both males and females.

Table 2

Provider Facilitators/Barriers Identified in REDCap Survey, N=2

	Provider 1	**Provider 2**
Facilitators		
Practice participates in VFC	X	X
Clinic has reminders within the EHR		
Adequate time available to educate patients about HPV		X
Pts have good understanding of HPV risks		X
Pts believe in primary prevention	X	X
Pts aware of VFC		X
Pts have good family/peer support to vaccinate		X
Barriers		
Vaccine not stocked/low availability		
Practice not adequately reimbursed	X	
Not time to discuss HPV/vaccine	X	
Provider long-term safety concerns		
Provider uncomfortable discussing HPV/vaccine		
Provider does not agree with ACIP recommendation		
Patient long-term safety concerns	X	X
Patients unlikely to return for doses 2 & 3	X	X
Vaccine not required for school	X	X
Patients concerned about pain		

Provider Focus Group

Focus group data was recorded and transcribed by the PI and briefly reviewed with the providers at the conclusion of the focus group. The comments were then grouped by theme. No identifying information was recorded during the focus group in order to keep the discussion confidential. Three of the four providers that practice at the clinic participated in the focus group. There was both physician and advanced practice nurse representation.

Perceived facilitators to recommending the HPV vaccine.

Use of the electronic medical record (EMR). The implementation of the electronic medical record, which occurred April 23, 2013 in this clinic, was mentioned as both a facilitator and a barrier during the focus group. The providers perceived the uncomplicated access to the immunization record as a facilitator as it provides immediate access to the patient's vaccination status. They agreed that having access to vaccination status is important for reducing missed doses. One provider also noted that there were several options that he/she had been using within the EMR including having the nurse chart "patient refusal" under the vaccination tab anytime that a vaccine was declined, and entering a request for a nurse visit when the patient received the initial vaccine dose so that the front desk was prompted to make return visits for second and third dose upon check-out. The other participating providers were not aware of these options within the EMR prior to the focus group discussion.

Perceived Barriers to Recommending the HPV Vaccine.

Inconsistencies between male and female patients. One provider noted that he/she inconsistently offered the vaccine to male patients and was much more likely to

offer the vaccine to female patients. The provider noted that since the recommendation to vaccinate males was more recent, it had not become habit to offer it to every patient. The other providers stated that they offered the vaccine to both males and females equally, but they felt that parents of male patients were less likely to be aware of the ACIP recommendations for males and they often required additional counseling regarding the vaccine and were more likely to decline or defer vaccination.

Patient/parent knowledge and beliefs. The themes that emerged related to patient and parent knowledge and beliefs included low medical literacy of patients and their parents, language barriers, and the impression that because the vaccine is not mandatory that it is not necessary. The providers pointed out that they felt that their particular patient population had lower medical literacy, especially concerning the HPV vaccine. They care for a fairly large number of international patients, and frequently the 11-12 year old well-child exam is the first time the patient and parents have heard of the vaccine. Because of this, vaccination is frequently deferred at that visit. The lower education level of the parents and frequent use of medical interpreters during visits make the discussion about the vaccine even more difficult. One provider stated that it "would be less complicated if the HPV vaccine was mandated for school entry, because patients and parents would be more likely to accept vaccination."

Uncertainty about documentation in EMR. While some aspects of the electronic medical record have been helpful in vaccinating patients, implementation of the system has also added barriers. Currently in the EMR, there is not a specific place to document patient counseling. Two of the providers said that they attempt to remember to document counseling as a free text under the "discussion" tab, but that it is difficult to remember

since they are not prompted. One provider stated that his/her documentation of counseling was much more consistent prior to the implementation of the electronic system.

Time. At this clinic, providers have approximately 15-20 minutes to spend with patients during well-child exams. The providers acknowledged that patients often used their well-child exams as problem visits and for medication refills, leaving very little time for patient counseling regarding the HPV vaccine and other topics. While patients are given an information sheet about the vaccine by the nurse when they enter the exam room, the providers felt there is not always adequate time for them to review that information with patients and parents.

Difficulty with patient follow-up. The providers all noted that follow-up for second and third doses of the HPV vaccine were problematic. They reported that it was difficult to get patients to return to the clinic for vaccination. They cited the following reasons for not returning: lack of patient transportation to clinic for visits, high no-show rates within the clinic, and insufficient clinic staffing so that it was difficult to send out patient reminders prior to visits.

Provider Suggestions for Improvement. The providers agreed that they needed to have a discussion about a routine place to document vaccine counseling. Additionally, they agreed that when the HPV vaccine was administered to an adolescent patient, they needed to enter a nurse visit to prompt the front desk to make appointments for the second and third doses at clinic check-out. They also concluded that the best approach to recommending and offering the vaccine included presenting the HPV vaccine as a potential preventive measure against cancer.

Discussion

The ACIP recommends that adolescents receive the HPV vaccine at age 11-12 so that all doses can be completed prior to the initiation of sexual activity. This provides the best protection against HPV infection (Markowitz et al., 2007). The retrospective chart review showed that while this primary care clinic had HPV vaccine initiation rates for male adolescents above the U.S. average, the rate for female adolescents was well below both the U.S. and Kentucky averages. Additionally, provider recommendation for vaccination was not consistently documented during well-child exams, and patient follow-up for second and third vaccine doses was inconsistent.

This clinic is not unique with its low vaccination rates. The President's Cancer Panel (PCP) issued a report in February 2014 to discuss urgent actions needed to increase vaccination rates in the U.S. One of the goals detailed in this report is to "reduce missed opportunities to recommend and administer HPV vaccine" (PCP, 2014, p. ii). To meet this goal, healthcare providers should strongly recommend the HPV vaccine to all male and female patients that are eligible for vaccination. Additionally, they should use electronic medical records to assist in reducing missed opportunities (PCP, 2014). According to the 2012 NIS-teen, 84% of girls that had not received the HPV vaccine had record of an appointment where they received a vaccine but not the HPV vaccine (CDC, 2012a).

The provider survey and focus group results indicated that the providers at this clinic find that their participation in VFC, their patients' beliefs in primary prevention, and the fact that the vaccination record is easily accessed in the EMR facilitated recommending and initiating the HPV vaccine. However, the main obstacles reported

were inconsistencies in provider recommendation between male and female patients, patient concerns about long term safety, difficulty with patient follow-up for second and third doses, lack of a vaccine mandate for school entry, low medical literacy of parents and patients, inadequate time to discuss vaccine with patients, and uncertainty of proper documenation within the EMR.

The barriers expressed during the provider focus group are not unique, and similar obstacles have been described in other studies. Systematic reviews have found that a knowledge gap among patients regarding HPV (Holman et al., 2014), parental beliefs about the HPV vaccine (Holman et al., 2014), vaccine cost (Holman et al., 2014; Rambout, Tashkandi, Hopkins, & Tricco, 2014), and patient concerns about vaccine safety (Rambout et al., 2014) were some of the leading obstacles to vaccine acceptance. Conversely, patients reported that lack of strong provider recommendation was a barrier. A strong provider recommendation was linked to increased vaccine acceptance and initiation (Holman et al., 2014; Rambout et al., 2014). Social pressures and perceived vaccine benefit also increased likelihood that patients would initiate the vaccine series (Rambout et al, 2014).

Finally, while this clinic had better vaccine initiation rates for males than the U.S. average in 2012, there is still room for improvement. During the focus group one provider acknowledged that they were less likely to recommend the HPV vaccine to their male adolescent patients due to forgetfulness. This provider noted that since the ACIP recommendation was only released for males in 2011, it had not become routine practice for them. Research has indicated that providers should focus on educating parents about the etiology of HPV infection and the vaccine's role in preventing cancer in males when

discussing the HPV vaccine with the parents of male adolescents (Thomas, Strickland, DiClemente, & Higgings, 2014). Additionally, parents may not be aware that vaccination of all 11-12 year old males is an ACIP recommendation since it was released in 2011.

Limitations

There were several limitations to this project including the small sample size (N=60). However, since this sample included all 11-12 year old patients that were seen for a well-child exam during the specified timeframe, it is a good indicator of how many adolescent patients are typically seen annually prior to sixth grade entry at this clinic. Another limitation is the start date of the retrospective chart review (April 23, 2013). This date was chosen because it was the date that the clinic began using electronic health records exclusively. This could be a potential disadvantage because there was a learning curve with using the EMR, and initially the clinicians were not familiar with charting within the system. A third limitation is that only two providers completed the REDCap survey. Finally, there are potential limitations with using focus groups to gather information. There is a possibility that the providers would not feel comfortable sharing their true thoughts and patient practices with other providers present.

Implications for Practice

Suggestions to improve practice include improving standardizing documentation. Providers should come to a consensus about a consistent place to document vaccine counseling. Additionally, they should enter a nurse visit for every patient that initiates the HPV vaccine. This will prompt the front desk to make the patient return visits for second and third vaccine doses at patient check-out. In addition, recommendations from the provider survey and focus group include being consistent about offering the HPV

vaccine to all eligible patients. If possible posters in the patient rooms and prompts within the EMR to offer the vaccine could serve as a good reminder. Providers should offer educational materials regarding the HPV vaccine in a variety of languages for their international patients. Finally, while it may be costly for clinic staff to send patient reminders, it may be possible for automated reminders to be sent to patients via email or text. Some research has indicated that text reminders have potential to increase HPV vaccine completion rates among adolescents (Matheson et al., 2013).

The providers within this clinic are knowledgeable about the HPV vaccine and are enthusiastic about offering it to their patients. Minor adjustments in practices and modifying the EMR system to simplify practice will help promote increased vaccine acceptance and initiation. While there is not currently a Healthy People 2020 goal for adolescent males, they should strive to increase the number of males that initiate and complete vaccination and increase the number of female adolescents that completed the three-dose series to meet the Healthy People 2020 goal of 80%. They should focus on increasing provider recommendation of the HPV vaccine, standardizing documentation of vaccine recommendation, and improving return rates for second and third vaccine dose to improve their HPV vaccine completion rates.

Chapter 5

Capstone Report Conclusion

Conclusion

Although implementation of routine vaccination of adolescents with the three-dose HPV vaccine has proven to be safe and effective in reducing infection with vaccine HPV types, rates of vaccination in the U.S. are suboptimal. Healthcare policy aimed at mandating HPV vaccines for adolescents prior to sixth grade entry have been largely unsuccessful. Low vaccination rates have triggered both the U.S. Department of Health and Human Services (HHS) and the President's Cancer Panel (PCP) to take action. One of the Healthy People 2020 goals is to increase the number of females ages 13 to 15 that have completed the three-dose HPV vaccine series to 80% (HHS, 2012). Additionally, the President's Cancer Panel (PCP) recommends that any barriers that prevent providers from strongly recommending the HPV vaccine be removed. The PCP also calls for the development of a Healthy People 2020 goal for HPV vaccine completion in male adolescents (PCP, 2014).

A quality improvement project with the goal of assessing providers' facilitators and barriers to recommending the HPV vaccine to their adolescent patients was conducted in an urban primary care clinic. The results showed that vaccination rates within the clinic were inadequate, and that documentation of vaccine recommendation was not consistent. Providers within the clinic identified barriers to recommending the HPV vaccine to their patients including lack of time during patient visits, a tendency to recommend the vaccine more often to females than males, language barriers between providers and patients, low medical literacy of patients and their parents, low likelihood that patients would return for follow-up vaccine doses, the fact that the vaccine is not

currently mandated for sixth grade entry in Kentucky, and lack of a standardized place to document HPV vaccine recommendation.

Primary care providers can play an integral part in increasing HPV vaccine rates among adolescents. They should continue to strongly recommend the HPV vaccine to all eligible patients according to ACIP recommendations. Additionally, it is important for providers to be aware of facilitators and barriers in practice and how they affect HPV vaccine recommendation. Finally, providers should stay educated regarding ACIP recommendations, Healthy People 2020 goals, and healthcare policy related to the HPV vaccine so they can offer well-informed guidance to their patients. The completion of this project is a step toward that goal. The primary care clinic has been given a summary of findings to assist in the development of interventions to improve HPV vaccination rates.

Appendix A

Assessing Providers' Facilitators and Barriers to Recommending the HPV Vaccine Chart Audit Tool

Study number:_____
Gender:_____
Age:_____
Race:_____
Insurance:_____

At the patient's 11/12 year old well-child visit, were the following documented:

Information	Yes	No	Comments
Was counseling on the HPV vaccine provided?	By: ___ CMA ____NP/MD		
Was the HPV vaccine offered?			
Patient's response if vaccine was offered	__ Accepted __ Deferred __ Declined		
Was the HPV vaccine series initiated?			
Was the vaccine series initiated or completed prior to this visit?			

Doses given (Y/N)? #1_____ #2_____ #3_____
On-time? Y/N Y/N Y/N

Appendix B

Assessing Providers' Facilitators and Barriers to Recommending the HPV Vaccine: Survey/Questionnaire

Please answer the following questions by selecting the answer that best represents your experience as a provider:

1. **How often do you offer the HPV vaccine during routine well-child exams for 11-12 year old FEMALES?**

	100%		25-49%
	75-99%		0-25%
	50-74%		

2. **How often do you offer the HPV vaccine during routine well-child exams for 11-12 year old MALES?**

	100%		25-49%
	75-99%		0-25%
	50-74%		

3. **When offered, what percentage of your FEMALE patients accept HPV vaccination:**

	100%		25-49%
	75-99%		0-25%
	50-74%		

4. **When offered, what percentage of your MALE patients accept HPV vaccination:**

	100%		25-49%
	75-99%		0-25%
	50-74%		

Which of these factors affect your decision to recommend the HPV vaccine in your current practice? Please select all that apply:

Practice Facilitators		**Practice Barriers**	
	My practice participates in the Vaccines for Children (VFC) program.		The HPV vaccine is not stocked or there is low availability in my practice.
	My clinic has reminders within the AEHR for HPV vaccination.		My practice is not adequately reimbursed for HPV vaccine administration.
	My clinic uses a form during well-child exams that prompts for CDC recommended vaccinations.		I do not have time to discuss HPV vaccination during patient visits.
	I have time to educate my patients about HPV and the vaccine.	Other:	
Other:			

Which of these factors affect your decision to recommend the HPV vaccine in your current practice? Please select all that apply:

Provider Facilitators		**Provider Barriers**	
	I strongly recommend the HPV vaccine to all eligible patients.		I have concerns about the long-term safety of the HPV vaccine.
	I have completed continuing education regarding HPV and/or the HPV vaccine.		I feel uncomfortable discussing a vaccine for a sexually transmitted infection with my patients and/or their parents.
	I am aware of the CDC/ACIP recommendations for HPV vaccination.		I do not agree with the CDC/ACIP recommendations for HPV vaccination.
Other:		Other:	

Patient Facilitators		**Patient Barriers**	
	My patients have a good understanding of the risks of HPV infection.		My patients are unaware of the risks of HPV infection.
	My patients/their parents believe that they are at risk for HPV.		My patients think the cost of the HPV vaccine is too high.
	My patients have a belief in primary prevention.		My patients are worried about the long-term safety of the HPV vaccine.
	My patients are aware of the Vaccines for Children (VFC) program and its coverage.		My patients are unlikely to return for the 2nd and 3rd dose of the vaccine series.
	My patients have positive peer/family support regarding HPV vaccination.		My patients are unlikely to get the vaccine because it is not required for school entry.
Other:			My patients are concerned about the pain associated with the HPV vaccine.
		Other:	

Please answer the following questions about the CDC/ACIP recommendations for HPV vaccination to the best of your knowledge:

8. **What is the recommended interval for HPV vaccination?**

a. 0, 3, and 6 months

b. 0, 1-2, and 6 months

c. 0, 3, 6, and 9 months

d. 0, 6, and 9 months

9. **What is the ideal age of vaccination for males and females?**

a. ages 11-12, can be given as early as 9

b. ages 13-15, can be given as early as 11

c. ages 9-13, can be given as early as 9

d. ages 15-18, can be given as early as 9

10. What are the recommendations for catch-up vaccination for males and females?

a. Catch-up for unvaccinated men and women ages 13-18.

b. Catch-up for unvaccinated men and women ages 13-21.

c. Catch-up for unvaccinated men ages 13-21 (and up to 26 for special populations), catch-up for women 13-26.

d. Catch-up for unvaccinated men ages 15-21 (and up to 26 for special populations), catch-up for women 15-26.

Comments: Please feel free to share any comments or ideas you have related to the HPV vaccine recommendations for 11-12 year olds in your clinic…

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