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# Human Papillomavirus Vaccine Program

Magdalena Ruiz

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## ABSTRACT

### HUMAN PAPILLOMAVIRUS VACCINE PROGRAM

Pediatric primary care focuses on maintaining patients' health, preventing diseases, and assessing children's developmental milestones. Vaccine administration and disease prevention are key components of a well-child exam for pediatric patients; however, vaccine refusal is an important complication of pediatric patient care. Of particular interest to this researcher is the HPV vaccine which was approved by the Federal Drug Administration and is currently recommended by the Centers for Disease Control and Prevention (2016) for both males and females, beginning at 11 or 12 years of age through age 26 years. The HPV vaccine protects against diseases and cancers caused by the HPV virus; thus, it is important that primary caregivers of pediatric patients be informed about the benefits of this vaccine to ensure that more caregivers give their consent to administer the vaccine. This Doctor of Nursing Practice (DNP) project was designed to evaluate parental refusal for the human papillomavirus (HPV) vaccine via in-person interviews, vaccine teaching sessions, and a subsequent evaluation of the effect of these sessions on parental consent to the HPV vaccine. This project took place in a rural pediatric health clinic, and a total of 12 parents completed the one-month follow-up phone assessments. The results of this study noted a positive impact of the vaccine teaching sessions on the parental decision to consent to the HPV vaccine in the clinic, revealing that seven parents (58%) changed their decision from refusing the HPV vaccine to consenting to its administration.

Magdalena Ruiz  
May 2019



HUMAN PAPILLOMAVIRUS VACCINE PROGRAM

by

Magdalena Ruiz

A project

submitted in partial

fulfillment of the requirements for the degree of

Doctor of Nursing Practice

California State University, Northern Consortium

Doctor of Nursing Practice

May 2019

APPROVED

For the California State University, Northern Consortium  
Doctor of Nursing Practice:

We, the undersigned, certify that the project of the following student meets the required standards of scholarship, format, and style of the university and the student's graduate degree program for the awarding of the Doctor of Nursing Practice degree.

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## CHAPTER 1: INTRODUCTION

### **Introduction**

As a nurse practitioner working in a rural healthcare setting, the author of this study understands that preventative healthcare is a priority in medical practice. The focus of preventative healthcare is to prevent disease, and one way to accomplish this is to administer vaccines recommended by the Centers for Disease Control and Prevention (CDC). As advised and scheduled by the CDC and approved by the American Academy of Pediatrics (AAP) (2013), vaccines have been shown to protect against life threatening illnesses (CDC, 2016). This study focused on the human papillomavirus vaccine (HPV) which prevents infection from strains that are associated with many cancers, including throat, cervical, oral, and penile (CDC, 2016). The HPV vaccine is recommended at age nine years for both female and male pediatric patients. The goal of this project for the Doctor of Nursing Practice, (DNP) was to create an HPV program which determined the reasons for parental refusal and implemented a vaccine education program for parental providers which could increase vaccine compliance and vaccine completion series rates.

### **Background**

Immunization is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine (World Health Organization [WHO], 2015). The Food and Drug Administration has approved three vaccines that prevent infection due to HPV strains: Gardasil, Gardasil 9, and Cervarix (National Cancer Institute [NCI], 2018). HPV is a very common virus with nearly 80 million people—about one in four—currently infected in the United States (CDC, 2016). About 14 million people, including teens, become

infected with HPV each year (CDC, 2016). Risks of the HPV virus vary, but the most serious conditions include oral cancer, genital cancer, genital warts, and cervical cancer (CDC, 2016). According to research conducted by the CDC, adolescents in rural areas obtain the HPV vaccine less often than those who live in urban areas (CDC, 2018). The vaccine is routinely given at 11 or 12 years of age, but it may be given as early as age nine and as late as age 26 (CDC, 2016).

Vaccine completion is as follows: adolescents 9 through 14 years of age receive the HPV vaccine as a two-dose series with the doses separated by 6 - 12 months; individuals who begin HPV vaccination at 15 and older should get the vaccine as a three-dose series with the second dose given 1 - 2 months after the first dose and the third dose given 6 months after the first dose (CDC, 2016). Parental refusal to allow the administration of the HPV vaccine has been identified as a common obstacle in vaccine compliance and health promotion in adolescent patients who live in rural areas. According to the National Cancer Institute at the National Institute of Health, the combination of HPV vaccination and cervical screening can provide the greatest protection against cervical cancer (NCI, 2018). The primary goal of this vaccine program research project was to encourage caregivers/parents to consent to the administration of the HPV vaccine to their children by providing the former with information that focused on the importance of HPV disease prevention and vaccine education. The implementation of vaccine education programs such as this in other healthcare settings may lead to positive changes that will increase HPV vaccine compliance and decrease parental vaccine refusal.

## **Problem Statement**

Vaccine compliance and parental refusal have become issues that advanced practice nurses need to address. Despite the importance of vaccines in preventing communicable diseases, there has been a large increase in vaccine refusal in the 21<sup>st</sup> century (WHO, 2015). Globally, one in five children still does not receive routine life-saving immunizations, and an estimated 1.5 million children still die each year of diseases that could have been prevented by vaccines that are already in existence (WHO, 2015). In primary care settings, such as rural healthcare clinics where pediatric patient care is provided, there has been an increase in parental refusal to vaccines, including the HPV vaccine. According to a survey conducted by the Academy of Pediatrics in 2009, 11.5% of parents with children 17 years and younger reported refusing at least one vaccine (American Academy of Pediatrics [AAP], 2013). Through the evaluation of parental vaccine knowledge, promoting provider/parent communication, and implementing a vaccine program, this study identified barriers to vaccine compliance.

## **Purpose of the Project**

The purpose of this HPV vaccine program was to identify and address barriers for vaccine refusal for adolescent patients in the rural healthcare clinic setting. Additional goals of this program were to evaluate the impact of a vaccine education program on vaccine compliance, increase vaccine rates in a rural health care clinic, and determine whether or not provider/parental dialogue could improve the likelihood of parents agreeing to the HPV vaccine series.

The emphasis of public healthcare is to address barriers affecting a specific patient population. In caring for pediatric patients in the rural healthcare setting, it is important to acknowledge parents' behavior toward their children's healthcare interventions, including immunizations. In providing patient care, advanced

practice nurses can use various nursing theories to help impact patient care and health outcomes.

### **Theoretical Framework and Application to Practice**

The health belief model (HBM) is the nursing theory that may be applied to the vaccine non-compliance issue and vaccine parental refusal in the pediatric primary care setting. The HBM is a theory that focuses on health behavior which was originally developed in the 1950s to predict whether individuals would be willing to engage in programs aimed at preventing and detecting disease (Gerend & Shepard, 2012). The HBM was first developed by social psychologists working in public health services within the U.S. The social psychologists who developed the model looked at ways to explain why so few people were participating in programs aimed at preventing and detecting disease (Butts & Rich, 2018). During the 1950s, HBM was used to evaluate the polio vaccine and its risks for public health. The factors identified soon became the basis for the HBM and have been used throughout the public healthcare field to explain why people adopt behaviors that lead to better health (Smith, et al., 2011). Researchers included six main constructs pertaining to the model: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cue to action, and self-efficacy (Butts & Rich, 2018). Focusing on the identified six constructs regarding parents' views on disease prevention may guide vaccine programs to work toward increasing vaccine compliance and preventing or decreasing parental vaccine refusal.

To conduct the HPV vaccine program, this researcher addressed the above-mentioned HBM constructs in the following manner:

1. Perceived susceptibility of HPV infection: educate parents on HPV risk and infection.

2. Perceived severity of disease: explain HPV risks in causing cervical cancer.
3. Perceived benefits: explain that decreasing the risk of HPV may decrease the risk of diseases, including oral and cervical cancer.
4. Perceived barriers: explain that complying with scheduled vaccine doses may prevent HPV infection.
5. Cue to action: provide advanced practice nurse recommendation and a parent/provider education time.
6. Self-efficacy: obtain parental permission to administer vaccine to adolescent patient.

This vaccine program used these six constructs of the HBM as a guide in acknowledging parental feelings toward vaccines and to work toward increasing the vaccine compliance rate. Focusing the HBM in this research study not only helped this researcher identify strategies to change health behaviors regarding vaccine compliance, but it may also continue to guide advance practice nurses to implement changes that may benefit their pediatric patients.

### **Summary**

A key element to advanced practice nurses is focusing on preventative health measures while providing primary care to patients. When caring for pediatric patients, it is important to acknowledge parental concerns and health beliefs while creating parental/provider rapport which may improve patient healthcare outcomes. The following HPV vaccine program may assist health care providers, such as nurse practitioners, in determining factors associated with parental vaccine refusal. Identifying these barriers to vaccine compliance may then guide interventions needed for increasing vaccine compliance rates in



pediatric rural healthcare clinics. The following chapter reviews the literature which examined the reasons for parental HPV vaccine refusal.

## CHAPTER 2: LITERATURE REVIEW

During the research aspect of this HPV vaccine program, the literature was reviewed regarding parental concerns about administering the HPV vaccine to their children. The primary database used for this research was California State University, Fresno's online library search engine, including search websites such as Science Direct. Most of the research suggested that education and misconceptions are among the leading reasons for refusal of the HPV vaccine (Kinder, 2016). This literature review examines various studies which identified reasons for parental refusal of the HPV vaccine and also examines the gaps in research which were identified in the vaccine program conducted by this researcher.

### **Parental Refusal of the HPV Vaccine**

#### **Primary Caregiver Views on HPV Vaccine.**

Kinder (2016) examined and evaluated parental refusal of the Gardasil Vaccine in a pediatric clinic. This study used a mixed-methods approach using parental surveys that were conducted after visits in which parents had deferred the Gardasil Vaccine. Kinder (2016) collected 23 surveys. A descriptive statistics approach was used to analyze the data collected in survey answers. The results in answers varied, but most parents (75%) deferred administration of the HPV vaccine because they believed it was too new or required further research (Kinder, 2016). One limitation to this study was the sample size; this study was a pilot study, but it seemed to confirm and share findings with other studies concerning the vaccine (Kinder, 2016). A strength to this study included the determination of implications for nurse practitioners: recommendations of necessary changes to and

new strategies in the approach nurse practitioners use in offering the Gardasil vaccine (Kinder, 2016).

### **Medical Provider Views on Vaccine Refusal.**

Fleming, Sznajder, Nepps, and Boktor (2018) utilized a different approach and researched the healthcare providers' points of view toward Gardasil vaccine education programs as well as their views on barriers to the administration of the Gardasil vaccine. This study took place in Pennsylvania and surveyed providers who practiced within the federally funded Vaccines for Children (VFC) program. The design of this research was cross-sectional; data were gathered using emailed surveys which contained 18 questions that were obtained from the validated PA VFC program's "Annual Program Satisfaction Survey" (Fleming, Sznajder, Nepps, & Boktor, 2018, p. 449). The survey used three types of questions: closed-ended, Likert-scale, and open-ended. Descriptive studies were used to analyze the data. After contacting 1478 providers via email surveys, a total of 772 surveys were completed. In the study, the healthcare providers' facilitators and barriers to human papillomavirus (HPV) vaccination were evaluated (Fleming et al., 2018). The survey results concluded that the most important factor identified by providers was counseling parents and adolescents on the benefits of HPV vaccination, (79.5%). The findings of this study indicated that the providers identified that parental concerns about the HPV vaccine and sexual behavior are barriers to the HPV vaccine (Fleming et al., 2018). This study also revealed that providers preferred web-based training regarding vaccine education. The strengths of this research included the identification of vaccine education programs for pediatricians, an emphasis on pediatrician views on parental vaccine refusal. The latter may guide pediatric practice vaccine programs for providers and parents.

Furthermore, a final strength of this study was its large sample size. The limitations of this study pertained to respondents and the lack of a pilot survey: not all respondents were pediatricians, and a pilot survey was not conducted prior to using the survey during research study; this could have potentially created an issue during data collection (Fleming et al., 2018).

### **Pediatrician Point of View on Vaccine Refusal.**

Leib, Liberatos, & Edward (2011) conducted a quantitative study, in which surveys were sent to 600 pediatricians. The pediatricians were chosen randomly via a computer during November and December 2007, and surveys were returned by February 2008 (p. 14). The sample consisted of a total of 133 pediatricians (a 31% response rate) who filled out a 28-item survey via mail. The study took place in pediatric clinics in Connecticut. The pediatricians who participated in surveys were all members the Hezekiah Beardsley Connecticut Chapter of the AAP and received consent from the organization to participate (p. 14). The pediatricians were asked questions focusing on providers' experiences with family vaccine refusal, identifying the vaccines being refused, and whether physicians dismissed these families from their practice. The data analysis was conducted using a chi-square analysis. The results showed that nearly three-quarters of the pediatricians reported "an increase in parental concerns and refusals compared with 10 years ago" (Leib, Libratos, & Edward 2011, p.16). One strength of the study was its focus on the pediatricians' point of view rather than just parental thoughts on the Gardasil vaccine. The low response rate of 31%, is a limitation to the study. It would be helpful to obtain a larger response rate to help identify further patterns leading to parental vaccine refusal. (Leib et al., 2011).

Javaid et al. (2017) conducted a study on the barriers to the Gardasil vaccine. The researchers sent surveys via email to medical facilities in the state of Texas. There was a total of 1132 responses that were received, representing healthcare providers, administration, and other managerial staff. A descriptive statistics analysis was conducted using the survey software, Qualtrics. Javaid et al. (2017) found that parental perceptions about HPV, parental knowledge, and safety concerns were barriers affecting Gardasil vaccine rates (Javaid et al., 2017). Providers stated that vaccine refusal was primarily related to misconceptions about the HPV disease, the safety of the vaccine, and society's views about why the vaccine should be administered. The nursing implications of this study are that such misconceptions should be addressed when providing patient care, and parents should be educated about the vaccine's purpose; this may help increase vaccination rates and decrease vaccine refusal. A limitation of this study would be the mode of survey distribution via email. Methods such as in-person interviews and follow-up surveys may increase survey distribution and response rate. In this study, the respondents varied in profession and medical background; focusing on primary care providers such as physicians, nurse practitioners, and physician assistants may provide a better evaluation of parental barriers to vaccine administration. Parents often consider the medical advice given to them by their primary care provider the best for their children's health decisions. Parents may rely on the primary care providers' medical advice to make decisions about medical care, including preventative care such as vaccines (Javaid et al., 2017).

### **Health Belief Model Impact on Vaccine Refusal.**

Krawczyk et al. (2015) conducted a study to identify key differences between parents who consented and parents who refused the Gardasil (HPV)

vaccine for their daughters. This study took place in a free vaccination clinic in Quebec, Canada, and included a large randomized sample size and return rate. Parental surveys were sent and returned via mail. A total of “834 parents returned the questionnaire, and the overall response rate was 33%. Of those, 774 (92.8%) questionnaires had complete data for all relevant items and were included in the present quantitative analyses” (Krawczyk et al., 2015, p. 324). Those surveyed were parents of girls who were 9 to 10 years of age. Of these 774 participating parents, 88.2% reported that their daughters received the HPV vaccine. The theoretical framework used for this study was the HBM which was used to investigate whether parental beliefs about the Gardasil vaccine guided their decision to vaccinate their daughters (Krawczyk et al., 2015). The study focused on how the HBM influenced parental perceptions in their decision to vaccinate their daughters and how the knowledge of the Gardasil vaccine guided interventions and vaccine programs. A limitation of this study was that it only included parents attending a free vaccine clinic; thus, the results may not be applicable to parents of children with insurance (Krawczyk et al., 2015).

### **Vaccine Education.**

Lechuga, Swain, and Weinhard (2012) conducted a study to evaluate parental decisions to consent to the Gardasil vaccine as a result of the use of the Decision Aid (DA). The DA is a tool that guides parents through their decision to vaccinate their children by explaining what the vaccine is/does and addressing parental concerns regarding a specific vaccine. This study was a mixed method study using a survey approach which took place within four Health Department clinics in Milwaukee, Wisconsin. The sample group consisted of 150 mothers of girls, aged 9 - 17 years, who had not received the vaccine and were receiving WIC

assistance from one of four clinics in Milwaukee. The mothers completed questionnaires which focused on intention to vaccinate, emotions toward the Gardasil vaccine, the vaccination of boys, and the use of a DA. The questionnaires also assessed ethnicity, age, years of education, insurance, and employment status. The researchers “conducted a content analysis to investigate emergent themes in answers to the open-ended item assessing vaccination related concerns” (Lechuga, Swain, & Weinhard, 2012, p. 217). A chi-square analysis, ANOVA, was used to analyze quantitative data. Results showed that, overall, mothers benefitted from a DA to assist them in understanding the purpose of the Gardasil vaccine. With regard to ethnic groups, African American mothers found the decision aid useful in their decision-making process. Hispanic mothers verbalized benefiting from hearing other parents’ experience with the Gardasil vaccine. This study also found the need for physician guidance in parental vaccine compliance. In this study, there was a low parental (mother) concern regarding the vaccine’s initiation of early sexual behavior in their children, these results were “3% of Hispanics, 6% of African American, and 7% of non-Hispanic White” (Lechuga et al., 2012, p. 219). A strength of the study was that data were collected from four health departments. In addition, the study was able to evaluate various ethnic groups; this may help providers focus on specific parental views of the vaccine. A limitation of this study is that the sample group only included mothers of girls who did not receive a vaccine; no mothers of boys were surveyed. This study could be changed to include mothers of all adolescents—both boys and girls—to further look at parental consent or refusal to vaccinate (Lechuga et al., 2012).

### **Impact of Parent and Provider Communication.**

Rahman, Laz, McGrath, and Berenson (2015) evaluated the association between parental HPV awareness and Gardasil vaccine initiation/completion rates in adolescent children 13 to 17 years of age (p. 371). The study examined whether or not communication with a provider impacted parents' decisions to administer the Gardasil vaccine to their adolescent children. The researchers used cross-sectional surveys already completed via the CDC which were national immunization surveys of teens aged 13 - 17 years. Statistical data were analyzed using STATA 12 svy command and logistic regression models to examine the independent variable and dependent variable. The sample size was large: 11,236 adolescent girls and 12,328 adolescent boys. Overall, the study noted the importance of including provider recommendation of vaccine programs in the United States to increase Gardasil vaccine administration. A strength in this study was its use of data from a reliable source, the CDC. A limitation in this study was its lack of examples (such as program websites, parental teaching handouts, or vaccine education tools) of how providers might improve communication with their patients and their parents to increase Gardasil vaccine success rates (Rahman, Laz, McGrath, & Berenson, 2015).

Brown, Gabra and Pellman (2017) examined reasons for parents' acceptance or refusal of the HPV vaccine in a pediatric practice. The study was conducted over a period of one year, using parental surveys and evaluating the reasons for agreeing or refusing initial HPV vaccination following a practitioner recommendation (Brown, Gabra, & Pellman, 2017, p. 42). Parents were surveyed after their children's doctor appointments at which HPV vaccine education was provided by the provider. A total of 200 parents participated in surveys, answering questions about demographics and reasons for accepting or refusing the



vaccine. In evaluating the data collected, “a univariate descriptive statistic was used to examine age, gender, familial/friend diagnosis, and reasons for or against vaccination” (Brown, et al., 2017, p. 43). The study revealed that the physicians’ recommendation was the major factor (84.1%) in parents’ decisions to administer the HPV vaccine to their children (Brown et al., 2017). The most common reason identified for vaccine refusal was the need for further research (Brown et al., 2017, p. 43). The survey’s small sample size was considered a limitation to the study. Overall, the researchers found that physician recommendation for HPV vaccine influenced parental decision in accepting the vaccine for their child.

### **Teaching Tool Evaluation.**

Cipriano, Scoloveno, and Kelly (2018) also examined parental attitudes and consent or refusal of the HPV vaccine by evaluating a parental intervention focused on increasing parental knowledge of the HPV vaccine. The study took place in a pediatric clinic in the state of New Jersey, using a pre- and post-intervention design. The researchers used a computer-based training module in which parents were given the HPV vaccine education and then were given post surveys. A limitation noted by the researchers was the possibility of parental misunderstanding of the vaccine information that was given to Spanish-speaking parents on the digital tablet they were provided. The researchers concluded that the main reasons for parental refusal for the HPV vaccine was a lack of understanding regarding the HPV vaccine and children were not sexually active at the time of the administration of the vaccine. Overall, the study focused on increasing parental comprehension of the HPV vaccine, and the results indicated that there was an increase in knowledge.

### **Summary**

An examination of past research studies which focused on parental refusal of the HPV vaccine highlighted gaps regarding provider/parental communication, vaccine education, and parental comfort with vaccine side effects. Therefore, it is necessary for advance practice nurses to address parental feelings about the HPV vaccine, for this may positively influence patient health outcomes. If such intervention is implemented in the healthcare system, advance practice nurses will have the opportunity, through consultations, to build trusting relationships with parents. The following chapter outlines the HPV vaccine program in which vaccine refusal, vaccine education, and parental/provider rapport are evaluated.

## CHAPTER 3: METHODOLOGY

### **Project Design**

In this study, a qualitative content analysis was conducted to evaluate the reasons for parental refusal of the HPV vaccine. The purpose of this study was to interview 10 - 12 parents who had refused the HPV vaccine for their adolescent children and determine the reasons for this refusal. Through this study, the researcher provided each parent with a teaching session followed by a follow-up interview over the phone one month later to assess outcomes and determine if the teaching session had changed parental decisions to refuse the vaccine.

### **Program Setting**

The HPV vaccine program and interviews took place at Dr. Javier Amu Professional Corporation, a rural pediatric healthcare clinic located in Reedley, California. Interviews with parents were conducted by this researcher in a conference room at this clinic. Additionally, phone call assessments were conducted using the confidential phone in the clinic office.

### **Sample Population**

The subject population included parents who had refused the HPV vaccine for their adolescent children and who received primary care in the rural health clinic.

### **Recruitment of Participants**

The study subjects consisted of parents who obtained pediatric patient care services for their adolescent children in this pediatric rural healthcare clinic. The researcher obtained Institutional Review Board (IRB) approval from the California State University, Fresno, and from Dr. Amu, the pediatrician/owner of the rural

health clinic, prior to beginning the research study and parental interviews (see Appendices F and G).

### **Sampling Procedures**

Participants for the interviews and the phone call assessments were collected through the clinic's electronic medical record, PRAXIS. Adolescent patients who were delinquent with any of the HPV vaccine doses were identified, and parental information was obtained. The researcher contacted each parent/participant and asked for voluntary participation in interview and phone call assessment for this vaccine program. After parents agreed to participate in this study, informed consents which explained the research study program were obtained, and the researcher then initiated interviews (see Appendix H).

### **Ethical Considerations**

Risk from ethical problems in this study was minimal, for informed consent was obtained from parents (study subjects) prior to in-person interviews and phone-call assessments. This study was approved by the IRB at California State University, Fresno.

### **Measures**

Using a qualitative research design by means of semi-structured face-to-face interviews, the researcher identified and evaluated reasons for parental HPV vaccine refusal. After implementing a parental teaching session, follow-up phone call assessments took place one month later to evaluate parental decisions to accept or refuse the HPV vaccine.

## Research Design

### Data Collection Methods

The parental interview addressed the four survey questions which were used as part of Kinder's (2016) research in evaluating parental refusal of the HPV vaccine (see Appendix A). Permission to use these questions for the purposes of this study was obtained from assistant professor at La Salle University, Frances DiAnna Kinder, PhD, RN (see Appendix B). For this project, this researcher asked the following questions to assess vaccine refusal:

1. How many times has the vaccine been offered to you?
2. Where do you obtain most of your medical information? (Kinder, 2016, p. 555).
3. What was your reason for refusal of HPV vaccine for your child?
4. What would influence your decision to consent for HPV vaccine easier?

(See Appendix A).

As part of the interview, the following demographics were requested: relationship to child, educational level of parent, parental age, and patient age and sex (see Appendix C).

The second component of the HPV vaccine program was an educational teaching session with parents. The researcher included all of the recommended vaccines in the teaching session such as HPV infection information, HPV vaccine, and a vaccine schedule calendar. A 10-minute educational session was provided to each parent which took place in the same session as the interview, using a resource tool provided by the CDC, "6 Reasons to Get HPV Vaccine for Your Child" (CDC, 2018). (See Appendix D). The resource tool was provided in the parents' native speaking language (Spanish or English). If parents had requested

information in a different language, the researcher would have provided the information as needed, however no other language resources were required.

The third component to this vaccine program consisted of a follow-up phone call assessment conducted by the primary researcher one month after the appointment at the health clinic. Each parent that was interviewed and participated in the teaching session received a call. The questions asked were as follows:

1. Can you remember why you refused HPV vaccine for your child?
2. What did you learn about the HPV vaccine after the teaching session?
3. Has your opinion changed about consenting to the vaccine for your child? If so, why?
4. Will you consent for refuse HPV vaccine for your child?

The primary researcher followed a detailed script while conducting each phone call assessment (see Appendix E).

After the interviews, teaching sessions, and follow-up phone calls took place, parental responses were evaluated to determine whether there were any specific or common barriers/themes to parental refusal of the HPV vaccine. A content analysis was conducted as an evaluation of the effectiveness of the teaching session for parental decision to consent for the HPV vaccine. As previously described, the data analysis method was a qualitative study using semi-structured interviews with parents who refused the HPV vaccine for their adolescent children aged 11 – 17 years.

### **Data Analysis**

The content analysis included the data/answers gathered from interviews and follow-up phone call assessments which were completed during this vaccine

program. As defined in Melnyk and Fineout-Overholt (2015), content analysis involves extracting themes, patterns, processes, essences, and meanings from textual data. Based on these findings, future studies may be implemented, addressing parental concerns and reasons for the refusal of the HPV vaccine.

### **Summary**

Parent interviews and phone-call assessment answers were evaluated and identified in relation to barriers to HPV vaccine acceptance and reasons for HPV vaccine refusal. This vaccine program also focused on parental/provider education and analyzed its influence on parental acceptance or refusal of the HPV vaccine. Results of this study will provide further vaccine program interventions, education tools, and parental support for increasing parental vaccine compliance. In the following chapter, there is a content analysis discussion on the results of the HPV vaccine study.

## CHAPTER 4: RESULTS

This chapter summarizes this vaccine program's in-person interviews, follow-up phone-call assessments, and patient and parent demographics. The qualitative research study design includes the content analysis conducted with data collected during the vaccine program.

### **Sample Characteristics**

This study included 13 parents who participated in the vaccine program, including in-person interviews, teaching sessions, and phone-call assessments. Table 1 shows the demographic information of the 13 parents who participated in the study. The interviewed participants included a total of two fathers and 11 mothers. Parental age groups varied from 31 to 52 years of age. Parents' education levels varied from a completion of the sixth grade to a college bachelor's degree. Ethnicity also varied: there was one White father, one Native American mother, one Hispanic American mother, and 10 Hispanic parents who participated in the study. The sex and age of the participants' children were also identified as part of the demographic information for the study. Seven parents had female children (54%), while six parents had male children (46%). The children's ages varied from 11 to 14 years.

### **In-person Interviews Data Analysis**

#### **Qualitative**

A total of 13 in-person parental interviews were conducted by the researcher and took place in the conference room of the clinic. The following section reviews the data collected during the interviews which used four open-ended questions. The first interview question asked about the amount of times the



HPV vaccine had been offered to the parents. One parent stated, “The vaccine has never been offered to me” (8%). Six parents (46%) verbalized that the vaccine had been offered once. There were two parents (15%) who said the vaccine was offered twice. Three parents (23%) claimed that the vaccine was offered three times. One parent (8%) stated the vaccine was offered multiple times.

Table 1. Demographic Characteristics of the Participants (N=13)

Characteristic	Percentage
Relationship to patient	
Mother	84.6
Father	15.4
Parental age	
31-40	46.2
41-48	23.1
>49	30.7
Parental education level	
Sixth grade	15.4
Junior High School	7.7
High School	38.5
Some college – Bachelor’s	38.5
Parent Ethnicity	
White	7.7
Hispanic	84.6
Native American	7.7
Patient sex	
Male	46.2
Female	53.8
Patient age	
11-12	61.5
13-14	38.5

The second question of the interview asked parents where they obtained their medical information, and answers included the internet, clinic, medical providers, and research articles. A couple of parents stated that they obtained medical information from multiple sources. A total of nine parents (69%) obtained their information from the medical clinic or doctor. There were eight

parents who stated they received their medical information from websites (61%). Three parents (23%) obtained their information from research-based articles/data.

### **Reasons for Parental Vaccine Refusal**

**Lack of information or vaccine education.** Interview data for questions three and four are discussed using themes in qualitative content analysis. The third assessment question addressed the reasons for parental refusal of the HPV vaccine. The largest theme/reason verbalized by parents for their refusal of the vaccine was the lack of education or information provided regarding the purpose for the HPV vaccine. Parents verbalized not “knowing and understanding” the HPV virus and how the vaccine prevented cervical cancer and genital warts. In reviewing these data, a common theme for parental refusal of the HPV vaccine, as verbalized by many parents, was their fear of the vaccine’s side effects.

**Vaccine side effects.** During the interviews, a frequent concern and reason for refusal that was voiced by many parents was the side effects of the vaccine. Whether the parents misunderstood the side effects or read about the side effects online, it was clear that these views impacted parents’ decisions to refuse the vaccine for their children. One parent stated, “I read a story online in which a young lady received the HPV vaccine and went into a vegetative state.” Another mother stated that she had refused the HPV vaccine because she was “worried [her] daughter could have a reaction to the vaccine.” To address parental concerns about side effects, there is a Vaccine Information Sheet (VIS) that is provided during patients’ physical exam at recommended age that identifies the possible side effects of the HPV vaccine.

**Young age of patient at the time of HPV vaccination.** During the parental interviews, three out of the 13 parents expressed their concern about their children being “too young” to worry about the HPV virus. One father stated he felt that the “HPV vaccine would give [his] daughter a false sense of protection against sexually transmitted viruses.” This father continued to discuss why he felt his daughter, at her young age, was unable to understand the purpose of the HPV vaccine or the significance of the HPV virus. These three parents questioned why the vaccine was necessary at this stage when their child would not be exposed to the virus. The recommended age for the HPV vaccine is between 9 and 11 years of age, and in this rural health clinic, it was recommended at 11 years old. Because of their concerns about the young age of the children, parents’ hesitancy about discussing the HPV virus with their children and how the virus is transmitted sexually was a large part of parental vaccine refusal.

**Underlying illness or medical concern.** Another common reason for vaccine refusal was postponing physical exams due to children’s underlying medical history, whether these were acute or chronic. For example, illnesses such as type 1 diabetes, cold symptoms, or hives/allergy symptoms were commonly used as reasons for postponing the vaccination. Parents of children with such conditions expressed concerns about how their children would react to the HPV vaccine because of their underlying illnesses. In addition, common reasons for vaccine refusal or missed doses included being unaware of a required second dose, missing physical exams, or not scheduling exams. One mother stated, “I was not told about the vaccine dose schedule during my son’s physical exam.” Non-compliance for completing the vaccine series, misinformation regarding the purpose of the HPV vaccine, and lack of knowledge regarding the vaccine

schedule were common concerns in both the literature reviewed for this study and within this study's parental interview responses.

### **Decision to Consent**

**Vaccine education.** The final open-ended question of the in-person interview was intended to determine what might support parental decisions to consent to the HPV vaccine. The most common answer to this question was the need for more vaccine education. Parents verbalized the need for clarification regarding vaccine purpose, side effects, and the vaccine schedule. One father stated, "I need to see more data, statistics, and opposing data in regard to the HPV vaccine." Another father wanted to know more about the vaccine's benefits: "I want to know more about the studies and research about how the HPV vaccine works." One mother wanted to hear more about how the vaccine could prevent future medical problems for her child. Understanding the pros and cons of the HPV vaccine was a clear theme noted as a result of this open-ended question.

**Vaccine schedule reminders.** The second common theme indicated by the data was the need for more reminders and clarification of the vaccine schedule. Providing vaccine series education to parents could support their decision to consent to the HPV vaccine and comply with vaccine doses. As parents continued to discuss the need for further detailed information on the HPV vaccine schedule, many mentioned how they felt as if frequent reminders and communication with the clinic providers and staff could increase vaccine compliance, and as a result, parents would be more likely to consent to vaccinate their child.

## **Phone-Call Assessment Data**

**Vaccine side effects.** A phone-call assessment which consisted of four questions was conducted with each parent one month after the personal interviews. There was a total of 12 parents who participated in the phone call assessments (92%). The first assessment question asked if parents recalled their reason for refusing the HPV vaccine for their children. Once again, the leading reason parents indicated for their refusal of the vaccine was concerns about the possible side effects of the vaccine. One mother was concerned about possible neurological side effects, such as autism or other developmental issues; other parents feared unknown side effects that perhaps have not been found or shared with the general public. One mother stated a concern that her daughter might possibly have “an allergic reaction because the HPV vaccine would be a new vaccine for her.” As indicated in the literature, parents may require more information on the vaccine’s actual side effects, for these real-life examples may decrease parental refusal of the HPV vaccine.

**HPV virus sexual connectivity.** A common theme noted in the literature reviewed for this study regarding parental refusal to the HPV vaccine was its connectivity to sexual behavior or sexually transmitted diseases. This notion was also present in the data from this study. One father stated that he refused the vaccine because he was “worried about giving [his] daughter the false illusion of protection against sexually transmitted diseases.” In this case, health care provider education could have impacted the father’s understanding of the HPV virus, HPV related diseases, and overall purpose of the vaccine. Evaluating parental knowledge of the HPV virus may create parental/provider rapport and create a clearer parental understanding of the significance of the vaccine for children.

Lastly, this program's first follow-up question indicated that the need for further education and a lack of parental understanding of the vaccine played a large part in parental refusal of the vaccine. If medical providers cannot clarify the reasons for vaccine refusal, such refusal cannot be addressed, compliance cannot be achieved, and preventative health cannot be prioritized.

### **Teaching Session Lessons**

Question number two of the follow-up assessment asked parents to discuss what they had learned from the teaching session that was conducted by the researcher following their interviews; overall, parents expressed that, as a result of the session, they had gained a clearer understanding of the diseases caused by the HPV virus. One mother specifically stated that she "learned about the benefits of the vaccine regarding cervical cancer and other cancers that [she] was not aware could be a concern." Another mother indicated that, because of the teaching session, she had learned "how beneficial the vaccine was."

### **Parental Opinion to Consent**

**Understanding the vaccine to consent or refuse.** When parents were asked during the follow-up assessment whether or not they had changed their opinion about consenting to the HPV vaccine, many parents took the opportunity to further discuss the vaccine. While assessing parents who had consented to give the HPV vaccine to their children, this researcher noticed that such parents wanted to discuss their feelings in more detail; this allowed for the parents to once again verbalize their understanding and decision to give their child the HPV vaccine, discuss the importance of the vaccine, and ask more questions about the HPV vaccine. Out of the 12 parents who participated in the follow-up assessments, one

parent said she would continue to think about her decision to vaccinate her child. There was a total of seven parents (58%) who decided to consent to the HPV vaccine. During the phone call assessment, one mother stated, “I now understand the importance of this HPV vaccine for my son.” Four parents (33%) continued to refuse the HPV vaccine for their children. All parents stated that they understood the HPV vaccine’s purpose after participating in the teaching session with the researcher.

### **Parental Consent or Refusal of the HPV Vaccine**

The final question of the phone assessment focused on the decision of the parent to consent or refuse the administration of the HPV vaccine. After participating in the interview, teaching session, and phone call assessment, parents were asked if their decision had changed. Four parents continued to refuse the vaccine for their children; all three parents had daughters. One parent was unable to make a decision to consent for her daughter at that time and stated that she wanted “more time to think about the vaccine and its purpose for her daughter.” A total of seven parents decided to change their decision to refuse the vaccine and consented to the administration of the HPV vaccine to their children. Figure 1 demonstrates the parental decisions to consent or to continue to refuse the HPV vaccine for their children.

As seen by the results in Figure 1, this study’s vaccine program positively impacted parental decisions regarding the HVP vaccine by encouraging seven parents (58 %) to change their decision and consent to the vaccine. In the following chapter, the strengths, limitations, and nursing implications of this HPV vaccine program study are analyzed.

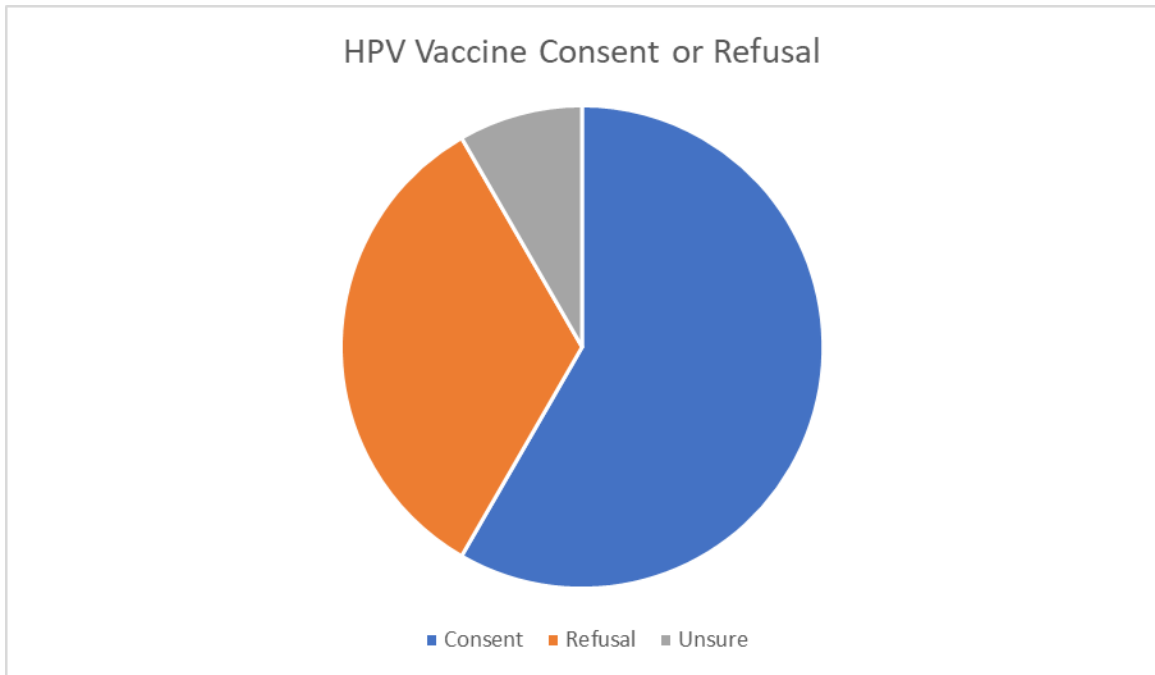


Figure 1. Chart depicting HPV vaccine parental consent or refusal.



## CHAPTER 5: DISCUSSION

The goal of this HPV vaccine program/study was to identify and evaluate the reasons for parental refusal of the HPV vaccine in a rural healthcare clinic setting. In the literature reviewed, there were various methods for identifying parental vaccine refusal. This study and vaccine program focused on open-ended in-person interviews, parental vaccine teaching sessions, and a one-month follow-up assessment which evaluated the parents' change in consenting to the HPV vaccine for their children.

### **Project Outcomes**

The primary outcome for this HPV vaccine program was the identification of reasons for parental refusal to the HPV vaccine. The in-person interview questions served as a mode of communication between the researcher and parents. During the interviews, parents were able to answer each question regarding the HPV vaccine and their reasons for refusing the vaccine for their children. The second outcome was the use of the teaching session or educational tool which helped increase parental knowledge of the HPV vaccine. Finally, the follow-up phone-call assessments conducted one month after parent interviews were used to evaluate the interviews and teaching sessions' impact on changing parental refusal of the HPV vaccine. Overall, this study increased parental understanding of the HPV vaccine, including the vaccine's purpose and preventative measures. This study/vaccine program resulted in several parents' changing their decision from refusing the HPV vaccine to consenting to the administration of the HPV vaccine for their children.

### **Nursing Implications**

As noted in the literature review provided in this study, parents and caregivers need more information about the HPV vaccine. Some studies evaluated the use of a decision aid or someone who could further explain the HPV vaccine after a medical provider recommended the vaccine. Cipriano et al. (2018) used a self-directed, computer-based learning tablet application which helped teach parents about HPV vaccine. Various parents within this study's interview process also indicated that more information regarding how the HPV vaccine works could impact their decision to consent to the vaccine. Parental resistance or fear to consenting to the HPV vaccine for their children may decrease with a health care provider's emphasis on vaccine education and explanation of HPV related diseases. Clarifying the HPV virus risks, vaccine research, and children's future risks may impact the parental decision to consent to the vaccine.

**Parental vaccine education.** Application of this vaccine program's findings may help those in the medical profession to identify parental education focus points and may decrease parental fears and resistance to the HPV vaccine for their children. A study conducted by Brown et al. (2017) revealed that a deciding factor for parental refusal was the feeling that their children were not old enough for the vaccine (p. 43). As discussed in Chapter 4, during the parental interviews for this study, parents also expressed that their children's age/young age was a factor in refusing to administer the HPV vaccine at the recommended time. The interviews and assessment results of this study revealed a change in parental decisions to consent to the HPV vaccine after attending the teaching session provided by this study's vaccine program. Thus, stressing the possible future implications of the HPV virus exposure to parents is an important aspect of HPV vaccine education.

**Recommended age and sexual behavior.** Parental concerns of sexual behavior or connectivity of sexual activity associated with the HPV vaccine was also a common theme in both this study and the literature. One study discussed the parental worry about the HPV vaccine's being related to sexual intercourse and behaviors; this concern was a primary factor in many parents' decision to refuse the vaccine for their children (Fleming et al., 2018). Multiple studies confirmed the common reason for parental refusal of the HPV vaccine stemmed from the early age at which the vaccine was given: many felt the vaccine was given too early, for children were not sexually active at the time. In this study, some parents did not feel comfortable with administering the vaccine, believing it was connected to a virus which was sexually transmitted.

**Teaching intervention.** This researcher was able to conduct parental teaching sessions which increased parental vaccine understanding. Healthcare providers such as nurse practitioners may continue to focus on health promotion and preventative healthcare, such as vaccine education and parental teaching support. During this vaccine program, the teaching sessions created opportunities for parents to not only learn about the HPV vaccine but to also reevaluate their decision to vaccinate their children. The positive impact of the vaccine education session was noted in the follow-up assessments, as seven parents (58%) changed their decisions to consent to and administer the vaccine to their children.

**Vaccine schedule and compliance.** Understanding the HPV vaccine schedule and doses can improve patients' vaccine series compliance. As stated by various parents during the in-person interviews, the lack of reminders on the HPV vaccine series doses and scheduling their follow-up appointments impacted their decision to refuse or complete the HPV vaccine doses. One parent asked about the vaccine schedule and how the vaccine schedule was reinforced in the rural

healthcare clinic. Vaccine schedule reminders may vary, and in this study, there were some parents who were unaware of there being a second HPV vaccine dose. Healthcare providers such as nurse practitioners may impact vaccine series compliance by creating better vaccine appointment protocols and reminders in outpatient rural pediatric clinics.

### **Strengths**

One strength of this study's HPV vaccine program is that the vaccine program provided an educational tool: the teaching session increased parents' understanding of the HPV vaccine and influenced their decision to vaccinate their children. Another strength of this study was the ability of the researcher to provide the interview questions, teaching session, and phone call assessments in the parents' native language: Spanish or English. Additionally, this study was the only one in this researcher's knowledge which used in-person interviews followed by parental teaching sessions and a one-month follow-up phone assessment which evaluated the reasons for parental consent to or refusal of the HPV vaccine. The last strength of this study was the positive impact which the study had on changing parental decisions to consent to the HPV vaccine for their children.

### **Limitations**

A limitation to this study was the program's focus on only one specific patient and parent population in a rural healthcare clinic. Future studies may be conducted in larger pediatric and family practice clinical health settings, increasing research data findings. This vaccine program was limited to the parents whose children received their primary care at the identified rural healthcare clinic. Another limitation noted in the study was the inability of the researcher to contact one parent to complete this parent's follow-up phone call assessment.

### **Recommendations for Further Studies**

This HPV vaccine program focused on one vaccine, the HPV vaccine, which is often refused by parents in the rural healthcare clinic setting. Notable in the results of the one-month follow-up assessments was the fact that parents learned about the HPV vaccine individually; this positively impacted their decision to consent to the vaccine. Further research studies may focus on other recommended pediatric vaccines also refused by parents. Future vaccine programs may follow this study's methodology, using in-person interviews, parent teaching sessions, and one-month follow-up assessments to increase consent to other vaccines that are often refused. The goals of such vaccine programs should be as those provided in this study: to address, identify, and evaluate the reasons for parents' refusal of these vaccines.

In conducting this study, this researcher found a gap in parental understanding of the purpose for and schedule of the HPV vaccine. Focusing on increasing parental vaccine education—whether it incorporates more vaccine handouts, longer teaching sessions with parents, or introducing vaccine programs within clinical settings—healthcare providers such as nurse practitioners may positively impact vaccine education and vaccine series compliance.

Future vaccine programs such as this study may impact clinical vaccine protocols and promote positive patient care outcomes within pediatric and family practice settings. For healthcare providers and nurse practitioners, the focus on health promotion and preventative health measures such as vaccines are a large part of pediatric patient care. While conducting this vaccine program, the researcher was able to create a learning environment for parents, conduct vaccine education, and re-evaluate the parental decision to administer the HPV vaccine to their children. This vaccine program may be used to promote parental knowledge

of the HPV vaccine and other vaccines and to impact vaccine series compliance rates for pediatric and adolescent patients.

### **Conclusion**

This vaccine study identified the reasons for parental refusal of the HPV vaccine in a pediatric rural health clinic. The vaccine program's findings noted the influence of teaching sessions in changing parents' decisions to consent to the HPV vaccine for their children. Preventative services such as vaccines, specifically with the HPV vaccine which prevents diseases caused by the HPV virus, may be impacted by successfully administering all the doses within the vaccine series. Healthcare providers, such as nurse practitioners who care for pediatric patients, should continue to focus on communicating with their patients' parents by using vaccine programs such as this one to create a positive impact on their patients' health.

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## REFERENCES

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## APPENDICES

APPENDIX A: KINDER SURVEY VACCINE  
REFUSAL QUESTIONS

### **Kinder Survey Vaccine Refusal Questions**

1. How many times has the vaccine been offered to you?
2. Where do you obtain most of your medical information?
3. What was your reason for refusal of HPV vaccine for your child?
4. What would influence your decision to consent for HPV vaccine easier?

**APPENDIX B: PERMISSION TO USE KINDER SURVEY  
QUESTIONS**

## Permission to Use Kinder Survey Questions

Dear Magdalena

You have my permission to use the questions from the survey in my study. I would ask that you please share your data with me as I would be interested in learning from it.

Thank you,

Dr. Kinder

Frances DiAnna Kinder, PhD, RN, CPNP-PC

Assistant Professor

La Salle University

School of Nursing and Health Sciences

St. Benilde 4432

215-951-1258

[Kinder93@lasalle.edu](mailto:Kinder93@lasalle.edu)

---

**From:** Magdalena Ruiz <[rociom10@mail.fresnostate.edu](mailto:rociom10@mail.fresnostate.edu)>

**Sent:** Friday, July 13, 2018 4:57:05 PM

**To:** Frances Kinder

**Subject:**

Dr.Kinder

Thank you so much for allowing me to use the survey questions from your study. I will definitely share my project results with you.I hope to start to implement my study in the fall.

Sincerely,

Magdalena Ruiz NP-C (DNP student)

APPENDIX C: DEMOGRAPHIC FORM



**Demographic Form**


1. Relationship to patient
2. Educational level
3. Parent age
4. Parent ethnicity
5. Patient sex
6. Patient gender

APPENDIX D: 6 REASONS TO GET HPV VACCINE FOR  
YOUR CHILD

6 Reasons to Get HPV Vaccine for Your Child


# [ 6 REASONS TO GET HPV VACCINE FOR YOUR CHILD ]

**1** HPV is a common virus that infects teens and adults.



**80%**  
of people will get an HPV infection in their lifetime.

**2** HPV vaccination works.




**71%**

Infections with HPV types that cause most HPV cancers and genital warts have **dropped 71 percent** among teen girls.

---

**3** HPV vaccination prevents cancer.




**30,000**

cases of cancer could be prevented with HPV vaccination each year.

**101**

Shows as the average attendance for a football game.


**4** Preventing cancer is better than treating it.



HPV infections can cause six types of cancer, but doctors only routinely screen for cervical cancer. The other five types may not be detected until they cause health problems.


---

**5** Your child can get protection from HPV cancers during the same visit they are protected against other serious diseases.



measles • mumps • rubella


**6** HPV vaccination provides safe, effective, and long-lasting protection



**100**  
million

Doses distributed in the U.S. Data continues to show HPV vaccine is safe and effective.

[ Talk to your child's doctor or nurse about HPV cancer prevention. ]



**HPV VACCINE**  
IS CANCER PREVENTION

[www.cdc.gov/HPV](http://www.cdc.gov/HPV)

**APPENDIX E: SCRIPT FOR PHONE CALL ASSESSMENT**

### **Script for Phone Call Assessment**

Hello, my name is Magdalena Ruiz, I am the nurse practitioner and primary investigator who conducted your face-to-face interview and teaching session that took place one month ago at Dr. Amu's pediatric clinic. First, thank you for your time and willingness to participate in this HPV vaccine research study. I will now be asking you four questions as part of the study:

1. Can you remember why you refused HPV vaccine for your child?
2. What did you learn about the HPV vaccine after teaching session?
3. Has your opinion changed about consenting vaccine for your child? If so why?
4. Will you consent or refuse HPV vaccine for your child?

Thank you so much for your time and participation in this vaccine study. If you have any future questions about research, please feel free to contact me at 559-743-7340.

APPENDIX F: CSU, FRESNO, IRB APPROVAL



California State University, Fresno  
School of Nursing  
IRB Approval

Date: August 8, 2018

RE: DNP 1804 Human Papillomavirus Vaccine Program

Dear Magdalena Ruiz,

As the Chair of the School of Nursing Research Committee, serving as the Institutional Review Board for the School of Nursing, I have reviewed and approved your review request for the above-referenced project for a period of 12 months. I have determined your study to meet the criteria for Minimal Risk IRB review.

Under the Policy and Procedures for Research with Human Subjects at California State University, Fresno, your proposal meets minimal risk criteria according to section 3.3.7: Research in which the risks of harm anticipated are not greater, probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

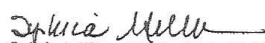
The Research Committee may periodically wish to assess the adequacy of research process. If, in the course of the study, you consider making any changes in the protocol or consent form, you must forward this information to the Research Committee prior to implementation unless the change is necessary to eliminate an apparent immediate hazard to the research participant(s).

This study expires: August 8, 2019

The Research Committee is authorized to periodically assess the adequacy of the consent and research process. All problems having to do with subject safety must be reported to the Research Committee. Please maintain proper data control and confidentiality.

If you have any questions, please contact me through the CSU, Fresno School of Nursing Research Committee at [symliller@csufresno.edu](mailto:symliller@csufresno.edu).

Sincerely,

  
Sylvia Miller, EdD, RN, FNP-C  
School of Nursing, Research Committee, Chair

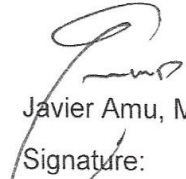
School of Nursing  
California State University, Fresno • McLane Hall, Room 190  
2345 East San Ramon Avenue M/S MH25 • Fresno, California 93740-8031  
P 559.278.2041 F 559.278.6360 [www.FresnoState.edu/chhs/nursing](http://www.FresnoState.edu/chhs/nursing)

THE CALIFORNIA STATE UNIVERSITY

APPENDIX G: JAVIER AMU, M.D., PROJECT PERMISSION



I, Javier Amu, MD, give Magdalena Ruiz, California State University, Fresno, School of Nursing Doctor of Nursing Practice student, permission to conduct a study at my office located at 1093 11<sup>th</sup> St., Reedley, California.

  
Javier Amu, MD  
Signature:  
Date: 06-22-18

**APPENDIX H: RESEARCH STUDY CONSENT FORM**

Consent to participate in a research study

Study title: Human Papillomavirus Vaccine Program

Principal Investigator: Magdalena Ruiz NP-C

Contact information: 559-743-7340

This is a research project focusing on the Human Papillomavirus vaccine. The researcher and primary investigator is a Doctor of Nursing Practice student at the California State University, Fresno. Magdalena Ruiz is the nurse practitioner and primary investigator which will be conducting the study taking place at Dr. Amu rural health clinic in the city of Reedley.

**Purpose of research study:**

The purpose of this study is to evaluate and identify the reasons for parental refusal to the HPV vaccine by conducting parent interviews, evaluate a resource tool and education provided by the primary investigator, and determine how an education session can increase vaccine compliance rates via a one-month follow-up assessment.

**Consent form:**

The purpose of this consent form is to obtain participation consent from the parents who will be interviewed, participate in teaching session, and a phone call follow-up assessment all conducted by the primary investigator.

**Where will study take place:**

1. Interviews and teaching sessions will take place in conference room at the pediatric rural health care clinic located on 1093 11<sup>th</sup> St. Reedley, CA.

**Procedures**

1. You will be contacted using the electronic medical records demographic system by the researcher. Interview should take approximately 10-15 minutes.
2. You will check in front office and will be taken back to conference room with provider for a face-to-face interview regarding vaccine refusal.
3. After interview the primary investigator will use resource tool to provide education about the HPV vaccine. Both interview and education session will be recorded for research purposes.
4. A month later you will be contacted via phone call assessment.
5. Decision to participate in study is completely voluntary and there will be no change to patient treatment with primary care provider based on parent participation.
6. At any point in time during interview or follow-up phone call subject can feel free to not answer a question.

**Potential risks of study**

1. Potential risks of study could be risks can include confusion and your feeling pressured to consent to HPV vaccine.

### **Benefits of study**

1. Interviews will help identify reasons for parental refusal to HPV vaccine.

### **Confidentiality**

In participating in study, your answers and personal information will be kept safely in a laptop file in which only researcher has password to.

### **Voluntary consent for participation in study and withdrawing option**

It is completely voluntary to participate in study and you can withdraw from study at any time.

### **Investigators readiness to answer questions regarding research**

Please feel free to contact Magdalena Ruiz NP-C if you have any questions regarding research study or your participation in parental interview at 559-743-7340.

### **Compensation**

Currently there is no cost to you or any compensation for your participation in study. Your participation in this research is greatly appreciated.

### **Consent to participate in study**

If you wish to participate in the parental interview for the Human Papillomavirus Vaccine Program study, please sign below.

Date:

Participants printed name: \_\_\_\_\_

Participants signature for consent: \_\_\_\_\_

Date:

Printed name of person obtaining consent: \_\_\_\_\_

Signature of person obtaining consent: \_\_\_\_\_

Date:

Investigator's printed name: \_\_\_\_\_

Investigator's signature: \_\_\_\_\_