PARENTAL EDUCATION ON HUMAN PAPILLOMAVIRUS VACCINATION:

DOES IT POSITIVELY AFFECT THE DECISION TO VACCINATE THEIR

ADOLESCENT?

by

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Abstract

Human papillomavirus (HPV) is a sexually transmitted infection that affects nearly 79 million Americans, with half of the new cases each year occurring in people 15-24 years of age. Certain subtypes of HPV can be linked to genital warts, oropharyngeal and anogenital cancers; with medical costs related to HPV-associated illness estimated to be around $8 billion per year in the Unites States. The HPV vaccine is recommended for all adolescents at age 11or 12; yet uptake is consistently lower than other vaccines recommended for the same age group. Commonly cited reasons for parental refusal are lack of both knowledge about the vaccine and strong recommendation from the healthcare provider. This evidence based practice project sought to address these issues by sending an educational mailing with FAQs about the HPV vaccine along with a provider letter recommending the vaccine to the parents of 11 and 12 year old adolescents prior to the scheduled well exam. Parents of those who received the vaccine were asked to complete a survey to determine if the educational mailing helped them to make the decision to vaccinate. When compared with the number of eligible adolescents who received the HPV vaccine in the previous year, results were significant for the intervention group with $z= 1.7$; $p= 0.0433$ (<0.05); CI=95%. This intervention is easily adaptable and has the potential to decrease HPV related morbidity and mortality in the United States.

Keywords: Human papillomavirus vaccine, HPV, adolescent immunization, barriers, knowledge deficit

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Chapter One: Overview of the Problem of Interest

Human papillomavirus (HPV) is a group of over 150 viruses that can lead to papillomas or warts- and in some cases- cancer of the mouth, throat, anus, rectum, penis, vulva, vagina, and cervix (Centers for Disease Control and Prevention [CDC], 2016b). It is estimated that almost one in four Americans are infected with HPV, which can be passed through intimate skin-to-skin contact, but most often through vaginal or anal sex (CDC, 2016a). While HPV infection can sometimes cause genital warts, many times, people who have HPV have no symptoms for months to years and can spread infection even when asymptomatic (CDC, 2016a).

In most cases, the body can clear the HPV virus in about 24 months; but when this clearing doesn't occur, chronic HPV infection can lead to cancer (American Cancer Society, 2016). According to the CDC (2016a), "every year in the United States, HPV causes 30,700 cancers in men and women." Seven out of ten cervical cancers are caused by HPV 16 and 18; while 9 out of 10 anal and genital warts are caused by HPV 6 and 8 (Children's Hospital of Philadelphia [CHOP], 2016).

Since 2006, HPV vaccination has been recommended in the United States (U.S.) for all adolescents beginning at age 11 or 12 (CDC, 2016a). Despite this recommendation, as of 2015, only 37.1% of females and 27.1% of males aged 13-15 completed the HPV vaccine series (Healthy People 2020 website, 2017). HPV vaccination compliance is much lower than other routinely recommended adolescent vaccines, such as meningococcal (MCV4) and tetanus, diphtheria and acellular pertussis (Tdap), with over 80% immunization rate for both (CDC, 2017b).

Researchers have studied this disparity, and have identified several reasons that parents do not consent to the HPV vaccine for their children. A systematic review of the literature indicates that parents feel they are not well informed about the vaccine, they are not certain it is needed or if it might influence their child's sexual behavior, and they do not know if it will be covered by insurance. In addition, many of these parents indicated that they would choose to vaccinate if it was recommended by their healthcare provider (Holman et al., 2014).

Background

Since the introduction of the first vaccine, there have been people who oppose vaccination for a variety of reasons- most often due to spiritual beliefs, philosophical ideations or political motivation (The College of Physicians of Philadelphia, 2016). This trend continues to perplex medical scientists, who have provided extensive research on vaccine safety, as well as documented success in reducing morbidity and mortality from vaccine-preventable diseases (U. S. Department of Health and Human Services [HHS], 2016). Approximately 70% of all children in the U. S. are fully vaccinated according to the recommended vaccine schedule, including all childhood vaccines -Diphtheria, Tetanus and Pertussis (DTaP); Polio; Measles, Mumps and Rubella (MMR); Haemophilus influenza type B (Hib); Hepatitis B (Hep B); Chickenpox (Varicella); Pneumococcal conjugate vaccine (PCV); and the recommended adolescent doses of MCV4 and Tdap (CDC, 2012). Conversely, fewer than 40% of all eligible adolescents in the U.S. are fully immunized against HPV despite recommendations of the CDC (Healthy

People 2020 website, 2017). This statistic prompted those in the science and medical communities to research the reasons for this disparity.

Human papillomavirus is transmitted primarily via intimate skin-to-skin contact and sexual activity (CDC, 2016a). Included in the CDC's sexually transmitted disease guidelines (2010) are recommendations for vaccination against Hepatitis A and B, as well as HPV. Statistics show that more children are routinely vaccinated for Hepatitis A (53%) and Hepatitis B (70%) than for HPV (Healthy People 2020 website, 2017). While hepatitis can be spread via sexual activity, there is also risk through fecal/oral or blood borne routes (CDC, 2010). Approximately 20% of parents were concerned about giving the HPV vaccine at such a young age because of fears that it may influence the sexual activity of the adolescent, or it may prompt a discussion about sexuality that the parents may be uncomfortable having (Holman et al., 2014). Some felt that vaccination was not needed until the adolescent was older, yet were receptive learning about the benefits for cancer prevention (Holman et al., 2014).

Healthcare providers also create barriers to HPV vaccination by possessing limited knowledge about the vaccine; harboring personal biases such as the belief that most parents don't support it; recommending the vaccine primarily to older adolescents or on a risk-based evaluation; and avoiding routine recommendation due to time or cost constraints (Holman et al., 2014). It is interesting to note that safety and efficacy of the vaccine were not concerning for healthcare professionals; rather, HPV was not always seen to be an important health threat by some providers (Holman et al., 2014).

Significance

Human papillomavirus is a risk for significant morbidity and mortality of all sexually active people, with nearly 79 million people having one or more strain of HPV (Rigaud, 2015). Worldwide, cervical cancer remains the second leading cause of cancer-related death in women; with over 4200 deaths of women in the U.S. yearly (National Institutes of Health [NIH], 2013). Virtually all cervical cancers can be attributed to a high risk strain of HPV 16 or 18, which can be prevented by the HPV vaccine (Rigaud, 2015). In addition to women's health issues, approximately 9000 HPV related cancers occur in males yearly in the U.S., with a rise in HPV-related oropharyngeal cancers (Rigaud, 2015). Medical costs for treatment of HPV-related illnesses in the U. S. are estimated to be in the billions of dollars each year (Rigaud, 2015).

Vaccination with a 4-valent HPV vaccine such as Cervarix or Gardasil, has been found to be nearly 100% effective in preventing persistent HPV 16 and 18 cervical infections (National Cancer Institute [NCI], 2016). The newest HPV vaccine is the 9-valent Gardasil 9, which has been found to be at least as effective as the previous HPV vaccines in protecting against cervical infections caused by HPV 6, 11, 16 and 18; and "97% effective in preventing cervical, vulvar, and vaginal disease caused by the five additional HPV types (31, 33, 45, 52 and 58) that it targets" (NCI, 2016, para. 21).

Holman et al. concluded that "receiving a physician's recommendation or discussing the HPV vaccine with a physician was associated with vaccine acceptance and initiation in numerous studies" (2014, para. 16). Additionally, parents frequently cited "not having a physician's recommendation as the reason for not vaccinating their child"

(Holman et al., 2014, para. 16). According to the CDC (2015), the recommendation for the HPV vaccine by a healthcare provider is key to affecting the parent's decision; and providers are encouraged to recommend the HPV vaccine in the same manner as other routine vaccines.

Question Guiding Inquiry

Evidence-based practice involves the use of scientific evidence generated from multiple studies, along with clinical expertise and patient preference in order to promote the highest quality of care and patient outcomes in clinical practice (Melnyk & Fineout-Overholt, 2011). In an effort to guide the development of an evidence-based practice project, "clinical questions are often asked in a PICO(t) format (i. e. *P*atient population, *I*ntervention or *I*ssue of interest, *C*omparison intervention or group, *O*utcome, and *T*ime frame)" (Melnyk & Fineout-Overholt, 2011, p. 11). This format helps to create a focused framework for scholarly inquiry, with the intention of identifying interventions that can be used consistently to guide clinical practice.

Due to the problem of parental perception regarding lack of adequate information about the HPV vaccine, an evidence-based practice project (EBPP) was developed to address this factor in decision-making. The PICO question for this project was "In parents of adolescents aged 11-12, does the addition of written educational materials about HPV vaccination, provided within the two weeks prior to the routine well exam, positively affect the decision to begin the HPV vaccine series at the recommended age?"

Population. The population for this EBPP was parents and/or guardians of all adolescents aged 11 or 12, who were scheduled for their routine well child exam at Mountaintop Pediatrics, P. C. during the project timeline of May through August 2017.

Intervention. The intervention was the provision of written educational materials on HPV vaccination that was recommended at the well exam. A letter addressing the need for vaccination, as well as an HPV vaccine tear sheet created by the Children's Hospital of Philadelphia Vaccine Education Center, were mailed to the patient's home within the 2 week period prior to the well exam to allow the parent sufficient time to review the information.

Comparison. A chart review was conducted to determine if there was an increase in the percentage of adolescents who received the vaccine in the previous year during the same timeframe compared to the percentage of those included in the project.

Outcome. The measured outcome was twofold: 1) Did the total percentage of adolescents between the ages of 11 and 12 who received the HPV vaccine increase during the project year; 2) Did the parent or guardian of those who did receive the vaccine state that the written information provided positively influence their decision to vaccinate?

System and Population Impact

The practice of routine HPV immunization in the U. S. is only about 10 years old; so much of the impact will not be realized for decades (Markowitz, 2015). Systematic reviews and meta-analyses were conducted on data from several high-income countries, including the U. S., within four years of HPV vaccine introduction. In countries where more than 50% of women younger than 20 years old received the HPV vaccine, there was

an approximately 60% decrease in high risk strains 16 and 18 as well as the incidence of genital warts (Markowitz, 2015). There was also an indication that vaccination can provide some herd immunity, as reflected in the decrease in anogenital warts in women older than 20 and in men (Markowitz, 2015).

In several studies, including data analysis from the National Health and Nutrition Exam Survey, there was found to be a "56% decrease in population prevalence of vaccine type HPV in self-collected cervical-vaginal samples from females aged 14 to19 years in the 4 years after vaccine introduction, whereas no significant changes were observed in older females" (Hariri, Markowitz, Dunne, & Unger, 2013, p. 681). The ability to collect data on results of HPV vaccination has been affected by changes to Pap test guidelines to include later age at initiation, which will result in the diagnosis of fewer cervical lesions overall (Hariri et al., 2013). While there are challenges to evaluating the full impact of HPV vaccination, early indications are promising that show an overall decrease in many vaccine-related strains of HPV in several countries.

Many analyses of cost-effectiveness of healthcare interventions rely on projected quality-adjusted-life-year gained (QALY) which can be calculated using various methods. The cost-effectiveness of a proposed healthcare intervention is often deemed favorable if the cost per QALY is below $50,000-$100,000 (Neumann, Cohen, & Weinstein, 2014). One simplified analysis of routine HPV vaccination estimated a range of $3,906-$14,723 per QALY, which was consistent with the results of published studies using more complex models (Chesson, Ekwueme, Saraiya, & Markowitz, 2008). This analysis indicates that routine HPV vaccination is a relatively low-cost intervention that

has the potential to significantly decrease HPV-related morbidity and mortality in the future.

Purpose

The scholarly project was intended to assimilate nursing knowledge while incorporating the DNP Essentials to improve patient care using an evidence-based approach (Moran, Burson, & Conrad, 2014). The purpose of this EBPP was to determine if a simple, low cost intervention that is aimed at educating parents or guardians of adolescents about HPV vaccination is effective in improving the percentage of vaccination uptake by the recommended age of 11 or 12.

Objectives

1) Utilize expert coaching and guidance to promote HPV vaccination of all adolescents;

2) Educate healthcare decision-makers, to include parents and guardians of adolescents, on the benefits of HPV vaccination;

3) Initiate evidence-based protocol for practice to address the Healthy People 2020 goal of higher percentage of adolescents who are fully vaccinated against HPV;

4) Decrease the number of patients affected with HPV-related illness, while contributing to the development of herd immunity;

5) Decrease future healthcare costs due to HPV-related illness.

Research indicates that parents who receive a recommendation to vaccinate their child against HPV are more inclined to do so (Holman et al., 2014). Along with other primary

care providers, the APRN is in a unique position to promote an intervention other than lifestyle change that can prevent cancer- truly a breakthrough in modern medicine. The desired outcome of this EBPP was to use the current evidence to develop a plan for other healthcare providers to address the issue of HPV vaccination within their practices throughout the country.

Chapter Two: Review of the Evidence/ Literature

Review of the literature shows that HPV vaccination has been recommended for adolescents in the U. S. since 2006. While the HPV vaccine is recommended along with the tetanus, diphtheria and acellular pertussis (Tdap) and meningococcal (MCV) vaccines, uptake for the HPV vaccine has not approached the Healthy People 2020 goals at the same rate as the others (Zimmerman et al., 2016). Many reasons have been cited for lack of uptake of HPV vaccination, however, according to data collected from the 2008-2009 National Immunization Survey-Teen, the strongest motivator to vaccinate is identified as doctor recommendation, and the primary obstacle to vaccination is lack of knowledge (Hirsch, 2012). The literature review for this EBPP focused on addressing these primary concerns.

Methodology

The Misericordia University library holdings were accessed and an exhaustive literature search was conducted. Academic Search Complete, CINAHL, Health Source Nursing/ Academic edition, and MEDLINE databases were searched using the key words human papillomavirus, HPV vaccine, adolescent immunizations, knowledge deficit, barriers and education. The original search using 'human papillomavirus" produced 54,458 results; the addition of "vaccine" further narrowed the search to 13,635. "Human papillomavirus vaccine" plus "adolescent immunizations" produced 156 results; the addition of "barrier" and "knowledge deficit" resulted in 16 and 11 respectively, however, these articles were very narrow in scope. The combination of "human papillomavirus vaccine", "adolescent immunizations" and "education" returned 12

results; this search also produced too few articles that were narrow in scope. The term "education" was omitted and the search was narrowed by date to include only literature between 2007 and 2017, and by language to include English only which produced 99 results. Articles were then reviewed for relevancy to the EBPP and those that were selected included randomized controlled studies, observational reviews, and clinical guidelines that specifically included information on provider recommendation, patient education, and barriers to HPV vaccination uptake. In addition to the aforementioned databases, the Cochrane Library was searched and resulted in one relevant systematic review which addressed the barriers and facilitators to HPV vaccination uptake.

Findings

Randomized controlled trials. Many randomized controlled trials (RCTs) that focus on HPV vaccination are geared towards safety and effectiveness of the vaccine itself. In recent years, however, research has shifted to include barriers to, and recommendations to improve HPV vaccination uptake. The literature search returned two RCTs that were particularly relevant to the EBPP.

The aim of one RCT (Fiks et al., 2013) was to study the effectiveness of targeted automated vaccine support to families, clinicians, or both on improving HPV vaccination rates. The study included 22,486 girls aged 11-17 who were patients of 22 different primary-care practices within the Children's Hospital of Philadelphia (CHOP) Pediatric Research Consortium (PeRC), and were eligible for the HPV vaccine. Participants were randomized within each practice to receive family-focused telephone calls, clinician-focused reminders, combined or no intervention.

The primary care practices were randomized to receive "electronic health record (EHR) based vaccine alerts, education, and audit and feedback or no practice level interventions" and "nested within this design was a patient-level randomized intervention of automated educational reminder calls" (Fiks et al., 2013, p. 1115). Participants in each practice were included based on age and eligibility to receive the vaccine. In addition, they were required to have had a physical exam within 15 months prior to randomization in order to ensure a similar level of health utilization.

Statistical analysis for the study was completed using "Kaplan Meier plots revealing overall vaccination rates among eligible subjects over time… for differences across sites in patient characteristics not balanced by randomization, Cox proportional hazard regression models were implemented accounting for the clustered design and including covariates" (Fiks et al., 2013, p. 1117). Outcomes were determined by comparing the intervention- family based, clinician based, combined, or none- as well as the specific intervention in relation to uptake of HPV dose #1, 2 or 3. The study concluded that clinician-based intervention had a significant impact on initial vaccination, while family-based intervention was favorable for completing the series (Fiks et al., 2013). The study concluded that combined clinician and family based interventions increased the percentage of patients who completed the full 3-dose series of the HPV vaccine (1.6, 95% CI [1.2-2.1], p= 0.001).

The intervention examined in this RCT, which was family education and clinician reminders that encourage the provider to make the recommendation to begin HPV vaccination in adolescents starting at 11 years of age, is consistent with the PICO

question guiding this EBPP. The outcome studied is the impact of the intervention on the uptake of HPV vaccination in eligible adolescents, which is consistent with the outcome in the proposed EBPP.

Another RCT that focused on improving HPV vaccination rates uses the "4 Pillars Practice Transformation" (4 Pillars) program (Zimmerman et al., 2016, p. 110).

> The 4 Pillars program is founded on four key, evidence-based domains: Pillar 1- convenient vaccination services; Pillar 2- communication with patients about the importance of immunization and the availability of vaccines; Pillar 3- Enhanced office systems to facilitate immunization; Pillar 4- Motivation through an office immunization champion.

This study was designed to take a multifactorial approach to HPV vaccination with the aim of evaluating the effectiveness of such an intervention on vaccination rates. This practice-level intervention "took place in 20 pediatric and family practice sites in the Pittsburgh metropolitan area using a randomized controlled cluster trial" (Zimmerman et al., 2016, p. 110). Optimal Design software was used to calculate sample size and randomize practices into the intervention arms. Each practice was required to have at least 50 adolescent patients, with estimated vaccine rates below national goals, and a willingness to make practice changes. According to Zimmerman et al. (2016, p. 112):

> Strategies that have been studied include: education programs for parents and patients, patient reminder/ recall systems using postcards, phone calls, text messaging, social marketing, provider education, EMR alerts, incentives, and audit and feedback. Each practice could choose from among many of these

previously studied strategies that were combined into the 4 Pillars program and tailor their implementation to fit their practice's unique setting, population and culture.

EHR extractions were used to collect demographic data, office visit and vaccination data that had identifying information removed. Office champions completed a survey to identify which strategies had been used during the active study period. Statistical analyses were completed to measure practice-level cumulative HPV series initiation and completion at the end of baseline and active study periods. Chi square tests and Cox proportional hazard models were completed to examine the factors related to vaccination rates. While there are limitations to this study based on the specific interventions used in each practice, the overall findings indicate that there was an increase in HPV series initiation for those guided by the 4 Pillars program, vs. the control group. In addition, those practices using > 10 strategies saw the greatest improvement.

Both of the reviewed RCTs focused on similar interventions using a combination of patient education and provider recommendation to improve the uptake of HPV vaccination in adolescents beginning at 11 or 12 years of age. Critical evaluation of these RCTs indicates that the results can be considered reliable and applicable to the proposed EBPP.

Systematic review. A systematic review (SR) was conducted to include studies that relied upon qualitative research methods such as interviews or observations, and questionnaires with the intent to gather information about individual perceptions and decision-making for HPV vaccination in young women (Ferrer, Trotter, Hickman, &

Audrey, 2014). The SR identified 41 studies for inclusion, done mainly in the U.S. and United Kingdom. Two reviewers independently assessed the literature, and disagreements were resolved by discussion. Each study was evaluated using the "Critical Appraisal Skills Programme criteria for evaluating qualitative research" for inclusion in the SR. Key findings from the researchers indicate that the decision to vaccinate is affected by health policy; social norms and values; the views and actions of healthcare professionals; and parental consent. An important factor in determining uptake was the decision of the healthcare provider to recommend the vaccine. Parental consent is another factor that determines whether an adolescent receives the HPV vaccination. The SR concluded that interventions aimed only at the adolescent have little effect on overall uptake of the HPV vaccine, and parents and healthcare providers play an important role in decision making. Based on critical analysis and review of the methodology, the results of this SR can be considered reliable.

Guideline. The Advisory Committee on Immunization Practices (ACIP, 2016) recommends that all adolescents receive 2 doses of the HPV vaccine beginning at age 11 or 12; and 3 doses if the series is started after age 15. While the recommendation to receive the HPV vaccine has been in effect since 2006, recent research has prompted many professional medical associations to encourage healthcare providers to take a more proactive approach. The American Academy of Family Physicians (AAFP, 2017) acknowledged that "a physician's recommendation is the single best predictor of vaccination" and evidence shows that clinicians should discuss vaccines as a "bundle". By doing so, this "normalizes" the HPV vaccine and leads to parents having a better

understanding and acceptance of this vaccine. In addition, the American Academy of Pediatrics (AAP, 2017) has introduced the HPV Champion Toolkit designed with the knowledge that physician recommendation matters most to parents.

Additional evidence.

There are numerous qualitative studies and surveys that support similar findings related to low uptake of HPV vaccine. Some commonly identified barriers are "concerns about HPV vaccine effect on sexual behavior, low perceived risk of HPV infection, social influences, and cost" (Holman et al., 2014, para. 3). Despite these concerns, studies have shown that uptake of HPV vaccination improves when: 1) parents receive education about the vaccine, and 2) it is recommended by the healthcare provider (AAFP, 2017; AAP, 2017; CDC, 2015; Hirsch, 2012; Holman et al., 2014; Zimmerman et al., 2016).

Limitations

Since the initial recommendation for routine HPV vaccination was made in 2006, a significant amount of research has focused on vaccine safety and effectiveness- which has traditionally been a factor in clinical decision-making. Statistics have shown that there has been an improvement in uptake of other routine adolescent vaccines such as Tdap and MCV; however, HPV vaccination remains lower than desirable (Zimmerman et al., 2016). Due to the many variables that cause patients to decline HPV vaccination, there is a limited amount of research into specific approaches that are beneficial. There are currently broad theories with some evidence to support which interventions are most effective, but the details about how to best implement these changes into a variety of practices remain elusive. Many of the educational interventions rely on the use of EHRs

for data collection and clinician reminders- which exclude smaller practices that may have less elaborate systems in place. Despite these limitations, the use of specific education and provider recommendation has been shown to improve vaccination rates, and warrants a change in clinical practice that encourages all providers to consistently recommend HPV vaccination in the same manner as all other routine immunizations.

Conclusions

The literature review of HPV vaccination uptake, including barriers and facilitators, reveals a multifactorial issue. Medical evidence supports the effectiveness of HPV vaccination in preventing several types of oral and anogenital cancers; and a 2-dose series started at 11 or 12 years of age confers the same or better protection as the 3-dose series given to older adolescents (CDC, 2016a). Even with this evidence, many barriers remain that prevent adolescents from receiving the full series of the HPV vaccine. The primary factors affecting the decision to vaccinate remain consistent among scholarly research and more informal surveys- lack of parental information regarding HPV vaccination, and lack of provider recommendation (CDC, 2015). There is emerging evidence to support a multifaceted approach to public education and provider recommendation to increase the number of eligible adolescents that are immunized against HPV.

Chapter Three: Theoretical Framework

Vaccination is an effective form of primary prevention, which is considered "action to avoid or forestall the development of illness or disease" (Pender, Murdaugh, & Parsons, 2011, p. 36). Primary prevention is an important component of health promotion, in that the focus is on avoidance of disease as a main contributor to wellness, rather than treatment of disease after the fact. Health benefits, such as increased longevity and decreased morbidity, have been shown as a result of primary prevention and health promotion. In fact, according to Pender et al. (2011) the goal of improving population health is best served by interventions guided by these concepts.

Because of the natural cohesiveness between primary prevention and health promotion, the Health Promotion Model (HPM) developed by Nola Pender was used to guide the EBPP. According to Pender et al. (2011), the HPM was developed as a guide "to explore the complex biopsychosocial processes that motivate individuals to engage in behaviors directed towards enhancing health" (p.44). The HPM integrates concepts from social cognitive theory and expectancy value theory along with a nursing perspective to view the person in a holistic manner (Pender et al., 2011).

The HPM identifies three main areas of focus: Individual characteristics and experiences; Behavior-specific cognitions and affect; and Behavioral outcome. Within each focus area are other specific factors that contribute to the adoption of changes that are aligned with health promoting behaviors. The original HPM was revised to include additional variables: activity- related affect, commitment to a plan of action, and immediate competing demands and preferences (Pender et al., 2011).

Conceptual definitions

Individual characteristics and experiences.

According to Pender et al. (2011), "Each person has unique personal characteristics and experiences that affect subsequent actions, and the importance of their effect depends on the target behavior being considered" (p. 45). The person's actions can be further evaluated by prior related behavior and personal factors.

Prior related behavior. Many times, evaluation of past behavior is an effective method for predicting future behavior. These behaviors can be affected by strength of habits and repetition; previous emotions affiliated with similar changes; and amount of time to realization of perceived benefit (Pender et al., 2011). In the HPM, the role of the nurse is to help the individual identify ways to overcome barriers to behavioral changes related to past experiences.

Personal factors. Personal factors can be categorized as biological, psychological, and sociocultural and directly affect the beliefs of the individual regarding the target behavior. Biological factors can include "age, body mass index, pubertal status, menopausal status, aerobic capacity, strength, agility or balance"; psychological factors include "self-esteem, self-motivation and perceived health status"; and sociocultural factors include "race, ethnicity, acculturation, education and socioeconomic status" (Pender et al., 2011, p. 46). In order to apply the HPM effectively, the nurse includes only those factors that are related to the target behavior.

Behavior specific cognitions and affect.

Behavior specific variables include "perceived benefits, perceived barriers, perceived self-efficacy, activity-related affect, interpersonal influences, and situational influences" and constitute the critical "core" for intervention (Pender et al., 2011, p. 46). These factors appear to be of major significance and must be measured in order to determine if the intervention motivated change.

Perceived benefits of action. The perceived benefits of action are "mental representations of the positive or reinforcing consequences of a behavior" (Pender et al., 2011, p. 46). Research shows that individuals will be more motivated to pursue a goal that is likely to produce positive results. While the belief in a positive outcome is a necessary component of behavior change, it is not enough to create change without additional supporting factors.

Perceived barriers to action. Perceived barriers to action include "perceptions about the unavailability, inconvenience, expense, difficulty or time-consuming nature of a particular action" and usually prompt feelings of avoidance (Pender et al., 2011, p. 47). These barriers create direct and indirect blocks to action according to the HPM, as they create not only immediate avoidance, but also decrease overall commitment to behavior change.

Perceived self-efficacy. Self-efficacy is "the judgment of personal capability to organize and carry out a particular course of action" (Pender et al., 2011, p. 47). This factor is not affiliated with the skill to carry out an action, but the belief in oneself that he/she can carry it out. Interestingly, greater perceptions of efficacy alone create more

positive outcomes; as opposed to positive outcomes creating greater efficacy (Pender et al., 2011).

Activity related affect. Activity related affect consists of subjective feelings prior to, during, and after the action that can create a positive or negative feeling about the action. Behaviors associated with positive affect are likely to produce continued action. Few behaviors include only positive or negative feelings, and it is important to explore the range of emotions when promoting behavioral change.

Interpersonal influences. Interpersonal influences are "cognitions involving the behavior, beliefs and attitudes of others" which may or may not coincide with reality (Pender et al., 2011, p. 48). Primary sources of interpersonal influence are peers, family, and healthcare providers. Social norms and cultural traditions may also play a role in the willingness or ability of the individual to carry out a behavior change.

Situational influences. Situational influences include "perceptions and cognitions of any situation or context that facilitate or impede behavior" (Pender et al., 2011, p. 48). These influences include environmental factors and work-related regulations that would influence health-related behaviors. Situational factors have a moderate influence on behaviors and may be important in designing effective interventions.

Commitment to plan of action.

Commitment to plan of action initiates the behavior change and must be associated with specific strategies in order to transition from good intentions to an actual plan (Pender et al., 2011). Specific strategies include identification of time and place of

the intervention, people involved, as well as details for "eliciting, carrying out and reinforcing the behavior" (Pender et al., 2011, p. 49).

Immediate competing demands and preferences.

Competing demands and preferences include any responsibilities or activities that interfere with the implementation of the behavioral intervention, whether by time limits or simply by choice. Identification and acknowledgement of these competing factors is required in order to formulate a plan that will lead to successful change.

Behavioral outcome.

The final piece to the HPM is the behavioral outcome, which is the health promoting behavior. Successful adoption of the health promoting behavior is key to making permanent changes in the individual which result in overall improved health and wellness.

Relationship of HPM to the EBPP

As stated previously, primary prevention- in this case, immunization with the HPV vaccine- is an integral part of health promotion, which serves as the basis for Pender's theoretical model. The HPM can readily be applied to the EBPP of parental education on HPV vaccination in order to increase immunization rates in adolescents beginning at age 11 or 12, as the goal of the intervention is consistent with the outcome of behavioral change to improve overall health.

Individual characteristics and experiences of the parent affect the way health decisions are made, including the decision to vaccinate. Prior related behavior in this case can be related to the decision to vaccinate the child previously for communicable

diseases as recommended by the CDC. Additional examples of this type of behavior are uneasiness about the choice to vaccinate, and concern about possible side effects; history of trauma in the child related to the administration of vaccines in the past, or the recalled experience of pain. The nurse has the opportunity to address these past experiences and reinforce known facts. Personal factors that may affect the parent's decision can include the age of the child, cultural views on vaccines, religious conflicts, costs associated with vaccines and the ability to pay.

Behavior –specific cognitions and affect include perceived benefits of action, such as the reassurance that the decision to vaccinate against HPV offers the child some protection from HPV related cancers. Perceived barriers to action include cost, lack of information, lack of recommendation by a health care provider, inconvenience of a 2-3 shot series, as well as the belief that vaccination against HPV can lead to earlier initiation of sexual activity in the child (Ferrer et al., 2014). Perceived self-efficacy of the parent in this case relates to the parent's perception of their ability to make a well-informed decision about the HPV vaccine. Activity related affect includes the feelings that the parent has surrounding the decision to vaccinate, which may include guilt, fear or uncertainty. This factor also includes feelings surrounding the child's reaction to previous vaccines or general thoughts about getting injections.

Interpersonal influences that may have an effect on the initiation of HPV vaccination can include perceived ill effects of vaccination from other parents, and the beliefs of family members or religious groups. One of the most relevant interpersonal influences in this case is that of the healthcare provider, as one of the reasons consistently

cited for the uptake of HPV vaccination is the recommendation of a physician (Holman et al., 2014). Situational influences can be either positive or negative. In this case, the fact that HPV vaccination is not a requirement for school can lead the parent to believe that it is not necessary.

Commitment to plan of action requires that the parent has fully accepted the benefits of vaccination, and they are prepared to counter inclination for the child to refuse the vaccine. This factor can be reinforced by the provision of educational materials prior to the well visit in which the vaccine series would be initiated. Immediate competing demands include the child's refusal, participation in an activity on the day of the appointment which would be negatively affected by the development of injection site pain, and unknown costs or copays.

The behavioral outcome desired in the EBPP was the uptake of the HPV vaccine by adolescents at age 11 or 12. The intervention was designed to address the commonly identified barriers to vaccination, and to provide the parent or guardian with the information needed to make an informed decision. The goal was that by providing information about the actual risk vs. benefits and addressing common concerns-along with provider recommendation- the parent will choose the health promoting behavior which will positively impact the child in the future.

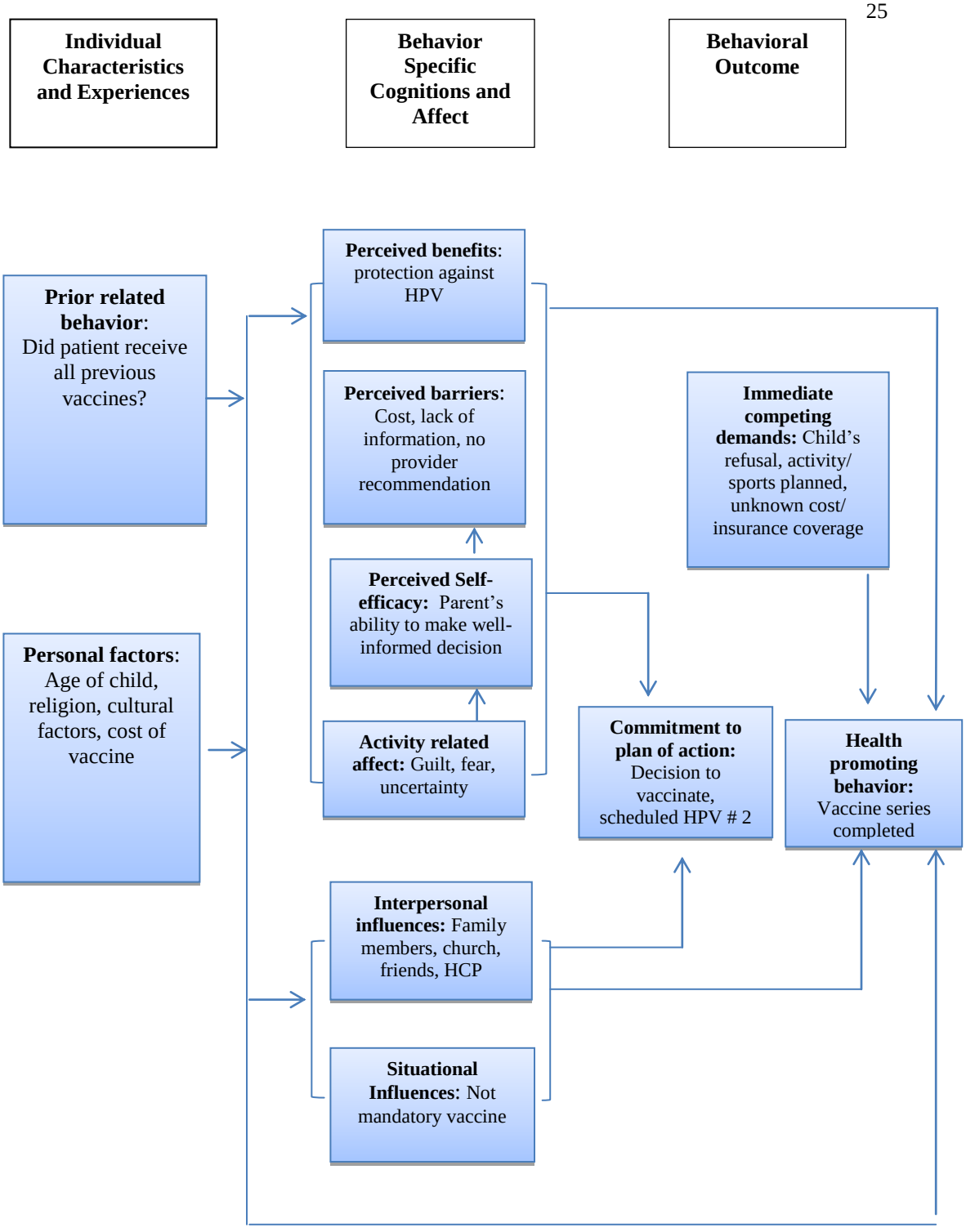

Figure 1. Concepts of HPV vaccination intervention following Pender's Health Promotion Model

Chapter Four: Project Design

The purpose of this EBPP was to determine if the low cost intervention of providing educational materials about HPV vaccination to the parents of adolescents between 11 and 12 years of age, prior to the well exam, will improve the uptake of HPV vaccination by the recommended age. The HPV vaccine is routinely offered to eligible adolescents at the yearly well exam along with the meningitis and Tdap vaccines. The current practice is to verbally inquire if the parents would like to have their child receive these vaccines, which often results in parental hesitation and the desire to do more research on the HPV vaccine before initiating the series. The intervention for this EBPP was intended to initiate a change in practice, which can be considered a quality improvement (QI) approach (Moran et al., 2014). This chapter will discuss the plan leading to the implementation of the EBPP.

Collaboration

In order to design the EBPP, a collaborative effort was undertaken in which meetings were held with the physician/ owner of the practice, nurse practitioner colleagues, clinic nurses, medical assistants and vaccine representatives. Brainstorming sessions were conducted in order to determine which methods of educating parents would be accurate, efficient, cost-effective, and practical for a small independent practice. The group addressed multifactorial aspects of the project from the perspective of each discipline. This effort allowed for the development of a project design for which implementation would not interfere with usual work flow or productivity.

Institutional Review Board (IRB) Approval

Initial IRB application was submitted to course faculty on February 19, 2017 for review. Revisions were made and the IRB application was forwarded to the IRB chairperson, Dr. Hunter Manasco on April 16, 2017. Further clarification and revision of dates were completed and IRB approval for *Parental Education of Human Papillomavirus Vaccination: Does it Positively Affect the Decision to Vaccinate their Adolescent* was granted on May 15, 2017.

Implementation Plan

Participants were selected from the existing population of 11 and 12 year old adolescents who had an established appointment for their well exam at Mountaintop Pediatrics, P. C., from the time after IRB approval and August 18, 2017. The number of patients who would meet the criteria was estimated to be between 15 and 30. While this project focused on HPV vaccine uptake, the CDC recommends that when discussing adolescent immunization recommendations with the parent/ caregiver, the provider should "tell parents that they need three vaccines today to help prevent meningitis, HPV cancers, and pertussis" (CDC, 2015, para. 1).

The written educational materials that were used are HPV and meningococcal vaccination tear sheets developed by the Children's Hospital of Philadelphia Vaccine Education Center, and available for purchase to healthcare providers for the purpose of patient education. After verifying from the patient intake form that the parent/caregiver agreed to be contacted by mail, a brief letter along with the HPV and meningococcal tear sheets were sent to the home (see Appendix A). Letters were grouped for mailing

according to the scheduled exam date, with a targeted mailing date within the 2 week period prior to the exam.

At the time of the well exam, and according to current practice at the routine office visit, the parent was informed which vaccines were recommended for their child at this age and asked if they consented to receiving them. All desired vaccines were prepared and administered by the medical assistant or nursing staff in the office as per current clinical practice.

Data Collection Tools

The participants who consented to the HPV vaccine were given the option to complete an anonymous survey to determine if the written educational materials provided prior to the visit affected the decision to vaccinate. The survey took approximately 1-2 minutes to complete, and was given to the parent/ caregiver while the vaccines were being prepared- which was routinely time spent in the treatment room waiting for the nurse to return with the vaccines. The survey contained no identifying information, listed no protected health information, and contained no potentially damaging or harmful information that would negatively impact the participant (see Appendix B). The anonymous surveys were sealed by the participants and dropped into a locked box located near the front desk at the pediatric office. Surveys were collected from the box weekly by the DNP candidate and stored in a locked file cabinet within the DNP candidate/ nurse practitioner's office at Mountaintop Pediatrics, which was shared with the physician/ owner of the practice, who was also the clinical preceptor for this project.

Upon completion of the evidence based project, a chart review was done by using the same search criteria- individuals between 11 and 12 years of age who had their well exam between the dates in 2016 that corresponded with the start and end date of the EBPP (see Appendix C). As it was standard practice in the office to offer all age-appropriate recommended immunizations at the time of the well exam, the information gathered from the chart review would indicate whether the patient did or did not receive the HPV vaccine based on standard office practice alone. No identifying patient information was included in the final analysis, and charts were accessed only by the DNP student in order to obtain this information. A z-test for proportion was completed to determine if there was a statistically significant difference between the group that received standard recommendation alone and the group that received the printed educational materials.

Resources Needed

This project was designed as a QI intervention that could be easily carried out in multiple settings. The EBPP took place in a small independent pediatric practice, and was set to target 15-30 patients over the course of the project. Manpower resources were needed initially in order to input data into a computerized, searchable format for identification of eligible patients by age. These costs were assumed by the practice, as the data entry coincided with the need to update patient records due to the recent opening of a second location.

The educational tear sheets were purchased by the DNP student at a cost of $4 per pad of 25 ($0.17 per sheet). The mailing consisted of an HPV and meningococcal

vaccine tear sheet, letter, envelope, and postage ($0.49) at an estimated cost of $0.85 per mailing. The box and lock for survey collection cost an additional $25. The total estimated cost for the EBPP was between $40-50 for materials and $25 for approximately 2 hours of medical assistant time used to print labels and prepare mailings for 15-30 patients, for a total cost of $65-75. As the data entry and updated vaccine information were required as part of routine practice management, no additional funds were required for implementation.

Budget Justification

The National Committee for Quality Assurance (NCQA) updated the quality measures for Healthcare Effective Data and Information Set (HEDIS) in 2017 to combine data on adolescent immunizations. Previously, the HEDIS measurements for *Human Papillomavirus for Male and Female Adolescents* and *Immunizations for Adolescents*, which included Tdap and meningococcal vaccination for male and females by age 13 were separate measures. As of 2017, HPV vaccine was included along with the Tdap and meningococcal vaccines in the *Immunizations for Adolescents* HEDIS measurement (NCQA, 2017). This change would tend to lower overall HEDIS scores, as uptake for Tdap and meningococcal vaccines- which had previously been higher- would no longer be considered unless HPV vaccination is current as well. HEDIS measures determine overall performance of a provider or practice, and contribute to reimbursement for services. A small investment of less than $1 per mailing per eligible adolescent has the potential to maintain or improve HEDIS scores.

Chapter Five: Implementation of the Evidence Based Practice Project

The EBPP was designed so that it could be carried out in a variety of healthcare settings without a significant investment of time or money. The location in which this project was carried out is a small, independent pediatric practice with a total patient census of approximately 6000. The office currently does not utilize an electronic medical record (EMR); but instead uses a cloud- based hybrid charting system. Education-based interventions are commonly used in healthcare via mail, text or SMS messaging, email or audio recording. After careful examination of the possible delivery methods for the parental HPV education, a mailing was determined to be most appropriate for this setting.

Since the main goal of the project was to provide information to the parents prior to their child's well exam, pre-made vaccine information tear sheets were chosen. These tear sheets were compiled by the Vaccine Education Center at Children's Hospital of Philadelphia (VEC) to be used by healthcare professionals to educate their patients and families. The VEC is "an educational resource for parents and healthcare professionals and is composed of scientists, physicians, mothers and fathers who are devoted to the study and prevention of infectious disease" (Vaccine Education Center [VEC], 2016, p. 1). As the sample size was predicted to be between 15-30 patients, and in order to start the project immediately after IRB approval, two tear pads of each of the following were ordered: "Human Papillomavirus: What You Should Know" and "Meningococcus: What You Should Know".

The HPV parental education packet includes a letter from the office introducing the vaccines for which the patient was eligible, along with the HPV and meningococcal tear sheets (Appendix A). Envelopes and first class postage stamps were purchased, and packets were made and prepared to be addressed. A lockable, metal box with an opening to drop the final survey was ordered and set up in the office in a secure location near the front desk. The HPV vaccination surveys were printed and placed at the front desk for ease of access during implementation.

The next step in the process was to identify the patients who met inclusion criteria as follows: male or female, between 11 and 12 years of age, with a well exam scheduled between the time of the IRB approval of May 15, 2017 and August 18, 2017. This was accomplished by searching the schedule between those dates with a "birthdate" filter. The potential participants' charts were reviewed to determine if they had already received the HPV vaccine at a previous visit.

After final IRB approval, address labels were generated for the identified participants and placed on the prepared packets. Envelopes were grouped by appointment week, and mailed within the 2 week period prior to the scheduled appointment.

As eligible patients presented to the office for their well exams, they were informed which vaccines were recommended at that visit. All adolescents between the ages of 11 and 12 were offered Tdap, meningococcal and HPV vaccines. The parent/ guardian of those patients who did receive the HPV vaccine at the well exam were given a survey to complete (Appendix B) to determine if the addition of the educational packet

they received prior to the well exam helped them to make the decision to vaccinate. The survey was placed in the locked box near the front desk to be collected by the DNP student weekly or when the box became full. The surveys were kept in a locked filing cabinet until they were needed for data collection.

Table 1. Task List

Task	**Action**
Educate staff about EBPP project	Completed
Order HPV and meningococcal information tear sheets from VEC	Completed
Gather additional supplies needed for implementation-envelopes, stamps, survey box, etc.	Completed
Obtain IRB approval	Completed
Prepare educational packets for mailing	Completed
Mail packets within 2 week period before scheduled well exams	Completed
Project implementation with survey collection	Completed
Chart review of HPV vaccination data from same period in previous year	Completed
Data collection and analysis	Completed
Complete final DNP paper	Completed
Oral defense of EBPP	Scheduled

Table 2. Time Line

Timeline Goal	Task	Completed	Notes
September 2015-November 2015	Initial data collection for HPV vaccination intervention	November 2015	
October 2015	Discussed PICO-T / DNP project and obtained approval for intervention from medical office where intervention is to take place (Mountaintop Pediatrics)	November 2015	
November 2015	Human Subjects Protection Education	November 2015	Required by MU
October 2016	Review changes to ACIP guidelines for HPV vaccination	October 2016	
January / February 2017	Submit IRB application to Misericordia University for review	February 19, 2017; final revision April 16, 2017; approval May 15, 2017	
January/ February 2017	Obtain approval from Mountaintop Pediatrics for DNP project	February 9, 2017	
March 2017	Order CHOP Vaccine Education Center vaccine tear sheets for patient education	April 2017	Ordered revised HPV tear sheet reflecting current guidelines
March 2017	Search patient database to estimate sample size of those meeting inclusion	March 2017	

	criteria for project		
March 2017	Compose cover letter to accompany CHOP VEC tear sheet	February 10, 2017	
March 2017	Print address labels/ prepare envelopes for mailing	May 2017	Printing delayed until after IRB approval
April 2017	Develop survey to assess if printed materials influenced the decision to begin vaccination	February 11, 2017	
April 2017	Install survey collection box in office	May 2017	
April 2017	Educate nursing/ medical assistant staff about EBP and their roles in providing vaccinations	April/ May 2017	HPV vaccination is currently a routine offering at well exams beginning at 11 yrs. of age
May 2017	Identify patients meeting inclusion criteria with scheduled well exams in June and July & August	May 2017	
May 2017	Initiate EBPP by mailing prepared educational materials	May 16, 2017	
May-July 2017	Offer HPV vaccine to all eligible patients. Ask parent to complete survey at the end of the visit for those who did receive the HPV vaccine	June-July, 2017	
June- July 2017	Work on EBPP capstone paper	June-July, 2017	

July 2017	Gather and analyze Data	July, 2017	
August 2017	Complete final chapter of EBPP capstone paper	August 12, 2017	
August 2017	Disseminate findings of EBPP project/ Oral defense	August 16, 2017	

Chapter Six: Evaluation and Outcomes

The desired outcome for this EBPP was to increase the percentage of eligible patients of both genders who initiated the HPV vaccine series at the recommended age of 11 or 12 by implementing an educational intervention aimed at addressing parental concerns about the HPV vaccine. This project was readily accepted by providers and staff at Mountaintop Pediatrics, P.C., as HPV vaccination uptake has been consistently lower than for Tdap or meningococcal vaccines offered at the same age. This trend is consistent with the national vaccination data for the same age group (CDC, 2017b).

After receiving IRB approval, the implementation phase of this project was carried out from June 2, 2017 through July 20, 2017 in the Mountain Top location of Mountaintop Pediatrics, P. C., as this was the primary practice site for the DNP student/ primary investigator. In addition to the educational intervention and to obtain data for comparison, a chart review was completed to gather HPV vaccination information for 11 and 12 year old adolescents who were seen in 2016 during the same timeframe from June 2, 2016 through July 20, 2016. Review of the data suggests that there was an increase in the rate of vaccination for eligible adolescents with the addition of the written educational materials.

Evaluation

The patient database identified 32 (n=32) adolescents (22 male and 10 female), who met the inclusion criteria- which required that they be age 11 or 12, scheduled for a well exam within the EBPP timeframe, and had not previously started the HPV vaccine series. Educational mailings addressed to the parent/ guardian were sent to each eligible

participant's home within the 2 week time frame prior to the scheduled well exam. At the time of the well exam, the parent/ guardian was informed that the adolescent was eligible for the following vaccines- Tdap, meningococcal and HPV as per current office protocol. The adolescent was then administered any vaccines for which consent was obtained. The parents/ guardians who were sent mailings, and who consented for their child to receive the HPV vaccine at the visit, were given the opportunity to complete a survey to determine if the educational materials helped them to decide to vaccinate.

Of the 32 who received the mailing, 15 (7 male and 8 female) chose to begin the HPV vaccine series. The parent/ guardian was then given the survey to complete that asked the following questions:

- Did you receive the printed educational handout *Human Papillomavirus: What you should know?*
- Did you read the materials?
- Which of the following statements best describes your feelings on the decision to have your child vaccinated against HPV today?
    - I had some unanswered questions about the HPV vaccine prior to the appointment, and the provided educational material helped me make the decision to vaccinate.
    - I had already decided to vaccinate my child according to the CDC guidelines, and I feel I would have done so even without having received the educational material.

. The surveys did not include any identifying information and they were deposited into a locked collection box, so there was no way to compare the survey responses to the gender of the adolescent who received the HPV vaccine. Four of the 15 stated they did

not receive or review the materials prior to the appointment, so they were grouped with those who chose to vaccinate regardless of the educational intervention. Of the 11 remaining participants, 7 replied that the educational materials helped them to make the decision to vaccinate; while 4 stated that they would have done so even without the materials. A simple percentage calculation (7/11 who vaccinated) was performed to determine that approximately 63% of those who decided to vaccinate did so because of the educational materials.

Table 3.	**Used Information Packet to Guide Decision Making Process to Receive Vaccine**	**Had Previously Decided to Vaccinate Regardless of Information Packet**	**Total**
Read Educational Information packet	7	4	11
Did Not Read Educational Information Packet	**n/a**	**4**	**4**

Table 3*. Individuals who were sent information packet and consented to HPV vaccination.*

The focus of this EBPP was to determine if there was an increase in the rate of HPV vaccination for eligible adolescents with the addition of the educational intervention. The hypothesis- based on the percentage of people who responded that they decided to vaccinate after reading the educational materials- was that there would be an increase in the vaccination rate of adolescents during the EBPP period when compared to the same timeframe in the previous year.

A chart review was completed on all patients who would have been 11 or 12 years of age and had well exams between June 2 and July 20, 2016. The review identified 30 (n= 30) individuals who met the criteria, 12 males and 18 females. Of these individuals, 8 began the HPV vaccine series at the time of the well exam, while 22 declined.

Outcomes

Between June 2 and July 20, 2017, there were 32 adolescents between the ages of 11 and 12 who were eligible to receive the HPV vaccination. Each of these families was mailed the educational materials addressing frequently asked questions about the HPV vaccine, along with a cover letter recommending the vaccine by the healthcare providers. The parents/ guardians of 15 of the 32 adolescents consented to the HPV vaccine at the well exam.

During the same timeframe in 2016, there were 30 adolescents who met the eligibility requirements for the HPV vaccine. The standard practice protocol was followed, in which the staff nurse or medical assistant informed the parent/ guardian that the individual was eligible to receive the Tdap, meningococcal, and HPV vaccines. Eight of the 30 adolescents received the HPV vaccine at the time of the well exam based on the chart review. This EBPP was not specifically designed to compare data between males and females who started the HPV vaccine series; however, the investigator made note of the number of males and females in the sample for the year 2016 in order to evaluate whether any change in uptake could potentially show a correlation with the national averages of male vs. female vaccination trends.

Table 4.	2016	2017
Adolescents Age 11-12 who Started HPV Vaccine Series	8	15
Adolescents Age 11-12 who Did Not Start the HPV Vaccine Series	22	17
Total	30	32

Table 4. Comparison of HPV vaccine uptake in eligible adolescents.

Because this EBPP focused on categorical data collection that focused on increased uptake of the HPV vaccine, a one-tailed, 2 sample Z-test to compare sample proportion was done using Ausvet EpiTools (2017). The proportion was first calculated for each group which resulted in 0.26 for the 2016 group, and 0.47 for the 2017 group. Data was then entered, including sample size of 30 in 2016, and 32 in 2017. Results were significant for the intervention with 1.7, 95%CI [0.32-0.62], p =0. 04.

Table 5.		
	Sample 1 (2016)	**Sample 2 (2017)**
Sample proportion	0.26	0.47
95% CI (asymptotic)	0.1283 - 0.3917	0.3249 - 0.6151
z-value	1.7	
P-value	0.0433	
Interpretation	Statistically significant, reject null hypothesis that sample proportions are equal	
n by pi	n * pi >5, test ok	

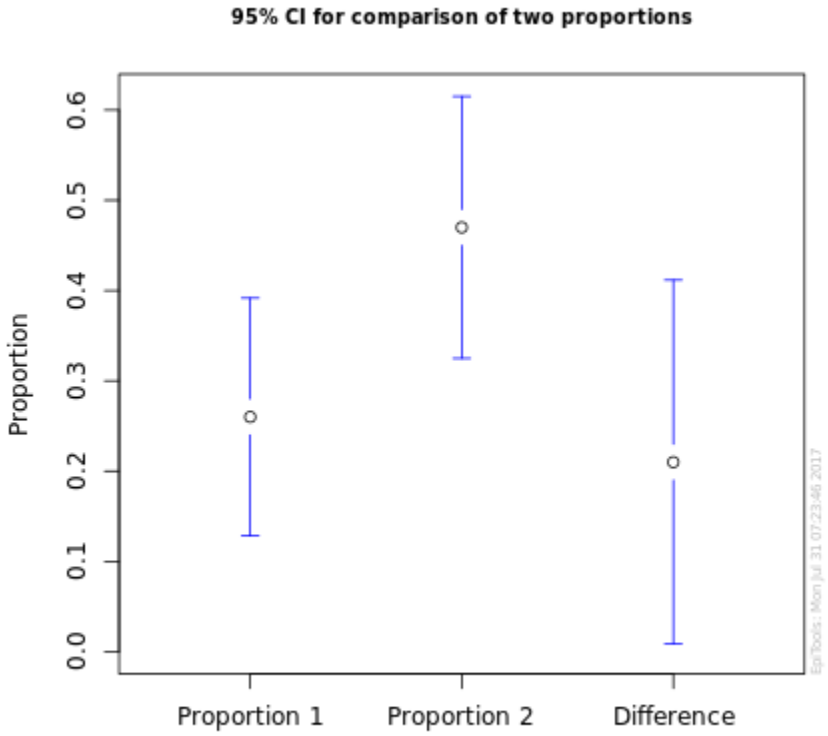

Figure 2. Proportion 1- 2016 HPV uptake; Proportion 2- 2017 HPV uptake

Discussion

The EBPP showed a statistically significant result when a comparison of HPV vaccine uptake was examined for the groups that received only general recommendation in 2016 and parental educational intervention in 2017. Although this EBPP did not focus on whether the adolescent was male or female, an interesting observation was made. According to national data, HPV vaccine uptake is consistently lower for males than females (CDC, 2017b). The sample groups of adolescents for each year were similar in size (n=30; n=32), however the number of males to females was not comparable. In 2016, there was a total of 30 individuals- 12 male (0.40) and 18 female (0.60); while in

2017 there was a total of 32 individuals- 22 male (0.68) and 10 female (0.32). One could hypothesize that the total uptake would be lower in the year in which there was a greater proportion of males, however, the opposite was true. This data indicates the need for further research, as there may be an even greater benefit than suggested by this EBPP for females, for whom there is a greater perceived risk for HPV cancers.

Chapter Seven: Implications for Nursing Practice

HPV is estimated to cause almost 32,000 cases of cancer of the cervix, vagina, vulva, penis, rectum, anus and oropharynx each year (CDC, 2017a). Despite these numbers and the recommendation to be vaccinated against HPV, only 66 % of teen girls and 50% of teen boys receive the vaccine (CDC, 2017b). These rates are improving, but still are not comparable to the 80 % vaccination rates for Tdap and meningitis that are also recommended for the same age group. Research shows that patient education and recommendation by the healthcare provider have been shown to increase uptake of the HPV vaccine (Ferrer et al., 2014; Hirsch, 2012). The educational intervention performed for this EBPP is a cost effective way to increase the likelihood that eligible adolescents will comply with the recommendation to initiate the HPV vaccine series by age 11 or 12.

Implications for Nursing Practice

Advanced practice registered nurses (APRNs), including nurse practitioners, offer a holistic approach to care that includes disease prevention, health education and counseling (American Academy of Nurse Practitioners [AANP], 2017). A cost-effective, education-based project, that has a disease prevention intervention as its goal, fits nicely within the model of healthcare practiced by APRNs. Since nurse practitioners care for patients in a variety of settings- including rural health clinics, primary care offices, and school-based clinics- an effective intervention must be adaptable to multiple different patient populations and environments. While this EBPP focused on a traditional mailing, the research on which it was based- patient education and provider recommendation- can be presented in multiple formats. Smaller, independent practices with paper charts can

follow this protocol exactly at a cost of around $1 per eligible patient; while those with EMRs can send email, text messages or automated phone calls. Regardless of the delivery method, a multifaceted approach to educate parents and recommend the HPV vaccine can help to reach the Healthy People 2020 goal of 80% vaccination of males and females with the full series by age 13-15 (Healthy People 2020 website, 2017).

Strengths of the EBPP

Strengths of this EBPP included the low cost, adaptability to multiple settings, minimal time commitment by office staff, no measurable disruption to the provider schedule, and ease of implementation. Beyond the practical business aspects of the EBPP, one of the most important benefits of the project is the increased vaccination of adolescents against HPV, which leads to lower morbidity and mortality of the next generation of healthcare consumers.

Low cost. This project design included the use of pre-made patient education handouts developed by the some of the leading experts in the field of pediatric immunizations at the Children's Hospital of Philadelphia (CHOP). By using these handouts, the most accurate, evidence-based information was provided to the patient with no additional development time required by the implementation team. Each educational mailing cost less than $1 per eligible patient, including postage. There were one-time costs such as the metal lock box, which would not pose any additional financial burden to continue this intervention throughout the year.

Adaptability to multiple settings. The intervention in this EBPP consisted of providing education on the HPV vaccine to parents of eligible adolescents, along with a

letter containing the recommendation of the provider to begin the HPV vaccine series via first class mail. This project could be carried out in any practice setting, regardless of size or patient population, as long as there is mail service in the area.

Minimal time commitment by office staff. This project required an initial patient database to be developed, which was completed by the DNP student. This database was designed so that new patients' information is entered upon joining the practice; therefore, any future searches would require no additional data entry. Searchable lists and mailing labels could be printed within minutes. The number of eligible patients between 11 and 12 years of age who would be due for well exams is estimated to be between 5 and 7 per month. Preparation of this small amount of mailings would not require more than twenty minutes of medical assistant time per month. No additional time would be required for surveys if this were to become an ongoing practice.

No measurable disruption to the provider schedule. The educational materials were sent prior to the well exam, which included answers to some of the most frequently asked questions. By providing the parent with basic information about the HPV vaccine ahead of time, the provider actually spent less time educating the patient and had more time to answer well-informed questions.

Ease of implementation. The intervention outlined in this EBPP did not require additional staff training and could have easily been delegated to non-medical office staff if desired. The skills required to gather patient information and print mailing labels would be present in those already employed in the office.

Limitations of the EBPP

Limitations for this EBPP included the need to build a patient data base, as the practice setting in which the project took place maintains a paper charting system with little information kept in a digital format. While this process took significant time and effort on the part of the DNP student, the system remains in place for future use.

There were 32 participants who met inclusion criteria for the EBPP, and to whom mailings were sent. Four of those who received the HPV vaccine and were given the survey afterwards reported that they did not receive and/or review the information prior to the visit, therefore, they were excluded from data collection.

Small sample size (n= 28) and short time frame for the project to be carried out also may not have provided an accurate assessment of the effectiveness of the project in meeting the goal of increased vaccination rates. In addition, the proportion of males (n=20) to females (n=8) may have produced inaccurate data when applied to the general population, as the percentage of males who typically receive the HPV vaccine is lower than females in the same age range (CDC, 2017b).

Linkage to DNP Essentials

The DNP Essentials are the core competencies required as the foundation of DNP education, "regardless of specialty or functional focus" (American Association of Colleges of Nursing [AACN], 2006, p. 8). There are eight identified competencies that guide DNP practice which were applied in the design and implementation of this EBPP.

Essential I: Scientific underpinnings for practice. This EBPP was based on statistical data on HPV vaccination and clinical guidelines. Currently, the percentage of

adolescents between the ages of 11 and 12 who begin HPV vaccination is well below the goal of 80% (Healthy People 2020 website, 2017). Additionally, the intervention was based on scientific research that shows that lack of both information and provider recommendation contributed to the refusal of HPV vaccination for eligible adolescents (Ferrer et al., 2014).

Essential II: Organizational and systems leadership for quality improvement and systems thinking. This EBPP was designed as a quality improvement project with a focus on increasing the percentage of patients within the practice who are vaccinated against HPV at the appropriate age. The project was implemented in such a way that it can be seamlessly continued to identify and reach all patients as they become eligible in the future.

Essential III: Clinical scholarship and analytical methods for evidence based practice.

> The scholar applies knowledge to solve a problem via the scholarship of application (referred to as the scholarship of practice in nursing). This application involves the translation of research into practice and the dissemination and integration of new knowledge, which are key activities of DNP graduates (AACN, 2006, p. 11).

This EBPP was not designed to generate new knowledge; rather, it incorporated multidisciplinary research findings which were then applied to a specific patient population to address a significant problem in clinical practice.

Essential IV: Information systems technology and patient care technology for the improvement and transformation of healthcare. This EBPP was carried out in a setting in which an electronic medical records system was not yet in place. A key component of this project included building a searchable patient database from which information could be searched and extracted to identify patients meeting specific inclusion requirements- such as age, date of last physical exam, etc. This database remains in use at the practice and can be used for other quality improvement initiatives in the future.

Essential V: Health care policy for advocacy in health care. This EBPP was implemented in a small independent practice, and was shown to be effective in improving vaccination rates. The office has adopted the practice of sending pre-printed educational materials prior to the well exams to educate parents about key issues ahead of time. The success of this project in a small setting with few resources has implications for community health organizations that may have limited funding in order to decrease disparities among vulnerable populations.

Essential VI: Interprofessional collaboration for improving patient and population health outcomes. This EBPP was developed in part by collaboration with the physician-owner of the practice and medical staff therein. Concerns and recommendations from each discipline were considered when designing the project. This ensured that there was buy-in from all involved, which contributed to the success of the project.

Essential VII: Clinical prevention and population health for improving the nation's health. The central focus of this EBPP was increasing the rates of HPV vaccination in

order to decrease morbidity and mortality from a vaccine-preventable disease. By reducing the number of people who contract HPV in individual clinics, the overall health of the nation will improve- thus reducing health care costs in the future.

Essential VIII: Advanced nursing practice. Key elements involved in advanced nursing practice are the demonstration of "advanced levels of clinical judgment, systems thinking, and accountability in designing, delivering, and evaluating evidence-based care to improve patient outcomes (AACN, 2006)".

This EBPP contains the elements requires for DNP practice, and offers a valuable method for providers across multiple settings to increase HPV vaccination rates. In addition, the project can be easily adapted for larger practices with EMR and automated message delivery capabilities.

Chapter Eight: Summary

In the United States, it is estimated that 1 in every 4 people are infected with at least one strain of HPV. While not all of these lead to cancer, virtually all cancers of the anogenital tract are related to one of the high- risk strains of HPV (American Cancer Society, 2016). HPV infection risk is highest in those in their teens and early twenties (Kostas-Polston & Johnson-Mallard, 2017), yet HPV vaccine uptake remains well below the Healthy People 2020 goal of around 80%.

Research shows that some of the most often cited reasons for low uptake of HPV vaccination include parental knowledge deficit and lack of strong recommendation by the healthcare provider (Ferrer et al., 2014). Because HPV is transmitted by intimate contact, many parents feel that the recommended age for vaccination of 11 or 12 years is too young (Holman et al., 2014). While it is true that many young people are not engaging in sexual intercourse at that age, it is important to be protected at an early age to have sufficient time to develop immunity before potential exposure. It is equally important to note that skin-to-skin contact with an infected individual can spread HPV, and many people are asymptomatic carriers of the virus (CDC, 2016a).

Summary of Project and Conclusions

An evidence-based practice project was designed to address the problem of low uptake of HPV vaccination in clinical practice. Individuals were chosen for participation in the EBPP who were between 11 and 12 years of age, with a scheduled well-exam between June 2 and July 20, 2017, and who did not already receive the HPV vaccine. Preprinted HPV and meningococcal vaccine information tear sheets from the VEC at

CHOP were compiled into a packet, along with a provider letter stating which vaccines were recommended at the upcoming appointment. No additional information on the Tdap vaccine was included, as the child would have previously received these vaccine components with routine immunizations, therefore it was not considered to be a new vaccine. These educational packets were mailed to the parent or guardian of the adolescent in the 2 week period just prior to the well exam. Individuals were offered the HPV, meningococcal and Tdap vaccines per CDC and ACIP guidelines at the time of the visit. Those parents/ guardians who consented to the HPV vaccine were asked to complete a voluntary survey to determine if the educational intervention helped them to make the decision to vaccinate. HPV vaccine rates of the intervention group were compared with the vaccine rates of eligible 11 and 12 year old adolescents who had a well exam during the same time frame in the previous year.

There was found to be a statistically significant increase in the rate of vaccine uptake in the intervention group when compared with a similar group from the previous year. In addition, despite the national trend for lower vaccination rates in males, the intervention group, which consisted of more males than females, still demonstrated an increase in HPV vaccination.

Dissemination Plans

Essential III of the DNP essentials provides that the DNP-prepared APRN: "applies knowledge to solve a problem via the scholarship of application. This application involves the translation of research into practice and the dissemination and

integration of new knowledge, which are key activities of DNP graduates" (AACN, 2006, p. 11).

The results of this EBPP were significant enough to warrant practice change at both locations of Mountaintop Pediatrics, P.C. to include educational mailings prior to the well exams of all 11 and 12 year old adolescents. Information was shared with the staff and all providers to determine the best method to continue the project within the practice.

The EBPP was presented as a DNP Capstone Project at Misericordia University to peers and faculty, many of whom are APRNs who can readily incorporate the information into their existing practices. In addition, plans for dissemination include poster presentations at local and national conferences pending approval.

Future Ideas

This EBPP lends itself to multiple formats and is adaptable to numerous practice settings. Healthcare informatics offers numerous platforms through which providers can reach their patients and provide individualized guidance. Some of these methods include electronic, text, or SMS messaging; email; and automated message systems. All of these areas have the potential to increase the knowledge base of the patient and allow the provider to offer recommendations without investing a significant amount of time.

Additional research on the effect of educational support paired with provider recommendation is needed. There is also a need to develop educational materials prepared at a 4th to 5th grade reading level for those with low health literacy, as CHOP does not currently have such resources. This EBPP offers a simple outline that can serve

as the base for multiple similar projects aimed at increasing the uptake of HPV vaccination in the U. S. - which in turn, will make the future brighter and healthier for the next generation.

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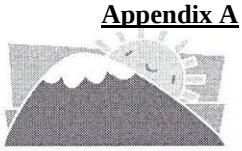
Appendix A



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Date

Dear *Parent*,

All of the healthcare providers at Mountaintop Pediatrics are committed to ensuring the good health and wellbeing of our patients, and we want to help you to make informed decisions regarding your family's health.

We feel that vaccination against disease is one of the most important steps you can take to keep your child well. Your preteen is scheduled for a well exam within the coming weeks, and it is time to begin the next round of recommended vaccines:

Tdap- Tetanus, Diphtheria and acellular Pertussis booster

Meningococcal (MCV4)- with another booster around 16 yrs of age

Human Papillomavirus (HPV)- 2 dose series when started at 11-12 yrs; 3 dose if older

You will find detailed information about the HPV and Meningococcal vaccines enclosed in this mailing, as your child has already received the tetanus, diphtheria and pertussis vaccines when they were younger. Please take a moment to read the information prior to your child's appointment. As always, we will be happy to answer any questions you may have at the visit.

Sincerely,

Dr. Irene Man-Hsiao, Catherine Zurawski CRNP & Sarah Magula CRNP

Q&A

Volume 5, Winter 2016

Human Papillomavirus: What you should know

The Children's Hospital of Philadelphia
VACCINE EDUCATION CENTER

Human papillomavirus (HPV) is a virus that can lead to genital warts and various forms of cancer, including those of the cervix and other reproductive organs as well as cancers of the head and neck. HPV is the most common sexually transmitted infection in the United States and around the world; in fact, each year, about 300,000 women die from cervical cancer caused by HPV.

Q. What is human papillomavirus?

A. Human papillomavirus (HPV) is a family of viruses that commonly infect the genital area and lining of the cervix. Some types of HPV infect the genital areas of men and women, causing warts. Genital warts can be unsightly and emotionally debilitating. Other types of HPV cause cervical cancer, as well as other cancers of the reproductive organs. On occasion, HPV infections can lead to cancers of the head and neck.

Q. How common is HPV?

A. HPV is the most common sexually transmitted infection in the United States and around the world. More than half of sexually active people will be infected with HPV at some time in their lives. Twenty million Americans are currently infected with HPV, and another 6 million become infected every year. Half of those newly infected with HPV are between 15 and 24 years of age.

Q. Is HPV dangerous?

A. Yes. Most of the time, HPV goes away on its own and doesn't cause any health problems. But sometimes HPV can linger and lead to cancer. Every year in the United States, approximately 39,000 men and women develop cancers caused by HPV. Cervical cancer is one of the most common cancers in women, killing about 300,000 every year worldwide.

Q. How do you get HPV? How can you avoid it?

A. HPV in the genital area is passed from one person to another through genital contact, most often, but not always, during sex. The best way to avoid HPV infection is to abstain from any sexual activity. You can also lower your chance of getting HPV by having sex with only one person who isn't infected with HPV. But most people who have HPV don't know they have it, so it can be hard to avoid. Although condoms are recommended as a way of decreasing sexually transmitted infections, they don't offer complete protection against HPV.

Q. Can't women avoid cervical cancer by getting routine Pap tests?

A. Not always. Once, cervical cancer was the most common cause of U.S. cancer deaths. The Pap test changed that. HPV infection causes changes in the cervix that can result in cancer. The Pap test is performed by scraping cells from the cervix and examining them to see whether they show changes consistent with the early development of cancer (called precancerous changes). If these changes are detected, the doctor can perform surgery on the affected areas before cancer develops. Typically, the length of time from infection with HPV to development of cervical cancer is decades. So, although most HPV infections occur in teenagers and young adults, cervical cancer is more common in women during their 40s and 50s.

The Pap test is one of the most effective cancer screening tests and has dramatically reduced the incidence of cervical cancer in the United States. But the test isn't entirely predictive of cancer, and not all women get tested as often as they should. Further, the Pap test will not detect cancer caused by HPV in areas other than the cervix.

Q. Is there a vaccine to prevent HPV?

A. Yes. Gardasil® 9, protects against nine types of HPV. Studies in thousands of girls and young women found the vaccine to be safe and effective in preventing persistent infections caused by HPV. Studies in boys and young men found that the HPV vaccine was safe and prevented anal and genital warts. The vaccine is given as a series of two or three shots depending on the age of the recipient. Those who are younger than 15 years old should get two doses separated by 6 to 12 months. Those 15 years and older or any recipient with a compromised immune system should get three doses. The second shot should be given one or two months after the first, and the third shot, six months after the first.

more ▸

For the latest information on all vaccines, visit our website at

vaccine.chop.edu

Q&A

VOLUME 7, WINTER 2016

Meningococcus: What you should know

The Children's Hospital of Philadelphia® | VACCINE EDUCATION CENTER

Meningococcus can be devastating — claiming a child's life in hours. Although infants less than 1 year of age are at the highest risk of getting this disease, adolescents and teens are most likely to die from it. One meningococcal vaccine that protects against four of the five types of meningococcus is recommended for all adolescents and teens and for some infants. A newer vaccine, specific for type B meningococcus, is recommended for some high-risk groups as well as for adolescents between 16 and 18 years of age.

Q. What is meningococcus?

A. Meningococcus is a bacterium. Meningococcal bacteria live on the lining of the nose and throat and are spread from one person to another by close personal contact. Occasionally, the bacterium enters the bloodstream and causes severe disease.

Five different types of meningococcal bacteria, classified on the basis of a complex sugar that coats the bacteria (called polysaccharide), cause virtually all meningococcal disease in the world. These five different types of meningococcal bacteria are called types A, B, C, Y and W-135.

Q. Is meningococcus dangerous?

A. Yes. Every year in the United States approximately 500 people are infected with meningococcus and as many as 50 die from the disease. Also, about one of every five survivors live the rest of their lives with permanent disabilities, such as seizures, loss of limbs, kidney disease, deafness and mental retardation. The highest incidence of meningococcal disease occurs in infants less than 1 year of age. In children between 2 and 10 years of age, the incidence of meningococcal infections is low, but starting in adolescence the incidence of disease rises. Although adolescents are less likely to be infected than infants, they are more likely to die when infected. Meningococcal bacteria are particularly dangerous because they rapidly make large quantities of a poison called endotoxin. Endotoxin damages blood vessels and causes low blood pressure and shock. For this reason, meningococcal bacteria can kill people soon after they enter the bloodstream. Children can be perfectly healthy one minute and dead four to six hours later; the disease can be so rapid and overwhelming that even appropriate, early medical care may not be sufficient. Because outbreaks occur in colleges, schools, childcare centers, army barracks and other areas where people have close contact, meningococcal infections often cause panic in the community.

Q. What are the symptoms of meningococcal infection?

A. Meningococcus infects the bloodstream (causing sepsis) as well as the lining of the brain and spinal cord (causing meningitis). Symptoms of sepsis include fever, chills, rash, low blood pressure and dark purple spots on the arms and legs. Symptoms of meningitis include fever, headache, confusion and stiff neck.

Q. Is there a vaccine to prevent meningococcus?

A. Yes. Two different vaccines are now available. The vaccine recommended for all adolescents between 11 and 12 years of age protects against four of the five different types of meningococcus (A, C, Y and W-135), but not meningococcus type B. The second vaccine protects against meningococcus type B, which accounts for two-thirds of all meningococcal disease in infants and one-third of cases in adolescents. This vaccine is currently recommended for high-risk groups, including those with complement deficiencies, no spleen or a spleen that does not function, lab personnel regularly exposed to the bacteria, and individuals or groups at risk during an outbreak, such as on a college campus. The vaccine has also been recommended for all adolescents between 16 and 18 years of age.

Q. How are the meningococcal vaccines made?

A. The meningococcal vaccine currently recommended for all 11- to 12-year-olds is made using the complex sugar (called polysaccharide) that resides on the surface of the bacteria. Polysaccharides are stripped from the surface of four of the five different types of meningococcal bacteria that cause disease (types A, C, Y and W-135) and each is linked (conjugated) to a harmless protein. The four conjugated polysaccharides are combined into a single shot and protect against four different types of meningococcal bacteria. High-risk infants can also get this version (Menactra®) or one of two similarly manufactured versions (Menveo®). Menveo, like Menactra, contains types A, C, Y and W-135.

The meningococcal serogroup B vaccines, Trumenba® and Bexsero®, contain two or four proteins, respectively, that reside on the surface of the bacteria.

more ▸

For the latest information on all vaccines, visit our website at

vaccine.chop.edu

Appendix B

Human Papillomavirus (HPV) Vaccination Survey

You have been asked to complete this survey today because you have chosen to have your child vaccinated against HPV. Your participation in this survey is voluntary and anonymous. No information obtained will be shared or included in the patient's medical record.

A few weeks ago, educational materials were mailed to your home containing information about the vaccines that are recommended by the CDC for adolescents. These materials were provided to inform you about frequently asked questions regarding these vaccines, and to help you to have the knowledge needed to make informed decisions about your child's medical care.

1. Did you receive the printed educational handout entitled *Human Papillomavirus: What you should know*?
    a. Yes
    b. No

    If you answered no, you may skip to the end of the survey.
2. Did you read the materials presented?
    a. Yes
    b. No

    If you answered no, you may skip to the end of the survey.

3. Which of the following statements best describes your feelings on the decision to have your child vaccinated against HPV today?

    a. I had some unanswered questions about the HPV vaccine prior to the appointment, and the provided educational material helped me make the decision to vaccinate.
    b. I had already decided to vaccinate my child according to the CDC guidelines, and I feel I would have done so even without having received the educational material.

Additional comments:_____

Thank you for your participation!

Appendix C

Chart review checklist for HPV vaccine Evidence Based Practice Project (EBPP)

Was the well exam completed between June 2nd and July 20th of 2016?

1. Yes
2. No (chart review complete, criteria not met)

Was the patient between 11 and 12 years of age at the time of the well exam?

1. Yes
2. No (chart review complete, criteria not met)

Did the patient receive the HPV vaccine at the well exam?

1. Yes
2. No

No identifying information will be included in the data collection. Data collection and evaluation will include only whether the eligible patients did or did not receive the HPV vaccine. The HPV vaccine is offered routinely at all well exams when patients are eligible, so no additional data will be collected.