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Walden University

College of Health Sciences

This is to certify that the doctoral study by

Tawa Ibikunle-Salami

has been found to be complete and satisfactory in all respects, and that any and all revisions required by the review committee have been made.

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Walden University 2015

Abstract

Educational Intervention to Impact Parental Decisions to Consent to Human Papillomavirus Vaccine

by

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MSN, Indiana Wesleyan University, 2010 BSN, Indiana Wesleyan University, 2005

Project Submitted in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Nursing Practice

Walden University

September 2015

Abstract

Human Papillomavirus (HPV) is a global health issue that is transmitted sexually and affects both genders. Evidence shows that approximately 79 million people are affected in the United States with 14 million newly affected yearly. The Centers for Disease Control and Prevention indicates that teens and young adults under age 25 are at particular risk, so it is important to begin the vaccination series between 9 and 17 years of age. Parental voluntary acceptance of HPV vaccine for their minor children was noted as a problem in a clinic in Northwest Indiana, and 8% clinic HPV series completion rate is significantly lower than the targeted federal goal of 80% by 2020. A literature review indicated that an educational intervention provided by healthcare professionals could serve as one of the strongest predictors of HPV vaccine acceptance. The purpose of this project was to develop an evidence-based parental educational process to support providers' influence on parents of children ages 9 to 17 to provide consent for the HPV vaccine. The project goals focused on parental knowledge, beliefs, and attitudes. The clinic providers will utilize assessment tools validated by experts and evidence-based educational materials to promote HPV and HPV vaccine awareness. The theoretical foundations of the project were the theory of reasoned action and Pathman's pipeline that target the parents directly through individual educational sessions to achieve knowledge gain and behavioral change. Implementation of educational materials by clinic providers may improve parental knowledge of HPV and the HPV vaccine acceptance. Social change may result from the integration of the project into clinical practice to increase the HPV vaccine acceptance rates, which will ultimately reduce the effects of HPV and its sequelae leading to long-term wellness promotion.

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Dedication

The proposed developmental project dedicated to parents who worried about their children's safety regarding the Human Papillomavirus vaccine. The willingness and cooperation to share their beliefs, cynicism, led to the development of this educational intervention, provided by the providers to enhance parents' knowledge of the HPV and the HPV vaccine was well appreciated. The parents' acceptance of the proposed educational intervention will lead to increase in the HPV vaccine administration at the studied clinic in Northwest Indiana.

Acknowledgments

My sincere appreciation goes to the faculty members of Walden University, Dr. Marisa Wilson, Dr. Murielle Beene, Dr. Jennie De Gagne, and Dr. Nancy Moss for your expertise, support, and necessary advice towards the completion of this project. Your team effort and leadership role will forever be remembered. My profound gratitude also goes to my preceptor Dr. Ellen Hennessy-Harstad despite her busy assignments, out of love for the nursing profession, creates time to see me through this project. To my colleagues in the program, thank you all for sharing your advanced practice knowledge with me throughout this journey. I wish you all the best in your future endeavors. All of you contributed immensely to make this project a success.

To my immediate family, especially my wonderful husband of 21 years (Dr. Ibikunle Salami) who encourages me at every step in the pursuance of my dreams over the last decade. My wonderful daughters (Mofoluwaso, Blessing, Oluwagbemisola, Wisdom, and Charity) who stood by me throughout the course of the program and assisted when needed; your unconditional love is well appreciated. I will forever be indebted to you all.

Finally, to God Almighty whose power and grace is above any human imagination; thank you God for your guidance, protection, wisdom and understanding from above, which sail me towards the completion of this project. I will always serve and live for you.

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Translation of Evidence Into Practice

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Rightsholder:

ISBN: Author/Editor: Publisher: 978-0-8261-0615-5 White, Kathleen Springer Publishing

Company

SPRINGER PUBLISHING COMPANY, INC.



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Pagination: 221 Country of publication: United States of America

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Section 1: Nature of the Project

Introduction

Human Papillomavirus (HPV) infection is the most common sexually transmitted infection in men and women in the United States. Approximately 79 million people are currently infected with HPV, with about 14 million people newly infected yearly in the United States (Centers for Disease Control [CDC], 2014). United States population-based studies conducted by the CDC demonstrated that 66% of cervical cancer, 55% of vaginal cancers, 79% of anal cancers, and 62% of oropharyngeal cancer attributed to HPV Types 16 or 18. Yearly, an estimated 26,000 new cancers attributed to HPV in which about 17,000 are diagnosed in women and 9,000 are diagnosed in men (CDC, 2014).

The CDC (2010) is committed to the vision of health for all by the year 2020. The CDC identified immunization and infectious disease control as their number 23 targeted objectives in ensuring population health by the year 2020 (healthypeople.gov, 2010). The information obtained from Children Hoosier Immunization Registry Program (CHIRP) showed that in the state of Indiana in 2014, only 7% completed HPV three-dose series in the state of Indiana, with only 8% completed the three-dose series in Children and Family Health Clinic (CFHC), and about 5% completion in the Lake County Indiana, where the above named clinic located (K. Cameron, personal communication, February, 5th, 2015). CHIRP is where individual clinics must document their vaccine record in the state of Indiana for uniformity and easy access by all providers due to different usage of electronic health record (EHR).

There was the need to advocate for HPV vaccination administration. A lack of HPV vaccine acceptance or uptake will most likely increase HPV infection prevalence. During most interactions in office visits with patient ages 9 to 17 years old, I observed that parents does not consent easily for HPV vaccination and some parents lacked knowledge of HPV infections and the available vaccines thereby affecting HPV vaccine acceptance and administration. The review of literature indicated the most common barriers to parental acceptance of HPV vaccine are cultural and religious beliefs, parental attitude, public health resources, and intervention.

Parental decisions not to consent to the HPV vaccine was due to a lack of knowledge, behavior, attitude, and their belief that their child or children are not sexually active and do not require HPV vaccination (Thomas, Strickland, DiClemente, Higgins, & Habber, 2012; Walhart, 2012). Other parents believed that their teen was too young to be sexually active or too young to have contacted a sexually transmitted infection (STI). Parents may have a low perceived risk of infection, concerns about vaccine safety, and concern about promoting sexual promiscuity by vaccinating their adolescent with HPV vaccine (Okoronkwo, Sieswerda, Cooper, Binette, & Todd, 2012).

Some providers do not promote HPV vaccination due to the burden of explaining the HPV vaccine relationship to HPV infection during an encounter with cynical parents who have negative perceptions of the vaccine (McCave, 2010). The provider may feel uncomfortable discussing sexual activity and HPV vaccine, particularly with parent of the preadolescents during a wellness clinic visit (McCave, 2010). Krawczyk et al. reported that educational interventions enhance parental HPV knowledge and vaccination

intentions thereby increasing HPV vaccination rates. Developing an evidence-based educational intervention for parents and patients will be a goal in achieving increasing rates of human papillomavirus vaccine uptake.

Problem Statement

The problem addressed in this study was the development of an educational intervention needed to increase the HPV vaccination rate among children age 9 to 17 years. Educational intervention provided by health care providers and professionals serves as one of the strongest predictors of HPV vaccine acceptance (Dunne et al., 2007; Krawczyk et al., 2012). According to the CDC Morbidity and Mortality weekly report in January 2014, there was a decline in acceptance of HPV vaccine from 2011 to 2012. This decline puts vaccine rates far below the Healthy People 2020 targets. The CDC also indicated that the coverage for adolescent girls with the first three-doses in 2012 shows wide variation from state to state, especially with the three-dose coverage of HPV vaccine for adolescent girls. In Mississippi, the coverage is as low as 12.1%, and in Rhode Island the coverage is as high as 57.7%. The coverage data revealed a concerning trend among adolescent girls that needs immediate public health interventions.

The above information serves as a call to action regarding the nonvoluntary acceptance of the parents at the CFHC during child wellness clinic visits in terms of HPV vaccine consent and was deemed a concern triggering the conduct of a needs assessment. The needs assessment was necessary to ensure that the intervention will meet the targeted population objective and goals of designing the program. The goal of conducting a needs assessment must be to identify health care needs (meaning gaps) of the identified

population, educational need as in this identified population health issue, and the resource needs of the targeted population to increase HPV vaccine uptake (Hodges & Videto, 2011). The federal goal is to vaccinate 80% of boys and girls against HPV by 2020 (McCabe, 2014). The rate of HPV vaccination completion for the three-dose series in children ages 9 to 17 are low in the state of Indiana in general as indicated in Table 1. At the CFHC, the coverage was very low compared to other vaccines as evidenced by nonvoluntary acceptance of the parent during child wellness visit. For Lake County Indiana, in which the CFHC clinic is located, the coverage was no different. Table 1 illustrates these facts. For the table below, the date of birth range was from January 1, 1997 to December 31, 2005. All information was obtained from CHIRP.

Table 1

HPV 3 Dose Series Completion Rates: 9-17 Years of Age

As of January 1, 2014 to As of July 1, 2014 to						
December 31, 2014				December 31, 2014		
Location	Total # of Patient Records	Patients receiving three doses	Series Completion Rate	Total # of Patient Records	Patients receiving three doses	Series Completion Rate
Indiana	747, 593	53, 319	7%	589, 973	40, 007	7%
Lake	46, 075	2, 471	5%	34, 951	1, 777	5%
Children and Family Health Clinic	220	18	8%	213	17	8%

K. Cameron, personal communication, February, 5th, 2015

The table showed there was a need for the student in charge of the program in collaboration with the CFHC providers' to develop an educational intervention to educate

the parents of the target population in order to increase their willingness to consent to HPV vaccine administration during a wellness clinic visit. The gap in knowledge needs to be fixed through an educational intervention to prevent the HPV infection and its sequelae among this age group, while at the same time increasing HPV vaccine acceptance, thereby promoting wellness. The proposed strategies for increasing adolescent HPV vaccine coverage rates in the United States, according to the CDC (2014) report are as follows:

- Ensure education of patients, parents and providers about the vaccine and the disease that it prevents.
- Provide a reduction in out of pocket cost for HPV vaccine for the patient
 with insurance since their other counterpart, who are Medicaid eligible
 obtains the vaccine at no cost under the Vaccines for Children program
 (VFC).
- Utilize alternative sites other than clinic settings to reach the target population such as schools.
- Targeting government programs that would add HPV vaccine as part of
 the school requirement considering HPV sequelae as in (genital warts,
 oropharyngeal, and cervical cancer), since school requirement has increase
 other vaccine coverage in the past as in (Tetanus, diphtheria, pertussis,
 Measles, Meningitis etc.).

To ensure that the project question, which was focused on an educational intervention to impact the decision of parents to have their children ages 9 to 17 years old

vaccinated against HPV, was properly addressed, a PICOT strategy was developed. The PICOT helps narrow the search for literature and to lay out the questions that inform the current practices while at the same time improving patient outcomes (Elkins, 2010). The proposed project problem to be addressed was outline in this PICOT question

- P: The population of interest was parents of children age 9 to 17 years old.
- I: The proposed intervention was parental education on HPV infection and available vaccines.
- C: The comparison group or current standard was pre and post education influence on HPV vaccination to see if the HPV three-dose series completion increases from 8% in 2014 post education program development and integration.
- O: The proposed desired outcome was that education would increase parental knowledge about HPV infections and thereby increase a vaccination acceptance.
- T: The proposed time intervals for the above project problem will be about three to four month period.

Purpose Statement

The purpose of the proposed quality improvement (QI) project was to develop an educational intervention to increase the uptake of the HPV vaccine at the CFHC located in Lake County Indiana. The collaborative team for the proposed project will provide a ready-made comprehensive HPV written pamphlet and educational plan in the form of a parental guide to HPV vaccination that will be available during the clinic visit (Appendix

The proposed recommendation also includes a one to one parental counseling or education session related to HPV and HPV vaccine during wellness child visit.

Goals and Objectives

The proposed educational intervention targeted the parents of children ages 9 to 17 years old in the CFHC in northwest Indiana. The goals and objectives of the educational intervention were to increase the acceptance of HPV vaccine in the clinic population based on an educational intervention strategy to impact parents' decision to have their children ages 9 to 17 given the HPV vaccine. According to CHIRP report of children in CFHC with birth date ranges from 01/01/1997 to 12/31/2005, out of 213-220 children, only 17-18 completed the HPV three dose series. This quality improvement project was developed to target the children at CFHC from the first dose to the three-doses completion during the wellness visit and via a subsequent telephone call to ensure adequate coverage, while at the same time attempting to reach the federal target goal of vaccinating 80% boys and girls in 2020 (McCabe, 2014).

Theoretical Foundation

Theory informs nursing practice. Theories clarify and define nursing practice through provision of goals for assessment and intervention while at the same time providing direction leading to the improvement in the client outcomes of care (McEwen & Wills, 2011). The theory appropriate to the population health issue was the theory of reasoned action (TRA), also known as the theory of planned behavior (TPB). The TRA was widely used both nationally and internationally and accepted by most groups as a

source of establishing changes in the parental beliefs, attitude, behavior, and the intentions leading to their behavioral performances (White & Dudley-Brown, 2012).

To appropriately complement the identified proposed developmental project, Pathman's pipeline model was used as an evidence-based model to reduce the gap in HPV vaccination issues. The model was developed by Pathman, a pediatrician, in collaboration with Konrad, Freed, Freeman, and Koch in 1996 to ensure patient compliance with the health provider recommendation for the vaccine (White & Dudley-Brown, 2012). The theory and model supported the need for an educational intervention for the parents' of children ages 9 to 17. TRA or TPB and Pathman's pipeline model explained in detail in Section 2.

Significance of the Project

The Institute of Medicine (2010) recommended nurses to be full partners with other health care professionals in redesigning health care in the United States. In doing so, nurses are encouraged to be the lead for change in health care related issues and policy decisions to bridge the gap and advance health systems thereby improving patient outcomes of care. The development of an educational intervention for the parents' of the identified population should lead to increased knowledge of HPV and HPV vaccine and thereby increased HPV vaccine acceptance. Parental knowledge increase will lead to a reduction in HPV infection and its sequelae. Increased parental knowledge will also promote health and well being among the targeted population in the long term.

Implication for Social Change

A DNP graduate is expected to apply the scholarship of application in a clinical setting. DNPs graduates are expected to appraise everyday practice and provide the intervention that improved the practice. According to the DNP Essential III, the scholar applies knowledge to solve the practice problems through scholarship of application via translation of evidence-based knowledge, integration and dissemination of new knowledge to the advance clinical practice (American Association of Critical-Care Nurses [AACN], 2006). The Americans Nurse Association (ANA) code of ethics for nursing Number 2 indicates that the nurses primary responsibility is to show the commitment to the patient, whether as an individual, family, group, or community in the promotion of health and wellness (Zaccagnini & White, 2011).

The development and integration of the proposed educational intervention project into the clinical practice will have a significant impact in the parents of the children aged 9 to 17 years old by improving or changing their beliefs and barriers against HPV and HPV vaccine. The successful development and integration of the project into the clinical practice will improve the acceptance of HPV vaccine thereby reducing the effects of HPV infection in those identified population age group. Since HPV affects people anywhere irrespective of their geographical location, the program, if successfully integrated into the clinical practice, may have the potential impact in other clinics locally within the state, nationally as well as globally

Definitions of Terms

Behavior: A specific behavior that should occur for the individual understanding of the needed action, for whom the action is to be performed, when and where applicable. According to the theory of reasoned action, individuals are rational and their behavior is link to their beliefs, attitudes, and their intentions. Based on the above, the individual must have a positive attitude towards the needed change, must be empowered and have control over the change and have the ability to perceive the change would promote positive influence within their social groups (White & Dudley-Brown, 2012).

Education: Parental education needed structure in such a way that would promote acceptance of the HPV vaccine and increase HPV vaccine rate. Sometimes, educational intervention culturally tailored to specific group of parents can promote understanding thereby promote health education and awareness. Novelas for television, radio, and print developed targeting Spanish-speaking communities with low level of literacy serves as a useful tools in increasing awareness of and interest in HPV vaccination among Hispanic parents (Kepka, Coronado, Rodriguez, & Thompson, 2011).

Human Papillomavirus: HPV are groups of over 150 related viruses. They are referred to as papillomaviruses since sometimes-certain types may progress to cause warts, or papillomas and mostly are benign (noncancerous) in nature. Other types of HPV are associated with specific types of cancer and they referred to as high-risk, oncogenic or carcinogenic HPVs. Out of over 150 types of HPV, over 40 types can passed directly from person-to person contact. The infection from the HPV viruses may go unnoticed and

other times may progress to specific types of cancer as in cervical, genital or oral cancers (cancer.gov. 2014).

Prevalence: The number of existing cases of a disease or health condition in a population at a designated time (Friis & Sellers, 2014, p.751).

Incidence/Incidence rate: This is considered a measure of the risk of a specified health-related event within a given period in a specified population. It is measure in terms of incident rate, looking at the number of the new cases, the population at risk and the period in which the cases or incident accrue (Friis & Sellers, 2015).

Immunization/Vaccination: The process by which all or part of a dead or weakened bacteria or virus in form of vaccine are been injected into the individuals to invoke an immunologic response (antibodies) that will fight against any microbes or infective organism. The effect mimics the natural infection with little or no risk to the recipient (Friis & Sellers, 2014). The need for preventative health care in the form of primary care is one of the main agenda of the Affordable Health Care Act (ACA). Evidence strongly shows that preventative services such as immunization can substantially improve health outcomes. The Advisory Committee on Immunization Practices (ACIP) of the CDC, identified 13 vaccines preventable diseases, for which the health benefits outweighs any associated risks for children or adults, or both (Bernstein, Chollet, & Peterson, 2010).

Assumptions and Limitations

Assumptions

Assumptions are beliefs about phenomena that one must accept to be the true. An assumption sometimes is based on accepted knowledge, beliefs, or values. An assumption may not be susceptible to testing; but philosophically argued (McEwen & Wills, 2011).

- An educational intervention should promote parental knowledge of HPV and HPV vaccine.
- 2. An educational intervention should increase the decision of the parent to have their children ages nine to seventeen years old vaccinated against human papilloma virus.
- 3. An educational intervention should increase HPV vaccine rate in the project clinic.
- 4. An educational intervention should be cost effective without putting an additional cost to the sponsoring clinic.

Limitations

Limitations are the lack of theoretical and methodological ability of a particular study that may decrease the generalizability of the particular study findings (Grove, Burns & Gray, 2012). The following are the limitations for the present study.

- 1. The educational intervention developed for the proposed QI project may not be generalizable in another clinic setting.
- 2. The development, implementation and evaluation for this proposed QI project may not be applicable in another clinic setting.

- 3. I am employed at the study clinic (CFHC) at the time of the proposed QI project. As a result, my NP leadership may influence the educational intervention of the project.
- 4. The lack of effective team participation from other clinic staff members and the providers including the clinic owner due to the clinic structure may limit the generalization of the project.
- 5. The effect of time constraint by the other clinic providers to provide necessary educational materials and guidance to the study group parents may affect the result of the study.
- 6. The lack of enough literature targeting males may have an effect in the generalization of the proposed QI project.

Summary

The Section 1 included a brief overview of HPV and parental influence on the acceptance of HPV vaccine. I provided a framework and research evidence that would guide the successful implementation of the developmental project. The successful implementation and the integration of the educational intervention project into the clinical practice could lead to the improvement in the acceptance of HPV vaccine, thereby reducing the effects of HPV infection in the identified population age group.

Section 2 was a review of the literature and the theoretical framework with the conceptual model that support an educational intervention leading to increase parents' decision to have their children ages 9 to 17 given the HPV vaccine. The first part of the Section 2 was a review of the specific and general literature informing HPV and HPV

vaccine. The section concluded with a theoretical framework from the context of the theory of reasoned action or theory of planned behavior and supported with Pathman's pipeline conceptual model.

Section 2: Review of Literature and Theoretical and Conceptual Framework

Introduction

The purpose of this quality improvement project was to develop and prepare a plan for implementation of an educational intervention that would have impact on the parents' decision to have their children ages 9 to 17 given the HPV vaccine. The review of the literature justifies the need for an educational intervention leading to increase the parents' decision to have their children given HPV vaccine. This section of the manuscript includes information on the synthesis of the scholarly literature related to HPV and the HPV vaccine. The section contains the information on the conceptual models and theoretical frameworks that guided the program development.

Literature Search Strategy

The search for evidence-based literature was conducted electronically using the following search engines or databases: CINAHL, Cochrane, Medline, ProQuest utilizing Walden University Library, as well as the CDC database from January to December, 2014. Articles published more than 10 years ago were discarded to ensure that current information was used to inform the project. The search results produced evidence that was reviewed and rated. When possible, more than one research article was used to supported each of the terms and recommendations. The specific terms used for the search were: *Human papillomavirus, papillomavirus vaccine, child in asterisk, parents*, and *education*.

Specific Literature

Human Papillomavirus

HPV is one of the sexually transmitted infections affecting both males and females. HPV is the most common sexually transmitted infection worldwide (Drewry, Garces-Palacio, & Scarinci, 2010; Palli, Mehta, & Aparasu, 2012; Walhart, 2012). Drewry et al. indicated that the HPV infection rate for sexually active women ranges from 20 to 80%. Prevalence figures showed about 6 million new infections yearly with at least 90% of cervical cancer diagnoses being associated with HPV infection. Palli et al. indicated that persistent exposure to the high-risk type of HPV increases the individual chances of developing cervical cancer. Palli et al. showed that HPV infection has been associated to other types of anogenital cancer, cervical cancer, and genital warts. The prevalence showed that about 20 million people in the United States are currently infected with HPV, with about 6.2 million within the age of 14 to 44 years affected annually.

Walhart (2012) noted that about 75% of people will be affected, diagnosed, or experience one of the many HPV strains during their sexual lifetime. Walhart indicated that although adolescents represent only 25% of sexually active population, they have a 50% higher prevalence of HPV exposure, which could be attributed to the combination of many factors as in sexual behavior, biological and cultural influences.

In the United States, HPV is the most commonly transmitted sexual infection (Cates, Ortiz, Shafer, Romocki, & Coyne-Beasley, 2012; CDC, 2014; Dunne et al., 2007; Gamble, Klosky, Parra, & Randolph, 2010; Oldach & Katz, 2012; Sussman et al., 2007;

Thomas, 2008; Yitalo, Lee, & Mehta, 2013). HPV prevalence in United States showed an estimated overall infection of about 20 million to 79 million. An estimated 6.2 to 14 million people aged 14 to 59 are newly or currently infected (CDC, 2014; Markowitz et al., 2014; Palli et al., 2012). A study of 32 counties of Ohio Appalachia departments of health also supported the HPV as a commonly transmitted infection in the United States (Oldach & Katz, 2012). An estimated prevalence rates of 42.5% for females aged 14-59 years. 53.1% for males aged 18-70 years who reported having sex only with females. About 53.8% among those aged 20-24 years (Markowitz et al., 2014; Oldach & Katz, 2012).

A woman in the State of Indiana loses her life every 3 days to cervical cancer on average. Cervical Cancer-Free Indiana (CCFIN) is a form of coalition that believes in providing educational information on the preventative services with available community resources help to prevent women from developing cervical cancer. CCFIN hopes to lower the rates of cervical cancer diagnosis by promoting awareness of HPV and its linkage to cervical cancer while at the same time increasing access to HPV vaccine (CCFIN, 2014). CCFIN in 2011 launched Cancer Education Network (CEW) program with the aim of providing face-to-face cervical cancer and HPV education prevention to the medically deprived patients in Marion County, Indiana clinic sites. Cervical cancer is 100% preventable; the purpose of this study was to provide the educational intervention that impact the parents' decision in acceptance to give HPV vaccine to the targeted population age group study.

HPV is more prevalent among other ethnic groups (African-American and Hispanic) as well is the higher incidence of cervical cancer (CDC, 2014; Thomas, 2008; Yitalo et al., 2013). Based on the aforementioned, the Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination with HPV4 or HPV2 for females and males aged 11-12 years. The committee also recommends vaccination for females age 13 to 26 years and males 13 to 21 years of age who are not yet immunized against HPV (Markowitz et al., 2014).

Vaccine

Approval of HPV vaccine for use in both females and males ages 9 to 26 and 9 to 21 in 2006 and 2009 respectively was one of the public health breakthroughs in the history of health prevention. The first HPV vaccine (Gardasil) approved in June 2006 for people ages 9 to 26 years proved to be effective against HPV infection and its sequelae - cervical cancer/genital warts (Sussman et al., 2007). Despite all of the above evidence, parents are resistant to consent for HPV vaccine administration for their child or children. Parental concerns to freely consent to HPV vaccine was due to lack of knowledge, as well as their belief that their child/children are not sexually active and do not require vaccination.

Presently, HPV infection prevalence increases yearly, mostly in the United States. The increase is due to sexual activity preferences and parents' being not well informed about the HPV vaccine availability and its effectiveness against cervical, oral, and anal cancer, as well as genital warts. In the U. S., Gardasil, produced by MERCK and approved by the Food and Drug Administration (FDA) in 2006, offered protection

Gardasil nine packs that will provide more HPV and cancer protection. Gardasil nine packs covers the first four HPV strain covered presently as well as HPV Types 31, 33, 45, 52, and 58. Gardasil used by females aged 9 to 26 years and males aged 9 to 15 years. Maximum protection provided HPV vaccine given prior the individual becoming infected with the HPV types covered by the vaccine.

Gardasil nine packs followed the same protocol of administration period as in Gardasil (quadrivalent) vaccine type (Lowes, 2014). Health care providers have not done a good job of encouraging and educating parents on present HPV vaccine; however, the new vaccine approval released on December 10, 2014 offered a more preventative measure. According to Lowes (2014), the vaccination was a critical public health measure "stated Midthun." The vaccine helps to lower the risk of most cervical, genital, and anal cancer caused by HPV. The lack of HPV vaccine acceptance or uptake most likely increase HPV infection prevalence. The need for change indicated by the federal government goal planning to vaccinate 80% of boys and girls against HPV by the year 2020. The federal goal is far higher than 38% girls and 14% boys who completed the three doses of HPV vaccine in 2013, as reported by National Immunization Survey data (McCabe, 2014).

Education

Educating parents on the importance of vaccination has become increasingly difficult in recent years due to antivaccine literature and negative media coverage. Parental inability to freely consent to HPV vaccine has been attributed to lack of knowledge and cynicism that their child or children are not sexually active and do not require HPV vaccination. Multiple researchers showed that parents' lack of knowledge of HPV and HPV vaccine affects the rate of acceptance of HPV vaccine for their children ages 9 to 17 years. Research evidence has also demonstrated that an educational intervention increases the uptake of the HPV vaccine among the target population.

Educational interventions for parents and patients (booklets and videos) have increased the HPV vaccination rates for children and adolescents (Fernandez, Allen, Mistry, & Kahn, 2010; Reiter, Stubbs, Panozzo, Whitesell, & Brewer, 2011; Krawczyk et al., 2012; Mayne et al., 2012; Wetzel et al., 2007). According to Krawczyk et al. there was a comprehensive HPV educational protocol information booklet containing a script for the clinicians available and a booklet for patients and their parents containing pictures, diagrams, and phrases. Mentioned in the booklet was the policy to increase educational efforts of the HPV vaccines acceptance as prerequisite for school entrance and immigration (Fernandez et al., 2010). The pre and post education PowerPoint presentation on HPV and HPV vaccine for school and healthcare staff serve as other identified best education practices (Reiter et al., 2011).

The clinicians' educational focus in the form of immunization alerts, education, and feedback built into electronic medical record (EMR) of the health information

technology (HIT) used in the primary care was another best practice approach that target clinicians and lead to increase in HPV vaccination. The utilization of the Radionovela, which was a sort of short stories in Spanish language for television, radio, and print developed through involvement of Latino community, to increase awareness of HPV and HPV vaccine. These short stories formed health promotion messages that targeted the Spanish-speaking community with low level of literacy (Kepka, Coronado, Rodriguez, &Thompson, 2011). Mayne et al. (2012) identified family focus educational interventions in which telephone reminder and voice messages utilized. Mayne et al. advocated direction to educational content inform of online educational materials or reminder to utilize pamphlet on HPV and HPV vaccines provided on clinic visit to serve as a guide in increasing HPV vaccination.

Researchers have supported educational intervention regarding HPV acceptance thereby increase HPV vaccine uptakes are (CDC, 2014; Gonik, 2006; Kennedy, Sapsis, Stokley, Curtis, & Gust, 2011; Okoronkwo et al., 2012; Spleen, Klushman, Clark, Dignan, & Lengerich, 2012). There are many ways to provide the educational materials to the parents of studied population. The clinicians or health care providers should provide the necessary educational information related to HPV and HPV vaccine on an individual basis. The individualized education tailored according to the parent's background, age, and educational level in order to yield needed intention of increasing HPV vaccine knowledge and HPV vaccine acceptance (Gonik, 2006).

There was also a need for the strategies to increase the adolescent HPV vaccine coverage rate in the United States through the educational intervention provided for

patients and parents of the aforementioned age group population. Providers should also be encouraged to educate the parents of the population study group and make a strong recommendation during wellness visit. The most significant predictor of the HPV vaccine acceptance in clinical setting was through providers' recommendation since parents trust their providers (CDC, 2014). All of these approaches are for the purpose of increasing HPV vaccination rate among the young adolescent. Spleen et al. utilized community-based educational intervention to educate parents in Appalachian Pennsylvania in an effort to increase parental intent to vaccinate their daughters against HPV.

The Appalachian community had a high incidence of cervical cancer and a high mortality rate. Okoronkwo et al. suggested a sustained educational campaign prior to the fall school start in Thunder-Bay, Canada. This campaign will offer a beneficial approach to increase the parental knowledge of HPV and HPV vaccine. Okoronkwo et al. believed that parental education supplied by a provider (physician) might also lead to an increasing number of parents to consent for their daughters for vaccination against HPV. Kennedy et al. adopted the CDC educational flyer targeted to the parents of adolescent girls and noted the increase in HPV vaccine knowledge and attitudes. The aforementioned also improve parental acceptance of HPV vaccine for their daughters.

In regards to different educational approach based on different research studies, the most appropriate and less cost effective educational intervention was one-to-one individualized education based on the parental knowledge and behavior towards HPV and HPV vaccine. I repurposed the Kennedy et al. approach by utilizing an existing HPV pamphlet from the Patient Point fliers, from the Indiana government site and from CDC

site. There was no need to recreate the educational materials considering the time limit for the project. Apart from specific literature reviewed that targeted HPV and HPV vaccine and education, there was general that offers other information, such as the cause-effect to HPV infection and HPV-related cancers.

General Literature

Researchers have addressed HPV ranging from various forms of cancers, such as cervical, anogenital cancer, and oropharyngeal, to genital warts and cancers (Dunne et al., 2007). Epidemiology helped to uncover the relationship between HPV and cervical cancer. The first vaccine (Gardasil) was approved by the FDA on June 8, 2006 to prevent the four types of cervical cancer caused by an exposure to HPV. It was approved to be used in females aged 9 to 26 years (Friis & Sellers, 2014).

HPV is the most common causative organism for cervical cancer worldwide. Cervical cancer is the third most common cancer in women in the world (Lee et al., 2013; Scarin et al., 2010). Cervical cancer was first in under-developed countries and third in United States following skin and breast cancer (Lee et al., 2013; Scarin et al., 2010). Lee et al. indicated that a healthy vaginal microbiota consists of lactic-acid producing bacteria known as Lactobacillus found in the vaginal epithelium. Lactobacillus is a normal flora that helps to maintain the low PH level of the vaginal wall. It helps to prevent the vaginal wall from being susceptible to the urogenital diseases. If there is any abnormality in microbiota, such as in the case of bacterial vaginosis (BV) thus leading to the increase in health risk of the upper genital tract, other health issues are miscarriages, recurrent abortion, preterm delivery, HPV infection, and other sexually transmitted disease

including HIV. However, normal host biochemical and immunological response to the microbiota is a healthy indicator of the vaginal environment that plays a protective role in women's health (Lee et al., 2013).

Cervical cancer has an increased burden in under developed countries as in Africa, Southeast Asia, Central, and South America. In United States, approximately 6.2 million cases are documented annually. Out of these cases, 11,070 led to invasive cervical cancer. About 3870 death related cases reported annually (CDC, 2008; Hezog, Vallerie, Smith, & Wright, 2008; Scarinci et al., 2010). Oncogenic type of HPV affects quality of life, with significant financial implication (Herzog et al., 2008). There are notable quality of life changes in relation to the psychosocial effect of HPV infection such as in different emotional and mental health. Such responses include but are not limited to depression, anxiety, anger, and relationship issues. Men also exhibit a higher level of stigma (Herzoget et al., 2008; Sandfort & Pleasant, 2009; Royer & Falk, 2012). Henderson et al. (2011) proposed that the provision of accurate and relevant information of the level of the protection HPV vaccine offers was very important in prevention of the HPV infection. Further education offered to the vaccinated girls to values the importance of cervical screening for additional protection against cervical cancer.

According to Kevin (2006), the annual cost for cervical screening and HPV-related cancer was about \$26,415 per 1000 women. Two thirds of that \$16,746 was attributed to routine screening. Each genital warts case has an average total cost of \$436, with the total office visit average being three times with an annual cost of \$1692 per 1000 persons. About five cases per 1000 patients per year in men age 25 to 29 years cost of

\$1717 (Kevin, 2006). Based on the analysis, an effective budget that would target recent and future care of the identified population is of paramount importance. The social agency (CFHC) resources forecasted the need for periodic review to provide better outcome of care that meet the need of identified population health. Herzog et al. showed that in the United States, the direct cost for cervical precancerous conditions in 2001 was about \$3.6 billion, with an estimated annual cost in HPV related conditions between 2.3 billion to 4.5 billion. The cost was even more significant in the developing countries due to the high incidence rate of cervical cancer.

Improving vaccination coverage would be an important strategy to reduce the burden of cancer and diseases caused by HPV. Health education to improve the knowledge of HPV and HPV vaccines among parents and adolescent patients will increase the HPV vaccination acceptance rate. Individualized education intervention reduced the HPV prevalence and improve the HPV vaccine adoption (CDC, 2014; Herzog et al., 2008; Markowitz et al., 2014; Royer et al., 2012; Sandfort et al., 2009). A strong recommendation by the health care provider during a clinic visit notably increased HPV vaccine adoption since patients trust their providers (CDC, 2014).

Conceptual Models/Theoretical Frameworks

The health issue of concern for the QI project was HPV infection and HPV vaccination within the targeted population being 9 to 17 years old. I provided the guided information that addressed the barriers to parental acceptance of HPV and the impact of the educational intervention through the application of theoretical frameworks and model. The theory appropriate for the study population health issue was TRA also known as TPB. The TRA or TPB assumes that individuals are rational and they must have a positive attitude toward change. The individual must have the feeling of control towards the change and that the changes are perceived as positive by their social group. The theory was widely used both nationally and internationally. Most groups accept it as a source of establishing changes in the parental beliefs, attitude, behavior, and the intentions leading to their behavioral performances (White & Dudley-Brown, 2012).

The TRA or TPB came about in the late 1960s by Ajzen and Fishbein. The theory was used to explain the relationship among beliefs, attitudes, intentions, and behavior.

Based on the theory, a person's behavior is manifested as a result of their intention.

According to social psychologist, intention is the cognitive representation of an individual's readiness to perform a certain behavior (McEwen & Wills, 2011). The same are determined by the items below:

 The attitude toward the behavior, which is in the form of salient belief either positive and or negative, thus leads to cumulative individual behavioral pattern.

- 2. Subjective norm or normative beliefs, which mostly seen as a social and peer pressure. The kind of behavior projected to meet the other people expectation of an individual behavior in an attempt to comply with the wishes of the significant others.
- 3. Perceived behavioral control is the perceived power of factors that may accelerate or impede the behavior.

Overall, individual beliefs and intention affect their behavioral pattern. TRA or TPB typically utilized in nursing in the area of health promotion as in HPV population health problem. The theory can be used to educate parents to make them aware of HPV infection and its sequelae such as cervical cancer or genital warts. It can also be used to identify the need for the educational interventions that will lead to positive behavioral change and promote HPV vaccine acceptance (McEwen & Wills, 2011). The theory could be used to assess parental beliefs and intention to vaccinate their loved ones' against HPV vaccine during undertaking of this project.

Askelson et al. (2011) used TPB as a framework for their study because this framework helps to predict people intention to perform or engage in a specific behavior. The purpose of their study was to evaluate the physician/provider intention to discuss HPV vaccine since physician supported the vaccine due to its approval by professional organizations particularly ACIP and CDC. The providers that have the positive attitude, perceived willingness, and behavioral control towards HPV vaccine are more freely to have the greater intention to discuss with 9 to 15 years old females about sex in relation to HPV vaccination. Attitude, subjective norms, and perceived behavioral control

reported by Askelson et al. as important predictors of provider intention to discuss sexrelated topic to 9 to 15 years old female patients during vaccination against HPV. It was noted that HPV vaccine does provide an opportunity for the provider to discuss sexrelated issue to young female patients. In the past, providers have found it difficult to discuss sex-related issues with their young female's patients. Recently, the need for HPV vaccination have improved the provider intent to talk about sex after administering the HPV vaccine (Askelson et al., 2011).

Juraskova et al. (2012) did a meta-analysis of 161 studies utilizing TPB indicates attitudes, subjective norms, and perceived behavior control (PBC) accounted for 39% differences in intentions. With about 25% differences in the behavior, PBC shows the predictability of behavior alone over intention is about 2%. The purpose of the study was to explore the impact of the educational intervention in increasing vaccination intention/behavior. The TPB demonstrated efficacy application to the study by highlighting the importance of moral norms in the individual behavior such as in relation to the HPV vaccine acceptance.

Roberto, Krieger, Katz, Goei, and Jain (2011) investigated the ability of TPB or TRA in predicting whether or not providers encouraging parents of the adolescent children allowed them to vaccinate against HPV. Adopted theory showed that attitudes and norms should be a target while dealing with the HPV topic and related population audience. Roberto et al. indicated that developing theory-based intervention using TRA or TPB should be excellent in facilitating providers to encourage the adolescents' parents to vaccinate their daughters against HPV.

Walhart (2012) in a study of the parents, adolescent children, and the HPV vaccine used TPB and concluded that it is a common theoretical framework used in exploring parental beliefs about HPV vaccine. Walhart used a randomized nationwide population-based survey of 13946 parents (11187 are girl's parents with 2759 of boy's parents) in an attempt to investigate gender differences in relation to parental intention to vaccinate their adolescents' with HPV vaccine. Walhart showed that about 70% of boys' parents thought it was a good idea to vaccinate the girls while only 54% of girls' parents thought it was necessary to immunize the boys. The result of the study was a proven source that could influence parental behavior in vaccinating their adolescent with HPV vaccine as a form of peer group pressure intervention.

The TRA assumes individual are rational and connect the individual's behavior to their beliefs, attitude and intentions, see below definitions and how it is linked in Figure 1 in explaining its adaptive usage for the proposed HPV project. Behavior-a specific behavior that need to occur for individual to understand the need for action, for whom the action was directed to, when and where. Intention-is the best predictor that a behavior will occur which is influenced by attitude and norms. Attitude-the individual is positive or negative feelings in the process of performing the behavior. Norms-the individual's perception of other's opinion in relation to the behavior (White & Dudley-Brown, 2012).

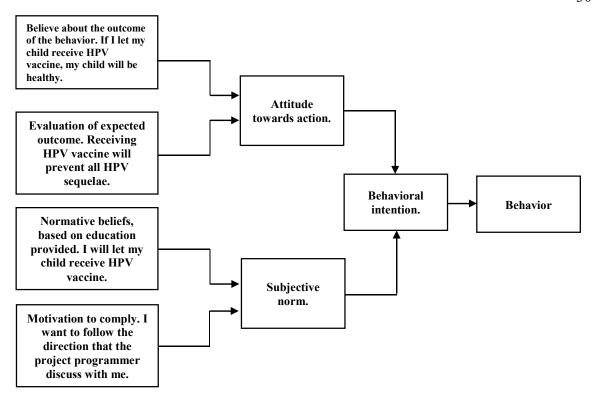


Figure 1. Theory of Reasoned Action. From White, K. M. and Dudley-Brown, S. (2012). Translation of Evidence Into Practice. Reproduced with permission of Springer Publishing Company in the format Thesis/Dissertation via Copyright Clearance Center.

Pathman's Pipeline Model

I used information on the Pathman's pipeline model as an evidence-based model to reduce the gap in HPV vaccine knowledge. Pathman, a pediatrician, in collaboration with Konrad, Freed, Freeman, and Koch in 1996, developed the model. They studied vaccine compliance and designed a multistage model for moving the evidence into practice while making sure the model support identification of factors that prevent utilization and adherence to the vaccination. The model composed of seven stages that involve evidence to action: awareness, acceptance, applicable, able, act on or adopt, agree, and adhere. Those facets are mostly what providers face when trying to help parents understand and accept the HPV vaccine. Incorporating the Pathman's pipeline model with TRA or TPB assisted in recognizing health promotion strategies as a provider and project planner, while at the same time addressing parental issues related to the HPV vaccine acceptance.

This ensured the right path to the identified population optimal health outcomes, as well as moving from evidence to practice (White & Dudley-Brown, 2012). Both the theoretical framework and model have showed different utilization and effectiveness in addressing HPV health population issue in the identified population from the past research studies. Although Pathman's pipeline model have not been effectively used in many research studies, barriers to new knowledge development and implementation can occur at any stage of the seven steps in the process. For the purpose of this developmental project, I focused on four out of the seven facets in the process: acceptance, awareness, adhere, and agree. The application of the stages by the project development team ensure

that parents receive the necessary educational support that leading to an awareness of HPV infection and available HPV vaccine. Also, encouraging the parents to agree to the provided information, facilitate the acceptance of HPV vaccine, and encourage adhering to the process involved in completing the three doses that offered the protection for the identified population against HPV. In this proposed developmental project, I may be among the first to use Pathman's pipeline model in addressing the impact of an educational intervention on parents' decision to have their children ages 9 to 17 given the HPV vaccine.

Awareness Different research articles related Acceptance to HPV and HPV vaccine. This will enable the provision of the Parental awareness and appropriate information to the knowledge improvement related to HPV and HPV vaccine parents. through educational intervention Adhere Provide different educational information in the form of pamphlets and flyers to inform parents of Agree HPV and HPV vaccine. Parents based on educational knowledge provided consent to give their children HPV

Figure 2. Pathman's Pipeline Model. From White, K. M. and Dudley-Brown, S. (2012).Translation of Evidence Into Practice. Reproduced with permission of SpringerPublishing Company in the format Thesis/Dissertation via Copyright Clearance Center.

Summary

Section 2 focused on reviewed of different scholarly research articles. The specific literature review that informed the project through details explanation of HPV, HPV vaccine, and different educational interventions used in the past. The general literature review will have impact on the general aspect of the project such as the effect of HPV as in cervical cancers, oropharyngeal cancers, and cancers, and genital warts. Despite different research articles on HPV and HPV vaccine, there still existing significant gap in literature that targeted by a unified educational intervention. Consistent and unified educational intervention thus adequately impacted parental decisions to have their children ages 9 to 17 given the HPV vaccine.

Section 3 was a description of the approach to the proposed QI initiative to develop an educational intervention that increased the parental decision to have their children vaccinated against HPV at CFHC. The section also covered the details regarding the project development including review of already available educative materials with the clinic providers, the targeted population identification, Institutional Review Board approval and the plans for implementation and evaluation.

Section 3: Methodology

Introduction

The purpose of this proposed QI project was to develop an educational intervention and implementation plan utilizing existing information from the CDC, vaccinate Indiana government sites and Patient Point (PP). The implementation and evaluation plan developed with the organization mission and values in mind by the collaborative team. This section was an outline of the strategies used in the project development and a description of the process in which the planned educational intervention implemented and evaluated. Figure 3 was the Gantt chart timetable.

- 1. Put together collaborative project team of the clinic providers
- Discuss with the team the relevant evidence and literatures that support the proposed developmental project
- 3. Review with the team the already existing educational intervention that informed the project
- 4. Obtain validation using experts in the filed for the proposed project questions in the form of parental assessment tools
- 5. Develop an evaluation plan

Tools Nows	Q3		Q4		Q1			Q2					
ask Name		Aug		Oct		Dec		Feb	Mar	Apr	May		
Fall-2014						59							
Project Plan					49								
IRB Approval													3
Meeting with Clinic Stakeholders on a Regular Basis							1						238
Review of the Proposal Project Plan									30				
Overview of the Project Development and Implementation Plan											30		
Complete Evaluation Plan										11			
Submit Project to Walden													. 7

Figure 3. Gantt chart with Project timeline.

Interdisciplinary Project Team

TRA or TPB as the framework and Pathman's pipeline model in addressing the plan project question. This social psychology theory could be used during this proposed project development to change unhealthy behavior to healthy behavior (McEwen & Wills, 2011). The team members who are mainly the clinic providers will also utilized the educational intervention proposed for the project planned through printed educational material (pamphlet and flyer) as indicated in Appendix C. Face-to-face interaction and education in relation to HPV and HPV vaccine and answering patient questions and concerns during the clinic visit of the studied population will serve as another mode of delivering planned education to the parents.

TRA or TPB could also be used to address the parents of studied population directly in one to one counseling or educational section. TRA or TPB used during the proposed project development will ensure the promotion of healthy behavior. The theory could be used to promote the people awareness of health problems with the proposal of positive behavioral change (McEwen & Wills, 2011). The theory was used in the majority of nursing research studies, most importantly in the provision of an educational

intervention that informed HPV and HPV vaccine as mentioned in section two of the project. This would be accomplished with the use of validated questionnaire in the form of parental assessment tools in Appendix B.

Pathman's pipeline model would help to identify factors that promote adherence and utilize on individual basis during one to one parental discussion for the proposed project. The model will be used during the proposed project to observe the leak in parental knowledge or barriers to the implementation of new knowledge and how to breakdown those barriers (White & Dudley-Brown, 2013). The model will help to provide the strategies needed during the proposed plan implementation of the educational intervention that would ensure sustainability of the project.

Review Evidence

Researchers of HPV in the past have mostly used the cross-sectional study for the design of their population study. For the purpose of this QI project, there would be a variety of activities involved in order to ensure the educational intervention strategies would target the identified population. In the guidance for health economics study presented to Advisory Committee on Immunization Practices (ACIP), different methods employed to ensure the intervention strategies are identified and described with a baseline included. The cost values and resources are incorporated into the program, with both direct and indirect medical and nonmedical cost of immunization in reasonable perspective were presented to the ACIP by the programmer. The economic model used cost-benefit, cost-effectiveness, and cost analysis that covered all the diverse vaccine-related issues to enable ACIP to understand the purpose of the program (Lieu, Meltzer, &

Messonnier, 2007). The committee ensures that the cost effectiveness of the vaccine was directly proportional to the outcome effect of the vaccine prior to the presentation to ACIP. The proposed developmental project will utilize the rational planning model similar to the above model used by Lieu et al. The rational planning model tied the resources to the program goals and objectives. It also utilizes available data in the decision-making process to ensure the successful outcome of the program (Kettner, Moroney, & Martin, 2013).

Population and Sampling

The proposed sample characteristics for the QI project are parents of 9 to 17 year old children who are yet to complete or initiated the three series of HPV vaccine at CFHC. The sample populations will include all ethnic groups that meet the age criteria and attend CFHC for their wellness visit. The CFHC policy was not to immunize children when they are running fever or on antibiotics and the proposed project would follow the same protocol.

Ethical Considerations

The ethical consideration involves in the proposed QI project followed by submitting all the necessary paperwork to obtain approval from Walden University Institutional Review Board (IRB) prior to developing an Educational Intervention to Impact on Parents' Decision to have their Children ages 9 to 17 given the HPV vaccine. Permission to use all diagrams as in TRA or TPB and Pathman's pipeline model, and PP requested and included in the proposed project plan.

Develop Implementation Plan

The development of the implementation plan will transpire with the project team leader in communication with the collaborative team members.

- Baseline data for this QI project will be collected to determine the pre acceptance rate of HPV vaccination among the parents' of the studied population.
- Due to the cost of treating the HPV related conditions, the financial implications of the project need consideration during the proposed project development.
- 3. No separate budgeting available for the proposed project since no new wheel created regarding the educational materials.
- 4. The proposed QI project was a cost effective project and uses available resources and activities to improve the existing service while promoting parental better understanding of HPV and HPV vaccine.

The proposed project had all the necessary resources within the clinic system. There are easy printing access of the flyers, the pamphlet from PP, CDC site, and vaccinate Indiana government site with no additional cost to the clinic. When parents accept to vaccinate their children for HPV vaccine based on knowledge improvement, the vaccine was readily available through Vaccine for Children Program (VFC). Majority of the children seen at the CFHC covered under the above program due to their Medicaid insurance coverage.

Develop Evaluation Plan

Program evaluation was the most important of the program and must be a continuous or ongoing process. The evaluation activities and the derived information must be significant and useful to the program planner, the clinic staff, and the targeted population studied (Hodges & Videto, 2011). The evaluation helps the collaborative team to revisit the project strategies effectively for better program outcome. The initial plan would be meeting with the collaborative team member such as the clinic owner, manager, health care providers, the parents of the identified population, and other clinic supporting staff members. It will be an ongoing process throughout the proposed plan program evaluation, in ensuring everyone is well informed and that the program is leaning towards meeting its goal and objectives.

The collaborative team have the options of utilizing the validated questionnaire to the parents' of the proposed studied population in the form of parental assessment tools (Appendix C). The patient and the public want to involve in their health care and treatment decisions (McKennah, Keeney, & Hasson, 2009). Additional plan proposed educational intervetion inform of face-to-face discussion and distribution of free pamphlet from PP, flyers copied from vaccinate Indiana government sites and the CDC. The educational materials will inform parents' of HPV and HPV vaccine, for the purpose of targeting their behavior and improving their knowledge.

There are four stages of evaluation: formative, process, impact, and outcome evaluation (Friis & Sellers, 2014). Formative evaluation is a type of evaluation adopted early in the program as soon as the program conceived. It helps to ensure all forms of

activities, materials, procedures, plans, and modifications during the implementation of the program work. Process evaluation involves describing, monitoring, and documenting the organization and program-related issues in order for the program planner to improve effectively, the proposed program and provide support for the program. It will also ensure theories and model applied in accordance to the goal and objectives of the proposed program.

Process evaluation allows for charting progress review in ensuring meeting the goals and objectives of the proposed developmental plan program. Resource evaluation was conducted, which includes budget review and assessment of training provided to the staff. Investigating the process in place to ensure time allotted to implement and conduct the program activities were sufficient was also a necessary part of the proposed project evaluation (Hodges & Videto, 2011). The purpose of the outcome evaluation was to measure how well the program meets its intended long-term goal. The proposed plan evaluation will also measures the impact of the program on health status changes or quality of life improvement.

The proposed quality improvement project will use impact evaluation. Impact evaluation determines changes in program participants instead of the organizations or the communities. Impact evaluation seeks to answer the program plan design questions. The purpose of impact evaluation was attempting to see if the program has an impact and provide a positive outcomes or program results. The proposed plan impact evaluation also aims to establish a cause and effect relationship between a program and its outcome (Hodges & Videto, 2011). The proposed plan impact evaluation will be used to examine

the improvement in behavior, environment, predisposing, reinforcement, and enabling factors based on goals and objective of the developmental program (Hodges & Videto, 2011).

Overview or final evaluation of the proposed plan project development will help to provide the information on what works and what did not work during the plan project implementation. I proposed utilization of cause and effect impact of education to the collaborative team during the proposed project development phase which measure based on looking at the pre HPVvaccination rate prior education intervention and post effect of education on the HPV vaccination rate. The proposed project will also compare the pre and post impact of educational intervention on parents' decision to have their children ages 9 to 17 given human papillomavirus vaccine results that will be shared with the social agent stakeholders.

Table 2

Impact Program Evaluation

Successful	Program Question	Program Design →	Desired Result
Program→	\rightarrow		
(Theory)	(Cause)	(Intervention)	(Effect)
Theory of reasoned action. Application of Pathman's Pipeline model.	Impact of educational intervention on parents.	Self-appraised questionnaire. Flyer, chart review, and pamplets.	Increase parental knowledge of HPV and HPV vaccine. Parental knowledge leds to increase HPV vaccine rate.

Summary

The parental lack of knowledge, attitudes, and behavior towards HPV and HPV vaccine best addressed through a planned educational intervention. The proposed plan educational intervention will create the parental awareness of HPV and HPV vaccine. The proposed plan implementation of an educational intervention project would provide opportunity for the change in the clinical practice thereby, increase parents' decision to have their children ages 9 to 17 given human papillomavirus vaccine. The educational strategies for the proposed project would lead to increase acceptance of the HPV vaccine and promote wellness. This developmental project proposal has been reviewed and approved by the Walden University IRB with the approval number (07-08-15-0469221). Overall, Section 3 of the proposed QI project focused on how the project developed, how the proposed project implemented, and the data collection to allow for evaluation of the parental knowledge post educational intervention.

Section 4: Findings, Discussion, and Implications

Summary of Findings

The purpose and the main objective of this proposed QI project was to develop an educational intervention to increase the uptake of the HPV vaccine at the study clinic in Lake County Indiana. Since, this was a developmental project, it allows for dialogue within the collaborative team as to how the project could be fully implemented and evaluated in future utilizing already available resources within the organization as indicated in (Appendices C and D). This developmental project does not involved pilot study since HPV vaccine always made available to the patient but the acceptance rate was an issue that led to low uptake at the study clinic. In bridging the gap in practice, the discussion emerged with the collaborative team member involvement in designing parental education intervention that would improve the HPV vaccine acceptance rate. By following the guidelines stipulated in this developmental QI project, the study clinic will be able to implement the educational intervention as developed in meeting the Federal goal of vaccinating 80% of boys and girls against HPV by 2020 (McCabe, 2014).

Since the project was at the developmental stage, there were no study findings or corresponding supporting research literature to support further project discussions. This section was a further exploration of the development of an anticipated project strengths, limitations and recommendations. In addition, potential implication for policy, practice, research and social change also discussed by the collaborative team.

Discussion

This quality improvement project explored and document anticipated developmental project strength, limitations and recommendation as a guidance for the collaborative team. Program implementation could be daunting, even the best program if not structured to the audience does not always work. Since the major barrier to acceptance and uptake of the HPV vaccine was parental lack of education. It has been noted that sometimes, it is not the same group of people that plan and develop a program that implement them. For that same reason, the program must be tailored to the intending audience in order to meet the objective for adoption, implementation and sustainability (Hodges & Videto, 2011).

Policy Impact

As an advanced nurse practitioner, I believed the health care group cannot practice in isolation. Due to the rising cost of health care, there was a need for health care providers training to add a population orientation to their current role of caring for individuals in their various areas of practice (Bodenheimer & Grumbach, 2012). During this project development, I conducted a word format interview with the Director of Immunization in the State of Indiana. During the process, I was able to realize the low rate of acceptance of HPV vaccines in the State. Despite the global consensus on which vaccines generally offered benefits that outweigh the risk and strong cost-effectiveness, recommendation for specific vaccine usage and priority for targeted group for national immunization programs are still inconsistent across countries (Nieburg & McLaren, 2011). The proposed project development if implemented will be used to influence policy

and policy makers by providing well prepared information to the health care core players; familiarizing and utilizing core positions and networking; identify and team up with other nurses in influential position outside the nursing profession; and communicating one's standing on issues through appropriate strategies (Hewison, 2007). The primary goal of this developmental QI project was to follow the principle of risk-benefit analysis as part of health care decisions and recommendations in keeping the patient safe, while at the same time providing best outcome of care to the consumer of healthcare (Zaccagnini & White, 2011).

Clinical Practice

Bridging the gap in practice initiate the discussion within the team members that led to the development of this QI project in the form of an educational intervention to impact on parents decision to have their children ages 9 to 17 given the Human Papillomavirus Vaccine. Advanced knowledge by the nurse providers provides an array of opportunity for new knowledge and translation of the knowledge quickly and efficiently to the benefit of the patients in their daily demands practice environments (AACN, 2006). I have noted through different research studies that parental decisions not to consent to the HPV vaccine was due to a lack of knowledge, behavior, attitude, and their belief that their child or children are not sexually active and does not required HPV vaccination (Thomas, Strickland, DiClemente, Higgins, & Habber, 2012; Walhart, 2012). It was reported that educational interventions enhance parental HPV knowledge and vaccination intentions thereby increasing HPV vaccination rates (Krawczyk et al., 2012). Evidence showed the most significant predictor of the HPV vaccine acceptance in clinical

setting was through provider recommendation since parents trust their provider (CDC, 2014). Clinical practice would benefit from this developmental project if properly implemented utilizing available educational resources and developed project questions in the form of parental assessment tool thereby, leading to increasing rates of human papillomavirus vaccine uptake.

Research

Chang, Russell and Jones (2010) identified in their study, time as one of the barriers why nurses were unable to widely adopt evidence-based practice (EBP). However, clinician guided education promote parental HPV acceptance especially if it is individualized based on parental background, age, and educational level (Gonik, 2006). Despite various research evidence on parental educational intervention there was no direct assessment tool to inform the project. The expert validated developed project questions in the form of parental assessment tool during this QI project development, if well implemented may support future research studies by answering the following questions such as:

- Thus improving or changing parents of 9-17 years old involved in the study beliefs against HPV and HPV vaccine affect HPV vaccine uptake?
- Thus improve the acceptance of HPV vaccine thereby reducing the effects of HPV infection on the studied population such as (genital and anal warts, oral, cervical and anal cancer)?
- Would the successful program integration and implementation impact other clinics locally within the state, nationally as well as globally?

Social Change

Educational intervention improved parental barriers to acceptance of HPV vaccine thereby increase HPV vaccine uptake (CDC, 2014; Gonik, 2006; Kennedy, Sapsis, Stokley, Curtis, & Gust, 2011; Okoronkwo et al., 2012; Spleen, Klushman, Clark, Dignan, & Lengerich, 2012). It was discovered during the developmental project that most parent has barriers such as: lack of knowledge of HPV vaccine and beliefs that their children are too young to engage in sexual activities (Thomas et al., 2012; Walhart, 2012). According to Kotter, understanding change takes a long time thus improve chances of success. Sharing of the proposed educational intervention that would increase parental knowledge of HPV and HPV vaccine was the primary focus for this developmental project. Patients have entrusted their care in our hands; nurses should maintain the knowledge and integrity while partnership with other healthcare groups in ensuring safe, cost-effective, outcomes of care for the patients. Parents needed education in order to meet the goal of the federal government that is to vaccinate 80% of boys and girls against HPV vaccine in the United States by the year 2020 (McCabe, 2014).

Project Strengths, Limitations, and Recommendations

Project Strengths

The strength for this developmental project would be effective communication within the collaborative team. According to Covey (2003), whether someone is writing or providing information to others, all are forms of communication. Same are speaking and listening to what others have to say. We communicate almost every minute in our day-to-day activities. For effective project implementation and evaluation, the team members must be able to communicate and ready to work with one another's (teamwork) to ensure the success of the proposed developmental project. It was imperative as a collaborative team to communicate efficiently in order to disseminating new initiatives and innovations in clinical practice as well as research findings and other ideas in nursing to bridge the gap in practice (Oermann & Hays, 2011). Utilization of the proposed project questions in the form of parental assessment tool will serve as a guide to parental education to improve parental acceptance of HPV vaccine and increase HPV uptake

Project Limitations

Despite the fact that this proposed developmental project generate discussion in relation to an educational intervention that would promote parental acceptance of HPV vaccine, the main limitation of the project was that it has not been fully implemented. Presently, there is no opportunity for me, to statistically evaluate the outcomes of the educational intervention. I was limited in the terms of the literature targeting males during the time of the project development. Time allocated to the providers during patient wellness visit and stakeholders' involvement anticipated to be the barrier that may limit

the sustainability of the project. According to Miake-Lye et al. (2011), their evidenced-based project seemed feasible in the beginning and went through multiple changes, but unable to sustain the project due to lack of leadership involvement and staff commitment. I am employed at the study clinic at the time of the initiation of the proposed QI project. I developed the proposed project questions in the form of parental assessment tools (Appendix C) which was validated by the experts in the field. This could create bias and limit the tool validity and generalization of the study (Terry, 2012)

Limitation Recommendations

Since there was no pilot study, as the project developer, I was limited in this project recommendation. For the future evidence-based project implementation, will anticipate the barriers above at the inception of the project and incorporate needed strategies to ensure generalization of the proposed QI project.

Analysis of self

Scholar

The DNP program has provided me the opportunity to develop and evaluate healthcare delivery approaches that meet the current, future, and daily prospective needs of the patient populace in references to evidence-based research findings in nursing, other clinical sciences, organizational, political and economic sciences (AACN, 2006). The DNP journey has afforded me the opportunity in identifying practice gap and developed different evidence-based project through the practicum experiences incorporated into the program, leading into the enhancement of knowledge to improve nursing practice, and patient outcomes (Terry, 2012). In conjunction with various evidence-based research that support this developmental project, its approval facilitated my scholarship of practice in nursing (AACN, 2006). The scholarship of discovery through evidence-based research, integration and application of the discovered knowledge has helped me in this developmental project, which if implemented successfully would help to guide improvements in the clinical practice and patient outcome of care.

Practitioner

As an advanced practitioner, the DNP program has afforded me an array of opportunities in the following areas, such as: quality improvement strategies, collaborating with others in various practice management based on professional standard, political skills, and utilization of principles of economics and finance to redesign cost effective care without jeopardizing the provision of quality care (AACN, 2006). Healthcare delivery is currently at its fast pace, lack of effective education to parents of

ages 9-17 years in relation to HPV infection and available HPV vaccine will increase HPV infection rate and reduce HPV uptake thereby increase cost of healthcare. In the spirit of common good as justification for access to healthcare, effective implementation of the developed expert validated project questions in the form of parental assessment tool, I developed to provide an educational intervention to the parents' of the children ages 9 to 17 years would improve the uptake of HPV vaccine and reduce the cost of HPV sequelae.

Project Developer

This developmental project proposal has gone through a lot of scholarly review and recommendations. The process afforded me the opportunity to understand the process involved in designing and managing a program. As the project developer, the ability to identify the goals and objectives of the planned project with the thoughtful implementation and evaluation plan as in the impact evaluation for this project proposal would enhance the project successful implementation and sustainability (Kettner, Moroney, & Martin, 2013). Developing this proposal that received IRB approval involves collaborative team effort, effective communication strategies that is an attributes to possess by a successful project developer.

Project Contribution for Future Professional Development

The emergent of this developmental QI project has inversely contributed to my clinical knowledge, advancement in practice and professional development. The knowledge gained through the evidence-based research gave me the opportunity to developed intervention that would bridge the gap in clinical practice. Despite the fact that this proposal was in its developmental stage, effective utilization of the educational intervention materials and the expert validated proposed project questions in the form of parental assessment tool will assist the provider in gaining parental acceptance of HPV vaccine thereby increase HPV vaccine uptake.

Summary and Conclusions

The DNP developmental proposal as a form of QI project was to promulgate into the clinical setting a form of an educational intervention to impact on parents' decision to have their children ages 9 to 17 given the HPV vaccine. There are multiple evidence-based research efforts in favor of girls' within the studied population age group than the boys. The federal target goals is to immunize 80% of both boys and girls by the year 2020 in the U.S with the HPV vaccine (McCabe, 2014).

This developmental QI project addressed issues related to low acceptance of HPV vaccine and the educational intervention proposed to improve HPV acceptance and HPV vaccine uptake. It has been noted through different research studies that parental decisions not to consent to the HPV vaccine was due to lack of knowledge, behavior, attitude, and their belief that their child or children are not sexually active and do not require HPV vaccination (Thomas et al., 2012; Walhart, 2012). The anti-vaccine

campaign in the media that discourages most parents' to vaccinate their children against HPV vaccine. Due to the above reasons, this developmental project reviewed different available evidence-based resources to provide parental educational intervention that would improve acceptance and increase HPV vaccine uptake. An educational intervention improved parental barriers to acceptance of HPV vaccine thereby increase HPV vaccine uptake (CDC, 2014; Gonik, 2006; Kennedy et al., 2011; Okoronkwo et al., 2012; & Spleen et al., 2012). Research evidence shows that clinician guided education promote parental HPV acceptance especially if individualized based on parental background, age, and educational level (Gonik, 2006).

The developmental educational intervention will utilize the already existing educational resources as indicated in (Appendix D) in providing the necessary educational intervention to the parents of the studied population. The expert validated proposed project questions in form of parental assessment tool would be utilized by the providers in tailoring the individualized parental education. The subsequent or final chapter focused on the scholarly project product and dissemination.

Section 5: Scholarly Product

Introduction

The DNP developmental QI project was initiated to investigate and provide necessary information that led to the initiation of an educational intervention to impact on parents' decision to have their children ages 9 to 17 given the HPV vaccine through collaborative team effort. For this scholarly product to emerge, assessment was conducted that led to an evolution of a practice gap requiring planning that involves research evidence for practice through effective dissemination of identifiable evidence to improve healthcare outcomes (AACN, 2006). DNP prepared providers are expected to "translate knowledge quickly and effectively to benefit patients in the daily demands of practice environments", for this reason, impact program evaluation was incorporated into this developmental project from the inception of the project proposal (AACN, 2006, pp. 9). This section of the developmental QI project further examined the project background, recommendations for future project study, dissemination plan and publication aspirations of the researcher or the project developer.

Background

HPV is the most common sexually transmitted infection worldwide (Drewry, Garces-Palacio, & Scarinci, 2010; Palli, Mehta, & Aparasu, 2012; Walhart, 2012)

In the United States, HPV is the most commonly transmitted sexual infection with the overall infection prevalence showed that about 20-79 million people currently infected with HPV. About 6.2 million between the ages of 14 to 44 years are affected annually (Cates, Ortiz, Shafer, Romocki, & Coyne-Beasley, 2012; CDC, 2014; Dunne et al., 2007; Gamble, Klosky, Parra, & Randolph, 2010; Oldach & Katz, 2012; Sussman et al., 2007; Thomas, 2008; Yitalo, Lee, & Mehta, 2013).

Educational interventions have been a proven strategy demonstrated through different evidence-based research studies leading to improve parental acceptance of the HPV vaccine thereby increasing HPV vaccine uptake (CDC, 2014; Gonik, 2006; Kennedy et al., 2011; Okoronkwo et al., 2012; & Spleen et al., 2012). This developmental proposed QI project also utilized TRA or TPB to address the parents of studied population directly in one to one counseling or educational section. The theory utilized to promote the parental awareness of health problems with the proposal of positive behavioral change (McEwen & Wills, 2011). Pathman's pipeline model would help to identify factors that promote adherence and utilize on individual basis during one to one parental discussion for the proposed project. The model used during the proposed project to observe the leak in parental knowledge or barriers to the implementation of new knowledge and how to breakdown those barriers (White & Dudley-Brown, 2013). The theory and the model application will help to provide the strategies needed during the

proposed planned implementation. The educational intervention will improve parental knowledge and increase acceptance of the HPV vaccine thereby increase HPV vaccine uptake.

Patients trust their providers. As a result, research studies confirmed that clinician guided education to promote parental HPV acceptance especially if individualized and tailored based on parental background, age, and educational level will work (Gonik, 2006). Providers effectively utilizing the expert validated proposed project questions in the form of parental assessment tools would serve as a base for educational intervention, anticipating improvement and increase in the HPV vaccination rate within the studied age range population.

Proposal and Future Project Strengths

This proposal strength originates from the team approach, which provides effective communication strategies that led to the approval of an educational intervention to impact parents' decision to have their children ages 9 to 17 given the HPV vaccine. There is a need for more research targeting males of the studied population. This project utilizes existing educational intervention materials to promote parental understanding of the HPV infection and the available HPV vaccine. Effective utilization of the expert validated project questions inform of parental tool assessment may afford the provider initial assessment of parental knowledge of HPV and HPV vaccine.

Recommendations for Future Project Study

This was a developmental project with limited parental assessment tools based on the research, as a result, the clinic providers are encouraged to utilize the proposed expert validated project questions in the form of parental assessment tool in (Appendix C) to evaluate parental knowledge of HPV and HPV vaccine prior educational intervention implementation. Utilization of all the available educational resources as in (Appendix D) will be incorporated to provide safe and cost-effective care (AACN, 2006). There was limited research evidence focusing specifically on boys in the studied population, as a result future research study of on the impact on boys is recommended for generalization and global utilization.

Dissemination Plan

Dissemination serves as a final stage of research study which involves "diffusion or communication of research findings by presentation and publications to variety of audiences, such as nurses, other health professionals, policy developers and consumers" (Grove, Burns & Gray, 2013, p. 692). The major goal of any DNP project is to utilize the findings to improve practice thereby improving health outcomes. The goal is achievable only through effective dissemination of the project findings. The topic of my DNP project was providing parental education to impact the decision of parents to consent to giving children 9 to 17 years of age the HPV Vaccine.

According to Zaccagnini and White (2011), there are many approaches that may be used to disseminate project findings. Many are similar to dissemination of research such as publication in a journal. Some may be personally advantageous to the author.

The author must consider the timeline from the submission to the publication and dissemination as this will affect the utilization of the essential evidence-based findings into practice. Podium or poster presentations, Internet webinar sessions, and media communications in form of YouTube, and journal clubs allows for dialogue and may be viewed for a longer time compared to a poster presentation by the targeted audience which may only be available for months. Poster presentations may be very useful in academic settings. Community presentations are another forum for disseminating research. Whichever forum is utilized, the targeted audience must be considered.

Poster Board Presentation

In the case of this developmental project in which the targeted audience is parents with various educational and ethical backgrounds, a poster presentation would be more valuable with handouts to further buttress and clarify the ideas on the poster. According to Hand (2010), the poster is less stressful in terms of anxiety involved compared to the oral presentation. Posters, if meticulously prepared, provide an excellent means for dissemination of the evidence-based project. In addition, since the information on posters is limited it affords the presenter the opportunity to engage with the interested audience.

The strengths of a poster presentation are: 1) allows sharing of information in a concise storyboard manner; 2) serves as a means of communicating information to interested parties while the project is still in progress; 3) allows for one-to-one dialogue between the presenters and the interested viewer, thus provide opportunity to ask questions from the poster presenters and the viewer to take informed information back to their various workplaces to further disseminate the EBP; 4) serves as a means of small

group discussion while disseminating the current EBP in a non-threating atmosphere that allows for active participation and learning (Forsyth, Wright, Scherb, & Gaspar, 2010). The quality and design, when properly combined in a poster, could serve as a catalyst for effective dissemination of the project findings to colleague and other targeted audience (Forsyth et al., 2010).

Publication Aspiration

DNP project was a form of quality improvement project to bridge the gap in practice while at the same time implementing a new way of doing things through evidence-based practice for a better outcome of care. As a scholar-practitioner and a nurse leader, developing the project without dissemination would not fulfill the purpose of the DNP program. As a member of the Sigma Theta Tau International, I will use my membership opportunity to request information on how to prepare and submit my developmental project abstract for review in obtaining access for publication. I would also explore other journal publication options as the project evolves. Apart from the poster presentation, my plan is to further disseminate this developmental project in the form of a strategy that the providers can use to provide an educational intervention to improve patient acceptance of the HPV vaccine thereby increasing HPV vaccine uptake. This could be achievable through podium presentations via my professional organization such as the Society of Nurse in Advance Practice (SNAP) and National Conference for Nurse Practitioner in the organization's annual conference (NCNP). A scholarpractitioner serves as a skilled and knowledgeable individual who is very proficient in quality improvement strategies and helps in creating and sustaining changes at the

organizational and policy levels through dissemination of evidence-based findings (AACN, 2006).

Conclusion

The dissemination of the scholarly project goes beyond the requirement of the DNP degree only, instead it serves as a means of integrating and applying evidence-based research and tools to improve the outcomes of care delivery by the advanced practice providers at the clinical practice level (Zaccagnini & White, 2011). I have been committed to this developmental QI project in ensuring an educational intervention that would promote parental acceptance of the HPV vaccine. This can be accomplish through collaborative teamwork, effective communication, and dissemination of the evidence-based research to the clinical practice. The scholastic integration and application of the educational intervention would reduce cost of HPV sequelae and improve patient health care outcomes or experiences. (AACN, 2006).

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Appendix A: Permission to use Translation of Evidence Into Practice

Pagination: 221 Country of publication: United States of America

Translation of Evidence Into Practice

воок

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Permission to use MERCK Educational Fliers

Tawa B. Ibikunle-Salami

9838 Sequoia Court

Munster IN, 46321

Fax # 219-924-4527 Tel # 219-924-2783

E-Mail: Lecutydapper@att.net

Attention,

MERCK National Service Center,

Permission to use Merck Educational Fliers for Doctoral Study
I am a nursing doctoral student from Walden University. I hereby request MERCK
permission to use below fliers for my doctoral study in educating parents' of children
ages 9-17 years. 1) The HPV Vaccine & Your Child: A Parent's Guide 2) Parent's Guide
to HPV: Human Papillomavirus Facts for Teens & Preteens both PatientPoint.

- 1) What is the Purpose of duplicating or using the material? To serve as an additional educational material for my Doctor of Nursing Practice project. Providers' resources in providing educational intervention to parent of children 9-17 years to ensure understanding of HPV and HPV vaccine thereby increase HPV vaccine uptake.
- 2) How the material be maintained? The cover of the fliers would be scan into my project without personally utilizing the contents information in my project. The scanning of the fliers is just to direct the readers to look for the pamphlet for further reading and information on HPV and HPV vaccine.

I call in to MERCK today 08/26/2015 to request timely permission for the usage of above fliers for my doctoral project. My service request# is 1-14113101383.

Appreciate your organization cooperation and timely response of my request.

Sincerely,

Tawa B. Ibikunle-Salami

Walden University Doctor of Nursing Practice Student



Permission Request Form

In order to properly evaluate your request, please provide the information requested below and email to:

iena.medina@merck.com

jena.medina(a)merck.com	
Date: 09/19/2015	
Requestor's name, title, department, phone number	Tawa B. Ibikunle-Salami Walden University DNP Student 219-781-0670
Name of organization/entity requesting permission	Doctoral Student from Walden University
Organization/entity contact person, phone number, email address	Walden University Doctorate Student Tawa B. Ibikunle-Salami 219-781-0670 Tawa.ibikunle-salami@waldenu.edu or Lecutydapper@att.net
Title of Work or Trademark to be used and reason for use:	PatientPoint for HPV HPV Vaccine and your child: A Parent's Guide. Using for a doctoral level project title Educational Intervention to Impact Parental Decisions to Consent to Human Papillomavirus Vaccine.
Describe the scope and context of how and where the work or trademark will be used	The trademark picture using as a reference guide for patient to look for and read in the form of educational material.
Length of time of proposed use and country in which work will be used	Unsure, since it is a doctoral level project. Will be in public domain for educational purpose to increase parental knowledge of HPV and HPV vaccine. Knowledge increase will lead to increase HPV vaccine

	acceptance, thereby, reduce HPV sequelae
Provide copy of work including title page showing copyright or trademark statement	Attached with this form as an E-mail.

Dear Ms. Ibikunle-Salami,

This email is to notify you that the Institutional Review Board (IRB) confirms that your study entitled, "Development project on An Educational Intervention Impact on Parents' decision to have their Children ages 9 to 17 given the Human Papillomavirus (HPV) vaccine," meets Walden University's ethical standards. Our records indicate that your project does not include the types of activities that require a traditional IRB review. This Confirmation of Ethical Standards (CES) has an IRB record number of 07-08-15-0469221.

This confirmation is contingent upon your adherence to the exact procedures described in the final version of the IRB materials that have been submitted as of this date. This includes maintaining your current status with the university and this confirmation of ethical standards is only valid while you are an actively enrolled student at Walden University. If you need to take a leave of absence or are otherwise unable to remain actively enrolled, this is suspended.

If you need to make any changes to your project, you must obtain IRB approval by submitting the IRB Request for Change in Procedures Form. You will receive confirmation with a status update of the request within 1 week of submitting the change request form and are not permitted to implement changes prior to receiving approval. Please note that Walden University does not accept responsibility or liability for projects conducted without the IRB's approval, and the University will not accept or grant credit for student work that fails to comply with these policies and procedures related to ethical standards in research.

When you submitted your IRB application, you made a commitment to communicate both discrete adverse events and general problems to the IRB within 1 week of their occurrence/realization. Failure to do so may result in invalidation of data, loss of academic credit, and/or loss of legal protections otherwise available to you.

Both the Adverse Event Reporting form and Request for Change in Procedures form can be obtained at the IRB section of the Walden web site or by emailing irb@waldenu.edu:

http://researchcenter.waldenu.edu/Application-and-General-Materials.htm

Please note that this letter indicates that the IRB has approved your project. You may not move forward with your project, however, until you have received the **Notification of Approval to Conduct the Project** e-mail. Once you have received this notification by email, you may move forward with your project.

Both students and faculty are invited to provide feedback on this IRB experience at the link below:

http://www.surveymonkey.com/s.aspx?sm=qHBJzkJMUx43pZeqKImdiQ_3d_3d

Sincerely, Libby Munson Research Ethics Support Specialist Office of Research Ethics and Compliance Email: irb@waldenu.edu

Fax: 626-605-0472 Phone: 612-312-1341

Office address for Walden University: 100 Washington Avenue South

Suite 900

Minneapolis, MN 55401

Information about the Walden University Institutional Review Board, including instructions for application, may be found at this link: http://researchcenter.waldenu.edu/Office-of-Research-Ethics-and-Compliance-IRB.htm

Appendix B: IRB Approval

Dear Ms. Ibikunle-Salami,

This email is to serve as your notification that Walden University has both approved your doctoral project proposal and confirmed that the project meets the university's ethical standards. As such, you are approved by Walden University to conduct the project.

Please contact the Office of Student Research Administration at <u>dnp@waldenu.edu</u> if you have any questions.

Congratulations!

Libby Munson

Research Ethics Support Specialist, Office of Research Ethics and Compliance

Leilani Endicott

IRB Chair, Walden University

Information about the Walden University Institutional Review Board, including instructions for application, may be found at this link: http://academicguides.waldenu.edu/researchcenter/orec

Appendix C: Proposed Project Questions in the form of Parental Assessment tools

Human Papillomavirus (HPV) Proposed Vaccine Project Questionnaire **Instructions**: To be filled out by parent/guardian with the help of the clinic staff as needed. Please return to the office staff prior leaving the clinic.

Socio-demographic data

Gender of	the child		
0	Male		
0	Female		
Indicate ag	ge of the child		
	f children in householdarental/Guardian education completed		
Level of p	archian Guaranan caucation completed		
Yearly Household Income			

- o Less than \$19,500
- o \$19,501 \$29,999
- o \$30,000 \$50,000
- o Greater than \$50,000

Insurance Provider

- o Private
- o Public
- o Self-Pay
- No insurance

Race of the participant

- o African American
- o Asian
- o Hispanic
- Multiracial
- o Caucasian (White)
- o Other

Participant Language

- o English
- o Spanish

o Other

Paren	tal/Guardian know	ledge of HI	PV/HPV vaccine	
Circle	the answer of your o	choice		
	1. My child may contact HPV and not know it.			
	Yes	No	Not Sure	
2.	My child can be inf	fected with	HPV through sexual act.	
	Yes	No	Not Sure	
3.	3. HPV infection can lead to cervical cancer.			
	Yes	No	Not Sure	
4.	HPV can spread thi	rough skin t	to skin contact.	
	Yes	No	Not Sure	
5.			all types of sexually transmitted infections (STIs).	
	Yes	No	Not Sure	
6.	_	d HPV vac	cine do not have to use the condom during sexual	
	intercourse.		N 0	
	Yes	No	Not Sure	
Comm	nents:			
Chan	ge in parental attiti	ude and inc	crease knowledge of HPV/HPV vaccine	
	ge in parental attitute the answer of your c		crease knowledge of HPV/HPV vaccine	
Circle	the answer of your of	choice.	e HPV vaccine prior being sexually active.	
Circle 1.	the answer of your of It is important my of Yes	choice. child receive No	e HPV vaccine prior being sexually active. Not Sure	
Circle 1.	the answer of your of It is important my of Yes	choice. child receive No	e HPV vaccine prior being sexually active.	
Circle 1. 2.	the answer of your of It is important my of Yes It will be beneficial Yes	choice. child receive No I for my chi No	e HPV vaccine prior being sexually active. Not Sure ld health if vaccinated with HPV vaccine.	
Circle 1. 2.	the answer of your of It is important my of Yes It will be beneficial Yes	choice. child receive No I for my chi No	e HPV vaccine prior being sexually active. Not Sure Id health if vaccinated with HPV vaccine. Not Sure	
Circle 1. 2. 3.	the answer of your of It is important my of Yes It will be beneficial Yes HPV vaccine is bei	choice. child receive No I for my chi No Ing adopted No	e HPV vaccine prior being sexually active. Not Sure Id health if vaccinated with HPV vaccine. Not Sure to make money for drug companies. Not Sure	
Circle 1. 2. 3.	It is important my or Yes It will be beneficial Yes HPV vaccine is beil Yes I think the HPV vac	choice. child receive No I for my chi No Ing adopted No	e HPV vaccine prior being sexually active. Not Sure Id health if vaccinated with HPV vaccine. Not Sure to make money for drug companies. Not Sure	
Circle 1. 2. 3. 4.	the answer of your of It is important my of Yes It will be beneficial Yes HPV vaccine is being Yes I think the HPV vac Yes	choice. Child receive No I for my chi No Ing adopted No Coine is safe	e HPV vaccine prior being sexually active. Not Sure Id health if vaccinated with HPV vaccine. Not Sure to make money for drug companies. Not Sure e.	
Circle 1. 2. 3. 4.	the answer of your of It is important my of Yes It will be beneficial Yes HPV vaccine is being Yes I think the HPV vac Yes	choice. Child receive No I for my chi No Ing adopted No Coine is safe	e HPV vaccine prior being sexually active. Not Sure Id health if vaccinated with HPV vaccine. Not Sure to make money for drug companies. Not Sure e. Not Sure	
Circle 1. 2. 3. 4. 5.	the answer of your of Yes It is important my of Yes It will be beneficial Yes HPV vaccine is bein Yes I think the HPV vac Yes My child is too your Yes	choice. No I for my chi No Ing adopted No ccine is safe No ing to receive	e HPV vaccine prior being sexually active. Not Sure Id health if vaccinated with HPV vaccine. Not Sure to make money for drug companies. Not Sure Not Sure Not Sure ve a vaccine for STI as in HPV.	
1. 2. 3. 4. 5.	It is important my or Yes It will be beneficial Yes HPV vaccine is beir Yes I think the HPV vac Yes My child is too you Yes The vaccine is not or Yes	choice. No I for my chi No ng adopted No ccine is safe No ing to receiv No effective in	e HPV vaccine prior being sexually active. Not Sure Id health if vaccinated with HPV vaccine. Not Sure to make money for drug companies. Not Sure e. Not Sure we a vaccine for STI as in HPV. Not Sure preventing cervical cancer or genital warts. Not Sure	
1. 2. 3. 4. 5.	the answer of your of Yes It is important my of Yes It will be beneficial Yes HPV vaccine is bein Yes I think the HPV vac Yes My child is too your Yes The vaccine is not of Yes If my child receives	choice. No I for my chi No Ing adopted No ccine is safe No Ing to receiv No effective in No s HPV vacc	e HPV vaccine prior being sexually active. Not Sure Id health if vaccinated with HPV vaccine. Not Sure to make money for drug companies. Not Sure E. Not Sure we a vaccine for STI as in HPV. Not Sure preventing cervical cancer or genital warts. Not Sure tine, it will be a license to involve in sexual activity.	
1. 2. 3. 4. 5.	It is important my or Yes It will be beneficial Yes HPV vaccine is beir Yes I think the HPV vac Yes My child is too you Yes The vaccine is not or Yes	choice. No I for my chi No ng adopted No ccine is safe No ing to receiv No effective in	e HPV vaccine prior being sexually active. Not Sure Id health if vaccinated with HPV vaccine. Not Sure to make money for drug companies. Not Sure e. Not Sure ve a vaccine for STI as in HPV. Not Sure preventing cervical cancer or genital warts.	

Comments:			

Questionnaire was developed and validated by experts in the field (The student, the preceptor, NPs in the office, including Dr. Omar Sheriff (clinic manager).

Cuestionario de proyecto de vacuna virus del papiloma humano (VPH)

Instrucciones: Para ser llenado por el padre/tutor con la ayuda del personal de la clínica según sea necesario. Por favor devuelva a la previa de personal de oficina dejando la clínica.

Datos socio-demográficos

Género del niño

- o Macho
- o Hembra

Indicar la edad de la niña _____

Número de niños en hogares _____

Nivel de completed de Educación de los padres/tutores

Ingreso anual

- o Menos de \$19.500
- o \$19.501 \$29.999
- o \$30.000 \$50.000
- o Más de \$50.000

Proveedor de seguros

- o Privado
- o Público
- o Auto-pago
- o Sin seguro

Carrera del participante

- o African American
- o Asiático
- o Hispanos

	0	Otros		
Idi	oma	n participante		
	0	Inglés Español Otros		
C	ono	cimiento de los padr	es/tutores de la va	cuna contra HPV/VPH
		o de la respuesta de si		
1.	Mi	hijo puede contactar	•	
2	м.	Sí	No	No estoy seguro
2.	IVI1	hijo puede estar infe		
2	Inf	Sí Cacaión aon al VDU n	No vodo conducir a cón	No estoy seguro acer de cuello uterino.
٥.	1111	Sí	No	No estoy seguro
4	VP	PH puede propagarse :	· -	, ,
••	' -	Sí	No	No estoy seguro
5.		·=		o tipo de infecciones de transmisión sexual
		Sí	No	No estoy seguro
6.				VPH no tienen que usar el condón
	duı	rante las relaciones se		
		Sí	No	No estoy seguro
Co	mer	ntario:		
Ac	titu	d de los padres/tuto	res nara vacuna co	ontra el VPH
110	uu	a de 105 padi es, tato	res para vacana ec	
Cíi	cul	o de la respuesta de si	u elección.	
1.	Es	•	-	la vacuna de VPH sexualmente activo.
2	Sat	Sí ró banafiaissa nara la	No	No estoy seguro
2.	SCI	Sí	No	vacunados con la vacuna contra el VPH. No estoy seguro
3.				a para dar dinero a las compañías
		Sí	No	No estoy seguro
4.	Cre	eo que es segura la va		Н.
		Sí	No	No estoy seguro

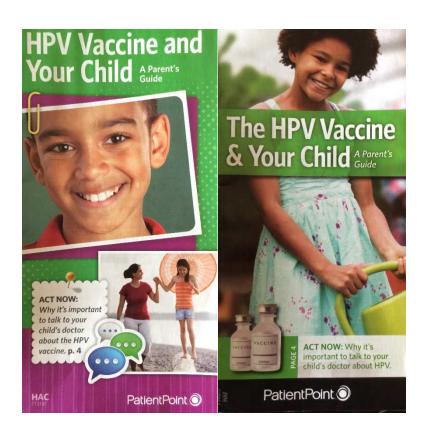
o Multirracial

o Caucásico (blanco)

5.	Mi niño es demasiado joven para recibir una vacuna para ITS como VPH.			
	Sí	No	No estoy seguro	
6.	. La vacuna no es eficaz en la prevención del cáncer de cuello uterino o de verrugas			
	genitales.			
	Sí	No	No estoy seguro	
7.	Si mi niño recibe	la vacuna contra e	el VPH, será una licencia para involucrar en la	
	actividad sexual.			
	Sí	No	No estoy seguro	
Co	mentario:			

Cuestionario fue desarrollado y validado por expertos en la materia (el estudiante, el preceptor, NPs en la oficina, incluyendo el Dr. Omar Sheriff (Gerente de la clínica). Translated with Microsoft Translator.

Appendix D: Educational Materials





HPV Vaccine is Recommended for Boys

CDC recommends that you get your boys and girls vaccinated at 11 or 12 to prevent cancers caused by HPV.
Get your boys vaccinated.

Why do I need to protect my son against HPV-related diseases?

A lot of parents know that HPV vaccine protects girls against cervical cancer. But did you know that vaccinating boys can protect them against cancer, too?



HPV is short for Human Papillomavirus, a common virus in both women and men. HPV can cause anal cancer and mouth/throat (oropharyngeal cancer), and cancer of the penis in men. Every year, there are over 9,300 HPV-related cancers in men. Many of these cancers could be prevented by HPV vaccine.

One HPV vaccine—Gardasil—is recommended by doctors and health experts for boys at age 11-12 years old. The vaccine can also help prevent genital warts. HPV vaccination of boys is also likely to benefit girls by reducing the spread of HPV viruses.



Learn how you can close the door to HPV-related cancers by watching this short video, (http://www.youtube.com/watch?v=ULbB0SdVe94&feature=youtu.be)

Why does my son need this at 11 or 12 years old?

HPV vaccines offer the best protection to girls and boys who receive all three vaccine doses and have time

to develop an immune response before they begin sexual activity with another person. This is not to say that your preteen is ready to have sex. In fact, it's just the opposite—it's important to get your child protected before you or your child ever think about this issue. The immune response to this vaccine is better in preteens, and this could mean better protection for your child.

If you haven't already vaccinated your sons (and daughters!), it's not too late. Ask your child's doctor at any appointment about getting HPV vaccine. The series is 3 shots over six months' time. Take advantage of any visit to the doctor—such as an annual health checkup or physicals for sports, camp, or college—to ask the doctor about what shots your preteens and teens need.

Is HPV vaccine safe?

HPV vaccine has been studied very carefully and shown to be safe. Studies showed no serious safety concerns. Common, mild adverse events reported during these studies include pain in the arm where the shot was given, fever, dizziness and nausea.

Some preteens and teens—both boys and girls—might faint after getting the HPV vaccine or any shot.

Preteens and teens should sit or lie down when they get a shot and stay like that for about 15 minutes after the shot. This can help prevent fainting and any injury that could happen while fainting.

How can I get help paying for HPV vaccine?

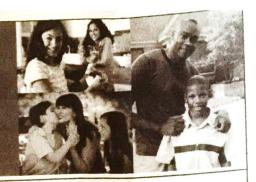
Families who need help paying for vaccines should ask their health care provider about <u>Vaccines for Children (VFC) (http://www.cdc.gov/Features/vfcprogram/)</u>. The VFC program provides vaccines at no cost to uninsured and underinsured children younger than 19 years. You can find your state's VFC coordinator online. Or call 1-800-CDC-INFO (232-4636) and ask for the phone number of your state's VFC Coordinator.

More Information

- More Information about HPV [204.7 KB] (http://www.cdc.gov/vaccines/vpd-vac/hpv/downloads/dis-HPV-color-office.pdf)
- HPV Vaccine for Preteens and Teens
 (http://www.cdc.gov/vaccines/who/teens/vaccines/hpv.html)
- Vaccines for Preteens and Teens (http://www.cdc.gov/vaccines/who/teens/index.html)
- Resources for Health Professionals about Preteen and Teen Vaccines (http://www.cdc.gov/vaccines/who/teens/for-hcp.html)

Did you know that HPV can cause cancer?

Protect your child from the risk... get your child the HPV vaccine!



What is HPV?

Human papillomavirus (also called HPV) is the most common sexually transmitted disease (STD) in the U.S. There are over 40 different types of the HPV virus. HPV can cause infections, like genital warts, but can also lead to many different cancers in both men and women.

How do you get HPV?

You can get HPV during sex acts. HPV is so common that most people who have sex will get HPV and may not even know it.

Is HPV serious?

Yes, HPV is very serious. HPV is the main cause of cervical cancer in women. In the U.S., about 12,000 women will get cervical cancer each year, and as many as 4,000 will die from it. HPV can also lead to other cancers, like cancer of the mouth, throat, sex organs (vagina and penis), and rectum.

How can I protect my child from HPV?

Vaccination (shots) is the best way to protect against HPV.

Why should I vaccinate my young child against HPV?

The vaccine works best if the shots are given before a person ever starts to have sex (that is, when they are young). However, even if a person has already started having sex, the vaccine can still give protection against HPV.

Is the HPV vaccine safe?

Yes - the FDA has approved the vaccine as safe. As of July 2012, over 46 million doses of the vaccine had already been given in the United States. The FDA continues to watch the vaccine for safety.



Both girls and boys should get the shots starting when they are 11 or 12 years old. Your child will get 3 doses of the HPV vaccine over a 6-month period. Older teens and young adults (up to age 26) should also get the HPV vaccine, too.

How can I get my child the HPV vaccine?

Ask your child's doctor for the HPV vaccine or go to your local health department.



www.vaccinateindiana.org

ese materials were created by the Indiana Immunitation Coalison hows by the Indiana State Cepartment of Health through a grant for Disease Control and Prevention (Award No. 5H23IP522522-11).

