SUPPORTING IMMUNIZATION CLINIC NURSES IN FRAMING THE CONVERSATION: RECOMMENDING HPV VACCINATION FOR 11-12-YEAR-OLD ADOLESCENTS TO INCREASE HPV IMMUNIZATION RATES

by

Kelli Elizabeth McLoughlin

A scholarly project submitted in partial fulfillment
of the requirements for the degree

of

Doctor of Nursing Practice

in

Family and Individual Health

MONTANA STATE UNIVERSITY
Bozeman, Montana

April 2019

DEDICATION

This project is dedicated to all those who have ever been given an HPV diagnosis and have been forced to deal with its sequalae. HPV cancers do not discriminate. Let us protect as many as possible through the gift of immunization, all the while still working towards a cure.

ACKNOWLEDGEMENTS

This project would not be possible without the expertise, guidance, and unwavering support from my DNP committee chair, Dr. Jennifer Sofie, DNP, FNP-C, ANP-BC. Dr. Sofie embodies all that a graduate-level professor should be, plus more, and is the type of nurse practitioner I can only hope to become. I would also like to thank my project committee members, Dr. Maria Wines, PhD, RN, Dr. Janice Hausauer, DNP, APRN, FNP-BC, and Mary Kay Thurston, MN, APRN, CNP, FNP-BC, for their time and feedback which was instrumental to this project.

A very special thank you to Ashley Peters, BSN, RN, CLC, who was a huge supporter of the project from the beginning, as well as the nurses and staff within the Immunization Clinic at the Flathead City-County Health Department. I will forever be grateful for their participation, enthusiasm, feedback, time, and kindness. Their dedication to health promotion and disease prevention is an invaluable asset to the Flathead County community. I would also like to thank and acknowledge Carolyn Parry, MPH, CDC Public Health Advisor, from the Montana Immunization Program, for all of her help, feedback, and expertise in data collection and analysis.

Last, but certainly not least, thank you to Christopher, my loving fiancé, who continues to inspire me every day. He challenged me to challenge myself in returning to graduate school, going for the DNP degree, and selecting a project with a true purpose. I am blessed beyond belief to have him as my partner in this adventure called life!

TABLE OF CONTENTS

TABLE OF CONTENTS CONTINUED

TABLE OF CONTENTS CONTINUED

LIST OF TABLES

Table Page

LIST OF FIGURES

Figure Page

ABSTRACT

Despite the widespread availability of a safe and effective vaccine to prevent cancers caused by high-risk strains of human papillomavirus (HPV), vaccination rates in the United States remain low. Rates in Flathead County, Montana, have historically been even lower, below Healthy People 2020's goal of 80% series completion, and below state HPV immunization rates. Existing literature supports a strong recommendation for HPV vaccination (HPVV) from a health care professional (HCP) as the single most influential factor in vaccination behavior (Chuang et al., 2017; Gilkey et al., 2016; Sturm et al., 2017). The aim of this project was to educate and empower the nurses within the Flathead City-County Health Department's (FCCHD) Immunization Clinic in how to make strong, clear, and consistent recommendations for HPVV with the overall goal of increasing HPVV series initiation and completion rates for 11-12-year-olds. Staff were surveyed to assess baseline HPV knowledge and perceived barriers to HPVV. A series of communication interventions based on specific language from the Centers for Disease Control and Prevention's (CDC) "You are the Key to HPV Cancer Prevention" campaign was used to train HCPs in more frequently and confidently recommending HPVV to parents and patients. Interventions were instituted during the Immunization Clinic's scheduled nurses' meeting by a change agent (DNP student), over the course of six months. A post-survey was administered upon project completion. A resource binder for the HCPs was developed which included handouts for HPVV hesitant parents, infographics for the clinic and patient rooms, succinct information on how to recommend HPVV, upcoming continuing education credits involving recommending HPVV, appointment reminder cards for parents/adolescents, and the clinic's HPVV policies. Lippitt's Phases of Change Theory served as the framework for this project. Efficacy was assessed by comparison of pre- and post-survey results, the actual number of HPV vaccines administered during the intervention period, and rates of HPVV series initiation and completion in 11-12-year-olds pre- and post-intervention. The communication intervention increased the comfort and confidence of HCPs as well as HPVV initiation and completion rates. An intervention such as this can help increase the uptake of HPVV and in turn, protect adolescents from HPV-associated cancers.

CHAPTER ONE – INTRODUCTION

Introduction

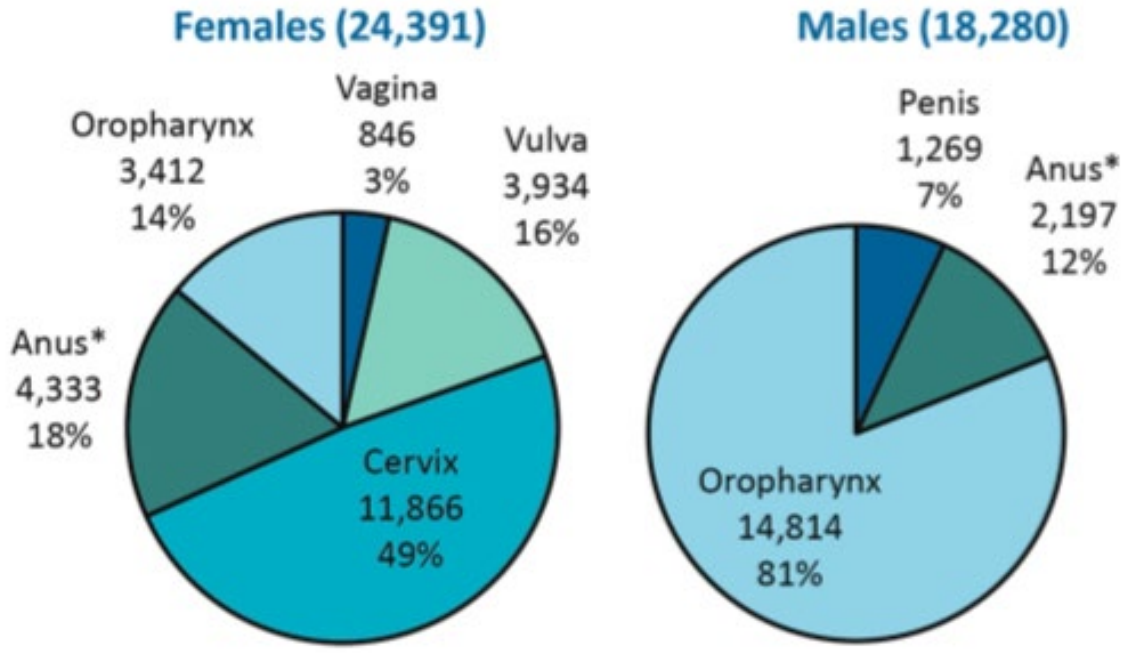
Human papillomavirus (HPV) is a virus that causes cancer. Most commonly, it is transmitted through sexual contact. It is alarmingly common and affects both males and females. It is most prevalent in adolescents and adults. "HPV is so common that nearly all sexually active men and women get the virus at some point in their lives," (Centers for Disease Control and Prevention [CDC], 2017a). Worldwide, HPV has been attributed to over 600,000 cases of cancer and 250,000 premature deaths every year (Saraiya et al., 2015). It also causes genital warts and a rare but serious disease, recurrent respiratory papillomatosis (RRP). In the U.S., 79 million people are currently infected with HPV and approximately 14 million people become newly infected annually; the ages of half (7 million) of those infected each year are between 15 and 24 years-old (Markowitz et al., 2016).

Prevalence of HPV

HPV-associated cancers are defined as "cancers at specific anatomic sites with specific cell types in which HPV DNA frequently is found," (Van Dyne et al., 2018, p. 918). A major challenge in accurately tracking HPV-associated cancers is that most cancer registries do not test for HPV DNA in cancerous tissue at the time of cancer diagnosis (Van Dyne et al., 2018). The overall mortality rate is hard to establish for HPV-associated cancers as a result. More commonly, incidence and mortality rates are

reported individually according to the type of cancer. Almost all cervical cancers, 70% of oropharyngeal cancers, 69% of vulvar cancers, 75% of vaginal cancers, 63% of penile cancers, and 91% of anal cancers are caused by HPV (Saraiya et al., 2015). In the U.S., HPV causes more than 42,700 cases of cancer every year; more than half of those cases occur in females (CDC, 2018a). Figure 1, from the CDC, details the number of HPV-associated cancers each year in the U.S. by sex. In 2015 alone, 43,371 HPV-associated cancers were recorded, an increase of 30% since 1999. An estimated 8,000 people in the U.S. die from HPV-associated cancers every year (American Academy of Pediatrics [AAP], n.d.). Half of those deaths are from cervical cancer.

Figure 1: Number of HPV-Associated Cancers Each Year in the U.S.

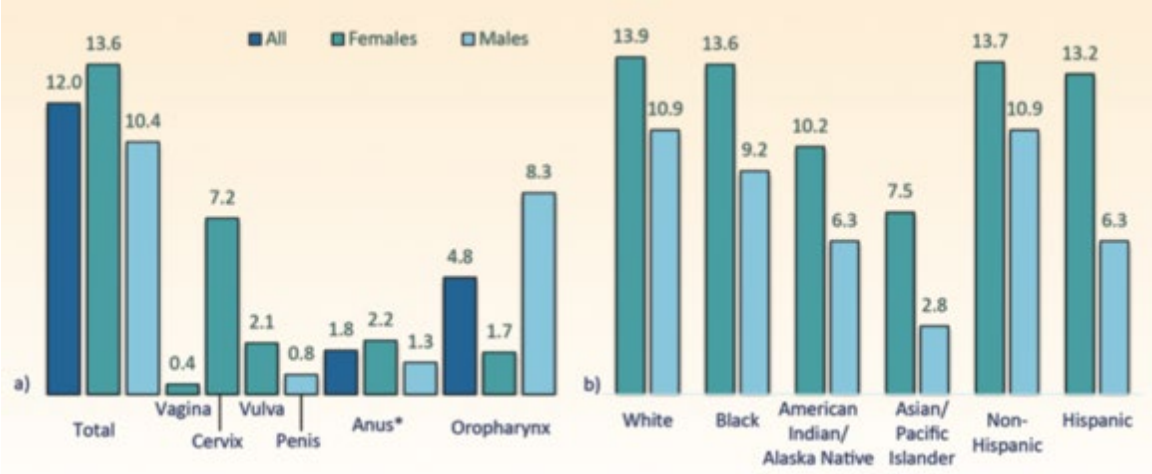


(CDC, 2018a)

Based on data from 2011-2015, the CDC (2018a) determined incidence rates of HPV-associated cancers to be higher in females for every race/ethnicity (Figure 2, b).

White females and males have the highest incidence rates of HPV-associated cancers and Asian/Pacific Islanders have the lowest (Figure 2, b).

Figure 2: Rates of HPV-Associated Cancer by Sex and Cancer Type (a) and Rates of HPV-Associated Cancers by Sex and Race/Ethnicity (b)



(CDC, 2018a)

Non-Hispanics have higher rates than Hispanics for both sexes. Differences do exist by cancer site (Figure 2, a), most significantly in the oropharynx, where the rates in males are disproportionally higher than for females. Oropharyngeal cancer is now the most prevalent HPV-associated cancer in males, but rates have also been steadily increasing in females (CDC, 2018a; Sonawane, et al., 2017).

Cervical Cancer

More than 300,000 women worldwide and 4,000 in the U.S. die annually from cervical cancer caused by HPV (Van Dyne et al., 2018). In 2015, there were 11,788 cases of HPV-associated cervical cancer in U.S. females (Van Dyne et al., 2018). From 1999-2015, rates decreased 1.6% per year in the U.S., with the largest decreases observed

in females age 20-24. Rates continued to decrease in all other age groups as well as ethnicities (Van Dyne et al., 2018).

Oropharyngeal Cancer

The oropharynx includes the tonsils, soft palate, uvula, throat, and base of the tongue. In 2015, there were 15,479 (82%) recorded cases directly attributable to HPV in males and 3,438 (18%) in females. From 1999-2015, oropharyngeal cancer rates increased in males by 2.7% and in females by 0.8%. Oropharyngeal cancer is now the most common cancer caused by HPV in the U.S. Rates are more than 4.5 times higher in males versus females. In addition, increases were seen among men in all age groups 40 years-old and above, with the 60-69-year-old cohort experiencing the highest increase at 4% each year. Rates were highest among White males (3.3% per year) and differed by region, with the highest occurring in the Midwest (3.2% per year) as compared to other ethnicities and regions of the country (Van Dyne et al., 2018).

Vulvar Cancer

Rates have increased by 1.3% each year from 1999-2015. Females aged 50-59 saw the highest increases (2.9% each year) while those under age 40 actually saw a decrease of 0.5% each year. Rates were higher among White females (1.5% per year) and in the Northeast and Midwest (1.5% per year respectively) (Van Dyne et al., 2018).

Vaginal Cancer

Rates have decreased 0.6% each year from 1999-2015. All age groups and ethnicities experienced lower vaginal cancer rates. The largest decreases were among

Black females (-2.7% each year) and women under age 40 (-2.8% each year) (Van Dyne et al., 2018).

Penile Cancer

Rates have remained stable in males from 1999-2015. Those 40-49 years-old experienced an increase in penile cancer rates by 0.6% each year while the rates for all other age groups decreased. Asian or Pacific Islanders and Hispanic males experienced the greatest rate decreases (-0.9% per year) (Van Dyne et al., 2018).

Anal Cancer

Cancers in this area also include rectal cancers. HPV-associated anal cancer rates increased the most in females from 1999-2015 at 2.9% each year. The rates were particularly high in females ages 60-69 (4.8% per year) and 50-59 (4.6% per year). In males, rates increased by 2.1% each year and were greatest for those 50-59 years-old. A decline of 2.9% was seen in males under age 40 (Van Dyne et al., 2018).

Summary

The increase in oropharyngeal and anal cancers in both sexes has been attributed to differences in sexual behavior. In particular, "White men have the highest number of lifetime oral sex partners and report first performing oral sex at a younger age compared with other racial/ethnic groups," (Van Dyne et al., 2018, p. 920). Historically, tobacco and alcohol use were credited with causing the majority of oropharyngeal cancers. However, we know now about 70% of oropharyngeal cancers are caused by HPV (CDC, 2018a). From 1999-2015 in the U.S., HPV-associated cancer rates decreased in those

under age 40, for both sexes, in every type of cancer discussed above, with the exception of oropharyngeal cancer in females (Van Dyne et al., 2018). Cervical cancers have significantly decreased largely due to increased cervical cancer screening and the availability of a vaccine to combat the most virulent strains of HPV, which first became available to females only in 2006. Recommendations for routine HPV vaccination (HPVV) in males began in 2011.

As nearly all cervical cancers are preventable with HPVV, every incidence of cervical cancer after 2006, when the vaccine first became available, is tragic, to say the least. The majority of oropharyngeal, vulvar, vaginal, penile, and anal cancers can also now be prevented with HPVV (Van Dyne et al., 2018). While it may be too early to draw correlations between the decrease in overall prevalence of HPV and HPV-associated cancers as related to HPVV, the numbers are encouraging and may even indicate the beginnings of herd immunity (Markowitz, Gee, Chesson, & Stokley, 2018). Table 1, from the CDC's Morbidity and Mortality Weekly Report, further details the number of HPV-associated cancers in the U.S. by sex, type of cancer, and age, in 1999 as compared to 2015.

Table 1: Annual Number and Annual Age-Adjusted Rates and Trends in HPV-Associated Cancer by Sex, Cancer Type, and Age Group – United States, 1999–2015

Cancer type/ age group (yrs)	Period of diagnosis		
	1999	2015	1999–2015
	No. (rate)*	No. (rate)*	AAPC (95% CI)
Total	**30,115 (11.2)**	**43,371 (12.1)**	**0.5† (0.2–0.9)**
Females			
All HPV-associated cancers	**21,008 (14.6)**	**24,432 (13.6)**	**-0.4† (-0.7 to 0.2)**
Cervical carcinoma	**13,125 (9.3)**	**11,788 (7.2)**	**-1.6† (-2.2 to -1.0)**
15–19	21 (0.2)	—**	—**
20–24	161 (1.8)	74 (0.7)	-4.2† (-5.3 to -3.1)
25–29	677 (7.1)	535 (5.0)	-2.6† (-3.7 to -1.5)
30–34	1,252 (12.5)	1,069 (10.1)	-1.2† (-2.1 to -0.4)
35–39	1,663 (14.8)	1,296 (13.0)	-0.8 (-2.1 to 0.4)
40–44	1,799 (16.4)	1,531 (15.4)	-0.8† (-1.2 to -0.3)
45–49	1,571 (16.1)	1,436 (14.0)	-1.2† (-2.2 to -0.2)
50–54	1,266 (15.0)	1,315 (11.8)	-1.6† (-2.3 to -0.8)
55–59	1,095 (16.6)	1,292 (11.8)	-2.0† (-2.9 to -1.2)
60–64	877 (16.0)	1,053 (10.8)	-2.7† (-3.4 to -1.9)
65–69	772 (15.4)	808 (9.8)	-2.9† (-3.4 to -2.4)
≥70	1,970 (13.2)	1,377 (7.9)	-3.2† (-3.8 to -2.6)
Vulvar SCC	**2,615 (1.7)**	**3,890 (2.0)**	**1.3† (1.1 to 1.6)**
<40	192 (0.2)	154 (0.2)	-0.5 (-1.3 to 0.3)
40–49	354 (1.7)	385 (1.9)	0.3 (-0.6 to 1.2)
50–59	361 (2.4)	778 (3.5)	2.9† (2.4 to 3.4)
60–69	396 (3.8)	905 (5.0)	2.4† (2.0 to 2.9)
≥70	1,312 (8.6)	1,668 (9.1)	0.5 (-0.2 to 1.2)
Vaginal SCC	**730 (0.5)**	**809 (0.4)**	**-0.6† (-1.1 to -0.1)**
<40	28 (0)	20 (0.0)	-2.8† (-4.3 to -1.2)
40–49	84 (0.4)	64 (0.3)	-0.4 (-1.5 to 0.8)
50–59	110 (0.7)	136 (0.6)	-0.2 (-1.0 to 0.6)
60–69	144 (1.4)	219 (1.2)	-0.5 (-1.6 to 0.5)
≥70	364 (2.4)	370 (2.0)	-0.6† (-1.0 to -0.2)
Anal SCC	**2,129 (1.5)**	**4,507 (2.2)**	**2.9† (2.5 to 3.3)**
<40	91 (0.1)	89 (0.1)	-1.2 (-2.5 to 0.1)
40–49	379 (1.8)	377 (1.8)	0.4 (-0.6 to 1.4)
50–59	426 (2.8)	1,347 (6.0)	4.6† (3.7 to 5.6)
60–69	434 (4.1)	1,476 (8.2)	4.8† (4.4 to 5.3)
≥70	799 (5.3)	1,218 (6.9)	2.1† (1.7 to 2.4)
Oropharyngeal SCC	**2,409 (1.6)**	**3,438 (1.7)**	**0.8† (0.5 to 1.1)**
<40	66 (0.1)	71 (0.1)	1 (-0.2 to 2.2)
40–49	262 (1.3)	305 (1.5)	0.4 (-0.8 to 1.6)
50–59	550 (3.6)	1,046 (4.6)	2.1† (1.5 to 2.6)
60–69	653 (6.2)	1,050 (5.8)	0.4 (-0.1 to 1.0)
≥70	878 (5.9)	966 (5.6)	0.3 (-0.3 to 0.8)

(Van Dyne, 2018)

Table 1 Continued

Cancer type/ age group (yrs)	Period of diagnosis 1999 No. (rate)*	2015 No. (rate)*	1999–2015 AAPC (95% CI)
Males			
All HPV-associated cancers	**9,107 (7.4)**	**18,939 (10.5)**	**2.4† (2.2 to 2.6)**
Penile SCC	**973 (0.8)**	**1,224 (0.8)**	**-0.2 (-0.6 to 0.3)**
<40	40 (0.1)	34 (0.0)	-0.7 (-2.1 to 0.8)
40–49	95 (0.5)	99 (0.5)	0.6 (-0.4 to 1.6)
50–59	180 (1.3)	210 (1.0)	-1.4† (-2.4 to -0.5)
60–69	242 (2.6)	287 (1.8)	-2.0† (-2.6 to -1.4)
≥70	416 (4.5)	594 (4.6)	0.8† (0.2 to 1.4)
Anal SCC	**1,168 (1.0)**	**2,236 (1.3)**	**2.1† (1.4 to 2.8)**
<40	129 (0.2)	103 (0.1)	-2.9† (-4.1 to -1.6)
40–49	262 (1.3)	303 (1.5)	0.8 (-0.3 to 1.9)
50–59	246 (1.7)	678 (3.2)	4.0† (3.2 to 4.8)
60–69	214 (2.3)	610 (3.7)	2.7† (1.9 to 3.5)
≥70	317 (3.2)	542 (4.2)	1.5 (-0.7 to 3.8)
Oropharyngeal SCC	**6,966 (5.6)**	**15,479 (8.5)**	**2.7† (2.5 to 2.9)**
<40	147 (0.2)	133 (0.2)	-0.9 (-2.3 to 0.4)
40–49	1,217 (6.0)	1,387 (6.7)	0.8† (0.2 to 1.5)
50–59	2,224 (15.6)	5,106 (23.7)	2.7† (2.2 to 3.2)
60–69	1,891 (20.4)	5,745 (35.2)	4.0† (3.6 to 4.3)
≥70	1,487 (14.9)	3,108 (23.1)	2.8† (2.3 to 3.4)

Sources: CDC's National Program of Cancer Registries and the National Cancer Institute's Surveillance, Epidemiology, and End Results program.
Abbreviations: AAPC = average annual percent change; CI = confidence interval; SCC = squamous cell carcinoma.

* Per 100,000 persons, age-adjusted to the 2000 U.S. standard population.
† Significant at $p<0.05$. Trends were measured with AAPC in rates and were considered to increase or decrease if $p<0.05$; otherwise rates were considered stable.
§ HPV-associated cancers were defined as cancers at specific anatomic sites with specific cell types in which HPV DNA frequently is found. All cancers were microscopically confirmed. Cervical cancers (*International Classification of Diseases for Oncology, Third Edition* [ICD-O-3] site codes C53.0–C53.9) are limited to carcinomas (ICD-O-3 histology codes 8010–8671, 8940–8941). Vaginal (ICD-O-3 site code C52.9), vulvar (ICD-O-3 site codes C51.0–C51.9), penile (ICD-O-3 site codes C60.0–60.9), anal (including rectal SCC; ICD-O-3 site code C20.9, C21.0–C21.9), and oropharyngeal (ICD-O-3 site codes C01.9, C02.4, C02.8, C05.1, C05.2, C09.0, C09.1, C09.8, C09.9, C10.0, C10.1, C10.2, C10.3, C10.4, C10.8, C10.9, C14.0, C14.2 and C14.8) cancer sites are limited to squamous cell carcinomas (ICD-O-3 histology codes 8050–8084, 8120–8131).
¶ Cancer incidence compiled from cancer registries that meet the data quality criteria for all invasive cancer sites combined (covering approximately 97.8% of the U.S. population).
** Data suppressed for rates when the number of cases was <6 in a year.

(Van Dyne, 2018)

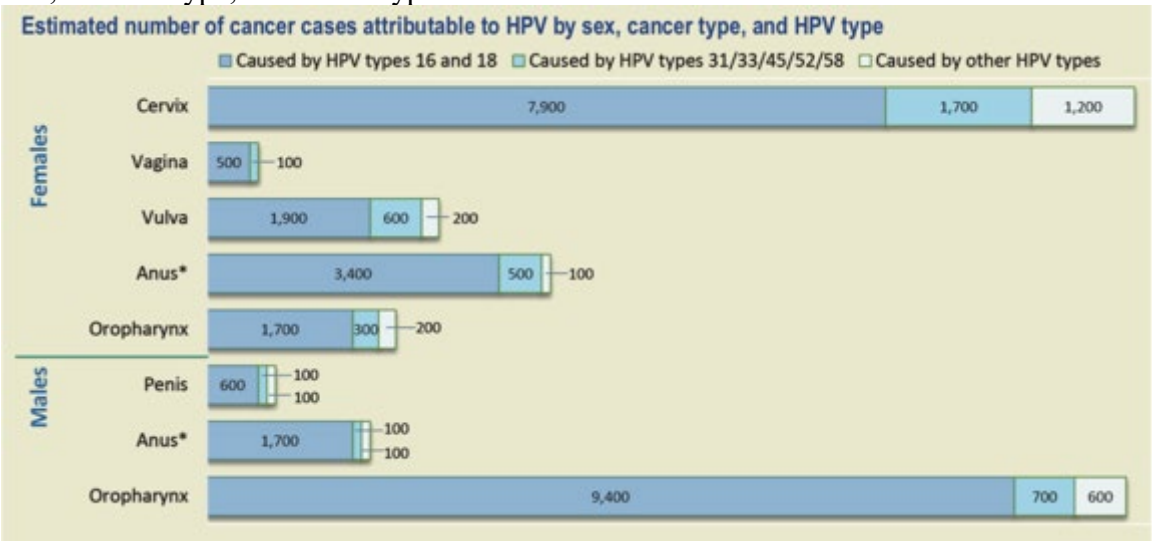
Background

Over 150 individual strains of HPV have been identified. HPV is the most common sexually transmitted infection (STI) in the U.S. (Meites, Kempe, & Markowitz, 2016). Virtually everyone who has been sexually active, even once, will be exposed to it (Markowitz et al., 2014). In most instances, the immune system of a healthy individual is able to recognize HPV as a virus and rid the body of it. However, a number of strains have been discovered that the body is less likely to be able to clear over time. This results in infection with the potential to cause cancer, genital warts, and a disease called recurrent respiratory papillomatosis (RRP). Repeated exposure to HPV can also result in chronic or reoccurring infections. There is no cure for HPV infection.

These more resistant strains are further subtyped as low or high risk, in regard to their ability to alter the normal development of epithelial cells into cancerous cells. Basal epithelial cells cover the skin and line the surfaces of many organs in the body. They are most abundant inside the mouth, throat, and rectum as well as the cervix, vagina, and vulva in females, and the penis in males. For this reason, infection with HPV can lead to cancer in all of these areas. Unfortunately, the host immune response to infection in epithelial cells is weak so many people with HPV infection do not develop antibody levels that are high enough to even be detected (Markowitz, 2014). If antibodies are not developed, HPV is able to replicate, and thickened lesions are formed. These lesions naturally progress to tumors and have the potential to become cancerous. Certain strains of HPV are more likely (virulent) to cause cancer than others. HPV vaccination (HPVV) targets these virulent strains as well as those that predominantly cause genital warts.

Subtypes 16 and 18 are categorized as “high risk” because they are the most virulent, and most frequently are the cause of HPV-associated precancerous and cancerous lesions (Figure 3) (Meites, Kempe, & Markowitz, 2016).

Figure 3: Estimated Number HPV-attributable Cases of Cancer in the United States by Sex, Cancer Type, and HPV Type



(CDC, 2018a)

This includes about 50% of cervical precancerous lesions and 70% of cervical cancers. HPV 16 is particularly virulent as it causes most other HPV-associated cancers (oropharyngeal, vulvar, vaginal, penile, and anal) (Markowitz, Gee, Chesson, & Stokley, 2018). Subtypes 6 and 11 predominantly cause genital warts as opposed to cancer, hence are categorized as low risk strains (Meites, Kempe, & Markowitz, 2016). Warts caused by HPV can also be found on other areas of the body such as the hands and feet. This is not to be confused with herpes simplex, another virus with the ability to cause warts in similar areas of the body.

The HPV "low risk" designation can be misleading. RRP is a rare but serious disease, caused by "low risk" HPV type 6 or 11, in which numerous benign but recurrent tumors grow throughout the respiratory tract. The respiratory tract involves the pathway air takes when entering and exiting the body and includes the nose, mouth, throat, and lungs. These tumors can cause trouble breathing, swallowing, and talking, with even greater severity in children. Treatment for RRP requires frequent (annually or as often as every few weeks) surgical removal of the tumors to keep the airway passages open. In severe cases, a tracheostomy may be performed. There is no cure. (U. S Department of Health and Human Services [DHHS], National Institute on Deafness and Other Communication Disorders [NIDCD], 2017).

Transmission of HPV

Any skin-to-skin contact with an area of the body that is infected with HPV can result in transmission, but HPV is most commonly spread through intimate skin-to-skin touch. This includes vaginal, oral, and anal intercourse as well as genital contact. Condoms do not fully protect against HPV (CDC, 2017). Less commonly, HPV is also transmitted from mother to baby if genital warts subsist at the time of delivery on the mother. The warts may be so small and innocuous the mother may be unaware they are even there. The baby would then carry HPV and could develop RRP as an infant, child, or even adult (U.S. DHHS, NIDCD, 2017).

Following infection with any strain of HPV, autoinoculation is common, in which the infected individual spreads HPV around their own body (CDC, 2018). Many people are also repeatedly infected with HPV even after previously clearing the virus or having

cancerous, precancerous, or suspicious lesions removed. HPV can lay dormant in the immune system for many years and then precipitously become active if the immune system is compromised. As it can take 15-20 years for even an active form of HPV infection to develop into cervical cancer in an immunocompetent female (5-10 years if immunocompromised), symptoms of cervical cancer, for example, may not present until very advanced stages (WHO, 2018). In this way, HPV can be spread even if the infected individual is not symptomatic. This makes determining the original carrier of HPV very difficult and nearly impossible to establish, thus HPV continues to be transmitted unknowingly.

Detection of HPV and Screening Modalities

Currently, "HPV tests are not recommended or approved for use in men or adolescents, for detection of HPV in partners, or at anatomic sites other than the cervix" in females (Markowitz et al., 2014, p. 3). The United States Preventive Services Task Force (USPSTF) recommends routine cervical cancer screening (Papanicolaou [Pap] test) for females beginning at age 21 but testing for HPV is not recommended until age 30 or older. The rationale being, to give the body time to clear HPV on its own because treatment modalities for precancerous and cancerous lesions can be costly and are not without risk. To test for HPV, a swab of cells is taken from the cervix by a health care professional (HCP), preserved in a special liquid, and examined in a laboratory for the presence of HPV DNA. This is usually done in conjunction with a Pap test, which assesses the size, shape, and number of cervical cells (cytology). Co-testing is the term used when these two tests (Pap and HPV) are performed together. In order to detect

cellular changes around and on the cervix, regular Pap tests are imperative to establish a baseline and aid in the identification of lesions before they progress to invasive cancer. Unfortunately, "more than half of the women in the U.S. who get cervical cancer have never had or rarely had a Pap test," (American Cancer Society, 2016). There is no available test that can detect a prior infection of HPV if the immune system has cleared it.

The presence of HPV DNA on co-testing greatly increases the risk for cervical cancer and genital warts as well as oropharyngeal, vulvar, vaginal, and anal cancers. The risk of genital warts and oropharyngeal, anal, and penile cancers is also higher for exposed male partners. In both males and females, routine exams of the mouth and oropharynx by a HCP, dental hygienist, dentist, or even through self-examination may lead to the discovery of existing precancerous or cancerous lesions, but visual inspection alone cannot determine or eliminate with certainty the simple presence of HPV infection (American Cancer Society, 2016). While "screening is the best method for early detection and prevention of cancer, … prophylactic HPVV may offer protection to those at highest risk for abnormal Pap screenings," (Sandri et al., 2014) thus making the completion of the HPVV series of utmost importance in establishing protection against HPV-attributable cancers.

Risk Factors for HPV Infection and HPV-Associated Cancers

Differences in sexual behavior as well as HPV vaccine uptake are two main factors that influence the likelihood of HPV infection and HPV-associated cancers. According to the National Institute of Health's National Cancer Institute (2015) and Van

Dyne (2018), additional factors that may increase the risk of HPV-associated cancers include:

- Initiation of sexual intercourse at an early age
- Multiple sexual partners or many throughout a lifetime
- Tobacco use
- Numerous chronic co-morbidities
- Weakened or suppressed immune system (i.e. chronic inflammation, organ transplant, chemotherapy, chronic steroid use, HIV infection)
- Prolonged use of oral contraceptives
- Unprotected sex, specifically oral, and unprotected receptive anal sex
- Poor oral hygiene

Many of the above risk factors can be mitigated with access to regular primary (HPVV), secondary (cervical cancer screening, dental visits), and tertiary (tobacco cessation, prompt removal of precancerous and cancerous lesions) services.

Of note, rural residents face unique challenges in accessing primary, secondary, and tertiary services. A major contributing factor is the shortage of primary care, mental health, and dental providers. For this reason, rural areas have disproportionally lower HPVV rates compared to their more urban and highly populated counterparts (Sandri, 2014; Walker et al., 2017). This holds true even with health insurance coverage. In addition to rural residents, males, younger adolescents, privately-insured adolescents, and non-Hispanic whites are populations that have been identified as having disproportionally

lower HPVV rates (Dorell, Yankey, Kennedy, & Stokley, 2013; Walker et al., 2017; Wong et al., 2011) and are therefore at higher risk for HPV-associated cancers.

Treatment

There is no cure for HPV infection. HPV is one of the most expensive STIs due to the costly and often lifelong expenses of treating HPV-associated cancers. Chesson et al. (2012) estimated the direct medical cost burden attributable to HPV in the U.S. to be $8 billion per year. The majority of this cost ($6.6 billion) was allocated to cervical cancer screening and follow-ups. The treatment modalities that do exist target lesions caused by HPV including precancers, cancers, genital warts, and RRP. Numerous uncomfortable office or operating room procedures such as a colposcopy, cone biopsy, or loop electrosurgical excision procedure (LEEP), may be necessary to confirm, stage, and remove cervical lesions in females. Treatments are generally localized and vary based on the size, location of the lesion(s), and diagnosis but may also require radiation, chemotherapy, or surgical removal.

Warts in the oropharyngeal and anogenital areas are typically treated with either laser or electrosurgical procedures. Topical options for external anogenital warts include trichloroacetic acid, bichloroacetic acid, and cryotherapy, applied by an HCP (CDC, 2015). Imiquimod, podofilox, and sinecatechins are topicals that can be applied by patients at home (CDC, 2015). Antiviral therapy is not currently recommended. Although HPVV after infection with a particular strain of HPV will not protect against the infective strain, it still offers protection against additional strains and immunization should be strongly recommended by HCPs to those within the recommended age range.

Prevention

Over 30,000 cases of cancer could be prevented each year through HPVV (CDC, 2018a). Figure 3, from the CDC, illustrates the number of estimated HPV-associated cancer cases attributed to HPV by sex, cancer type, and HPV strain. The 9-valent HPV vaccine protects against all of the strains listed (16, 18, 31, 33, 45, 52, 58) in addition to two others, 6 and 11, which primarily cause genital warts and RRP. Primary prevention is the most efficacious as well as cost effective method to prevent diseases. Immunization is the foundation of primary prevention and is "a key preventive cornerstone of pediatric care" (Bernstein & Bocchini, 2017). Routine HPVV is recommended as the standard of care for adolescents, specifically 11-12 years old, because the vaccine is more effective in immune systems that have not yet been exposed to HPV. It is almost certain that everyone will be exposed to HPV during their lifetime (Markowitz et al., 2014), hence primary prevention in the form of HPVV is essential.

As even individuals who have only had one sexual partner can become infected with HPV, abstaining from sexual activity with another person (including all genital contact), in addition to HPVV, is the best way to prevent genital HPV infection. Condoms, when used correctly, lower the chances of HPV transmission about 70% of the time (Winer et al., 2006). Male circumcision has been found to be a protective factor for both circumcised males as well as their female partners in randomized clinical trials (as cited in Markowtiz et al., 2014). Other factors that lower the chances of HPV transmission and infection include a "monogamous relationship with [only] one partner,

limiting [the] number of sex partners, and choosing a partner who has had no or few previous sex partners," (Markowtiz et al., 2014, p. 7).

The Vaccine: Gardasil®9

In 2006, Merck and Co, Inc., produced the first HPV vaccine which was licensed by the Food and Drug Administration (FDA) for females age 9-26 years-old. The Advisory Committee on Immunization Practices (ACIP) approved and subsequently recommended the vaccine the same year. The vaccine is composed of recombinant L1 capsid proteins that assume the shape of virus-like particles. These particles closely resemble the shape and size of HPV but are non-infectious and non-oncogenic (CDC, 2018c). The 3-dose series first consisted of a quadrivalent vaccine (4vHPV) that targeted HPV strains 6, 11, 16, and 18. Another company, GlaxoSmithKline, released a bivalent vaccine, (2vHPV), targeting just HPV strains 16 and 18 in 2009. This was also a 3-dose series and only recommended for females. Because the original clinical trials to gage vaccine efficacy were only conducted in females, it was not until 2011 that the 4vHPV was recommended for males aged 9-26 years-old. The U.S. was the first country to routinely recommend HPVV for males aged 11-12 (Markowitz, Gee, Chesson, & Stokely, 2018).

In 2014, a third HPV vaccine, developed by Merck and Co., was licensed in the U.S. by the FDA. It was later approved and recommended by the ACIP in 2015 for males and females age 9-26 years-old, as a 3-dose series. This 9-valent HPV vaccine (9vHPV) continues to offer protection against the 4 strains in the 4vHPV in addition to

five other strains of HPV that can cause cancer - strains 31, 33, 45, 52, and 58. The 9vHPV is called Gardasil®9 and has been the only HPV vaccine sold and available in the U.S. since the end of 2016. In 2016, the ACIP updated their HPVV recommendations based on results of safety and efficacy data; the amendment reduced the series from 3 doses to 2 doses, for males and females, who began the HPV immunization series before their 15th birthday (Meites et al., 2016). Adolescents and adults starting the series on or after their 15th birthday should continue to receive 3-doses (Meites et al., 2016). At this time, the ACIP does not recommend restarting or prolonging the series if different types of HPV vaccine were administered.

Safety

Indications and timing for HPV vaccination have evolved as evidence has established a long pattern of safety and efficacy (Castellsagué et al., 2011). HPV vaccine is not a new vaccine. It has been in use since 2006, which has generated 12 years of safety data. HPV vaccine has been given over 250 million times around the world, in over 180 countries, and over 100 million doses have been safely administered in the U.S. (CDC, 2018). There have never been any reported serious side effects caused by the vaccine in either children or adults (Castellsagué et al., 2011; Saslo & Perkins, 2018).

The most common adverse effects of Gardasil®9 are local injection site reactions that include swelling, redness, and pain. These adverse effects are not unique to Gardasil®9. Systemic effects have been cited in only about 10% of recipients and include headaches and syncope. Pre-syncopal and syncopal events have been intensely scrutinized and conclusive evidence surmises it is the thought of actually getting a shot,

not the vaccine content itself, that leads to occasional fainting after injection in adolescents (Castellsagué et al., 2011; CDC, 2018b). To combat the possibility of any syncopal events, adolescents should be advised to remain seated for up to fifteen minutes following injection. Adverse effects are continually monitored by the Vaccine Adverse Event Reporting System.

Efficacy

Since 2006, infections with HPV strains that most commonly cause cancer and genital warts have dropped 71% among adolescent females (Montana Immunization Program, 2018), despite suboptimal uptake of HPVV in the U.S. Females who received the full series of HPVV prior to age 14 were 75% less likely to develop cervical precancers compared to their nonvaccinated peers (AAP, n.d.). Markowitz, Gee, Chesson, and Stokely (2018) have concisely demonstrated the findings from numerous population studies that examined the prevalence of HPV before and after routine HPVV was recommended by the ACIP (Table 2).

After only four years of HPVV in U.S. females, a 56% decrease was observed in the prevalence of the HPV strains that were included in the HPV vaccine. Within 8 years, a 71% reduction in HPV vaccine type prevalence in females 14-19 years-old and a decrease of 61% in females 20-24 years-old was observed. Declines in HPV-associated genital warts and cervical precancerous lesions are also detailed. These findings are not only encouraging but have led to additional studies that have examined the cost-effectiveness of HPVV. "Numerous modeling studies have indicated that routine HPVV is an efficient use of public health resources and will yield substantial reductions in HPV-

associated disease over time," (as cited in Markowitz et al., 2018, p. S5 & Chesson, Ekwueme, Saraiya et al., 2011). For younger adolescents, HPVV is not only cost-effective, but cost-saving (Saslow & Perkins, 2018).

Table 2: Selected Postlicensure Monitoring: Evidence of Declines in HPV Prevalence and HPV-Associated Outcomes, United States

Outcome	Population	Comparison Years	Main Findings
HPV prevalence	Female participants; National Health and Nutrition Examination Surveys	2007–2010 with 2003–2006[59]	56% decrease in prevalence of 4vHPV types in cervical-vaginal samples among 14- to 19-year-olds (11.5%–5.1%)
		2009–2012 with 2003–2006[60]	64% decrease in prevalence of 4vHPV types in cervical-vaginal samples among 14- to 19-year-olds (11.5%–4.3%) and 34% decrease among 20- to 24-year-olds (18.5%–12.1%)
		2011–2014 with 2003–2006[61]	71% decrease in prevalence of 4vHPV types in cervical-vaginal samples among 14- to 19-year-olds (11.5%–3.3%) and 61% decrease among 20- to 24-year-olds (18.5%–7.2%)
	Female enrollees screened for cervical cancer in integrated health care plans, northwestern United States	2012–2013 with 2007[62]	42% decrease in prevalence of 4vHPV types among 20- to 29-year-olds (10.6%–6.2%)
	Female patients attending primary care and sexually transmitted disease clinics, Cincinnati, Ohio	2009–2010 with 2006–2007[63]	58% decrease in prevalence of 4vHPV types among 13- to 26-year-olds (31.7%–13.4%)
		2013–2014 with 2006–2007[64]	75% decrease in prevalence of 4vHPV types in cervical-vaginal samples among 13- to 26-year-olds (34.8%–8.7%)
Genital warts	Female and male enrollees; claims data from privately insured patients, nationwide database	2007-2010 with prevaccine era[65]	Decrease in anogenital wart prevalence among female enrollees aged 15–19 years, from 2.9/100,000 person-years in 2006 to 1.8/100,000 person-years in 2010
	Female and male enrollees; claims data from primary care clinics, Boston, Massachusetts area	2013 with 2004[66]	Decrease in rate of genital warts in 16- to 26-year-olds, from 3.5% to 1.5% among female and from 3.6% to 2.9% among male enrollees
Cervical cancer precursors	Population-based surveillance in 5 sites across the United States	2013–2014 with 2008–2010[67]	CIN2+ decrease in estimated screened women, from 690 to 207/100,000 among 18- to 20-year-olds and from 1107 to 732/100,000 among 21- to 24-year-olds
	Statewide surveillance, New Mexico	2014 with 2007[68]	CIN2 decrease in estimated screened women, from 896 to 415/100,000 among 15- to 19-year-olds and from 1028 to 627/100,000 among 20- to 24-year-olds
	Claims data from privately insured women, nationwide database	2014 with 2007[69]	CIN2+ decrease in screened women, from 14.8 to 4.9/1000 person-years among 15- to 19-year-olds and from 20.5 to 11.3/1000 person-years among 20- to 24-year-olds

HPV indicates human papillomavirus; 4vHPV, quadrivalent HPV vaccine; CIN2, cervical intraepithelial neoplasia, grade 2; and CIN2+, cervical intraepithelial neoplasia, grade 2 or worse or adenocarcinoma in situ.

(Markowitz et al., 2018)

Among females that have never had HPV infection, Gardasil®9 is over 95% effective at preventing cervical pre-cancers caused by HPV strains 16 and 18. It is almost 100% effective at preventing vulvar and vaginal pre-cancers as well as genital warts in females. In males, Gardasil®9 is over 90% effective at preventing genital warts caused by HPV as well as 75% effective in preventing anal pre-cancers (Immunization Action Coalition, n.d.). In addition, studies have found immunity to last over ten years after vaccination (Meites et al., 2016). While it is important for both males and females to receive the full series of HPVV, it can be inferred from population studies, such as those completed in Australia where HPV vaccine uptake has been much greater, that lower overall prevalence of HPV may be due to herd immunity (Machalek et al., 2018). By 2016, 78.6% of females 15 years-old and 72.9% of males had been fully immunized against HPV in Australia. This had a significant impact as seen in the drop in HPV prevalence among females age 18-24 from 22.7% to 1.1% from 2005 - 2015 (Machalek et al., 2018).

Vaccine Schedule Recommendations

The ACIP, a federal advisory committee, provides expert vaccination recommendations to the director of the CDC for children, adolescents, and adults in the U.S. ACIP approved recommendations are then published in the CDC's Morbidity and Mortality Weekly Report (MMWR) and become official guidelines of the CDC. Current guidelines recommend HPVV in adolescents ages 11-12 as the standard of care for cancer prevention (Meites, Kempe, & Markowitz, 2016). This is endorsed by the

American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists (ACOG), the American College of Physicians (ACP) and the American Cancer Society (Immunization Action Coalition, n.d.). Internationally, the World Health Organization (WHO) and the European Centers for Disease Prevention and Control follow the same recommendation (Owsianka & Ganczak, 2015).

Routine HPVV should be initiated at age 11 or 12 but can be administered as early as 9 years-old and up to age 26 in both males and females. For adolescents who receive their first dose between the ages of 9 and 14, only one additional dose is needed, with the second dose administered 6-12 months after the first. Those adolescents who receive their first dose before their 15th birthday should receive 2 doses. Three doses should be given to adolescents and adults who start the series on or after their 15th birthday, up to age 26 years-old, as well as for those who are immunocompromised. This schedule would entail a second dose administered 1-2 months after the first, followed by a third dose which is given 6 months after the first (Meites, Kempe, & Markowitz, 2016).

The established target ages for HPVV initiation and series completion are 11-12 years old in both males and females for several reasons. One, younger adolescents are able to generate a more robust immune response and therefore are better protected from HPV with only 2 doses of vaccine versus 3 for older adolescents (Meites et al., 2016). Second, better protection is provided when the body has not yet been exposed to HPV. HPV prevalence rates indicate the vast majority of those infected are between the ages of 15 and 24 years-old (Markowitz et al., 2016). Most adolescents age 11-12 have not yet

become sexually active (Kann et al., 2016), thus making this an optimal time frame for HPVV prior to exposure. Third, as children age, studies have shown they present much less frequently for health care, thus opportunities for vaccination are limited (as cited in Holman et al., 2014). Lastly, age 11-12 years is also the age for two other recommended vaccines, tetanus-diphtheria-acellular pertussis (Tdap) and meningococcal conjugate vaccine (MCV). As both of these vaccines are required by law in many states for public school, adding HPVV to be administered at the same time was done to facilitate administration (Markowitz et al., 2014).

The ACIP does not recommend HPVV for pregnant or lactating women at this time; however, a registry does exist to monitor the outcomes of those women who have been inadvertently vaccinated (Markowitz et al., 2014). While there is now only one type of HPV vaccine dispersed in the U.S., vaccination with any previously approved HPV vaccine does not warrant additional doses or the need to repeat the vaccination series. Of note, the FDA recently approved the expanded use of Gardasil®9 for use in males and females through 45 years-old (Saslow & Perkins, 2018). This means that vaccinating persons age 27-45 is no longer considered off-label. There is no question that HPVV is safe for any age group (Saslow & Perkins, 2018). However, the ACIP has not yet approved this expanded use.

The ACIP generally meets three times per year, with the next meeting in February 2019, and publishes updated recommendations in the summer. As the FDA primarily looks at safety and efficacy, the ACIP will continue to review extensive data on the effectiveness of HPVV as related to age and cost-benefit. If approved by the ACIP with

a Category B recommendation or greater, the Affordable Care Act mandates insurance cover the cost (Saslow & Perkins, 2018); it is likely that other federal, state, and private insurance companies will then follow suit. For a detailed HPV vaccine dosing schedule, please refer to the most up-to-date ACIP recommendations in the MMWR by Meites, Kempe, and Markowitz (2016), which includes footnotes for immunocompromising conditions, special populations, and interrupted schedules. Table 3 is an excerpt from the full article. Further information can also be found on the CDC's website (CDC, 2017).

Table 3: HPV Vaccination Schedule

TABLE. Recommended number of doses and intervals for human papillomavirus (HPV) vaccine, by age at series initiation and medical conditions — United States, 2016

Population	Recommended number of HPV vaccine doses	Recommended interval between doses
Persons initiating HPV vaccination at ages 9 through 14 years,* except immunocompromised persons†	2	0, 6–12 months§
Persons initiating HPV vaccination at ages 15 through 26 years¶ and immunocompromised persons† initiating HPV vaccination at ages 9 through 26 years	3	0, 1–2, 6 months**

* ACIP recommends routine HPV vaccination for adolescents at age 11 or 12 years; vaccination may be given starting at age 9 years.
† Persons with primary or secondary immunocompromising conditions that might reduce cell-mediated or humoral immunity (see also: Medical conditions)
§ In a 2-dose schedule of HPV vaccine, the minimum interval between the first and second doses is 5 months.
¶ For persons who were not adequately vaccinated previously, ACIP recommends vaccination for females through age 26 years and for males through age 21 years; males ages 22 through 26 years may be vaccinated. Vaccination is recommended for some persons aged 22 through 26 years; see Medical conditions and Special populations.
** In a 3-dose schedule of HPV vaccine, the minimum intervals are 4 weeks between the first and second doses, 12 weeks between the second and third doses, and 5 months between the first and third doses.

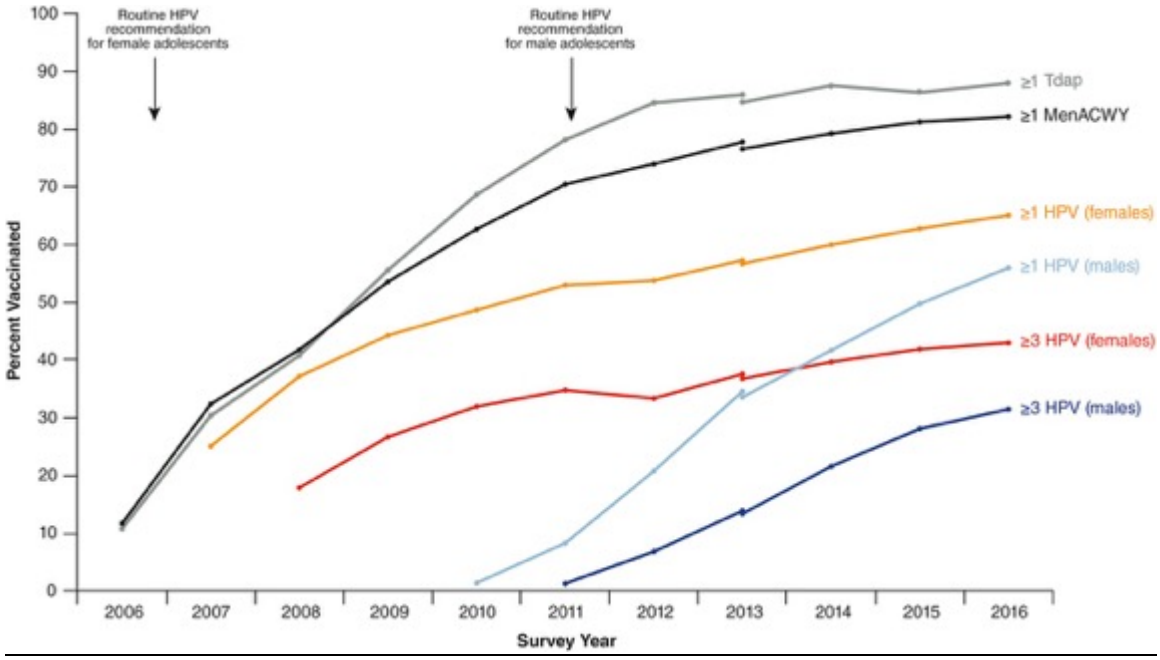
(Meites, Kempe, & Markowitz, 2016)

HPV Vaccination Coverage Rates

In the U.S., vaccine coverage pertaining to adolescents aged 13-17 years old is measured by data from the National Immunization Survey-Teen (NIS-Teen). Results from the NIS-Teen are released annually by the CDC and reflect coverage rates of the preceding year nationally, regionally, and by state. While coverage has been increasing for HPVV since the vaccine's inception in 2006, rates are drastically lower than the other two vaccines, Tdap, and MCV, which are recommended for the same age group (Figure

4). Significant variation in HPVV rates has been observed and varies by sex, age, state, region, ethnicity, and socioeconomic level (Walker et al., 2016).

Figure 4: Estimated Vaccination Coverage among Adolescents Aged 13 to 17 years, National Immunization Survey-Teen, United States, 2006 - 2016.



(Markowtiz et al., 2018). Coverage on the basis of provider records; a revised definition of adequate provider data was used starting in 2013. HPV = human papillomavirus vaccine; Tdap = tetanus, diphtheria, and acellular pertussis vaccine; and MenACWY = meningococcal ACWY vaccine.

The latest NIS-Teen results were released in August 2018 (Walker et al., 2018), based on a sample of 20,949 U.S. adolescents age 13-17 years-old (Table 4). Only 48.6% of adolescents were considered up-to-date (UTD) with HPVV and fully protected against the majority of cancer-causing HPV strains. In other words, they had received the full number of doses of HPVV for their age as recommended by the ACIP. The rates in Montana were comparable at 49.1% series completion but historically have been significantly lower (Table 4) (Reagan-Steiner et al., 2015; Reagan-Steiner et al., 2016;

Walker et al., 2017). Within the Immunization Clinic (IC) at the Flathead City-County Health Department (FCCHD), only 14% of adolescents age 13-15 years-old were HPV UTD. These numbers are considerably low and even more so when compared to those of Tdap and MCV, which are recommended for adolescents of the same age.

In 2017, among the same sample of adolescents in the NIS-Teen, 88.7% (nationally) and 90.4% (Montana) had received ≥1 Tdap dose while 85.1% (nationally) and 71.2% (Montana) had received ≥1 MCV dose. Among adolescents at the IC, 73% had received ≥1 Tdap dose while 29% had received ≥1 MCV dose (Walker et al., 2018). Of note, Tdap vaccination is required by law for adolescents in public school in Montana and most other U.S. states. The high percentage of adolescents who have received Tdap and MCV vaccination nationally suggests missed opportunities to protect these same adolescents against HPV-associated cancers.

When these numbers are further examined by sex, females have historically had much higher rates of HPVV series initiation (≥1 HPV) and series completion (HPV UTD) compared to males. In 2014, 60% of females versus 41.7% of males nationally and 57.2% of females versus 33.1% of males in Montana had ≥1 HPV. Only 39.7% of females and 21.6% of males were HPV UTD in the U.S. in 2014 while 42.9% of females and 13% of males in Montana were HPV UTD. By 2017, however, significant strides had been made. Nearly 69% of female adolescents in the U.S. had ≥1 HPV and 53.1% were HPV UTD. About 63% of U.S. male adolescents had ≥1 HPV and 44.3% were HPV UTD. In Montana, state rates for males exceeded the national rates for males as well as the rates of ≥1 HPV for females, for the first time, in 2017.

Walker et al. (2018) also highlighted lower HPVV rates in adolescents who lived rurally compared to those in urban areas, higher HPVV rates in adolescents enrolled in Medicaid versus private insurance, and higher HPVV rates in adolescents living below the federal poverty level than those at or above the poverty level. Trends in HPVV coverage by ethnicity/race have largely remained unchanged, with non-Hispanic Black adolescents attaining higher ≥1 HPV coverage rates compared to White adolescents (Reagan-Steiner et al., 2016). Table 4 catalogues the rates of Tdap, MCV, and HPV immunizations in the U.S. compared to the state of Montana in 2017. A full table can be found in Appendix A, which includes data from 2014 - 2017. Where available, data from the IC was added (in gray) for comparison, as well as rates for females vs. males.

Table 4: (Excerpt from full table in Appendix A) National Immunization Survey, Teen (NIS-Teen): Rates of Tdap, MCV, and HPV Immunizations, 2017

2017

	All Adolescents (n = 20,949)				Females (n = 9,845)		Males (n = 11,104)	
	≥1 Tdap	≥1 MCV	≥1 HPV	HPV UTD	≥1 HPV	HPV UTD	≥1 HPV	HPV UTD
U.S. Overall 13-17 yrs. old	88.7%	85.1%	65.5%	48.6%	68.6%	53.1%	62.6%	44.3%
Montana 13-17 yrs. old	90.4%	71.2%	65.5%	49.1%	64.5%	50.1%	66.4%	48.1%
n = 1553								
FCCHD Immunization Clinic 13-15 yrs. old As of 8/7/17	73%	29%	26%	14%	n/a	n/a	n/a	n/a

In recognizing the severe underutilization of HPVV in the U.S. and the potential ramifications of these low rates, Healthy People 2020 created specific objectives to help mobilize HPVV initiatives. Objective 11D of Healthy People 2020 is to increase routine vaccination coverage levels for adolescents (Healthy People 2020, 2018). Within this objective, 11D-11.4 and 11D-11.5 further outline the goals and target measures pertaining to HPVV:

- 11D-11.4: Increase the percentage of female adolescents aged 13 through 15 years who receive 2 or 3 doses of human papillomavirus (HPV) vaccine as recommended.
    - Target measure: 80% (series completion)
- 11D-11.5: Increase the percentage of male adolescents aged 13 through 15 years who receive 2 or 3 doses of human papillomavirus (HPV) vaccine as recommended.
    - Target measure: 80% (series completion)

Vaccination efforts are being realized; HPVV rates have increased about 5% from 2016 to 2017 (Walker et al., 2018). Most encouragingly, however, are the very high rates of Tdap immunizations and increasing rates of MCV immunizations. This further signifies that if barriers to HPVV can be reduced, HPVV rates could be comparable to those of Tdap and MCV. Rates of HPVV even have the potential to surpass Healthy People 2020's goal of 80% series completion (Walker et al., 2018).

Problem

HPVV is a public health priority. Rates in the state of Montana, as well as those nationally, fall short of Healthy People 2020's goal of 80% HPVV series completion. The underutilization of HPVV highlights the need for interventions to help health care professionals (HCPs) communicate the urgency and importance of HPVV in their

recommendations to parents of adolescents. HPVV can prevent cancers caused by HPV and is widely available and accessible in the U.S. Years of research and utilization, both internationally and nationally, have solidified this vaccine's safety and efficacy. Yet, HPVV rates are significantly lower when compared to Tdap and MCV vaccination rates in the U.S. and lag behind those of other developed countries such as Australia. This is despite an increase in the overall total number of HPV-associated cancers in both males and females, which could largely be reduced through HPVV (Fedewa et al., 2018; Van Dyne, Henley, Saraiya, Thomas, Markowitz, & Benard, 2018).

HPV has been identified as a silent epidemic. Based on U.S. data from 2011-2015, the CDC (2018a) estimated that of the all the cancers caused by HPV collectively, (cervical, oropharyngeal, vulvar, vaginal, penile, and anal) 33,700 of these cancers (79%) were directly attributable to HPV each year. A shocking 93% of those cancers could have been prevented by vaccination with Gardasil®9, the 9-valent HPV vaccine (CDC, 2018). Several major health organizations have called for urgency in accelerating HPV vaccine uptake and have allotted numerous resources towards HPVV media campaigns. Internationally, the World Health Organization (WHO) has responded with calls for action to prevent cervical cancer through increased vaccination and screening efforts (WHO, 2018). Nationally, the President's Cancer Panel, the CDC, American Cancer Society, and the Immunization Action Coalition have created action plans to address the low vaccination rates. On the state level, over 42 states have introduced legislation since 2006 to fund HPV vaccine, educate the public about HPVV, or require HPVV for public school attendance.

Historically, HPVV rates in the state of Montana have been lower than the national average and among the lowest in the nation in regards to HPVV for males (Walker et al., 2017). In 2017, only 49% of adolescents in Montana had completed the HPVV series, which is far below Healthy People 2020's goal of 80%. The number of adolescents at the IC in Kalispell, Montana that are HPV UTD is more than three times lower than national and state rates. Perhaps a casual inference may be made in that cancer was the number one cause of death in Montana and Flathead County from 2012 - 2015, whereas heart disease was number one in the U.S. (Flathead City-County Health Department [FCCHD] Kalispell Regional Healthcare, & North Valley Hospital, 2016; National Center for Health Statistics, 2018).

The Montana Department of Public Health and Human Services has partnered with the Montana Immunization Program to increase the HPVV rates in line with Healthy People 2020's goals. Under the Montana Comprehensive Cancer Control Plan 2016-2021 (Table 5), Objective 3 is to "increase the number of adolescents fully immunized against HPV." Strategy 1 details "partnering with the Montana Immunization Program to promote policy and systems change and educate youth and parents to increase HPV vaccinations," (Montana Department of Health and Human Services, Chronic Disease Prevention & Health Promotion Bureau, n.d., p. 17). Furthermore, the Flathead County Community Health Needs Assessment and the FCCHD Strategic Plan further prioritize HPVV among adolescents as public health priorities (FCCHD, Kalispell Regional Healthcare, & North Valley Hospital, 2016).

Table 5: Montana Comprehensive Cancer Control Plan 2016-2021, Objective 3

Measure	**Data Source**	**Baseline (year)**	**Target**	**Healthy People 2020's Goal**
The percent of adolescent girls aged 13-17 years in Montana who are fully immunized against Human Papilloma Virus (HPV).	National Immunization Survey – Teen	43% (2014)	60%	80%
The percent of adolescent boys aged 13-17 years in Montana who are fully immunized against Human Papilloma Virus (HPV).	National Immunization Survey – Teen	13% (2014)	40%	80%

(Montana Department of Health and Human Services, Chronic Disease Prevention & Health Promotion Bureau, n.d.)

Purpose

The aim of this quality improvement project was to increase the confidence of the nurses within the Flathead City-County Health Department's (FCCHD) Immunization Clinic in Kalispell, Montana, to make more frequent recommendations for HPVV that conveyed strong, clear, and consistent recommendations. Research findings from the CDC's "You are the Key" campaign were translated to the point of care for implementation in practice. A secondary aim included increasing HPVV series initiation and completion rates within the clinic. A practice change in this way has the potential to protect additional adolescents in the community from developing HPV-associated cancers during their lifetime.

CHAPTER TWO – REVIEW OF THE LITERATURE

Review of Literature

A thorough literature review was performed for research articles and studies written in English from the first year of HPVV introduction, 2006, through Fall 2017. Databases searched included PubMed, CINAHL, Medline, Cochrane, and Google Scholar. Search terms included various combinations of the following phrases: HPV vaccination and provider recommendation, HPV immunization and provider recommendation, HPV vaccination and health care provider recommendation, HPV vaccination and provider recommendation intervention, HPV vaccination and communication intervention, HPV vaccination and effective recommendation, HPV vaccination and presumptive recommendation, and HPV vaccination and communication techniques. While the project intervention was based on literature from this time period, the change agent (DNP student) continued to review HPV-based literature up until the present, as new HPVV literature was released frequently from 2017 to 2018.

First, barriers to HPVV were examined globally. Parents' perspectives were explored as well as those of health care providers and health care professionals (HCPs). These were further narrowed down to include barriers to HPVV only in the U.S. Next, strategies to increase HPVV rates in the U. S. were investigated. Strategies targeting providers and HCPs, particularly communication techniques on how to recommend HPVV using specific language, were emphasized as greatly needed within systematic reviews (Gilkey & McRee, 2016; Holman et al., 2014; Newman et al., 2018; Rosen,

Shepard, & Kahn, 2018). This is largely based on findings that parental beliefs and attitudes are more influential than HPV knowledge during the process of making decisions about HPVV. While numerous studies examined barriers to HPVV uptake and several explored the effects of specific HPVV recommendations on vaccination rates, there was only one randomized control trial (RCT) that studied the impact solely of a communication training intervention for HCPs in recommending HPVV. As a result, an evidence table was not found to be of benefit to this project.

Parents' Barriers to HPV Vaccination

Parental barriers to HPVV are multifaced but identifying them is the first step in helping HCPs learn how to address them. A systematic review by Holman et al. (2014) examined barriers to HPVV among U.S. adolescents aged 11-17 years-old, from 2009 to 2012. Fifty-five research articles, which primarily reported quantitative information, met the inclusion criteria and were analyzed according to the target population. Target populations included health care professionals (HCPs), parents, underserved or disadvantaged populations, and males. "Parents consistently cited HCPs' recommendations as one of the most important factors in their decision to vaccinate their children," (Holman et al., 2014, p. 2) and not receiving a recommendation from a physician or HCP was the number one reason for not vaccinating their child.

While the majority of parents were aware of the HPV vaccine, they cited knowledge as a barrier and wanted more information regarding HPV and HPVV (Holman et al., 2014). Some parents were concerned about the possibility of HPVV increasing

sexual promiscuity and also cited cost as a barrier. In addition, some parents did not perceive their child as being at risk for HPV infection or irregularly sought preventative care for their adolescent, which allowed for less opportunities to vaccinate and further decreased the probability of HPVV series completion. Parents of younger adolescents or males were more likely to decline or delay HPVV versus those of older adolescents or females. Parents that perceived HPVV to be the social norm had higher levels of HPV vaccine acceptance. Interestingly, religion did not appear to predict HPV vaccine acceptance or behavior.

Thompson et al. (2017) explored the primary reasons for HPV non-vaccination and vaccine hesitancy from 2012 - 2015, almost right where Holman et al. (2014) left off, but focused solely on parental barriers. Parents or caregivers of adolescents aged 13-17 years-old who had indicated on the National Immunization Survey-Teen (NIS-Teen) (in 2012, 2013, 2014, or 2015) their adolescent had not yet received any HPV vaccine doses, were asked how likely it was their adolescent would receive an HPV immunization shot within the next year. Those that answered, “not too likely;” “not at all likely,” or “not sure/do not know” (N = 59,897) were then asked to describe the main reasons for choosing not to vaccinate their child with HPV vaccine. The five primary reasons given by parents for nonvaccination remained the same across all four years of the study period and included not receiving a recommendation from an HCP, the HPV vaccine was not needed or not necessary, lack of knowledge about HPV or HPVV, their adolescent was not sexually active, and safety/side effect concerns.

A systematic review and meta-analysis by Newman et al. (2018) examined factors that positively correlated with HPVV among parents of adolescents ≤ 18 years-old (n = 840,838). Seventy-nine studies were included that spanned 15 different countries, including the U.S (69.6%, n = 55). Uptake of HPVV collectively among the adolescents of the parents reviewed was 41.5% (≥1 dose) and was twice as high for female adolescents (46.5%) than for male adolescents (20.3%). Consistent with previous studies, the meta-analysis (62 studies) revealed that a recommendation for HPVV from an HCP had the greatest influence on parents' decision to vaccinate their adolescent (r = 0.46 (95% CI 0.34 to 0.56)). Safety concerns about the HPV vaccine (r = - 0.31 (95% CI -0.41 to -0.16)) had the second greatest influence on parents' HPVV decisions. Of note, the terms HCP and physician were used interchangeably in these studies as the majority did not specify the type of HCP nor the type of physician.

HCP's Barriers to Recommending HPV Vaccination

The systematic review by Holman et al. (2014), also examined barriers experienced by HCPs in vaccinating adolescent patients against HPV. HCPs cited parents' attitudes and concerns about HPVV as the number one barrier to uptake of HPVV for adolescents within their practice, followed by potential barriers related to cost. Financial concerns encompassed the costs to HCPs, the cost to practices due to inadequate insurance coverage or reimbursement, and the cost to parents. Knowledge gaps about the link between HPV and cancers (other than cervical) as well as genital warts were likewise named as barriers. HCPs also cited preferences in recommending

HPVV more for females versus males and older adolescents more than younger adolescents. This may indicate discomfort in recommending HPVV for certain populations and ages. Concerns about the safety and efficacy of the HPV vaccine did not appear to be common HCPs barriers.

Among all pediatricians (n = 134) surveyed by Farias et al. (2017) in Texas in 2015, the top five greatest barriers to HPVV included infrequent office visits made by adolescent patients (n = 115, 82.8%), personal discomfort talking about sexually transmitted infections (STIs) with parents and patients (n = 98, 73.1%), difficulty ensuring patients would complete the 3-dose HPV vaccine series (n = 98, 73.1%), HPV is not required for school attendance (n = 95, 70.9%), and the time it takes to discuss HPV vaccine with patients and parents (n = 86, 64.2%). Greater than 80% of surveyed pediatricians did not feel their level of knowledge about HPV, vaccine safety, or vaccine efficacy were barriers to HPVV. Of note, the revised ACIP dosing schedule of two doses of HPV vaccine for adolescents starting the immunization series before age 15 (instead of 3 doses) was not released until 2016, about two years after the survey.

A survey representative of various primary care clinicians (pediatricians, family medicine physicians, family nurse practitioners, and pediatric nurse practitioners) (n = 280) from over 52 different clinical sites in Minnesota and Wisconsin, was conducted by Rutten et al. (2017). Rutten et al. (2017) assessed HCP barriers to HPVV as well as sought to determine the relationship between HCP's HPV knowledge and attitudes with actual HPVV rates of patients aged 9 to 18 years-old (n = 68,272). The top barriers cited by the HCPs included HPVV is not required for school attendance (50.4%), concern

about adding another vaccine to the vaccine schedule (43.6%), concern about vaccine safety (43.2%), discussing STIs (41.8%), administering a new vaccine with a limited safety track record (41.8%) and ensuring the completion of the 3-dose HPVV series.

In addition, Rutten et al. (2017) asked HCPs about the barriers they thought prevented parents of adolescents from agreeing to HPVV for their teens (perceived parental barriers to HPVV). Lack of parental education or understanding about HPV (54%), requests by parents to defer HPVV (49.8%), and parents' belief their child was not at risk for HPV (48.6%), were the top three perceived parental barriers cited. In line with the hypothesis by Rutten et al. (2017), HCPs who perceived parental barriers to HPVV to be highest, had lower rates of HPV vaccine initiation and completion; lower perceived barriers correlated with higher rates of vaccine initiation and completion. HCPs who rated their HPV knowledge as high had higher HPVV rates. What is concerning however, is that when surveyed to assess baseline HPV knowledge, over one third of HCPs incorrectly answered that genital warts and cervical cancer were caused by the same HPV strains; 20% of HCPs did not recognize that HPV can also cause head and neck cancers.

A qualitative study by Perkins and Clark (2013) was incorporated into this literature review to examine any additional barriers unique to those in federally qualified community health centers (FQCHCs), the setting of the organization utilized in this project. Thirty-four HCPs (pediatricians, family medicine physicians, family nurse practitioners, and pediatric nurse practitioners) from four different FQCHCs in Boston, Massachusetts, shared their experiences through semi-structured interviews in

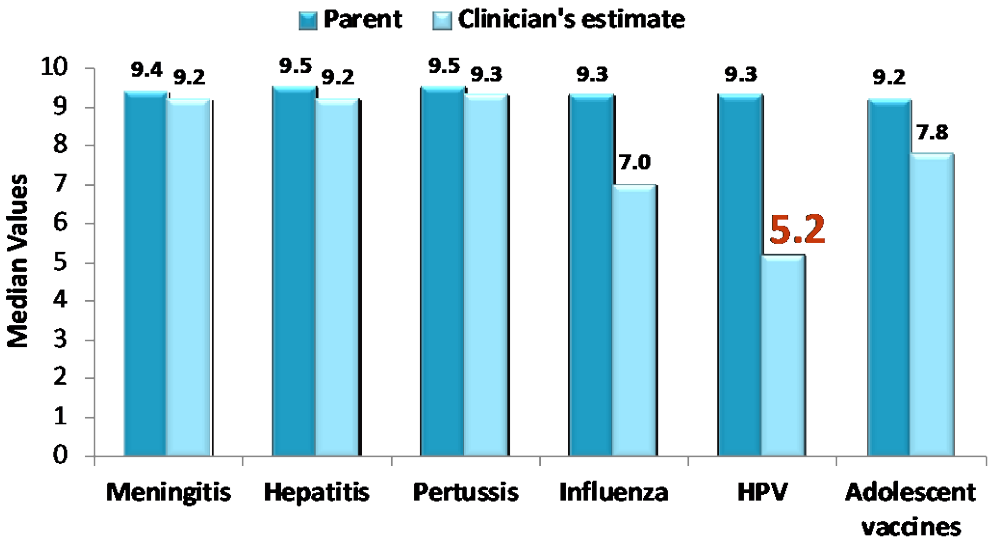
recommending HPVV to primarily low-income and minority parents. The perceived parental barriers by HCPs within this population included HPV vaccine safety and the belief that HPVV would promote early or risky sexual behavior. HCPs also expressed sentiments echoed in the literature previously - immigrant parents and those of low socioeconomic backgrounds almost always accepted HCPs HPVV recommendations and were grateful for the cancer-protection provided by the vaccine, whereas parents of White-middle class adolescents were more likely to defer or decline HPVV, citing safety or sexual promiscuity concerns.

A qualitative systematic review by Rosen, Shepard, & Kahn (2018) studied HCPs HPV knowledge, attitudes, immunization rates, recommendation practices, and barriers to HPVV in the U.S. Sixty articles were included with publication dates from 2008 to 2016. HCPs included pediatricians (n = 29), family practitioners, (n = 26), physicians not otherwise classified (n = 13), nurse practitioners (n = 13), obstetricians and gynecologists (n = 12), general practitioners (n = 8), internal medicine physicians (n = 7), registered nurses (n = 6), physician assistants (n = 5), preventative medicine physicians (n = 2), and school nurses (n = 2). Barriers to HCP's recommendations for HPVV included knowledge deficit about HPV and HPVV as well as a range of beliefs and attitudes about the HPV vaccine. These beliefs included but were not limited to concerns about safety, hesitancy to recommend multiple vaccines at once, discomfort talking about STIs, low perceived control over recommending HPVV, and perceptions that HPVV is less important than other vaccines. Factors that facilitated HPVV recommendations by HCPs included but were not limited to higher knowledge about HPV, anticipating parental

concerns, and beliefs that the vaccine was safe and effective. Consistent with other studies, HCPs were more likely to recommend HPVV for females and older adolescents.

A survey of parents and providers in Texas by Healy, Montesinos, and Middleman (2014) identified a mismatch between the perceived parental value of the HPV vaccine by HCPs and the actual value parents placed on the HPV vaccine (Figure 5).

Figure 5: Clinicians Perceived Value Parents Place on Vaccines Compared to the Actual Value Parents Place on Vaccines



(CDC, 2018c; Adapted from Healy et al., 2014)

Parents not only indicated they highly valued adolescent vaccines overall, but they rated the importance of the individual vaccines almost identically. The clinicians (pediatricians, nurses, and medical assistants) correctly identified the high value parents placed on all of the vaccines with the exception of the HPV vaccine. Clinicians

incorrectly believed parents did not feel the HPV vaccine was as important as the other vaccines. This landmark study highlighted the big disconnect between parents and HCPs that is unique to HPVV. The authors concluded that "the perceived and real concerns of parents influence how the [HCP] recommends and administers HPV vaccine," (Healy, Montesinos, & Middleman, 2014), which in turn, impacts HPVV uptake.

Misconceptions as Barriers to HPV Vaccination

The relationship between parental barriers, HCPs barriers, HCPs perceived parental barriers and actual HPVV rates is important because it is the crux of understanding why the uptake of HPVV in the U.S. is so low. When HCPs perceive parents as hesitant to accept a recommendation for HPVV, they are less likely to make a recommendation. Less recommendations render less vaccinations. Misperceptions about parental HPVV feelings impact the way HCPs make HPVV recommendations and to whom.

Parents that receive a strong recommendation for HPVV are nine times more likely to vaccinate their child against HPV (Gilkey et al., 2016). When HCPs delay their recommendations for HPVV or do not give strong recommendations, precious opportunities are missed because "adolescents generally encounter the health care system less frequently than any other age group," (as cited in Holman et al., 2014, p. 8). Emphasis needs to be placed on capitalizing upon every opportunity to vaccinate adolescents, stressing the urgency of HPVV before exposure to HPV for maximum effectiveness and cancer prevention (Holman et al., 2014; Rand & Goldstein, 2018).

While extensive evidence supports the safety of the HPV vaccine for both males and females of all ages (Meites et al., 2016) parents and even a small minority of HCPs still continue to cite concerns about safety due to the "newness" of the vaccine.

The same can be said for sexual promiscuity, which has also been extensively studied and refuted. A large population study by Ogilvie et al. (2018) examined the sexual health behaviors of adolescent females before and after the implementation of the HPV vaccine. There was a significant decrease (3%, adjusted odds ratio 0.79) in the proportion of female adolescents who self-reported ever having intercourse from 2003 (pre-HPV vaccine) to 2013 (post-HPV vaccine) and also a decrease in the number of female adolescents who self-reported engaging in sexual intercourse before age 14. There was no significant change in the number of sexual partners self-reported after HPV vaccine implementation. Moreover, the reported use of condoms and contraception increased after HPV vaccine implementation and pregnancy rates decreased. These findings are significant in that they dispel any association between HPVV and increases in promiscuous sexual behavior.

As there is no cost for ACIP recommended vaccines in the U.S, (Farias et al., 2017) it is concerning that those studies conducted after changes to the Affordable Care Act, regarding immunizations, still cite cost as a barrier for both HCPs and parents (as cited in Farias et al., 2017). Furthermore, parents have reported confusion on the necessity of HPVV because it is not required for school attendance. HCPs subsequently cite parental resistance as a barrier due to this confusing message from the government. This is reflected in the high coverage rates of Tdap vaccinations both in the state of

Montana and the U.S. compared to the low rates of HPVV. The rates of MCV immunizations are also much higher in states that require the vaccination for public school. Since 2006, more than 42 U.S. states and territories have attempted to enact legislation to require HPVV for school, fund HPVV programs, or to disseminate HPVV education in communities and schools. To date, only Rhode Island has been successful in requiring HPVV for seventh graders. "Some stakeholders who support access to [HPVV] do not support a school mandate, citing concerns about the drug's cost, safety, and parents' rights to refuse," (National Conference of State Legislatures, 2018).

The implementation of HPVV in other countries has been welcomed with open arms and a greater sense of urgency compared to the U.S., where its cancer-prevention purpose has become distorted emotionally, morally, and politically due to sexual connotations (Gollust, LoRusso, Nagler, & Fowler, 2016). Strategies to increase HPVV uptake in the U.S. include communication techniques that target HCPs as a "provider's recommendation is so highly influential that over 70% of adolescents who receive a recommendation initiate HPV vaccination" (Dorell et al., 2013). The National Vaccine Advisory Committee and the President's Cancer Panel have called for a focus on improving HCP HPV vaccine recommendations, and in turn, parental acceptability, to increase HPV vaccine uptake in the U. S. (Fedewa et al., 2018).

Despite its recommendation by the ACIP as the standard of care for adolescents age 11-12 years-old, many parents report not receiving a recommendation for HPVV. It has been appreciated that while HCPs may report routinely recommending HPVV, parents may perceive not having received a recommendation (Holman et al., 2014). This

is due to immense variations in the way HPVV is recommended, with some HCPs offering weak or poor-quality recommendations. Holman et al. (2014) highlighted a lack of consistency in the way the vaccine was recommended; some HCPs offered it as optional, some gave very little information about HPV or HPVV, while others gave extensive and more detailed information for HPVV than that of other vaccines (Holman et al., 2014).

When HCPs perceive parents to undervalue HPVV or misinterpret parents' questions / hesitancy as resistance to HPVV, they change the way they recommend HPVV (Perkins & Clark, 2013). Some HCPs many not recommend the vaccine at all or give a weak recommendation instead. "Providers' negative perceptions of parents' views may lead to lower rates of offering [HPV] vaccination secondary to feelings that parents are not interested in [HPV] vaccination and that providers have little ability to influence parental behavior" (Perkins & Clark, 2013, p. 829). Despite these perceived barriers, only 20% of parents will choose to ask more questions (and possibly defer or refuse the vaccine) when an HCP makes a strong recommendation for HPV immunization (CDC, 2018c; Gilkey et al., 2016).

This means that 80% of parents will accept a strong recommendation for HPVV without hesitation, making the anticipation of parents' refusal a fruitless exercise (Gilkey et al., 2016). If more HCPs understood that what they say to parents about HPVV and how they say it matters, the rates of HPVV could be as high as those for Tdap and MCV immunizations in the U.S. HCPs could benefit from "guidance on communicating HPVV recommendations to patients and parents," (Holman et al., 2014, p. 2), which would

initiate stronger HPVV recommendations and better prepare HCPs to address parental concerns when hesitancy is intimated.

HCP's Recommendation for HPV Vaccination

Opel et al. (2013) conducted a cross-sectional observational study that analyzed the communication between HCPs (pediatricians and nurse practitioners) and parents when discussing vaccines. In order to measure the relationship between vaccine-hesitancy and provider recommendations, the researchers used the Parent Attitudes about Childhood Vaccines survey to assess for vaccine-hesitant parents (VHPs) prior to the provider-parent conversations. One hundred eleven health supervision visits were videotaped and analyzed of HCPs recommending vaccines to parents of children aged 1 to 19 months old. In a preliminary study, two provider vaccine communication techniques had been identified - a presumptive recommendation and a participatory recommendation. Presumptive recommendations were action statements that assumed immunizations would be completed that day, such as "Well, we have to do some shots." Participatory recommendations had a conversational tone that gave parents more authority in the decision-making, such as "Are we going to do shots today?" and could be open-ended such as "What do you want to do about shots?"

Seventy-four percent of the HCPs in the study by Opel et al. (2013) started their vaccine conversations with a presumptive versus participatory recommendation format. Parental resistance to participatory vaccine recommendations was much higher than presumptive recommendations (adjusted odds ratio: 17.5; 95% confidence interval: 1.2-

253.5). This was also true among VHPs (89% vs 30%; $P < .001$). Of the 41% of parents who initially expressed hesitancy or resistance to provider recommendations as a whole, the majority of parents were identified as VHP. Remarkably, only 50% of providers who experienced parental resistance continued to pursue and emphasize the importance of their original vaccine recommendation, which resulted in a startling 47% of these parents accepting the subsequent recommendation.

Findings from Opel et al. (2013) reinforced that HCPs are one of the most trusted sources of health care information for parents and that HCPs' vaccine recommendations are "a key factor in parental vaccine decision making," (Opel et al., 2013, p.1038). Furthermore, "how providers initiate and pursue vaccine recommendations is associated with parents' vaccine acceptance," (Opel et al., 2013, p. 1037). The authors also made a point to underscore the emotional toll cited by HCPs in the study when engaging in conflict with VHPs. Results from studies such as this one by Opel et al. (2013) can help HCPs deduce the most effective and efficient ways to communicate with parents when recommending vaccines. While this study did not specifically study HPVV recommendations or conversations with parents of adolescents, the strong findings may be generalizable to all vaccine recommendations. Additionally, extensive steps were taken to minimize the Hawthorne effect, which strengthened the study's results.

In a pilot study, Shay et al. (2016) examined HCPs (physicians, advanced nurse practitioners and nurses) use of presumptive versus participatory recommendations specific to HPVV. The study built upon the prior work by Opel et al. (2013); strength and content of the HCP's recommendations was also described. The study examined 43

discussions between parents and providers (n =12). The majority of providers initiated conversations with a participatory introduction and made weak recommendations. There were only 11 discussions in which providers gave strong recommendations for HPVV. As there was only one conversation that began with a presumptive introduction, correlations were unable to be drawn between the presumptive introduction and the reception of HPVV during that visit (n = 1, 100%). The parents that received weak recommendations had the lowest HPVV initiation rates (44%) whereas strong recommendations resulted in HPVV initiation rates of about 64%.

When providers delivered a rationale immediately following their HPVV recommendation, HPVV initiation rates the day of service were 72.2%. Parents were also more likely to accept HPVV recommendations when specific rationales were given such as cancer prevention and vaccinating at age 11-12 due to prevention prior to HPV exposure. Shay et al. (2016) also discovered that hedges, qualifiers, and indirect speech by HCPs negatively impacted HPVV rates. This was evident in that when providers emphasized the decision as up to parents or offered that HPVV was not necessary to do that day, they inadvertently undercut their own recommendation (only 38% and 27% of children were vaccinated respectively). Shay et al. (2016) concluded that, "providers would benefit from communication skills training on how to make explicit recommendations with an evidence-based rationale" (p. 1452).

Despite numerous studies calling for communication skills training to educate HCPs how to best recommend HPVV, the only true RCT available for review that examined this intervention specific to HPVV prior to this project's intervention period

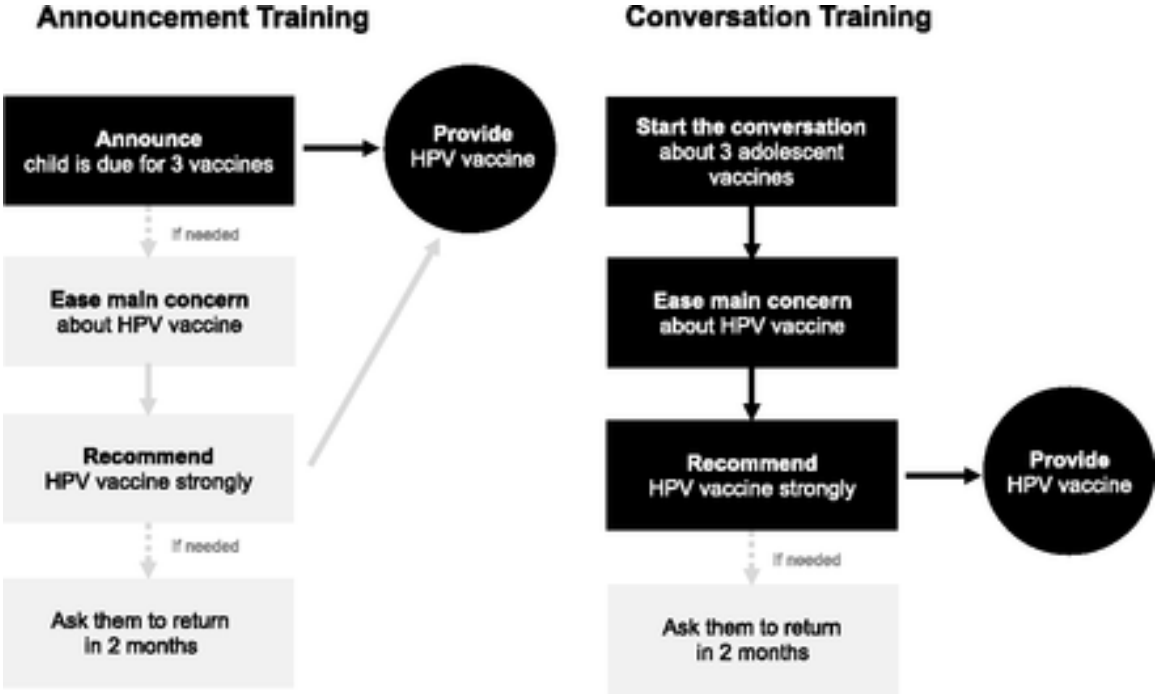
was performed by Brewer et al. (2017). In 2015, 30 family medicine and pediatric clinics in North Carolina were randomized to receive announcement training (presumptive), conversation training (participatory), or no training at all (control) in recommending HPVV to adolescents 11-12 years-old (n = 17,173). There was a mean of 5 "vaccine prescribers" at each of the clinics. HPVV recommendations for adolescents aged 13-17 (n = 37,796) were also recorded. A physician educator (not affiliated with the clinics) held a 1-hour training at each of the clinics randomized to receive HPVV communication training. These trainings were available to physicians, physician assistants, nurse practitioners and any other clinic staff that was involved in the process of vaccine discussions with parents of adolescents. Attendance at the communication trainings was 90% for the announcement training and 89% for the conversation training. Providers received up to one continuing education credit for attending and intervention clinics were compensated with $800 for participating. Control clinics were given $200. The intervention clinics were not told which training strategy they would learn, nor were patients at the clinic alerted to the training.

Survey findings from the literature and the work by Opel et al. (2013) helped inform the training content (Figure 6) for both the announcement and conversation training interventions performed in this study by Brewer et al (2017). In addition, several key elements were emphasized in each training.

> We instructed providers to first announce that the child is due for 3 vaccines to be given today. Key elements of this first step included providers mentioning the child's age; announcing the child is due for 3 vaccines recommended for children this age, placing HPV vaccine in the middle of list; and saying they will vaccinate today. Only if parents raised a concern would providers then identify and ease parents' main concern about HPV

vaccine, using a structured approach and strongly recommending same-day HPV vaccination. Key elements of this final step included providers giving a motivational statement, ending with the phrase "I recommend …" and encouraging parents to get HPV vaccine that day. In contrast, the conversation training built on the principles of shared decision making. It differed from the announcement training primarily in the first step. We instructed providers to first start the conversation about 3 adolescent vaccines. Key elements of this first step included providers introducing the 3 vaccines recommended for children this age, placing HPV vaccine in the middle of the list to deemphasize it and make it routine, discussing the health benefits of these vaccines, and inviting parents' questions while saving the recommendation for later in the conversation.

Figure 6: Content of Announcement and Conversation Training in Recommending HPV Vaccination



(Brewer et al., 2017)

Additionally, the communication trainings were first piloted in two other clinics and extensive feedback was sought via HCP's comments and satisfaction surveys that were utilized to refine the trainings prior to this RCT. Emphasis from HCPs was on needing

brief but effective recommendations that did not focus on sex. HCPs also wanted to provide parents the opportunity to ask questions without completely derailing the recommendation into a confrontational or charged conversation.

The selected outcome measure was the change in HPVV initiation (≥1 dose of HPV vaccine) of adolescents ages 11-12 from baseline (0 months) and 6 months after the intervention. Clinics that received announcement training saw an increase of HPVV initiation amongst 11-12-year-olds by 5 percentage points when compared to the control clinics (5.4% difference, 95% CI 1.1% to 9.7%, $P = .02$). This was a difference of 37 additional adolescents who initiated HPVV; increases were already evident by 3 months for females as well as males ($P = .003$). Coverage rates at the clinics that received conversation training were similar to those of the control and did not experience any increases in HPVV initiation rates. Interestingly, HPV series completion (3 doses), Tdap, and meningococcal vaccination rates did not differ in either communication intervention or the control group. The same can be said for adolescents aged 13-17, indicating that the way in which HCPs recommend initiation of HPVV to parents of 11-12-year-olds truly is unique from that of all other adolescent vaccines.

Summary of Current Knowledge

As receiving a recommendation from an HCP is one of the strongest and most consistent predictors of adolescent vaccination (Dorell et al., 2013), and most specifically HPVV (Hofstetter & Rosenthal, 2014), recent research has focused precisely on communication techniques to guide HCP's in making strong and effective

recommendations for HPVV as well as strategies that have proven successful in addressing parental hesitancy. The CDC has synthesized all of this evidence-based research and developed a series of training sessions in the form of slide sets, web-on-demand videos, and resources for clinicians entitled "You are the Key to HPV Cancer Prevention" campaign. Strategies targeting HCP's communication techniques in framing recommendations for HPVV have helped HCPs change the way they recommend the vaccine, better address parental concerns to HPVV, and increase HPVV initiation and completion rates within their practice (Brewer et al., 2017; Cates, Crandell, Diehl, & Coyne-Beasley, 2018; Dempsey et al., 2018a; Farmer et al., 2016; Krantz, Ollberding, Beck, & Burkhardt, 2018; O'Leary et al., 2017; Perkins et al., 2015).

CHAPTER THREE – THEORETICAL UNDERPINNING

Use of the *DNP Essentials* in Theory Selection

The American Association of Colleges of Nursing (AACN) outlines eight core competencies for advanced practice registered nurses (APRNs) which are incorporated into the curriculum for the Doctor of Nursing Practice (DNP) degree. These competencies, collectively referred to as the *DNP Essentials* (AACN, 2006), were foundational in the selection of a change theory to guide the project intervention. The *DNP Essentials* require the DNP student to cultivate skills in translating knowledge from evidence-based research to improve patient and health care outcomes. To effect change, the focus of care is not only on the individual patient, but on the needs of a target population or community. "DNP graduates engage in leadership to integrate and institutionalize evidence-based clinical prevention and population health services for individuals, aggregates, and populations," (AACN, 2006, p. 15). DNPs are called to initiate quality improvement strategies that are not only effective but sustainable and cost-efficient. This requires interprofessional collaboration, knowledge of health care policies, strong communication skills, and leadership abilities.

The *DNP Essentials* build upon the provisions of the Code of Ethics for Nurses (American Nurses Association, 2015) which stress the responsibility and obligation of all nurses to promote health and safety, advocate for patients, and prevent illness with risk reduction strategies. The *DNP Essentials* challenge APRNs to respond to national calls for action, such as with Healthy People 2020, to improve the health of the nation and

address the unique challenges of vulnerable populations that have resulted in significant health disparities. Progress cannot be made without change, and implementation of change, especially organizational change, necessitates the use of a framework for that change to be successful.

Lippitt's Phases of Change Theory

Planned change within an organization is necessary but challenging. A change theory framework can serve as a model to assist change agents in planning, managing, assessing, and evaluating change (Mitchell, 2013). There are many factors, or forces, that must be considered. Some of these forces are driving factors in that they compel change while others are restraining factors which impede change. Kurt Lewin is considered the pioneer of change theory. His Theory of Planned Change consists of three stages (as cited in Mitchell, 2013, p. 32): "Unfreezing (understanding change is needed), Moving (the process of initiating change), and Refreezing (establishing a new status quo)." Lewin recognized those involved in instituting change needed to plan for it as well as understand the driving and restraining forces to ensure the change was successful and sustainable.

Ronal Lippitt, also a change theorist, is credited with the creation of the Phases of Change Theory, which expands upon Lewin's three stages by using seven phases in comparison. Lippitt's Theory was selected for use as the guiding theory in this project because it is more defined than Lewin's and also closely resembles the nursing process (Figure 7). In addition, Lippitt's Theory utilizes a "change agent" to assess, plan,

implement, and evaluate the change, a role well within the scope of practice of a DNP student and highlighted in the *DNP Essentials*. Furthermore, the framework of Lippitt's Theory involves a deeper investigation into the variables that could impair the implementation or sustainability of the change such as readiness and motivation of those who will be involved in or impacted by the change (Lippitt, Watson, & Westley, 1958).

Figure 7: Lippitt's Theory Compared with the Steps of the Nursing Process

Nursing process elements	Lippitt's theory
Assessment*	*Phase 1*. Diagnose the problem
	Phase 2. Assess motivation/capacity for change
	Phase 3. Assess change agent's motivation and resources
Planning†	*Phase 4*. Select progressive change objective
	Phase 5. Choose appropriate role of the change agent
Implementation‡	*Phase 6*. Maintain change
Evaluation‡	*Phase 7*. Terminate the helping relationship

Key: * Assessment = Lewin's unfreezing stage
† Planning/implementation = Lewin's moving stage
‡ Implementation/evaluation = Lewin's refreezing stage

(Mitchell, 2013)

Phase 1 of Lippitt's Phases of Change Theory involves *diagnosing the problem*. First, the change agent (DNP student) became aware of the problem - low rates of HPVV of adolescents age 11-12 years-old, within the state of Montana and Flathead County, during a pediatric clinical rotation. The change agent then reviewed literature specific to

HPVV in the U.S. and goals of Healthy People 2020. Next, the change agent made contact with nurses within the Immunization Clinic (IC) at the Flathead City County Health Department (FCCHD). HPVV rates from the IC were compared to the state and national rates and the problem was diagnosed. The change agent then spent time cultivating relationships with IC staff and observed weekly within the IC during Phase 2, *assessing motivation/capacity for change.* Dialogue with key stakeholders as well as a pre-intervention survey that specifically addressed readiness, appropriateness, and motivation for a change project within the IC was administered.

IC staff were asked to include intervention suggestions on the pre-survey. Phase 3, *assessing change agent's motivation and resources,* involved dialogue between the change agent and the IC about the amount of time each week the change agent could commit to as well as feedback from the change agent's scholarly project committee about project feasibility. While input from the survey results was foundational to the project, the change agent was unable to incorporate some suggested interventions after an assessment of resources such as finances, time, and access to specific populations such as within the school system. This assessment of resources prior to the intervention period allowed for modifications of the intervention beforehand to optimize success. In Phase 4, *selecting a progressive change objective,* the change agent identified and defined the change problem as well as the time frame and roles of those involved. A plan was developed to have the communication interventions occur during the scheduled staff meetings (about 3 per month) and be listed on the meeting agenda. This made the

information presented easier to process (in small manageable parts) and also minimized cost as all nursing staff normally attended the meetings.

The IC staff and key stakeholders had expressed interest in an intervention to improve their HPVV rates but did not have any staff unencumbered enough to take on another project. Phase 5, *choosing an appropriate role for the change agent,* entailed the DNP student owning the role as the change agent within the IC. This role was communicated to staff and patients. In Phase 6, *maintaining change,* the implementation process occurred in which the change agent instructed and educated staff on how to most effectively recommend HPVV to parents of adolescents based on the literature (the intervention). Rational was provided to support the change and clinical examples were given to inspire motivation amongst staff. Feedback and progress were assessed during the staff meetings. This occurred over six months. In phase 7, the final phase, *the helping relationship is terminated.* The change agent evaluated outcomes of the intervention by comparing HPVV rates from before and after the change. Plans were made to create a story board, present the project to IC leadership, and incorporate the project into the FCCHD's annual report. With the intervention period at its conclusion, the change agent then stepped back to allow the IC to continue its new existence with the change (Lippitt, Watson, & Westley, 1958).

Tools and frameworks can be used to bring clarity to leaders, especially in health care, and are largely successful for quality improvement projects. Lippitt's Theory was selected for this project because it provides a framework that guides the change agent in proactively and systematically assessing factors involved in change. As attempts to

implement change are often numerous and unsuccessful, Lippitt's Theory helps the change agent anticipate barriers; by working through each phase, potential barriers are reduced preemptively, thus increasing chances of success. Expert nurses such as the DNP student, "have a unique skill set [that places them] … in the best position to identify those areas of clinical concern that require further research/improvement and to help ensure that the healthcare needs of patients within the community…are being addressed" (Moran & Burson, 2017, p. 89). In this case, the DNP student, acting as the change agent, educated the IC staff about the most effective way to communicate their recommendations for HPVV to parents of adolescents. By changing the current way HPVV is recommended within the IC, HPVV uptake may be increased, and in turn, protect additional adolescents from developing HPV-associated cancers and genital warts. It is wise to utilize a framework to optimize success when implementing change.

CHAPTER FOUR – METHODS

Ethical Considerations

Institutional Review Board (IRB) approval was sought, and this project was granted exempt status (Appendix B). A link to the pre-intervention and post-intervention surveys from SurveyMonkey was sent to a nurse within the Immunization Clinic (IC) who then forwarded the survey link to IC HCPs. The change agent's (DNP student) contact information was provided on both surveys, and staff were encouraged to indicate any concerns with the project or presence of the change agent within the IC. Both surveys were anonymous and without any personal identifiers. Every effort was made to remove identifying demographic questions on the post-survey when there was staff turn-over within the IC, thus reducing the sample size and in turn, anonymity. While observing at the IC, the change agent's role and title were continually disclosed. A name badge was always worn. Patients were always asked permission for the change agent to observe their IC visit and were given the opportunity to decline. Patient confidentiality and HIPPA compliance were maintained at all times. All immunization reports were declassified and transmitted using ePASS, a secure online file transfer service for the state of Montana.

Setting

Located in Northwest Montana, Flathead County is comprised of the towns of Kalispell, Whitefish, and Colombia Falls, as well as 16 additional census designated

places. It is the third highest populated county in Montana and the second largest in total area at 5,098 square miles. The most current U.S. Census, from 2010, estimated the population at 90,928 people, an increase of 22.1% in 10 years. Ninety-four percent of the land is designated as State or National Forrest Land with a population density of 17.9 people per square mile. A drive through the center of Kalispell, Whitefish, or Columbia Falls during the summer months may lead one to believe these "urban clusters" are bustling when in fact 51.5% of the population lives rurally.

In 2010, 8.4% of families and 11.7% of the population were estimated to be living below the poverty line. About 18% of those living below the poverty line were under the age of 18. The median income for a household was $44,998 in 2010 and $53,940 for a median family income. The racial profile for the county is not diverse; almost 96% of the population is White. One percent is American Indian, 0.6% Asian, 0.2% Black or African American, 0.1% Pacific Islander, 0.4% from other races, and 2.1% listed as from two or more races.

Kalispell Regional Healthcare owns and operates the two main hospitals, Kalispell Regional Medical Center in Kalispell, and North Valley Hospital, in Whitefish, as well as the majority of outpatient clinics and care facilities. The Flathead City-County Health Department (FCCHD), a federally qualified health center, is the only other major healthcare organization in the area. Community health centers are the "healthcare safety net" (Shin, 2016) that provides affordable care for all, regardless of insurance or the ability to pay. The FCCHD houses an IC, a community health center, a women, infants, and children program (WIC), a family planning clinic, and a health insurance division.

The IC falls under the department of community health services. The clinic is located in downtown Kalispell; it is easily accessible, on the first floor, and open Monday through Friday with extended hours on Wednesday evenings. In addition, outreach into the communities of Whitefish and Columbia Falls is offered monthly in which immunizations are provided at locations that are more accessible to residents. A wide range of immunizations are available including those required for school, work, travel, and those recommended by the ACIP. Immunizations are administered by nursing staff, supported by standing orders from a physician. Consults are also performed by nurses. The specialized nature of the IC allows members of the community the utmost flexibility to get their immunizations with a rolling walk-in schedule. The IC also supports the care delivered by many of the primary care providers (medical doctors, nurse practitioners, and physician assistants) and pediatricians in the community.

The patient population is primarily those of low-income and underserved areas. The majority of the children have insurance through state or federal programs. Many of the adults have primary care providers established within the FCCHD and also receive state or federal assistance for health insurance coverage. Some of the adults are Kalispell town employees or work nearby within the Kalispell community. A larger proportion of the patients are female, possibly due to the various state and federal insurance assistance programs offered for women and children.

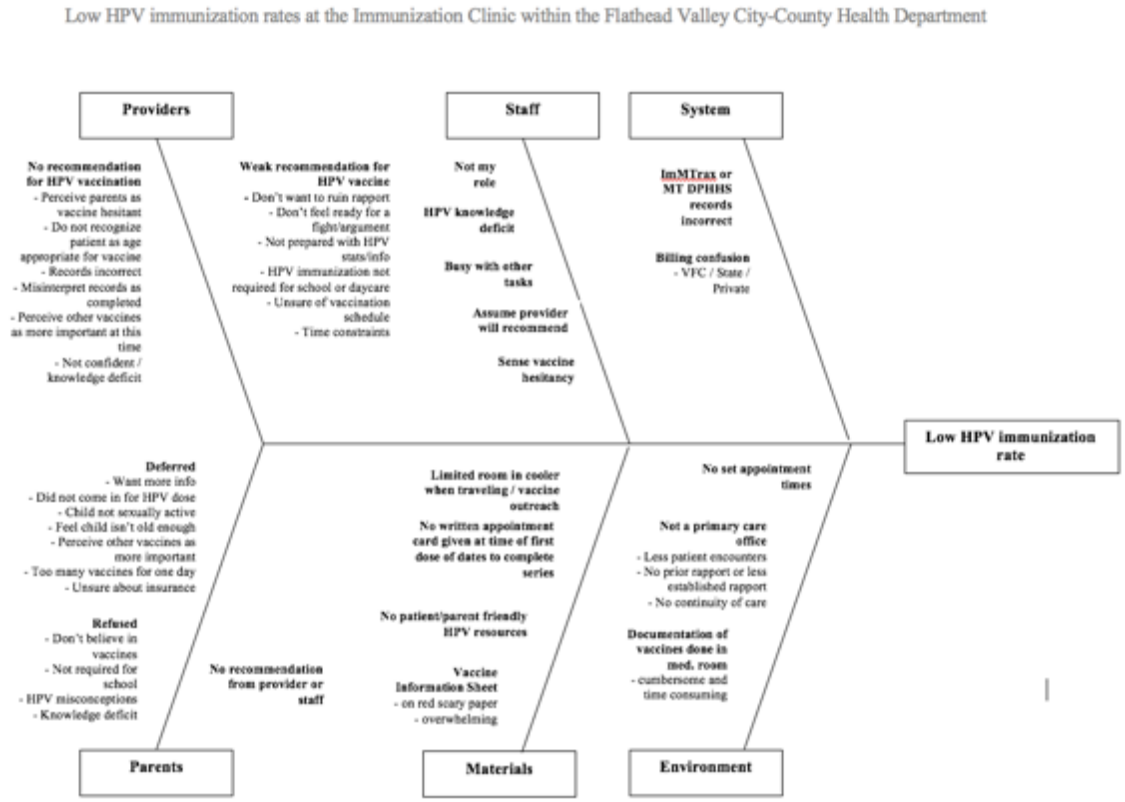
Intervention

After a thorough literature review, contact was made with a nurse at the Immunization clinic (IC) at the Flathead City-County Health Department (FCCHD), with the objective of assessing HPVV rates within the IC. Once it was established that HPVV rates were low and far below Healthy People 2020's goal of 80% series completion, meetings were initiated during Fall 2017 to discuss project ideas and feasibility. Increasing HPVV rates within the clinic was a priority for the organization and the IC. Coincidentally, increasing HPVV rates was already an objective that had been established in the FCCHD's community action plan and one of the IC's goals within the Montana Immunization Program's Assessment, Feedback, Incentives, and eXchange (AFIX) process. However, the IC had yet to identify a staff member unencumbered enough to chair such a project. Lippitt's Phases of Change Theory was utilized as a framework by the DNP student, in embracing the role as "change agent," to guide this project (Lippitt et al., 1958).

In January 2018, an IC nurse and the change agent (DNP student) established the IC's baseline HPVV numbers and received approval from the IC's manager and the Infectious Disease Prevention & Control Coordinator, to survey the HCPs within the IC. After a brief orientation to the FCCHD, permission was granted for the change agent to observe within the IC. A Fishbone Analysis (Figure 8) was utilized to help determine the root cause of the IC's low HPVV rates. Based on clinic observations, findings from the Fishbone Analysis, and validated surveys in the literature (as discussed in literature review chapter), a pre-intervention survey for HCPs within the IC was developed and

administered online via SurveyMonkey (Appendix D). The survey included questions pertaining to baseline HPV knowledge, comfort level in recommending HPVV, barriers to HPVV within the IC, and readiness for an HPVV project. Several demographic questions, a question about intervention formats that would be most helpful within the IC, and a free-text area to list any additional comments, were also included.

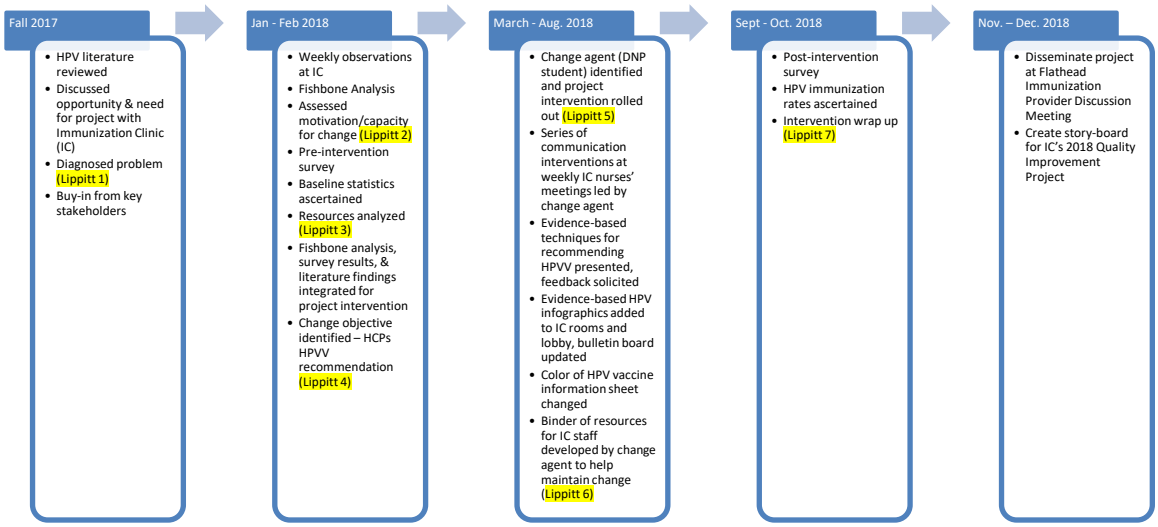
Figure 8: Fishbone Analysis Depicting Potential Causes of Low HPV Vaccination Rates Within the Immunization Clinic



Findings from observations within the IC, discussion with key stakeholders and IC staff, Fishbone Analysis results, pre-intervention survey results, and literature review findings revealed discomfort from HCPs in specifically recommending HPVV compared to other adolescent vaccines due to the anticipation of parental refusal, hesitation, or

confrontation. Intervention efforts were then focused on improving, strengthening, and increasing the frequency of HCP's recommendations for HPVV within the IC. It was hypothesized that education and training for HCPs would increase confidence and frequency in recommending HPVV. This, in turn, was postulated to help increase HPVV rates within the IC. In addition, HCPs would be better prepared to address parental questions and some common HCP and parental HPVV misconceptions may be dispelled. A project timeline was developed (Figure 9).

Figure 9: Project Timeline Utilizing Lippitt's Phases of Change Theory



Evidence-based literature, slide-sets, and videos from the CDC's "You are the Key to HPV Cancer Prevention" campaign were utilized extensively in the presentation of small, 20-30 minute communication interventions, about three times per month, over the course of 6 months (CDC, 2018c). During each intervention presentation, a topic was presented by the change agent to the HCPs within the IC for a portion of their regularly scheduled

staff meeting. This staff training and education was built upon in each subsequent meeting. Feedback was always solicited. The subject of each presentation varied and was modified depending on which staff members were present. Topics included:

- Discussion of pre-survey results
- Basic HPV education
- ACIP HPVV schedule
- Who is considered immunocompromised per the ACIP guidelines and needs 3 doses of Gardasil®9?
- HPVV Algorithm
- Why do we focus on vaccinating adolescents 11-12 years-old?
- HPVV rates in the US compared to global rates
- HPVV rates in Montana and IC compared to other U.S. states
- Proposed color change of the vaccine information sheet (VIS), provided evidence-based literature and infographics for review to display within the IC, and discussed updating bulletin boards in the lobby and IC
- What you say and how you say it matters when making vaccine recommendations
- CDC- You are the Key to Cancer Prevention presentation (broken up into several presentations)
- How to make an effective recommendation for HPVV
- Videos from the CDC - How to make an effective HPVV recommendation
- How to make an effective recommendation recap
- Acronym to help remember what to talk about for HPVV recommendation - CASE
- Discussion - what is working, what is not?
- Research articles given and shared
- Other modalities to increase rates - discussed reminder cards by computer or on badge, changing process of reminder postcards for additional doses, posting to Facebook and social media
- You are the Key to Cancer Prevention presentation (new staff)
- New Merck (vaccine manufacturer) materials discussed and distributed
- Binder of resources for staff and upcoming CE opportunities presented

A resource binder was created for staff. The color of the binder chosen (teal) was the same color IC staff had voted for when the color of the HPV VIS was changed from the previous color, red. Teal was chosen because it is gender neutral as opposed to pink or purple (to continue to dispel misconception of HPVV only needed for females), it does

not commonly evoke strong feelings like the color red (such as caution, stop, danger, or emergency), is easier to read, and is one of the colors used by the CDC in the "You are the Key to HPV Cancer Prevention" campaign (CDC, 2018c). Each section of the binder included numerous evidence-based and up-to-date resources specific to that section's content. The five sections were titled: "Handouts for Parents and IC," "How to Recommend HPVV for HCPs," "Continuing Education (CE) Credits and Recommending HPV Vaccine Training for CEs," "Vaccine Dose Reminder Cards," and "IC HPVV Policies." The front of the binder contained an HPVV Vaccination Algorithm (Appendix C), from the Montana DPHHS, that was agreed upon for use during one of the IC intervention meetings. This also included specific immunocompromising conditions that would warrant three doses of vaccine versus two. IC staff specifically asked for information and infographics from a variety of sources for those parents who were "anti-government" or "anti-vaccines." Evidence-based and up-to-date information from various organizations included the CDC, AAP, Children's Hospital of Philadelphia (CHOP), HealthyChildren.org, Immunization Action Coalition, American Cancer Society, Merck, and the Montana Department of Public Health and Human Services (DPHHS).

HCPs within the IC were re-surveyed upon project completion (Appendix E). Post-intervention statistics were ascertained from the Montana DPHHS CDC Public Health Advisor. The actual number of HPV vaccines administered before, during, and after the intervention period (Appendix F) was recorded by the IC manager and given to the change agent in the form of a bar graph that was broken down by month and year

(2014 - 2018). Plans were made to create a story board for the FCCHD's quality improvement project in late December 2019, and to disseminate the project findings during a Flathead Immunization Provider Discussion.

Intervention Rationale

An HCP-based intervention strategy to improve HPVV recommendations for adolescents age 11-12 years-old was selected in line with findings from the literature, Fishbone Analysis, observations at the IC, and pre-intervention survey results. Project feasibility, timeframe, and costs as well as needs of the IC were likewise assimilated into the project intervention rationale. An HCP-based intervention that translates the most up-to-date findings on effectively recommending HPVV to adolescents is applicable to the role of a nurse practitioner, fits within the criteria of the eight Doctor of Nursing Practice (DNP) Essentials, and is in compliance with the Scholarly Project design (American Association of Colleges of Nursing [AACN], 2006). Furthermore, this type of intervention was cost-effective, had very few ethical concerns, and was applicable to all settings in which HCPs made vaccine recommendations. It could be easily adapted and modified in the future and disseminated to other departments within the FCCHD.

Original project plans did include incorporating other areas of the FCCHD, such as the Community Health Clinic and the WIC Program, in phases, to increase the effect size, but challenges in measuring outcomes, the limited availability of time to meet with staff collectively, and project time constraints adjourned project expansion. Original plans also included hosting the HPV documentary "Someone You Love: The HPV

Epidemic," but the cost to receive a license for a community screening as well as continuing education credit for HCPs was outside the budget of this project and the organization at the time. However, it will continue to be discussed as key stakeholders have found it valuable and impactful. A link to watch the documentary for free, with CEUs provided, was included in the binder of resources for IC staff.

Unfortunately, none of the advanced practice providers responded to the initial survey and did not attend any of the meetings in which communications strategies were discussed. The title of the project was subsequently changed, and project ideas were modified from a focus on provider recommendations for HPVV to a health care professional's (HCPs) (nurses and support staff) recommendation. This included revisiting the literature for HCPs specific communication interventions in making effective HPVV recommendations and changing the wording during communication discussions from provider to HCP or nurse. Of note, the vast majority of the HPVV literature used terms such as provider and HCP interchangeably, which is a limitation of the current literature available.

Baseline Statistics

Baseline data for the first project aim, increasing the frequency and confidence of HCPs within the IC in making strong recommendations for HPVV, was established with a pre-intervention survey (Appendix D). Baseline data for assessing the second aim, increasing HPVV series initiation and completion rates within the clinic, was established in two ways. First, the total number of HPV vaccines given at the IC every month since

2014 was ascertained (Appendix E). Next, contact was established with the Montana DPHHS CDC Public Health Advisor. The Advisor generated immunization reports based on Montana's Immunization Information System, (imMTrax), through a program called CASA. One report, the IC's AFIX, was generated every six months. The second report, the Bi-annual report, was generated twice per year. Similar data points are assessed in each report with the exception being the age of the adolescents. Adolescents 13-15 years-old were the sample in AFIX reports and adolescents age 13-17 were assessed in the Bi-annual report. In trying to examine immunization rates in those 11-12 years-old, the state examined the ages indicated above to best capture the data which also correlates with most national reports. This project was coordinated to start in February when an IC AFIX was generated and planned to conclude in September when the Bi-annual report was completed. Data points that were evaluated and compared included: ≥1 HPV, HPV up-to-date (UTD), 1 Tdap, and 1 MCV (Appendix A). A post-intervention survey (Appendix F) was administered following the intervention period and compared to the baseline data (Appendix D).

CHAPTER FIVE – OUTCOMES / RESULTS

Pre-Intervention Survey

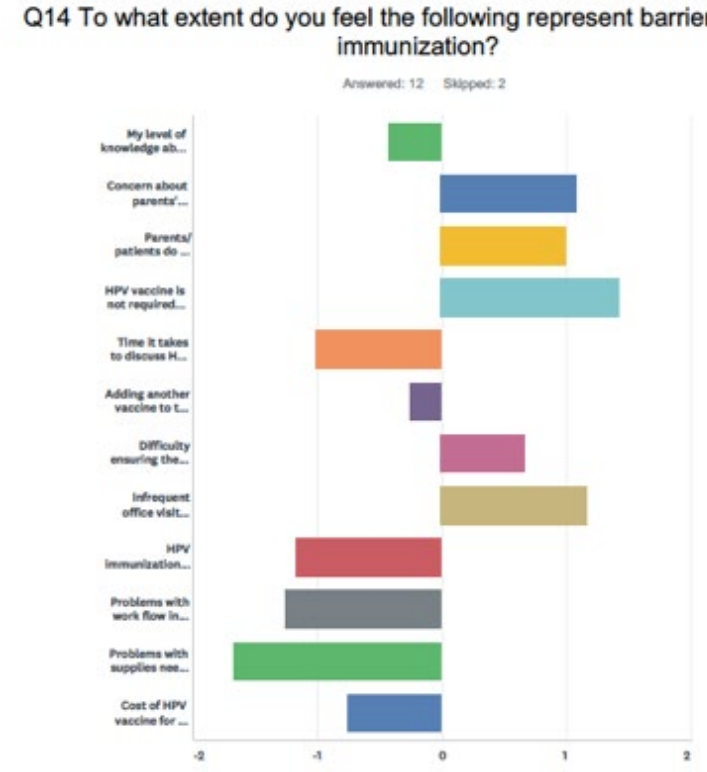
Demographics

Fourteen HCPs, which included nurses and front office staff within the IC, completed the pre-intervention survey (Appendix D), for a completion rate of over 50% (N = 25). All of the respondents were female, and the majority were between thirty and sixty years-old. Four of the respondents were support staff (medical assistant, certified nursing assistant or aid, front desk, administration, laboratory, undergraduate student, or other) and ten were nurses (LPN or RN). Four respondents had been practicing in their current role for less than 5 years, 4 had been in their current role for 5-10 years, 4 had been in their current role for 11-20 years, and 2 had been practicing in their current role for more than 20 years.

Barriers

Twenty-five percent (n = 3) of pre-survey HCP respondents indicated their level of knowledge about HPV was “a minor barrier” to HPVV, 33% (n = 4) indicated it was “somewhat of a barrier,” and 8.33% (n = 1) indicated it was “a major barrier” (Figure 10). The average (mean) quiz score was 85% on questions that assessed baseline HPV knowledge. The majority of HCPs were able to correctly identify the cancers most

Figure 10: Excerpt from Pre-Intervention Survey, Question 14 (Appendix D); Survey Question Assessing HCP Barriers to Immunization at the Immunization Clinic



	NOT A BARRIER AT ALL	A MINOR BARRIER	SOMEWHAT OF A BARRIER	A MAJOR BARRIER	UNKNOWN / UNSURE	TOTAL	WEIGHTED AVERAGE
My level of knowledge about HPV	33.33% 4	25.00% 3	33.33% 4	8.33% 1	0.00% 0	12	-0.42
Concern about parents' negative perceptions about HPV vaccine	8.33% 1	8.33% 1	33.33% 4	50.00% 6	0.00% 0	12	1.08
Parents/ patients do not understand the link between HPV and cancer	0.00% 0	25.00% 3	25.00% 3	50.00% 6	0.00% 0	12	1.00
HPV vaccine is not required for school attendance	0.00% 0	8.33% 1	16.67% 2	66.67% 8	8.33% 1	12	1.42
Time it takes to discuss HPV vaccine with patients and parents	33.33% 4	50.00% 6	16.67% 2	0.00% 0	0.00% 0	12	-1.00
Adding another vaccine to the vaccination schedule	16.67% 2	41.67% 5	33.33% 4	8.33% 1	0.00% 0	12	-0.25
Difficulty ensuring the patient will complete the 2 or 3 dose HPV vaccine series	8.33% 1	25.00% 3	25.00% 3	41.67% 5	0.00% 0	12	0.67
Infrequent office visits made by adolescent patients	8.33% 1	8.33% 1	25.00% 3	58.33% 7	0.00% 0	12	1.17
HPV immunization is not a priority in my work setting	58.33% 7	25.00% 3	8.33% 1	8.33% 1	0.00% 0	12	-1.17
Problems with work flow in my work setting	58.33% 7	25.00% 3	16.67% 2	0.00% 0	0.00% 0	12	-1.25
Problems with supplies needed for immunization in my work setting	83.33% 10	8.33% 1	8.33% 1	0.00% 0	0.00% 0	12	-1.67
Cost of HPV vaccine for the patient or my work setting	25.00% 3	50.00% 6	25.00% 3	0.00% 0	0.00% 0	12	-0.75

commonly caused by HPV (Appendix D, Question 13). However, two respondents did not recognize that nearly everyone that is sexually active will be exposed to HPV at some point in their lives (Appendix D, Question 5) or that condoms do not fully prevent HPV (Appendix D, Question 7). Only 36% of survey respondents understood that genital warts and cervical cancer are caused by different strains of HPV (Appendix D, Question 9). Fifty-eight percent of IC HCPs "strongly agreed" or "agreed" that parents of 11-12-year-olds have been more likely to refuse or defer HPV vaccination as compared to older adolescents (Figure 11). Similarly, 50% of HCPs "strongly agreed" or "agreed" that parents of 11-12-year-olds have been upset a vaccine is being offered for an STI, yet only one HCP believed it was necessary to discuss sexual activity when recommending HPVV (Figure 11). None of the HCPs believed the HPV vaccine was not safe or encouraged earlier or riskier sexual behavior (Figure 11).

Figure 11: Excerpt from Pre-Intervention Survey, Question 15 (Appendix D); Survey Question Assessing HCP's Perceptions as Barriers to HPVV in the Immunization Clinic

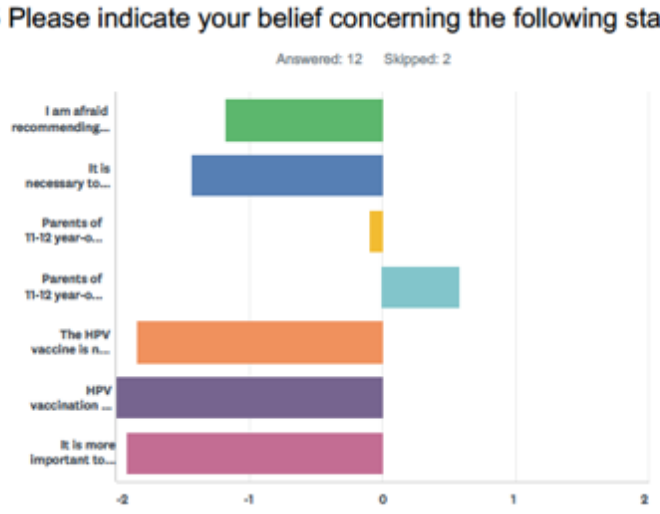


Figure 11 Continued

	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE	UNKNOWN / UNSURE	TOTAL	WEIGHTED AVERAGE
I am afraid recommending HPV vaccination will ruin my rapport with patients and/or patients' parents.	0.00% 0	8.33% 1	58.33% 7	33.33% 4	0.00% 0	12	-1.17
It is necessary to discuss sexual activity before recommending the HPV vaccine to patients.	0.00% 0	8.33% 1	33.33% 4	58.33% 7	0.00% 0	12	-1.42
Parents of 11-12 year-old patients have been upset that I am offering a vaccine against a sexually transmitted infection in someone 11-12 years-old.	16.67% 2	33.33% 4	25.00% 3	25.00% 3	0.00% 0	12	-0.08
Parents of 11-12 year-old patients have been more likely to refuse or defer HPV vaccination than parents of older adolescents.	25.00% 3	33.33% 4	25.00% 3	0.00% 0	16.67% 2	12	0.58
The HPV vaccine is not safe.	0.00% 0	0.00% 0	16.67% 2	83.33% 10	0.00% 0	12	-1.83
HPV vaccination may encourage earlier or riskier sexual behavior.	0.00% 0	0.00% 0	0.00% 0	100.00% 12	0.00% 0	12	-2.00
It is more important to prioritize HPV immunization for females vs. males.	0.00% 0	0.00% 0	8.33% 1	91.67% 11	0.00% 0	12	-1.92

Comfort and Confidence Level

Interestingly, none of the HCPs indicated discomfort or a lack of confidence in making HPVV recommendations and the large majority did not feel it was hard to start a conversation about HPVV (Appendix D, Question 16). This was in stark contrast to observations made by the change agent within the IC, which are discussed further below. The largest majority of HCPs felt comfortable and confident recommending HPVV for females age 19-26 years-old (83.33% strongly agree, 16.67 % agree). The majority also indicated a greater comfort in recommending HPVV for females over males, and older adolescents versus younger (Appendix D, Question 17). This was also captured in a free-text answer: "I find the hardest age group to bring up HPV vaccinations is age 11 to mid-teen years, especially for vaccinating boys. It's harder to sell parents regarding the boys, as most people still think [HPV vaccine is] for females," (Appendix D, Question 22).

Intervention Ideas and Readiness Assessment

When asked about interventions that would most support them in making a strong recommendation for HPVV, 75% of HCPs indicated an HPV video documentary, 58% indicated informational material from the CDC for providers and patients, 58% indicated the presence of a designated vaccine champion, and 50% indicated an annual online learning module on HPV vaccination strategies would be beneficial (Appendix D, Question 18). Ninety-two percent of those surveyed felt an HPVV intervention on framing conversations about HPVV for providers and staff was appropriate and beneficial for their work setting (Appendix D, Question 19 & 21). All HCPs indicated that management would be supportive of such an intervention (Appendix D, Question 20). These results along with direct input from key stakeholders was used to formulate a plan for interventions that would target nurses and staff within the IC and would also work well for the IC. Leadership underscored the need for a vaccine champion and staff indicated their preference for short, manageable pieces of information, to be discussed weekly rather than in one or two longer presentations. All of this input was honored and incorporated to the best of the change agent's abilities and resources.

Pre-Intervention Immunization Clinic Observations

The change agent observed for twelve days, averaging 6 hours per day, within the IC to assess work flow, garner intervention ideas, identify gaps not previously established in the literature, and to ascertain any challenges that may have been unique to the IC setting or population. Effort was made to observe during different times (morning,

afternoon, and evening), as well on various days of the week. In addition, the change agent also observed during an off-site outreach clinic day in Columbia Falls and Whitefish. The change agent perceived smooth work flow and a very cohesive IC team.

All of the nurses were scheduled on a monthly calendar for shifts administering shots within the IC. These shifts usually consisted of 4-6 hours. The nurses appeared to wear many hats within the IC. They not only administered vaccinations on a walk-in basis but had specific roles regarding the vaccines (checking temperatures, re-stocking, ordering, etc.), and simultaneously managed numerous extraneous projects that reflected the IC's priorities at that specific time (i.e. influenza clinics, lead testing, community outreach, etc.). The nurses frequently traveled off-site to different areas of the community such as the local prison or schools. All of the nurses had previously worked in other settings and this was reflected in their knowledge and inclination to discuss certain vaccines at length over others as well as their comfort level in administering vaccines to certain populations (pediatric vs. adult). It was clear that a great deal of knowledge and a thorough understanding of the ACIP's recommended vaccination schedule was necessary to establish a strong patient rapport, which needed be done in a very succinct time frame.

In regard to HPVV recommendations specifically, the change agent observed all staff either offering or discussing the HPV vaccine in a participatory manner. Although the two front desk staff members (no healthcare qualifications) did not recommend any vaccines upon patient registration and check-in, they were often asked questions about which immunizations were needed and also received phone calls when a reminder

postcard was received in the mail by a patient or parent. Of note, the reminder postcards informed patients or parents a vaccine way due at the IC but did not indicate which one. Sometimes the front office staff were able to correctly ascertain that HPVV was indicated or overdue during these phone calls and other times they were not.

Two main themes that emerged included the importance of rapport and the feeling of a "salesman" mentality when making HPVV recommendations. This was further underscored when one of the HCP's explained that HPVV is "…a harder sell to parents regarding the boys," (Appendix D, Question 22). The change agent observed the importance of developing a good rapport to gain the trust of patients, ensure a smooth vaccination process, and inspire patients or parents to return for additional immunizations in the future. Several HCPs verbalized feeling afraid to push too hard while making vaccine recommendations, especially for HPVV, because they did not want parents to become disgruntled, not return, or refuse additional vaccines during their visit. The majority of the population served by the IC generally presented with a preset notion of which vaccines they needed because they had been notified by the public-school system, day-care agency, or their agency of employment. This left staff feeling as if they needed to "upsell" the HPV vaccine and convince parents that although they came in for only one immunization, they should really leave with two.

Post-Intervention Survey

Demographics

From June 2018 – October 2018, the IC experienced HCP turn-over of three full-time employees: one nurse retired, one resigned for personal reasons, and one went out on maternity leave. Additionally, one of the two front office staff members was gone for an extended period of time due to illness and a family emergency. In August 2018, one full time RN was hired and a temporary LPN was hired. As a result, a heavier than normal work load was carried by the other HCPs within the IC during the busiest periods of back-to-school season (August and September) as well as influenza season (Fall 2018). Consequently, the post-intervention survey was only sent to 9 HCPs, of which 7 then completed the survey. Several demographics questions were eliminated to maintain anonymity. The average age of respondents increased from 30-44 years-old to 45-60 years-old (Appendix F, Question 1) and interestingly, the majority of respondents (42.86%, n = 3) had been in practice less than 5 years (Appendix F, Question 2).

Quiz Scores

The mean quiz score increased by 3%, the median score remained the same at 85%, and the range significantly decreased (from 31 to 7). In addition, the lowest quiz score improved from 69% to 85%. Baseline HPV knowledge scores improved significantly on content that addressed the transmission of HPV, prevention of HPV, and HPV-associated cancers. One hundred percent of HCPs correctly identified that HPV can cause mouth and throat, penile, cervical, vulva and vaginal, as well as anal cancers

compared to the pre-intervention survey scores which were 91.67%, 83.33%, 100%, 83.33%, and 83.33% respectively. Scores did not improve on two of the true or false questions which asked about the non-symptomatic nature of the majority of HPV infections and the fact that genital warts and cervical cancer are caused by different HPV strains.

Barriers

A greater number of HCPs indicated their level of knowledge was not a barrier at all to HPVV (71.43% compared to 33.33%) on the post-intervention survey. A greater number of HCPs also indicated much less concern about parents' negative perceptions about the HPV vaccine and the time it takes to discuss HPVV with parents. None of the HCPs surveyed on the post-intervention survey "strongly agreed" that parents of 11-12-year-olds have been upset they were offering a vaccine against an STI and less HCPs "strongly agreed" or "agreed" that parents of 11-12 year-old adolescents were more likely to refuse or defer HPVV than parents of older adolescents.

Comfort and Confidence Level

The overall comfort and confidence level of HCPs in recommending HPVV as well as responding to parents' HPVV refusal or deferral improved. More specifically, comfort and confident in recommending HPVV to female adolescents 11-12 years-old, male adolescents 11-12 years-old, male adolescents 13-26 years-old, and males 19-26 years-old all improved.

Number of HPV Vaccines Administered

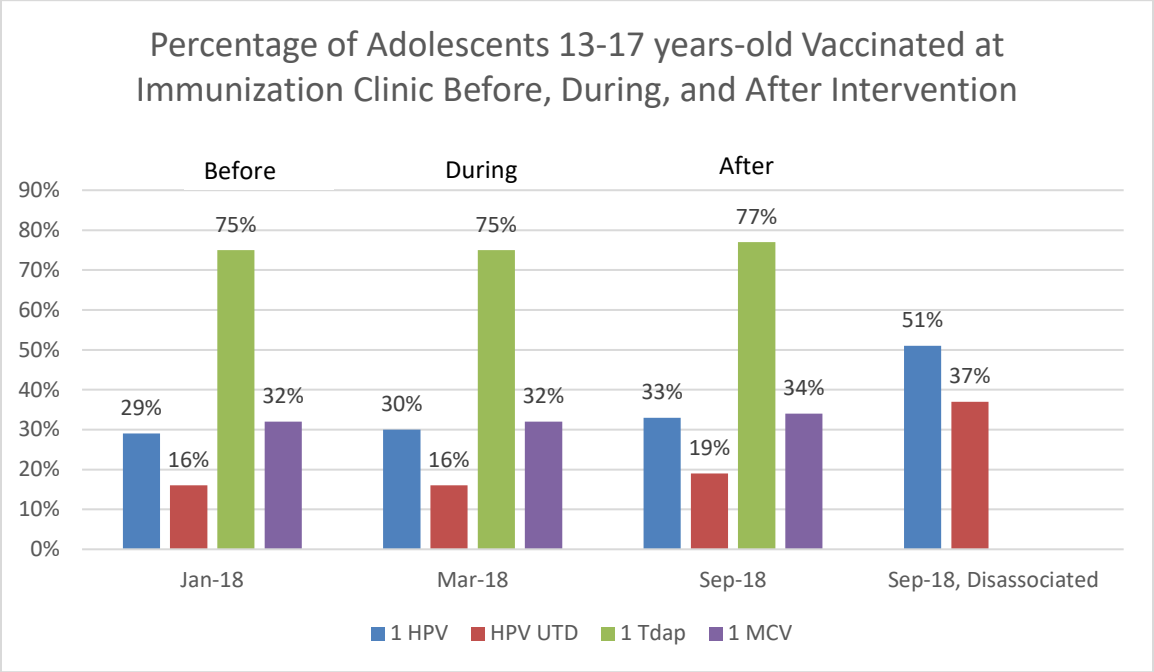
From March 2018 – September 2018, the number of HPV immunizations administered within the IC increased every month when compared to the number of HPV immunizations administered during the same month in 2016 and 2017, with the exception of April (2016 and 2017 rates slightly higher) and May (only 2016 rate higher) (Appendix E). The number of HPV immunizations administered in 2018 compared to 2017 doubled during the months of March and September and was highest during the back-to-school rush in August with a total of 104 HPV immunizations administered. Of note, varicella vaccination became a required vaccination for public school attendance in Montana in 2015. The rates of HPVV administered in August 2015 are the highest (127 immunizations) when compared to all other months from 2014-2018.

Immunization Clinic HPV Vaccination Rates

The percentage of adolescents age 13-17 years-old who initiated HPVV (defined as 1 HPV) increased by 4% from before the project intervention period in January 2018 to after project completion in September 2018 (Figure 12). The percentage of adolescents who completed the full HPVV series in the same age group increased by 3%. Similar increases were also seen in the percentage of adolescents who received Tdap and MCV immunizations, which are recommended for the same age group. In September of 2018, the IC made a concentrated effort to disassociate or remove patients that had been assigned to the IC even though they had not been seen by an HCP in two or more years.

This significantly reduced the sample size by almost half, which in turn improved the IC's HPV rates (Figure 12).

Figure 12: Comparison of Immunization Rates of HPV, Tdap, and MCH within the Immunization Clinic in 2018, before, during, and after Project Intervention.



CHAPTER SIX – DISCUSSION

Discussion

Baseline HPV knowledge, as assessed on the pre-intervention survey, was high. This was a good indication that knowledge pertaining to HPV and HPVV was not a barrier within the IC. This finding was expected due to the experience of the HCPs surveyed, results of the Fishbone Analysis, and the specialized nature (immunization-focused) of the IC. Scores were even higher on the post-intervention survey with a greater percentage of staff able to correctly identify all of the types of cancer caused by HPV and recognize that condoms do not fully protect against HPV. As the intervention period was sustained over six months, the retention of the HPV information by the HCPs is encouraging and appears to have been effective.

On the pre-intervention survey, one HCP (8.33%) indicated it was necessary to discuss STIs when recommending HPVV, yet 6 HCPs (50%) "strongly agreed" or "agreed" that parents of adolescents 11-12 years-old became upset they were recommending a vaccine for an STI. During the intervention period, the change agent emphasized that discussing STIs while making initial HPVV recommendations was not effective, and rather discouraged HPVV. A focus on cancer prevention and making a bundled recommendation for Tdap, HPV, and MCV immunizations was taught, demonstrated, and explained based on evidence-based rationales (CDC, 2018c). Efforts by the change agent to dispel the belief STIs must be discussed while making HPVV recommendations appeared to be successful as none of the HCPs on the post-survey

indicated it was necessary to discuss STIs when recommending HPVV. In addition, less HCPs (42.86%) indicated parents of adolescents 11-12 years-old were becoming upset they were recommending a vaccine for an STI.

On the pre-survey, over half of the HCPs "strongly agreed" or "agreed" that parents of 11-12-year-olds were more likely to refuse or defer HPVV compared to parents of older adolescents. This may be due to the use of participatory HPVV recommendations, which may not be interpreted as a recommendation for HPVV by parents. When HCPs perceive a parent to be hesitant or likely to defer or refuse a recommendation for HPVV, they may frame their vaccine recommendation differently, not as effectively, or may not make a recommendation at all. When HCPs give a strong recommendation for HPVV and frame the recommendation as cancer prevention, parents are more likely to accept HPVV recommendations. Observations at the IC as well as results from the pre-intervention survey indicated the perception, and possibly even anticipation, of HCPs within the IC, that parents of adolescents age 11-12 years-old would defer or decline a recommendation for HPVV. The change agent utilized ACIP guidelines and current evidence-based literature to underscore the importance of capitalizing upon every opportunity to make a strong recommendation for HPVV as the standard of care for adolescents age 11-12.

Similar to findings in the literature (Rutten et al., 2017) only 36% of HCPs on the pre-intervention survey and 29% on the post-intervention survey correctly indicated their understanding that genital warts and cervical cancer are caused by different strains of HPV, despite extensive education pertaining to this topic during the intervention period.

This distinction is important and needs to be emphasized in future interventions. If HCPs do not understand some strains of HPV are more virulent than others, they may not be correctly communicating this to parents, stressing the importance of HPVV for cancer prevention within their immunization recommendations, or accurately assessing the propensity of high-risk strains of HPV to develop into cancerous lesions.

The first aim of this project was to improve the comfort and confidence of HCPs in recommending HPVV with the hypothesis that increased comfort would propagate stronger and more frequent HPVV recommendations. Overall, HCPs indicated higher levels of comfort and confidence in making HPVV recommendations on the post-intervention survey, especially for younger adolescents and males, compared to results from the pre-intervention survey. This translated to increased HPVV acceptance and uptake by parents; the number of HPV immunizations administered increased every month, with the exception of April, when compared to the same months in 2017. The percentage of adolescents that initiated and completed HPVV also increased following the project intervention when compared to the baseline statistics. In addition, HCPs perceived parental resistance to be less of a barrier on the post-intervention survey results. Parents valued HPVV similarly to other vaccines. If parental questions about HPVV are addressed, 80% of parents subsequently accept HCPs' HPVV recommendations (Gilkey et al., 2016). HCPs within the IC were more successful in increasing HPVV uptake by changing the way in which they approached and delivered HPVV recommendations to parents of all ages.

Limitations

The low sample size of HCPs within the IC as well as staff turnover during the intervention period greatly limited the generalizability of the project's results. The timing of the staff meetings in which interventions were initiated as well as the non-mandatory participation in the project may also have contributed to the low sample size and lack of participation of advanced practice providers. Original plans encompassed the inclusion of multiple departments with the FCCHD, which would have increased the sample and effect sizes, but project time constraints as well as challenges in accurately measuring vaccination rates across all departments were limiting factors. Financial constraints limited the change agent's ability to introduce some interventions suggested by HCPs on the pre-intervention survey such as the HPV video documentary and a far-reaching community media campaign. Similarly, continuing education credits would likely have enticed more HCPs as well as advanced practice providers such as physicians, nurse practitioners, and physician assistants, but were not financially feasible to offer to a large group.

During the intervention period, the IC had obligatory priorities depending on the time of year such as influenza clinics, vaccinating the Head Start programs, or lead testing of government employees. There were numerous times when project interventions were planned but had to be rescheduled due to a mobilization of IC resources (staff, time, etc.) to manage communicable disease outbreaks. If the change agent was more familiar with the nature of the IC and had already been an established member of the team, it is likely the timeline could have been better adapted to anticipate

some of these compulsory events. In addition, it would have taken less time to gain the trust of HCPs within the IC, cultivate buy-in, identify the key stakeholders, and begin the project.

Data collection was another challenge. The change agent was not able to run immunization reports independently and had to establish contact with key stakeholders within the IC as well as at the state-level to assess immunization rates. Furthermore, these stakeholders were very busy and only ran reports at predetermined times during the year. These reports were hard to compare to one another as they often evaluated different age groups such as 13-15-year-olds or 13-17-year-olds. The reports also differed in selection criteria such as 1 HPV immunization, ≥ 1 HPV immunization, or HPV UTD (which could mean 2 or more immunizations, depending on the age the first immunization was given).

Strengths

Strengths of this project included the negligible costs (paper and binder supplies) and the change agent's ability to help the IC accomplish a change project that had not previously been possible due to a lack of unencumbered staff, despite its priority status. Furthermore, the project was evidence-based and could be easily replicated or modified. The IC now has a binder of resources for reference which can be used to update HPV information around the clinic, given to patients or parents, or used to orient new staff members. Results stemming from this project's intervention may continue to be realized as HCPs hone their HPVV recommendations and teach others how to do so as well.

Interest was expressed to elicit budget dollars to host a community showing of an HPV video documentary, as well as disseminate project findings to other areas within the FCCHD.

Implications for Practice

By educating HCPs to make simple changes to the way they recommend HPVV to parents and patients, especially those of patients 11-12 years-old, the potential exists to protect endless numbers of adolescents from HPV-associated cancers, RRP, and genital warts for the duration of their entire lives. This is not only cost-effective but cost-saving. Furthermore, the need for potentially painful and/or harmful procedures is averted. Life expectancy may be increased and premature deaths from HPV-associated cancers decreased. Reductions in the overall prevalence of HPV in both males and females has already been realized in countries such as Australia (Machalek et al., 2018). It is time for HCPs in the U.S. to answer the call to action to reduce the HPV burden and its sequalae by minimizing missed opportunities and treating HPVV as the standard of care for adolescents age 11-12 years-old.

Healthy People 2020's goal of 80% HPVV series completion is attainable. This is corroborated by the high Tdap and MCV vaccination rates in U.S. adolescents of the same age. A HCP's recommendation for HPVV remains the most influential factor in parental HPVV acceptance and uptake. Further research should make an effort to specify the type of HCP participating in the study (pediatrician, family medical doctor,

family nurse practitioner, physician assistant, nurse, etc.) to assess for differences in recommendation quality (Newman et al., 2018), strength, and overall uptake of HPVV.

CHAPTER SEVEN – CONCLUSION

Conclusion

Despite its recommendation as the standard of care for adolescents 11-12 years-old by the CDC and endorsements from nearly every major U.S. health care organization, parents cite never having received a recommendation from an HCP as a common reason for not vaccinating their child against HPV (Holman et al., 2014). HCP's perceptions surrounding parental feelings about HPVV (whether true, perceived, or misconstrued), uniquely impact the way the vaccine is recommended (Farias et al., 2017) and may even preclude HCPs from making a recommendation at all (Dixon et al., 2017). Parents' decision to vaccinate their adolescents against HPV is not beyond the control of HCPs, although they may perceive this to be so. Educating HCPs to understand how influential their recommendations are has the potential to increase HPVV rates and offer protection against HPV and its sequalae to endless numbers of adolescents.

An HCP-based intervention that translated the most up-to-date findings on how to effectively recommend HPVV to parents of adolescents 11-12 years-old successfully increased HPVV rates within the FCCHD's IC in Kalispell, Montana by 3% over the course of six months. While generalizability is limited due to the low sample size of HCPs and lack of advanced practice provider participation, the potential to protect every adolescent that encounters the health care system through one HCP at a time is justified. This project's intervention was applicable to the role of a nurse practitioner, was harmonious with the eight Doctor of Nursing Practice (DNP) Essentials, and was in

compliance with the Scholarly Project design (American Association of Colleges of Nursing [AACN], 2006). Furthermore, this kind of an intervention appeared to be low-hanging fruit; it was cost-effective, had very few ethical concerns, and was applicable to all settings in which HCPs made vaccine recommendations.

It is the duty of all HCPs to stress health promotion and disease prevention. Recommendations for HPVV need to come from HCPs whenever opportunity for immunization presents itself. This includes making strong presumptive HPVV recommendations based on guidelines set forth by the ACIP and reinforcing these recommendations with an evidence-based rationale when parental hesitancy is intimated. Advanced practice registered nurses (APRNs), such as family nurse practitioners, are uniquely qualified to answer this call to action. APRNs excel in establishing and maintaining strong patient-provider relationships, which is reflected in the high quality of care delivered. APRNs are not only making care more accessible for patients but they are one of the most trusted sources of healthcare information for patients and parents. APRNs need to embrace this role and not fall back on the false belief that a subsequent HCP will make a recommendation for HPVV at a later visit. APRNs need to believe they are that adolescent's best chance at cancer prevention and a strong recommendation should be made for HPVV at every opportunity.

Recommendations should be made confidently and presumptively rather than conversationally (Brewer et al., 2017). HPV is an extremely common infection that causes extremely common cancers; cancers that could be prevented through routine immunization. A greater emphasis on HPVV as cancer prevention and the standard of

care for adolescents age 11-12 years-old is imperative for immunization rates to improve. "A high-quality recommendation by a health care provider is a uniquely potent motivator of HPV vaccine uptake, yet many providers make these recommendations hesitantly, late, or not at all" (Brewer & Fazekas, 2007). In addition, the strength of the recommendation not only increases HPVV acceptability but translates to actual completed immunizations.

The aim of this project was to increase the frequency as well as the strength of HCP recommendations for HPVV within the Immunization Clinic (IC) at the FCCHD. The overall goal to increase provider and staff recommendations for HPVV in adolescents age 11-12 was realized and impactful. High HPV prevalence rates, the ease of HPV transmission, limited screening modalities, the absence of a cure for HPV infection, and the natural progression of HPV to cancer demands the full attention of all HCPs, especially APRNs. HCPs need to utilize their position as the most trusted source of health information for parents in making strong and consistent recommendations for HPVV in the age groups recommended by the ACIP. Communication training interventions to support HCPs in this endeavor can increase the uptake of HPVV.

REFERENCES CITED

American Academy of Pediatrics. (n.d.). HPV vaccine is important to give to boys and girls [Fact Sheet]. Retrieved from https://www.aap.org/en-us/Documents/AAPFact%20Sheet_HPV%20vaccine.PDF

American Association of Colleges of Nursing. (2006). *The essentials of doctoral education for advanced nursing practice*. Washington, DC: Retrieved from https://www.aacnnursing.org/Portals/42/Publications/DNPEssentials.pdf

American Cancer Society. (2016). *HPV and cancer.* Retrieved from https://www.cancer.org/content/dam/cancer-org/cancer-control/en/booklets-flyers/hpv-and-cancer-english.pdf

American College of Obstetricians and Gynecologists. (2018). Practice advisory: Cervical cancer screening (update). Retrieved from https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Advisories/Practice-Advisory-Cervical-Cancer-Screening-Update

American Nurses Association. (2015). *Code of ethics for nurses, with interpretive statements*. Silver Spring, MD: American Nurses Association, Nursebooks.org, Publishers.

Brewer, N. T., & Fazekas, K. I. (2007). Predictors of HPV vaccine acceptability: A theory-informed, systematic review. *Preventative Medicine, 45*(2-3), 107-114. doi:10.1016/j.ypmed.2007.05.013

Brewer, N. T., Hall, M. E., Malo, T. L., Gilkey, M. B., Quinn, B., & Lathren, C. (2017). Announcements versus conversations to improve HPV vaccination coverage: A randomized trial. *Pediatrics*, *139*(1), 1-9. doi:10.1542/peds.2016-1764

Castellsagué, X., Muñoz, N., Pitisuttithum, P., Ferris, D., Monsonego, J., Ault, K., Luna, J., Myers, E., Mallary, S., Bautista, O. M., Bryan, J., Vuocolo, S., Haupt, R. M., … Saah, A. (2011). End-of-study safety, immunogenicity, and efficacy of quadrivalent HPV (types 6, 11, 16, 18) recombinant vaccine in adult women 24-45 years of age. *British Journal of Cancer*, *105*(1), 28-37.

Cates, J. R., Crandell, J. L., Diehl, S. J., & Coyne-Beasley, T. (2018). Immunization effects of a communication intervention to promote preteen HPV vaccination in primary care practices. *Vaccine, 36*(1), 122-127. doi:10.1016/j.vaccine.2017.11.025

Centers for Disease Control and Prevention. (2013). Human papillomavirus vaccination coverage among adolescent girls, 2007-2012, and postlicensure vaccine safety monitoring, 2006-2013 — United States. *MMWR Morbidity and Mortality Weekly Report, 62,* 591-595.

Centers for Disease Control and Prevention. (2015). 2015 Sexually transmitted diseases treatment guidelines: Anogenital warts. Retrieved from https://www.cdc.gov/std/tg2015/warts.htm

Centers for Disease Control and Prevention. (2017a). Human papillomavirus (HPV): Human papillomavirus (HPV) statistics. Retrieved from https://www.cdc.gov/std/hpv/stats.htm

Centers for Disease Control and Prevention. (2017b). Human papillomavirus (HPV): Vaccination schedules & recommendations. Retrieved from https://www.cdc.gov/hpv/hcp/schedules-recommendations.html

Centers for Disease Control and Prevention. (2018a, August). *Cancers associated with human papillomavirus, United States - 2011-2015* (USCS Data Brief No. 4). Retrieved from Centers for Disease Control and Prevention's website: https://www.cdc.gov/cancer/hpv/pdf/USCS-DataBrief-No4-August2018-508.pdf

Centers for Disease Control and Prevention. (2018b). *HPV and Cancer.* Retrieved from https://www.cdc.gov/cancer/hpv/statistics/cases.htm

Centers for Disease Control and Prevention. (2018c). *HPV vaccine courses: You are the key to HPV cancer prevention - 2018.* Retrieved from https://www.cdc.gov/vaccines/ed/hpv/index.html

Chesson, H. W., Ekwueme, D. U., Saraiya, M., Watson, M., Lowy, D. R., & Markowitz, L. E. (2012). Estimates of the annual direct medical costs of the prevention and treatment of disease associated with human papillomavirus in the United States. *Vaccine, 30*(42), 6016-6019. doi:10.1016/j.vaccine.2012.07.056

Dempsey, A. F., & O'Leary, S. T. (2018). Human papillomavirus vaccination: Narrative review of studies on how providers' vaccine communication affects attitudes and uptake. *Academic Pediatrics, 18*(2s), S23-s27. doi:10.1016/j.acap.2017.09.001

Dempsey, A. F., Pyrzanowski, J., Lockhart, S., Campagna, E., Barnard, J., & O'Leary, S. T. (2016). Parents' perceptions of provider communication regarding adolescent vaccines. *Human Vaccines & Immunotherapeutics, 12*(6), 1469-1475. doi:10.1080/21645515.2016.1147636

Dempsey, A. F., Pyrznawoski, J., Lockhart, S., Barnard, J., Campagna, E. J., Garrett, K., . . . O'Leary, S. T. (2018). Effect of a health care professional communication training intervention on adolescent human papillomavirus vaccination: A cluster randomized clinical trial. *JAMA Pediatrics, 172*(5), e180016. doi:10.1001/jamapediatrics.2018.0016

Dorell, C., Yankey, D., Kennedy, A., & Stokley, S. (2013). Factors that influence parental vaccination decisions for adolescents, 13 to 17 years old: National Immunization Survey-Teen, 2010. *Clinical Pediatrics (Phila), 52*(2), 162-170. doi:10.1177/0009922812468208

Fedewa, S. A., Preiss, A. J., Fisher-Borne, M., Goding Sauer, A., Jemal, A., & Saslow, D. (2018). Reaching 80% human papillomavirus vaccination prevalence by 2026: How many adolescents need to be vaccinated and what are their characteristics? *Cancer*. Advance online publication. doi:10.1002/cncr.31763

Flathead City-County Health Department, Kalispell Regional Healthcare, & North Valley Hospital. (2016). Flathead County Community Health Needs Assessment, 2015-2016. Retrieved from http://healthinfo.montana.edu/morh/Flathead-County-CHNA.pdf

Gilkey, M. B., Calo, W. A., Moss, J. L., Shah, P. D., Marciniak, M. W., & Brewer, N. T. (2016). Provider communication and HPV vaccination: The impact of recommendation quality. *Vaccine, 34*(9), 1187-1192. doi:10.1016/j.vaccine.2016.01.023

Gilkey, M. B., & McRee, A. L. (2016). Provider communication about HPV vaccination: A systematic review. *Human Vaccines & Immunotherapeutics, 12*(6), 1454-1468. doi:10.1080/21645515.2015.1129090

Gollust, S. E., LoRusso, S. M., Nagler, R. H., & Fowler, E. F. (2016). Understanding the role of the news media in HPV vaccine uptake in the United States: Synthesis and commentary. *Human Vaccines & Immunotherapeutics*, *12*(6), 1430-1434.

Healthy People 2020. (2018). Immunization and infectious disease. Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives

Healy, C. M., Montesinos, D. P., & Middleman, A. B. (2014). Parent and provider perspectives on immunization: Are providers overestimating parental concerns? *Vaccine, 32*(5), 579-584. doi:10.1016/j.vaccine.2013.11.076

Hofstetter, A. M., & Rosenthal, S. L. (2014). Factors impacting HPV vaccination: Lessons for health care professionals. *Expert Review of Vaccines, 13*(8), 1013-1026. doi:10.1586/14760584.2014.933076

Holman, D. M., Benard, V., Roland, K. B., Watson, M., Liddon, N., & Stokley, S. (2014). Barriers to human papillomavirus vaccination among US adolescents: A systematic review of the literature. *Journal of the American Medical Association Pediatrics, 168*(1), 76-82. doi:10.1001/jamapediatrics.2013.2752

Immunization Action Coalition. (n.d.). Dear colleague letter: Give a strong recommendation for HPV vaccine to increase uptake! Retrieved from http://www.immunize.org/letter/recommend_hpv_vaccination.pdf

Kann, L., McManus, T., Harris, W. A., Shanklin, S. L., Flint, K. H., Hawkins, J., . . . Zaza, S. (2016). Youth risk behavior surveillance - United States, 2015. *MMWR Surveillance Summaries, 65*(6), 1-174. doi:10.15585/mmwr.ss6506a1

Krantz, L., Ollberding, N. J., Beck, A. F., & Carol Burkhardt, M. (2018). Increasing HPV vaccination coverage through provider-based interventions. *Clinical Pediatrics, 57*(3), 319-326. doi:10.1177/0009922817722014

Lippitt, R., Watson, J., & Westley, B. (1958). *Dynamics of Planned Change.* New York, New York: Harcourt, Brace, & Company.

Machalek, D. A., Garland, S. M., Brotherton, J. M. L., Bateson, D., McNamee, K., Stewart, M., . . . Tabrizi, S. N. (2018). Very low prevalence of vaccine human papillomavirus types among 18- to 35-year old Australian women 9 years following implementation of vaccination. *Journal of Infectious Diseases, 217*(10), 1590-1600. doi:10.1093/infdis/jiy075

Markowitz, L. E., Dunne, E. F., Saraiya, M., Chesson, H. W., Curtis, C. R., Gee, J., . . . Unger, E. R. (2014). Human papillomavirus vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recommendations and Reports, 63*(Rr-05), 1-30.

Markowitz, L. E., Gee, J., Chesson, H., & Stokley, S. (2018). Ten years of human papillomavirus vaccination in the United States. *Academic Pediatrics, 18*(2s), S3-S10. doi:10.1016/j.acap.2017.09.014

Meites, E., Kempe, A., & Markowitz, L. E. (2016). Use of a 2-dose schedule for human papillomavirus vaccination - Updated recommendations of the Advisory Committee on Immunization Practices. *MMWR Morbidity and Mortality Weekly Report, 65*(49), 1405-1408. doi:10.15585/mmwr.mm6549a5

Mitchell, G. (2013). Selecting the best theory to implement planned change. *Nursing Management, 20*(1), 32-37.

Montana Department of Health and Human Services, Chronic Disease Prevention & Health Promotion Bureau. (n.d.). Montana Cancer Coalition: *Montana comprehensive cancer control plan 2016-2021*. Retrieved from ftp://ftp.cdc.gov/pub/Publications/Cancer/ccc/montana_ccc_plan.pdf

Montana Department of Public Health and Human Services. (2017). HPV vaccination algorithm. Retrieved from https://dphhs.mt.gov/Portals/85/publichealth/documents/Immunization/2017/HPV algorithm.pdf

Montana Immunization Program. (2018). 5 Reasons to get HPV vaccine for your child. Retrieved from https://dphhs.mt.gov/Portals/85/publichealth/documents/CDEpi/Infographics/HPVVaccination08242018.pdf

Moran, K. & Burson, R. (2017). The phenomenon of interest. In K. Moran, R. Burson, & D. Conrad (Eds*.), The Doctor of Nursing Practice scholarly project: A framework for success* (pp. 87-112). Burlington, MA: Jones & Bartlett.

National Center for Health Statistics. (2018). Stats of the state of Montana. Retrieved from https://www.cdc.gov/nchs/pressroom/states/montana/montana.htm

National Conference of State Legislatures. (2018). HPV vaccine: State legislation and statutes. Retrieved from http://www.ncsl.org/research/health/hpv-vaccine-state-legislation-and-statutes.aspx

Newman, P. A., Logie, C. H., Lacombe-Duncan, A., Baiden, P., Tepjan, S., Rubincam, C., Doukas, N., … Asey, F. (2018). Parents' uptake of human papillomavirus vaccines for their children: A systematic review and meta-analysis of observational studies. *BMJ Open*, *8*(4), e019206. doi:10.1136/bmjopen-2017-019206

Ogilvie, G. S., Phan, F., Pedersen, H. N., Dobson, S. R., Naus, M., & Saewyc, E. M. (2018). Population-level sexual behaviours in adolescent girls before and after introduction of the human papillomavirus vaccine (2003–2013). *Canadian Medical Association Journal, 190*(41), E1221-E1226. doi:10.1503/cmaj.180628

O'Leary, S., Pyrzanowski, J., Lockhart, S., Barnard, J., Campagna, E., Garrett, K., . . . Dempsey, A. (2017). Impact of a provider communication training intervention on adolescent human papillomavirus vaccination: A cluster randomized, clinical trial. *Open Forum Infectious Diseases, 4*(Suppl1), S61.

Opel, D. J., Heritage, J., Taylor, J. A., Mangione-Smith, R., Salas, H. S., DeVere, V., . . . Robinson, J. D. (2013). The architecture of provider-parent vaccine discussions at health supervision visits. *Pediatrics, 132*(6), 1037-1046. doi:10.1542/peds.2013-2037

Owsianka, B., & Ganczak, M. (2015). Evaluation of human papilloma virus (HPV) vaccination strategies and vaccination coverage in adolescent girls worldwide. *Przegl Epidemiol, 69*(1), 53-58.

Perkins, R. B., & Clark, J. A. (2013). Providers' perceptions of parental concerns about HPV vaccination. *Journal of Health Care for the Poor and Underserved, 24*(2), 828-839. doi:10.1353/hpu.2013.0080

Perkins, R. B., Zisblatt, L., Legler, A., Trucks, E., Hanchate, A., & Gorin, S. S. (2015). Effectiveness of a provider-focused intervention to improve HPV vaccination rates in boys and girls. *Vaccine, 33*(9), 1223-1229. doi:10.1016/j.vaccine.2014.11.021

Rand, C. M., & Goldstein, N. P. N. (2018). Patterns of primary care physician visits for US adolescents in 2014: Implications for vaccination. *Academic Pediatrics, 18*(2s), S72-s78. doi:10.1016/j.acap.2018.01.002

Reagan-Steiner, S., Yankey, D., Jeyarajah, J., Elam-Evans, L. D., Singleton, J. A., Curtis, C. R., … Stokley, S. (2015). National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 years — United States, 2014. *MMWR Morbidity and Mortality Weekly Report*, *64*(29), 784–792.

Reagan-Steiner, S., Yankey, D., Jeyarajah, J., Elam-Evans, L. D., Curtis, C. R., MacNeil, J., . . . Singleton, J. A. (2016). National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 years — United States, 2015. MMWR Morbidity and Mortality Weekly Report, 65(3), 850–858. doi:10.15585/mmwr.mm6533a4

Rosen, B. L., Shepard, A., & Kahn, J. A. (2018). US health care clinicians' knowledge, attitudes, and practices regarding human papillomavirus vaccination: A qualitative systematic review. *Academic Pediatrics, 18*(2), S53-S65. doi:10.1016/j.acap.2017.10.007

Rutten, L. J. F., St. Sauver, J. L., Beebe, T. J., Wilson, P. M., Jacobson, D. J., Fan, C., . . . Jacobson, R. M. (2017). Clinician knowledge, clinician barriers, and perceived parental barriers regarding human papillomavirus vaccination: Association with initiation and completion rates. *Vaccine, 35*(1), 164-169. doi:10.1016/j.vaccine.2016.11.012

Sandri, K. J., Verdenius, I., Bartley, M. J., Else, B. M., Paynter, C. A., Rosemergey, B. E., . . . Harper, D. M. (2014). Urban and rural safety net health care system clinics: No disparity in HPV4 vaccine completion rates. *PLoS One, 9*(5), e96277. doi:10.1371/journal.pone.0096277

Saraiya, M., Unger, E. R., Thompson, T. D., Lynch, C. F., Hernandez, B. Y., Lyu, C. W., . . . Goodman, M. T. (2015). U.S. assessment of HPV types in cancers: Implications for current and 9-valent HPV vaccines. *Journal of the National Cancer Institute, 107*(6), djv086. doi:10.1093/jnci/djv086

Saslow, D., & Perkins, R. (2018, October 12). Approved expansion of HPV vaccination to age 45: What does it mean? [Webinar]. In *National HPV Vaccination Roundtable.* Retrieved from http://hpvroundtable.org/resource-library/#filter=.hpv-roundtable-product

Shay, L. A., Street, R. L., Baldwin, A. S., Marks, E. G., Lee, S. C., Higashi, R. T., . . . Tiro, J. A. (2016). Characterizing safety-net providers' HPV vaccine recommendations to undecided parents: A pilot study. *Patient Education and Counseling, 99*(9), 1452-1460. doi:10.1016/j.pec.2016.06.027

Shin P. (2016). The health care safety net: Community health centers' vital role. *The National Institute for Health Care Management,* Washington, D.C. https://www.nihcm.org/categories/the-health-safety-net-community-health-centers-vital-role

Sonawane, K., Suk, R., Chiao, E. Y., Chhatwal, J., Qiu, P., Wilkin, T., . . . Deshmukh, A. A. (2017). Oral human papillomavirus infection: Differences in prevalence between sexes and concordance with genital human papillomavirus infection, NHANES 2011 to 2014. *Annals of Internal Medicine, 167*(10), 714-724. doi:10.7326/m17-1363

Thompson, E. L., Rosen, B. L., Vamos, C. A., Kadono, M., & Daley, E. M. (2017). Human papillomavirus vaccination: What are the reasons for nonvaccination among U.S. adolescents? *Journal of Adolescent Health, 61*(3), 288-293. doi:10.1016/j.jadohealth.2017.05.015

U. S. Department of Health and Human Services, National Institute on Deafness and Other Communication Disorders. (2017). *NIDCD fact sheet - Voice, speech, and language: Recurrent respiratory papillomatosis or laryngeal papillomatosis* (NIH Publication No. 10-4214). Retrieved from https://www.nidcd.nih.gov/sites/default/files/Documents/health/voice/RecurrentRespiratoryPapillomatosis.pdf

U. S. Department of Health and Human Services, U. S. Food & Drug Administration. (2018). *FDA approves expanded use of Gardasil 9 to include individuals 27 through 45 years old* (Press Release). Retrieved from https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622715.htm

Van Dyne, E. A., Henley, S. J., Saraiya, M., Thomas, C. C., Markowitz, L. E., & Benard, V. B. (2018). Trends in human papillomavirus–associated cancers — United States, 1999–2015. *MMWR Morbidity and Mortality Weekly Report, 67*(33), 918–924. doi:10.15585/mmwr.mm6733a2

Walker, T. Y., Elam-Evans, L. D., Singleton, J. A., Yankey, D., Markowitz, L. E., Fredua, B., … Stokley, S. (2017). National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 Years — United States, 2016. MMWR *Morbidity and Mortality Weekly Report, 66*(33), 874–882. doi:10.15585/mmwr.mm6633a2

Walker, T. Y., Elam-Evans, L. D., Yankey, D., Markowitz, L. E., Williams, C. L., Mbaeyi, S. A., … Stokley, S. (2018). National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 years — United States, 2017. MMWR *Morbidity and Mortality Weekly Report,* 67(33), 909–917. doi:10.15585/mmwr.mm6733a1

Winer, R. L., Hughes, J. P., Feng, Q., O'Reilly, S., Kiviat, N. B., Holmes, K. K., & Koutsky, L. A. (2006). Condom use and the risk of genital human papillomavirus infection in young women. *New England Journal of Medicine, 354*(25), 2645-2654. doi:10.1056/NEJMoa053284

Wong, C. A., Berkowitz, Z., Dorell, C. G., Anhang Price, R., Lee, J., & Saraiya, M. (2011). Human papillomavirus vaccine uptake among 9- to 17-year-old girls: National Health Interview Survey, 2008. *Cancer, 117*(24), 5612-5620. doi:10.1002/cncr.26246

World Health Organization. (2018). Human papillomavirus (HPV) and cervical cancer. Retrieved from http://www.who.int/news-room/fact-sheets/detail/human-papillomavirus-(hpv)-and-cervical-cancer

APPENDICES

APPENDIX A

COMPILATION OF TDAP, MCV, AND HPV IMMUNIZATIONS FROM THE NATIONAL IMMUNIZATION, SURVEY – TEEN AND FLATHEAD CITY-COUNTY HEALTH DEPARTMENT'S (FCCHD) IMMUNIZATION CLINIC

National Immunization Survey, Teen (NIS-Teen):
Rates of Tdap, MCV, and HPV Immunizations

2014

	All Adolescents (n = 20,827)			Females (n = 10,084)			Males (n = 10,743)	
	≥1 Tdap	≥1 MCV	≥1 HPV	≥2 HPV	≥3 HPV	≥1 HPV	≥2 HPV	≥3 HPV
U.S. Overall 13-17 yrs. old	87.6%	79.3%	60.0%	50.3%	39.7%	41.7%	31.4%	21.6%
Montana 13-17 yrs. old	84.7%	60.2%	57.2%	51.0%	42.9%	33.3%	19.1%	13%

2015

	All Adolescents (n = 21,875)			Females (n = 10,508)			Males (n = 11,367)	
	≥1 Tdap	≥1 MCV	≥1 HPV	≥2 HPV	≥3 HPV	≥1 HPV	≥2 HPV	≥3 HPV
U.S. Overall 13-17 yrs. old	86.4%	81.3%	62.8%	52.2%	41.9%	49.8%	39%	28%
Montana 13-17 yrs. old	89.5%	65.8%	55.0%	41.8%	34.8%	46.0%	33.3%	21.7%

2016

	All Adolescents (n = 20,475)				Females (n = 9,661)		Males (n = 10,814)	
	≥1 Tdap	≥1 MCV	≥1 HPV	HPV UTD	≥1 HPV	HPV UTD	≥1 HPV	HPV UTD
U.S. Overall 13-17 yrs. old	88%	82.2%	60.4%	43.4%	65.1%	49.5%	56.0%	37.5%
Montana 13-17 yrs. old	85.7%	67.6%	55.3%	39.9%	68.2%	52.5%	43.0%	27.9%

2017

	All Adolescents (n = 20,949)				Females (n = 9,845)		Males (n = 11,104)	
	≥1 Tdap	≥1 MCV	≥1 HPV	HPV UTD	≥1 HPV	HPV UTD	≥1 HPV	HPV UTD
U.S. Overall 13-17 yrs. old	88.7%	85.1%	65.5%	48.6%	68.6%	53.1%	62.6%	44.3%
Montana 13-17 yrs. old	90.4%	71.2%	65.5%	49.1%	64.5%	50.1%	66.4%	48.1%

n = 1553

FCCHD Immunization Clinic 13-15 yrs. old As of 8/7/17	73%	29%	26%	14%	n/a	n/a	n/a	n/a

2018
(NIS-Teen not yet available)

	All Adolescents				**Females**		**Males**	
	≥1 Tdap	**≥1 MCV**	**≥1 HPV**	**HPV UTD**	**≥1 HPV**	**HPV UTD**	**≥1 HPV**	**HPV UTD**
U.S. Overall 13-17 yrs. old	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Montana 13-17 yrs. old	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

n = 1524

FCCHD Immunization Clinic 13-15 yrs. old As of 8/7/18	75%	33%	32%	17%	n/a	n/a	n/a	n/a

APPENDIX B

MONTANA STATE UNIVERISTY – IRB APPROVAL

MONTANA STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD

For the Protection of Human Subjects
FWA 00000165

960 Technology Blvd. Room 127
c/o Microbiology & Immunology
Montana State University
Bozeman, MT 59718
Telephone: 406-994-6783
FAX: 406-994-4303
E-mail: cherylj@montana.edu

Chair: Mark Quinn
406-994-4707
mquinn@montana.edu
Administrator:
Cheryl Johnson
406-994-4706
cherylj@montana.edu

MEMORANDUM

TO: Kelli McLoughlin and Jennifer Sofie

FROM: Mark Quinn Mark Quinn Chj
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: March 19, 2018

RE: *"Framing HPV Vaccination Conversations between Health Care Providers, Parents, and Patients to Increase HPV Vaccination Using the CFC's Evidence-based 'You Are the Key' Campaign"* [KM031918-EX]

The above research, described in your submission of March 19, 2018, is exempt from the requirement of review by the Institutional Review Board in accordance with the Code of Federal regulations, Part 46, section 101. The specific paragraph which applies to your research is:

____ (b) (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

__X__ (b) (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

____ (b) (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

____ (b) (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

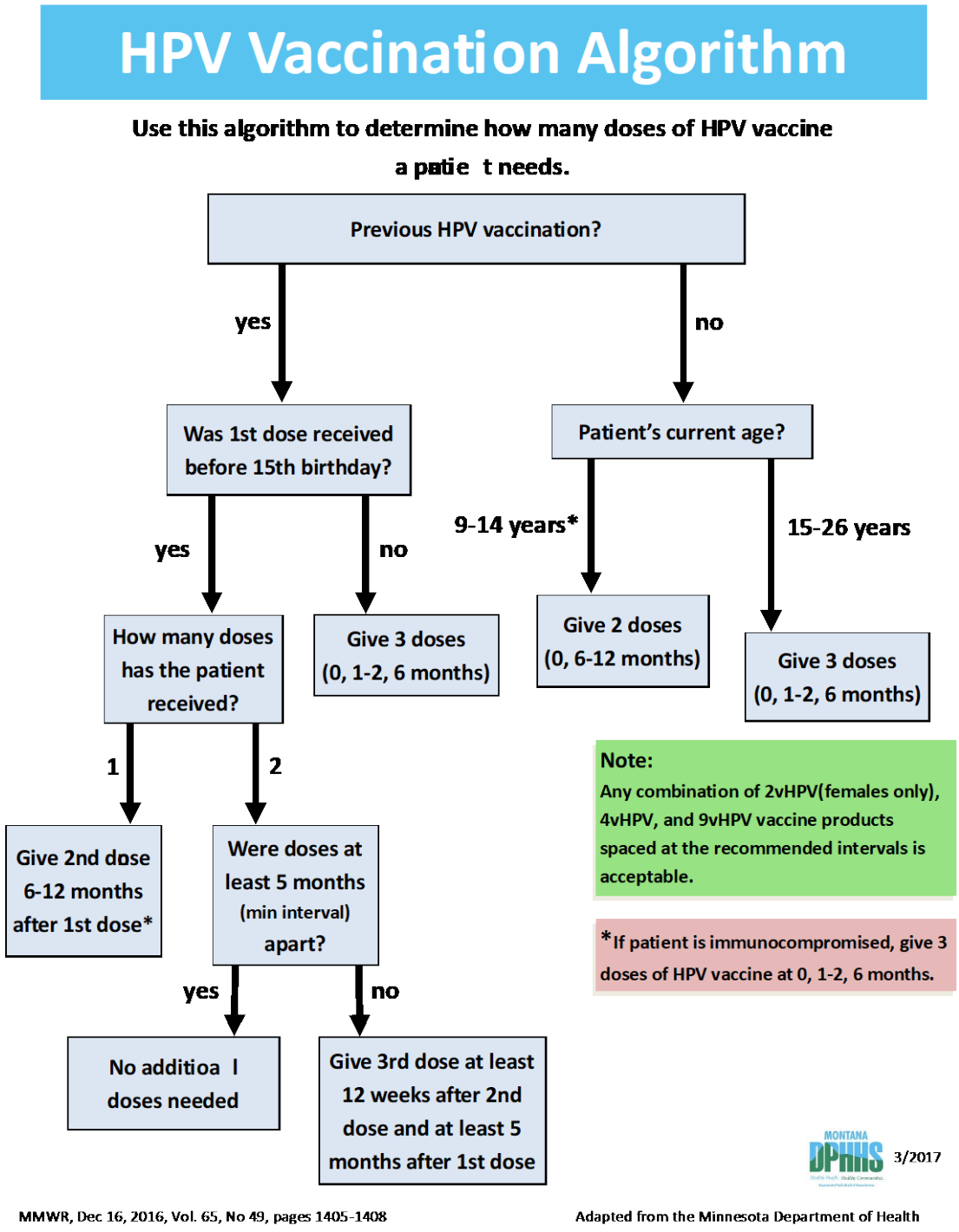
____ (b) (5) Research and demonstration projects, which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

____ (b) (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA, or approved by the EPA, or the Food Safety and Inspection Service of the USDA.

Although review by the Institutional Review Board is not required for the above research, the Committee will be glad to review it. If you wish a review and committee approval, please submit 3 copies of the usual application form and it will be processed by expedited review.

APPENDIX C

HPV VACCINATION ALGORITHM



(Montana Department of Public Health and Human Services, 2017)

APPENDIX D

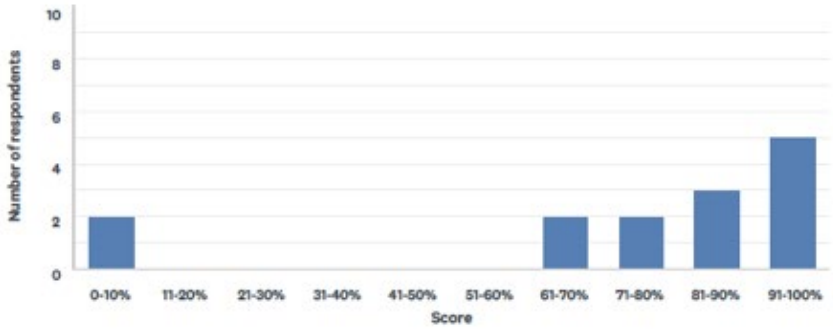
PRE-INTERVENTION SURVEY RESULTS

Pre-Intervention Survey Results

Quiz Summary

AVERAGE SCORE

85% • 11.1/13 PTS



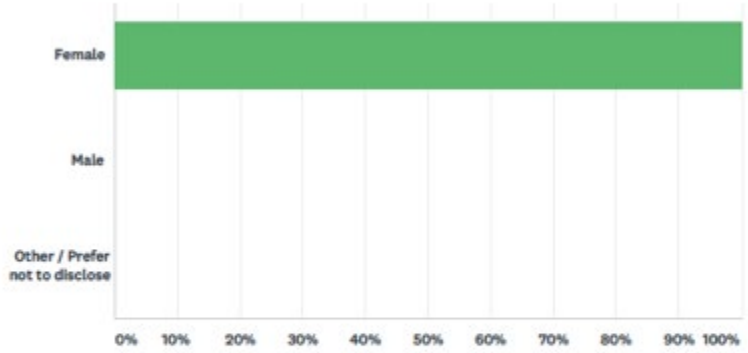
STATISTICS		
Lowest Score 69%	Median 85%	Highest Score 100%
Mean: 85%		
Standard Deviation: 11%		

Question Ranking

QUESTIONS (9)	DIFFICULTY	AVERAGE SCORE
Q9 Genital warts are caused by the same HPV types that cause cervical cancer.	1	42%
Q10 The incidence of HPV is highest among women in their 30's.	2	67%
Q5 Almost everyone that is sexually active will contract HPV at some point in their lives.	3	83%
Q7 Condoms are one way to fully prevent the spread of HPV.	3	83%
Q13 Please select all of the types of cancer that have been linked to HPV:	5	88%
Q8 Almost all cervical cancers are caused by HPV infection.	6	92%
Q11 Sexually active adolescents should be tested for HPV before starting HPV vaccination.	7	100%
Q6 Most people that have HPV are symptomatic.	7	100%
Q12 The HPV vaccination series should be started after an adolescent becomes sexually active.	7	100%

Q1 I identify my sex as:

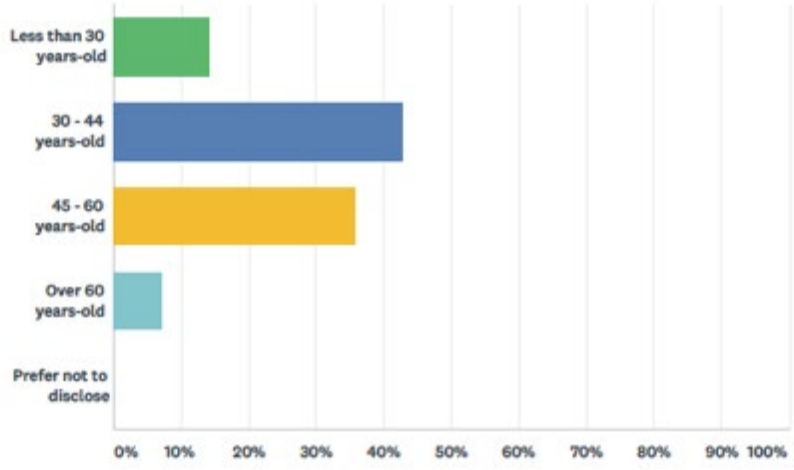
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Female	100.00%	14
Male	0.00%	0
Other / Prefer not to disclose	0.00%	0
TOTAL		14

Q2 What is your age?

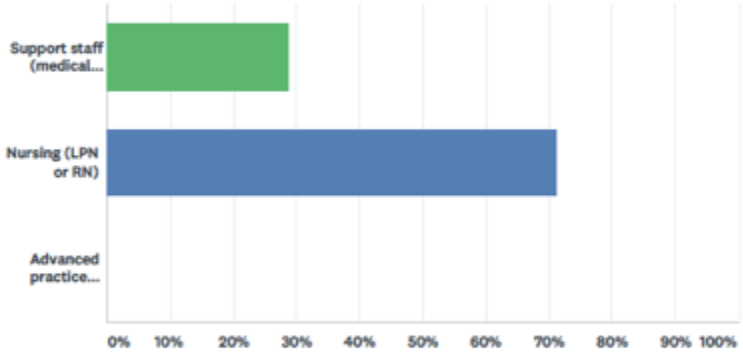
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Less than 30 years-old	14.29%	2
30 - 44 years-old	42.86%	6
45 - 60 years-old	35.71%	5
Over 60 years-old	7.14%	1
Prefer not to disclose	0.00%	0
TOTAL		14

Q3 What is your job role?For more than one role, please indicate your role in the setting in which you received the survey (i.e. at clinical rotation as graduate student, please select graduate student).

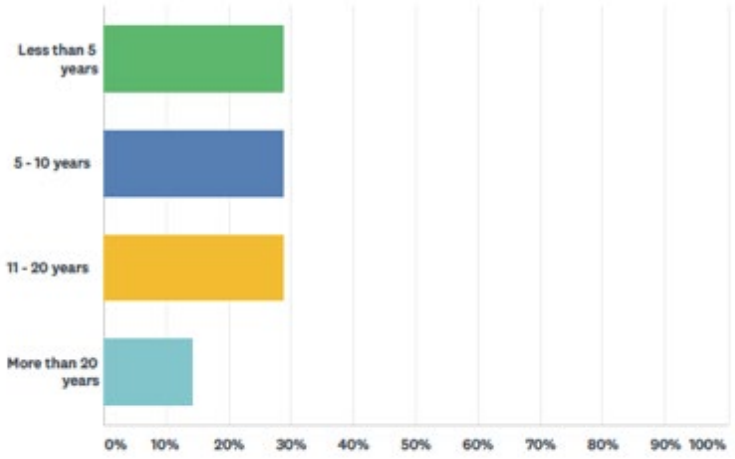
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Support staff (medical assistant, certified nursing assistant or aid, front desk,administrative, laboratory, undergraduate student, or other)	28.57%	4
Nursing (LPN or RN)	71.43%	10
Advanced practice provider (graduate student, medical resident, advanced practice registered nurse, clinical nurse specialist, nurse practitioner, medical doctor, physician)	0.00%	0
TOTAL		14

Q4 How many years have you practiced in this role?

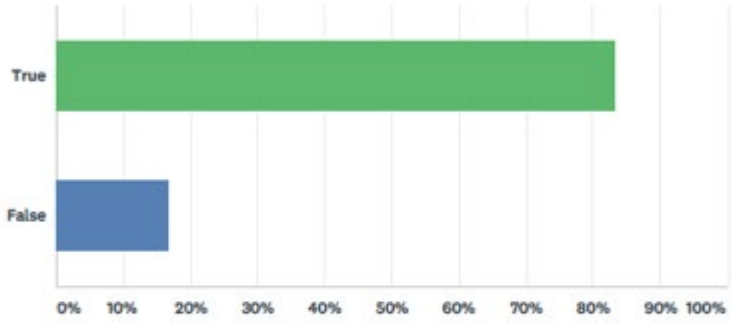
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Less than 5 years	28.57%	4
5 - 10 years	28.57%	4
11 - 20 years	28.57%	4
More than 20 years	14.29%	2
TOTAL		14

Q5 Almost everyone that is sexually active will contract HPV at some point in their lives.

Answered: 12 Skipped: 2

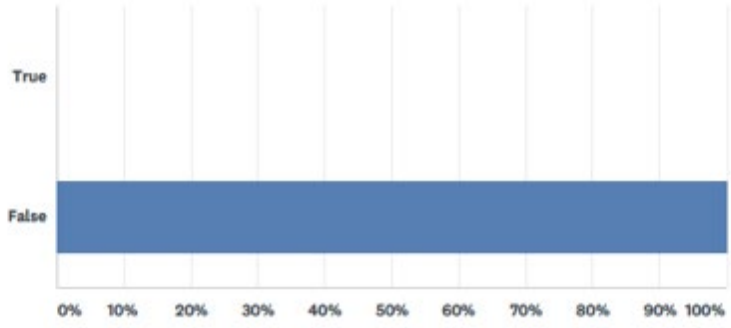


QUIZ STATISTICS			
Percent Correct 71%	Average Score 0.8/1.0 (83%)	Standard Deviation 0.39	Difficulty 3/9

ANSWER CHOICES	SCORE	RESPONSES	
✓ True	1/1	83.33%	10
False	0/1	16.67%	2
TOTAL			12

Q6 Most people that have HPV are symptomatic.

Answered: 12 Skipped: 2

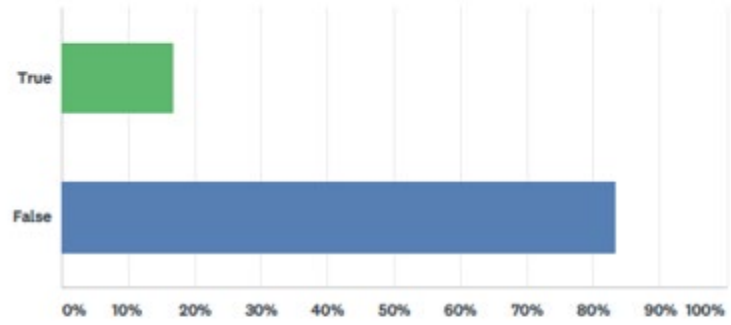


QUIZ STATISTICS			
Percent Correct 86%	Average Score 1.0/1.0 (100%)	Standard Deviation 0.00	Difficulty 7/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	0.00%	0
✓ False	1/1	100.00%	12
TOTAL			12

Q7 Condoms are one way to fully prevent the spread of HPV.

Answered: 12 Skipped: 2

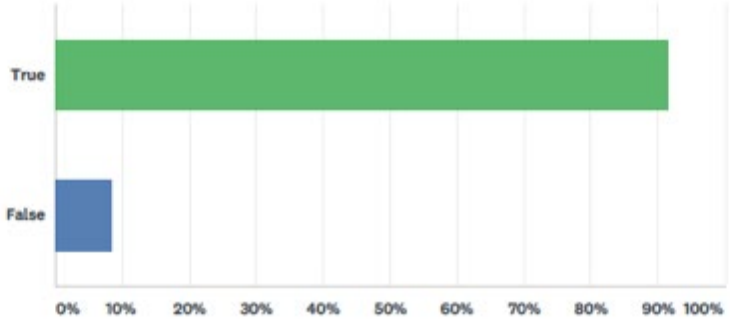


QUIZ STATISTICS			
Percent Correct 71%	Average Score 0.8/1.0 (83%)	Standard Deviation 0.39	Difficulty 3/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	16.67%	2
✓ False	1/1	83.33%	10
TOTAL			12

Q8 Almost all cervical cancers are caused by HPV infection.

Answered: 12 Skipped: 2

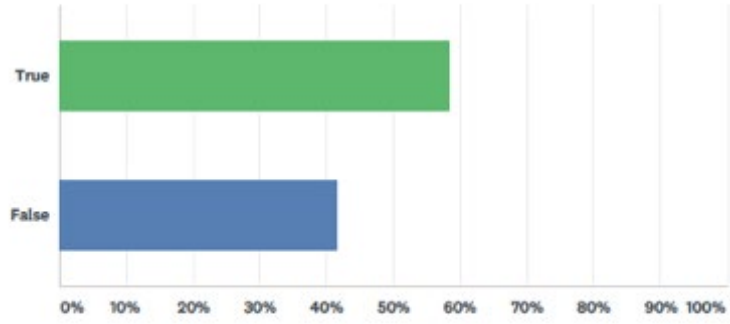


QUIZ STATISTICS			
Percent Correct 79%	Average Score 0.9/1.0 (92%)	Standard Deviation 0.29	Difficulty 6/9

ANSWER CHOICES	SCORE	RESPONSES	
✓ True	1/1	91.67%	11
False	0/1	8.33%	1
TOTAL			12

Q9 Genital warts are caused by the same HPV types that cause cervical cancer.

Answered: 12 Skipped: 2

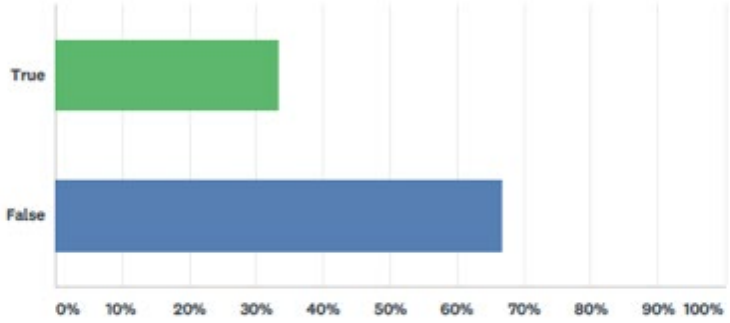


QUIZ STATISTICS			
Percent Correct 36%	Average Score 0.4/1.0 (42%)	Standard Deviation 0.51	Difficulty 1/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	58.33%	7
✓ False	1/1	41.67%	5
TOTAL			12

Q10 The incidence of HPV is highest among women in their 30's.

Answered: 12 Skipped: 2

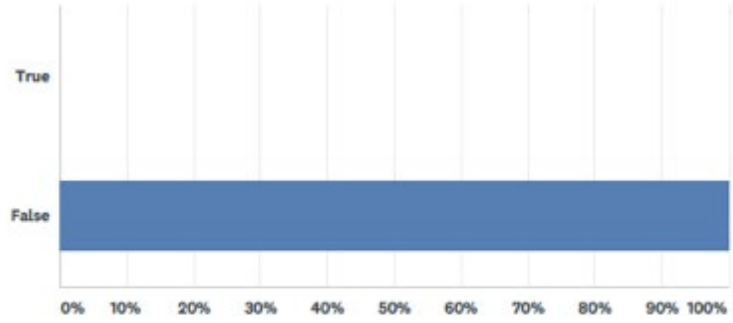


QUIZ STATISTICS			
Percent Correct 57%	Average Score 0.7/1.0 (67%)	Standard Deviation 0.49	Difficulty 2/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	33.33%	4
✓ False	1/1	66.67%	8
TOTAL			12

Q11 Sexually active adolescents should be tested for HPV before starting HPV vaccination.

Answered: 12 Skipped: 2

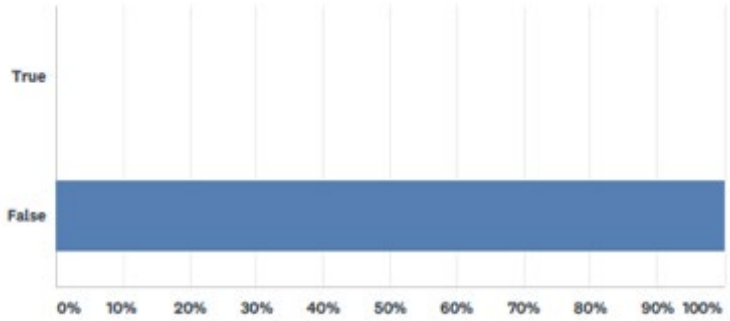


QUIZ STATISTICS			
Percent Correct 86%	Average Score 1.0/1.0 (100%)	Standard Deviation 0.00	Difficulty 7/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	0.00%	0
✓ False	1/1	100.00%	12
TOTAL			12

Q12 The HPV vaccination series should be started after an adolescent becomes sexually active.

Answered: 12 Skipped: 2

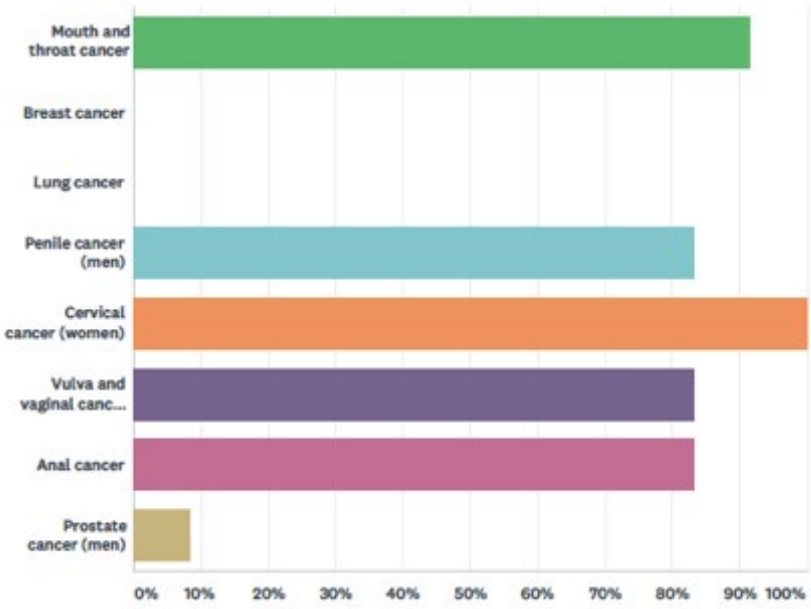


QUIZ STATISTICS			
Percent Correct 86%	Average Score 1.0/1.0 (100%)	Standard Deviation 0.00	Difficulty 7/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	0.00%	0
✓ False	1/1	100.00%	12
TOTAL			12

Q13 Please select all of the types of cancer that have been linked to HPV:

Answered: 12 Skipped: 2

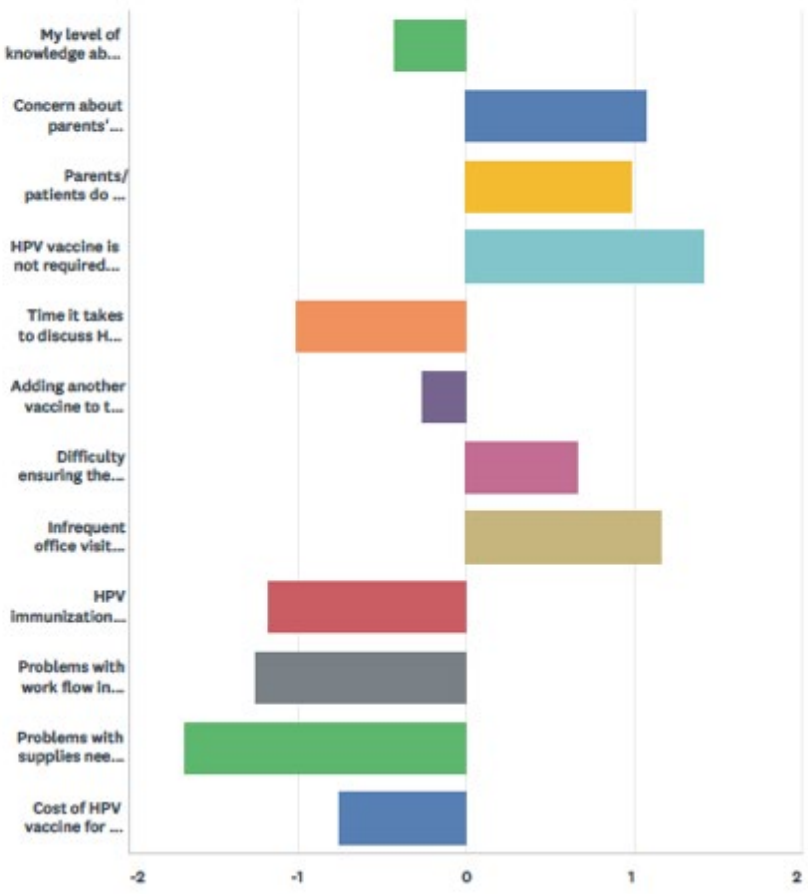


QUIZ STATISTICS			
Percent Correct 64%	Average Score 4.4/5.0 (88%)	Standard Deviation 1.16	Difficulty 5/9

ANSWER CHOICES	SCORE	RESPONSES	
✓ Mouth and throat cancer	1/5	91.67%	11
Breast cancer	0/5	0.00%	0
Lung cancer	0/5	0.00%	0
✓ Penile cancer (men)	1/5	83.33%	10
✓ Cervical cancer (women)	1/5	100.00%	12
✓ Vulva and vaginal cancer (women)	1/5	83.33%	10
✓ Anal cancer	1/5	83.33%	10
Prostate cancer (men)	0/5	8.33%	1
Total Respondents: 12			

Q14 To what extent do you feel the following represent barriers to HPV immunization?

Answered: 12 Skipped: 2

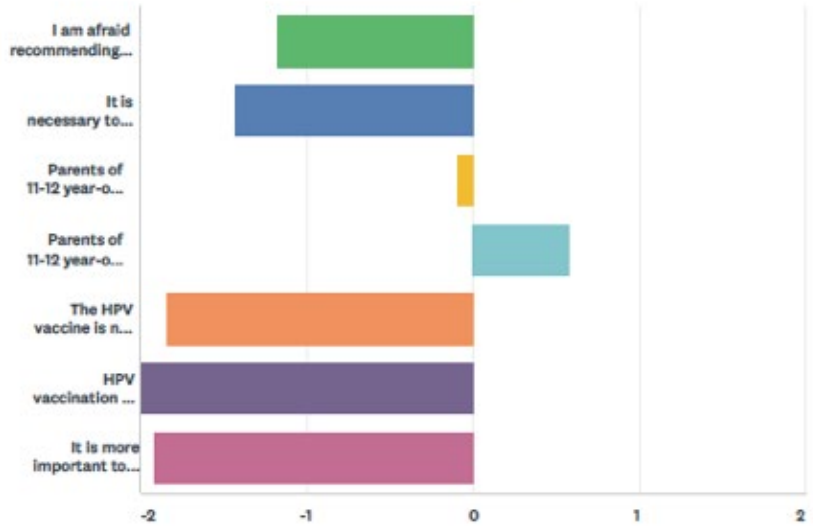


	NOT A BARRIER AT ALL	A MINOR BARRIER	SOMEWHAT OF A BARRIER	A MAJOR BARRIER	UNKNOWN / UNSURE	TOTAL	WEIGHTED AVERAGE
My level of knowledge about HPV	33.33% 4	25.00% 3	33.33% 4	8.33% 1	0.00% 0	12	-0.42
Concern about parents' negative perceptions about HPV vaccine	8.33% 1	8.33% 1	33.33% 4	50.00% 6	0.00% 0	12	1.08
Parents/ patients do not understand the link between HPV and cancer	0.00% 0	25.00% 3	25.00% 3	50.00% 6	0.00% 0	12	1.00
HPV vaccine is not required for school attendance	0.00% 0	8.33% 1	16.67% 2	66.67% 8	8.33% 1	12	1.42

Time it takes to discuss HPV vaccine with patients and parents	33.33% 4	50.00% 6	16.67% 2	0.00% 0	0.00% 0	12	-1.00
Adding another vaccine to the vaccination schedule	16.67% 2	41.67% 5	33.33% 4	8.33% 1	0.00% 0	12	-0.25
Difficulty ensuring the patient will complete the 2 or 3 dose HPV vaccine series	8.33% 1	25.00% 3	25.00% 3	41.67% 5	0.00% 0	12	0.67
Infrequent office visits made by adolescent patients	8.33% 1	8.33% 1	25.00% 3	58.33% 7	0.00% 0	12	1.17
HPV immunization is not a priority in my work setting	58.33% 7	25.00% 3	8.33% 1	8.33% 1	0.00% 0	12	-1.17
Problems with work flow in my work setting	58.33% 7	25.00% 3	16.67% 2	0.00% 0	0.00% 0	12	-1.25
Problems with supplies needed for immunization in my work setting	83.33% 10	8.33% 1	8.33% 1	0.00% 0	0.00% 0	12	-1.67
Cost of HPV vaccine for the patient or my work setting	25.00% 3	50.00% 6	25.00% 3	0.00% 0	0.00% 0	12	-0.75

Q15 Please indicate your belief concerning the following statements:

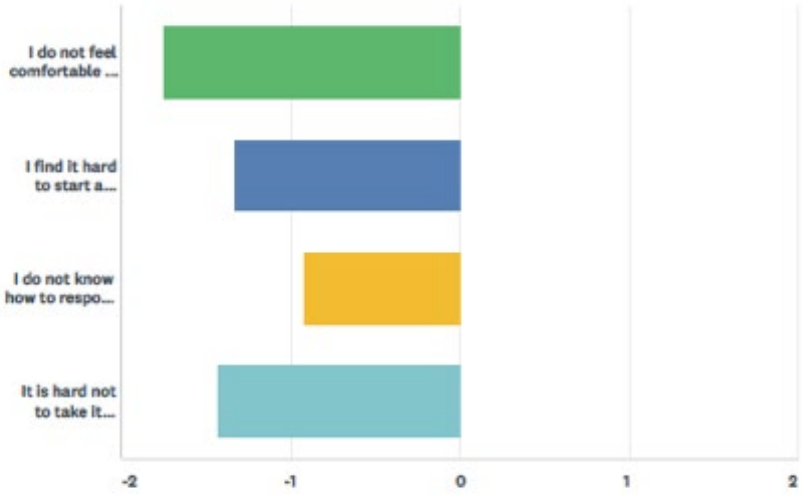
Answered: 12 Skipped: 2



	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE	UNKNOWN / UNSURE	TOTAL	WEIGHTED AVERAGE
I am afraid recommending HPV vaccination will ruin my rapport with patients and/or patients' parents.	0.00% 0	8.33% 1	58.33% 7	33.33% 4	0.00% 0	12	-1.17
It is necessary to discuss sexual activity before recommending the HPV vaccine to patients.	0.00% 0	8.33% 1	33.33% 4	58.33% 7	0.00% 0	12	-1.42
Parents of 11-12 year-old patients have been upset that I am offering a vaccine against a sexually transmitted infection in someone 11-12 years-old.	16.67% 2	33.33% 4	25.00% 3	25.00% 3	0.00% 0	12	-0.08
Parents of 11-12 year-old patients have been more likely to refuse or defer HPV vaccination than parents of older adolescents.	25.00% 3	33.33% 4	25.00% 3	0.00% 0	16.67% 2	12	0.58
The HPV vaccine is not safe.	0.00% 0	0.00% 0	16.67% 2	83.33% 10	0.00% 0	12	-1.83
HPV vaccination may encourage earlier or riskier sexual behavior.	0.00% 0	0.00% 0	0.00% 0	100.00% 12	0.00% 0	12	-2.00
It is more important to prioritize HPV immunization for females vs. males.	0.00% 0	0.00% 0	8.33% 1	91.67% 11	0.00% 0	12	-1.92

Q16 Please indicate the level in which you agree with the following statements:

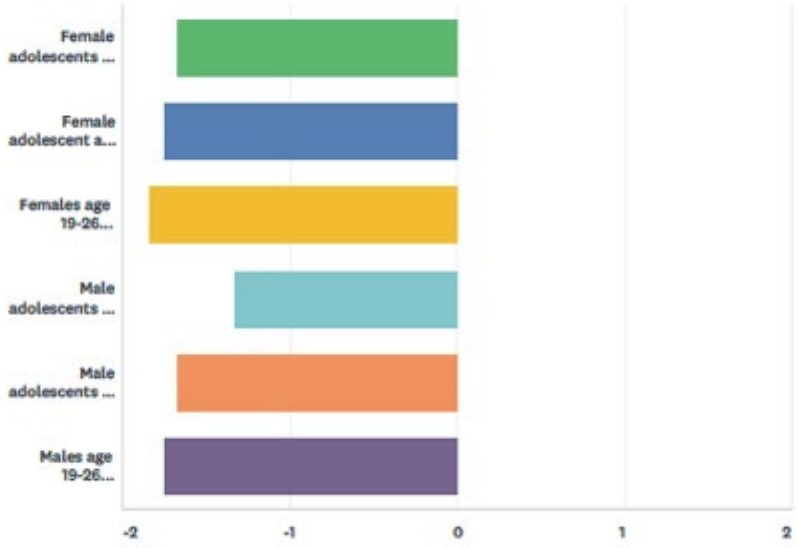
Answered: 12 Skipped: 2



	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE	UNKNOWN / UNSURE	TOTAL	WEIGHTED AVERAGE
I do not feel comfortable or confident recommending the HPV vaccine.	0.00% 0	0.00% 0	25.00% 3	75.00% 9	0.00% 0	12	-1.75
I find it hard to start a conversation about HPV vaccination.	0.00% 0	8.33% 1	25.00% 3	58.33% 7	8.33% 1	12	-1.33
I do not know how to respond when a parent or patient refuses or defers HPV vaccination.	8.33% 1	8.33% 1	50.00% 6	33.33% 4	0.00% 0	12	-0.92
It is hard not to take it personally when I recommend the HPV vaccine and it is refused.	0.00% 0	16.67% 2	8.33% 1	75.00% 9	0.00% 0	12	-1.42

Q17 I feel comfortable and confident recommending the HPV vaccine for:

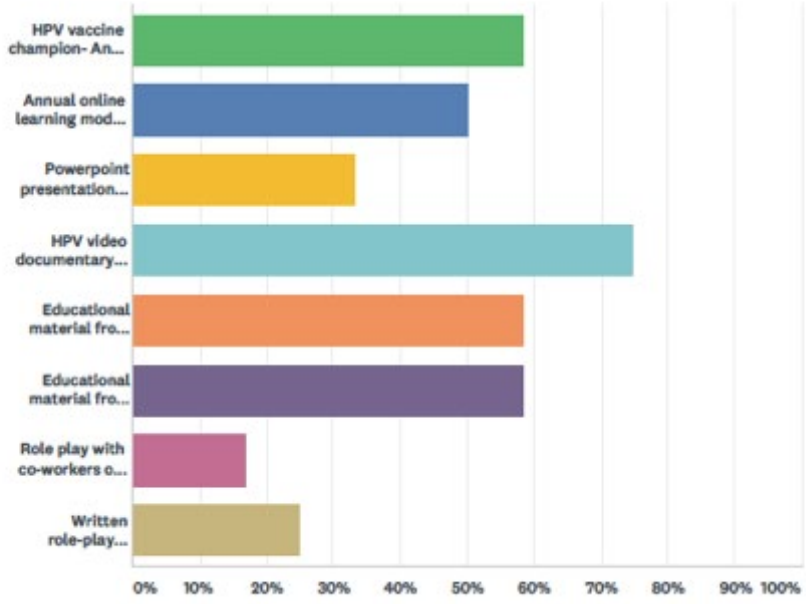
Answered: 12 Skipped: 2



	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE	UNKNOWN / UNSURE	TOTAL	WEIGHTED AVERAGE
Female adolescents age 11-12 years-old.	66.67% 8	33.33% 4	0.00% 0	0.00% 0	0.00% 0	12	-1.67
Female adolescent ages 13-26 years-old.	75.00% 9	25.00% 3	0.00% 0	0.00% 0	0.00% 0	12	-1.75
Females age 19-26 years-old.	83.33% 10	16.67% 2	0.00% 0	0.00% 0	0.00% 0	12	-1.83
Male adolescents age 11-12 years-old.	58.33% 7	25.00% 3	8.33% 1	0.00% 0	8.33% 1	12	-1.33
Male adolescents age 13-26 years-old.	66.67% 8	33.33% 4	0.00% 0	0.00% 0	0.00% 0	12	-1.67
Males age 19-26 years-old.	75.00% 9	25.00% 3	0.00% 0	0.00% 0	0.00% 0	12	-1.75

Q18 What would most support you in making a strong recommendation for HPV vaccination in your work setting? (Select all that apply)

Answered: 12 Skipped: 2



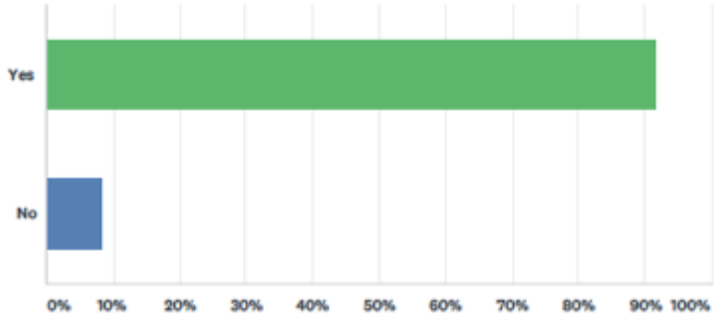
ANSWER CHOICES	RESPONSES	
HPV vaccine champion- An identified individual in your work setting who is knowledgeable, supportive, and a resource to others concerning HPV vaccination	58.33%	7
Annual online learning module on HPV vaccination strategies	50.00%	6
Powerpoint presentation on HPV vaccination strategies	33.33%	4
HPV video documentary with CME / CNE offering- Illustrates the effects of HPV in the lives of real people with HPV and HPV associated cancers - (80 minutes)	75.00%	9
Educational material from the Centers for Disease Control and Prevention (CDC) for providers	58.33%	7
Educational material from the CDC for patients	58.33%	7
Role play with co-workers on how to frame HPV vaccination conversations	16.67%	2
Written role-play script for me to read on how to frame HPV vaccination conversations	25.00%	3
Total Respondents: 12		

#	OTHER: (FREE TEXT)	DATE

1	I feel very comfortable talking about HPV and recommending the vaccine. I think a community event would be a great way to spread information to providers (offer cont. education credit) and most importantly parents of young children. A showing of the HPV documentary at the middle school or high school would be great! With a possible panel discussion after including a provider, public health representative, and possibly a cervical cancer or some cancer that is HPV related survivor. I know this was done in (I think) Bozeman and was very well received. I think having info from a non government agency is nice to have, such as CHOP. There are many people in the clinic that don't 'trust' the government and want outside information.	3/15/2018 11:23 AM
2	I think that in our immunization setting, we have a very strong culture of offering all recommended vaccinations at every visit- not just HPV. I don't feel that the barrier lies in us not making strong recommendations because we have had substantial training through webinars, powerpoints, presentations, etc. on how to make these recommendations. It has been a struggle with newer staff to ensure they receive the same training and guidance about how to offer and recommend vaccines.	3/15/2018 11:02 AM

Q19 An intervention to support staff and providers in framing conversations about HPV vaccination is appropriate for my work setting.

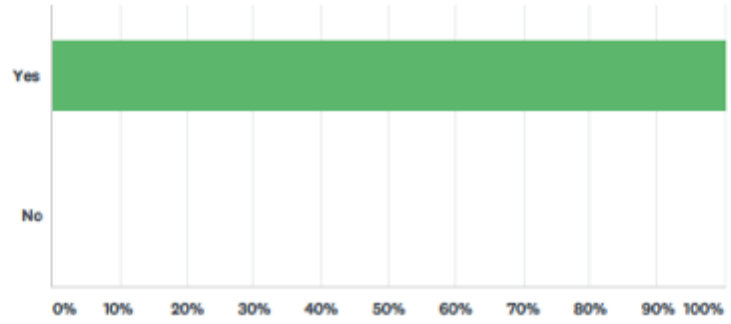
Answered: 12 Skipped: 2



ANSWER CHOICES	RESPONSES	
Yes	91.67%	11
No	8.33%	1
Total Respondents: 12		

Q20 I think management would be supportive of an HPV vaccination intervention in my work setting.

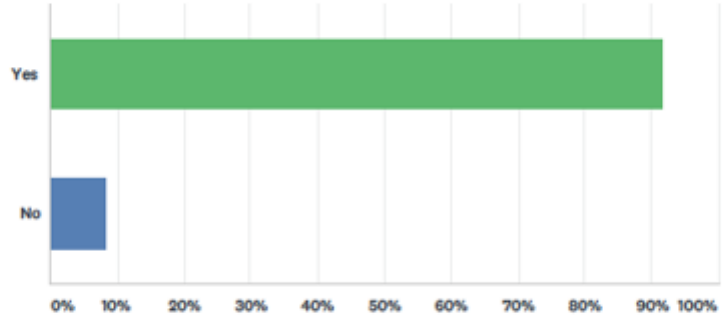
Answered: 12 Skipped: 2



ANSWER CHOICES	RESPONSES	
Yes	100.00%	12
No	0.00%	0
Total Respondents: 12		

Q21 An intervention to frame conversations about HPV vaccination would be beneficial in my work setting.

Answered: 12 Skipped: 2



ANSWER CHOICES	RESPONSES	
Yes	91.67%	11
No	8.33%	1
Total Respondents: 12		

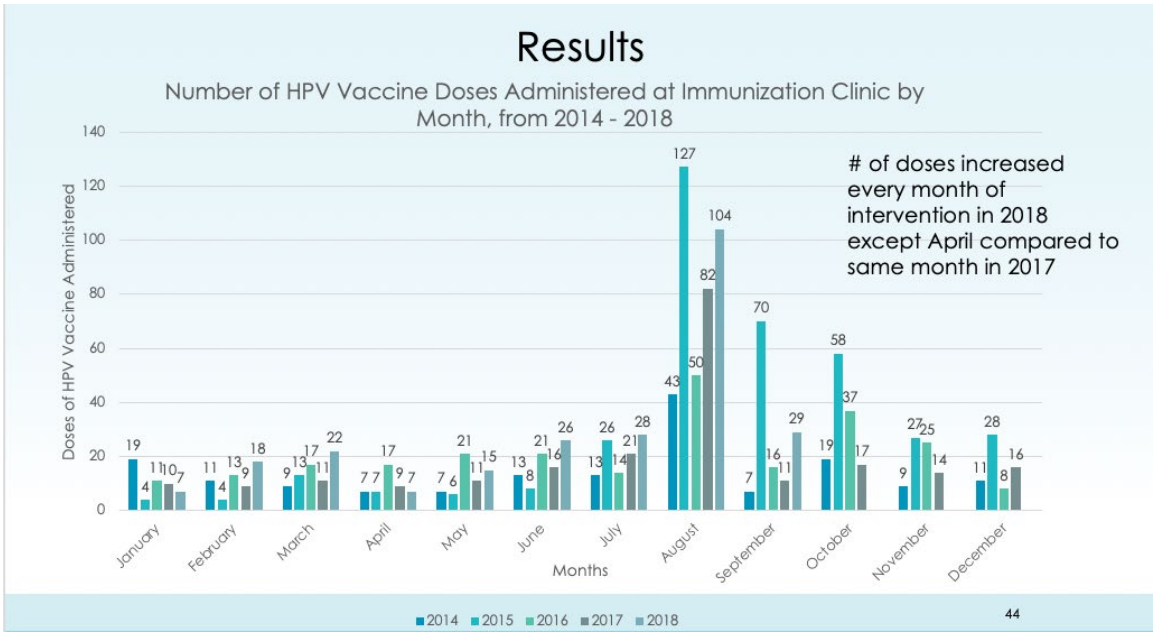
Q22 Optional: Please share any additional comments, barriers, suggestions, or concerns you may have about this topic or a possible intervention on this topic in your work setting.

Answered: 2 Skipped: 12

#	RESPONSES	DATE
1	I find the hardest age group to bring up HPV vaccinations is age 11 to mid-teen years, especially for vaccinating boys. It's a harder sell to parents regarding the boys, as most people still think of it as a vaccine for females.	3/20/2018 3:21 PM
2	Any reluctance on my part would be my dislike of role playing.	3/15/2018 11:25 AM

APPENDIX E

NUMBER OF HPV VACCINES ADMINISTERED WITHIN THE IC BY MONTH FROM 2014 – 2018


Results
Number of HPV Vaccine Doses Administered at Immunization Clinic by Month, from 2014 - 2018
# of doses increased every month of intervention in 2018 except April compared to same month in 2017
Doses of HPV Vaccine Administered
Months
January
February
March
April
May
June
July
August
September
October
November
December
2014
2015
2016
2017
2018
44

APPENDIX F

POST-INTERVENTION SURVEY RESULTS

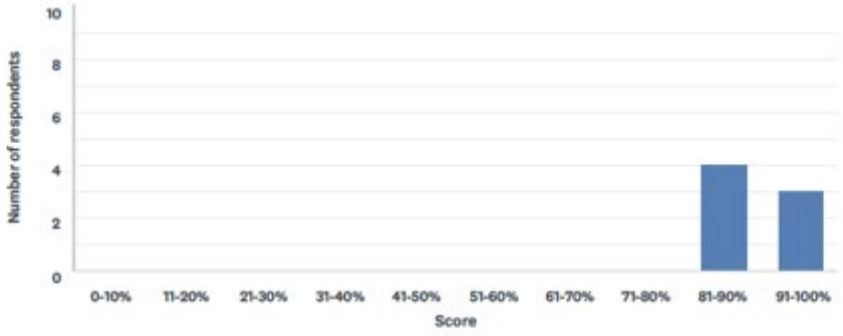
Post-Intervention Survey Results

Post- Survey: Human Papillomavirus (HPV) Vaccination SurveyMonkey

Quiz Summary

AVERAGE SCORE

88% • 11.4/13 PTS



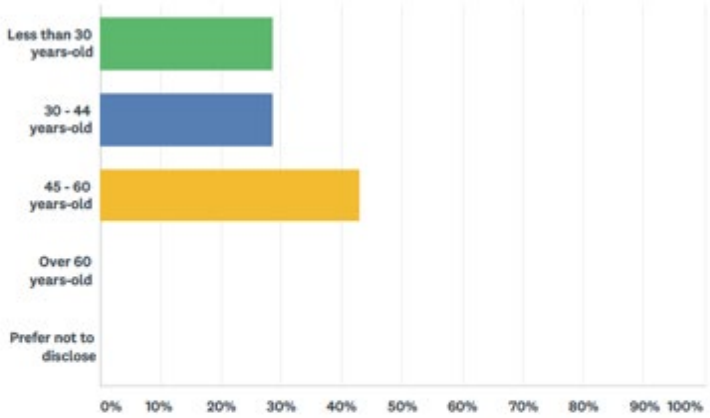
STATISTICS		
Lowest Score 85%	Median 85%	Highest Score 92%
Mean: 88%		
Standard Deviation: 4%		

Question Ranking

QUESTIONS (9)	DIFFICULTY	AVERAGE SCORE
Q7 Genital warts are caused by the same HPV types that cause cervical cancer.	1	29%
Q8 The incidence of HPV is highest among women in their 30's.	2	57%
Q4 Most people that have HPV are symptomatic.	3	71%
Q5 Condoms are one way to fully prevent the spread of HPV.	4	86%
Q3 Almost everyone that is sexually active will contract HPV at some point in their lives.	5	100%
Q6 Almost all cervical cancers are caused by HPV infection.	5	100%
Q9 Sexually active adolescents should be tested for HPV before starting HPV vaccination.	5	100%
Q10 The HPV vaccination series should be started after an adolescent becomes sexually active.	5	100%
Q11 Please select all of the types of cancer that have been linked to HPV:	5	100%

Q1 What is your age?

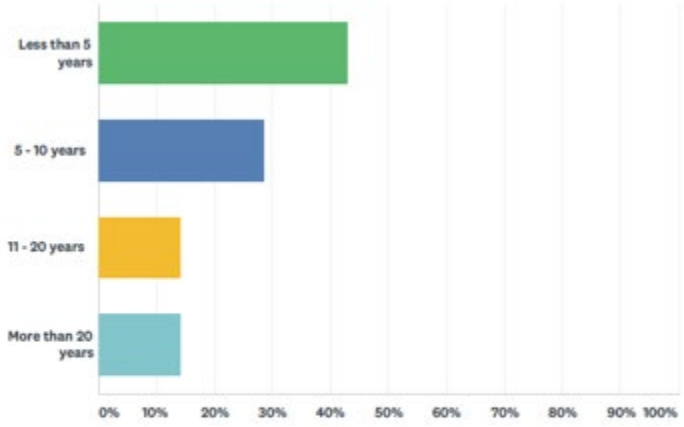
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Less than 30 years-old	28.57%	2
30 - 44 years-old	28.57%	2
45 - 60 years-old	42.86%	3
Over 60 years-old	0.00%	0
Prefer not to disclose	0.00%	0
TOTAL		7

Q2 How many years have you practiced in this role?

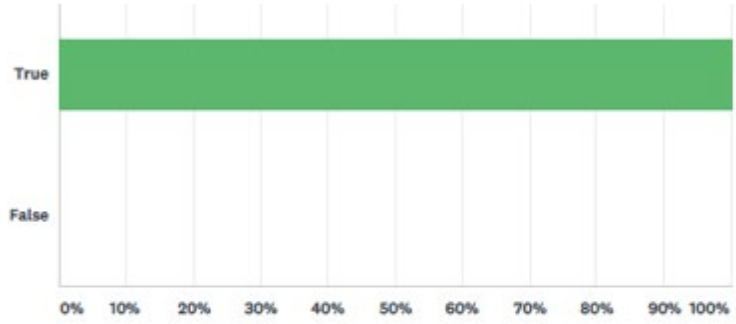
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Less than 5 years	42.86%	3
5 - 10 years	28.57%	2
11 - 20 years	14.29%	1
More than 20 years	14.29%	1
TOTAL		7

Q3 Almost everyone that is sexually active will contract HPV at some point in their lives.

Answered: 7 Skipped: 0

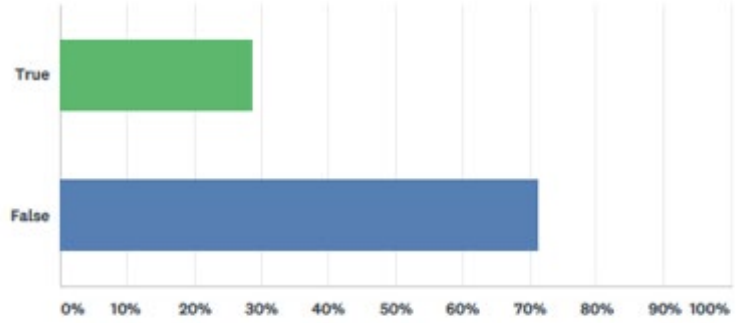


QUIZ STATISTICS			
Percent Correct 100%	Average Score 1.0/1.0 (100%)	Standard Deviation 0.00	Difficulty 5/9

ANSWER CHOICES	SCORE	RESPONSES	
✓ True	1/1	100.00%	7
False	0/1	0.00%	0
TOTAL			7

Q4 Most people that have HPV are symptomatic.

Answered: 7 Skipped: 0

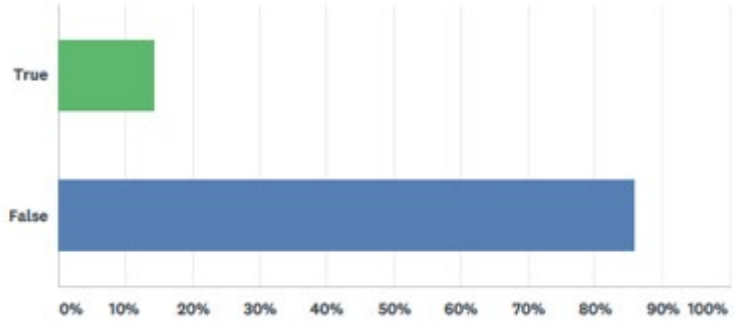


QUIZ STATISTICS			
Percent Correct 71%	Average Score 0.7/1.0 (71%)	Standard Deviation 0.49	Difficulty 3/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	28.57%	2
✓ False	1/1	71.43%	5
TOTAL			7

Q5 Condoms are one way to fully prevent the spread of HPV.

Answered: 7 Skipped: 0

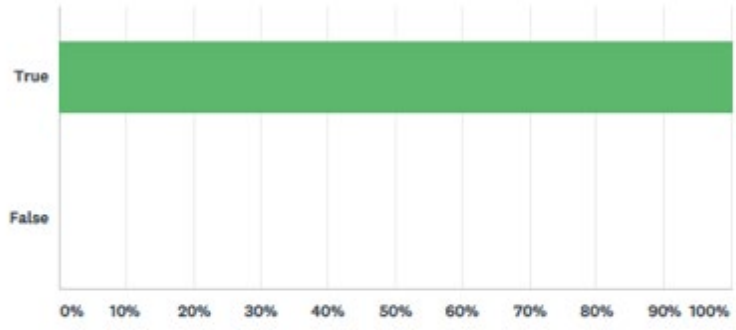


QUIZ STATISTICS			
Percent Correct 86%	Average Score 0.9/1.0 (86%)	Standard Deviation 0.38	Difficulty 4/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	14.29%	1
✓ False	1/1	85.71%	6
TOTAL			7

Q6 Almost all cervical cancers are caused by HPV infection.

Answered: 7 Skipped: 0

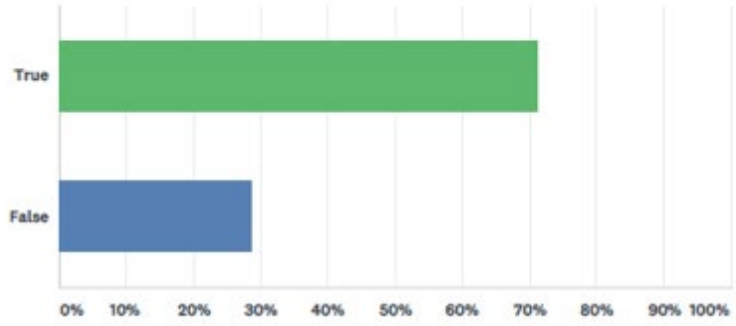


QUIZ STATISTICS			
Percent Correct 100%	Average Score 1.0/1.0 (100%)	Standard Deviation 0.00	Difficulty 5/9

ANSWER CHOICES	SCORE	RESPONSES	
✓ True	1/1	100.00%	7
False	0/1	0.00%	0
TOTAL			7

Q7 Genital warts are caused by the same HPV types that cause cervical cancer.

Answered: 7 Skipped: 0

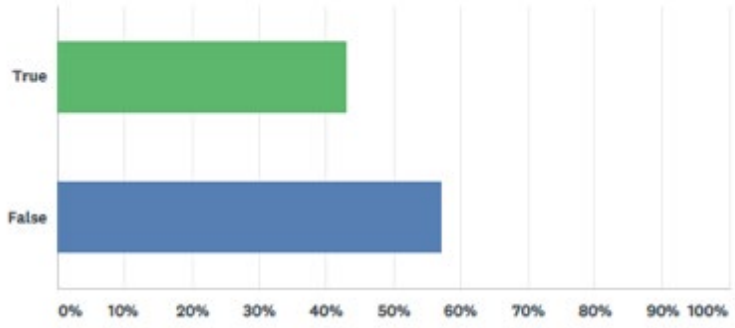


QUIZ STATISTICS			
Percent Correct 29%	Average Score 0.3/1.0 (29%)	Standard Deviation 0.49	Difficulty 1/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	71.43%	5
✓ False	1/1	28.57%	2
TOTAL			7

Q8 The incidence of HPV is highest among women in their 30's.

Answered: 7 Skipped: 0

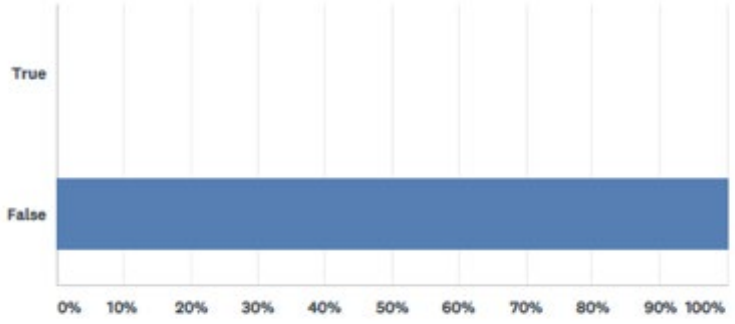


QUIZ STATISTICS			
Percent Correct 57%	Average Score 0.6/1.0 (57%)	Standard Deviation 0.53	Difficulty 2/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	42.86%	3
✓ False	1/1	57.14%	4
TOTAL			7

Q9 Sexually active adolescents should be tested for HPV before starting HPV vaccination.

Answered: 7 Skipped: 0

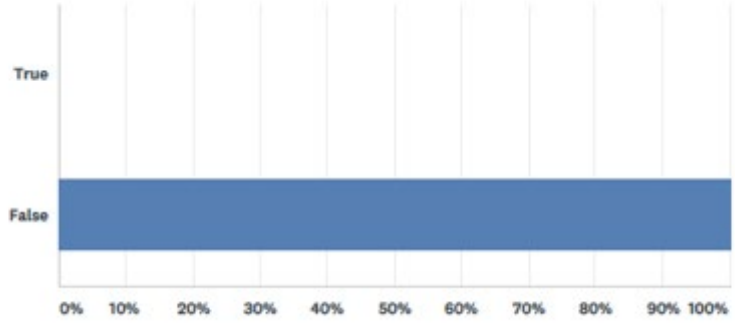


QUIZ STATISTICS			
Percent Correct 100%	Average Score 1.0/1.0 (100%)	Standard Deviation 0.00	Difficulty 5/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	0.00%	0
✓ False	1/1	100.00%	7
TOTAL			7

Q10 The HPV vaccination series should be started after an adolescent becomes sexually active.

Answered: 7 Skipped: 0

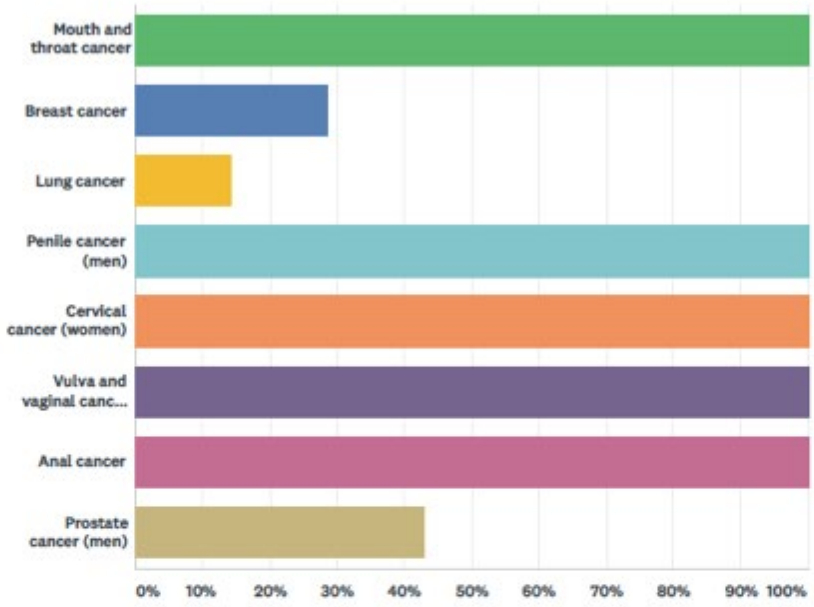


QUIZ STATISTICS			
Percent Correct 100%	Average Score 1.0/1.0 (100%)	Standard Deviation 0.00	Difficulty 5/9

ANSWER CHOICES	SCORE	RESPONSES	
True	0/1	0.00%	0
✓ False	1/1	100.00%	7
TOTAL			7

Q11 Please select all of the types of cancer that have been linked to HPV:

Answered: 7 Skipped: 0

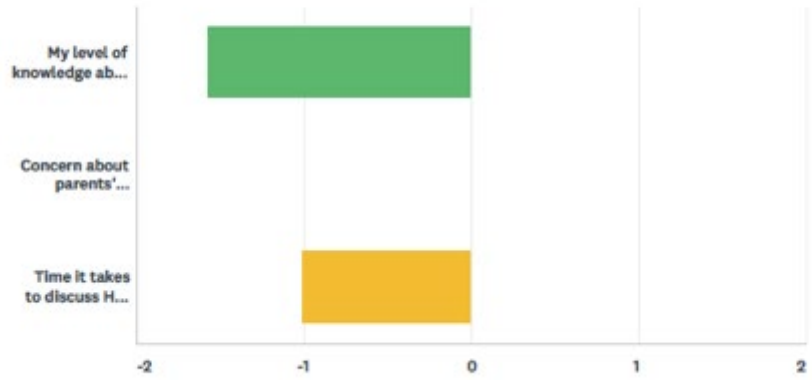


QUIZ STATISTICS			
Percent Correct 100%	Average Score 5.0/5.0 (100%)	Standard Deviation 0.00	Difficulty 5/9

ANSWER CHOICES	SCORE	RESPONSES	
✓ Mouth and throat cancer	1/5	100.00%	7
Breast cancer	0/5	28.57%	2
Lung cancer	0/5	14.29%	1
✓ Penile cancer (men)	1/5	100.00%	7
✓ Cervical cancer (women)	1/5	100.00%	7
✓ Vulva and vaginal cancer (women)	1/5	100.00%	7
✓ Anal cancer	1/5	100.00%	7
Prostate cancer (men)	0/5	42.86%	3
Total Respondents: 7			

Q12 To what extent do you feel the following represent barriers to HPV immunization?

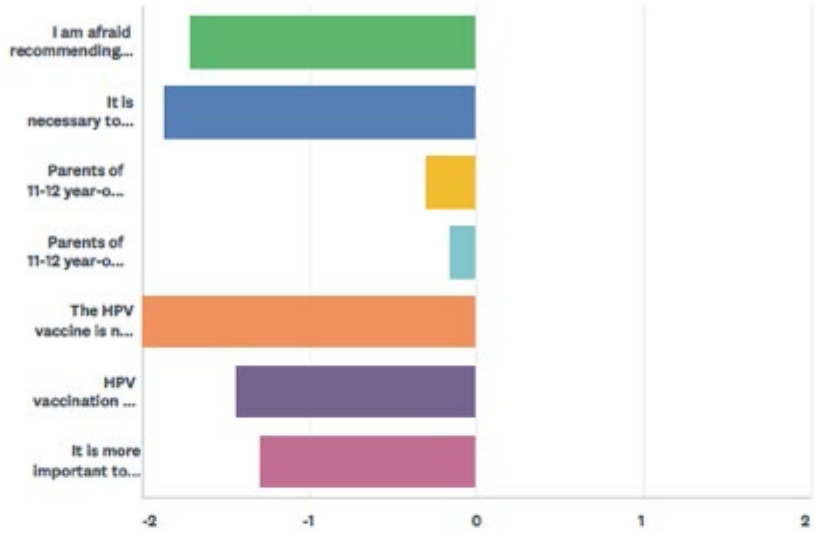
Answered: 7 Skipped: 0



	NOT A BARRIER AT ALL	A MINOR BARRIER	SOMEWHAT OF A BARRIER	A MAJOR BARRIER	UNKNOWN / UNSURE	TOTAL	WEIGHTED AVERAGE
My level of knowledge about HPV	71.43% 5	14.29% 1	0.00% 0	0.00% 0	14.29% 1	7	-1.57
Concern about parents' negative perceptions about HPV vaccine	28.57% 2	28.57% 2	0.00% 0	42.86% 3	0.00% 0	7	0.00
Time it takes to discuss HPV vaccine with patients and parents	57.14% 4	14.29% 1	28.57% 2	0.00% 0	0.00% 0	7	-1.00

Q13 Please indicate your belief concerning the following statements:

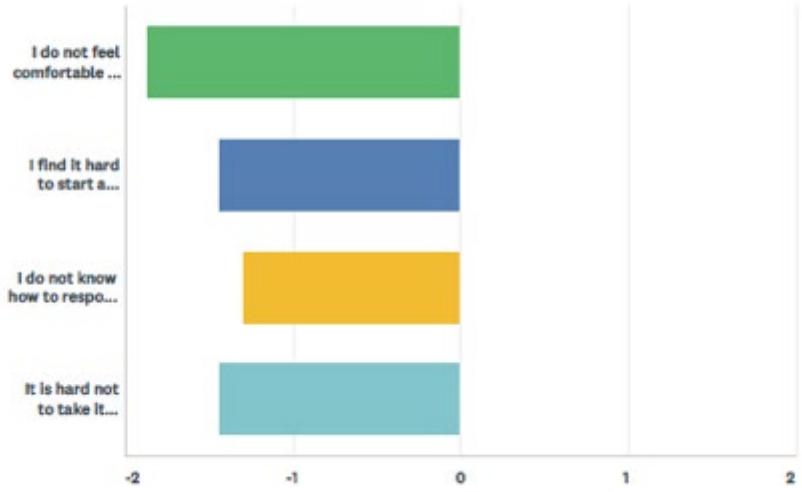
Answered: 7 Skipped: 0



	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE	UNKNOWN / UNSURE	TOTAL	WEIGHTED AVERAGE
I am afraid recommending HPV vaccination will ruin my rapport with patients and/or patients' parents.	0.00% 0	0.00% 0	28.57% 2	71.43% 5	0.00% 0	7	-1.71
It is necessary to discuss sexual activity before recommending the HPV vaccine to patients.	0.00% 0	0.00% 0	14.29% 1	85.71% 6	0.00% 0	7	-1.86
Parents of 11-12 year-old patients have been upset that I am offering a vaccine against a sexually transmitted infection in someone 11-12 years-old.	0.00% 0	42.86% 3	42.86% 3	14.29% 1	0.00% 0	7	-0.29
Parents of 11-12 year-old patients have been more likely to refuse or defer HPV vaccination than parents of older adolescents.	14.29% 1	14.29% 1	28.57% 2	14.29% 1	28.57% 2	7	-0.14
The HPV vaccine is not safe.	0.00% 0	0.00% 0	0.00% 0	100.00% 7	0.00% 0	7	-2.00
HPV vaccination may encourage earlier or riskier sexual behavior.	14.29% 1	0.00% 0	0.00% 0	85.71% 6	0.00% 0	7	-1.43
It is more important to prioritize HPV immunization for females vs. males.	14.29% 1	0.00% 0	14.29% 1	71.43% 5	0.00% 0	7	-1.29

Q14 Please indicate the level in which you agree with the following statements:

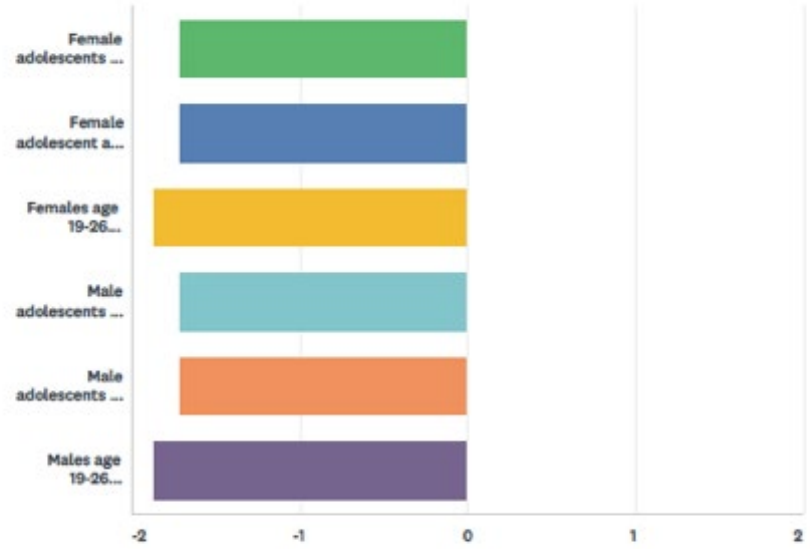
Answered: 7 Skipped: 0



	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE	UNKNOWN / UNSURE	TOTAL	WEIGHTED AVERAGE
I do not feel comfortable or confident recommending the HPV vaccine.	0.00% 0	0.00% 0	14.29% 1	85.71% 6	0.00% 0	7	-1.86
I find it hard to start a conversation about HPV vaccination.	0.00% 0	0.00% 0	28.57% 2	57.14% 4	14.29% 1	7	-1.43
I do not know how to respond when a parent or patient refuses or defers HPV vaccination.	0.00% 0	14.29% 1	28.57% 2	57.14% 4	0.00% 0	7	-1.29
It is hard not to take it personally when I recommend the HPV vaccine and it is refused.	0.00% 0	0.00% 0	28.57% 2	57.14% 4	14.29% 1	7	-1.43

Q15 I feel comfortable and confident recommending the HPV vaccine for:

Answered: 7 Skipped: 0



	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE	UNKNOWN / UNSURE	TOTAL	WEIGHTED AVERAGE
Female adolescents age 11-12 years-old.	71.43% 5	28.57% 2	0.00% 0	0.00% 0	0.00% 0	7	-1.71
Female adolescent ages 13-26 years-old.	71.43% 5	28.57% 2	0.00% 0	0.00% 0	0.00% 0	7	-1.71
Females age 19-26 years-old.	85.71% 6	14.29% 1	0.00% 0	0.00% 0	0.00% 0	7	-1.86
Male adolescents age 11-12 years-old.	71.43% 5	28.57% 2	0.00% 0	0.00% 0	0.00% 0	7	-1.71
Male adolescents age 13-26 years-old.	71.43% 5	28.57% 2	0.00% 0	0.00% 0	0.00% 0	7	-1.71
Males age 19-26 years-old.	85.71% 6	14.29% 1	0.00% 0	0.00% 0	0.00% 0	7	-1.86

Q16 Optional: Please share any additional comments.

Answered: 1 Skipped: 6

#	RESPONSES	DATE
1	I find a lot of people who think the HPV vaccine is "new" still, when in fact it's been out over 10 years. Too much misinformation on the internet, parents don't think the vaccine is safe.	10/29/2018 3:25 PM