Improving First Dose Administration of the HPV Vaccine for Adolescents in a Pediatric Primary Care Clinic

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The document mentioned above has been reviewed and accepted by the student’s advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student’s DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

Scarlett Mikesell-Pierce, Student

Dr. Elizabeth Tovar, Advisor
Improving First Dose Administration of the HPV Vaccine for Adolescents in a Pediatric Primary Care Clinic

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

at the University of Kentucky

By

Scarlett G Mikesell-Pierce, RN, BSN

New Albany, IN

2020
Abstract

BACKGROUND: Nationwide more than 90% of cervical cancer cases are caused by the human papilloma virus (HPV). Cervical cancer can be largely prevented by administration of the HPV vaccine for children before becoming sexually active. However, vaccination rates in the United States, remain low at 60%, and only 39.7% through series of completion, despite the strong evidence to support the effectiveness of the HPV vaccine. Research indicates a clinician’s recommendation, providing information and opportunity for discussion about the vaccine are strong motivators for parents to vaccinate their children, regardless of ethnicity. This study addresses the barriers to parent/caregiver intent to vaccinate, and clinician time to discuss the vaccine, by implementing an RN-led educational intervention regarding the HPV vaccine for 11-17 year-old children.

Purpose: The purpose of this study is to evaluate the effect of an RN-led educational intervention on 1) parent/caregiver intent to initiate the HPV vaccination 2) to evaluate effect on HPV vaccination rates, and 3) evaluate satisfaction with the education provided in a pediatric primary care clinic.

Methods: The design was a multi-phased quasi-experimental pre/post baseline assessment study that had 4 phases: a chart review (Phase 1), a study introduction (staff meeting: Phase 2), an educational intervention (Phase 3), and an outcome evaluation (Phase 4). The RN-led education intervention focused on the caregiver of adolescent children to address questions and barriers regarding the HPV vaccine. The setting for all phases of the study were done at a pediatric primary care clinic in Southern Indiana. The clinic is responsible for the management and treatment of pediatric patients. The sample for the study included: any caregivers of 11-17 year-old children being seen in the office for a non-acute visit. These children had never received any
doses of the HPV vaccine and were English speaking. Exclusion criteria was any caregiver of a 11-17 years of age being seen for a sick visit, or any that had previously received any dose of the HPV vaccine. Evaluation methods included: chart audit tool that recorded child demographics, information on HPV counseling provided, a pre- and post- educational survey to measure knowledge, intent to vaccinate, and evaluation of the educational intervention.

**Results:** Pre- intervention surveys indicated most parents had heard of HPV vaccinations (80%), knew that it was recommended (87%), and felt it was part of cancer prevention (100%). While scores increased, there were no significant differences between pre- versus post-educational intervention surveys in caregivers who intended to have their child receive the vaccination today (M=4.3 vs M=6.7) or in the future (M=5.9 vs 6.9). The HPV vaccination rates for the initial dose of the vaccine increased from 19.1% to 40.8%, and for any dose from 58.4% to 64.3%. These results indicate the clinic surpassed their goal of 60% after the intervention was provided. Post-survey results showed caregiver evaluation was favorable when measuring satisfaction and helpfulness with educational intervention provided. Vaccination rates improved after a 1:1 brief educational discussion between the caregiver and the RN; this finding suggests that the 1:1 interaction to discuss facts and answer questions may be associated with improved vaccination rates.

**Conclusion:** HPV vaccination rates increased after a brief educational intervention regarding the HPV vaccine was provided to caregivers of 11-17 year-old children. This finding suggests that education may have been beneficial; however, overall vaccination rates were still low and the need for improvement remains. Future work should seek to identify which specific elements of this intervention contributed to the success and strategies to sustain the improvements as well as
identify additional strategies to further improve vaccination rates. An important next step is to initiate efforts to increase vaccine series completion rates.
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Introduction

More than ninety percent of cervical cancer cases are caused by the human papilloma virus (HPV). The Center for Disease Control (CDC; 2019) reports 300,000 cervical precancerous cases, 44,000 cervical cancer cases, and 4,000 deaths related to HPV every year in the United States. Human Papilloma Virus affects men as well as women. Every year in the U.S 25,000 women and 19,000 men get cancers caused by HPV, comprising nearly four out of every ten cancer diagnoses caused by the virus (CDC, 2019). Cervical cancer was once the leading cause of cancer deaths among women in the U.S., but the HPV vaccine and cervical cancer screening have made it one of the most preventable cancers. Screening alone will not protect men or women from HPV cancers. The HPV vaccination helps prevent these cancers by preventing the infections that cause them (CDC, 2019).

Cancers and diseases secondary to the human papilloma virus (HPV) may be prevented through the administration of the HPV vaccination. However, vaccination coverage percentages remain below the standards set by the Healthy People 2020 initiatives (Harris, 2017). These initiatives set a goal that 80 percent of adolescent boys and girls from ages 13 to 15 years should receive the three-dose series of the HPV vaccine through completion (Smulian, Mitchell, & Stokley, 2016). At present, however, approximately only 60 percent of girls and boys ages 13 to 17 years have received only one dose of the vaccination; and only 39.7% received the vaccination through to completion of all three doses (Smulian, Mitchell, & Stokley, 2016). In 2014, the rates among boys aged 13 to 17 years were considerably lower with 41.7% receiving only the first dose, and only 21.6% completing the three-dose series (Smulian, Mitchell, & Stokley, 2016). Therefore, it is imperative that primary care providers work toward efforts to increase vaccination coverage.
In a 2014 study, Holman found that lack of parental knowledge of vaccination was a major barrier to providing the HPV vaccine to adolescents. For example, a significant number of parents in that study reported needing more information before vaccinating their children. The parents voiced concerns about the vaccine’s effect on sexual behavior and demonstrated a low perception of their children’s risk of contracting HPV. These parents also identified social influences, irregular preventive care, and vaccine cost as potential barriers. Additionally, some parents of sons reported not vaccinating their sons because of the perceived lack of direct benefit. Parents consistently cited health care professionals’ recommendations as one of the most important factors in their decision to vaccinate their children (Holman, 2014). In a 2011 study, the proportion of physicians who reported “always” recommending HPV vaccine was 40% for early adolescent girls, 55.3% for middle adolescents, and 51.8% for late adolescents/young adults (Vadaparampil, 2011). A study from the CDC (2019) states that providers identified that limited staff resources, challenges of electronic health records, issues with state immunization registries, patient misinformation about vaccines and vaccine stigma, cultural/language barriers, competing priorities, levels of funding, staff buy-in, training needs, and low health literacy were barriers to recommending the HPV vaccine (CDC, 2019).

Continued efforts are needed to ensure that health care professionals and parents understand the importance of vaccinating adolescents before they become sexually active. Research suggests that further efforts are also needed to reduce missed opportunities for HPV vaccination when adolescents interface with the health care system. A study from the American Academy of Pediatrics (2014) concluded that many missed opportunities for HPV vaccination occur not because parents and providers feel that vaccination is unimportant but because both parties tacitly agree to delay vaccination until there is a perception that the adolescent is at risk
for sexual activity (AAP, 2014). Health care professionals may benefit from guidance on communicating HPV recommendations to patients and parents. Dempsey (2019) and Chuang (2017) suggest future practices should include continuing education for providers on the importance of educating parent/caregivers of adolescents ages 11-17 years old using improved information technologies (IT) techniques (Dempsey, 2019). Chuang (2017) also recommends placing posters and prompts in the exam rooms and in their individual office spaces as a way of providing additional education on the vaccine to parents/caregivers.

**Purpose**

This project was initiated to improve rates of the administration of the HPV vaccination in the pediatric primary care setting. The setting for the study was the St. Vincent Pediatric Clinic in Salem, Indiana. The clinic identified that at their current 58.4% vaccination rate, they were falling short of their goal of 60% of patients receiving the HPV vaccine each month. The ultimate clinic target goal was set at 80% to meet the Healthy People 2020 goal of and 80% HPV vaccination rate (Harris, 2017). The providers at the clinic verbalized the need for an intervention to aid in meeting their target monthly goal. They recommended patient/caregiver education because they identified the lack of education as a major barrier.

This project implemented and evaluated a parent/caregiver educational intervention to increase intent to vaccinate and evaluate vaccination rates among 11-17- year-old adolescent patients and their caregivers. The specific aims were to evaluate the effect of an RN-led educational intervention on:

1) Caregiver intent to initiate the HPV vaccine for their child

2) HPV vaccination rates for the clinic

3) Satisfaction with the educational intervention provided to the caregivers
Theoretical Framework

The theoretical framework that shaped and contributed best to the design of this study was the Consolidated Framework for Implementation Research (CFIR; Garbutt, 2018). Garbutt (2018) used the CFIR to develop a pragmatic intervention to increase implementation of the HPV vaccine guideline recommendation and HPV vaccination rates in pediatric primary care practices (Garbutt, 2018). The CFIR was used to systematically investigate and characterize factors that may strongly influence vaccine use. Then the Behavior Change Wheel (BCW) and the Theoretical Domains Framework (TDF) were used to analyze provider behavior and identify behaviors to target for change and behavioral change strategies to include in the intervention. The BCW and TDF identified facilitators and barriers to guideline use across the five CFIR domains: most distinguishing factors related to provider characteristics, their perception of the intervention, and their process to deliver the vaccine. The CFIR domains using the theory included: intervention characteristics, outer setting, inner setting, characteristics of individuals, and process. Targeted behaviors using this theory suggested that providers should recommend the HPV vaccine the same way and at the same time as the other adolescent vaccines, to answer parents’ questions with confidence, and to implement a vaccine delivery system (Garbutt, 2018).

According to Garbutt (2018), the intervention should be aimed at improving provider’s capability (knowledge, communication skills) and motivation (action planning, belief about consequences, social influences) regarding implementing guideline recommendations, and increasing their opportunity to do so (vaccine delivery system). Behavior change strategies included: providing more information, adding communication skill training with graded tasks and modeling, feedback of coverage rates, goal setting, and social support. The theory
demonstrates strategies that were combined in an implementation intervention to be delivered using practice facilitation, educational outreach visits, and cyclical small tests of change.

This framework was consistent with goals set forth for this study. Using the CFIR theory and the associated BCW and TDF helped facilitate the development of a pragmatic, multi-component implementation intervention to increase use of the HPV vaccine in the primary care setting. These implementation strategies, according to theory, should be adopted into the primary care offices to increase the use of clinical recommendations towards the HPV vaccine.

**Methods**

The study design was a multi-phased quasi experimental pre/post baseline assessment study that had 4 phases: a chart review (Phase 1), a study introduction (staff meeting: Phase 2), an educational intervention (Phase 3), and an outcome evaluation (Phase 4). The project focused on working with the parent/caregiver of adolescent children to address questions and barriers regarding the HPV vaccine. Providing education and an opportunity to discuss questions and answers with the parent/caregiver may help to overcome knowledge deficit and correct misinformation. Overcoming barriers by providing an educational discussion may have an impact on intent to initiate the HPV vaccination, therefore, leading to an increase in HPV vaccination rates.

**Setting**

The setting for all phases of the study was St. Vincent Pediatric Clinic located in Salem, Indiana. The clinic is part of a large healthcare organization, Ascension Healthcare. Annually, the clinic is responsible for the management and treatment of pediatric patients in Southern Indiana. This clinic is responsible for the management and treatment of pediatric patients. The clinic staff consisted of: two APRN’s, one RN, two MA’s, and a front desk receptionist. On
average between the two providers they see approximately 70 patients per week. The clinic baseline rate of any dose of the HPV vaccine was 58.4%. They were falling short of their goal of 60% of adolescents receiving the HPV vaccine each month with the ultimate goal of reaching the Healthy People 2020 initiative of 80% of the adolescents being vaccinated (Harris, 2017). The providers at the clinic verbalized the need for an intervention to aid in meeting their targeted monthly goal and they suggested caregiver education. The providers identified a lack of knowledge amongst caregivers, and the providers felt they do not have time to discuss the vaccine during the visit. Therefore, this project implemented and evaluated an RN led caregiver educational intervention to increase intent to vaccinate and evaluate vaccination rates in the clinic.

**Sample**

For phase one, a convenience sample of 100 chart reviews were completed on medical records from patient charts dated October 15, 2019 through January 15, 2020 were reviewed to determine the clinic’s baseline HPV vaccination rate. Criteria for inclusion in the educational intervention study were any parent/caregiver of a child 11-17 years of age being seen in the office for a non-acute visit. Exclusion criteria for the study included 1) any parent/caregiver of a child 11-17 years of age being seen for a sick visit, 2) any parent/caregiver of a child that is non-English speaking, and 3) any parent/caregiver of a child that does not meet age criteria of 11-17 years old. Variables that were included in the chart review were whether counseling was provided, who provided vaccine counseling, whether the vaccine was offered by the provider, whether the patient accepted/declined/deferred vaccination, if the vaccine series was initiated, and if it was completed. Gender, age, and race were also recorded. A chart audit tool was used to record this information (Appendix D).
Phase four of the study was done after one month of providing the educational intervention. The follow-up chart review evaluated vaccination rates for adolescents seen in the office by a provider during the time period of January 15, 2020 to February 15, 2020. The post-chart audit included a convenience sample of 100 chart reviews on medical records dated January 15, 2020 to February 15, 2020. The charts were reviewed until a sufficient sample size of 100 was reached. Inclusion and exclusion criteria were the same for both pre- and post- audit chart reviews.

**Procedures**

The study started with a baseline chart review to establish current vaccination rates. The study goal was to educate 120 parents/caregivers on the significance of initiation of the first dose of the HPV vaccine during their well-child exam. The DNP project was implemented at this location to aid in increasing first dose HPV vaccination rates and provide an RN-led educational intervention to improve intent to vaccinate by providing a question and answer session with the parent/caregiver, therefore helping the office increase vaccination rates and reach their current goal.

**Phase 1 – Chart Review**

Phase 1 included a chart review of recent medical records to determine the baseline vaccination rate at the clinic. One hundred medical records were randomly selected from charts dated October 15, 2019 through January 15, 2020 meeting age criteria 11-17 years old until a sufficient sample size of 100 was obtained. Variables that were determined by reviewing the chart included whether vaccine counseling was provided, who provided vaccine counseling, whether the vaccine was offered by the provider, whether the patient accepted/declined/deferred
vaccination, if the vaccine series was initiated, and if it was completed. Gender, age, and race were also recorded. A chart audit tool was used to record this information (Appendix D).

**Phase 2 – Study Introduction/Staff Meeting**

Once the chart review was completed, a staff meeting was held (Phase 2). All staff working in the clinic as providers, nurses, medical assistants, and/or at front desk were invited to attend the staff meeting through flyers posted in the office. There were 6 possible participants including: 2 APRN’s as providers, 1 RN, 2 MA’s, and one front desk receptionist. Invitation to staff meeting attached (Appendix J). All clinic staff were informed of the study using a script as a guide for the discussion (Appendix K). The purpose of the staff meeting was to inform them of the educational intervention that was going to be provided by the PI in the clinic. Educational pamphlets and pre-/post-educational intervention surveys were discussed to familiarize the staff with the content the PI was planning to provide to caregivers.

Additionally, the staff meeting was designed to inform the staff of their current baseline rate of vaccination and to describe the educational intervention and process that was going to be provided by the PI in the clinic. The clinic staff was not involved in conducting the study. Educational pamphlets (Appendix G) and pre-/post-surveys (Appendices E and Appendix F) were discussed to familiarize the staff of the content the PI was planning to provide to parents/caregivers. Any questions the staff had regarding the educational intervention were answered by the PI.

**Phase 3 – Clinic-Led Educational Intervention**

The first contact with the parent/caregiver was the staff member assigned to the front desk of the clinic. A script for the introduction of the study was given to the staff member (Appendix H). The educational intervention planned was outlined by script (Appendix L) with
the parent/caregiver of the adolescent regarding the HPV vaccine. The PI answered any questions the parent/caregiver had regarding the vaccine. The primary investigator reviewed the educational pamphlet (Appendix G) with the patient. Any questions or concerns were addressed during the discussion.

**Step 1.** Staff member at the front desk distributed the cover letter provided (Appendix C). The cover letter was given to the parent/caregiver of adolescents in the identified age group.

**Step 2.** The child and caregiver were placed in an exam room by the medical assistant (MA). The MA provided the educational pamphlet to parent/caregiver (Appendix G). The parent/caregiver was instructed to review the material. The PI was invited in only if the parent/caregiver gave verbal agreement to participate in the study. The RN or MA notified the PI of the verbal agreement. Pre-educational survey (Appendix E) was given to the parent/caregiver per the PI if they were interested in the study.

**Step 3.** The primary investigator ensured that the parent/caregiver understood the study and confirmed by verbalizing understanding, per a verbal response from the parent/caregiver. A verbal response had to include an answer of yes or no to the question: “Do you understand the study?” Answering yes to the question was considered as verbal understanding of the study. The PI requested that the pre-educational intervention survey be filled out prior to beginning the educational intervention with the parent/caregiver.

**Step 4.** The educational intervention occurred prior to the office visit with the provider, after the patient had been roomed and was waiting for the provider. The goal was to speak with the parent/caregiver prior to their interaction with the provider. However, consideration of clinic flow and provider schedules was always a priority, so at times the PI spoke with the parent/caregiver after the provider visit was complete. The PI discussed the vaccine with the
parent/caregiver, using the educational pamphlet as the guide. Any questions regarding the vaccine were discussed. The educational pamphlet was reviewed (Appendix G). The script for this discussion is attached (Appendix L). All questions regarding the vaccine were answered by the PI, who is a licensed RN and DNP-FNP student.

**Step 5.** After discussing the vaccine and addressing all questions the parent/caregiver had, the parent/caregiver of the adolescent was then asked about their intent to vaccinate. The PI provided a post-educational intervention survey to be completed by the parent/caregiver (Appendix F). The decision to vaccinate was documented by the PI. The parent/caregiver was asked to leave the pre-/post-educational intervention surveys in the exam room after the visit to be collected by the PI. If the parent/caregiver chose to receive vaccination, the PI facilitated vaccine initiation by informing the provider who then ordered the vaccine administration to be given by the certified MA/RN.

**Step 6.** The pre- and post-educational intervention surveys (Appendix E and Appendix F) were used to evaluate whether the educational intervention increased first dose administration of the HPV vaccine and was successful in overcoming child/parent knowledge barriers of the HPV vaccine.

**Phase 4 - Chart Review**

After one month of providing the educational intervention to parent/caregivers of the adolescents aged 11-17 years old, a follow-up chart review evaluated post-intervention rates (Phase 4). Data were collected from 100 charts selected by convenience sampling technique to determine if the vaccination goal was met using the same chart audit tool (Appendix D) for post assessment. The charts were selected by convenience sampling technique from children aged 11-17 years old that were seen in the clinic by a provider during the time-period of January 15,
2020 to February 15, 2020. Data were collected from the charts, included patient age, gender, and race, whether counseling was offered regarding HPV vaccination, by whom, whether the HPV vaccine was offered, whether the patient accepted/refused/deferred vaccination, whether the HPV vaccine series was initiated, and whether the HPV vaccine series was completed. Data were collected from the chart audits by the PI. The survey data were entered into SPSS, version 25, and analyzed by a statistician. The St. Vincent (Ascension) Institutional Review Board granted approval (#R20190145) prior to the start of this project.

**Instruments**

**Parent/Child Pre-Educational and Post-Educational Intervention Surveys.**

Parent/Caregiver knowledge of the HPV vaccine and parent/caregiver intent to initiate the HPV vaccination was measured by an investigator-developed instrument called the *Parent/Child Pre-Educational Intervention Survey*. This is a 6-item survey. Two items are answered with “yes/no” responses, two are answered with “true/false” responses, and two are answers with a 10-point Likert-type scale (with 0 being no chance and 10 very likely). The pre-educational survey was designed to measure knowledge of the HPV vaccine and intent to vaccinate prior to the educational intervention. The *Post-Educational Intervention Survey* was the same as the *Pre-educational Intervention Survey* for questions 2-4, and then the post-survey added questions 5-7 that were designed to measure intent to administer the vaccine after an educational intervention was given. The final question asked if the RN led educational intervention was helpful in their decision to vaccinate their child?
Improving Rates of First Dose Administration of the HPV vaccine Chart Audit Tool.

Chart audits were conducted to determine the baseline vaccination rate for the clinic as well as the post-intervention vaccination rate for the clinic. An instrument called the *Improving Rates of First Dose Administration of the HPV Vaccine Chart Audit Tool* was used to ensure consistency in data collection from randomly selected charts. The following information was collected: gender, age, race, whether counseling on the HPV vaccine was provided; whether the HPV vaccine was offered; patient’s response if vaccine was offered; whether the HPV vaccine series was initiated today; whether the vaccine series initiated or completed prior to this visit; and the date documented for doses of the vaccine the child received prior to the study.

**Data Analysis**

Descriptive statistics were used to analyze variables such as age, gender, and ethnicity. HPV vaccination rates were examined pre- and post-educational intervention using Chi-square test. Means of interval variables on the pre- and post-educational intervention survey responses were analyzed using an independent samples t-test. All data analysis was conducted using SPSS, version 25. Microsoft Excel was used to create frequency tables.

**Results**

**Phase 1: Baseline Chart Review**

The sample for the baseline chart audits were predominantly Caucasian (97%, n=97) and female (females 56%, n=56; males 44%, n=44) with the average age of 13.9 years (pre-, n=100, see Table 2). One hundred medical records were charts selected by convenience sampling technique dated October 15, 2019 through January 15, 2020 meeting age criteria 11-17 years old until a sufficient sample size of 100 was obtained. Of the 100 charts selected by convenience
sampling technique, 100% were counseled by the provider who was an APRN, 100% were offered vaccine, and 19.1% (see Table 1) chose to be vaccinated.

The results of the study were based on vaccination rates for those who had not received any of the vaccine series prior to this visit. One hundred four children had received doses of the HPV vaccine through completion. There were 47 eligible charts for the pre-audit. Table 3 presents data for those receiving their initial dose of the HPV vaccine before the intervention. From this total of 47, 9 had been vaccinated pre-intervention, leaving 38 who had chosen not to be vaccinated prior to the intervention.

There were 15 caregivers in the intervention group. Prior to the education intervention, parent/caregivers were given the opportunity to share their knowledge and intent to vaccinate with a pre-educational intervention survey (Appendix E) (Table 5). These parents/caregivers had high knowledge scores in the baseline assessment. In the pre-intervention surveys, most parents knew that it was recommended (80%), and felt it was a part of cancer prevention (100%); see Table 5). Using a scale of 0-10, with 10 being absolutely planning to receive the vaccination that day and 0 not planning on receiving the vaccine at all. To receive the vaccination today (M=4.3) or in the future (M=5.9, Table 2).

Phase 2: Chart Review

The sample for the post-intervention chart audits were predominantly Caucasian (94%, n=94), and evenly split between females and males (females {50% n=50} and males {50%, n=50}), with the average age of 13.6 years (n=100) (see Table 2). Of the 100 charts selected by convenience sampling technique, 100% were counseled by the provider, the counseling was provided by an APRN, 100% were offered vaccine, and 40.8% (see Table 3) chose to be vaccinated.
Following the educational intervention parent/caregivers were given the opportunity to share feedback of the educational intervention (post-educational intervention survey, Appendix F) and their intent to vaccinate (Table 2 and Table 3). After the educational intervention, of those who did not complete their series of vaccination that day (n=96), there was a significant increase from 19.1% (pre-) to 40.8% (post-) who chose to be vaccinated with their initial dose of the HPV vaccine (p=0.21; see Table 1). According to the pre- versus post- educational intervention results, satisfaction overall with helpfulness, on a scale of 0-10 with 10 being the most helpful, parents thought the intervention was helpful (M=9.3, SD=1.3), the pamphlet was helpful (M=9.4, SD 1.3), and the principal investigator discussion was helpful (9.7, SD 1.0) (See Table 5).

The results of the study were based on vaccination rates for those who had not received any of the vaccine series prior to this visit. One hundred four children had received doses of the HPV vaccine through completion. There were 49 eligible charts to review for the post-audit. Table 3 presents data for those receiving their initial dose of the HPV vaccine before and after the intervention. Per the chart reviews out of 49 total, there were 20 post- intervention patients that chose to be vaccinated and 29 chose not to be vaccinated. This shows a significant increase, from 19.1% to 40.8% for those who received their first dose of the vaccine. Unfortunately, there is no way to tell which part of the convenience sample post- intervention received the educational intervention.

Table 4 presents the data for the pre- and post- intervention vaccination rates. Prior to the educational intervention, the clinic reported their vaccination rates at 58.4% of adolescents who had received some or all of their vaccination series. The clinic monthly rate for vaccination for February 2020, following the study, was 64.3% (p= .044), see Table 4). These results indicate the clinic surpassed their goal of 60% after the intervention was provided in the clinic.
Discussion

The purpose of this study was to evaluate the effect of an RN-led educational intervention and the impact of the intervention on the intent to vaccinate and vaccination rates in a specific pediatric primary care setting. The HPV vaccination rates for the initial dose of the vaccine increased from 19.1% to 40.8% (p=.21, see Table 3) and for any dose from 58.4% to 64.3% (p=.044, see Table 4). These results indicate the clinic surpassed its’ goal of 60% after the intervention was provided. The increase in parents/caregivers choosing to vaccinate their child after the educational intervention suggests that the intervention may have led to an increase in vaccination rates. Although this study was not designed to test for causation, it is encouraging that there was a significant improvement in vaccination rates after a brief and simple educational session with the parent/caregivers. Because baseline knowledge scores were already high and perceptions started out positive, it is not likely the parent/caregivers learned new information; however, it is possible that simply discussing the HPV vaccine brought it to the forefront of their attention and thus made them more likely to vaccinate.

The finding of improved vaccination rates for both first dose and consecutive doses of the HPV vaccine are encouraging, however rates are still well below the national goal of 80% (Harris, 2017), and this low rate may lead to preventable morbidity and mortality related to HPV cancers. There could be many reasons for the rates remaining low; including religious or personal beliefs regarding vaccinations, and the lack of understanding of the reasoning behind initiating the series at such a young age (Vadaparamil, 2014). It is also supported in the literature that the barriers that exist can be overcome by increasing education to caregivers.
It is likely that the brief education to caregivers may have played a role with the increase in rates. However, knowledge is a necessary, but not sufficient, precursor to decision-making and future studies should expand beyond just knowledge barriers. Further investigation is needed to identify how to overcome those perceptions and what specific element of the session led to the improvement in rates. Vaccination rates improved after a 1:1 10-15 minute educational discussion between the caregiver and the RN; this finding suggests that the 1:1 interaction to discuss facts and answer questions can improve vaccination rates. Additionally, satisfaction scores when rating helpfulness were high, suggesting positive interaction between the parent/caregiver and provider. Next steps would include how to best incorporate this 1:1 educational opportunity into standard practice.

The finding of low vaccination rates is consistent with the national average of approximately 60% of girls and boys, ages 13 to 17 years who have received only one dose of the HPV vaccination (Smulian, Mitchell, & Stokley, 2016), but it is encouraging that this clinic increased rates from 19.1% to 40.8% (see Table 3), which is now closer to meeting the national average. Another recommendation would be to change the educational intervention to make it more interactive with both the parent and the child (Dempsey, 2019). This educational session took the PI around 10-15 mins to provide. It was an open discussion, although the child was present, the discussion was directed towards the caregiver. During the 1:1 discussion the PI clarified and allowed the parent to ask any questions they had about the HPV vaccine. During the educational sessions some of the barriers, misperceptions, and concerns expressed by the caregivers included: lack of benefit for their child, perception of their child being low risk, they did not understand why the HPV vaccine was initiated at such a young age, and they felt the HPV vaccine was falsely advertised. Using proper engagement methods, aimed towards
involving both participants, is important to ensure both the parent and child understand the education being provided.

The parent/caregiver participants in this study all had good baseline knowledge scores and positive perceptions about the importance of administering the HPV vaccine, which suggests that they are knowledgeable, willing, and able to complete the first dose administration of the HPV vaccine. However, time to provide education regarding the vaccine appears to be a significant barrier that needs to be addressed for the providers in the clinical setting.

In a study by Carhart (2018), time constraint and inconsistent or lack of recommendation by the health care provider (HCP) were found to be barriers to parents’ decision to vaccinate. One stakeholder in the study stated that providers are not making the strong recommendation for the vaccine and organizations are not holding them accountable (Carhart, 2018). This is a barrier in a lot of places, but in the study site the providers recommended it 100% of the time. Therefore, provider recommendation is not a reason for low rates in this clinic, therefore, other factors need to be considered.

The vaccine has had a huge impact on preventing HPV, yet vaccination rates remain low despite the strong evidence to support how it prevents cervical cancers and related morbidity and mortality rates (CDC, 2019). It is essential that we understand factors that influence the decision to vaccinate and implement evidence-based strategies to improve vaccination rates. Several barriers to vaccination were identified in this study may be categorized as; provider- based, patient/caregiver- based, and system- based.

Providers in the clinic recognized that they recommend the HPV vaccine most of the time, but do not have time to discuss these recommendations with parents in depth. Patient/Caregiver barriers found in the literature reported parents needing more information before choosing to
vaccinate their child (Vadaparamil, 2014). Parents in this study reported feeling the vaccination would have a negative effect on sexual behavior and most of them felt that their child’s risk of contracting HPV was low. Other studies (Dempsey, 2019) and (Chuang, 2017), identified more barriers such as; social influences, irregular preventative care, and vaccine cost.

System- based barriers include the absence of reminder systems and problems within the electronic health records. It was identified by (Vadaparamil, 2014) that knowledge and perception of the HPV vaccine directly influenced caregiver intent and decision to vaccinate. Additionally, an evidence-based strategy to improve education and intent includes; offering a 1:1 educational session between the healthcare provider and caregiver (Vadaparamil, 2014). This strategy was used as a focus for this study.

Providers may not offer the vaccine because they do not typically see children in the recommended age group of 11-17 years-old, for wellness visits. When children 11-17 years-old are seen in the office it often occurs after sexual activity has been initiated. Providers acknowledged that it may be difficult for young adults to locate a healthcare provider who will accept and file insurance for the vaccinations.

Another barrier reported (Vadaparamil, 2014) is that the providers have a difficult time getting adolescents to their appointment because they are usually healthy, and the parents do not seek wellness appointments for them. Many providers in the study reported addressing vaccination only at wellness visits; however, a few providers were trying to address it at all visits to avoid “missed opportunities.” Time constraint and the need to prioritize care, however, can limit how much is covered during an acute care visit. Time constraint was addressed in the study by limiting participants to only those seeking wellness, non-acute visits to limit the biasing effect of type of visits on results.
Family practice providers reported too many competing priorities, such as the requirement for patients to have depression screening versus providing vaccination recommendations (Carhart, 2018). Even though providers have the intention of recommending the HPV vaccine, they may lose track and forget to do it (Carhart, 2018). The study site had issues regarding HPV vaccination recommendation. Providers found they had time to recommend the vaccine, but they reported difficulty finding time to provide education or answer questions regarding the vaccine. This may have left the parent/caregiver feeling uncertain at times and not ready to make decisions regarding vaccination, therefore, influencing vaccination rates negatively.

Holman (2014) found that parental attitudes towards vaccination were a major barrier to providing the HPV vaccine to adolescents. For example, a significant number of parents in that study reported needing more information before vaccinating their children. The parents voiced concerns about the vaccine’s effect on sexual behavior and demonstrated a low perception of their children’s risk of contracting HPV. These parents also identified social influences, irregular preventive care, and vaccine cost as potential barriers. Parents consistently cited health care professionals’ recommendations, and the information they provide, as one of the most important factors in their decision to vaccinate their children (Holman, 2014). Vaccination rates for the study clinic improved when the RN provided a 1:1 brief educational discussion. This finding suggests that the 1:1 interaction to discuss facts and answer questions can improve vaccination rates.

In addition, parent/caregivers were very engaged during the educational intervention and appeared to appreciate knowing more about the vaccine. Further investigation is needed to determine what specific element of the educational intervention led to this improvement. Brief education for parents/caregivers may have played a major role in the increased vaccination rates.
Studies have shown that efforts such as increased education to parent/caregivers can increase HPV vaccination rates in the primary care setting (Dempsey, 2019).

The increase in vaccination rates is a positive and encouraging finding from this study; however, the vaccination rates are still low and evidence-based strategies to sustain this improvement with educational opportunities are needed. An example of an effective sustainment strategy that worked well in other settings and would be appropriate in this study’s setting is increasing the use of audio-visual materials and improvement in IT technologies for education. Dempsey (2019) provided an intervention of a digital video in a study, then parents/caregivers viewed the video while waiting for the visit. This research suggested the education by video increased vaccination rates. Another strategy mentioned by Chuang (2017) could be included by using scorecards or monthly provider audits by an appointed team leader in the clinic to help providers keep track of their own vaccination rates. The study site utilizes an appointed leader to track these rates, therefore, contributing to a 100% recommendation rate for the providers in the clinic.

One of the leading approaches as an evidence-based strategy that helped improve HPV vaccination rates in the primary care setting is the use of information technology (IT). Dempsey (2019) found the use of an educational video in the waiting room to overcome knowledge barriers to receiving the HPV vaccine to be particularly helpful in the primary care setting. Clinics could also show an educational video to the parent/caregiver while waiting on the provider. In this study having a dedicated health care professional available to spend time with the parent/caregiver to provide education was effective as suggested by an increase in vaccination rates. The educational intervention did have a positive outcome, though not as
dramatic as anticipated. With a few modifications, the 10-15 minute education intervention could be incorporated in the surrounding pediatric clinics with minimal expenditure of cost or time.

Other evidence-based strategies include empowerment of staff. It is supported in the literature that any staff member, including a trained Medical Assistant (MA), could provide this education. It would cost a clinic approximately $73,000 to assign an RN this responsibility in comparison to a MA, who would cost around $34,000 (Chuang, 2017). Next steps should include how best to incorporate this or similar 1:1 educational opportunity into standard practice for all pediatric clinics. Future practice should include continued education for providers on using improved IT techniques, such as an interactive I-pad, or module that could be done prior to the patient visit to assess knowledge of HPV. In addition, a policy change to consider, would be adding an educational printout to the mandatory school paperwork as a form that both adolescents and their caregivers could review that would provide necessary information regarding the HPV vaccine. These methods are time efficient and provide a collaborative approach that do not overburden the caregiver, provider, or office staff. These are all ways to improve the caregiver intent to vaccinate, therefore hopefully leading to a further increase in vaccinations.

**Implications for Practice**

Review of the literature suggested the need to explore the educational needs and methods utilized to provide education, among a variety of community settings (Chuang, 2017). Research also indicated that knowledge of the HPV vaccine and need for further education was warranted (Chuang, 2017). Implementing a 1:1 educational session may have increased rates for this specific clinic, but a more robust longitudinal study would need to be conducted in the future. Next steps should include how best to incorporate this 1:1 educational opportunity into standard
practice. It is supported in the literature that any staff member, including an MA could provide this education. It would cost a clinic around $73,000 to assign an RN this responsibility in comparison to a MA, which would cost around $34,000 (Chuang, 2017).

An evidence-based strategy that should be considered for practice is training and empowering staff to help streamline the process (Chuang, 2017). Future practice should include continued education for providers on the importance of educating parent/caregivers of adolescents ages 11-17 years old, using improved IT techniques (Dempsey, 2019). One way to remind providers to provide further education on the vaccine would be to place posters and prompts in the patient rooms and in their individual office spaces (Chuang, 2017). Another beneficial method would be for the MA/RN to give the parent/caregiver a copy of an educational pamphlet to review while waiting. Additionally, it would also be worthwhile to implement a tracking measure to monitor screening and education adherence. The study clinic utilizes a team member to track current vaccination rates and report them to providers, but they may benefit from education adherence being added to the electronic health records as a reminder.

Limitations

Limitations of this study included a small sample size of patients seen during this time period for non-acute visits, aged 11-17 years old. It was emphasized by the clinic that their highest numbers of wellness visits occur from April to September; this study period was from October to February. The increase of adolescent visits normally take place from April to the beginning of the new school year due to the need for sports physicals during that time. During the winter months there are an abundance of children seen for sick visits, so the numbers were considerably lower.
The chart review method could have focused only on children that had never received a dose of the HPV vaccine. This result would have provided more concise data aimed towards the focus of this study. Additionally, I did not assign a unique identifier to intervention participants, thus, participants were unable to be matched with survey responses. This collection method would have helped the study match responses to decisions as to whether or not they chose to vaccinate.

In addition, this study took place at only one clinic over a period of a few months. Other settings and/or other populations may have yielded different results. The results were not generalizable due to using a convenience sample. This study took place at only one clinic over a period of a few months. Increasing the study reach to include multiple locations could have increased the number of parent/caregivers willing to participate in the study.

**Conclusion**

In conclusion, more than 90% of cervical cancer cases are caused by the human papilloma virus, and administration of the HPV vaccine to adolescents can reduce or eliminate this risk. However, vaccination rates for HPV among adolescents are still very low, at only 60% vaccinated (Smulian, Mitchell, & Stokley, 2016). A 1:1 educational discussion between the health care provider and the parent/caregiver is an effective evidence-based strategy that has improved vaccination rates in other studies, as well as the study described in this paper. Health care providers are one of the most important factors that influence parental/caregiver vaccination decisions, and we need to make sure there is sufficient time and opportunity for this interaction to occur between the caregiver and the health care provider. In addition to knowledge, misperceptions, and other barriers mentioned in this study, targeted interventions need to be determined and aimed towards eliminating these barriers for future studies.
Patients may only see their primary care provider once yearly or for sick visits, so educating the caregiver on the importance of vaccinating their child during these visits is essential, or they may go unvaccinated. Appropriate screening, overcoming parent/child knowledge barriers, and ultimately administration of the vaccine will decrease the incidence of HPV-related cancers (Harris, 2017).

Health care providers are one of the most important factors that influence vaccination decisions (Holman, 2014). This finding was supported in this study, thus, we need strategies that create ample opportunity for parents/caregivers to receive education and an opportunity for discussion with their health care providers. Because of the significant impact HPV vaccination can have on health outcomes, providers and office staff must continue to make efforts to increase the intent to vaccinate for parents and caregivers. The educational intervention is a brief way of increasing awareness and intent to vaccinate for HPV in the primary care setting. Therefore, it is imperative that primary care providers work toward efforts to increase vaccination coverage. It is essential that health care providers and public health organizations initiate efforts to increase HPV vaccination doses through completion of the two or three-dose series (Smulian, Mitchell, & Stokley, 2016).

In this study after a brief educational intervention that focused on increasing intent to vaccinate, there was an increase in administration of the HPV vaccine. However, vaccination rates were still low and the longer-term vaccination rates remained unchanged. There remains much need for improvement. The preliminary results from this study are indeed promising however in the future, a longitudinal and more robust study needs to be done to see if the educational intervention contributed to this increase in vaccination rates. Future work should seek to identify
which specific elements of this intervention contributed to the success, and strategies to ensure sustainability of these improvements.

References


HPV Cancers. (2019, April 29). Retrieved January 10, 2020, from
HPV Vaccination and Screening. (2013). Retrieved January 12, 2020, from

http://www.uspreventiveservicestaskforce.org/


Appendix A. Educational Intervention Outline

With each non-acute visit meeting age criteria 11-17 years old:

- Supportive staff will provide cover letter and educational pamphlet regarding HPV vaccine to each parent/caregiver at the beginning of the visit.

- The staff will reinforce that the primary investigator will be providing education on the vaccine that same day

- Any questions the parent/caregiver may have will be routed to the primary investigator

- Parent/caregiver will be asked to read cover letter introducing the study. Parent/caregiver will also be requested to read educational pamphlet and decide if they are interested in the study with the PI.

During each visit:

- If parents/caregivers are interested in the study the primary investigator will receive verbal consent and educate willing parent/caregivers on receiving HPV vaccination. The PI will distribute the pre-educational intervention survey prior to starting the educational intervention.

- The primary investigator will collect survey from parent/caregiver prior to beginning the educational intervention.

- The parent/caregiver will be informed of the intent to have the child receive the HPV vaccine that day.

- Any questions the parent/caregiver may have regarding the vaccine will be discussed.

- If the parent/caregiver decide to wait on vaccination, it will be requested that they take the educational pamphlets home with them and set up a future appointment with the provider to discuss vaccine further.
Appendix B. Consent Form

Institutional Review Board

AGREEMENT TO PARTICIPATE IN A RESEARCH STUDY
MEDICAL RESEARCH INFORMED CONSENT

Title of research study: Improving Rates of First Dose Administration of the HPV vaccine

Investigator: Lindsey Brough, NP Primary Investigator and Scarlett Mikesell-Pierce UK DNP student Co-Investigator

PARTICIPANT NAME ________________________________________________

Why am I being invited to take part in a research study?
You are being invited to take part in a research study about overcoming parent/child knowledge barriers to receiving the HPV vaccination. You are being invited to take part in this research study because you are the parent/caregiver of an adolescent patient at St. Vincent Pediatric Clinic, where the study is taking place. All parent/caregivers of patients meeting age criteria 11-17 years old will be invited to participate in this study.

What should I know about a research study?
You will not get any personal benefit from taking part in this study. If you decide to take part in this study, it should be because you want to volunteer. Your adolescent will not lose any benefits or rights they would normally have if you choose not to volunteer. You can stop at any time during the study and keep the benefits and rights you had before volunteering.

Why is this research being done?
The purpose of this study is to increase first dose administration of the HPV vaccine by providing an educational intervention that increases parent/caregiver knowledge regarding the vaccine.
**How long will the research last and what will I need to do?**
The research procedures will be conducted at St. Vincent Pediatric Clinic. The study will take place during normal clinic hours during your scheduled visit at the clinic. You will not be asked to volunteer any additional time.

**Is there any way being in this study could be bad for me?**
The risks to participating in this study may include some emotional discomfort due to the nature of HPV. You may experience a previously unknown risk or side effect of HPV.

**Will being in this study help me in any way?**
You will not get any personal benefit from taking part in this study.

**What happens if I do not want to be in this research?**
If you do not wish to participate, there are no other choices except not to take part in the study.

**Who can I talk to?**
The person in charge of this study is Lindsey Brough, NP from St.Vincent Pediatric Clinic and Scarlett Mikesell-Pierce, BSN, RN of the University of Kentucky, College of Nursing. She is being guided in this research by Elizabeth Tovar, Phd, RN, FNP-C. There may be other people on the research team assisting at different times during the study.

**What happens if I say yes, I want to be in this research?**
You will be asked to participate in an educational intervention that discusses the HPV vaccine. Educational pamphlets will be provided. Any questions regarding the HPV vaccine will be answered and open for discussion.

**What happens if I say yes, but I change my mind later?**
You can leave the research at any time it will not be held against you.

**Is there any way being in this study could be bad for me? (Detailed Risks)**
The risks to participating in this study may include some emotional discomfort due to the nature of HPV. You may experience a previously unknown risk or side effect of HPV.

**What happens to the information collected for the research?**
We will make every effort to keep confidential all research records that identify you to the extent allowed by law.
Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.
We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what the information is. No identifying information will be recorded
with the discussion, and this data will be password protected and only accessed by the principal investigator.
You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else.
Please be aware, while we make every effort to safeguard your data once received, given the nature of online information involving the internet, we can never guarantee the confidentiality of the data while still en route to us.

**Will the researchers benefit from my participation in this study?**
The researchers will not receive any rewards or payment for you taking part in this study.

**What else do I need to know?**
Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Scarlett Mikesell-Pierce (502) 644-7849 or email at scarlett.mikesell@uky.edu. If you have any questions about your rights as a volunteer in this research, contact the staff in the St. Vincent IRB Office at 317-338-2194. We will give you a signed copy of this consent form to take with you.
Your signature documents your permission to take part in this research. Please keep a copy of this Informed Consent for your records.

<table>
<thead>
<tr>
<th>Signature of subject</th>
<th>Date</th>
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<tbody>
<tr>
<td>Printed name of subject</td>
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<tr>
<td>Signature of person obtaining consent</td>
<td>Date</td>
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<td>Printed name of person obtaining consent</td>
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<tr>
<td>Signature of Legally Authorized Representative</td>
<td>Date</td>
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<tr>
<td>Printed name of Legally Authorized Representative</td>
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</tbody>
</table>

Check Relationship to Subject:

- [ ] Legal Guardian or Legally Authorized Representative for Medical Care (LARM)
- [ ] Spouse
- [ ] Adult Son or Daughter
- [ ] Mother or Father
- [ ] Adult Brother or Sister
- [ ] Other, explain:

Reason subject is unable to sign for self:
RESEARCH PATIENT BILL OF RIGHTS

I have been asked to participate in a research study. Before I make a decision on whether or not I want to participate in this study, I have the right:

1. To be told the reason why this study is being done.

2. To be told how the study will be done and what kind of medication or device will be used.

3. To know the different types of side effects to expect from my participation in the study.

4. To know what benefits I will receive from my participation in this study.

5. To be told what other treatment is available for me, including the risks and benefits.

6. To be told what other treatments are available to me after the study has been completed.

7. To be given an opportunity to ask any questions concerning the medical experiment or the procedures involved.

8. To stop the study at any time and know I will continue to receive good care.

9. To receive a copy of the patient rights and the signed and dated informed consent form.

10. To make up my mind about being part of the study without feeling forced to participate.
Appendix C. Cover Letter

Cover Letter

To Participant:

My name is Scarlett Mikesell-Pierce of the University of Kentucky, College of Nursing and I am being guided in research by Lindsey Brough, NP at St. Vincent Pediatric clinic and Elizabeth Tovar, PhD, RN, FNP-C. There are no institution(s) or companies involved in the study through funding or financial support, cooperative research, or by providing equipment or materials for this study.

I am inviting you to take part in a research study about human papilloma virus (HPV) vaccination. You will be asked to complete a short survey/questionnaire before and after a brief educational discussion about HPV vaccination. The surveys/questionnaires will help me to gain information about your understanding and knowledge regarding the HPV vaccine. Each survey will take about 2-5 minutes to complete and the educational discussion will take about 10 minutes. I hope to make evidence-based recommendations from the survey results on ways to increase your knowledge and overcome barriers in the clinic regarding the HPV vaccination.

Although you will not get personal benefit from taking part in this research study, your responses may help us understand more of the barriers that parents/children encounter when recommended the HPV vaccine.

We hope to receive completed questionnaires from all the patients in the identified age group at St. Vincent Pediatric Clinic, and your answers are important to us. Of course, you have a choice about whether or not to complete the survey/questionnaire, but if you do participate, you are free to skip any questions or discontinue at any time. Participation in this study is voluntary, and if you do not choose to complete the survey there will no penalties or loss of benefits. If you do not wish to complete this survey, there are no alternative surveys.

Your response to the survey is anonymous which means no names will appear or be used on research documents, or be used in presentations or publications. Your name will not be recorded on the surveys.

If you have questions about the study, please feel free to ask; my contact information is given below. If you have complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the St. Vincent IRB at 317-338-2194. Thank you in advance for your assistance with this important project. Please complete the pre-education survey if you want to participate in the study.
Sincerely,

Scarlett Mikesell-Pierce, BSN, RN

College of Nursing, University of Kentucky

PHONE: 502-644-7849

E-MAIL: scarlett.mikesell@uky.edu
Appendix D. Chart Audit Tool

Improving Rates of First Dose Administration of the HPV vaccine

Chart Audit Tool

Study number:_______________
Gender:_____________________
Age:________________________
Race:_______________________

At the patient’s 11/12 year old well-child visit, were the following documented:

<table>
<thead>
<tr>
<th>Information</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was counseling on the HPV vaccine provided?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>By: ___ CMA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>___NP/MD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the HPV vaccine offered?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient’s response if vaccine was offered</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>__Accepted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>__Deferred</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>__Declined</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the HPV vaccine series initiated today?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the vaccine series initiated or completed prior to this visit?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Doses given (Y/N)? #1_________           #2__________
To ages 11-14     On-time?  Y/N    Y/N

Doses given (Y/N)? #1_________           #2_________ #3__________
To ages 15-17     On-time?  Y/N    Y/N    Y/N
Appendix E. Parent/Child Pre-Educational Intervention Survey

Parent/Child Pre- Educational Intervention Survey

Please circle your response:

1. Have you heard of the HPV vaccine?       YES       NO

2. The HPV vaccine is recommended for children 11-17 years of age. TRUE FALSE

3. The HPV vaccine is recommended for cancer prevention caused by the human papilloma virus. TRUE FALSE

4. Were you planning on getting the HPV vaccine today? YES NO

5. How likely are you to get the vaccine today? Rate on scale 0-10 (0 being no chance and 10 very likely)
   
   0  1  2  3  4  5  6  7  8  9  10

6. How likely are you to get the vaccine at some point in the future? Rate on scale 0-10 (0 being no chance and 10 very likely)

   0  1  2  3  4  5  6  7  8  9  10
Appendix F. **Parent/Child Post-Educational Intervention Survey**

Parent/Child Post- Educational Intervention Survey

Please circle your response:

1. Are you more familiar with the HPV vaccine? YES NO

2. Were you planning on getting the HPV vaccine today? YES NO

3. How likely are you to get the vaccine today? Rate on scale 0-10 (0 being no chance and 10 very likely)

   0  1  2  3  4  5  6  7  8  9  10

4. How likely are you to get the vaccine at some point in the future? Rate on scale 0-10 (0 being no chance and 10 very likely)

   0  1  2  3  4  5  6  7  8  9  10

5. How helpful was the educational discussion in helping answer your questions regarding the HPV vaccine? Rate on scale 0-10 (0 being not helpful and 10 being very helpful)

   0  1  2  3  4  5  6  7  8  9  10

6. How helpful was the HPV educational pamphlet? Rate on scale 0-10 (0 being not helpful and 10 being extremely helpful)

   0  1  2  3  4  5  6  7  8  9  10

7. How helpful was the discussion with the primary investigator? Rate on scale 0-10 (0 being not helpful at all and 10 extremely helpful)

   0  1  2  3  4  5  6  7  8  9  10
The more we learn about health risks for our children, the more we can do to help protect them as they grow up. That’s why it’s so important to get the facts about human papillomavirus (HPV).

**5 THINGS A PARENT NEEDS TO KNOW ABOUT HPV**

1. HPV is a little virus that can have **big consequences**.

2. HPV can cause certain **precancers, cancers, and other diseases**.
   These can develop very slowly and may not even occur until later in life.

3. HPV infects **both genders**.
   *Both males and females can be infected with HPV. Exposure to the virus can happen with any kind of adolescent experimentation that involves genital contact with someone who has HPV — intercourse isn’t necessary, but it is the most common way to get the virus.*

4. HPV can be spread even when someone with the virus has **no signs or symptoms**.

5. **Being informed** is the first step in helping protect your child.

It’s important to talk to your child’s doctor before they are at risk.

The CDC and the American Cancer Society recommend HPV vaccination for girls and boys ages 11–12.

FOLLOW US ON: f@HPV. EDUCATING PARENTS ABOUT RELATED CANCERS. t@KNOWHPV

PROVIDED AS AN EDUCATIONAL RESOURCE BY MERCK. THERE’S MORE TO LEARN ABOUT HPV ON THE OTHER SIDE.
Appendix H. **Staff Member Script for Introduction of Study**

Staff member Script for introduction of study

Welcome

Introduction

There is a UK DNP student, Scarlett Mikesell-Pierce, currently working with the St. Vincent Pediatric Clinic to help us increase our vaccination rates for the HPV vaccine. Here is some information regarding the study. She will plan to meet with you prior to your visit with the provider today. Please read through the study while waiting for the provider so that she can address any questions you might have.

Conclusion

Please let me know if you have any questions while you are waiting.
Appendix I. HIPPA for Research Purposes

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

St. Vincent is dedicated to protecting the privacy rights of patients. Any uses and disclosures of personal health information are in accordance with a law called the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act (“HIPAA”). HIPAA is designed to protect the confidentiality of your health information. This document explains how your health information will be used and disclosed for the purposes of conducting, monitoring and auditing this study and describes your rights with respect to that information.

Your personal health information is information about you that could be used to identify you, such as your name, address, telephone number, photograph, date of birth, social security number, new and existing medical records, DNA samples, or the types, dates and results of various tests and procedures. This may include information in your medical and hospital records, as well as information created or collected during the study.

By signing this document you authorize the study physicians and St. Vincent Health and employees (collectively and individually “Researchers”) to use and disclose the following information about you to each other, the study sponsor and its representatives, the St. Vincent Health Institutional Review Board, and governmental agencies responsible for the oversight of this study, including the Food and Drug Administration and any foreign agencies as necessary: personal health information in your medical and hospital record including medical/surgical history, past and current medications, vital signs, physical examinations and laboratory results, other assessments, photographs and samples and analyses of blood, DNA and/or wounds. Your personal health information will be used to conduct the research study as described in the Informed Consent.

You will not be allowed to review the information collected for the study until after the study is completed. When the study is over you will have access to the information again.

St. Vincent Health will not condition treatment or payment on whether or not you sign this document. However, this document is required if you want to participate in the study.

Your authorization to disclose your personal health information in connection with the study will expire at the end of the study and after all study-related data has been transferred to the sponsor. You may revoke your authorization to use your personal health information for the study in writing at any time by writing to the St. Vincent Health Institutional Review Board at 8402 Harcourt Road, Suite 806, Indianapolis, Indiana 46260. You understand that if St. Vincent Health has already taken action in reliance on your authorization they do not have to undo that action. If you revoke your authorization to use and disclose personal health information in connection with the study, you will no longer be able to participate in the study.

Once information is disclosed, it can no longer be controlled by the study physician, St. Vincent Health or by you and may be re-disclosed by the recipient. Thus, your information would no longer be protected by HIPAA.

A copy of this document will be placed in your medical record and you will receive a copy.

If results of this study or future research you have authorized are published or reported in medical journals or at meetings, your name will not be included.
By signing this document, you acknowledge that you have read and understand this Authorization. Further, you authorize the Researchers to use or disclose your health information in accordance with the terms of this Authorization.

Printed name of subject
Signature of subject/ authorized legal representative Relationship of authorized legal representative to subject

TMP-509 HIPAA Authorization
St. Vincent Health Institutional Review Board Form Rev. 03/2018

//

Subject’s Date of Birth (mm/dd/yyyy)

Date
XXX-XX-
Subject’s Social Security Number (last 4 digits only)
Staff Meeting Invitation

St. Vincent Pediatric Clinic Staff Members

Attention to Providers
Nurses
Medical Assistants
and Front desk staff only

Research Staff Meeting
“Improving Rates of First Dose Administration of the HPV vaccine”

The purpose of this staff meeting is to inform clinic staff of the educational intervention that will be taking place in the office regarding overcoming parent/caregiver knowledge barriers of the HPV vaccination.

Date TBA
Time TBA
Location St. Vincent Pediatric Clinic Salem, IN
Lunch will be provided to participating staff

For additional information, please contact:
Scarlett Mikesell-Pierce, BSN, RN
(502) 644-7849
Appendix K. Staff Meeting Agenda

Improving Rates of First Dose Administration of the HPV Vaccine

Staff meeting agenda

Welcome

Thank you for coming to the staff meeting. I appreciate you being here so that I can inform you of the research study that is going to be taking place in this clinic.

Introduction

Introduction of principal investigator

Statement of Purpose

I am conducting this staff meeting to share information that I learned from the chart review and to discover barriers in this practice that affect recommendation of the HPV vaccine to patients. Your honest input is important and appreciated.

Brief Review of Chart Review Findings

5-10 minute presentation of chart review previously conducted on 11-17-year-old patients presenting to the clinic for non-acute visits. This chart review will focus on whether the patients were counseled on the HPV vaccine, whether the vaccine was offered, whether it was accepted/declined/deferred, and whether it was initiated. Some demographic data including gender, age, and race will also be recorded. The staff will be informed of my plans to provide an educational intervention to the parent/caregivers that are willing to participate regarding the HPV vaccination. Copies of the pre-/post- surveys and educational pamphlet will be available for staff to review, so they are aware of the tools that I will be using to collect data during the study.

Conclusion

Any further questions/concerns and thank participants again for their contributions.
Appendix L. **Script for Parent/Caregiver Educational Intervention**

**Script for Parent/Caregiver Educational Intervention**

To participant:

My name is Scarlett Mikesell-Pierce of the University of Kentucky, College of Nursing and I am being guided in research by Lindsey Brough, NP at St. Vincent Pediatric clinic and Dr. Elizabeth Tovar, PhD, RN, FNP-C.

This is a study about the facilitators and barriers that parents/caregivers encounter when recommended to receive the human papillomavirus (HPV) vaccine for their adolescent child. I am planning to provide some educational resources with intent to have your child vaccinated for HPV. I am available to answer any questions you may have regarding the HPV vaccine.

Of course, you have a choice whether to participate in this educational intervention, but if you do participate, you are free to ask any questions regarding the vaccine. You can choose to discontinue this study at any time as well. Participation in this study is voluntary, and if you do not choose to be vaccinated there will be no penalties or loss of benefits.

Your risk to participating in this study is minimal. Your risk may include emotional discomfort due to the nature of the vaccine and the development of HPV. Although we tried to minimize this, some of the discussion may make you feel uncomfortable.

The discussion with myself regarding the HPV vaccine is anonymous which means no names will appear or be used for research documents, or be used in presentations or publications. The research team will not know that any information you provided came from you, not even whether you participated in the study.

If you have any questions about the study, please feel free to ask; my contact information is given below. If you have any complaints, suggestions, or questions about the rights as a research volunteer, contact the staff in the St. Vincent IRB at 317-338-2194.

Thank you in advance for your assistance with this important project.

Sincerely,
Scarlett Mikesell-Pierce, BSN,RN
College of Nursing, University of Kentucky
PHONE: 502-644-7849
E-MAIL: scarlett.mikesell@uky.edu
Table 1. Pre- and Post-Educational Intervention Chart Review

Study Demographics

<table>
<thead>
<tr>
<th></th>
<th>Phase 1 –Pre % (N=100)</th>
<th>Phase 4 – Post % (N=100)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>44%</td>
<td>50%</td>
<td>.40</td>
</tr>
<tr>
<td>Female</td>
<td>56%</td>
<td>50%</td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>97%</td>
<td>94%</td>
<td>.40</td>
</tr>
<tr>
<td>African-American</td>
<td>1%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>2%</td>
<td>2%</td>
<td></td>
</tr>
</tbody>
</table>
Table 2. Pre- and Post-Educational Intervention Surveys

Intent to Vaccinate

<table>
<thead>
<tr>
<th>Planning on getting vaccinated at today’s appointment</th>
<th>Pre-education N (%) or Mean (SD) (N = 15)</th>
<th>Post-education N (%) or Mean (SD) (N = 15)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>5 (33%)</td>
<td>3 (20%)</td>
<td>.41</td>
</tr>
<tr>
<td>No</td>
<td>10 (67%)</td>
<td>12 (80%)</td>
<td></td>
</tr>
<tr>
<td>Likelihood of getting vaccine today (0-10)</td>
<td>4.3 (4.5)</td>
<td>6.7 (4.9)</td>
<td>.20</td>
</tr>
<tr>
<td>Likelihood of getting vaccine in the future (0-10)</td>
<td>5.9 (4.8)</td>
<td>6.9 (4.1)</td>
<td>.52</td>
</tr>
</tbody>
</table>
Table 3. Vaccination rates for administration of the HPV vaccine

Chart Audits Pre- and Post-

<table>
<thead>
<tr>
<th></th>
<th>Pre-education N (%)</th>
<th>Post-education N (%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccinated</td>
<td>9 (19.1%)</td>
<td>20 (40.8%)</td>
<td>.021*</td>
</tr>
<tr>
<td>Not Vaccinated</td>
<td>38 (80.9%)</td>
<td>29 (59.2%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>47 (100%)</td>
<td>49 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 4. Pre- and Post- Clinic Vaccination Rates

<table>
<thead>
<tr>
<th></th>
<th>Pre-education n (%)</th>
<th>Post-education n (%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccinated</td>
<td>303 (58.4%)</td>
<td>345 (64.3%)</td>
<td>.044</td>
</tr>
<tr>
<td>Not Vaccinated</td>
<td>216 (41.6%)</td>
<td>357 (59.2%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>520 (100%)</td>
<td>535 (100%)</td>
<td></td>
</tr>
</tbody>
</table>
Table 5. Pre-educational intervention knowledge of the HPV vaccine, (N=15)

Intervention Group

<table>
<thead>
<tr>
<th>Question</th>
<th>Pre-education N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heard of the HPV vaccination</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12 (80%)</td>
</tr>
<tr>
<td>No</td>
<td>3 (20%)</td>
</tr>
<tr>
<td>The HPV vaccine is recommended for children 11-17 years of age</td>
<td></td>
</tr>
<tr>
<td>True</td>
<td>12 (80%)</td>
</tr>
<tr>
<td>False</td>
<td>3 (20%)</td>
</tr>
<tr>
<td>The HPV vaccine is recommended for cancer prevention caused by the human papilloma virus?</td>
<td>15 (100%)</td>
</tr>
<tr>
<td>True</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>False</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>
Table 6. Post- Educational Intervention Survey Results

<table>
<thead>
<tr>
<th>Question</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>How helpful was the educational discussion? (use scale 0-10, with 0 being not helpful and 10 being very helpful)</td>
<td>9.27</td>
<td>1.3</td>
</tr>
<tr>
<td>How helpful was the educational HPV pamphlet? (0-10)</td>
<td>9.4</td>
<td>1.3</td>
</tr>
<tr>
<td>How helpful was the discussion with the principal investigator? (0-10)</td>
<td>9.73</td>
<td>1.0</td>
</tr>
</tbody>
</table>