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Getting to the Point: Promoting the HPV
Vaccine in a Primary Care Clinic

AN EVIDENCE-BASED PRACTICE PROJECT

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Getting to the Point: Promoting the Human Papillomavirus Vaccine in a Primary Care Clinic

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Successful implementation of a human papillomavirus (HPV) vaccination program has the potential to eliminate nearly 70% of all cervical cancers, 18% of head and neck cancers, and 90% of genital warts in the United States. However, although cancers associated HPV, which include cervical cancer in women and tonsillar cancer in males, are over represented in the military population, few Military Healthcare System beneficiaries eligible for the vaccine (i.e., between the ages of 9 and 26 years of age) have started the HPV series. The purpose of this evidence-based practice (EBP) project was to initiate and evaluate a HPV vaccination program within a military family practice clinic. Guided by the Rosswurm and Larrabee Model (1999), a two prong approach with deliberate organizational and individual strategies was utilized to promote HPV vaccination. Organizational strategies included identifying and engaging key stakeholders and ensuring the vaccine was available in the clinic. Individual strategies include synthesizing the literature, presenting a formal staff education program regarding HPV and current clinical practice guidelines for administration of the vaccine, and providing updates via posters and short presentations, as needed. The primary process

indicator for successful implementation of this project was measuring the change in patient vaccination rates over a three month period after the implementation of the formal education program. At the end of the three month period a small increase in the number of HPV immunizations was noted at the clinic (increasing from 59 the month before the intervention to 70 for three months following the intervention), and an increase from 25% to 38% in males receiving the vaccine. Although modest, this increase over the three month period was nearly equal to the half of the total number of HPV vaccinations given in the previous year (210 in three months following the intervention, 409 in the previous year). In addition, this EBP effort generated several new research questions for the investigator, gave this clinic an overwhelming desire to develop future nurse-led EBP programs, and motivated staff to continue to monitor and promote HPV vaccination among men and women.

This evidence-based practice project by Meryia D. Throop fulfills the dissertation requirement for the doctoral degree in Nursing Practice approved by Patricia McMullen, PhD, JD, CRNP, as Director, and by Janice Agazio, PhD, CRNP, and Diane Padden, PhD, CRNP, as Readers.

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DEDICATION

I dedicate this dissertation to my family, friends, and fellow Soldiers.

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CHAPTER I: NATURE AND SCOPE OF PROBLEM

Introduction

Globally, human papilloma viruses (HPVs) are the precursor to nearly all cervical cancers, one quarter of head and neck (H&N) cancers, and all genital warts (National Cancer Institute [NCI], 2008; Klozar, et al., 2010). Transmitted primarily via direct skin-to-skin contact during penetrative and oral sexual activity, HPV is considered the most commonly sexually transmitted infection in the world (National Cancer Institute [NCI], 2012; Centers for Disease Control [CDC], 2009; World Health Organization [WHO], 2010).

Although a vast majority of men and women are exposed to HPV, most will clear the virus via their own immunity mechanisms and no overt signs of infection or disease will be detected (CDC, 2009). However, because the HPV strains directly associated with the aforementioned cancers are asymptomatic, individuals may transmit the infection to their partners unknowingly (Jones & Cook, 2008). For those strains that are related to visible warts, removal is often physically painful and emotionally stigmatizing (Wilson, 2002).

Although there is no cure for HPV, two vaccines to prevent the most common mucosal strains of HPV are currently FDA approved and available in the United States. Introduced in 2009, Cervarix protects against HPV strains 16 and 18; introduced in 2006, Gardasil protects against HPV strains 6, 11, 16, and 18. Both HPV vaccines consist of a series of three intramuscular injections that are given over a six month period. Although originally approved only for females, since November 2009, Gardasil is recommended

for males and non-pregnant females between the ages of 9 and 26 years; Cervarix is recommended for non-pregnant females between the ages of 10 and 25 years. These two vaccines are highly effective, safe, and protect against the specific HPV strains, 6, 11, 16, and 18 for Gardasil, and 16 and 18 for Cervarix (de Carvalho et al., 2010; Haupt & Sings, 2011; Schwarz et al., 2012). Further, evidence indicates they are well tolerated (Bornstein, 2010; Slade et al., 2009).

Multiple studies have demonstrated that HPV vaccination is cost effective for female populations in both developing and developed nations (Armstrong, 2010; Marra, Cloutier, Oteng, Marra, & Ogilvie, 2009; Mennini, Rossi, Palazzo, & Lageron, 2009). More recently, HPV vaccination among men has demonstrated to be a cost effective method to prevent HPV associated non-cervical cancers and transmission of genital warts (Palefsky, 2010; Pirota et al., 2009). In addition to the CDC's Advisory Committee for Immunization Practices (ACIP) statement encouraging widespread HPV vaccination for males and females ages 9-26 years (2009; 2011), the Association of Women's Health, Obstetrics, and Neonatal Nurses (AWHONN) *2010 Position Statement* regarding HPV vaccination also encourages more research to expand the utilization and implementation of HPV vaccination (AWHONN, 2010).

By implementing a vaccination program, nearly 70% of all cervical cancers, 25% of H&N cancers, and 90% of genital warts in the United States could be prevented (CDC, 2008, Goon et al., 2010). However, reaching the young adult population to urge vaccination is historically difficult due to their limited exposure to healthcare providers

and vaccine education (Rand et al., 2007; Scarinci, Garces-Palacio, & Partridge, 2007).

Due to sexual nature of virus spread, an additional layer of hesitancy by the patient, parent, or healthcare provider is also associated with delay in initiating the HPV vaccine.

Therefore, clinicians must confidently leverage every patient encounter, to include primary care as well as acute and inpatient visits, as an opportunity to provide preventable disease education and immunization delivery.

Background

Specific in only human hosts, over 130 stains of HPV are currently known and most are considered highly contagious (Stanley, Pett, & Coleman, 2007). Approximately 40 HPV strains have an affinity for mucosal tissues and directly affect the genital tract and respiratory tissues. Of those, 15 strains are considered “high risk” due to their direct relationship with specific cancers found in cervical, peri-anal, and oral-pharyngeal tissues (de Carvalho et al., 2010). The two most common strains, types 16 and 18, are present in 70% of cervical cancers (Centers for Disease Control [CDC], 2008). In the past 30 years, the incidence of cancer originating in the head and neck region has steadily increased, and 25.9% of those cancers are also associated with the identical high risk HPV strains found in the genital tract (Goon et al., 2009; Kane, 2012; Klozar, et al., 2010).

Cervical Cancers

Because most U.S. women are treated for cervical abnormalities, the natural progressive history from HPV exposure to any cancer is difficult to determine. Goldie et al. (2004) calculated that without screening or treatment, 3.64% of American women

would progress from no detection of HPV to cervical cancer. High grade lesions and cervical cancer are most often found in women who have persistent HPV infection over the course of three or more years (Hawes & Kiviat, 2008). Although, most women are infected with only one high risk strain, Revzina and Diclemente (2005) estimated that 5-30% of women in the U.S. are infected with more than one high risk HPV strain. Therefore, HPV vaccination is recommended even for women who report a history of prior abnormal cervical cytology or genital wart infection (ACIP, 2009). With a combination of vaccination against HPV, routine cervical cancer screening, and prompt intervention when cervical abnormalities are detected, nearly all cervical cancers are preventable.

Anal Cancers

The anal canal in men and women contains a transitional zone approximately midway between the end of the large intestine and the anal verge. At the dentate line, the cells transition from columnar to squamous cells. Like cervical cancers, this zone may become infected by high-risk HPVs, resulting in low and high grade anal intraepithelial neoplasia (ACS, 2012). Anal cancers are more predominate among women verses men, with approximately 4,000 of the 6,000 total new cases in the U.S. diagnosed among women each year (Jemal et al., 2007). Additionally, HPV-associated anal cancers are common among men who have sex with men (Greene, 2009).

In a meta-analysis of HPV-associated anal cancers among men who have sex with men by Machalek et al. (2012), HPV serotype 16 is most common. In particular, this

research reported 35% of men that were human immunodeficiency virus (HIV)-positive and 13% of HIV-negative demonstrated a high-risk HPV seroprevalence. However, the researchers reported that unlike women, HPV-associated anal among men who have sex with men, dysplasia was slower to progress to cancer than cervical dysplasia.

Head and Neck Cancers

Currently, H&N cancers affect approximately 3-5% of the U.S. population (NCI, 2005). In contrast to cervical cancer, these types are limited to the head and neck and are found primarily in men over 50 years of age and involve mucosal tissues in the mouth, nose, and throat. Because the research regarding the relationship between H&N cancers and HPV is only recently emerging, little is known regarding their natural progression from HPV infection to overt cancer (Chaturvedi, 2010; Klozar et al., 2010). However, the risk factors for H&N cancers share many of the same risk factors associated with cervical cancer, such as tobacco use (NCI, 2008).

Genital Warts

Although not associated with cancer, genital warts are exclusively related to HPV infection. Approximately 10% of the population will develop genital warts in their lifetime (Saslow et al., 2007). Genital warts are more common in women than men, as two thirds of new cases are diagnosed in women (Dede et al., 2007). Among the HPV strains which result in visible warts, such as those present in the larynx and genitalia, 90% are HPV strains 6 and 11. These strains are similar to the high risk HPVs, since they are found exclusively in mucous membranes. More similar to common cutaneous

warts that are found on the hands and feet, visible HPV strains found in genital mucosal tissues are considered low risk and are not associated with cancer. However genital warts are often difficult and painful to treat (Wilson, 2002). Additionally, although rare, genital warts can be transmitted from the mothers to the respiratory tracts of infants during childbirth, causing future airway obstruction that is often difficult to eradicate (CDC, 2008; Sanslow et al., 2007).

Scope of Problem

Routine screening, a mainstay of health promotion to identify abnormal cervical cells prior to the diagnosis of overt cervical cancer, has been described as the most important factor associated with preventing invasive cervical cancer (CDC, 2007). However, with the increased incidence in H&N cancers in men and disproportionate burden of cervical cancer and genital wart incidence for women, vaccination may soon eclipse screening as an important factor associated with preventing most HPV infections in any population (Chaturvedi, 2010; Kane, 2012).

HPV Infection Sequelae

Cervical cancer.

Among women in the U.S., cervical cancer treatment is estimated to cost \$160 million every year (NCI, 2005). Annually, 12,000 new diagnoses of cervical cancer are expected and nearly 4,000 women will die from cervical cancer in the U.S. alone (CDC, 2007). Kim and Goldie found that extending HPV vaccination to the age of 26 years of

age is economically advantageous to deter cervical cancer and warts in adults, and respiratory papillomatosis in infants (2008).

Anal cancer.

Like cervical cancer, the natural history of anal cancer is not well understood (Newsom-Davis & Bower, 2010). Of note, unlike other cancers which are reduced among HIV positive population taking antiretrovirals, the incidence of anal cancer has not changed (Powles et al., 2009). In addition, although cytology testing is available, a consensus regarding screening men and women who engage in receptive anal intercourse has not occurred (Greene, 2009).

Head and neck (H&N) cancers.

Head and neck cancers include cancers which originate from mucosal surfaces in the oral cavity, sinuses, pharynx, salivary glands and associated lymph nodes in the head and neck region (NCI, 2005). In the U.S., \$3.2 billion is spent annually for the treatment of head and neck cancers and when thyroid cancers are included, these ailments represent 6% of all cancers (NCI, 2012). Ekwueme, Chesson, Zhang, and Balamuraugan (2008) state the exact cost of non-cervical HPV related cancer burden remains unreported, but estimate all HPV-associated cancers (including cervical and H&N) cost \$3.7 billion in lost lifetime productivity. For those H&N cancers directly related to HPV, over 8,000 new cases are expected annually in the U.S. (Ryerson et al., 2008).

Genital warts.

Genital warts have been described since antiquity and approximately one percent of all sexually active adults demonstrate symptoms of genital warts at any given time (Winer & Koutsky, 2008). Genital warts can be found in the internal and external mucosal tissues in the cervix, anus, penis, perineum, mouth, sinuses, and larynx. Visible lesions may be flat, popular, or pedunculated (CDC, 2007). Treatment includes cutaneous destruction by chemical, surgical or other physical means, such as by freezing or laser, or medications which provoke a cell-mediated immune response (Lacey, Woodhall, Wikstrom, & Ross, 2012).

None of the treatments for genital warts are particularly efficient and nearly all of these treatments are potentially painful, inconvenient for the patient, and may cause depigmentation or scarring at the treatment site (Kodner & Nasraty, 2004). In addition to undesirable physical symptoms, Piotta and colleagues reported significant negative psychosocial impact and adverse effect on quality of life with HPV infection detection (2009). Using fiscal year 2000 cost estimates, in 2004 Chesson and colleagues reported the average cost in the U.S. for treatment of newly diagnosed genital wart lesion(s) among 15-24 year olds as \$446 and direct costs for all U.S. age groups as \$167.4 million annually.

HPV Burden in Military Healthcare System

Within the U.S. Military Healthcare System (MHS), sexually transmitted infections are over represented as compared to the civilian population (Boyer, Pollack,

Becnel, & Shafer, 2008; Gaydos & Gaydos, 2008). In a study among all active duty Air Force men and women diagnosed with cancer over a 14 year period, cervical and vulvar cancers were significantly greater among the military population, with a standardized incidence ratio (SIR) greater than 3 for each, and confidence intervals (CI) of 2.7-3.7 for cervical and 1.7-6.3 for vulvar cancer, respectively (Yamane, 2006). When data were controlled for age and gender, among military women there was a greater proportion of thyroid and oral cancers, 12.4% and 1.2% as compared to 3% and less than 1%, respectively in civilian women; among military men, thyroid cancer was 6.1% as compared to less than 1% for civilian men (Ibid., p.792). The burden of genital warts in the MHS is not currently reported in the literature.

Although the literature and numerous clinical practice guidelines encourage HPV vaccination, less than 20% of women between the ages of 9-26 years who are enrolled in the MHS have initiated the HPV vaccine (Berry-Cabon & Buenaventura, 2009; Throop, 2010). Throop (2010) found in a sample of military women, only one third of female soldiers (n=84) between the ages of 18 – 26 years of age perceived their healthcare provider as encouraging them to initiate or complete the vaccine. However, nearly every participant in that study reported risk factors for HPV acquisition.

Statement of the Problem

Fostering health promotion and disease prevention are important to those who provide health care. The MHS provides care to more than 9.6 million beneficiaries in more than 400 hospitals and clinics throughout the world (Farrell, 2010). Due to unique global mission and commitments for military members and their families, the potential

for fragmented care is exaggerated by the multiple providers and clinics that beneficiaries will visit. Therefore, within the MHS, clinicians must capitalize on every encounter as an opportunity to prevent disease and espouse evidence based practice (EBP) health promoting activities.

Protecting military healthcare beneficiaries from preventable diseases through vaccination should be paramount at every out-patient encounter. In particular, diseases associated with HPV are expensive and through early vaccination, largely preventable. HPV is a common pathogen and is easily transmitted. Therefore, capitalizing on every encounter as an opportunity to promote vaccination must become the cornerstone to the prevention of HPV associated disease and cancers.

Project Objectives

The HPV vaccine is a three dose intramuscular injection regime that is administered over a six month period and is indicated for men and women less than 27 years in age who are not pregnant. The purpose of this nurse led, EBP intervention was to implement a targeted EBP program to increase HPV vaccination rates among men and women ages 9 to 27 years in a large, military family practice clinic.

The setting selected for this program was relatively naïve to EBP initiatives, especially those originating from nurses. Enabling the opportunity for the vaccine to be provided to eligible men and women required the vaccine to first be routinely available and encouraged by all healthcare providers. Therefore, the primary purpose of this EBP program was to support healthcare providers (nurses, mid-level providers (i.e., physician

assistant, nurse practitioners, and midwives) and physicians) to be aware of the HPV vaccine benefits and to confidentially encourage HPV vaccination.

Model

The Rosswurm and Larrabee Model (1999) was selected as the framework to underpin this EBP project. This model includes the elements of both EBP and change theory, and mirrors the nursing process. Processes to implement a HPV vaccination program include individual and organizational strategies, such as staff education via in-services and ensuring the vaccine is available on the unit.

Definition of Terms

The terms military health care system, HPV vaccination, and evidence based practice are defined both theoretically and operationally below. Additionally, a glossary of military terms is available in Appendix F.

Terms

Military Healthcare System (MHS).

Theoretical definition: A world class health care organization for service members and their family members, which encourages fitness, delivers top quality healthcare, and focuses on medical combat readiness (FM 7-21.13, 2004).

Operational definition: An organized entity comprised of healthcare providers (i.e., physicians, midwives, nurses, pharmacists, and unlicensed personnel), treatment facilities, and a variety of support mechanisms that provides medical care to military members of the U.S. Department of Defense (DoD), retired military members of the

DoD, their families, and all other persons designated by the Secretaries of Defense to receive care in DoD facilities. The site selected for implementation of this EBP program was a large, family practice teaching military treatment facility on the east coast.

Human papillomavirus (HPV) vaccination.

Theoretical definition: A primary intervention strategy, which involves introducing a mixture of four non infectious, inactivated virus particles (HPV 6, 11, 16, and 18) or two activated virus particles (HPV 16 and 18), via the intramuscular route, to stimulate a natural immunity from the previously mentioned HPV strains (Markowitz et al., 2007). In accordance with individual military service policies, HPV vaccination is recommended to commence at 11-12 years of age, but may be given as early as nine years of age. HPV vaccination consists of three doses, the second and third to be administered two months and six months respectively, after the initial dose. The vaccine is not recommended for women who are pregnant or individuals who may be allergic to yeast. Male and female military healthcare beneficiaries, including active duty members up to the age of 27 years of age who have not initiated or completed the series are encouraged, but not required to, complete the HPV vaccination series (Kiley, 2007; Loftus, 2007; Mateczun, 2007).

Operational definition: Previous HPV vaccination will be operationalized as those injections recorded in the military electronic medical record. Males and females who do not have a previous HPV vaccination recorded in the electronic record and who are less

than 27 years of age and greater than 11 years will be described as requiring the HPV vaccine. The vaccine available at the setting is Gardasil.

Evidence-Based Practice (EBP).

Theoretical definition: A systematic approach used in appraisal, problem solving, and delivery of quality healthcare utilizing best practices as described by evidence, clinician experience, and patient preferences (Melnyk & Fineout-Overholt, 2005).

Operational definition: The 2010 CDC *Advisory Committee on Immunization Practices* recommends all healthcare providers encourage the initiation or continuation of the HPV vaccine for all men and women greater than 11 and less than 27 years of age [Although vaccination may begin and will be measured for this effort at age nine years of age.] Evaluation for institutional acceptance and adoption of this component of the guideline included two process indicators. Proximal process indicators included measurements of staff attendance at educational efforts directed at increasing knowledge regarding the HPV vaccine, and number of vaccine eligible patients assigned to the clinic who received the Gardasil vaccine over a three month period of time.

Assumptions

This EBP project was based on the following assumptions:

1. The HPV vaccines are a safe and effective mechanism to prevent the majority of HPV associated cancers and diseases.
2. HPV vaccination protects men and women against HPV strains 6, 11, 16, and 18 when given before exposure to the virus.

3. The MHS electronic medical record reflects the most accurate and up to date vaccination record for military healthcare care beneficiaries.
4. Knowledge of current evidence, recommendations and vaccine side effects will enable a preponderance of healthcare providers to promote the HPV vaccine among men and women ages nine to 27 years of age.
5. Evidence-Based practices that promote vaccine acceptance and adoption of behavior are minimally different in military and civilian populations.
6. Individual behavior to receive vaccines by military healthcare beneficiaries is guided by rational considerations and significantly influenced by positive recommendations of healthcare providers.

Limitations

Due to the threat of potential deployment to variety of global locations, members of the U. S. Armed Forces receive many more vaccinations than their civilian counterparts (i.e., small pox, anthrax, etc). Therefore, service members, their family members, and healthcare providers may be more comfortable in discussing and subsequently, receiving vaccines. Therefore, caution should be taken in generalizing outcomes associated with this program to other populations. In addition, military healthcare beneficiaries may assume that they have previously received the HPV vaccine series during routine vaccination typically required for military duty, physical exams, and/or school enrollment.

Additionally, as a smaller and often insular community, military healthcare beneficiaries may limit and/or distort their answers to some questions, such as sexual history and risk taking behaviors with their healthcare provider. Likewise, military healthcare providers may underestimate the benefit of HPV vaccination among a population that reports previous [or risky] sexual activity or may generally underestimate HPV acquisition potential among a military beneficiary population.

Significance

As reflected in the preceding review above, HPV remains a tremendous health problem within the MHS and globally. Among younger adolescents ages 10-14 in the U.S., HPV vaccination is less than 50% (CDC, 2011). Although HPV vaccination is available and free to military personnel and their dependents, vaccination rates remain equally as low. Given the documented improvement in HPV transmission with vaccination, additional measures are needed to increase current rates of HPV vaccination, across all health care settings. While the primary purpose of this EBP project was to improve vaccine coverage among beneficiaries at one clinic, globally this endeavor will attempt to increase the number of military beneficiaries who elect to receive the HPV vaccine, and in the long term reduce most cervical cancers, one quarter of H&N cancers, and nearly all genital wart lesions within the DoD.

The primary purpose of this protocol was to implement a targeted EBP program to increase HPV vaccination among men and women ages nine to 27 years of age at a large military family practice clinic. Although beyond the scope of this EBP endeavor,

future research could include a longitudinal study to evaluate future cancer rates among the men and women who received HPV vaccination. Additionally, successful implementation of this program could be translated to other military and civilian settings.

Summary

Globally, HPV is considered the most common sexually transmitted infection and cervical cancer remains the second most common cancer in women (CDC, 2011).

Researchers have also noted an increase in non-cervical cancers, with a direct association with the same high risk HPVs as cervical cancer (Klozar et al., 2010). Largely due to the Papanicolaou (Pap) screening test initiated in the 1950s, the incidence of cervical cancer has significantly decreased in U.S. women and currently cervical cancer fails to be included in the top 10 cancer diagnoses for women in the past decade (CDC, 2009).

The introduction of the HPV vaccine in this decade has the potential to significantly decrease the burden of cervical cancer and abnormal cervical cytology in women. Additionally, a dedicated HPV program can decrease H&N cancers and genital warts among men and women. Cervical and H&N cancers tend to be over expressed in minority populations in the U.S. (Jemal et al., 2007; Ryerson et al., 2008) and in men and women serving in the military (Yamane, 2006). The burden of HPV is greatest among women, as more women are affected by HPV associated cancers, such as cervical and peri-anal cancers, and genital warts. Therefore, the necessity for the MHS to institute clinical practice guidelines regarding HPV vaccination is paramount, and time is of the essence. This project enabled clinicians to institute alternate avenues, based on the most

current evidence, to leverage the location of a family practice setting to maximize vaccination education and delivery. In the long term, HPV vaccination efforts will benefit both men and women in reducing or eliminating a largely preventable infectious disease and its sequelae.

CHAPTER II: SYNTHESIS AND ANALYSIS OF LITERATURE

Evidence Based Practice Framework

The Rosswurm and Larrabee Model (1999) was selected as the framework to underpin this EBP project. This model includes the elements of EBP and change theory, and mirrors the sequential nursing process, which in turn increases the likelihood for healthcare providers to gain a desire and willingness to change their practice (Melnik & Fineout-Overholt, 2005). Steps to introduce a change in practice in this model include assessing the need for change in practice; linking the problem with the intervention and outcome; synthesis of the best evidence, designing the practice change, implementing and evaluating the practice change; and integrating and maintaining the change as the standard of practice for the unit. (See Appendix A, Conceptual Model for HPV Vaccination).

In the conceptual model figure, the steps described by Rosswurm and Larrabee are italicized and highlighted in grey. Specific tasks for each step are described in the following two chapters and indicated by bold print in the figure.

Assessment.

The first step in the model, as described by Rosswurm and Larrabee, was formulated in the fall of 2009 during the dissertation work conducted by the author. Upon developing a greater understanding of the sequelae of HPV infection and noting increased risk factors for acquisition present among service members, the need to improve HPV vaccination efforts among beneficiaries became evident. Key stake holders, who had also identified the problem of poor HPV vaccination adoption among

the military beneficiary population, were recruited in the spring of 2010. A cursory review of the family practice policies by the clinic head nurse indicated limited current practice and policies to promote “best practices” for HPV vaccination. In addition, as noted by the Immunization Section staff nurses, current practice included decreased vaccination acceptance among beneficiaries and their parents, and hesitancy among healthcare providers to promote the vaccine.

Link Problem.

Using the PICO questions as described by Melnyk and Fineout-Overholt (2005) to drive a review and critique of the evidence, the following areas of interest population, intervention, comparison and outcome, were identified:

Population:

Primary :

HealthCare Providers

Physicians

Advance Practice Nurses

Physician Assistants

Nursing Staff (RNs/LPNs)

Secondary

Male and female beneficiaries greater than nine years and less than 27 years of age.

Intervention:

Primary

Healthcare providers to promote the HPV vaccine among eligible beneficiaries

Secondary

Male and female beneficiaries greater than nine years and less than 27 years of age to initiate, continue, or complete the HPV vaccine series.

Comparison: Standard practice of care in a military family practice clinic.

Outcome:

Primary

Improved HPV vaccine knowledge and confidence among healthcare staff members to promote the HPV vaccine.

Secondary

Increased eligible beneficiaries that initiate, continue, or complete the HPV vaccine series.

Synthesis of Best Evidence.

An extensive review of the literature was conducted and revealed the 2010 CDC *Advisory Committee on Immunization Practices* recommendations for both males and females ages 9-27 years of age should receive the HPV vaccine. The current evidence, including numerous research articles, policies, position statements, and clinical practice

guidelines, supported an HPV vaccine program in a MTF family practice setting. The steps used to conduct the synthesis of the evidence are described in greater detail below.

Keyword Search

The key word search included the terms evidence-based practice [EBP] and human papillomavirus [HPV] vaccine. The precursor for most cervical cancers, some head and neck (H&N) cancers, and all genital warts is exposure to HPV, which is a sexually transmitted infection (STI) and also broadly categorized as an a sexually transmitted disease (STD). Therefore all the aforementioned terms were also included in the search. Associated terms for MHS and the MHS beneficiaries included Department of Defense, DoD, Tricare beneficiaries, service members, family member, Soldier, Sailor, Marine, and Airman were incorporated as search terms. As the purpose of this project was an intervention to improve vaccination rates in a family practice clinic, additional search terms included vaccination, immunization and vaccine intervention, uptake, adoption, and delivery.

Sources for the search included: the Cochrane Library, CINAHL, PubMed, MEDLINE, Dissertation Abstracts International, Google Scholar, and the Institutes of Medicine. The search was conducted in October 2009, April 2010, and September 2011 and the search of literature extended as far back as 1930.

Introduction to the Review of the Literature

The current literature demonstrates a modest effort to describe HPV vaccination sentiments and behaviors. Most studies thus far have focused on parental acceptance of

the HPV vaccine for their adolescent daughters in the United States. In general, reports include limited parental knowledge regarding vaccine efficacy, stigma associated with HPV vaccination, parental fear regarding the potential for the vaccine to promote promiscuity, and limited knowledge regarding the relationship between HPV and cervical cancer (Bond & Brandt, 2009; Litton, Desmond, Gilliland, Huh, & Franklin, 2011). Among the young adult population (i.e., less than 27 years of age), Bond describes acceptance of the vaccine as generally favorable, although knowledge regarding the vaccine and cervical cancer is limited.

Among the studies that have been published since the original FDA approval of the HPV vaccine, Gardasil, few researchers have tested interventions to increase vaccine utilization beyond a fact sheet or pamphlet provided to the parent and/or patient. Interventions, which include engaging and influencing healthcare providers to discuss or encourage HPV vaccine for specific patient populations, are rarely reported. While many factors influence vaccination behaviors among a variety of young adult populations, the MHS beneficiary is often unique in terms of limited social support systems and increased potential for fragmented healthcare due to multiple geographical moves (Granger, Boyer, Weiss, Linton, & Williams, 2010; Padden, 2006). Unfortunately, little research regarding MHS beneficiaries, their healthcare providers, and HPV vaccination has been published and such studies are primarily descriptive in nature.

Among female service members in the MHS, Throop (2010) determined that in a sample of active duty female Soldiers ($n = 84$) nearly one in five were non-adherent in terms of initiating or completing the HPV vaccine, despite the fact that these individuals are able to obtain vaccine services free of charge. The CDC ACIP clearly supports HPV vaccination. This review seeks to describe in greater detail the literature germane to elements which promote HPV vaccination.

The pertinent literature regarding vaccine programs includes a description of HPV and the HPV vaccine, HPV knowledge among young adults, influences on HPV vaccination, and vaccine programs in the family practice setting and in the MHS. Because this project was conceived and conducted only recently after the HPV vaccine was approved for use in males, most of the literature was based on female populations and therefore males were not intentionally excluded from the synthesis of the literature.

Physiology related to HPV and HPV Associated Diseases

It is estimated that there are approximately 6.2 million new HPV infections among Americans aged 15 to 44 annually and of those, an estimated 74% occur in people between ages 15 to 24 (Dunne et al., 2007). Over 130 strains of HPV are currently known and most are considered highly contagious (Stanley, Pett, & Coleman, 2007). Approximately 40 HPV strains directly affect the genital tract, and HPV is considered the most common viral STI in the United States and worldwide (CDC, 2008). During their lifetime, over one half of sexually active women and men are estimated to have been infected with HPV (CDC, 2007).

Although a majority of women are potentially exposed to HPV, less than one third of the known HPV strains which affect the genital tract are considered high risk and directly linked to cervical cancer. The two most common high risk HPVs are types 16 and 18, which are present in 70% of the cervical cancers in the U.S. (CDC, 2007).

Nearly identical to cervical cancer in terms of pathology, physiology, risk factors for acquisition and screening tests, anal cancer originates in the transitional zone in rectum (Echenique & Phillips, 2011). Anal cancer is most common among women and men who have sex with men (Greene, 2009). The most common HPV type found in anal cancer is HPV 16, although additional high-risk types 18, 31, 33, and 45 have also been reported (ACS, 2012). Anal cancer is noted to be slower to progress and typically is diagnosed among men and women after 60 years of age (Machalek et al., 2012).

In addition to cervical and anal cancer, an increase in H&N cancers among men and women has been noted over the last 30 years (NCI, 2012). Marur, D'Souza, Westra, and Forastiere (2010) conducted a meta-analysis of all English and French publications related to H&N cancers over the last 30 years with samples greater than 25 oropharyngeal cancers or 50 head and neck tumors ($n = 57$). Marur and colleagues report the increased incidence of H&N cancers is directly attributable to the increase in cancers associated with HPV; and greater than 90% were specifically related to HPV strain 16. Although Marur et al. describe HPV-associated H&N cancers as sexually transmitted via oral sexual activity, the natural history and specific related behaviors remains unknown.

Finally, Marur et al. reported HPV associated H&N cancers effect men three times more frequently than women and found HPV predominately in the tonsils (50%) or the base of the tongue (40-80%).

The natural progression of HPV infection in H&N cancer currently remains unknown (Klozar et al., 2010; Marur et al., 2010). However, among women diagnosed with cervical cancer, most are thought to be exposed to HPV in late adolescence, develop mild cervical changes in their early 20s, progress to moderate or high grade lesions in their late 20s, and express cervical cancer when they are 40 to 50 years of age (Balasubramanian et al., 2008).

Interestingly, most women and men who are exposed to both high and low risk HPV strains will clear the virus via their own immunity mechanisms and no overt signs of infection or disease will be detected. Additionally, most high risk HPV infections are asymptomatic, so men and women do not know that they have the infection and thus, they transmit the infection to their partners unknowingly (Jones & Cook, 2008).

Introduction of the HPV Vaccine

In 2006, the Gardasil vaccination was introduced to decrease a women's risk of developing cervical cancer and it is effective against the two most common high risk HPV strains, HPV 16 and 18. This vaccine is also effective against HPV strains 6 and 11 which cause 90% of external genital warts (Wiley et al., 2002). Gardasil is currently Federal Drug Administration (FDA) approved for men and women 9-26 years of age. Cervarix, a second vaccine to prevent cervical cancer, gained FDA approval in October

2009. Cervarix is approved for women ages 10 to 25 years of age and protects against HPV strains 16 and 18. Cervarix, like Gardasil, is administered as a three injection series over a six month period. Both Cervarix and Gardasil require cold storage (i.e., between 36-46 degrees Fahrenheit) prior to immunization administration to the patient (Cervarix Package Insert, 2012; Gardasil Package Insert, 2011).

Cervarix and Gardasil have been reported as well tolerated by patients (Jones, 2009; Slade et al., 2009). Currently, there are no recommendations for boosters in females after the completion of the three injection series (Jones, 2009, Rowhani-Rahbar et al., 2011). Although Gardasil was approved in 2009 for use in males, widespread use among men has not been demonstrated (Liddon, Hood, Wynn, & Markowitz, 2010).

Through vaccination against HPV strains 16 and 18 prior to a woman's exposure to the virus, most cervical cancers in the U.S. are preventable (NCI, 2008). The efficacy for HPV vaccines to prevent cervical cancer related to HPV strain 16 and 18 has been reported as greater than 90% in several high level randomized control trials (Adams, Jasani, & Fiander, 2007; Carvalho et al., 2010; Haupt & Sings, 2011; Rivera-Medina et al., 2010; Schwarz et al., 2012; Slade et al., 2009).

However, to prevent HPV infection, the vaccine must be administered prior to HPV exposure. Therefore, vaccination is ideally provided in early adolescence (i.e., before sexual debut) rather than later in young adulthood (Advisory Committee on Immunization Practices [ACIP], 2009). Kim & Goldie (2008) report that the vaccination ratio for quality adjusted life years is the greatest for routine vaccination of 12 year old

girls. However, Kim and Goldie found even when extending vaccination to the age of 26 years of age, HPV vaccination is still economically advantageous to deter cervical cancer and warts in adults, and respiratory papillomatosis in infants. The long term benefits for males in terms of decreased H&N cancers, perianal cancers and genital warts has not been directly reported in the literature; however Kloazar et al. (2010) suggest a significant decrease in some H&N cancers in future generations as increased vaccine administration for males and females is realized.

HPV Knowledge Among Young Adults

Recent studies have noted an increase in knowledge among college aged women (and men) regarding the relationship between HPV and cervical cancer (Sandfort & Pleasant, 2009; Short et al., 2010). Respondents in the study by Short and colleagues noted that knowledge regarding the HPV vaccine was primarily derived from commercials. Other authors have hypothesized knowledge regarding HPV and cervical cancer in the U.S. is as a function of direct-to-consumer targeted advertisements by Merck, the manufacturer for one of two FDA approved HPV vaccines (Herzog, Huh, Downs, Smith, & Monk, 2008).

In a quantitative study of university women (n=875) who were generally less than 25 years of age (98.4%), Burke, Vail-Smith, White, Baker, and Mitchell (2010) reported 79% of the sample indicated they would get the HPV vaccine. The participants were enrolled in a mandatory university internet-based personal health course and were invited to complete the on-line survey regarding the HPV vaccine in 2007. The sample was

primarily white (76%) or African American (15.2%) and attending a university located on the east coast. Among the participants, 64% reported knowledge of the association between HPV and cervical cancer and 78% reported they knew that HPV was transmitted sexually. Among the participants that were sexually active, barriers to vaccine adoption included concerns regarding side effects (43%), cost (42%), and lack of vaccine knowledge (36%). For the respondents that self-reported never engaging in sexual activity (23%), potential barriers to receiving the HPV vaccine included concerns about side effects (34%), cost (33%), and lack of vaccine knowledge (34%). Limitations of this study included the relatively short time between the FDA approval of the vaccine (2006) and the survey (2007), and the reliability of self-reporting. Burke et al. did not report or measure participant self-reported risk factors for HPV acquisition in this sample. Additionally, this study did not measure the influence of the healthcare provider in terms of recommending the vaccine to the participants.

Sandfort and Pleasant (2009) also described the knowledge and attitudes of college students ($n = 1,282$) at a large Northeastern university regarding HPV following the HPV vaccine campaign by Merck. This quantitative study included predominately Caucasian (47.7%) and Asian (37.0%) students. Most of the respondents were unmarried (95.6%), female (57.1%) and the mean age was 19.4 years, with a range of 17 – 45 years of age. Most respondents indicated that they knew that HPV was transmitted sexually, 68% and 77% for the males and females, respectively. More women (89%) reported HPV as causing serious problems for women, than did men (81%). Overall, the male

participants tended to have lower scores on HPV knowledge than females and men had a higher stigma score regarding HPV. The differences in knowledge and stigma scores between the genders were both found to be statistically significant at the .01 level. Although most of the entire sample had heard of HPV (92%) and an HPV vaccine (78%), most reported hearing about the vaccine from television advertisements (65.7%), friends (37.7%), and the Internet (32%). Although Sandfort and Pleasant did not provide an exact percentage, a majority of the women reported preferring sexual health information from a gynecologist, family, and advertisements.

In a similar quantitative study by Gerend and Maglorie (n = 124), which included recruitment of students at a historically black university, most (94%) of the female participants had heard of HPV (2008). Information sources reported by the sample included the media (60%), healthcare providers (39%), and friends (32%). The mean age of students was 19 years, with a range of 18 to 26 years. All of the participants were single; nearly half of the sample were male (48%); and most participants were African American (57%) or Caucasian (32%). The majority of the participants reported they were sexually active (78%) and using condoms consistently (58%); most participants believed their personal risk for HPV was relatively low. A total of four women in the study reported receiving the HPV vaccine, but 65% reported they were interested in receiving the vaccine in the future. Gerend and Maglorie reported that vaccine interest in women was greatest in those with the greatest number of risk factors for HPV. The research conducted by both Sandfort and Pleasant (2008) and Gerend and Maglorie

(2008) included student populations who were of younger ages, and nearly all of the participants were single/unmarried. The study by Burke et al. (2010), did not report the marital status of respondents.

Influences on HPV Vaccination

Among the patient population.

In addition to describing the young adult's knowledge regarding HPV, researchers have also sought to gain a better understanding of other factors which can influence HPV vaccine intention and adoption. In a quantitative study of women ages 18-25 years of age attending health clinics or classes in a university setting (n = 399), Crosby and colleagues (2007), reported 45% of the sample indicated a likelihood to initiate the HPV vaccine. The average age for participants was 20.2 years (SD 1.5 years) and 93% were white, non-Hispanic. Participants who reported a previous STD or abnormal cervical cancer screening examination were statistically more likely to indicate interest in receiving the vaccine ($p < .05$). Of interest, 83% reported hearing about HPV, but previously hearing about HPV was not associated with greater likelihood for vaccination.

Several authors have noted a strong positive relationship between recommendation by their healthcare provider and intention to receive the HPV vaccine among women. In a cross-sectional interventional study by Dempsey, Zimet, Davis, & Koutsky (2006), HPV vaccine acceptance among parents of girls 12 years of age (n = 903) demonstrated a positive correlation between maternal attitudes and experience with genital warts. Attitudes included perceived benefits ($\beta = .38, p < .001$) and

perceived physician recommendation for the vaccine ($\beta = .19$, $p < .001$). However, Dempsey et al. reported no significant change in acceptance among those parents who only received an educational handout regarding the vaccine ($\beta = .03$, $p = .24$).

In a study using focus groups preceded by a brief informational presentation regarding HPV and cervical cancer, Scarinic, Garces-Palacio, and Partridge (2007) reported positive acceptance and intention to receive the vaccine among urban African American and Latina women ($n=27$ and 28 , respectively), ages $17-39$ years of age residing in Alabama. The African American women reported concerns about vaccine efficacy and increased risky sexual behaviors among all women after vaccination; while the Latina focus group, comprised mostly of recently immigrated women, reported increased comfort with vaccination when hearing multiple messages from healthcare providers. Among the African American focus groups, which included 78% unmarried women, concerns included negative judgment by their partner if they received the vaccine, however this was not reported among the Latina focus group, which included 85% of participants who were married or partnered. A limitation of this study was a focus on vaccine acceptance only, rather than actual vaccine behavior.

In a larger cross-sectional study of women between the ages of 13 and 26 years of age, Caskey, Lindau, and Alexander (2009) reported only 30% of the women initiated the HPV vaccine ($n = 1,011$). Caskey and colleagues (2009) conducted a quantitative Internet based study with an ethnically/racially diverse population reflective of the same proportion of women in the U.S. For the women between 18 and 26 years of age ($n =$

599), the mean age was 23 years, 19% had a Bachelor's degree, and only 9% had received at least one injection of the HPV vaccine series.

Caseky et al. reported that most respondents received information about Gardasil from advertisements (61%), healthcare providers (35%), and family members (31%). When stratified to those who had initiated the vaccine, a higher number of women reported receiving vaccine information from healthcare providers and family. In the subsample of women ages 18 to 26 years of age, 80% reported they would likely get the vaccine if recommended by their healthcare provider or a parent, followed by 55% if recommended by a friend. However, this study was limited to those participants that could read English and had access to the Internet. Additionally, in general, most of the studies regarding HPV and cervical cancer screening are limited by participant reliance on self-reporting and social desirability for answering the questions in a certain way.

Among the provider populations.

In a qualitative study of healthcare providers, Kahn, et al. (2007), performed semi-structured individual interviews with 31 pediatricians in the Midwest. Most of the physicians were female (55%), Caucasian (58%) or African American (29%), and nearly all (97%) worked in an urban or suburban setting. The mean age of the participants was 47 years (SD 11.8, range 30-78 years in age). The number of years in pediatric practice was not reported by the authors. Perceived barriers reported by the pediatricians for recommending the HPV vaccine included anticipating negative parental beliefs regarding the sexual behavior of their child and reluctance to discuss sexuality with the

preadolescent patient. The participants also reported difficulty in capturing the adolescent for a routine visit that includes discussing health promoting behaviors such as vaccination. Based on lack of knowledge about the vaccine and/or concern for efficacy, 9% of the physician participants reported they would not recommend the HPV vaccine. This study was limited to a small, somewhat homogenous population of physicians in the Midwest and physician's knowledge may have changed over the course of the last five years, however it supports a need to acknowledge and address healthcare provider knowledge base, in particular those with prescriptive authority, regarding HPV vaccination.

In a larger quantitative study by McCave (2010), a random sample of 227 healthcare providers with prescriptive authority (i.e., pediatricians, family practice physicians, gynecologists, nurse practitioners, and physician assistants) who hailed from Texas, New Mexico, North Carolina, and Louisiana completed a mailed survey. . Although one out of five participants reported limited knowledge regarding the HPV vaccine, nearly all of the participants (greater than 90%) reported encouraging the vaccine to patients ages 9-17 years of age. Unfortunately, over 20% of the healthcare providers reported concerns about vaccine safety and efficacy. Limitations of the study included limited demographical data regarding the sample and whether participant providers provided HPV recommendation for the patient population less than 17 years of age.

Among military healthcare beneficiaries.

Providing healthcare for military service members is a fundamental component of the U.S. military structure. Within two weeks of George Washington taking command of the Continental Army in July 1775, the Continental Congress proposed a resolution calling for a healthcare system to care for sick and wounded service members (Gillett, 1981). Of interest, in the same year George Washington also ordered mandatory variolation, a forerunner of vaccination, for his troops against smallpox (Grabenstein, Pittman, Greenwood, & Engler, n.d.). By the end of the American Civil War in 1866, the MHS established an acute interest in preventive healthcare measures, such as vaccination and field sanitation standards, to combat common ailments among service members such as smallpox, malaria, and typhoid (Bayne-Jones, 1968).

Soon after World War II, imbedded within a tax measure for expanded employee benefits, the MHS mission to care for service members was expanded to include family members (i.e., spouses and children) and retired service members (Granger, Boyer, Weiss, Linton, & Williams, 2010). As of today, the modern MHS includes over 400 hospitals and clinics, 150,000 clinicians, and provides care to over 9 million beneficiaries (Farrell, 2010). The beneficiary population includes service members, their family members, retired service members, and other patients designated by the Secretary of Defense. The MHS provides seamless healthcare worldwide, from care in combat theaters to tertiary care centers in the United States.

The prime focus of the MHS is the medical support of service members engaged in combat operations (Driscoll, 2009). However, an estimated 1.6 million children, or one fourth of the MHS population, are eligible for care in the MHS (Lopreiato & Ottolini, 1996). Using more current data, among the active duty force, over 44% (626,000) are less than 25 years of age and over 640,00 children (ages 7-22 years in age) receive healthcare through the MHS (Office of the Deputy Under Secretary of Defense, 2010). Most beneficiaries in the MHS receive primary care in a family practice clinic setting. The typical family practice clinic includes care of family members, and closely mirrors U. S. civilian practices, to include scheduled routine, acute, and “well” appointments. Military family practice clinics include a mix of physicians and mid-level providers and often include an immunization department co-located within the same structure as the practice.

The MHS is an open access system that provides care, free of cost for all healthcare services, to include the HPV vaccine. In a study by Berry-Caban and Buenaventura (2009) that looked at HPV vaccine among women 9-17 years of age at a large military hospital and satellite clinics (n = 6,154), nearly 77% of the population had not initiated the vaccine. Berry-Caban and Buenaventura reviewed all of the coded visits for HPV vaccination in MHS electronic medical records and reported that of the women between 9-17 years of age who initiated the vaccine (n = 1,406), most had not completed the vaccine, with only 26% completing the three injection series. Berry-Caban and Buenaventura’s research was descriptive in nature only and did not report any additional

information regarding the population studied or possible barriers related to HPV vaccination in the MHS.

In an older study among children who received care in the MHS setting, Lopreiato and Ottolini (1996) compared parental self report and the electronic medical record to assess immunization adherence. A majority (84%) of the children ages 2 months to 18 years were up-to-date (n=1857). However, children more than 12 years of age demonstrated a sharp drop in adherence, with only 50% up-to-date (n=187). The authors noted that in addition to age greater than 12 years (odds ratio [OR] 6.92, 95% confidence interval [CI] 4.95-9.66), univariate analysis demonstrated parental perception of immunization status (OR 3.59, CI 2.60-4.97), delayed health maintenance visits (OR 65.13, CI 44.97-94.53), and non-white race (OR 1.31, CI 1.01-1.17) were significantly associated ($p < 0.001$ and $p < .035$ for race) with immunization delay. Not surprisingly, the authors reported that parents who missed health maintenance visits were not notified of missing immunizations. However, parents with patient-held records were less likely to be delayed. Due to the time frame of this study, the most likely vaccine to be delayed was the measles-mumps-rubella (MMR) booster which is typically recommended at 12 years of age.

Women serving in uniform in the U.S. military forces (i.e., as Army, Navy, Air Force, and Marine Corps) represent 15% of the total force (Maxfield, 2009). However, akin to their male counterparts, a preponderance of women serving in the military are enlisted and younger than 27 years of age. For example, of the women serving in the

Army, 81% are enlisted (Maxfield, 2008) and over 90% of the enlisted women are between the ages of 19-24 years old (Hopkins-Chadwick, 2006).

Current DoD policies for military women in each of the branches of service encourage HPV vaccination, but do not require service men or women to receive the HPV vaccination (Kiley, 2007; Loftus, 2007; Mateczun, 2007). Ironically, military women are required to have routine cervical cancer screening annually (Army Regulation [AR], 40-501). Additionally, treatment for low grade cervical lesions (LGSIL), typically found earlier with consistent repeat screening, has been estimated in the MHS to cost approximately \$2000, while treatment for overt cervical cancer can range from \$15,000 to \$65,000 (Maxwell et al., 2002). In the civilian sector, the average cost for the HPV vaccine is approximately \$360 for the Gardasil three injection series (Ginsberg, Edejer, Lauer, & Sepulveda, 2009) and \$300 for the Cervarix series (Verheijen, 2011). In the MHS, Cervarix is not a formulary approved vaccine. The cost of the Gardasil vaccine series within the MHS is approximately \$105.61 (S. Jamison, personal communication, September 21, 2010), but military beneficiaries receive the series at no out of pocket cost.

In the author's dissertation research, Throop (2010) found that in a sample of Army women ($n = 84$), most had not initiated the HPV vaccine. Among the subsample of participants who completed a survey regarding attitudes and social norms regarding cervical cancer ($n = 72$), only 19% reported having initiated the HPV vaccine, and 11% reported completing the HPV vaccine series. The average age of the participants was 22.9 years (standard deviation (SD) 2.4), with an average of 3.1 years of military service

(SD 2.1). The race/ethnicity of the sample was reflective of the Army population and included a variety of military occupational specialties, such as logistical support (29%), human resources (19%) and medical services (14%).

Throop (2010) reported all participants as high school graduates or equivalent and 25% of the sample as completing four or more years of college. Nearly half the sample reported they were currently married (48%). With the exception of one participant, all of the respondents reported at least one risk factor for HPV acquisition. When risk factors were aggregated, participants reported an average of 2.8 (SD 1.5) risk factors, with the most common including number of lifetime partners greater than 5 (66%), age of sexual debut less than 17 years of age (47%), and condom use rare or never (36%).

Of particular interest in this study is that those participants who perceived their healthcare providers as encouraging the vaccine were statistically more likely to initiate the HPV vaccine ($B = .09$, $p = .02$, $CI = 1-1.29$). However, only one third of female soldiers perceived their healthcare provider as encouraging them to initiate or complete the vaccine. A tertiary aim of the study by Throop also included a comparison between vaccine self report of participants and electronic medical records (EMR) in the MHS. Of the respondents who initiated the HPV vaccine, 90% reported their last vaccine was administered in the MHS. However, only 39% of the HPV vaccinations were verified in the MHS EMR. Most respondents who provided a vaccine history reported completing the series, although no history of any HPV vaccine was recorded in the EMR.

Therefore, the female Soldiers in this study tended to over report their HPV vaccination history.

Delivery of Vaccination Programs in the Outpatient Setting

Surprisingly, a paucity of literature was available which specifically described effective measures to deliver immunizations in an out-patient, family practice setting. In searching for relevant evidence to describe effective programs to boost vaccination rates, nearly all of the literature was focused on improving physiologic efficacy of the vaccine itself. Other authors described efforts which targeted remote villages in developing nations, which were not reflective of the population of interest for this effort (Heffernan, Garland, & Kane, 2010; Kane, 2012; Kane 2010; Kane, 2008). As detailed above, several authors described common and unique barriers for HPV vaccination or predictors for vaccination. Nearly all of the authors called for a need to recognize, eliminate or decrease barriers to vaccination, but upon an exhaustive search, no authors had specifically tested methods to increase HPV vaccination rates among a young adult population.

Of note, several authors have reported various methods to enhance the delivery of pneumococcal vaccination in older, in-patient populations. Middleton et al. (2005) described a comprehensive effort to improve pneumococcal vaccination by implementing a standing order program [SOP]. The physician championed effort initially identified and categorized barriers to vaccination as patient, provider or institutional. For each barrier, the team developed recommendations to overcome or at least minimize the barrier.

For example, a common patient barrier was identified as patient concerns regarding vaccine side effects; the recommendation included reassurance for vaccine side effects and nursing staff providing literature about vaccine side effects. The authors reported provider barriers as requiring on-going education and training, and included support personnel. However, the authors also reported that “allowing individual physicians to opt-out of the SOP [standing order program] was a logical choice to avoid rancor, but was not necessarily in the patients’ best interest” (Middleton, 2005, p. 879). Finally, the authors reported the intuitional barriers as the most difficult to overcome and these often required sensitivity to the facility’s desire to tailor an effective program within unique facility identified requirements. Overall, the authors reported the program as successful. Measured over a two year period, the vaccine rates increased from 6% to 54% in the community hospital setting and from 1% to 32% in a tertiary hospital setting. In the conclusion, the authors reported a requirement for a significant investment by administration and close monitoring of the program in order to achieve success.

In a similar interventional study described by Eckrode, Church, and English (2007), a medical center implemented a program which required vaccine eligibility assessment by the registered nurse (RN) and implementation of standing orders for the pneumococcal vaccine in the non-intensive care settings of the facility. Very little in terms of the intervention that was utilized was described by the authors, however, a three month retrospective review of the patient records following the intervention demonstrated

an increase from 0% to 59% in vaccine assessment by the RN (n=338), and of those, 15% of the patients elected to receive the vaccine prior to discharge.

In contrast to standing orders, Thomas and colleagues (2005) developed and implemented a nurse coordinated algorithm to assess, order and administer the pneumococcal vaccine in a medical teaching unit in a tertiary in-patient care center located in Canada. In this study, a multidisciplinary team was assembled to develop an algorithm to identify patients who needed the vaccine. The algorithm included a series of standard vaccination delivery mechanisms, which included nurses providing vaccine education, ensuring physician orders in medical record for the vaccine, administering the vaccine, and documenting vaccination internally in the in-patient record and externally to the public health unit. The authors reported that over an eight week interventional period an increase from 0% to 54% of eligible patients (n=50) received the vaccine prior to discharge. Of particular interest in this interventional study, the authors reported a need for greater anticipation of on-hand vaccine availability, as the unit ran out of the vaccine within one week of starting the program.

In another effort to increase vaccine delivery, in this case, influenza, Donato, Motz, Wilson and Lloyd (2007) compared a physician reminder system to a manual standing order, and a manual standing order to a provider education component over a three year period. In this study at a 650-bed community hospital, nurses manually screened adult in-patients for vaccine eligibility and reminder stickers were placed on the patient record. The following year, the reminder on the chart was discontinued and a

standing order was utilized. In the third year, the standing order continued, however an educational campaign geared towards physicians and nurses was implemented in order to increase healthcare provider awareness was also included. The initial program that focused solely on manual reminders resulted in only 3% of eligible patients (n=287) receiving the vaccine prior to discharge; the standing order alone 21% (n=197); and when coupled with education, 43% (n=170) received the influenza vaccine prior to discharge. Of note, the authors reported a need to establish vaccine buy-in for benefit among the healthcare providers first, before administrative procedures would generate any improvement.

Summary of the Evidence to Improve HPV Vaccination

There is an adequate amount of high level evidence available in the literature for healthcare providers to confidently promote the HPV vaccine. Nearly every study notes that the benefits of vaccine administration outweigh vaccine risk and cost. The overall strength of the evidence was based on the evaluation rating developed by Steler et al. (1998) and the appraisal of the quality was conducted using the Johns Hopkins Nursing Quality of Evidence Appraisal guidelines (Newhouse, Dearholt, Poe, Pugh, & White, 2007). A preponderance of the literature regarding the vaccine was graded as Level I-II and “A” [High]; involving randomized clinical trials determining the safety and efficacy of the vaccines. Those graded as IV-VII and “B” [Good] were more likely to involve single descriptive studies determining the beliefs, attitudes, and behaviors regarding the vaccines or were opinion statements that supported the adoption of the vaccine.

However, no publications were found which described an EBP procedure or a specific clinical practice guideline initiative to promote HPV vaccination in a single setting. Table 1 summarizes the level and quality of evidence in the literature germane to support HPV vaccination in a military family practice setting.

Table 1a

Synthesis and Analysis of Significant Literature to Promote HPV Vaccination

	Level of Evidence (I-VII)	Quality of Evidence (A-C)
Vaccine Safety & Efficacy		
Adams, Jasani, & Fiander (2007)	VII	A
Saslow et al. (2007)	VII	A
ACIP (2007)	VII	A
AAFP, AAP, AANP (2008)	VII	A
NCI (2008)	VII	A
Kim & Goldie (2008)	V	A
ACIP (2009)	VII	A
Slade et al. (2009)	I	A
Bornstein (2010)	VII	B
de Carvalho et al. (2010)	II	A
Rivera-Medina et al. (2010)	II	A
Castellsagué et al. (2011)	II	A
Haupt & Sings (2011)	I	A
Rowhani-Rahbar et al. (2011)	III	A
Schwarz et al. (2012)	II	A

Table 1b

Synthesis and Analysis of Significant Literature to Promote HPV Vaccination

	Level of Evidence (I-VII)	Quality of Evidence (A-C)
Patient Conditions		
Dempsey et al (2006)	III	A
Scarinic et al. (2007)	VI	A
Crosby et al. (2007)	IV	A
Gerend & Maglorie (2008)	VI	A
Caskey et al. (2009)	III	A
Sandfort & Pleasant (2009)	IV	A
Bond & Brant (2009)	VI	B
Burke et al. (2010)	VI	B
Short et al (2010)	VI	B
Berry-Caban & Buenaventura (2009)	IV	A
Throop (2010)	VI	B
Litton et al. (2011)	VI	A

Table 1c

Synthesis and Analysis of Significant Literature to Promote HPV Vaccination

	Level of Evidence (I-VII)	Quality of Evidence (A-C)
Provider and Clinical Conditions		
Lopreiato & Ottolini (1996)*	VII	A
Thomas et al. (2005)*	VI	B
Middleton et al. (2005)*	VI	A
Eckrode et al. (2007)*	VI	B
Donato et al. (2007)*	IV	B
Kahn et al. (2007)	VI	B
McCave (2010)	IV	A

*non-HPV vaccine delivery

The current evidence, including numerous research articles, policies, position statements, and clinical practice guideline, supports an HPV vaccine program in a MTF

family practice setting. When weighed with the known risks of the vaccine and feasibility of implementing a vaccine program at this clinic, the benefits of adoption of this program were found to be acceptable among the key stake holders at the facility.

Summary of the Literature

Although there is no cure for HPV, the HPV vaccination can prevent the two most common strains related to cervical and H&N cancers, and the two most common strains related to genital warts. The benefits of vaccination continue for women several years into adulthood and the emerging research suggests that vaccination for men will be beneficial for both men and women.

Most women in the Army report at least one risk factor for HPV acquisition (Throop, 2010; von Sadvoszky & Ryan-Wenger, 2007). However, few MHS beneficiaries initiate the HPV vaccine (Berry-Cabon & Buenaventura, 2009; Throop, 2010). Reaching young adults for vaccination is historically difficult due to limited exposure to healthcare providers and vaccine education (Scarinci, Garces-Palacio, & Partridge, 2007). An older study among adolescents who received care in the MHS has demonstrated vaccine adherence is problematic in the MHS as well (Lopreiato & Ottolini, 1996). In an effort to reach more men and women in the MHS, this proposal sought to first target healthcare provider behavior to increase HPV awareness and vaccine risk and benefits. The next chapter describes the methods that were undertaken to implement an EBP HPV vaccine protocol in a large military family practice facility.

CHAPTER III

Methodology

This chapter will describe the methodology utilized in this EBP project. The purpose, implementation strategies, organization context, outcome measures, method of data collection and analysis, and protection of human subjects will be explained as well.

Strategies

Setting

Plan the Practice Change.

The setting for this project was one of the largest free standing multidisciplinary clinics in the DoD, providing direct care to over 39,000 military beneficiaries. This clinic is organized under and located within five miles of a medium sized, military teaching hospital in the mid south. At the beginning of the project, 4249 females and 7312 males between the ages of 9 and 26 years of age were enrolled in the clinic. In the previous year this clinic reported providing 24,000 immunizations, including over 400 HPV vaccinations (approximately 33 per month).

Providers and staff at the clinic included: 18 physicians, 6 nurse practitioners, 10 physician assistants, 13 registered nurses, 29 licensed practical nurses, 29-certified nurse assistants, and 13 clerks. At the time of this intervention, the clinic did not require reporting any immunizations as a Healthcare Effectiveness Data Information Set (HEDIS®) measure.

Current vaccination practice at this facility included a dedicated immunization section with signed, standing orders by the senior physician of the clinic. The standing

orders were originally prepared by MILVAX and are available on their website. The standing orders mirror the current DoD and ACIP vaccine guidelines for infants, children and adults and are updated yearly. The immunization section was open Monday- Friday during the same hours as the main clinic. The section was supervised by a registered nurse, and included 2-3 LPNs who are assigned to work most days in the unit. Patients typically are referred to the section by their healthcare provider immediately following “well” visits (i.e., sports physicals) and during seasonal vaccine programs (i.e., influenza). However, all beneficiaries may walk in the section during normal clinic hours and request their record to be reviewed and receive any immunizations that are recommended per the immunization section standing orders. This immunization section also maintains most vaccines which are recommended for most global deployments, i.e. typhoid.

Documentation for vaccination is performed by the immunization section staff member for elements such as patient education and vaccine delivery details in the EMR. Recipients of the vaccine are given the CDC handout for information on the vaccine they have received, and are asked to stay in the vicinity of the clinic for at least 15 minutes following any vaccine. Recipients are verbally counseled about the various vaccines they should receive by the unit staff member in a semi-private area behind a curtain.

During the counseling, the staff also inquires about the beneficiary’s overall health, specific vaccine precautions and contraindications, and concerns they may have regarding any vaccines, and in particular, the one they are receiving that day. Upon

receiving a vaccine, recipients are asked to be seated, but may elect to stand or lay on an exam table located in the semi-private area. Directly adjacent to the unit is an emergency cart with defibrillator and medications which are routinely given in response to allergic or anaphylactic reactions.

The clinic also conducts seasonal “outreach” to individual military units that are requested by the military unit chain of command. When requested, staff members from the clinic pull individual beneficiary immunization records (typically active duty service members) and deliver required vaccines to the requestors work site. This outreach program generally delivers over 200 vaccines in a single morning and usually distributes vaccines which are reportable by the unit chain of command (i.e., tetanus, yellow fever, and influenza). The HPV vaccine has not been given to service members during these outreach programs.

Benefits.

Upon vaccination prior to exposure to HPV 16 and 18, a 70% decrease in abnormal cervical cytology is estimated (Centers for Disease Control [CDC], 2007). Additionally, a 90% decrease in external genital warts is also found to occur. By reducing the potential for HPV in women, the ability to transfer the virus to their partner is also decreased. Benefits to patients and partners also may include fewer work days lost to follow up for cervical abnormalities and genital warts, and long-term, a potential decrease in head and neck (H&N) cancers. Among men, the benefits for vaccination also

include prevention of genital warts, HPV associated cancers, and transfer of the virus to partners (ACIP, 2011).

In terms of genital warts, approximately \$16.5 million is spent annually in the MHS for the three most common topical medications [Aldara, Condyllox, and Podophyllin] (personal communication, R. Goodman, October 5, 2010). It should also be noted that in Australia, 70% of all eligible women have been vaccinated and within three years, a decrease of 75% of new genital wart cases has been reported among women and a 30% drop among heterosexual men (Hammond, 2011).

In terms of cervical dysplasia, nearly all women who become infected with HPV will demonstrate abnormal cytology (Balasubramanian, Palefsky, & Koutsky, 2008). For those women who are identified with abnormal cytology, consequences include stigma associated with HPV detection and fear regarding a serious medical disease. In addition to the psycho-social burdens, follow up for abnormal cytology usual incurs several additional visits to the gynecology clinic to ensure the infection resolves, or removal of precancerous cells via excision or freezing.

Among the military beneficiary population, over 15% of family members (wives) and 30% of military women are estimated to have abnormal cervical cytology in their lifetime (Ollayos & Peterson, 2002). In terms of organizational benefits, the elimination of colposcopic examination, which averages \$2000 (Maxwell, et al., 2002), easily outweighs the cost of HPV vaccination at this clinic, a cost of \$261.65 to complete the series (A.Vitt, personal communication, December 8, 2010). Further, the elimination of

abnormal cytology and external genital warts can translate to greater patient appointment availability and decreased workload, as less colposcopic examinations and other associated follow up for the continued surveillance of HPV sequelae and treatments are required.

In the same setting, less than 30% of eligible military women initiated the HPV vaccine (Berry-Caban & Buenaventura, 2009). However, researchers have noted that women and men report greater likelihood to initiate the HPV vaccine when encouraged by a healthcare provider (Scarinci, Garces-Palacio, & Partridge, 2007; Throop, 2010). Therefore, in this clinical setting it was an ideal time to educate and encourage all eligible men and women to receive the HPV vaccine.

The direct costs and savings estimated for this clinic was based on known and estimated immediate benefits only among women who were eligible for HPV vaccination. The calculations included the following estimates; among 4200 women assigned to clinic, 15% (630) have received the vaccine, of the remaining group 20% were active duty (714), 30% of active duty (AD) women and 15% of family members (FM) were likely to have an abnormal cervical cancer screening exam due to HPV, and those who have an abnormal exam subsequently will be required to have at least two colposcopic exams costing \$2000 each. Estimates regarding the vaccine included the cost of the vaccine at \$262, and regardless of vaccination, and it is further hypothesized that 30% of women would still require a colposcopy.

Estimating that 30% of women would not benefit from the vaccine, a full vaccination program would potentially result in a cost to the clinic of \$935,340 in vaccine cost and \$772,000 in colposcopy, for a total of \$1,707,340 in costs associated with no vaccination. [Although, one could argue that the cost is only \$952,000 since without vaccination those women would still require a colposcopy regardless of their vaccine status.]

In contrast, estimating that 70% of the women would not require a colposcopy, the cost avoidance would result in a net gain of \$92,660. Although a relatively modest amount, this calculation does not take into account other factors associated with HPV, such as lost time from work; actual cost associated with a diagnosis of cancer in either a man or woman; stigma and emotional distress associated with a detected HPV infection, and/or pharmaceutical costs associated with treatment of genital warts. Therefore, in using only a simple calculation for colposcopic exams, the benefits of HPV vaccination are readily supported.

Table 2

Analysis of Direct Cost and Savings for HPV Vaccination in an Outpatient Setting

4200 assigned to clinic
-630 received full series previously (15%)
3570 require vaccine @ \$262 = \$935,340
30% will not benefit from vaccine and require at least 2 colpo exams
1071: (20%AD) 214 x .30 (abn pap) = 64 x \$4000 (colpo) = \$ 256,000
(80%FM) 857 x .15 = 129 x \$4000 = <u>\$ 516,000</u>
\$ 772,000
Total cost for program: \$935,340 + \$772,000 = \$1,707,340
70% will benefit from vaccine
2499:(20%AD) 500 x .30 (abn pap) = 150 x \$4000(colpo)= \$ 600,000
(80%FM)1999 x.15 = 300 x \$4000 = <u>\$1,200,000</u>
\$1,800,000
Total gain in avoiding Colposcopy \$1,800,000
Net Gain in program in terms of Colposcopy avoidance only
(Gain - Cost) = \$1,800,000- \$1,707,340 = \$92,660

Stakeholders.

Several staff members in the facility were identified in this program as key stakeholders. The clinical nurse officer in charge (CN-OIC) [or more commonly known as the head nurse or nurse manager] was the clinic champion who provided access to the setting and staff. In planning this program with the CN-OIC, core stakeholders within the

clinic were immediately identified as well. Foremost were the healthcare providers and staff members of the immunization section. Second, this program further depended on buy in from the midlevel providers and physicians seeing patients in the clinic to promote the vaccine during appointments. In addition, the nursing staff, including the LPNs and nursing assistants, were required to be actively engaged in the project in order to provide patients with accurate information regarding the immunization section and HPV vaccine itself. As observed in the setting, the LPN and assistants often encourage administration of vaccines, both formally during routine and well visits, and informally when patients and parents ask questions regarding vaccines.

In concert with recommendations in the literature, the team also contacted the pharmacy to ensure the HPV vaccine would be readily available in the immunization section for immediate delivery. It was believed that HPV program success would increase the overall immunization section workload. It was anticipated the HPV project would require additional staff efforts in terms of vaccine education and promotion. Therefore, strong staff buy-in was needed at all levels. Due to particularly high price of the vaccine and possible increase in common parental concerns associated with HPV vaccination, support of the clinic physician officer in charge [or commonly known as the medical director] was also fundamental for the successful implementation of the program. Last, in order to conduct the four separate chart reviews, one pre-education and monthly for three months following the educational component, support from the patient administration department (PAD) was required.

As indicated by the literature and clinical practice guidelines, HPV vaccination is clearly beneficial for nearly all men and women less than 27 years of age. For a variety of reasons the patient may elect to refuse the vaccine. The success for this program also required a sensitivity of the nurse to neutrally offer the patient a vaccine which defeats a virus which is spread primarily via sexual contact.

Organizational Context and Considerations.

Several obstacles were anticipated in generating interest in the project. Since HPV related cancer and genital warts are primarily transmitted sexually, a frank discussion regarding sexuality and the relationship between HPV and cancer was anticipated by the project director, particularly in terms of interactions with administrators and nurses. HPV vaccine has generated a great deal of publicity, and the literature supports the conclusion that nearly all staff members benefit from a review of vaccine indications, efficacy, and safety.

Several organizational systems were anticipated to facilitate acceptance and support for implementing this project. First, prior to the implementation of the program, the HPV vaccination was available for both men and women at this facility in the immunizations section. Therefore, from an administrative standpoint, this project represented a change in promoting a vaccine which has been available in the clinic for several years for women, and several months for men. Therefore, little change in structure (i.e., acquiring, storing the vaccine and administering the vaccine) was required. The immunization section reported confidence in being able to access more vials of the

vaccine from the main hospital in the event of a large increase in vaccination requests.

Individual Strategies.

A multi-pronged approach that included project and protocol development, a formal education program, and poster reminders, was utilized to encourage immunization within the out-patient clinical setting.

In-services. Formal education for the project was accomplished by the project director during the first week of November 2011. This included, the project director and CNO-IC (head nurse) conducting an in-service for nursing and medical staff in the clinic during regularly scheduled educational in-services. The in-service included a review of the current ACIP *Clinical Practice Guidelines for Quadvivalent HPV Vaccine*, a description of the burden of cervical cancer to the U.S. and military in terms of incidence, associated deaths, as well as costs and benefits for patients and clinicians. The in-service also included a short review on vaccine development, indications and contraindications, and side effects.

The in-service ended with open dialogue to identify potential barriers and strategies for the clinic staff could employ to promote HPV vaccination in the clinic setting [See Appendix B, In-service]. The in-service was based on the HPV education program available on-line from the CDC and included previous research concerned with military women. Although additional in-services regarding patient behavior to accept or decline the vaccine were offered at two to four weeks intervals, the CN-OIC reported staff as generally open to promoting the vaccine and no further questions arose regarding

the vaccine. Additional in-services were offered as “brush ups” and were planned to be less than ten minutes in duration, with time for open dialogue regarding adoption of program and revision of implementation strategies suggested by the staff.

Posters. In addition to the in-service, an informational poster regarding HPV vaccination was developed and displayed in the two staff break rooms for all staff members to review [See Appendix C, Staff Posters]. The poster included key vaccine literature and review of the CPG. The poster also included a section to update current statistics on patient adoption of the vaccine.

Informational posters were also directed toward the patients to garner interest in the HPV vaccine and these were displayed in the clinic waiting area [See Appendix D, Patient Poster]. In the immunization section of the clinic, patients received the standard HPV vaccine immunization handout developed by the CDC [See Appendix E, Patient Handout].

Lead Agents. A “lead agent” , who was prepared to answer questions and address concerns, was recruited from the immunization section. During the in-service session, this lead agent immediately self-identified an interest in the role. The lead agent received a booklet regarding HPV vaccination, seminal articles regarding HPV and the HPV vaccines, and a copy of the formal education program handout. The lead agent received additional training provided by the project director and the CN-OIC (i.e., role play regarding common clinical scenarios centered on HPV vaccination, questions regarding risk, vaccine efficacy, and vaccine safety.) In addition, the lead agent relayed several

discussion comments made by patients and parents regarding the vaccine (i.e., concerns regarding safety of the vaccine, what they had personally reviewed on the Internet regarding vaccines in general, wanting to wait an additional year before starting the vaccine, or belief that they or their child did not require the vaccine). The lead agent reported a plan to make copies of the several of the professional articles to give to parents which supported the safety of the vaccine.

Finally, the author and CN-OIC reviewed the clinic orientation check list for new staff members. Items on the checklist included ensuring information was offered to patients regarding the HPV vaccine and that teaching on administration of the HPV vaccination was included in the training. A representative from PAD was recruited to provide electronic delinked data (age, gender, number of previous HPV vaccine, and sponsor rank- grouped by lower enlisted, junior enlisted, senior enlist, warrant officers/junior officer, senior officer, and all other/unknown) for all males and females greater than nine years of age and less than 27 years of age assigned to the clinic during the study time frame for review by the project director.

Data Collection

Prior to the educational intervention, the following delinked information from the records of all men and women greater than nine years of age and less than 27 years of age assigned to the clinic was requested from the PAD department:

Patient demographics [Secondary objective]

previous history of vaccine (no/yes – received vaccine # 1/#2/#3)

sponsor's rank (Grouped E1-4; E5-6; E7+;All Warrant Officers
and O1-O3;O4+; and Other/unknown)

patient gender

patient age

Provider demographics: [Primary objective and provided by the clinic CN-OIC]

Level of education/certification were collected during the in-service and recorded on the staff in-service record sheet. The educational intervention was deemed complete when 80% of all staff members assigned to the clinic received the in-service. This was documented via the clinic in-service sign in sheets in the first week of November 2011.

30, 60, and 90 days after the education intervention, the following delinked information from the records of all men and women greater than nine years of age and less than 27 years of age assigned to the clinic was requested from the PAD department monthly.

Patient demographics [Secondary objective]

previous history of vaccine (no/yes – received vaccine # 1/#2/#3)

sponsor's rank (Grouped E1-4; E5-6; E7+;All Warrant Officers and
O1-O3;O4+; and Other/unknown)

patient gender

patient age

Outcomes

Variables and instrumentation

The primary variable of interest included the change in the number of HPV vaccines delivered at the clinic. A secondary variable of interest was the actual number of healthcare providers who received the HPV training. Descriptive variables included the patient's age, sponsor's rank, and previous HPV vaccine behavior.

Table 3

Method and Evaluation of Selected Process

Name	Evaluation	Method of Data Collection
Staff education [Primary]	Descriptive	Number and skill level of staff members who received formal education regarding HPV and HPV vaccine.
Patient behavior [Secondary] Dependent Variable: Vaccine Behavior	<i>t</i> -test and Generalized Estimating Equations (GEE)	Review of outpatient records post intervention at MTF at time period 0 (30 days prior), and time period 1 (30 days), time period 2 (60 days), and time period 3 (90 days) [Time 1 to start 1 week after 80% of staff received formal education]
Patient behavior [Secondary] Dependent Variable: Vaccine Behavior Independent Variables: Gender, Rank, Age	Descriptives χ^2 & Logistic Regression	Describe demographics (gender: men and women, age: greater than nine and less than 27 years of age, beneficiary sponsor's rank, HPV vaccine (yes/no and if yes #1, 2, or 3.) Determine if there is a difference among demographic variables and HPV vaccine behavior.

Goals.

During the first month, the initial goal was a 10% increase in eligible men and women who received the HPV vaccine. During the second and third months, the benchmark was an increase of an additional 10% vaccinations for each month. These

goals for vaccine administration were selected by the project director and the CN-OIC to reflect the similar initial vaccine improvement rates reported in in-patient settings (Eckrode, Church, & English, 2007; Middleton et al., 2005; Winston, Lindley, & Wortley, 2006).

Following program adoption within the clinic, a 12 to 18 month timeline was forecasted in congruence with the *Healthy People 2010* benchmarks of 90% vaccination among eligible men and women for a similar communicable disease, Hepatitis B. The current national goal for *Healthy People 2010* is that 90% of all Americans will be vaccinated against Hepatitis B. Hepatitis B is also a sexually transmitted infection with an associated immunization that can prevent some forms of liver cancer, and is offered in the postpartum, pediatrics and family practice settings. However, the current guideline and proposed guideline for *Healthy People 2020* does not include a benchmark for HPV vaccination.

Protection of Human Subjects

Proposal Regulatory Approvals

Upon approval by The Catholic University of America School of Nursing, the project director submitted an identical proposal to the Womack Army Medical Center (WAMC) Institutional Review Board (IRB) for approval of this EBP project. Following this approval [specifically delineation as “Exempt Research Status”], the protocol was submitted to The Catholic University Committee for the Protection of Human Subjects for secondary institutional review board (IRB) approval.

Risk.

The risks involved for the patients in this project were considered minimal and are primarily related to potential discomfort among healthcare providers and patients when discussing sexually transmitted diseases and potential loss of privacy among the patient population. However, several steps were taken by the author and project team to reduce or mitigate these potential risks.

Privacy measures were encouraged by all clinic staff members during the in-service to reduce potential loss of confidentiality. The need to assess for risk among patients, to include those which may occur during sexual activity, was highlighted during the in-service. During the in-service each staff member was encouraged to reflect on their professional practices. Staff members were asked to consider that a population of Airborne Soldiers may have a potential attraction to higher risk taking behaviors than their civilian counterparts, and that a common risk [HPV] associated with sexual activity maybe reduced through simple encouragement by a healthcare provider. [This “moment of reflection” elicited several chuckles and verbal “buy-in” by several staff members attending the in-service.]

When assessing sexually transmitted diseases and the benefit of prevention by means of vaccination, all staff members of the clinic were encouraged to provide patient counseling regarding HPV in a private room. In addition, the author and team ensured that patient records were handled in a secure fashion throughout the program. [Security of data is described in greater detail below in the “Data Management and Safety” section.]

Benefits.

Benefits of the study included immunization of the patient which may result in up to a 70% reduction in abnormal cervical cytology. Staff additionally benefit by participating in an evidence-based practice project that has the potential to greatly diminish HPV associated diseases. Long term, the patient population may benefit from prevention of HPV infection if they have not been previously exposed to the specific HPV strains covered by the vaccine. However, no monetary incentives or gifts were offered to the patient or clinic staff for participation.

Knowledge that was gained from this program can be used to further evaluate military relevant healthcare needs related to HPV and other vaccination efforts. This program may be used to develop guidelines for providers and administrators to address vaccination in other military and civilian settings.

Data Management and Safety.

Data collection occurred in accordance with The Catholic University of America (CUA) Committee for the Protection of Human Subjects protocols, WAMC's Institutional Review Board (IRB) requirements, and Health Insurance Portability and Accountability Act (HIPAA) guidelines. Data was de-linked by the PAD department and by the CN-OIC. De-linked data was then entered into SPSS v.17 solely by the project director only. Data saved in the electronic SPSS files was secured on a dedicated work computer by the project director. A backup SPSS file of the de-linked data was on the project director's networked computer at Walter Reed National Military Medical Center which is restricted via Identification Card access with password protection and additional

high level military network security. No transmissions of data or linkage to other databases occurred during this project.

Timeline

The goal of this EBP program was to introduce a HPV vaccination effort to reach eligible MTF beneficiaries in a family practice clinic. The following timeline describes the key elements for the program from time of commencement to the end of the project.

Table 4

Timeline for HPV Vaccine EBP Project

	Mar 2011 - Oct 2011	Nov 2011 Dec 2011 Jan 2012	Feb 2012 Mar 2012	Apr 2012 Oct 2012
IRB CUA	X			
IRB MTF	X			
Data Collection		X		
Intervention MTF		X		
Analysis		X	X	
Dissemination				X

Conclusion

Largely due to the Papanicolaou screening test initiated in the 1950s, the incidence of cervical cancer has significantly decreased in women. In the U.S., cervical cancer fails to be included in the top 10 cancer diagnosis for women in the past decade (NCI, 2005). However, HPV associated cancer is over expressed in minority populations in the U.S. (Jemal et al., 2007) and in men and women serving in the military women (Yamane, 2006). Worldwide, in many of the locations where service members travel in the course of their military career cervical cancer remains the second most common cancer in women (CDC, 2007).

Although HPV associated cancers, which include cervical cancer in women and tonsillar, perianal cancer in men and women, are over represented in the military population. And, unfortunately, few Military Healthcare System beneficiaries eligible for the vaccine (i.e., between the ages of nine and 26 years of age) have started the HPV vaccine series. This EBP program serves as a pilot for development and implementation of similar EBP programs to address and promote cancer preventing vaccine uptake in outpatient DOD settings.

CHAPTER IV

Results

The initial proposal for this effort was developed to be delivered in an in-patient, postpartum setting; however, the author was unable to overcome a major roadblock [concern for vaccine safety among postpartum women] at the facility. Therefore, the project was revised to be delivered in a family practice setting among young teens and adults. In March of 2011, the project received IRB approval [at the site and CUA], but was further delayed as it was determined at the site that a Cooperative Research and Development Agreement (CRADA) would be required prior to implementation of the project. In October 2011, a CRADA was obtained and approval for the project at the site was granted. Due to several holidays projected for December and January, and large staff turnover projected during the winter, the Clinical Nurse Officer in Charge (CN-OIC) recommended starting the project on the first day of November 2011.

Prior to implementation of this effort, approximately 200 beneficiaries received the vaccine at the clinic in the previous 90 days. Most were females (80%) and receiving their first (of three) injections in the series (70%). The total number of eligible men and women assigned to the clinic ages 9-26 years of age remained fairly stable over the three month period (average 11,416 [SD 1336]). However, additional demographics were not available later than October 2011 and only included the population that had received the vaccine. The rank of the sponsor reflected the typical division of rank in the clinic and in the military, approximately 80% enlisted and 20% officers. Throughout the effort

project, the age for those patients who received the vaccine was typically older, between 19-21 years of age, rather than the ACIP target, 11-13 years of age.

Table 5

Frequency Table for HPV Vaccination Oct 2011- Jan 2012

	Total assigned	Received vaccine	Gender	Vaccine #	Sponsor rank
Oct	10,016	59	Male 14 Female 45	# 1 30 # 2 25 # 3 4	E1-4 25 E5-6 10 E7+ 13 WO/O1-O3 7 O4+ 4
In-service Intervention					
Nov	11,561	70	Male 31 Female 39	# 1 44 # 2 17 # 3 9	E1-4 38 E5-6 18 E7+ 6 WO/O1-O3 5 O4+ 3
Dec	Unk*	70	Male 25 Female 45	# 1 31 # 2 26 # 3 13	E1-4 26 E5-6 17 E7+ 14 WO/O1-O3 11 O4+ 2
Jan	12,677	70	Male 24 Female 46	# 1 38 # 2 22 # 3 10	E1-4 29 E5-6 16 E7+ 16 WO/O1-O3 7 O4+ 2

*unable to be provided by PAD

Implement and Evaluate the Practice Change Among Staff.

On the first day of November, 2011 92% (n=108) of the staff were available and attended the in-service. The in-service was delivered by the CN-OIC and project director over a 60 minute period during the clinic's standard monthly training afternoon. The Medical Director was present throughout the in-service and verbalized excitement for the EBP project at the clinic. Key stakeholders (medical director, patient administration department representative, and immunization section staff) were contacted in-person the morning prior to the in-service by the project director and CN-OIC. Several weeks prior to the in-service, project posters and handouts were made available to the immunization section staff by the CN-OIC.

Throughout the in-service most staff members reported the primary focus of the HPV vaccine as being only for young women (ages 11-13) to prevent cervical cancer, but reported some parents asking for their sons to be vaccinated as well. As reported by the CN-OIC in reviewing the linked data set, several sibling sets (brother and sisters) were beginning to receive the vaccine over the previous three months. During the in-service, only one staff member reported knowledge regarding the association between HPV and some head and neck cancers. After the in-service several staff members inquired as to whether the vaccine age would increase such that women and men up to 40 years of age could be included.

Following the in-service, the project director met with the lead agent and immunization section staff to observe the clinical setting, review the typical patient flow

in and out of the section, and the conditions of the patient handouts and posters. The posters for patients were displayed prominently in the immunization section and the project handouts were readily available. The immunization clinic had several additional posters related to HPV vaccine that were hung in other high patient traffic locations in the clinic.

All of the immunization section staff had previously delivered at least one dose of the vaccine, but reported those individuals who had children had difficulty returning for the second and third dose. Several strategies were discussed with immunization staff members as to how to increase the number of return visits. Suggestions from the staff included linking the next vaccine with a “red letter” date (i.e., a birthday, anniversary, or upcoming holiday). In addition, the staff reported among school age children, June would likely be the best month to encourage starting the vaccination, with the second scheduled dose in August and the final dose during the winter school break (e.g., “end of school, beginning of school, and Thanksgiving or Christmas holiday break”). The immunization clinic also reported many parents as interested in the vaccine for their child, but wanted to wait to start the series until the following year (i.e., when starting high school rather than middle school). Very few staff members reported encouraging adults (greater than age 18 years of age) to receive the vaccine. The staff reported the focus of most adult visits was typically related to up-coming travel out of the country, pregnancy (influenza), or among adults who were not eligible for the vaccine.

Staff members of the immunization section and the project director conducted private meetings to discuss the challenges in reaching a young adult population. Parental concerns related to the HPV vaccine, were voiced and a plan to start to ask parents about their immunization status during each “well baby” visit was constructed. Several staff members at the clinic reported their interest in an EBP project at the setting but also voiced difficulty in convincing their peers on instituting a change in behavior. Later in the afternoon, the project director and the CN-OIC approached several of the providers in their offices to discuss the project and any individual questions they had regarding the vaccine. One provider inquired about the presence of adjuvant (specifically aluminum) in the vaccine. The vaccine insert was reviewed via the MILVAX website with the provider and aluminum was noted to be an adjuvant for this vaccine. The provider reported no previous use of the website, but due to the ease of use, planned to use the site in the future.

Although only half of the prescribing staff was available in the clinic during the rounding, nearly all reported that health promotion vaccine activities outside of flu season or during well baby visits were not typically discussed during most of their routine appointments. However, many of the support staff (LPNs and assistants) reported that they would consider changing their practice to ask and promote vaccination among all their patients while they were screening the patients prior to being seen by the mid-level or physician provider. One staff member suggested incentivizing vaccine promotion (i.e.,

a pizza party) between the clinic teams (although determining which team the patient was assigned to was beyond the scope or ability of this effort).

The posters were well received by the staff in the break areas and updated by the CN-OIC as data became available. However, due to delays in data retrieval by the PAD, the data was limited by hand counting the data in the clinic each month or using data that was several months older than desired. As presented in the following section, the availability of data from the PAD department proved to be roadblock in conducting the higher level statistical tests originally planned for the effort.

Discussion

Implement and Evaluate the Practice Change in the Patient Population.

Following the educational intervention on the first day of November, 2011, the average age for vaccination over the three month effort was 20.1 years of age (range 9-29 years, SD 4.8 years). A majority of the population who received the vaccine were females (61.9%). Most of the population receiving the vaccine were receiving their first dose of the vaccine, 44 the first month, 31 the second, and 38 the third. In the third month, 44 would have been due to receive their second dose of the vaccine, however the number of participants receiving their second vaccine was relatively stable, 9 in the first month, 13 in the second month, and 10 in the third month.

Although a small population, it was apparent that some efforts to improve returning for the vaccine were evident as the numbers for second and third doses trended

upwards during the effort. In addition, during project implementation more males elected to receive the vaccine as well. Surprisingly, the age of the patients receiving the vaccine was much older than the perceived typical vaccination age reported by the staff, 20 years in age, rather than age 14 as reported by the staff. In regards to the sponsor's rank, a military-specific correlate with socioeconomic conditions has been reported in most health promotion literature. In the present project, the sponsor's rank mirrored project participants versus non-participants. That is, approximately 20% of the sponsors were officers and 80% were enlisted sponsors.

Unfortunately, it was discovered that as a consequence of staffing changes in the PAD, several variables, the most significant being the demographics related to those beneficiaries who did not receive the vaccine, were not available at all or until several months after the intervention had begun. Therefore, in order to measure the change in practice, the CN-OIC hand counted only the vaccines given at the site each month.

In combination with the small numbers of patients who had received the vaccine, no significance among the groups was able to be calculated via the use of generalized estimating equations. Further, it was not possible to determine independence between each group, which would therefore violate assumptions required to properly conduct χ^2 and t-tests. For example, in developing future efforts to promote the vaccine, it would have been ideal to determine which populations were least likely to initiate the vaccine and/or return for a second or third vaccine. Further discussion regarding the program is continued in the final chapter.

CHAPTER V

Summary

Integrate Change in Practice.

Several opportunities for implementing an HPV “best practice” protocol were revealed in this applied EBP effort. A key finding was that a practical understanding of the dynamics involved in conducting a successful outpatient vaccination program is largely missing in the literature or from among leading organizations for immunization practice and policy (American Academy of Asthma, Allergy and Immunology (AAAAI) and American College of Allergy, Asthma and Immunology (ACAAI).

The *2010 National Vaccine Plan*, published by the U. S. Department of Health and Human Services, provides a broad vision and denotes several national strategies to promote and monitor vaccination, but fails to directly address clinical conditions to enhance immunizations (2010). MILVAX provides as impressive on-line library of resources, but a comprehensive clinical practice guideline is also missing. In addition, the MILVAX Immunization Leaders Vaccination Course mission reports a primary focus on anthrax, smallpox, and influenza vaccination programs (MILVAX, 2012).

In conducting this project, several organizational and individual practices reported in similar literature emerged that will inform future HPV vaccine practice, and can potentially enhance immunization delivery in military and civilian clinical settings. For example, vaccination should not be an afterthought following a “well child visit”, but rather should be employed as a primary health-promoting activity for every age group that receives any level of care (Skull et al., 2007). Unfortunately, the sparse literature

regarding immunization practice in the outpatient setting is typically in reference to preparing for pandemic disease.

However, some authors do offer insights for best practice measures which could be translated to address an endemic of vaccine-preventable infections such as HPV. Bourgeois et al. (2011) reported improvement in overall vaccine delivery via soliciting input from both staff and patients regarding clinic design and physical layout. For example, the waiting area was enlarged to accommodate multiple family members in the clinic and well as strollers for younger children. In that effort, the intervention to improve patient outcomes was geared towards healthcare providers and no input from the patient perspective was elicited. A future effort would likely be greatly enhanced by a stronger partnership between the healthcare providers and patient population. Perhaps a different clinical design could be explored to promote vaccination efforts (e.g., perhaps a satellite location with extended and weekend hours such as the commissary where family members visit more frequently, could enhance overall vaccination in the community).

Suggestions from the clinic staff included how to directly reach patients and parents in unique venues; for example by delivering the vaccine at local middle and high schools, during sports physicals, and in association with other common vaccines such as tetanus and MMR. Of note, Prosser and colleagues reported that offering non-traditional settings for influenza vaccination among adults offers cost-savings when compared with administering them during scheduled office visits (2008).

In addition, Mueller et al., report that healthcare providers miss opportunities to increase immunization rates (among Latino immigrants with historically low HPV vaccine awareness) by failing to leverage social network communications, specifically via television and internet, to improve vaccine awareness (2012). Several such vehicles for communicating information on HPV vaccine efficacy, safety and availability exist in the MHS, and include installation newspapers and internet sites. A number of authors have also reported modest improvement in pneumococcal vaccination rates in the in-patient setting by establishment of standing orders for immunizations (Eckrode, Church, & English, 2007; Lawson, Baker, Au, & McElhaney, 2000; Sokos et al., 2007). This practice is currently in place at most military treatment facilities, including the setting for this project.

An emerging theme noted in several publications suggested a need for multidisciplinary and multidimensional approaches to improve vaccination rates. In response to The Centers for Medicare and Medicaid Services' requirement for public reporting of the pneumococcal vaccine, Scheurer, Cawley, Brown and Heffner (2006) reported that physician education achieved only a small improvement in vaccination rates. However when combined with several approaches, such as including standing orders and encouraging high acceptance for vaccination among nurses, vaccination rates improved to a sustained rate of more than 95%.

Humair, Buchs, and Stalder (2002) also reported an improved influenza vaccination rate among an elderly out-patient population by utilizing a multifaceted

approach which included patient information, physician training, record reminders and peer feedback. In developing models to improve vaccination rates for both influenza and pneumococcal vaccines, Bakare and colleagues (2007) noted that although the immunization rates were similar, a nurse-driven model (in contrast to a physician-driven model) identified more patients requiring vaccination. While the Bakre effort was nurse-led, significant contributions from associated medical disciplines were largely missing. In a study regarding healthcare visits of adolescents, Rand et al.(2007) reported that many adolescents are not seen by pediatricians, who were noted as the most likely to promote vaccination, but rather by specialists such as orthopedists, dermatologists, psychiatrists, and obstetrician-gynecologists. Consequently, inviting other disciplines to consider and promote vaccination could expand and enhance the efficacy of a universal message for adolescents and their parents to initiate (or complete) the HPV vaccine. Ironically, although routinely screening for oral cancers, evidence of dentists' and orthodontists' presence as healthcare providers who could strongly promote HPV vaccination in an adolescent and younger adult population is largely absent in the literature.

In addition to organizational strategies, several individual healthcare team member strategies are evident in the literature and were highlighted in this project to enhance HPV vaccination. Described as the "...the most damaging medical hoax of the last 100 years." (Flaherty, 2011, p. 1302), Andrew Wakefield's 1998 publication suggesting an association between the MMR vaccine and autism ignited global parental concern for all vaccines. Following publication and dissemination of Wakefield's

dubious research, vaccination rates have declined and re-emergence of vaccine-preventable childhood diseases has increased (Ibid., 2012). Therefore, healthcare providers are strongly encouraged to take special care in describing vaccine-preventable diseases, vaccine side-effects and the mechanisms and efficacy through which immunizations work. As noted above, during the in-services reported here, all of the healthcare providers were invited to reflect on their practice and encouraged to consider directly addressing with parents the conditions which made Wakefield's research conclusions suspect (i.e., a non-random, less than 20-participant sample; clear conflict of interest regarding Wakefield and his newly-patented measles vaccine, ethical misconduct of the study (it was conducted with no institutional oversight); retraction by the publisher *The Lancet*; and the revocation of Wakefield's license to practice medicine).

In reference to framing the HPV vaccine benefit for both males and females, the staff in the current study reported minimal knowledge, but increased interest regarding the association between H&N cancers and HPV. Many staff members reported that they were surprised by this information and planned to change their vaccine counseling as a result. One staff member stated, "This is more than a *should*, now this vaccine is a *must*."

In spite of the staff enthusiasm documented here, it should be noted that Juraskova and colleagues reported that clinicians' reference to the importance of receiving HPV vaccine for preventing both cervical cancer and genital warts did not influence vaccination intent or behavior among eligible women; although most

participants reported preferring a vaccine that protected against cancer and warts (2011). The most commonly reported barrier among the Australian women in their study (n=159) was concern for vaccine safety (57%); and among those who believed the vaccine to be efficacious, the authors reported greater intent to vaccinate.

It should be noted that although there is scientifically-proven efficacy and a strong basis for vaccination, healthcare providers are still reticent to receive vaccination themselves (Ehrenstein et al., 2010; Galicia-García et al., 2006). However, the same interventions that increased influenza vaccination among healthcare providers in a large public Spanish teaching facility may be applied to a military setting. Llopia and colleagues (2010) reported an increase in HPV vaccination rates for HPV from 23% to 37% in facility healthcare provider immunization after adopting a horizontal flow model rather than the traditional vertical model (education for senior healthcare providers that is then pushed down to the staff). In addition to public commitment by senior management for vaccination, the intervention sought to capitalize on peer-to-peer communication via weekly advertisements with embedded educational components. Other interventional elements included enhancing accessibility to the vaccine, including a roving mobile vaccination unit that delivered immunizations to staff work sites. The program was also incentivized immunizations through two random prize drawing (prizes included meals, a weekend trip, a computer, and four I-Pods).

Several elements of the program among Spanish healthcare providers also highlighted success in a military setting for the mass smallpox vaccination of

approximately 40,000 Sailors before Operation Iraqi Freedom. Savitz and Stewart (2007) reported that high-level support by senior military officers receiving the vaccine, including distribution of photographs of them receiving the vaccine, led to fewer than 20 refusals; and as noted by the authors, this population had a previously established suspicion of the anthrax vaccination being related to Persian Gulf War illnesses. The authors also reported utilizing a consistent message via multiple communication channels as factors which supported vaccination in less than two months of this large and geographically diverse population.

As described previously, clinics in the military healthcare setting can further promote HPV awareness and vaccination on several organizational platforms. These platforms include direct outreach to the patient populations via social media such as the Armed Forces Network (AFN), radio and military community and base newspapers. Awareness also can be accomplished by promoting evidence-based healthcare knowledge among influential lay populations; e.g., via barbers and hairdressers, and family readiness groups. As highlighted several years ago by Turner, Waivers, and O'Brien (1990) and Lopreiato and Ottolini (1996), patient-carried reminders, which could be enhanced with e-mail or text elements, could reach and benefit populations that have started but not completed the series.

Community and occupational health nurses can be encouraged to leverage routine consultation for other disease management interventions by emphasizing the value of HPV vaccination during patient visits. Institutionalizing the promotion of the vaccine

can be accomplished by providing the first of three vaccine injections prior to discharge from the postpartum unit. This would be followed by delivering the second dose during the eight-week postpartum check-up in the GYN Clinic and the third during the two- and six-month well baby visits at the Immunization Clinic. This was a recommendation discussed with the immunization section which would require further collaboration and planning. In addition, the CN-OIC is planning to offer HPV vaccination at future mass vaccine programs offered at military work sites.

Maintain Change in Practice

Overall, this project demonstrated limited success in improving HPV vaccination in the clinic over a relatively short period of time; nonetheless, it serves as an exemplar for developing and implementing nurse-led EBP projects in family practice settings. Foremost, the significance of the enthusiasm exhibited by the staff at this clinic cannot be understated. Their support was most evident in feedback during and immediately after the in-service and from the CN-OIC with whom the project director had frequent contact over the course of the program. Notably, the staff feedback was less about provider concerns regarding vaccine safety and efficacy, as has been suggested in the literature, and about more direct focus on offering solutions to promote this vaccine in a military population and setting.

The staff immediately recognized the nuances for this vaccine that required buy-in from patients, and, when requiring administration to adolescents, from the parents as well. The recruited lead agent in the clinic reported the greatest boost in staff confidence

centered on their new found ability to provide parents with research articles which helped to debunk parental perceptions that vaccination invites risky sexual behavior (Liddon, Leichliter, & Markowitz, 2012); and that vaccines are not safe or effective (Slade, et al., 2009; Haupt & Sings, 2011). The immunization section staff and CN-OIC also reported increased confidence in searching, critiquing, and referencing vaccine-related literature.

The staff noted that under the ACIP guidelines, tetanus is usually required and administered at approximately 14 years of age (10 years after their last tetanus and diphtheria toxoids and acellular pertussis (Tdap) given around 4 years of age). Consequently, it may be a good opportunity to offer HPV education and administration concurrent with the tetanus immunization visit. In addition, the immunization section staff indicated a goal to encourage all providers to include routine vaccination information at all acute, well, and routine appointments; and the clinic staff has indicated that they plan to place a prompt on the back of each exam room door to remind both patients and providers to visit the immunization section before they exit the clinic facility.

Staff members were eager to reframe HPV vaccines as routine immunizations that all males *and* females should receive while in middle school. During the program and follow-up discussion with the CN-OIC, staff members reported a perception that at least one third of the local population of adolescents, to include those less than 15 years of age, were sexual active. Staff members reported the same population of adolescents did self-refer for healthcare and were only occasionally accompanied by their parents.

In addition, staff members indicated that Internet and cell phones were providing new and unique venues for initiating sexual activity. Comments by the staff included statements such as, “They all have heard of and know *other* friends who are sexting.” However, the staff also reported being sensitive that the decision to vaccinate rests primarily with the opinions and receptivity of parents, therefore efforts may need to directly address parents rather than focusing only on adolescents.

Following the in-service, the immunization section reported an increase in males who were receiving the vaccine. This perception was supported in the limited data that the project director received, with the number of males receiving the vaccine doubling in the first month. Implementation of the vaccine among male siblings was noted by the CN-OIC while collecting the data at the site. It was hypothesized by the team that siblings or a recent *Army Times* article may have led to the increase in males receiving the vaccine. The immunization section also reported that the primary driver for vaccinations is a requirement for school entry and pondered how many clinic patients were missing many routine vaccines among the home schooled population.

Potential ethical concerns about requiring rather than encouraging the HPV vaccine were discussed by the immunization section. Although increasing vaccination rates was expressed as desirable, overriding parental rights was actively discussed as a concern, but was not resolved prior to the conclusion of the program. The immunization section did, however, verbalize excitement in terms of future EBP programs (and potential research initiatives) within their department.

As previously noted by Donato, Motz, Wilson and Lloyd (2007), this immunization section also suggested that all nurses could identify and flag charts for mid-level and physician healthcare providers to remind them to encourage vaccination prior to the conclusion of each visit. In addition, the potential for the electronic medical record to self-populate and trigger health promoting activities was noted to be underutilized in the military healthcare setting, requiring reliance on patient self-reporting rather than prompting by the electronic system. Further, the staff suggested the physical layout of the clinic could be redesigned to include a more prominent location for the immunization section, i.e., in proximity to typical patient congregation and wait areas such as the pharmacy.

Limitations

Continued success with HPV vaccination will depend on the clinic identifying a champion for the project. In fact, the program project that was implemented here might have benefitted from the project director being an on-site staff member. The onsite CN-OIC remained committed to the project throughout the effort; however, due to military commitments, this individual will move before a follow-on program can be further developed and institutionalized. To assess and support sustainability for this protocol, the CN-OIC developed a general immunization overview in the clinic orientation competencies for all staff members that highlighted the evidence supporting HPV vaccination efficacy and safety for males and females greater than nine and less than 26 years of age.

Due to the length of time taken for the CRADA and IRB exemption (greater than nine months), a limitation of this effort included the significant delay between generating interest in the project to actual implementation. Additionally, the project director believes that future efforts would benefit by obtaining more statistically-relevant data from PAD. For example, this particular effort would have been greatly enhanced by the ability of the PAD department to generate “real time” data for the clinic to utilize. Ideally, the clinic would receive monthly reports, less than 1 week after the end of the month, with demographic data, such as age, sponsor rank, and race/ethnicity among the patients who received vaccine, missed a second or third vaccine, or had not received the vaccine. With a greater demographic understanding of the population who may delay vaccination and/or not return for second and third immunizations, tailored interventions would be enhanced. Future efforts would benefit by a having greater understanding of institutional PAD abilities to pull data specific elements, such as excluding the patients who have previously received the vaccine series, prior to implementation.

Implications and Future Research

Sustainability for this project requires a staff member to lead the program and continued interest by the new CN-OIC, PAD and clinic leadership to support the program. At a minimum, elements to maintain sustainability would include continuing the practice for updating standing orders annually, on-going unit orientation and training bi-annually, and updating the posters in the clinic and staff areas quarterly. In addition, as described in the literature, continued monitoring by the leadership and reporting to the

clinicians the number of vaccines given and those still required in the eligible clinic population would be ideal to highlight both the progress and continuing need to promote the vaccine. Other conditions which could further enhance this program would include partnering with the patients (i.e., creating a parent/patient immunization advisory council), partnering with other clinicians who frequently see adolescents and young adults to promote the vaccine (i.e., dentists, dermatologists, and psychiatrists), and delivering vaccines at work, school, or other non-clinical sites (i.e., at the post exchange).

Strategies to improve outpatient immunization would benefit by means of the development of a Clinical Practice Guideline (CPG) to formally appraise current practice and research literature and suggest best practice methods regarding HPV immunization delivery. Although this study was limited to HPV vaccination, several clinical and practical questions arose regarding how researchers can rigorously test and implement best practices for vaccine delivery. Furthermore, future research could probe which efforts would generate the greatest buy-in from the patient and parental populations for vaccine adoption in terms of behavior (rather than intent); and as asked, “What are the potential ethical conditions regarding compulsory vaccination or among children who are not subject to typical compulsory vaccination conditions (i.e., are home schooled)?”.

As shown in this effort, and reported by other authors such as Shen-Gunther, Shank, and Ta (2011), and Widdice, Bernstein, Leonard, Marsolo, and Kahn (2011), completion of the second and third vaccine is limited in practice. Therefore, it seems logical that future investigators determine those unique factors that promote vaccine

adherence or allow abandonment among the populations who have started the series.

Which practices would support greater HPV series completion?

Finally, HPV type prevalence is noted to be different among a military population in which travel to foreign countries is more frequent, Kim et al. have reported that the most common, high-risk HPV subtype among Korean females is HPV 56 (2011). The currently marketed vaccines would not protect this population. Due to this potential sexual spatial bridging, military beneficiaries may present different risks or needs for vaccination than their civilian counterparts.

Conclusions

This EBP program invited a large, military family practice clinic to utilize evidence to enhance their practice rather than relying only on what they had been previously taught or had perceived. During the program's educational phase, the staff received the best available evidence regarding HPV and the success of HPV vaccination in combating HPV-associated disease. In addition, the EBP initiative invited all of the healthcare providers, including clerks, LPNs, RNs, midlevel-providers, and physicians, to actively evaluate their own practice and to consider challenging the "practice as usual" orientation. In a targeted effort to increase vaccination, the immunization section was a key element for developing excitement about adopting an EBP "best practice" approach.

The review of the literature revealed that Gardasil, the vaccine currently in use at this clinic, is safe and efficacious, but healthcare providers may lack knowledge regarding HPV-associated disease, and/or confidence in promoting routine HPV

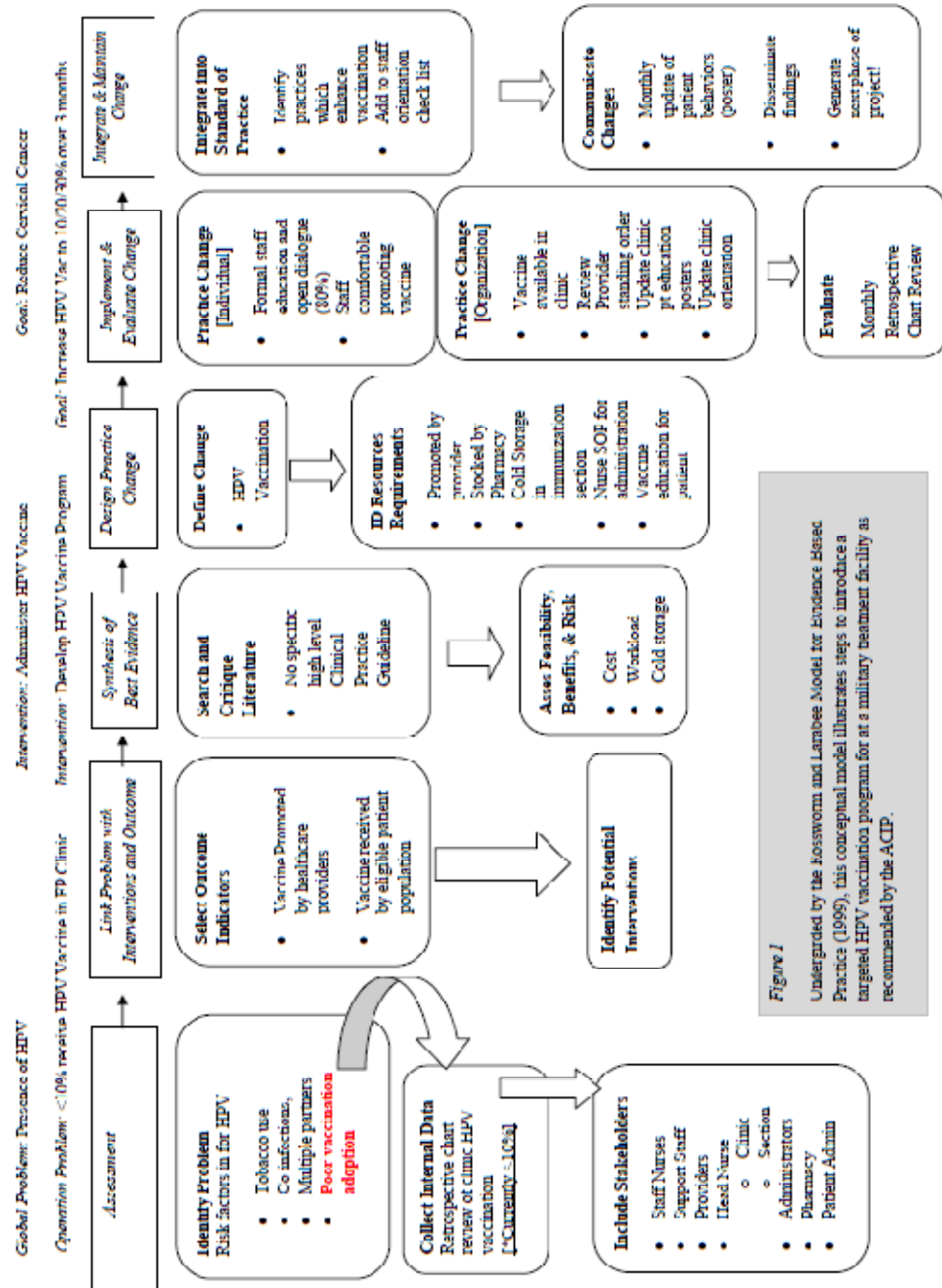
immunization. After the educational effort, staff members were provided monthly updates (albeit limited to the scope of the project) on vaccine delivery. A small increase in vaccination rates was noted over three subsequent months.

Ideally a second phase for this EBP would be developed and would include greater emphasis on multidisciplinary and multifaceted approaches. For example, as indicated elsewhere in the literature, future efforts would likely benefit from inclusion of nurses from every education level, physicians (including sub-specialists who often see adolescents and younger adult populations), dentists, and pharmacists. Inclusion of a patient partner could also greatly benefit access to the population to address under-recognized needs or concerns in the military community. Multifaceted approaches as described in the literature may also include leveraging social media, considering non-traditional vaccine delivery venues, considering older successful models (and perhaps retooling them to embrace current technology), and even incentivizing vaccine adoption in the community.

Successful implementation of a human papillomavirus (HPV) vaccination program has the potential to eliminate nearly 70% of all cervical cancers, 18% of head and neck cancers, and 90% of genital warts in the United States (Goldie, et al., 2004). Additionally, although the benefit for HPV-associated cancers, which include cervical cancer in women and tonsillar cancer in males, are over-represented in the military population, a minority of Military Healthcare System (MHS) beneficiaries who are eligible for the vaccine have either started or continued the HPV vaccine series.

The broad implementation of HPV vaccination in this decade has the potential to significantly decrease the burden of HPV-associated cancers, some of which are just being discovered, in civilian and military populations. Using the Rosswurm and Larrabee EBP model, this project invited healthcare providers in a large military family practice clinic to promote HPV vaccination for both males and females who, based on existing evidence, would likely benefit from receiving it. Further, this endeavor supported a culture of promoting and implementing an EBP protocol by nurses in the outpatient setting. Globally this endeavor was attempting to increase the number of men and women who elected to initiate and complete the HPV vaccine and prevent most HPV-associated cancers among MHS beneficiaries.

This program enabled clinicians to institute evidence-based practice to inform and protect men and women who could benefit from receiving the HPV vaccine while they are in the out-patient setting. In framing organizational and individual strategies to enhance vaccination, promoting immunization is a cost-saving effort that should be employed throughout every healthcare-delivery model. Vaccines can greatly reduce morbidity and mortality, and should be considered at every encounter, including in- and out-patient settings.



Appendix B: Staff In-service

Introducing HPV Vaccine Program

Meryia D. Throop, PhD,FNP
MAJ/AN

Agenda

- Purpose and Background
- Review of Evidence
 - (slides prepared by CDC)
- Review of EBP program at the Clark Clinic

Researcher Bio

- BSN 1995 Lewis University
- MSN 2003 USU (FNP)
- PhD 2010 CUA
- Experience-
 - Ward: Mother / Baby, Oncology, Surgical
 - FNP: Family Practice, OB, OIC AHC (2ID)
 - Deployment: Operation Pacific Haven

Purpose

To initiate and evaluate an Evidence-Based HPV vaccine program in the outpatient setting at a military treatment facility.

Development

- Dissertation work
 - Over reporting (45%)
 - Several Questions about HPV vaccine
 - Availability
 - Family History
- Following the next step
 - Bench to Bedside

Background

- Mean age for Cervical Cancer Diagnosis
 - Civilian women 48 years old
 - Military women 28 years old
- Very little research with military women
 - Vaccination no published reports (yet...)
- However...
 - Lots of CPG Recommends Vaccination
 - For males and females

Knowledge, Beliefs & Behavior

- Knowledge
 - Some is known
 - But knowledge fails to impact behavior
 - Influence by direct-to-consumer ads unknown
- Beliefs and Attitudes
 - Increase acceptance for daughters among mothers with history of genital warts

So what makes a difference?

- YOU- the healthcare provider!

And I got the research to back that up...

"social norms were found to be significant to predict those Soldiers who initiated the HPV vaccine, χ^2 (7, n= 68), 17.75, $p > .05$ "

History of Cervical Cancer Prevention

- 1920's
 - Dr Papanicolaou
- 1950's
 - "Pap" screening
- 1980's
 - HPV relationship
- 2000's
 - Pap's include HPV testing
- 2006
 - Vaccine

Human Papillomavirus (HPV) and HPV Vaccine

Epidemiology and Prevention of Vaccine-Preventable Diseases

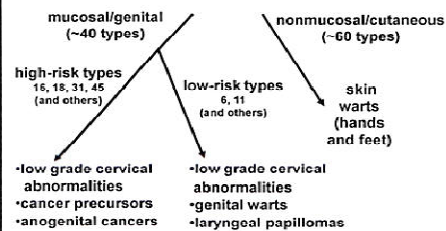
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Revised May 2009/Oct 2010

Human Papillomavirus (HPV)

- Small DNA virus
- More than 100 types identified based on the genetic sequence of the outer capsid protein L1
- 40 types infect the mucosal epithelium

Human Papillomavirus Types and Disease Association

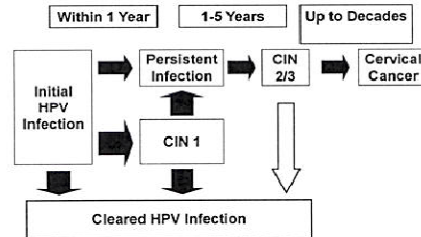


HPV-Associated Disease

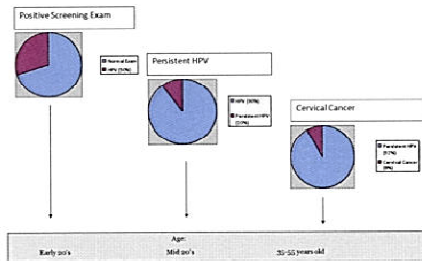
Type	Women	Men
16/18	70% of Cervical Cancer 70% of Anal/genital Cancer	70% of Anal Cancer Transmission to women
6/11	90% of Genital Warts 90% of RRP lesions	90% of Genital Warts 90% of RRP lesions Transmission to women

Increasing evidence of HPV in Head and neck cancers

Natural History of HPV Infection



Progression from Normal Exam to HPV Infection to Invasive Cervical Cancer



HPV Clinical Features

- Most HPV infections are asymptomatic and result in no clinical disease
- Clinical manifestations of HPV infection include:
 - anogenital warts
 - recurrent respiratory papillomatosis
 - cervical cancer precursors (cervical intraepithelial neoplasia)
 - Cancer (cervical, anal, vaginal, vulvar, penile, and some head and neck cancer)

HPV Epidemiology

- Reservoir: Human
- Transmission: Direct contact, usually sexual
- Temporal pattern: None
- Communicability: Presumed to be high

HPV Disease Burden in the United States

- Anogenital HPV is the most common sexually transmitted infection in the US
 - Estimated 20 million currently infected
 - 6.2 million new infections/year
- Common among adolescents and young adults
- Estimated 80% of sexually active women will have been infected by age 50
- Infection also common in men

Cervical Cancer Disease Burden in the United States

- The American Cancer Society estimates that in 2008
 - 11,070 new cervical cancer cases
 - 3,870 cervical cancer deaths
- Almost 100% of these cervical cancer cases will be caused by one of the 40 HPV types that infect the mucosa

Cervical Cancer Screening

- Cervical cancer screening – no change
 - 30% of cervical cancers caused by HPV types not prevented by the quadrivalent HPV vaccine
 - Vaccinated females could subsequently be infected with non-vaccine HPV types
 - Sexually active females could have been infected prior to vaccination
- Providers should educate women about the importance of cervical cancer screening

Human Papillomavirus Vaccine

- HPV L1 major capsid protein of the virus is antigen used for immunization
- L1 protein expressed in yeast cells using recombinant technology
- L1 proteins self-assemble into virus-like particles (VLP)
- VLPs are noninfectious and nononcogenic

HPV Vaccine Efficacy*

<u>Endpoint</u>	<u>Efficacy</u>
HPV 16/18-related CIN2/3 or AIS	100
HPV 6/11/16/18 related CIN	95
HPV 6/11/16/18 related genital warts	99

*Among 16-26 year old females. CIN – cervical intraepithelial neoplasia; AIS – adenocarcinoma in situ

HPV Vaccine Efficacy

- High efficacy among females without evidence of infection with vaccine HPV types
- No evidence of efficacy against disease caused by vaccine types or which participants were infected at the time of vaccination
- Prior infection with one HPV type did not diminish efficacy of the vaccine against other vaccine HPV types

Routine HPV Vaccination Recommendations

- ACIP recommends routine vaccination of females 11 or 12 years of age
- The vaccination series can be started as young as 9 years of age at the clinician's discretion
- “Catch-up” vaccination recommended for females 13 through 26 years of age

MMWR 2007;56(RR-2):1-24

HPV Vaccine Contraindications and Precautions

- **Contraindication**
 - Severe allergic reaction to a vaccine component (yeast) or following a prior dose
- **Precaution**
 - Moderate or severe acute illnesses (defer until symptoms improve)

HPV Vaccination During Pregnancy

- Initiation of the vaccine series should be delayed until after completion of pregnancy
- If a woman is found to be pregnant after initiating the vaccination series, remaining doses should be delayed until after the pregnancy
- If a vaccine dose has been administered during pregnancy, there is no indication for intervention
- Women vaccinated during pregnancy should be reported to the Merck registry (800.986.8999)

MMWR 2007;56(RR-2):1-24

Importance

- **Health Promotion**
 - NINR and ANC Goal
 - Nurse driven activity in Military
- **Cost**
 - Individual (Privacy, Fertility, Life)
 - Colpo's
 - \$65,000 (Chemo not included)

Protection of Human Subjects

- **Potential sources of risk**
 - Loss of privacy
 - Chart review
 - Coercion
 - New guideline
 - Patient information

Analysis

- SPSS v.17
- **Descriptives**
 - Interval and categorical data
 - Differences between pre-post intervention in vaccination among patient population
- **GEE**

Impact

- **Non adherence is a problem for military**
 - Individual cost to soldier (psycho-social, privacy, health)
 - Deployment issue (Redeploy or travel to GYN)
 - Invasive Ca is costly (\$65k vs \$2K for CIN I)
- **Benefits**
 - Increase knowledge about complex population
 - Guide development of targeted intervention

Conclusion

- Goal to Change Behavior
 - Introduce CPG
 - Individual Strategies
 - Organizational Strategies
 - Test via repeated retrospective chart reviews
- Support EPB Implementation for CPG

Pop Quiz!

- Who pioneered the test to screen for cervical cancer? (Bonus- why?)
- How many "high risk" human papillomaviruses have been identified?
- The HPV vaccine released in 2006 protects against what percentage of the HPVs that cause cervical cancer? (Bonus- which two?)
- Name 3 cofactors for cervical cancer or HPV acquisition?
- Name at least 3 "stake holders" that may be concerned with this EBP effort?

HPV Vaccine Storage and Handling

- Store at 36°F-46°F (2°C-8°C)
- Protect from light
- Do not expose to freezing temperature
- Remove from refrigeration immediately before administration

CDC Vaccines and Immunization Contact Information

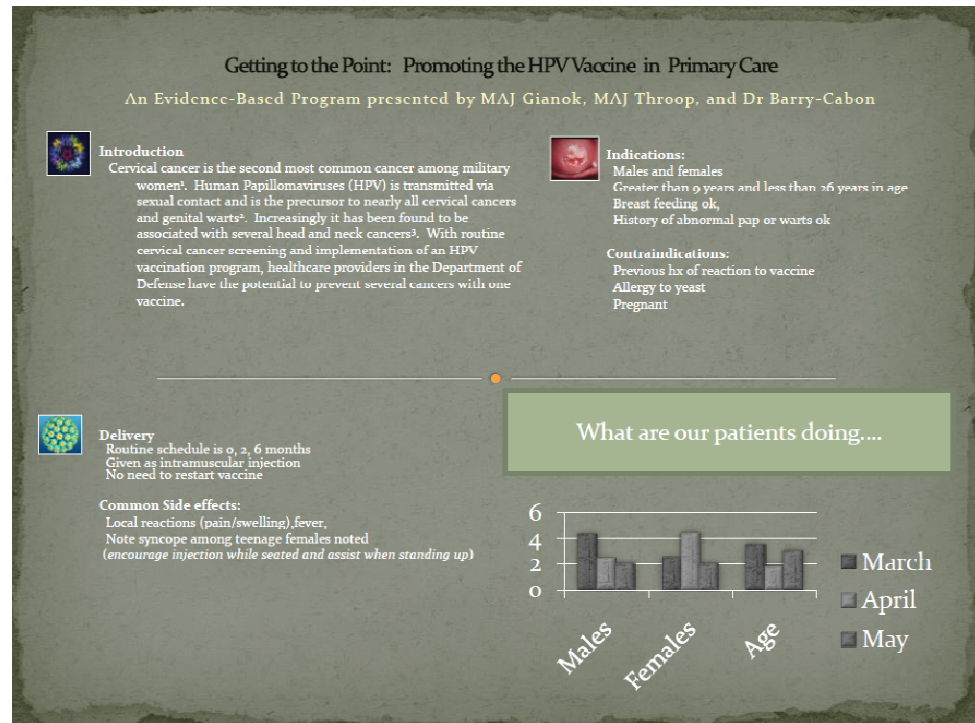
- Telephone 800.CDC.INFO
- Email nipinfo@cdc.gov
- Website www.cdc.gov/vaccines

Milvax Website

- Excellent Source of Information
- Up to date with current DoD policies


<http://www.vaccines.mil/>

Appendix C



Fact:

At least **50%** of
sexually active people
will get genital HPV.






Most won't know they have it.
Protect yourself from the possible
consequences of HPV.

Genital human papillomavirus (HPV) is passed on during sex. Most times, HPV has no symptoms and goes away on its own. But sometimes, certain types of HPV can cause genital warts. Other HPV types can cause cervical cancer in women.

You can prevent HPV-related diseases:

- Females should talk to their doctors about getting the HPV vaccine (available for 9- to 26-year-old females) and regular Pap tests.
- Men and women may lower their chances of getting HPV or developing HPV-related diseases by using condoms all the time and the right way.
- Men and women may also lower their chances of getting HPV by limiting their number of sex partners. But abstinence is the only sure way to prevent HPV.

For more information,
call 1-800-CDC-INFO or visit,
www.cdc.gov/std/hpv/



HPV (HUMAN PAPILLOMAVIRUS) VACCINE

Gardasil® WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See <http://www.immunize.org/via>.

1 What is HPV?

Genital human papillomavirus (HPV) is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause **cervical cancer** in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 10,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women and other types of cancer in both men and women. It can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

2 HPV vaccine - Why get vaccinated?

HPV vaccine is important because it **can prevent most cases of cervical cancer** in females, if it is given before a person is exposed to the virus.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.

The vaccine you are getting is one of two vaccines that can be given to prevent HPV. It may be given to both males and females. In addition to preventing cervical cancer, it can also prevent **vaginal and vulvar cancer** in females, and **genital warts** in both males and females.

The other vaccine is given to females only, and only for prevention of cervical cancer.

3 Who should get this HPV vaccine and when?

Females: Routine Vaccination

- HPV vaccine is recommended for girls 11 or 12 years of age. It may be given to girls starting at age 9.

Why is HPV vaccine given to girls at this age?

It is important for girls to get HPV vaccine before their first sexual contact – because they won't have been exposed to human papillomavirus.

Once a girl or woman has been infected with the virus, the vaccine might not work as well or might not work at all.

Females: Catch-Up Vaccination

- The vaccine is also recommended for girls and women 13 through 26 years of age who did not get all 3 doses when they were younger.

Males

Males 9 through 26 years of age may get HPV vaccine to prevent genital warts. As with females, it is best to be vaccinated before the first sexual contact.

HPV vaccine is given as a 3-dose series

1st Dose	Now
2nd Dose	1 to 2 months after Dose 1
3rd Dose	6 months after Dose 1

Additional (booster) doses are not recommended.

HPV vaccine may be given at the same time as other vaccines.

4 Some people should not get HPV vaccine or should wait

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to yeast.

- HPV vaccine is not recommended for **pregnant women**. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.

Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's HPV in pregnancy registry at 800-936-8999. This will help us learn how pregnant women respond to the vaccine.

- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a **moderate or severe illness** should wait until they are better.

5 What are the risks from this vaccine?

This HPV vaccine has been used in the U.S. and around the world for several years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Several **mild to moderate problems** are known to occur with HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given:
 - Pain (about 8 people in 10)
 - Redness or swelling (about 1 person in 4)
- Fever:
 - Mild (100° F) (about 1 person in 10)
 - Moderate (102° F) (about 1 person in 65)
- Other problems:
 - Headache (about 1 person in 3)
 - **Fainting.** Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. **Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls.** Tell your provider if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

6 What if there is a severe reaction?

What should I look for?

Serious allergic reactions including rash; swelling of the hands and feet, face, or lips; and breathing difficulty.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at <http://www.vaers.hhs.gov>, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine may file a claim with VICP by calling 1-800-338-2382 or visiting their website at <http://www.hrsa.gov/vaccinecompensation>.

8 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at <http://www.cdc.gov/hpv> and <http://www.cdc.gov/vaccines>



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Human Papillomavirus (HPV) *Gardasil* 3/30/2010

Back

Glossary of Terms.

Military – an organization made up of personnel who are trained to conduct operations to defend a nation or state.

Department of Defense (DoD)- the organization within the United States government, responsible for planning, funding, and training of defense related personnel that fall under the joint services: Army, Air Force, Navy, Marine Corps.

Service Member- term used in the United States military to describe a man or women who serves in uniform within the joint services.

Army- the ground fighting component of the US military.

Soldier- term used to describe a man or woman who serves in the Army.

Military Occupational Specialty (MOS)- designated code for the name of the occupational (job) skill members of the Army (e.g. 66P- Family Nurse Practitioner, 11B- infantry soldier, 88M- truck driver).

Air Force- military personnel and equipment organized to conduct air oriented warfare (i.e. not land or sea).

Airman- a term used to describe a man or woman who serves in the US Air Force.

Navy- military personnel who serve in the US naval (sea) forces organized to conduct sea based warfare.

Sailor- a term used to describe a man or woman who serves in the US Navy.

Garrison- location where most service members live and work, which may be located in the United States or overseas (e.g. forts, post, camp, or base).

Deployment – term given to military organizations that are operating away from their home garrison, either for training or in combat zones (e.g. Joint Readiness Training Center, Ft Polk, LA or Operation Iraqi Freedom (OIF), Camp Anaconda, Iraq).

Combat Zone- location where service members are deployed in support of combat operations.

Military Treatment Facility (MTF)- any facility in the DoD which provides health care to service members, their families, and retirees. Examples include fixed facilities located in the United States (Walter Reed Medical Center), clinics, and tents located in combat zones (28th Combat Support Hospital).

Battalion Aid Station (BAS)- echelon II level of health care services provided to soldiers, usually includes one provider and several medics. These elements are located in close proximity to where soldiers work and live when in garrison or deployed.

Primary Care Manager (PCM)- includes (military and civilian) personnel that are licensed to provide primary health care services (e.g. nurse, nurse practitioners, PA's, physicians, midwives, podiatrist, optometrist, and physical therapist.)

Medic- a term used for any basic trained Army soldier with training equivalent to basic emergency medical technicians, usually first line (echelon I) of healthcare and information for soldiers.

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