

DNP PROJECT PROPOSAL

INCREASING THE HPV VACCINATION RATE IN A FAMILY PRACTICE:

A QUALITY IMPROVEMENT PROJECT

BY

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Abstract

The purpose of this quality improvement project is to identify barriers in practice to recommending the HPV vaccine and to use this information to develop and implement a practice protocol to enhance the delivery of the HPV vaccine series. The project will take place in a family practice setting in Mooresville, Indiana. The Stetler Model will provide the framework in multiple stages during this project. A PowerPoint presentation will be presented to providers to address strategies for improving HPV vaccination rates and reducing barriers to recommending the vaccine. A pre and post educational survey will be used to evaluate changes in provider perceived confidence in and barriers to recommending the HPV vaccine. Descriptive and inferential statistics will be utilized to analyze the data from the pre and post education surveys as well as from chart audits on the HPV vaccination rate prior to and three months post intervention to determine if the HPV vaccination rates improve.

Introduction

Background Knowledge

The human papillomavirus (HPV) is the most common viral infection of the reproductive tract (World Health Organization [WHO], 2015). HPV is so common that nearly all sexually-active men and women will become infected with at least one type of HPV at some point of their lives. Most people with HPV never develop symptoms or health problems; low risk types may cause genital warts; however, sometimes an infection with a high risk HPV type will persist and can cause serious health problems that include: cervical cancer, oropharyngeal cancer, anal cancer, vulvar and vaginal cancer or penile cancer (CDC, 2015b).

In 2006, the U.S. Food and Drug Administration (FDA) approved a prophylactic HPV vaccine (Gardasil) targeting prevention of infection with HPV types most likely to cause cancer as well as genital warts for girls and women ages 9-26 years and males ages 16-26. Soon after, a second HPV vaccine (Cervarix) was approved for prevention of infection with the HPV types most likely to cause cancer. Most recently, the FDA has approved a 9-valent vaccine (Gardasil 9) that protects against 9 different types of HPV infections offering added protection against infection with high risk HPV types. Clinical trials have found the vaccines to be effective, safe, and well tolerated (Gerend & Magloire, 2007). Guidelines and government bodies recommend the use of a HPV vaccine in both males and females (American Academy of Pediatrics [AAP], 2015a); however, in the U.S., from 2013 to 2014, the vaccine coverage for ages 13-17 who received all three doses of the HPV vaccine was only 36.8% for girls and 21.6% for boys (CDC, 2015c).

According to the Centers for Disease Control and Prevention (CDC), missed clinical opportunities are the most important reason why the US has not achieved higher rates of HPV

vaccine uptake. Many vaccine-eligible adolescents do not receive the HPV vaccine during visits with their healthcare providers. As many as two-thirds of 11 and 12-year old vaccine eligible girls may not be receiving HPV vaccines at visits in which they receive at least one other vaccine (The Presidents Cancer Panel [PCP], 2013). Studies have shown that health care providers have the greatest influence on whether or not a parent decides to vaccinate their children for HPV (Holder, Katzenellenbogen & Middleman, 2013). Even though health care professionals play an instrumental role in facilitating the HPV vaccination many are failing to universally recommend the vaccine (Hofstetter & Rosenthal, 2013).

Statement of the Problem

The U.S. HPV vaccine rate is far below other adolescent vaccines and far below the U.S. Department of Health and Human Services *Healthy People 2020* goal of having 80% of 13 to 15 year old boys and girls fully vaccinated (U.S. Department of Health and Human Services[USDHH], 2015). In 2013, the CDC estimated that in the US increasing HPV vaccination rates from the current levels to 80% would prevent an additional 53,000 future cervical cancer cases among girls who were 12 years old or younger. In addition, thousands of cases of other HPV associated cancers would likely be prevented within the same timeframe (PCP, 2013).

In 2013, the President's Cancer Panel (PCP) issued a report to the President of the United States outlining the importance of establishing efforts to increase the rate of HPV vaccination. This report also recommended targeting efforts to address factors that keep health care providers from strongly recommending HPV vaccines; in addition, to use electronic health records and immunization information systems to avoid missed clinical opportunities for HPV vaccination and facilitate completion of the three dose regimen (PCP, 2013).

Nearly 80 million people in the US are infected with at least one strain of HPV and most will never develop symptoms (CDC, 2015b); therefore, it is important to vaccinate before the onset of sexual activity. In addition, it is known that an antibody response to the vaccine is highest at ages 9 through 15 years (AAP, 2015b). Studies have shown that health care providers have the greatest influence on whether or not a parent decides to vaccinate their children for HPV. In addition, many studies have found a common reason for non-vaccination was patients never being offered the vaccine (Holder, Katzenellenbogen & Middleman, 2013). Literature suggests the main factors affecting provider's intention to offer the HPV vaccine include: a limited understanding of the HPV vaccine and HPV related diseases, (especially in males), attitudes towards the vaccination, and time constraints (Holder, Katzenellenbogen & Middleman, 2013). Other significant factors include: discomfort of providers with discussing sexually transmitted infections (STI) with parents in the early target age groups, anticipating parental resistance, lack of reimbursement from insurance companies, and lack of systems to remind them to offer vaccines to age-appropriate patients (Bynum et al., 2013).

Literature Review

There are limited studies specifically exploring HPV vaccine related strategies for health care providers and how they affect the vaccine uptake rate. Most studies explore only provider perceptions of the vaccine. An intervention study was conducted by Perkins et al. (2014). The study used a provider-focused intervention program to improve the HPV vaccination rate and was conducted in a federally qualified community health center. The program consisted of repeated contacts, education, individualized feedback and quality improvement incentives. The education part of the program was focused on the morbidity and mortality from HPV, vaccine safety and vaccine efficacy. Individualized feedback was centered on vaccination rates relative

to the provider's practice vaccine rate versus their state and the national rates. The incentive was given in the form of continuing education credits. After the interventions the practice significantly increased the vaccine initiation rate and the completion rate. The improvements were also sustained in the maintenance periods. This study demonstrated that blending a multi-component medical education program with routine data collection using an EMR can cause practice changes and increase HPV vaccination rates.

Berenson, Rahman, Hirth, Rupp and Sarpong (2015) increased health care providers' HPV vaccine knowledge by conducting a brief educational presentation. The researchers assessed the knowledge levels of physicians, non-physician healthcare workers, and medical students before and after attending a 30 minute lecture. On average, knowledge scores significantly improved after the presentation. The researchers stated that improving provider knowledge may improve the quality and quantity of counseling regarding the HPV vaccine; thus, increasing the vaccine rate.

A survey conducted by McRee, Gilkey and Dempsey (2014) found that health care providers reported that parents frequently requested to delay the HPV vaccine or refused the vaccine all together. For that reason, providers were sometimes discouraged from offering the vaccine due to time constraints anticipating parental resistance. Their findings also suggested that providers with lower levels of confidence in addressing parents' concerns and those who believed that they were not able to influence parents to get the vaccine were less likely to recommend it. The high frequencies of hesitancy by the parents in combination of the reports of time constraints by providers were a contributor to low vaccine rates. The study proposed that improving providers' self-efficacy may increase provider confidence when dealing with parental concerns regarding the HPV vaccine.

Perkins and Clark (2013) conducted a survey to explore providers perceptions and parental concerns about HPV vaccination. In relation to providers they found no great differences in attitudes, concerns or discussion focus between providers with different types of training. Providers who primarily saw young children often used conversations related to cancer prevention when discussing the vaccine, while providers of care for adolescents more often addressed the HPV vaccination in a sexual context. Several communication gaps were found when they compared the parents' and the providers' views of the vaccine. Most parents revealed that they were not aware that HPV is a skin virus and can be transmitted from anal-genital and oral-genital contact. These findings suggest that there may be a provider knowledge gap about HPV transmission if this information is not being conveyed to parents. Another communication gap occurred around providers' fears of alienating patients by pushing the subject of HPV vaccination on those who had previously declined; however, parents stated they appreciated the multiple opportunities to speak with their providers about the vaccine. The authors of the study suggested providers' negative perceptions of parents' views may be leading to lower rates of offering the vaccine.

Bynum et al. (2014) looked at the factors associated with Medicaid providers recommendation of the HPV vaccine to low-income adolescent girls and found that the Family Medicine specialty was less likely to recommend the vaccine over other practice specialties. Discomfort discussing sexually transmitted infections with parents was associated with lower HPV vaccine recommendation in all age groups; and the more difficult providers perceived it was for early adolescents to complete the vaccine series the less likely they were to recommend the vaccine. As in other studies time constraints was also a factor for recommending the vaccine; in addition, providers who reported higher concerns that teens would practice riskier

sexual behaviors were less likely to report the vaccine recommendation. The researchers concluded that tools and strategies are needed to help providers with time constraints and communication.

Vadaparampil et al. (2011) conducted a study to determine the prevalence of physician recommendation of HPV vaccination in females. What the study found was across the main specialties, the prevalence of “always” recommending the vaccination was lowest for early adolescents aged 11-12 years. It also showed that Family Practitioners were the least likely to recommend the vaccination overall. This is one of multiple studies found that states a Family Practice setting is a good place to focus on an HPV intervention. The study also found that time constraints was strongly associated with the recommendation of the vaccine.

Local Problem

According to the CDC (2015d) National Immunization Survey (NIS) Table Data for 2014, in the state of Indiana, 61% of girls and 23% of boys age 13 to 17 have received one dose in the HPV vaccine series; 74% of girls and 61% of boys that started the series completed all 3 doses. The NIS is sponsored by the National Center for Immunizations and Respiratory Diseases (NCIRD) and conducted jointly by the NCIRD, the National Center for Health Statistics (NCHS) and the CDC. The NIS collects information on childhood immunizations by a list-assisted random-digit-dialing telephone survey followed by a mailed survey to children’s immunization providers.

There is debate whether or not to require girls and boys to be vaccinated against HPV. Since 2006, 42 states and territories have introduced legislation to require the vaccine and fund or educate the public or schools about the vaccine. At least 25 states and territories have enacted legislation, including Indiana. In 2007, Indiana Public Law No. 80 was passed requiring parents

of girls entering the sixth grade to receive information about the link between HPV and cervical cancer and the availability of the HPV vaccine. The bill does not mandate the vaccine for school attendance. In 2013, Indiana Public Law No, 13 was passed that adds the HPV vaccine to the list of vaccinations that pharmacists are allowed to administer with a prescription from a prescribing provider. In 2013, House Bill number 1236 was submitted to the Committee but remains unpassed. The bill states that a parent or guardian of a sixth grader must submit a written statement that the child is receiving, or will receive, or is not going to receive the HPV vaccination, or a statement that they will inform the school of their decision. Two bills were introduced in 2015. House Bill number 1177, which remains in the Committee, would require the state department of health to establish a strategic plan to identify and reduce morbidity and mortality from cancers associated with HPV. It would also require the department to collaborate with the social services administration and cancer facilities; allow workgroups; and create a report on the strategic plan and recommendations. House Bill number 1359 would require the state to establish a program to provide information about HPV to parents, health care providers and other individuals approved to administer the HPV vaccine. It would also establish goals and plans to increase the vaccination rate for HPV and require an annual report. This bill failed the House on February 25, 2015 (National Conference of State Legislatures [NCSL], 2016).

Mooresville Family Care (MFC) is a Family Practice and part of the Franciscan Physician/Franciscan Alliance Network. The practice is located in Mooresville, Indiana. Mooresville is a suburb of Indianapolis. According to the U.S. Census Bureau (2014), Mooresville's population is approximately 9,576. Median home value in Mooresville is \$126,200. The majority of the population, 88.4%, are high school graduates; and 13.1% have a Bachelor's degree or higher. The average household income is \$52,768.

The practice has five providers: three physicians, one Family Nurse Practitioner (NP) and one Physician Assistant (PA). The patient base age range is birth through elderly; in addition, the practice provides Obstetrics care (OB). The practice has approximately 1,400 patients between the ages of 11 years to 26 years. The average number of patients seen per day is 25-30 for the physicians; 17-20 for the NP; and 15-18 for PA. Patients are scheduled every 15 minutes for the physicians and every 20 minutes for the NP and PA. Well child appointments are scheduled for the same amount of time until the age of 21 when they are extended to 30 minutes for physicians and 40 minutes for the NP and PA. The practice stays busy often requiring providers to double book throughout the day for acute visits.

The office utilizes an EMR and uses EPIC software. Each provider is equipped with a laptop computer. A provider can see a patient's HPV vaccination status in multiple places within the EMR; in addition, the software is capable to retrieve information from the Indiana Immunization Registration Program "CHRIP" website. There is currently no office protocol to address the HPV vaccine with patients or assure the vaccine series is completed once started.

Guidelines for Practice

Advisory Committee on Immunization Practices (ACIP) recommends the HPV vaccine as part of routine vaccination for all girls and boys at age 11 or 12. Vaccination is also recommended for females aged 13 through 26 years and males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. Males 22 through 26 years may be vaccinated if they have not been previously vaccinated, engage in sexual activity with other men, or are immunocompromised (CDC, 2015a). In addition to the ACIP, other organizations that recommend the vaccine include: The American Cancer Society, American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP),

American College of Obstetricians (ACO), National Foundation for Infectious Diseases (NFID) and others (National Foundation for Infectious Diseases, 2014).

The Affordable Care Act (ACA) requires all new private insurance plans to cover the HPV vaccines for the recommended age groups for both boys and girls. The federally-financed Vaccines for Children (VFC) program pays for the HPV vaccination for all children through age 18 with Medicaid. Women and men ages 19 and 20 with Medicaid are eligible for Medicaid coverage of all ACIP-recommended vaccines as an Early and Periodic Screening Diagnosis and Treatment Program service. For adults 21 and older who qualify for Medicaid through other eligibility, vaccine coverage is an optional benefit and is decided on a state-by-state basis. The State Children's Health Insurance Program (CHIP) when separate from the state's Medicaid program must cover ACIP-recommended vaccines for beneficiaries since they are not eligible for coverage under the federal VFC. In the case of Gardasil 9, it is estimated most plans will begin covering the new vaccine January 2017. The ACIP recommended the VFC program cover Gardasil 9 in February 2015 for males and females ages 9 through 18 (The Henry J. Kaiser Family Foundation [HJKFF], 2016).

In August 2014, the NFID (2014) issued a Call to Action for U.S. health care professionals to play a leadership role in advocating for the HPV vaccine to parents. The foundation suggests health care professionals who have contact with adolescents and their parents play a leadership role in helping to reduce the burden of HPV-related cancers in the US by using five key steps: (a) Recommend the HPV vaccine with the same strength and conviction used to recommend other adolescent vaccines. (b) Educate themselves about HPV and HPV vaccines. (c) Inform their colleagues and staff so that everyone throughout the practice is delivering the same HPV messages. (d) Communicate vaccination benefits to parents and

adolescents at every opportunity. (e) Make vaccination procedures routine and focus on ways to reduce missed opportunities.

Following the NFID's call to action the AAP issued the HPV Champion Toolkit for health care professionals. The kit outlines the key points about the vaccine; printable resources; articles about HPV; success stories; and information about the NFID roundtable meeting that led to the call to action (AAP, 2015b).

In 2015, a collaborative letter was written by leaders of the AAFP, the AAP, American College of Obstetricians and Gynecologists (ACOG), American College of Physicians (ACP), the CDC, and the Immunization Action Coalition (IAC) that urges health care providers to strongly recommend the HPV vaccine. The letter states that providers need to not only recommend the vaccine but to think about how they recommend the vaccine to their patients; in addition, how the message is delivered matters. The letter delivers key facts about the HPV vaccine safety and effectiveness in hopes that it will lead providers to recommend the vaccine firmly and strongly to patients (American Academy of Family Physicians [AAFP], 2015).

Intended Improvement

The purpose of this project is to identify barriers in practice to recommending the HPV vaccine and to use this information to develop a practice protocol to enhance the delivery of the vaccine series. The goal of this project is to improve HPV vaccination rates for patients at Mooresville Family Care. The literature supports that a strategy of enhancing provider knowledge about the HPV vaccine and HPV related diseases; and addressing time constraints during patient appointments to discuss the vaccine will improve the overall rate of vaccine uptake. Provider outcomes expected from this project include improved self-efficacy regarding discussion about HPV and HPV vaccination with patients and parents and an increase in

compliance with the recommended HPV vaccine guidelines. Patient outcomes expected from this project include improved HPV vaccine rate for the patient population of the practice. It will take collaboration to implement this project. It will involve participation from practice providers, medical assistants, front office staff and the information technology (IT) staff.

Project Outcome Objectives

1. Health care providers and staff will develop a protocol/algorithm for consistent and efficient patient/parent education and recommendations regarding HPV/HPV vaccination and administration of HPV vaccine during the first month of the project.
2. Health care providers will report a 50% increase in confidence, from baseline, in addressing the HPV vaccine with parents and patients.
3. Health care providers will report a 50% decrease in barriers, from baseline, in discussing the HPV vaccine with parents and patients.
4. In the 3 months following implementation of the protocol there will be a 30% increase from baseline in HPV vaccination rates.

Theoretical/Conceptual Model Framework

The Stetler Model of Research Utilization will be used to guide this evidence-based quality improvement project. The Stetler model was first developed in 1976, and called the Stetler/Marram Model of Research Utilization, when there was little in the way of guidance for health care providers who wanted to implement research into practice. The model was developed with no theoretical underpinning; however, the original model has been refined three times. The revised Stetler Model is based on both conceptual work and planned action learning. The model is a prescriptive, critical thinking approach that consists of a sequence of interactive,

criterion-based decision-making steps designed to facilitate effective use of research and other relevant evidence (Rycroft-Malone & Bucknall, 2013).

Model Description

The Stetler Model is a practitioner-oriented guide for the application of research findings and other relevant evidence in practice. The model examines how to use evidence to create formal change within organizations, as well as how individual practitioners can use research on an informal basis as part of critical thinking and reflective practice (National Collaborating Centre for Methods and Tools [NCCMT], 2011).

The model communicates that research use occurs in three forms: instrumental use refers to the concrete, direct application of knowledge; conceptual use occurs when using research changes the way one thinks about an issue; and symbolic use or political/strategic use happens when information is used to justify a policy or decision, or otherwise influence the thinking and behavior of others. The Stetler model is based on the concept that the user's characteristics, as well as external environmental factors, influence use of knowledge (NCCMT, 2011; Stetler, 2001).

Model Concepts

The Stetler Model of evidence-based practice is based on six basic assumptions:

- The formal organization may or may not be involved in an individual's utilization of research.
- Utilization may be instrumental, conceptual, and/or symbolic.
- Other types of evidence and/or non-research-related information are likely to be combined with research findings to facilitate decision making or problem solving.

- Internal and external factors can influence an individual’s or group’s view and use of evidence.
- Research and evaluation provide us with probabilistic information, not absolutes.
- Lack of knowledge and skills pertaining to research utilization and evidence-based practice can inhibit appropriate and effective use (Rycroft-Malone & Bucknall, 2013).

The Stetler model has five phases: preparation, validation, comparative evaluation/decision making, translation/application, and evaluation. The latest model is formulated into two parts. The first part is a graphic model containing the five phases. The second part of the model contains clarifying information and options for each phase. The graphic model is illustrated in Figure 1 (Stetler, 2001).

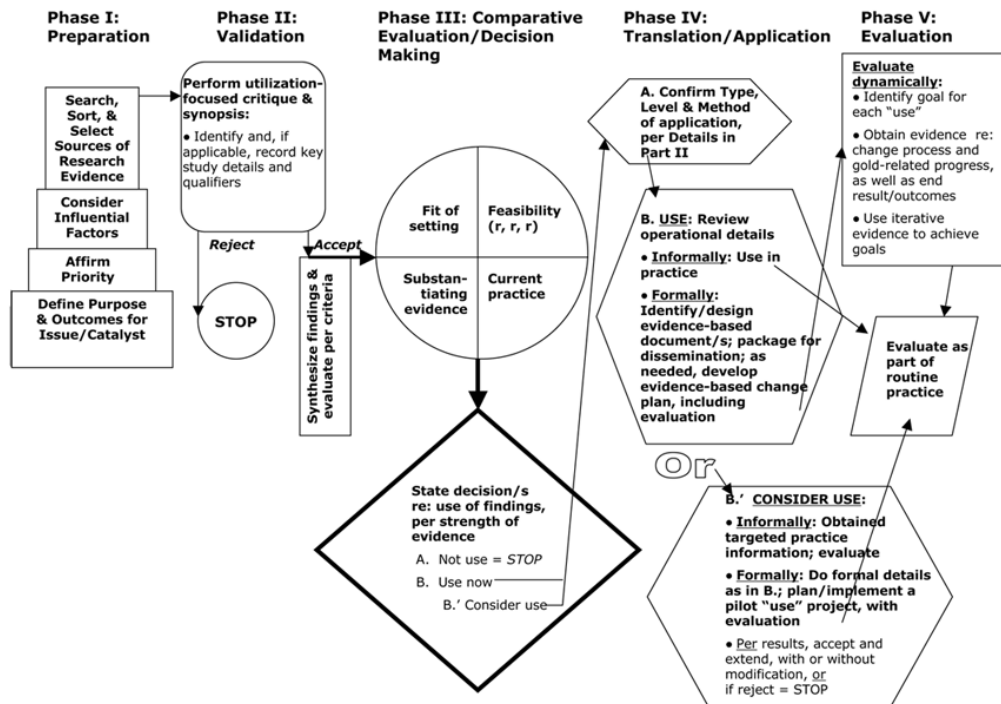


Figure 1. 2001 Stetler Model. Adapted from Stetler, C. (2001). Updating the Stetler model of research utilization to facilitate evidence-based practice. *Nursing Outlook*, 49, 272-9. DOI:1067/mno.2001.120517

The following describes each of the five phases within the graph:

Phase I focuses on the purpose, context and source of research evidence. The practitioner identifies potential issues and affirms their priority; decides whether to involve others; and considers influential internal and external factors, such as timelines. The practitioner then seeks evidence in the form of systematic reviews and selects research sources with a conceptual fit (Rycroft-Malone & Bucknall, 2013; Stetler, 2001).

Phase II focuses on the validation of findings and includes activities such as critiquing systematic reviews, rating the quality of each evidence source, and determining the clinical significance of the evidence. The evaluation is utilization-focused and the decision is made whether to accept or reject the evidence. If there is no evidence or the evidence is insufficient the process will be terminated when the evidence is rejected. Otherwise, the evidence is accepted and the practitioner progresses to Phase III (Rycroft-Malone & Bucknall, 2013; Stetler, 2001).

Phase III focuses on organizing and displaying the summarized findings from across all validated sources in terms of their similarities and differences. The practitioner then determines whether it is desirable or feasible to apply these summarized findings in practice, based on applicability criteria. The criteria are fit to the targeted setting, current practice, and feasibility. Feasibility entails the evaluation of risk factors, need for resources, or readiness of others involved (or “r, r, r” as shown in the graphic model). Based on the comparative evaluation, the user makes one of four choices: (a) decides to use the research findings by putting knowledge into effect and moving forward in terms of the appropriate types of uses; (b) considers use by gathering additional internal information before acting broadly on the evidence; (c) delays use since more research is required which the user may decide to conduct based on local need; (d) rejects or does not use the findings (Rycroft-Malone & Bucknall, 2013; Stetler, 2001).

Phase IV focuses on the evidence implementation process, beginning with the confirmation of type of use (conceptual, instrumental, symbolic), method of use (informal/formal, direct/indirect), and level of use (individual, group, organization). Then, the operational details are specified as to who should do what, when and how. In this phase, a decision is made regarding whether to use or to consider use of the evidence (Rycroft-Malone & Bucknall, 2013; Stetler, 2001).

Phase V focuses on the evaluation of the expected outcome relative to the purpose of seeking evidence whether the evaluation is related to a direct “use” or “consider use” decision. The “consider use” option requires pilot testing to enable further evaluation of the feasibility of the change in practice. Pilot data are then used to decide whether the evidence will be formally used. In the case of a “use” decision, the implementation process will be formally evaluated (Rycroft-Malone & Bucknall, 2013; Stetler, 2001).

Literature Support of Model Use

Despite more than two decades of continued effort to promote evidenced-based practice in the United States, a large number of evidence-based guidelines are still ignored (Solomon, 2010). Recently, the demand for greater attention to the rigorous study of how best to achieve change in the health care industry has been advanced for further action at the federal level. The need for a comprehensive strategy embracing implementation science is on the forefront by the call for validation projects by the Affordable Care Act (Bonham & Solomon, 2010). The National Institutes of Health (NIH), The Agency for Health-Related Quality (AHRQ) and the CDC have all issued grant-making programs to encourage implementation of evidence based research findings (Solomon, 2010). The NIH has traditionally been committed to discovery and spends about \$30 billion each year on basic and efficacy research. In 2010, the AHRQ spent

only about \$270 million on research relevant to health quality, dissemination, and outcomes. This means for each dollar spent in discovery, mere pennies are spent learning how interventions known to be effective can better be disseminated (Glasgow et al., 2012).

There is mounting interest in the use of theories, models and frameworks to gain understanding of the mechanisms by which implementation is more likely to succeed. Implementation studies borrow theories, models and frameworks from multiple disciplines including those outside of medicine in order to promote the systematic uptake of research findings (Price et al, 2015). The Stetler model is a well-known process model (or action model) used to describe or guide the process of translating research into practice. It offers practical guidance in the planning and execution of implementation endeavors and/or strategies. The model has been cited as a “classic model” for evidence based practice and as one of the “most established”. The Stetler model has continuously and systematically been used by advanced practice nurses. These experiences provide cases reports regarding the model’s application at multiple levels in multiple settings, from the 1980’s onward (Rycroft-Malone & Bucknall, 2013).

Velez, Becker, Davidson and Sloand (2014) used the Stetler model as a framework for an eight week evidence based educational interventional study to address provider behavior as it relates to utilization of community associated methicillin-resistant *Staphylococcus aureus* (CA-MRSA) guidelines. The researchers utilized all five phases of the model to integrate evidence based practice findings into the development of the intervention component of the study. During Phase I, the researchers identified the problem of the increasing CA-MRSA infection rate and the inconsistent use of the clinical guidelines by prescribers. During Phase II, the researchers critiqued qualitative and quantitative research and clinical guidelines as best practice treatments and determined the quality of evidence. During Phase III, evaluation revealed treatment of CA-

MRSA by prescribers as inconsistent with clinical guidelines; project steps were planned to reflect guided inquiry; operational details were planned to explain use of guidelines as best practice treatment for prescribers rather than current practice treatment; and the project was implemented. During Phase IV, outcomes of provider education and prescriber adherence were measured; in addition, the researchers reported and disseminated the project findings. The research concluded that the project was effective; thus, concluding the model was an effective framework for connecting evidence-based methods into practice.

Snyder, Facchiano and Brewer (2011) understood that failing to manage anxiety symptoms in Parkinson's patients results in diminished quality of life. The situation raised the clinical question of what is the best method for assessing anxiety in patients with Parkinson's disease (PD). The clinicians used the Stetler model to guide the knowledge search process to answer the clinical question of recognition of anxiety in patients with PD. Using the framework, during Phase I, guided by the clinical question that acted as inclusion and exclusion criteria, studies were selected from the results of a literature review. During Phase II, the clinicians critiqued and validated the literature with the clinician's utilization in mind. During Phase III, the clinician's completed a comparative evaluation of the evidence and a decision was made to use an anxiety assessment tool for patients with PD. While the clinicians did not use phase IV or V in their research project, they discussed the importance of the phases when using the framework as a strategy for ensuring quality care for patients. The utilization of the model led to findings that were used to change the clinician's practice to improve patient care with PD.

Evidence-based practice is the mantra for nursing in all settings. Randomized clinical trials (RCT) are the gold standard for testing interventions and publication of the RCT represents one study providing evidence. Scientific integrative, systematic, and meta-analytic literature

reviews are recognized as the power house publications that are the foundation of evidence-based practice because the literature reviews synthesize multiple studies addressing a problem (Cowell, 2015). The Stetler model has continuously and systematically been used as a guide to perform literature reviews and to develop an intervention or, at minimum, implications for practice (Rycroft-Malone & Bucknall, 2013).

Wanda and Moore (2005) used the Stetler model as a guide to conduct an in-depth literature review to examine the evidence for the use of humor as a coping tool for patients with cancer. In the first phase of the model, the purpose of the literature review was determined. A literature search was undertaken to examine the evidence for the use of humor as a coping tool for patients with cancer. The second phase guided the process of validation, or assessment of the scientific soundness of each article or study. The third phase of the model guided the researcher in deciding whether the findings from the literature review should be used, rejected, or delayed until further research is available. The researchers used the fourth phase to implement the findings into action terms. The fifth phase was used to clarify expected outcomes and acquire additional practical information through observing results, obtaining a consensus and conducting an action test of the findings. The researchers synthesized 20 research studies and found that humor is an effective intervention with a potentially enormous impact on the health and well-being of patients in numerous settings.

Freeman, Lara, Courts, Wanzer and Garmon (2009) used the Stetler model to identify and describe evidence based criteria for evaluating the appropriateness of policies for decontamination of noncritical equipment in the perioperative setting. An integrated literature review was guided by the Stetler model. The study consisted of five phases involving six data collection procedural steps. The phases of the project corresponded to the phases in the

integrative literature review process as operationalized in Stetler's Research Utilization. The study found there are minimal published evidence-based infection control criteria to guide the development and evaluation of existing protocols and policies used for disinfecting non critical items in perioperative areas. The researchers determined that standards and guidelines must be revised to ensure safe and clean environments for patients and staff in perioperative areas.

The Stetler model was originally developed for baccalaureate nurses; however, because of the complexity of the implementation process, Stetler subsequently focused more on advanced practice nurses in autonomous practice. The model has been consistently cited over the years in many articles concerning evidence based practice (Rycroft-Malone & Bucknall, 2013).

Use of Theory for Proposed Project

The Stetler Model will provide the framework in multiple stages during this project. In the first phase, preparation, the project director (PD) identified the purpose of the project based on a literature review demonstrating the U.S. HPV vaccine rate is far below the U.S. Department of Health and Human Services *Healthy People 2020* goal as well as a perceived low HPV vaccination rate at MFC. The PD determined that the project team would consist of the health care providers and staff at MFC.

In the second phase, validation, the PD searched for and critiqued studies conducted on low HPV vaccination rates. It was determined that health care providers have the greatest influence on whether or not a parent decides to vaccinate their children against HPV. An additional literature review found interventions that improved the vaccination rate focused on enhancing provider self-efficacy regarding discussing HPV and HPV vaccination with parents and addressed time constraints during patient appointments.

In the third phase, comparative evaluation/decision making, the PD will present an assessment of the findings to the project team. The team led by the PD will determine the level of suitability and usefulness of the project for the practice. Based on the strength of the evidence and previous discussion with the team the assumption is that the team will decide to continue with the project.

The fourth phase, translation/application, will involve the PD leading the team to translate the evidence into a plan for implementation into the clinical setting. The PD will evaluate provider readiness to implement evidence based practice guidelines and design specific interventions to facilitate change. The fifth phase will be used to formally evaluate the process and outcomes of the project. The PD will present data from this evaluation for the team to review and decide if the new protocol should be continued.

Strengths and Weakness of the Model

Major strengths of the Stetler model is it is practitioner oriented, critical thinking focused, grounded on implementation science and it has a strong relationship to the experiences of advanced level practitioners in the real world of application. The Stetler's model makes the process of decision making regarding evidence for the project clear. A weakness related to the model is not being a "popular" model to those outside the nursing field. After comparing it with 22 other models, the Stetler model was ranked in the top 8 based on selected criteria for clinical nursing but was not rated high on use by other clinicians (Rycroft-Malone & Bucknall, 2013). Some that will take part in the project will not have had hands-on, reflective experience with the model. If they are not familiar with the model's details they may not consider the strength of the evidence obtained during the project development. The PD will take the time to explain the phases of the model to the team members in relation to the project.

Project Design

Setting

This project will be implemented at Mooresville Family Care in Mooresville, Indiana. The providers in the practice include three MDs, one NP and one PA. Additional staffing includes one medical assistant (MA) per provider, one float MA, one phone triage nurse (MA) and four front office staff.

The patients served in the office range from birth through elderly; in addition, the practice provides OB care. Greater than 14% of the patient population is in the age of HPV vaccine need; 11 to 26 years. The office has an annual census of around 21,000 patient visits. The office is staffed Monday through Friday, 7:30am to 5pm. The individual providers' schedules are: one MD is in the office two days a week; two MDs and the NP work a four day work week; and the PA has a five day work week. Each MA works a four day work week and the front office works a five day work week. There are no extra providers to fill in for vacations or sick calls; however, there is a strength offered by the MA schedule since there is an extra float MA when the patient load is high. The average number of patients seen per day is 25-30 for the MD's; 17-20 for the NP; and 15-18 for PA.

Provider meetings and educational offerings take place prior to seeing patients in the mornings, on lunch breaks, patient time slots have to be blocked, or on personal time. The physical environment allows for easy face to face communication and is usually done in the break room or individual offices. Each provider, MA and office staff uses the same email as communication and all charting for patients is done on an electronic medical record (EMR) system.

The office takes all level of payment for care and is reimbursed mostly by private insurance and Medicaid. The office does not turn away patients or deny vaccine administration for the inability to pay or for lack of insurance. If a patient has insurance that is assigned to another network or provider at the time of an appointment they will be seen; in addition, vaccines will be administered if they are needed or requested. In return patients are asked to sign a waiver for payment and are assisted in changing their insurance to the proper network or provider if needed.

The EMR system provides quick access to the patient's HPV vaccine record in multiple areas within the patient's chart. When opening up a patient's record within the EMR the first screen viewed is the patient's "snap shot" which includes vaccine administration history. In addition, there is a vaccine tab located along the left side of the patient's record that can be accessed from anywhere within the patient's chart. If a patient is in the HPV vaccine age range and has not received all three doses of the vaccine, his or her chart will be flagged with a bright red "Best Practice" alert across the top of the screen. This is visible at all times while accessing the patient's record. A weakness to this is the "Best Practice" alert can be triggered by many things, not just HPV vaccine status. The EMR system has a direct interface with the Indiana State Immunization Registry Program or "CHIRP"; however, a weakness to this is the information is not automatically placed in the patient's immunization history area within the chart and it is not visible on the "snap shot" screen. "CHIRP" information is manually transferred into the patient immunization history by an MA when conflicting vaccine information is found. Due to this verifying that a patient needs the HPV vaccine takes multiple steps.

Vaccines are usually addressed at a patient's annual complete physical exam (CPE) or well child check (WCC). These types of visits include several steps and involve multiple staff

members. The first step is registration/check-in at the front window. This is done by the front office staff. The second step is rooming the patient. This is done by an MA and includes getting the patient's weight, vital signs, family history, past medical history, current medication and other pertinent history. The MA then collects details of the patient's reason for the visit using structured templates designed by the providers. During a CPE or WCC the MAs reconcile patient's immunization history using both the "CHIRP" interface and discussion with the patient and/or the patient's parents. If immunizations are needed the MAs preorder and pend the order for the provider to review. A weakness of this system is the MAs have no official training on immunizations; therefore, the provider still has to review the immunization history and authorize the immunization administration.

CPEs and WCCs are scheduled for 30 minutes for the MDs and 40 minutes for the NP and PA; otherwise, patients are scheduled every 15 minutes for the MDs and every 20 minutes for the NP and PA. A weakness of the schedule is frequently patients come in for an acute office visit and they are behind on their CPEs and WCCs. Providers frequently turn the visit into the longer visit and the patient is still in the shorter visit slot. This puts limits on the amount of time that can be spent with the patient to discuss the HPV vaccine.

If a patient needs to return to the office to complete the HPV vaccine series there is already a postcard reminder system in place. The provider indicates when the patient needs to return for the vaccine in the check-out box within the EMR. Once the visit is concluded, the patient goes through a check-out procedure at the check-out window. Check-out is done by a front office staff member who sees the patient needs to return for vaccine administration and creates a reminder postcard for the patient. This postcard gets placed in a corresponding folder system and the post card gets mailed to the patient in the month that the vaccine is needed.

If a patient has been seen in the office within the last year for a CPE or WCC they can come in for a “nurse only” visit and receive the HPV vaccine series without seeing a provider. Although the MAs have no official training on administration intervals of the HPV vaccine, the MAs are provided with the CDC guidelines for the vaccine. The providers have confidence that the MAs follow these guidelines and allow them to sign orders for the vaccine under the patient’s provider name and administer the vaccine during a nurse visit without prior authorization.

In addition to the clinic providers, MAs and the front office staff, members from the IT department will be important collaborators when it comes to generating the data and lists needed for this project. In the past, the IT department has created reports for the office that have identified patients needing mammograms, colonoscopies and other “Best Practice” items so it is anticipated the reports needed for this project can be generated. There will be minimal costs associated with this project since it will utilize resources that are already in place within the organization.

Weaknesses in the setting that may have a negative impact on the project are engaging a busy staff that together can see over 100 patients a day. Strengths include the providers and staff are committed to doing the right thing for patients and they work collaboratively together to achieve daily goals. Vaccinating children is among the highest priorities in the office; therefore, it is anticipated that all providers and staff will be willing to participate in this project. Strong communication with staff regarding the goals of this quality improvement project and using systems that are already in place such as the EMR and the patient reminder postcard system will ensure its success.

Population and Sample

The population for this project is the group of five providers, MAs and office staff at MFC. The providers will receive an educational focused intervention; the MAs will provide the patients with educational information and support the remind/revisit component; and the front office staff will support the remind/revisit component. The PD will provide information about the project to providers and staff at a staff meeting. There is no exclusion criterion. While not part of the project population, the patient population includes anyone who comes into the office and is due for the HPV vaccine.

Planning the intervention

A brief review of the Stetler Model includes: Phase I (preparation) in which the purpose of the study was determined based on literature review as well as a perceived low HPV vaccination rate at MFC; Phase II (validation) a literature review was completed and determined that there is evidence for continuation; Phase III (comparative evaluation/decision making) was completed and the PD made an evaluation of the best fit of evidence from all validated sources and determined it was feasible to apply the findings into practice, based on applicability criteria; Phase IV (translation/application) applies to this part of the project when the PD focuses on the implementation process beginning with the confirmation of the type and level of use. Operational details will be specified as to who should do what, when and how. In Phase IV, a decision is made regarding whether to use or to consider use of the evidence (Rycroft-Malone & Bucknall, 2013; Stetler, 2001).

The goal of the project is to improve HPV vaccination rates for patients at MFC. The outcome objectives include:

1. Health care providers and staff will develop a protocol/algorithm for consistent and efficient patient/parent education and recommendations regarding HPV/HPV vaccination and administration of HPV vaccine during the first month of the project.
2. Health care providers will report a 50% increase in confidence, from baseline, in addressing the HPV vaccine with parents and patients.
3. Health care providers will report a 50% decrease in barriers, from baseline, in discussing the HPV vaccine with parents and patients.
4. In the 3 months following implementation of the protocol there will be a 30% increase from baseline in HPV vaccination rates

The project timeline is as follows:

Summer 2016

- The PD will develop an educational PowerPoint presentation for providers to address strategies for improving HPV vaccination rates and reducing barriers.
- The PD will develop a draft protocol/algorithm for patient/parent education, recommendations, and administration of HPV vaccine.
- The PD will create pre and post education surveys for providers to assess changes in confidence and perceived barriers in discussing HPV vaccination with parents and patients.
- The PD will develop an informed consent document for providers to participate in study of outcomes of the project.
- The PD will submit an IRB approval application to Ball State University's (BSU) IRB and Franciscan St. Francis Health under the supervision of the faculty advisor.
- The PD will obtain agency and mentor agreements.

August 2016 – September 2016

- The PD will meet with IT to discuss obtaining data regarding current HPV vaccination rates, patients due for HPV vaccination and tracking HPV vaccination rates during the project.
- The PD will meet with BSU Qualtrics survey coordinator to set up pre and post-education surveys for online availability to providers.
- The PD will email the providers the links to complete the pre-education session survey, the informed consent document and the link to the HPV education PowerPoint.
- The PD will meet with the practice providers to review the drafted HPV protocol and patient education packets to allow for any revisions and to get their approval. Barriers to implementation of the protocol will be discussed and plans of action developed to reduce barriers.
- The PD will meet with MAs and front office staff to review the protocol and their role in the implementation.
- After the providers complete the pre-education session survey and the education PowerPoint the PD will email the providers with the link to complete the post-education session survey.
- The PD will continue collaboration with IT to explore strategies to facilitate easier access for providers and staff to patient vaccination status.

October to December 2016

- The MAs will call patients that are due for a HPV vaccine informing them that they are due for the vaccine and that the vaccine is recommended by their provider. Both patients that have not started the series and those that have started the series but have not received

all three doses will be contacted. The patient will be encouraged to make an appointment for the vaccine at the time of the call. In addition, an educational packet on HPV and the HPV vaccine, taken from the Centers for Disease Control and Prevention's website will be mailed to the patient. If the patient is not reached at the time of the call a scripted statement will be included with the packet that contains information on how to contact the office to schedule an appointment to receive the vaccine series.

- The PD will place HPV vaccine education packets in each exam room. During a CPE or WCC, when the MA is rooming a patient and identifies that he/she is due for a HPV vaccine, the MA will give an educational packet to the patient prior to the provider entering the room; in addition, the MA will notify the patient that the provider he or she is seeing that day encourages all patients between the ages of 11-26 to get the vaccine.
- The front office staff will send postcard reminders to patients who received a HPV vaccine and need to return for the 2nd or 3rd dose of the vaccine series, reminders will be provided using the already implemented postcard reminder system.
- The PD will email providers and staff every two to three weeks during implementation to obtain feedback. Barriers will specifically be addressed.

January – April 2017

- The PD will meet with BSU statistician to complete project outcome data analysis.
- The PD will meet with providers and staff three months after project implementation to review HPV vaccination rate data and discuss any changes in the HPV vaccination protocol that are needed. Strategies for ongoing implementation of the protocol will specifically be addressed.

- Project dissemination activities will be completed including: presentation to faculty and classmates; submitting an abstract for a poster presentation at a conference; preparing a poster; and writing a manuscript for journal submission.

Ethical Issues and Privacy

The intervention in this quality improvement project does not include experimental or new/untried interventions; therefore, risks to providers, staff, and patients are minimal. The providers and staff have agreed as a group to implement this quality improvement project. Participation of the providers in study of the outcomes of the project (i.e., pre/post education survey) is voluntary and the provider will be able to decline participation at any time. There is no incentive to participate in the project beyond an improvement of the HPV vaccine rate in the office. Due to the potential conflict of interest for the PD completing the project for academic purposes at the organization where she works, she will not be expected to be paid for the time spent on the project above and beyond the 40 hour work week and the project will not take away from productive patient time or patient care. Any paid time allowed by the organization for participation in the project is at the discretion of the organization.

Provider confidentiality will be protected by only sharing group data and by utilizing anonymous pre and post education session surveys through Qualtrics. Any raw data in paper form will be stored in the PD's locked carrycase. Electronic data will be stored on a password protected computer and only the PD will know the password. Patient confidentiality will be protected in data collection by collecting only aggregate information with no patient identifiers for project data; therefore, there should be no HIPAA compliance issues. The PD will ensure that the aggregate data is collected and kept based on the office's current regulatory requirements.

The PD will obtain a letter of support to conduct the project within the agency from the Director of Operations. The PD will obtain IRB approval from both BSU and Franciscan St. Francis Health prior to starting any aspect of the intervention.

Study of the Intervention

The intended goal of this project is to improve HPV vaccination rates for patients at MFC. The intervention includes implementation of a provider educational program on HPV and the HPV vaccine and implementing a protocol that offers patient/parent education and recommendations regarding the vaccine.

Project Outcome Objectives

5. Health care providers and staff will develop a protocol/algorithm for consistent and efficient patient/parent education and recommendations regarding HPV/HPV vaccination and administration of HPV vaccine during the first month of the project.
6. Health care providers will report a 50% increase in confidence, from baseline, in addressing the HPV vaccine with parents and patients.
7. Health care providers will report a 50% decrease in barriers, from baseline, in discussing the HPV vaccine with parents and patients.
8. In the 3 months following implementation of the protocol there will be a 30% increase from baseline in HPV vaccination rates.

Project Study Questions

1. Does use of the Stetler model facilitate the development of a protocol/algorithm for consistent and efficient patient/parent education and recommendation of administration of HPV vaccine?

2. Does delivering provider education on HPV and the HPV vaccine increase provider confidence in addressing the HPV vaccine with parents and patients?
3. Does delivering provider education on HPV and the HPV vaccine decrease provider's barriers in discussing the HPV vaccine with parents and patients?
4. Does implementation of an evidence-based protocol/algorithm for consistent and efficient patient/parent education and recommendation of administration of HPV vaccine increase the HPV rate in a Family Practice Setting?

Study Design

The proposed project will use a pre and posttest, quasi-experimental design for study of outcomes. This design is appropriate because the study of outcomes lacks components of a true experiment; it does not have one or two concurrently administered treatments or randomly assigned subjects. The existence of a randomly selected control group is the gold standard and provides the best evidence for determining whether projects have intended causal effect; however, this type of design is not feasible for this project (Cicutto, Dingae & Langmack, 2014). The pre and posttest design for this project is one of the more commonly used designs; however, it has threats to the study validity. Change in posttest scores might be due to memory of questionnaire items in addition to the effect of the educational treatment and evaluation apprehension (Grove, Burns & Gray, 2013). Additional factors impacting the internal validity of the project include: staffing issues (unexpected leaves of absence), technological problems (problems with the EMR), and/or history effect. An external validity factor is the sample size is small making it hard to be generalized to a larger group. In addition, one may consider the project setting a factor. The project is designed around a Family Practice setting; therefore, providing a detailed description of the project will help the reader replicate it to other practices.

Methods of Evaluation Outcome Objectives

The first objective of this project will be met by the completion of a written protocol/algorithm for providing patient/parent education and administration of the HPV vaccine. The quality of a system is often improved when objectives and methods are clearly thought through and described in a written protocol (CDC, 2015c). The protocol/algorithm developed for this project may be amended during and after completion of the project depending on feedback and the project outcome.

The second and third objective of this project will be evaluated by pre and post education survey scores. The survey will be disseminated anonymously by use of the computer software Qualtrics. The software program will facilitate ease of the distribution of the survey via email and has online data storage capability. The PD has access to the email addresses of the potential participants and will send personalized email with a link to the survey site. The PD will develop the pre and post educational survey evaluation instrument. The survey will be a combination of a 10-point confidence ruler and a 5-point Likert scale, which have been found to be valid and reliable (Amirtha & Shalini, 2013; Boudreaux et al., 2012). Responses will include a ruler of 0 being “not confident at all” to 10 being “extremely confident” and a scale of “strongly disagree” to “strongly agree”. It will consist of 20 to 30 questions and will be designed to elicit the providers’ confidence levels and perceived barriers to addressing HPV vaccine with parents and patients. Groves, Burns and Gray (2103) state internal consistency is stronger when using 20 or more questions compared to 10-15 question instruments. The survey questions will directly correlate with the outcome indicators: increasing confidence and decreasing barriers in discussing the HPV vaccine with parents and patients. The pre and posttest design poses a threat to both the validity and reliability of the study; however, half of the statements will be expressed

positively and half will be expressed negatively to avoid inserting response-set bias. Response-set bias is when the participant answers all the questions either consistently positive or negative (agree or disagree) (Grove, Burns & Gray, 2013).

Face validity means the instrument looked like it was valid or gave the appearance of measuring the construct it was supposed to measure. Face validity has been known to be subjective and is considered to be a weak form of validity (Grove, Burns & Gray, 2013). Face validity will be met by the providers of MFC completing the pre and post survey. The PD plans to determine content validity of the instrument by using only evidence from literature and content experts when developing the instrument; in addition, having the content reviewed by a BSU doctorate of nursing program faculty member.

The fourth objective will be evaluated by the PD collaborating with IT to obtain pre and post intervention HPV vaccination rates for the practice. The data collected will be broken down by which vaccine has been received in the series (vaccine initiation, 2nd shot, 3rd shot) and whether the vaccine was offered to the patient/parent but declined. Data collected will be only aggregate information with no patient identifiers. The PD will ensure that any data in paper form will be stored in a locked carrycase. If it is electronic data it will be stored on a password protected computer and only the PD will know the password. To manage data the PD will develop a plan for data collection and management and consult with the BSU statistician for data entry.

Phase V of the Stetler model focuses on the evaluation of the expected outcome relative to purpose of seeking evidence and whether the evaluation is related to a direct “use” or “consider use” decision. The evaluation of the “consider use” option requires pilot testing to enable further evaluation of the feasibility of the change in practice. Pilot data are then used to

decide whether the evidence will be formally used. In the case of a “use” decision, the implementation process will be formally evaluated (Rycroft-Malone & Bucknall, 2013; Stetler, 2001); therefore, if the data collected during the project results in meeting the project objectives a recommendation for a continued practice change will be made.

Methods of Data Analysis

Descriptive and inferential statistics will be utilized to analyze the data from the pre and post surveys and on the HPV vaccination practice rate prior to and three months post intervention. A BSU statistician will be consulted for assistance in setting up the data collection format for the surveys and vaccination rate information, data analysis, the interpretation and explanation of the data findings.

All quantitative data will be analyzed using descriptive statistics. To understand the comparison between the pre and posttest measurements the data obtained from this and the vaccination rates will be entered into a statistical program. Interval/ratio data will be collected and a t-test will be used to test for significant differences between the data. A t-test is a common parametric analysis to examine differences between pre and posttest measurements. (Grove, Burns & Gray, 2013). The small sample size and short time frame are limitations of this project; however, the effect of this project may provide a framework for larger studies with longer data collection periods.

Methods of Evaluation – Process Objectives

The process objectives for this project including responsible party, process participant(s) and the expected date of process objective completion are illustrated below in Table 1. The PD will maintain a detailed log of the project objectives, the dates in which the objectives are completed and any necessary revisions that occur.

Project Timeframe Table

Objectives	Responsible Party	Process Participants	Expected Date of Completion
1. Development of PowerPoint presentation for providers to address strategies for improving HPV vaccination rates and reducing barriers.	Project Director	Project Director	June 10, 2016
2. Develop a draft protocol/algorithm for patient/parent education, recommendations and administration of HPV vaccine	Project Director	Project Director	June 24, 2016
3. Create pre and post education surveys for providers to assess changes in confidence and perceived barriers in discussion HPV vaccination with parents and patients	Project Director	Project Director	July 8, 2016
4. Create an informed consent document for providers to participate in study of outcomes of the project	Project Director	Project Director	July 8, 2016
5. Obtain letter of support from appropriate representative for Franciscan's St. Francis Health	Project Director	Project Director Agency Representative	July 8, 2016
6. Submit IRB approval application to BSU's IRB and Franciscan's St. Francis Health under supervision of the faculty advisor	Project Director & BSU Faculty Advisor	BSU's IRB Board and St. Francis Compliance Officer	July 15, 2016
7. Obtain agency and mentor agreements	Project Director	St. Francis Compliance Officer and Medical Director of Quality	July 29, 2016
8. Meet with IT to discuss obtaining data regarding current HPV vaccination rates, patients due for HPV vaccination and tracking HPV vaccination rates during the project	Project Director	Project Director and IT representative	September 9, 2016

9. Meet with BSU Qualtrics survey coordinator to set up pre and post education surveys for online availability to providers	Project Director	Project Director and BSU Qualtrics Coordinator	September 16, 2016
10. Obtain informed consent from providers to participate in study of outcomes of the project	Project Director	Providers of MFC	September 23, 2016
11. Email the MFC practice providers the link to complete the pre-education session survey and the link to the HPV education PowerPoint	Project Director	Project Director and MFC Providers	September 23, 2016
12. Meet with the MFC practice providers to review the drafted HPV protocol and patient education packets to allow for any revisions and to get their approval	Project Director	Project Director and MFC Providers	September 30, 2016
13. Meet with Medical Assistants (MAs) and front office staff at MFC to review the protocol and their role in the implementation	Project Director	Project Director, MA's and Front Office Staff	September 30, 2016
14. Email MFC providers with link to complete the post-education session survey	Project Director	Project Director and MFC Providers	October 7, 2016
15. Patients will be called that are due for a HPV vaccine informing them that they are due for the vaccine and the vaccine is recommended by their provider.	Medical Assistants	Medical Assistants	October 14, 2016
16. HPV vaccination education packets will be placed in each exam room and will be given to each patient that is identified as needing the vaccine.	Project Director and Medical Assistants	Project Director and Medical Assistants	October 14, 2016
17. Emails will be sent to the MFC providers every two to three weeks during the implementation of the project to obtain feedback. Barriers will be specifically addressed.	Project Director	Project Director and MFC Providers	October, 14 & 28, 2016 November, 11 & 25, 2016
18. Meet with BSU statistician to complete project outcome data analysis	Project Director	Project Director and BSU Statistician	January to April, 2017
19. Meet with the providers and staff three months after project	Project Director	Project Director and	April 2017

<p>implementation to review HPV vaccination rate data and discuss any changes in the HPV vaccination protocol that are needed.</p>		<p>MFC Providers</p>	
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Appendix A

Informed Consent Table

Heading	Content (Use Exact Wording)	Notes
Project Title	Increasing the HPV Vaccination Rate in a Family Practice: A Quality Improvement Project.	
Project Purpose and Rationale	<p>The purpose of this quality improvement project is to identify barriers in practice to recommending the HPV vaccine and to use this information to develop and implement a practice protocol to enhance the delivery of the vaccine series.</p> <p>In 2013, the CDC estimated that increasing HPV vaccination rates from current levels to 80% would prevent an additional 53,000 future cervical cancer cases among girls who were 12 years old or younger. In addition, thousands of cases of other HPV associated cancers would likely be prevented. Missed clinical opportunities are the most important reason why the US has not achieved higher rates of HPV vaccine uptake. Many vaccine-eligible adolescents do not receive the HPV vaccine during visits with their healthcare providers. Studies have shown that healthcare providers have the greatest influence on whether or not a parent decides to vaccinate their children for HPV.</p>	
Inclusion/Exclusion Criteria	Because you are a health care provider who provides direct care to patients in the age of HPV vaccine need; 11 to 26 years, you are being asked to participate in this quality improvement project. You are eligible to participate in this project if you are 18 years of age or older are a health care provider (physician, nurse	

	<p>practitioner or physician assistant), at Mooresville Family Care, in Mooresville, Indiana.</p>	
<p>Participation Procedures and Duration</p>	<p>Please read the informed consent and then decide if you would like to participate in this project.</p> <p>As a participant in this quality improvement project you will be asked to:</p> <ol style="list-style-type: none"> 1. Complete an anonymous 20 question pre-intervention survey on confidence in recommending the HPV vaccine and barriers to recommending the vaccine on Qualtrics (the link to the survey is provided in the email invitation to participate in the project). 2. View a 15 slide PowerPoint presentation of the HPV vaccine and ways to overcome barriers to recommending the vaccine series (the link to the PowerPoint presentation is attached to the e-mailed invitation to participate in this project). 3. Complete an anonymous 20 question post intervention survey on Qualtrics after viewing the PowerPoint presentation (the link to the survey is provided in the email invitation to participate in the project). <p>I estimate that it will take 20 minutes or less to complete each of the surveys and 15 minutes to view the Power Point presentation.</p>	
<p>Audio or Video Recordings (if applicable)</p>	<p>n/a – participants will not be audio/video taped.</p>	

Disclosure of Alternative Procedures (procedure for those who do not participate)	n/a	
Data Confidentiality or Anonymity	<p>The information you provide on the Qualtrics surveys will be anonymous; there is no identifying information requested.</p> <p>The project director will be conducting chart audits to assess for HPV vaccine administration 3 months prior and 3 months after to the PowerPoint education presentation. The chart audits will not identify specific providers or patients. The chart audit data will include: patient birth year; if a HPV vaccine was received; if a HPV vaccine was received what number it was in the series; if a HPV vaccine was offered and declined. All data reported from the chart audits will be in aggregate form.</p>	
Storage of Data (include data retention)	<p>All chart audit data will be kept confidential in a locked file accessible only to the project director at the office site. All survey data will be stored on a password protected computer only accessible to the project director. The results of this project may be published and/or discussed in an education setting; no patient or provider names will be identified in any of the written materials used in this project. All data will be destroyed within one year after the project is completed.</p>	
Risks or Discomforts	<p>There are no known risks for participants Your participation in the Qualtrics surveys will be anonymous.</p>	
Who to Contact if Experience	<p>There are no perceived risks for participating in this</p>	

any Negative Effects from Participation	study.	
Benefits (only direct benefits to participant)	There will be no direct benefits to you for participating in this project. However, participation may improve the HPV vaccine rate in your practice.	
Voluntary Participation Statement	<p>You do not have to participate in this study. If you decide not to participate, there is no penalty. As a provider of Mooresville Family Care you can still view the PowerPoint presentation without completing the surveys.</p> <p>There is no monetary reward or cost for being part of this project.</p>	
IRB Contact Information	If you have any questions about your rights as a volunteer in this project, contact the Office of Research Integrity, Ball State University, Muncie, IN 47306, 765-285-5070	
Consenting Statement /Signatory Area	By completing and submitting the surveys on Qualtrics, you are agreeing to participate in this project.	
Project Director and Faculty Advisor Contact Information	For any questions or concerns, please feel free to call the project director, Jacki Stroud at 317-750-5409 or stroud2@bsu.edu . Faculty Advisor is Beth Kelsey, EdD, APRN, WHNP-BC at Ball State University, Muncie, IN, 304-940-9022, bkelsey@bsu.edu .	

Appendix B

Outcomes Evaluation Tools Table

List your Project Outcome Objectives	List the Types of Evaluation Tools You Plan to Use for Each Outcome	Rationale for Using Each Type of Tool
<p>1. Health care providers and staff will develop a protocol/algorithm for consistent and efficient patient/parent education and recommendations regarding HPV/HPV vaccination and administration of HPV vaccine during the first month of the project.</p>	<p>The protocol/algorithm will be completed and implemented. The PD will meet with staff every 2-3 weeks during implementation to obtain feedback that they are following protocol and to make any necessary changes to the protocol.</p> <p>Evaluation Tools – minutes from staff meetings related to the protocol/algorithm. This will document staff review and feedback on the protocol and any revision made.</p> <p>The final product will be a written protocol/algorithm for the practice.</p>	<p>Prior to the project a HPV vaccine protocol and patient education materials on HPV and the HPV vaccine were nonexistent.</p>

2. Health care providers will report a 50% increase in confidence, from baseline, in addressing the HPV vaccine with parents and patients.	Pre and post intervention survey	Surveys elicit provider’s confidence levels and approach to HPV vaccine recommendations before and after the project intervention.
3. Health care providers will report a 50% decrease in barriers, from baseline, in discussing the HPV vaccine with parents with parents and patients.	Pre and post intervention survey	Surveys elicit provider’s perceived barriers in discussing the HPV vaccine before and after the project intervention.
4. In the 3 months following implementation of the protocol there will be a 30% increase from baseline in HPV vaccination rates.	Chart audit	To evaluate the effectiveness of the project.

Complete the following tables that correspond with the evaluation tools you plan to use

Questionnaires – Pre and Post Intervention

What You are Planning to Assess	Yes or No	If yes, list the specific content that should be covered in the questionnaire	What types of response sets will you use? (e.g., open ended, close ended, Likert scale, rating scale, semantic differential scale – refer to Burns and Grove textbook). Provide rationale
Do you want to assess changes in knowledge?	No		
Do you want to assess changes in attitudes?	Yes	Confidence in addressing the HPV vaccine with parents and patients	10-point Confidence Ruler. Boudreaux et al. (2012) state the use of a confidence ruler for motivation assessments can be used on clinicians in primary care settings by asking few easy-to-understand questions. These questions can be re-administered over time and maintain their reliability and validity and are considered the most useful to predict behavior change in a health care setting.
Do you want to assess changes in intent to perform	No		

a particular behavior?			
Do you want to assess changes in satisfaction with care?	No		
Do you want to assess something else? - explain		Providers perceived barriers in discussing the HPV vaccine with parents and patients.	5-point Likert scale. Amirtha and Shalini (2013) used the Academic Behavioral Confidence (ABC) scale (a 5-point Likert scale) to assess the confidence level in academics among secondary school students. The scale was found to be both reliable and valid to measured self-efficacy in six areas in academics.
//////////	////	//////////	//////////
//////////	////	Provide Answer and Rationale	//////////
How will your questionnaire fit with your project theoretical/conceptual model framework?	////	The Stetler model is a well-known process model (or action model) used to describe or guide the process of translating research into practice (Rycroft-Malone & Bucknall, 2013). The translation of research knowledge into practice implies a need for change in providers' behavior to enable adoption and use of the new research-based knowledge (Pimjai, 2015). The questionnaire is designed to assess provider's readiness to change and behavior change before and after the intervention.	//////////
How do you plan to disseminate the questionnaire?	////	The questionnaire will be disseminated anonymously via email using the software program Qualtrics.	//////////
Are you planning to use an existing questionnaire? If yes answer these	///	The questionnaire will be designed from information obtained from literature and content experts such as the CDC, Healthy	//////////

<p>questions – What is the source of the questionnaire? Is there any reliability/validity information? Are you planning to use the entire questionnaire or only some of the questions?</p>		<p>People 2020 and the American Academy of Pediatrics. The survey will be reviewed by both the PD’s project mentor (a Family Practice Physician and Director of Quality) and a BSU doctorate of nursing program faculty member.</p>	
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Provide 5 questions with response sets you plan to include in your questionnaire.

<p>1. How confident are you in discussing the different types of HPV viruses with your patients and your patient’s parents? 0 being not confident at all and 10 being extremely confident</p>
<p>2. How confident are you in discussing the different types of cancers associated with HPV infections with your patients and your patient’s parents? 0 being not confident at all and 10 being extremely confident</p>
<p>3. How confident are you that you can respond to a patient’s questions regarding the safety of the HPV vaccine? 0 being not confident at all and 10 being extremely confident</p>
<p>4. It is difficult to find the time to address patient and parent concerns about the HPV vaccine. 1 being strongly disagree and 5 being strongly agree</p>
<p>5. I feel recommending the HPV vaccine to my patients is important. 1 being strongly disagree and 5 being strongly agree</p>

Chart Audits – Pre and Post Intervention

<p>What You are Planning to Assess</p>	<p>Yes or No</p>	<p>If yes, list the specific content that should be addressed in the chart audit.</p>
<p>Do you want to assess changes in healthcare provider behaviors?</p>	<p>No</p>	<p>Not by chart audits</p>
<p>Do you want to assess changes in patient outcomes?</p>	<p>Yes</p>	<p>HPV vaccination rate pre and post intervention (broken down by vaccine initiation, 2nd shot, 3rd shot). Information about vaccine being recommended by the provider but declined by the patient/parent will also be captured (if it is possible).</p>
<p>Do you want to assess something else? Explain</p>	<p>No</p>	

Do you need to include demographic information on patients as part of your assessment?	Yes	HPV vaccination rate by gender pre and post intervention; to see if providers are more likely to offer the vaccine to female or male patients. HPV vaccination rate by age pre and post intervention; to see if providers are more likely to offer to vaccinate to older patients within the 11-26 age range.
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Chart Audit Process	----- -	Provide Answer and Rationale
How will you choose which charts to audit?	----- -	All charts in the targeted age group (11-26 years).
How will you choose the number of charts and time span of when patients were seen for pre and post intervention audit?	----- -	All charts for patients in the targeted age group 3 months prior to the intervention and then 3 months post intervention.
Who in the clinical setting is responsible for monitoring HIPAA compliance?	----- -	IT monitors all data/HIPAA compliance.
How will you access the charts for your audit?	----- -	IT will run the reports.

Other Evaluation Tools /Instruments /Methods

What You Are Planning to Assess	Provide Answer and Rationale
What tool/instrument/method are you planning to use?	n/a
What information do you want to obtain and from whom? List specific content.	
How will this information apply to the evaluation of your project outcomes?	

How will this information fit with your project theoretical /conceptual model framework?	
How do you plan to disseminate or implement this tool/instrument/method?	

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