A Pilot Study Testing the Effect of a Decision Aid on Parental Decisional Conflict Related to Human Papillomavirus Vaccination

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A Dissertation presented to the Graduate Faculty
of the University of Virginia in Candidacy for the Degree of
Doctor of Philosophy

School of Nursing

University of Virginia
May, 2016

Abstract

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. HPV is responsible for multiple disease states and cancers around the globe of varying severity in both females and males. Although a vaccine is available to protect against the strains of HPV most likely to cause significant health effects, vaccination rates are disappointingly low compared to other recommended vaccines. The primary aim of this study was to test the feasibility and acceptability of implementing a short primary care, office-based, decision aid for a parent/child dyad deciding whether to accept HPV vaccination. The secondary aim of this study was to gather preliminary data for (a) describing the frequency of decisional conflict in parents scheduled to obtain the recommended HPV vaccine for their child in a primary care pediatric practice, (b) testing the hypothesis that parental post-intervention decisional conflict will be less than parental pre-intervention decisional conflict; (c) testing the hypothesis that there will be a difference between the proportion of parents with decisional conflict who accept the HPV vaccine and the proportion of parents with no decisional conflict who accept the HPV vaccine; and (d) testing the hypotheses that factors affecting parental vaccine acceptance include the adolescent's opinion regarding HPV vaccination, whether any children in the family have already received the HPV vaccine, and a personal or family history of HPV related disease, in addition to parental decisional conflict. An additional exploratory aim of this study was to gather preliminary data for describing the frequency of parental decisional regret two weeks post-vaccination decision. A single-arm prospective interventional pilot study was conducted using an interactive decision aid with 80 parent/child dyads considering HPV vaccine acceptance in a primary care pediatric office. Overall, participants found the decision aid to be acceptable (ease of use and time) and helpful. The majority of parents reported decisional conflict pre-intervention. Total decisional conflict as well as all subscale scores decreased post-intervention. As expected, using chi-square analysis, the proportion of parents with decisional conflict who accepted the HPV vaccine for their child was significantly lower than the proportion of parents with no decisional conflict who accepted the HPV vaccine. Using binary logistic regression, results indicate that three factors (having a child previously vaccinated against HPV, parental decisional conflict defined as a score of greater than 2.0 using the Decision Conflict Scale at the time of the vaccine decision and the adolescent's opinion regarding HPV vaccination) were significant predictors of parental acceptance of the HPV vaccine for their child. While the majority of parents reported low to no decisional regret two weeks after the vaccination decision, two of the three parents expressing significant decisional regret declined the HPV vaccine for their child at the time of the health visit.

Keywords: parental decision making; adolescents; human papillomavirus (HPV), HPV vaccine, decisional conflict, decision regret

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Dedication

This dissertation is dedicated to my daughter, Lisa, for her confidence, unfaltering support, and encouragement. You are my daily inspiration, my strength in times of weakness and my remedy for whatever ails me. I am a better person because of you. A special thank you to my Mom and Sister Mary for their support and especially to my Dad who taught me to value and love learning.

Acknowledgments

I am profoundly grateful to have had Dr. Patricia Hollen as my advisor and dissertation chair. Her wisdom, guidance, and attention to detail were essential to the realization of this research. Her consummate dedication to my success throughout this journey and to the advancement of nursing knowledge through research is inspiring. A heartfelt thank you to my dissertation committee members for their time, attention and exceptional feedback and advice: Dr. Elizabeth Epstein, Dr. Jessica Keim-Malpass, Dr. Martha Hellems, and Dr. Jeanita Richardson. I am immensely grateful to Dr. Virginia Rovnyak. Her time and valuable statistical expertise were critically important to the design, analysis and interpretation of this research. Thank you to my work family at Piedmont Pediatrics in Warrenton, Virginia for your gracious support of this study. It has been a blessing to work with and get to know the deans, faculty and staff at the UVa School of Nursing and so many gifted and supportive colleagues whom I am happy to call my friends.

Chapter 1

INTRODUCTION

In 2007, the Advisory Committee on Immunization Practices (ACIP) recommended use of the quadrivalent human papillomavirus (4vHPV) vaccine that was licensed by the Food and Drug Administration (FDA) in 2006 for females 9 to 26 years of age (Markowitz et al., 2007). The quadrivalent vaccine provides protection against HPV strains 6, 11, 16, and 18. In 2008, the state of Virginia put into effect a law that requires the HPV vaccine for girls on or after their 11th birthday but allows parents to exempt their child for any philosophical or religious reason (Immunization of patients against certain diseases, 2008). In 2009, the FDA licensed this vaccine for use in males 9 to 26 years of age (Centers for Disease Control [CDC], 2010). In 2010, the ACIP made a provisional recommendation for use in males but did not recommend routine vaccination in males (CDC, 2010). The recommendation was based on statistical analysis suggesting that routine vaccination of males was not cost effective if vaccination rates of females were greater than 80 percent (Brisson, Van de Velde, & Boily, 2009).

In 2011, the ACIP recommended routine use of 4vHPV for males 11 or 12 years of age, although vaccination can start as early as 9 years of age (CDC, 2011). The vaccine 4vHPV was recommended for males aged 13-21 years who were not previously vaccinated; males 22 through 26 years also may be vaccinated (CDC, 2011). This new recommendation was made after the ACIP considered the low vaccination rates against HPV in females and after the FDA added prevention of anal and oropharyngeal cancer in males as an indication (FDA, 2011). The vaccine is currently not mandated for males in the state of Virginia.

On December 10, 2014, the U.S. Food and Drug Administration (FDA) approved a new version of the HPV vaccine, Gardasil 9 (9vHPV), for females 9 to 26 years of age and for males from 9 to 15 years of age, that provides protection against strains 6,11, 16, and 18, included in the original vaccine as well as five additional strains, 31, 33, 45, 52, and 58 (Kirby, 2015). In February 2015, the ACIP recommended Gardasil 9 as one of the two HPV vaccines that can be used for routine vaccination in females and males at 11 or 12 years of age (Petrosky et al., 2015). The ACIP has advised that the vaccine can be given as early as 9 years of age and is recommended for females 13 through 26 years and males 13 through 21 years of age, who have not previously been vaccinated or who have not completed the three dose series of 4vHPV or 9vHPV (Petrosky et al., 2015). Males 22 to 26 years of age may be vaccinated and the ACIP recommends that men who have sex with men and immunocompromised persons be vaccinated if not previously vaccinated (Petrosky et al., 2015).

Vaccination rates. Despite the development of this potentially life-saving vaccine, the 2014 National Immunization Survey (NIS) reported that HPV vaccine dissemination rates remained lower than the targeted goal of 80% (CDC, 2014a). Approximately 40% of females and 22% of males nationally had completed the 3-dose

HPV vaccination series (CDC, 2014a). The vaccination initiation rate for the HPV vaccine in Virginia, for females 13-17 years of age was approximately 50% and 36% for males 13-17 years of age. Females who have received at least 3 doses of the HPV vaccine in Virginia, for females aged 13-17 years, was approximately 36% (CDC 2014a). Approximately 23% of males between 13 and 17 years of age had received 3 or more doses of the HPV vaccine in Virginia (CDC, 2014a). Approximately 65% of females and 76% of males who initiated the HPV vaccination series in Virginia had completed the series (CDC, 2014a).

It is important to note that studies that were conducted before or shortly after licensure of the HPV vaccine for females reported that most parents intended to vaccinate their daughters (Bair, Mays, Sturm, & Zimet, 2008; Brewer, & Fazekas, 2007; Constantine & Jerman, 2007; Rosenthal et al., 2008). Contrary to these early reports, current trends in the United States indicate that vaccination rates have not only been lower than predicted based on these intention to vaccinate outcomes but that vaccination rates have stagnated over time across ethnic groups and socioeconomic status (Jeudin, Liveright, del Carmen, & Perkins, 2014).

Barriers and disparities. Several studies have examined characteristics or profiles of vaccine acceptors versus non-acceptors. In one study, N=2185, data were collected using a Web-based survey and multivariate analyses determined that child age (11-13 years of age compared to 9-10 years), provider communication (strongly recommending compared to discussing without recommending) and gender (females compared to males) in the age groups over 10 years of age were significantly associated with HPV vaccine initiation (Donahue, Hendrix, Sturm, & Zimet, 2015). Unfortunately, healthcare providers did not discuss HPV vaccination with nearly 50 percent of mothers in this study (Donahue et al., 2015). Minority status was not found to be a significant predictor using the multivariate analyses, although the data were not collected from a nationally representative sample (Donahue et al., 2015). Donahue et al. (2015) reported that provider recommendation was the strongest predictor of vaccine initiation.

Using the 2013 National Immunization-Teen Survey (N=12,225) of males ages 13-17 years, Lu et al. (2015) found significant racial and ethnic disparities after controlling for other factors. Based on multivariable logistic regression models, vaccination initiation was more likely in non-Hispanic black or Hispanic males, living with a single mother, having a health visit in the past 12 months, having a well-child visit at age 11 or 12 years, having 1 or 2 vaccination providers, living in urban or suburban area and receiving immunizations from a variety of venues (Lu et al., 2015). Vaccination initiation was significantly less likely when the mother had at least some college education, having a higher family income to poverty ratio, living in the South or Midwest and those receiving vaccination from all STD/school/teen clinics or other facilities (Lu et al., 2015).

Jeudin et al. (2014) reported that vaccination initiation rates are about equal or better in the African American and Latino female population, and in those below the poverty level compared to white more affluent female adolescents; however, vaccine

completion rates are lower in these groups compared to white females and those above the poverty level. Unfortunately, this population of females is disproportionately affected by cervical cancer and would benefit most from HPV vaccination (CDC, 2012a). In summary, research on the impact of the quadrivalent HPV vaccine reported in the *Journal of National Cancer Institute* by Munoz et al. (2010) emphasized that strategies to improve HPV vaccination rates may lead to substantial reductions in HPV related disease and cancers.

Decisional conflict. Studies have shown that parents sometimes express doubt or uncertainty regarding acceptance of vaccines (Gust, Darling, Kennedy, & Schwartz, 2008; Hughes, Jones, Feemster, & Fiks, 2011; McRee, Brewer, Reiter, Gottlieb, & Smith, 2010). Gust et al. (2008) reported that 28% of parents (N=3,924) randomly surveyed in conjunction with the National Immunization Survey (NIS) in 2003 and 2004, reported some level of doubt about accepting vaccines for their child. According to Gust et al. (2008), doubt was self reported and the level of doubt was expressed in increasing order: a) got the vaccination for their child although they were not sure it was the best thing to do (unsure); b) delayed a vaccination for their child (delayed); or c) decided not to have their child get a vaccination (refused). Of the 28% of parents reporting doubt about vaccines, 8.9% reported vaccinating their child although they were not sure it was the best thing to do, 13.4% reported delaying vaccination and 6.0% reported refusing a vaccination for their child (Gust et al., 2008). Gust and colleagues reported (2008) that white parents constituted the largest proportion of refused (83.9%), compared with delayed (65.2%), and unsure (65.7%), doubt indicators. These researchers also reported that white parents also had the highest proportion of vaccine refusals while blacks had the highest proportion of unsure parents. Parents who vaccinated even though they felt unsure or delayed vaccination were more likely to be married females older than 30 years of age, with an annual income of $30, 000.00 or less, with 12 years or less of education and with two to three children (Gust et al., 2008). Parents who refused vaccination were more likely to be married women at least 30 years of age with at least some college education, with two or three children and an annual income of at least $50,000.00 (Gust et al., 2008). Parents who felt unsure or who refused vaccinations reported concerns about the safety or side effects of the vaccine as the main reason for their doubts for all vaccines (Gust et al., 2008). Parents who delayed vaccination most often reported doing so because their child was ill (Gust et al., 2008). The largest proportion of parents who changed their minds about delaying or refusing a vaccination reported doing so due to the recommendation of their healthcare provider (Gust et al., 2008). Parents who reported feeling unsure and parents who refused vaccination identified the varicella vaccine most often, followed by "not any one vaccine" as the vaccine(s) that most concerns them (Gust et al., 2008).

Although data for this 2008 study were collected prior to the more recent recommendations for adolescent vaccination with Tdap, Menactra and HPV, the doubt reasons are still relevant. Yet, similar findings may be expected with the HPV vaccine because (1) it is the most recent addition to the childhood vaccination schedule, (2) the purpose of the vaccine is to prevent diseases that are transmitted sexually, and (3) the

vaccine is recommended to be given at a young age that is not normally associated with topics related to sexual activity.

Decision aids. Making decisions without adequate and accurate information, without consideration of one's personal values and preferences, and without the benefit of decisional support can result in uncertainty or decisional conflict (Janis & Mann, 1977; Parayre, Labrecque, Roussear, Turcotte, & Legare, 2014). Decision aids have been shown to be an effective intervention to (a) encourage communication between a patient and their healthcare provider, (b) to explicate patient perceptions and values concerning health decisions, (c) to reduce decisional conflict, and (d) to improve the quality of decision making (Hsu, Liss, Westbrook & Arterburn, 2013; O'Conner, 1995; O'Connor et al., 1998; Wroe, Turner, & Owens, 2005). The literature emphasizes that health care providers may benefit from tools that guide their communication with patients and parents on HPV vaccine recommendations (Holman et al., 2014). Similarly, in the President's Cancer Panel Report 2012-2013, recommendations for research include the development of tools that can be used by providers to facilitate communication with parents and adolescents related to HPV associated diseases and HPV vaccines (U.S. Department of Health and Human Services, 2015). In a Cochrane database of systematic reviews, decision aids have been shown to be useful in many areas of health-related decision making in a non-emergent situation including seasonal flu vaccination, but to date there have been no studies demonstrating their effectiveness with the HPV vaccine (Stacey et al., 2014). Most importantly, decision aids have been shown to be effective in promoting parental participation in the decision-making process, improving parental perceptions of being informed, reducing decisional conflict and related anxiety while fostering parent communication with the provider related to vaccines (O'Conner, 1995; Wallace, Leask & Trevena, 2006; Wroe, Turner & Owens, 2005).

Adolescent involvement. In Virginia, parental consent is required to vaccinate anyone under 18 years of age unless they are emancipated (Virginia Code §54.1-2969). The American Academy of Pediatrics Committee on Bioethics (1995) clearly states that children and adolescents should be included in healthcare decision making along with their parents and healthcare providers to the extent that their developmental abilities allow unless extenuating circumstances exist. The importance of empowering children to participate in their healthcare to the extent of their abilities is crucial to the concept of *assent* (as defined by the American Academy of Pediatrics [AAP] Committee on Bioethics, 1995). The assenting process should be one in which information and values are shared and decisions are made with the participation of the minor, the parent, and the healthcare provider in an interactive fashion to include the following elements: (a) helping the minor achieve awareness of the health-related condition, (b) telling the minor what they can expect with tests or treatments, (c) assessing the minor's understanding of the information, d) gaining a better understanding of the factors that influence how the minor responds to the proposed test or treatment, and (e) obtaining feedback from the minor regarding their willingness to accept the proposed care. Involving the minor in discussions about their healthcare, even when it is not appropriate or possible to attain agreement or the opinion of the minor, may foster trust and a better relationship between

the minor and their healthcare team and may improve long-term health outcomes (American Academy of Pediatrics Committee on Bioethics, 1995).

Early adolescence is a transitional period that involves changes related to physical growth, hormone changes, cognitive, emotional, and social adjustments (Dahl & Gunner, 2009). Changes in the executive functioning of adolescents are representative of evolving or elasticity of cognitive functioning (Giedd et al., 1999). *Executive function* refers to a broad range of mechanisms that control or modulate and organize basic cognitive processes that allow goal-directed behavior (Tsuchida & Fellows, 2013). *Decision making* is a facet of executive functioning that involves the ability to consider the decision at hand, assess the available options, evaluate the risks and consequences, plan a course of action and follow through with the action (Baron, 2008). Executive functioning takes place in the prefrontal cortices that are still maturing in adolescence and are the last region of the brain to develop fully (Pustilnik & Henry, 2012). Connectivity of executive function and emotion, essential for rational decision making, is lacking in early adolescence and evolve over time (Pustilnik & Hendry, 2012)

As in adults, adolescent decision making is complex, has multi-factorial influences and rarely follows normative or "rational" decision-making processes (Casey et al., 1997). Decision making during adolescence should become increasingly independent of adult influence (American Academy of Pediatrics Committee on Bioethics, 1995). Early adolescents typically have qualities that may support and interfere with their successful participation in the decision-making process (Casey, Jones, & Sommerville, 2011). Participation is likely to be most successful when the adolescent is sufficiently prepared, supported by a parent or other trusted adult, and in a state of low stress or anxiety (van Duijvenvoorde, Jansen, Visser, & Huizenga, 2010). Learning how to make quality decisions can be taught through a cooperative process with a weaning of parental support throughout the adolescent years, as the adolescent feels comfortable, depending on the circumstances. To date in the literature, information about the adolescents' opinions regarding HPV vaccination and their influence on parental HPV vaccination decisions are lacking.

Knowledge gap and research purpose. This pilot study with 80 parent/child dyads will assess for the incidence of parental decisional conflict related to HPV vaccination for their child and test trends for the effectiveness of a decision aid to help reduce parental decisional conflict. This study will also assess the feasibility and acceptability of this two-part decision aid that will be presented by the study nurse and used interactively with the parent/child dyad. The intent is to improve HPV vaccination acceptance by reducing decisional conflict using informed, shared decision making. It is expected that the decision aid will (a) create an opportunity to gain knowledge, (b) address and clarify parental concerns and values, and (c) provide an opportunity for provider communication with the dyad at the time of the vaccination visit. The two-part decision aid includes (a) a practical information sheet "What can you do to prevent Human Papillomavirus (HPV)?" for parents and adolescents 15 to 17 years of age which was developed by the PI to address frequently asked questions and address myths in the media, and (b) a decisional balance sheet that addresses individual values and priorities. The information sheet provided to children/adolescents 11-14 years of age "What is human papillomavirus (HPV)?" was also developed by the PI to give information about HPV but does not discuss how HPV is transmitted.

In previous studies related to immunizations, particpants have used decision aids on their own rather than in an interactive forum with their healthcare provider (Chambers et al., 2012; Jackson et al., 2011; Shourie et al., 2013). This study will use a decision aid as an interactive educational tool with the dyad and study nurse to enhance shared decision making. The broad goal for this program of research is to test and promote a low-cost, interactive intervention with each dyad (parent and child), using a decision aid with feasibility and acceptability properties. At this stage of development, further evidence is needed for implication to practice. Testing by pediatric nurse practitioners using this unique format in a general pediatric practice where these vaccination decisions take place will provide this needed evidence.

Specific Aims

Broad Goal/Major Objective/Aims

The broad goal of this pilot study is to better understand parental decision making related to HPV vaccination. A major objective of this study is to help understand and reduce parental decisional conflict related to HPV vaccination and improve HPV vaccination rates toward the 80% vaccination goal for Healthy People 2020. It is expected that the decision aid will help reduce decisional conflict, improve vaccination rates and reduce follow-up decisional regret through improved shared decision making supported by the American Academy of Pediatrics, the Institute of Medicine and the Afffordable Care Act.

Specific aims of this study are:

1. To determine the feasibility and acceptability of implementing a short, primary care, office-based, decision aid (cognitive-behavioral skills intervention) for a parent/child dyad deciding whether to accept HPV vaccination.

   The feasibility of the study will be evaluated on the following criteria:

   1.1 The number of participants who can undergo the steps of recruitment, informed consent, and enrollment within the specified 9-month accrual period.

   The acceptability of the study will be evaluated on the following criteria:

   1.2 The number of participants (parents and children separately) who found the intervention helpful in the decision-making process and acceptable (ease of use/length of time for completion).

2. To gather preliminary data for:

   2.1 Describing the incidence of decisional conflict in parents scheduled to obtain the recommended HPV vaccine for their child in a primary care pediatric practice.

   2.2 Testing the hypothesis that post-intervention decisional conflict will be significantly less than pre-intervention decisional conflict.

2.3 Testing the hypothesis that there will be a difference in the proportion of parents with decisional conflict and parents with no decisional conflict who accept the HPV vaccine.

2.4 Testing the hypothesis that factors predicting parental vaccine acceptance include the adolescent's opinion regarding HPV vaccination, the number of children in the family that have already received the HPV vaccine, and a family history of HPV related disease.

An exploratory aim is:

3. To gather preliminary data for:

Describing the incidence of parental decisional regret 2-weeks post-vaccination decision.

Impact on the Field

The targeted HPV immunization goal for Healthy People 2020 is 80% (U.S. Department of Health and Human Services, 2015). Decision aids have been used successfully to enhance the decision-making process in other non-emergent situations (e.g., seasonal flu vaccinations, MMR), but to date no studies have demonstrated their effectiveness when used interactively or with the HPV vaccine (Herbert et al., 2013; Jackson et al., 2011; Shourie et al., 2013). It is expected that the results of this study will provide needed information related to the incidence of parental decisional conflict related to HPV vaccination and the effect of a decision aid on parental decisional conflict.

Scope of the problem. Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States (CDC, 2014b). Approximately 79 million people are currently infected with HPV in the United States and approximately 14 million people acquire new infection each year (CDC, 2014b). HPV related infections are responsible for multiple disease states of varying severity in both females and males including abnormal cervical cells, anogenital warts, respiratory papillomatosis, and anal, cervical, vulvar, vaginal, penile and oropharyngeal cancers (CDC, 2014b; Chaurvedi, Engels & Pfeiffer, 2011).

Cervical cancer is the second most common cancer in women worldwide, with 99% of cases linked to infection of the reproductive tract with HPV (World Health Organization [WHO], 2016). Worldwide, the prevalence of cervical cancer in 2008 was an estimated 530,000 cases and 275,000 cervical cancer related deaths (Arbyn et al., 2011). In the U.S., a study from 2004-2008 identified 33,369 HPV associated cancer cases (CDC, 2012b). The CDC estimated that approximately 26,000 new HPV associated cancer cases would occur each year (2012b). The most recent statistics from 2012 indicate that in the U.S., approximately 12,000 women were diagnosed with cervical cancer and approximately 4,000 women died from cervical cancer (CDC, 2012b). The prevalence of HPV related infections in females is greatest among those 20 to 24 years of age (Hariri et al., 2011).

Oropharyngeal cancer is the most common (72%) HPV related cancer affecting men and was four times as high in men compared to women (CDC, 2012b). Seventy two percent of oropharyngeal cancers are caused by HPV with an estimated 2,370 new cases

diagnosed in women and 9,356 new cases diagnosed in men each year in the United States (CDC, 2012b). The literature indicates that the incidence of oropharyngeal cancers caused by HPV infection in the United States is increasing (Ramqvist & Dalianis, 2010). Anal cancer was highest among white females and black males (CDC, 2012b). Cervical and penile cancer was higher among blacks and Hispanics compared to whites and non-Hispanics (CDC, 2012b).

Approximately 360,000 people develop genital warts from "low risk" strains of HPV in the United States each year (CDC, 2014b). Genital warts are growths or clusters of growths that affect the genitalia including the vulva, penis and anus. The term "low risk" is used to describe HPV strains that do not typically lead to cancer. Conversely, "high risk" strains of HPV typically are oncogenic or lead to cancer over time.

HPV strains 6 and 11 are considered "low risk" strains and together are responsible for approximately 90% of genital warts and 100% of recurrent respiratory papillomas (Lacey, Lowndes, & Shah, 2006). High-risk strains 16 and 18 together are responsible for 70% of cervical cancer (Munoz, et al., 2004). HPV 16 and 18 are also responsible for approximately 90% of HPV-positive cases of oropharyngeal squamous cell carcinoma, with HPV 16 present in nearly 87% of these cases (Kreimer, Clifford, Boyle, & Franceschi, 2005).

Goal of new vaccine. A quadrivalent vaccine that includes HPV strains 6, 11, 16, and 18 was licensed in 2006 (Markowitz et al., 2007). In clinical trials, the quadrivalent vaccine was efficacious in preventing persistent HPV infection of types 6, 11, 16 and 18 in females who had not already been infected with the respective HPV type (Markowitz, et al, 2007). The quadrivalent vaccine is completed in three doses with the second and third dose given at 1-2 and 6 months after the initial dose (Markowitz et al, 2007). The new HPV vaccine, Gardasil 9, includes the four HPV strains in the quadrivalent Gardasil and five additional HPV types 31, 33, 45, 52, and 58 (Kirby, 2015). The Gardasil 9 vaccine will increase protection from cervical cancer from 70% to 90% compared to the quadrivalent Gardasil vaccine (Kirby, 2015).

In summary, human papillomavirus related diseases and cancers remain an important public health problem (CDC, 2014b). With the development of a preventive vaccination available, healthcare providers are charged with the challenge of improving dissemination of information to the public and increasing HPV vaccination coverage to reduce the scope of this problem.

Chapter 2

REVIEW OF LITERATURE

An integrative review of the literature was conducted to explore the factors that contribute to parental acceptance and non-acceptance of the Human papillomavirus (HPV) vaccine for children and adolescents. The purpose of this review was to summarize the findings in order to identify common factors that influence parental decision making concerning HPV vaccination. Two separate reviews were conducted because information in the early literature included feedback from parents that related only to female children or adolescents. The early literature also included outcomes derived from hypothetical cases and intent to vaccinate rather than the actual act of vaccination. Thus, a second literature review was conducted after the U.S. Food and Drug Administration (FDA) licensed the HPV vaccine for males and literature emerged that included males who were eligible for HPV vaccination. The second literature review included males and females and also included data only from outcomes related to actual vaccination against HPV, rather than intent or hypothetical situations. Identification of substantive issues related to vaccination outcomes is imperative to guide future research.

Literature Review 1

This review considered factors influencing parental decision making including the intent to vaccinate or hypothetical acceptance of the HPV vaccine for eligible females.

Method

Search strategy. A comprehensive literature review was conducted using the following online databases: Medline, PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL), PsycINFO. Keywords for searching the databases were *decision making, parents, human papillomavirus, nursing, literature review, adolescents,* and *vaccines.* The time frame for the literature search was 2006 to 2012. The chosen time frame was based on the licensure year of the quadrivalent HPV vaccine for females and the year the review was conducted. Articles were restricted to English only.

Selection criteria. Articles were included if the study reported factors affecting parental decision making related to HPV vaccination. Using these criteria, a total of 45 articles were retrieved. Further exclusion for duplicates (n=9), studies conducted outside of the U.S. (n=14), outcomes that were not relevant to this review (n=5), and for publication types that were not primary research reports (n=1), returned 16 articles. The decision to exclude studies conducted outside of the U.S. was made based upon the premise that the barriers in one country might not be applicable to another country. For example, in the United Kingdom, adolescents can self-consent for medical treatment including vaccination (Brabin, Roberts, & Kitchener, 2007). Not having a parent available to consent for adolescent vaccinations is a potential barrier in the U.S.

Procedure

Data collection. Each research report was reviewed and each study was assessed for the following characteristics: purpose or aim, sample, theoretical approach, intervention or description, research design, outcome measures and results. Major themes and findings were identified for each of the studies.

Theoretical framework. Four of the 16 studies identified a theoretical framework. Three of the four studies that identified a framework used the health belief model (Dempsey, Zimet, Davis, & Koutsky, 2006; Gowda et al., 2012; McRhee, Reiter, & Brewer, 2012). Dempsey et al. (2006) used the health belief model and the theory of reasoned action. Allen et al. (2010) used the integrative model of behavioral prediction. Many of the constructs identified in the literature fit the theoretical framework of the health belief model even when not identified as such; thus, this framework was used to categorize results described here in greater detail.

The health belief model is a psychological model developed by G. Hochbaum (1958) to explain health-related behaviors. In its early development, the model was used to explain why people were not participating in programs to prevent or detect disease like the free tuberculosis screening programs offered in the 1950s by the Public Health Service (Hochbaum, 1958). According to Hochbaum (1958), the model was designed to better understand why some healthy people who have no symptoms or signs of illness take health-related actions to detect problems at an early stage or for preventing disease while others do not. The two principal dimensions of the early model included the *susceptibility* one felt to a particular disease or health condition and the *degree of seriousness* one associated with having the disease or health condition (Hochbaum, 1958). The model proposed that these two dimensions predicted a readiness to act or to take a particular course of action. The model continued to be developed by Rosenstock (1966) through ongoing research studies and was expanded to include additional constructs: a) *perceived benefits of taking action*, b) *perceived barriers to taking action*, and c) *cues to action*. Over time, the model became a theoretical framework for understanding preventive health-related behaviors of individuals as well as compliance or acceptance of illness related treatments (Becker et. al, 1978). The final model also included the construct of *self efficacy*, defined as an individual's belief that they will be able to successfully perform a recommended action (Rosenstock, Strecher, & Becker, 1988).

Analysis. The studies retrieved from the existing literature on HPV capture a variety of factors that influence parental HPV vaccine acceptance. The studies are multidisciplinary from within the healthcare arena. The literature represents the disciplines of medicine, nursing and public health. The majority (94%) of the reviewed studies used a descriptive research design. Data collection methods are shown in Table 2.1.

Table 2.1

Research Design and Method

Design	Survey	Interview	Questionnaire	Interview & Questionnaire	Total
Descriptive	5 studies	3 studies	6 studies	1 study	15 studies
Quasi-experimental	1 study	0	0	0	1 study
Total	6 studies	3 studies	6 studies	1 study	16 studies

All studies clearly stated the purpose of their study and the methods chosen to investigate the questions were appropriate to the stated purpose of the research. The majority of the studies (62.5%) used convenience sampling with clear descriptors of the sample characteristics and recruitment techniques as seen in Table 2.2.

Table 2.2

Sampling

Type of Sampling	Number of Studies	Percentage of Studies
National Panel	2	12.5%
Convenience	10	62.5%
Random Digital Dial	1	6%
Purposive	3	19%
Total	16	100%

Results

From the integrative review, a variety of factors were identified as contributors to the parental decision-making process for HPV vaccine acceptance. The constructs of the health belief model, *perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action* and *self-efficacy* were used to organize the identified factors as shown in Table 2.3.

Table 2.3

Major Factors Influencing Parental Decision Making for HPV Vaccine Acceptance

Construct	**Factors**	**Studies n/%**
Perceived susceptibility	Parent believes child is not sexually active	2/13
	Young age of child	3/19
Perceived severity	Concern that HPV causes cancer/death	1/6
Perceived benefits	Protection of the daughter from disease	3/19
	Eradication of an STI	1/6
	Belief in vaccines	1/6
	Cancer prevention	1/6
Perceived barriers	Perceived lack of information	5/31
	Social influence	2/13
	Negative attitude toward vaccine in general	2/13
	Vaccine safety concerns	5/31
	Perception of vaccine ineffectiveness	1/6
	Concern for encouraging sexual debut	1/6
Cues to action	Social Norms	2/13
	Media/Marketing messages	2/13
	Parent experience with HPV related disease	1/6
	Healthcare provider recommendation	6/38
Self-efficacy	Cost	2/13
	Vaccination series requiring multiple doses	1/6
	Lack of health insurance	1/6
	Missed opportunity	2/13

In summary, factors associated with parental acceptance of the HPV vaccine were most frequently reported within the constructs of *cues to action* and *perceived benef*its. Thirty eight percent of studies reported that healthcare provider recommendation within the construct of *cues to action* was a significant influence in parental HPV vaccine acceptance (Gowda et al., 2012; Griffioen et al., 2012; McRhee, Reiter, & Brewer, 2012; Rand et al., 2011; Rosenthal et al., 2008; Sanders, Arnold, & Notero, 2012). Protection from disease reported in 19% of studies, and cancer prevention reported in 6% of studies, within the construct of *perceived benefits* were reported as significant factors influencing HPV vaccine acceptance among parents (Bair et al. 2008; McRhee, Reiter, & Brewer, 2012; Sanders, Arnold, & Notaro, 2012; Sperber, Brewer, & Smith, 2007).

The constructs of *perceived susceptibility* and *perceived barriers* were most often associated with parental non-acceptance of the HPV vaccine. Factors within the construct *perceived susceptibility* that were associated with parental non-acceptance of the HPV vaccine were a parental belief that their child was not sexually active as reported in 13% of the studies (Oldach & Katz, 2012; Sanders et al., 2012). Parents reported feeling that their child was too young to receive the vaccine, as was reported in 19% of the studies (Bair, Mays, Sturm, & Zimet, 2008; Constantine & Jerman, 2007; Dempsey et al., 2006). These two factors may be highly correlated, and therefore, when combined represent 32% of the studies. Factors identified in the *perceived barriers* construct were the most numerous with six different variables identified. A perceived lack of information and concerns for vaccine safety were the two most reported factors associated with parental non-acceptance of the HPV vaccine. Parents reported a perceived lack of information or knowledge in 31% of the studies (Allen et al., 2010; Bair et al., 2008; Oldach & Katz, 2012; Woodhall et al., 2007; Yeganeh, Curtis, & Kuo, 2010). A lack of knowledge was the only factor associated with adolescents' lack of HPV vaccine acceptance in a study by Woodhall et al. (2007). Parents also reported concerns for vaccine safety or side effects as a reason for declining vaccination for their child in 31% of studies (Allen et al., 2010; Gowda et al. 2012; Oldach & Katz, 2012; Woodhall et al., 2007; Yeganeh et al., 2010). Gowda et al. (2012) suggested that perceived barriers might be the most important factor in determining parental acceptance of HPV vaccination.

Literature Review 2

The objective of this literature review was to identify and compare, based on child gender, the primary factors that influence *actual* parental decision making. For the purposes of this review, *actual* parental decision making is defined as a real time decision for their eligible child at the time of the health visit leading to vaccination or non-acceptance of the HPV vaccine.

Method

Search strategy. An integrative literature review was conducted using Medline, Cumulative Index of Nursing and Allied Health Literature (CINAHL), PsycINFO, and Pubmed for peer reviewed articles in the English language from 2007 to 2014 using the keywords: *decision making, HPV vaccine, adolescents, parents.* The timeframe was chosen to include 2007, the year that the HPV vaccine was first recommended by the Advisory Committee Immunization Practices (ACIP) for females to 2014, when the review was conducted. The early literature referred only to parents deciding to vaccinate females. The HPV vaccine was subsequently licensed for males and the ACIP recommended vaccinating eligible males in 2009. Studies that included parental decision making related to HPV vaccination in males has been more recent and is evolving.

Selection criteria. Articles were included if the study reported factors identified by parents of children and adolescents less than 18 years of age affecting the actual decision to accept or decline the HPV vaccine. This criterion was established because early studies reported 75% to 88% acceptability by parents making a hypothetical vaccination decision or intent to vaccinate (Constantine & Jerman, 2007; Woodhall et al., 2007; Zimet et al., 2005). To the contrary, the most recent National HPV immunization coverage data indicate that after eight years since the vaccine was recommended for females and six years since the vaccine was recommended for males, only approximately 60% of females and approximately 42% of males 13-17 years of age had begun the vaccination series (Reagan-Steiner et al., 2015). Articles were excluded if: 1) the article was not available, 2) the outcomes of the study were not relevant to the objective of this review, 3) the study was not conducted in the U.S., 4) the study was not original research, 5) the study was a duplicate found in another database, 6) vaccine recipients were over 17 years of age, and 7) the vaccination decision was intentional or hypothetical versus actual past or present.

Search outcome. As shown in the PRISMA flow diagram in Figure 2.1, the database search identified 126 articles. Thirty-seven duplicate articles were removed. From the 89 remaining articles, five articles were removed because a full text version was not available without purchasing the article. Fifty-four articles were excluded for outcomes that were not relevant to the objectives of this review. Twenty-four articles were excluded because they were conducted outside of the U.S.. Studies conducted outside of the U.S. were excluded because differences in cultural influences, health-care systems and vaccine consent laws are likely to affect outcomes pertinent to this review.

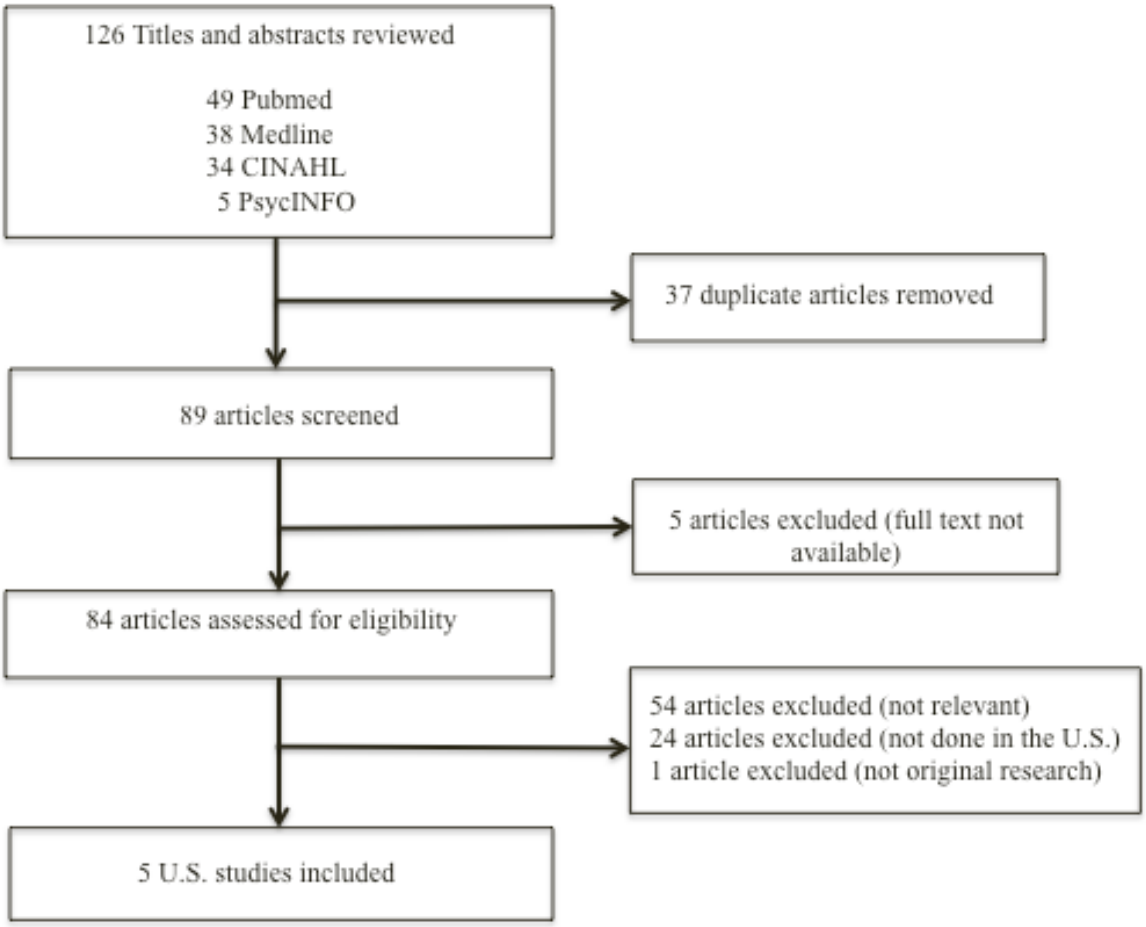

Figure 2.1 PRISMA Flow Diagram

Procedure

Data collection. A single reviewer, the author, assessed study eligibility and extracted data related to actual parental HPV vaccine acceptance or non-acceptance and the primary factors influencing their decision.

Theoretical framework. As in the first literature review, constructs from the health belief model were used to organize the findings. The health belief model has been successfully utilized to explain or predict heath-related actions (Rosenstock, Strecher, & Becker, 1988).

Analysis. Five studies were included in this review: three studies included actual past or present parental HPV vaccination decision making for females and two studies included actual past or present parental HPV vaccination decision making for males. All five studies used convenience sampling. Sample sizes ranged from 20 to 421 as shown in Table 2.4. The data were collected using surveys (2), interviews (2), and focus groups (1). All studies examined factors underlying parental decisions about HPV vaccination

for their child/adolescent. The studies were reviewed to determine common and unique factors that may influence HPV vaccine acceptance by gender.

Table 2.4.

Sample Size and Type of Sampling Used

Author & Date	Sample Size	Gender of Sample	Type of Sampling Used
Dempsey et al., (2009)	N=52	Females	Convenience
Hughes et al. (2011)	N=20	Females	Convenience-Purposive
Morales et al. (2012)	N=24 Mothers N=28 Daughters	Females	Convenience
Reiter et al. (2013)	N=421 (baseline) N=327 (f/u one year later)	Males	Convenience-National panel
Alexander et al. (2012)	N=21	Males	Convenience

A primary outcome of all of the studies included a description of factors (reasons or correlates of the parental decision to vaccinate against HPV). Two of the five studies obtained immediate information from the parent at the time of the vaccination decision (Alexander et al., 2012; Hughes et al., 2011). Hughes et al. (2011) reported only reasons for parental non-acceptance of the HPV vaccine and did not report reasons for parental vaccine acceptance. One study collected data from four focus groups that included a total of 24 Hispanic mothers of girls between 14 and 17 years of age (Morales-Campos et al., 2013). Only seven of the girls had actually been advised to receive the HPV vaccine by their healthcare provider. It was not clear if other girls had been to see their provider or not; thus, the information related to parental decision making was extracted from this study to include information only from these seven mothers related to their HPV vaccination decision. Study samples were variable as seen in Table 2.5.

Table 2.5.

Study Samples and Primary Outcomes

Author/Date	Study Samples	Primary Outcome
Dempsey et al. (2009)	N=52 Mothers of 11-17 year old females offered the HPV vaccine at a preventive care outpatient visit at a clinic within a large university healthcare system	Maternal reasons behind their HPV vaccination decision
Hughes et al. (2011)	N=20 Mothers of girls 11-18 years of age who were being seen by their primary care provider for a routine well visit and had not initiated HPV vaccination (60% African American and 40% White)	To explore parental decision making at the point of care
Morales-Campos et al. (2012)	24 Hispanic mothers of girls between 14 and 17 years of age. (Data from the 7 Hispanic mothers who had made an actual HPV vaccination decision was used in this review)	Knowledge about HPV and the HPV vaccine, willingness to vaccinate against HPV and factors that mothers considered when deciding to vaccinate their daughters
Reiter et al. (2013)	N=421 baseline N=327 follow up Parents of adolescent males 11-17 years of age	HPV vaccination at follow up among sons not vaccinated at baseline and the main reason for accepting/declining vaccination
Alexander et al. (2012)	N=21 Parents of 13-17 year old males (67% Black, 24% Hispanic and 10% White) from an adolescent primary care clinic in a low to middle socioeconomic Midwestern city	Demographics Vaccination decision Parent/Son decision-making process HPV vaccine decision making among parents

Results of Review 2

Using the constructs from the Health Belief Model, *cues to action* and *perceived benefits* were most influential for parents of eligible males and females who decided to accept the HPV vaccination as shown in Table 2.6. One study examined why parents chose not to vaccinate and did not assess for reasons parents chose to vaccinate (Hughes et al., 2011). Provider recommendation was reported as a primary reason for parental acceptance of the HPV vaccine in three of the five studies (Alexander et al., 2012; Morales-Campos et al., 2012; Reiter et al., 2013). Parents reported that provider recommendation was an influential factor in all studies that assessed for reasons parents vaccinated regardless of gender. Disease prevention was the second most common reason parents chose to vaccinate their child. Parents reported that protection from HPV related diseases or cancers was a primary factor that influenced their decision to vaccinate in one study of males and one study of females (Alexander et al., 2012; Dempsey et al., 2009). Parents of eligible females focused mainly on the benefits of cervical cancer prevention (Dempsey et al., 2009; Morales-Campos et al., 2012), while parents of eligible males focused mainly on the benefits of prevention of genital warts (Alexander et al, 2012).

The majority of factors associated with parental vaccine non-acceptance were within the construct of *perceived barriers*. Within this construct, a perceived lack of information was reported as a primary reason for declining vaccination in one study of males and one study of females. Parents reported that a perceived lack of information influenced their decision to decline vaccination in all of the studies concerning females and one of the two studies concerning males. The second most common primary reason parents declined the HPV vaccine for their child was within the construct of *perceived susceptibility*. Parents of females in two studies reported declining vaccination because they believed their daughter was not at risk because she was not sexually active or was too young to receive the vaccine. A lack of perceived susceptibility due to the young age of the child was reported in four of the five studies (three studies concerning females, one study concerning males) although only two of the five studies reported a lack of perceived susceptibility as the primary reason (both studies concerning females). Perceptions related to sexual activity and age may be strongly correlated. Although not reported as a primary factor, a common factor that parents reported in four of the five studies was concern for vaccine safety within the construct of *perceived barriers* when declining HPV vaccination. Concern for vaccine safety was expressed as concerns for the following: 1) side effects, 2) long-term effects, 3) what may not be known yet, and 4) the newness of the vaccine.

In summary, factors that affect parental decision making related to HPV vaccination in males and females are similar. Provider recommendation remains the strongest predictor of parental vaccine acceptance regardless of gender. This finding emphasizes the importance of the communication between the parent/child dyad and the provider when counseling about HPV vaccination and the potential benefits of interventions to improve this communication. Disease prevention is the second leading reason parents accepted the HPV vaccine for males and females, although the focus of prevention for most females was cervical cancer prevention compared to males who focused more on prevention of genital warts. Parents were influenced most often by a perceived lack of information and concerns for vaccine safety regardless of gender when declining the vaccine. Parents of females were more likely to perceive their daughters as not at risk when declining the vaccine.

Review limitations. For both integrated reviews, having a single reviewer was a potential limitation. Five studies were not included in the review due to the cost associated with accessing the articles. Several reviewers would have reduced the possibility of any bias in eliminating studies. The topic of HPV and HPV vaccination is rapidly evolving. As time passes, and parents and adolescents come in contact with additional or new information or have additional time to consider HPV vaccination, factors that influence their decision making may change.

Gaps in the literature. Literature on parental decision making related to HPV vaccination is evolving. Early studies focused on intention to vaccinate and hypothetical vaccination decisions. More recent literature included studies involving parents of eligible children and adolescents; but, much of the information was related to their

willingness or intent to vaccinate. Some of the more recent studies surveyed parents retrospectively about their HPV vaccination decision. Although this may elicit more meaningful information, there is the potential for inaccurate recall when reporting past experiences and feelings during the decision-making process. For instance, trying to recall if the provider recommended the vaccine versus discussed the availability of the vaccine may be difficult to accurately recall. More studies are needed to assess decision making at the time of the actual decision.

Most of the current real time studies in the second review were qualitative and had small samples. Although the interviews give more detailed information regarding the participants' experience, it is difficult to generalize this information. Some of the studies include minorities in the samples and children of different ages; yet, the samples are small, making it difficult to glean whether there is any significant difference based on the demographic profiles of the study population. Larger samples with homogeneity, as well as based on power analysis, are needed to examine patterns or similarities as well as uniqueness.

Parental uncertainty in decision making regarding HPV vaccination has been suggested in a number of studies (Allen et al., 2010; Kornfeld et al., 2013; Lechuga et al., 2012; Retier et al., 2013; Woodhal et al., 2007). A reduction in the personal uncertainty or decisional conflict when deciding about other vaccinations, including the measles, mumps, rubella (MMR) vaccine, has been associated with informed decision making in parents and an increase in vaccine uptake (Shourie et al., 2013). Additional studies exploring the presence of parental decisional conflict regarding the HPV vaccine are needed.

Based on the evidence to date, future studies should focus on interventions that specifically address helping parents and their child/adolescent with decision making for their HPV vaccination. Future studies are needed to evaluate effective interventions for information sharing, HPV vaccine counseling, and to encourage interactive dialogue among the health care provider, the parent and the child/adolescent concerning their values and beliefs throughout the decision-making process.

Table 2.6

Factors Associated with Parental HPV Vaccine Decision Making Using the Health Belief Model

Author & Date	**Perceived Susceptibility**	**Perceived Severity**	**Perceived Benefits**	**Perceived Barriers**	**Cues to Action**	**Self-Efficacy**	**Vaccination Decision**
Dempsey et al. (2009) N=52 Females	*Not at risk because not sexually active, too young, no family history of cancer* Parent feels their child is at risk due to belief or knowledge that they are sexually active, HPV is highly prevalent, don't know when their child will become sexually active	Cervical cancer is not deadly	***Disease/illness prevention against HPV related disease or cancers*** Belief that vaccines are generally beneficial	Lack of information Concerns for side effects Concern for long-term effects Concern for what may not be known yet Weak recommendation by provider Multiple vaccines needed Don't like vaccines	Family member with personal history of HPV related disease Provider recommended	Mother wants daughter to maker her own decision Daughter does not want the vaccine Lack of insurance coverage Religious values conflict with vaccine Mother wants child vaccinated while she is in control of medical decisions Insurance coverage will end soon	33 were vaccinated 19 declined vaccination
Morales-Campos et al. (2012) N=24 Females				*Cost* *Lack of information*	***Provider recommendation*** Mandatory immigration laws Family history of cancer		4 vaccinated 3 declined (only 7 of the 24 made an actual vaccination decision)

Table 2.6 *Factors Associated with Parental HPV Vaccine Decision Making Using the Health Belief Model (Cont.)*

Hughes et al. (2011)* N=20 Females	*Child is not at risk because she is not sexually active* Child is too young for the vaccine		Concern for lack of efficacy	Perceived lack of information Concern for side effects Provider presents the vaccine as "optional" Lack of provider recommendation			9 were vaccinated 11 declined vaccination
Alexander et al. (2012) N=21 Males	Sexual initiation is soon Sexual debut is happening at younger ages More STI's than when they were younger		***Protection from harm*** Protection from genital warts, cancer and STI Prevents spreading of STI to others	May encourage sexual activity Concern for vaccine side effects Adolescent may ask questions about sex	***Provider recommendation***	Father wanted to consult with his wife Teen is afraid of needles	19 were vaccinated 2 declined vaccination
Reiter et al. (2013) N=421 baseline N=327 (f/u one year later) Males				*Lack of information* *No provider recommendation* Concern for vaccine safety Vaccine is too new	***Provider recommendation***		8 males were vaccinated at baseline; 26 more were vaccinated by the time of follow up at one year

Note. Primary reason identified for vaccinating is in ***bold italics***; primary reason for not vaccinating is in *italics*; primary reasons(s) parents chose to vaccinate was not reported.

Chapter 3

METHODS

Study Design

The interventional pilot study, a single-arm prospective study, investigated the frequency of parental decisional conflict and regret related to HPV vaccination for their child/adolescent. This single-group study design assessed the feasibility of use and acceptability of the intervention, an HPV decision aid, used interactively with the parent/guardian and child/adolescent dyad. Testing the HPV decision aid sought to answer the question: For parents deciding whether to accept the HPV vaccine for their child/adolescent, does a decision aid reduce decisional conflict and post decisional regret? Parental decisional conflict was assessed pre- and post-intervention for change at a scheduled well visit for their child/adolescent. Parental decisional regret was assessed by telephone two weeks after the vaccination decision. The study schema is shown in Figure 3.1.

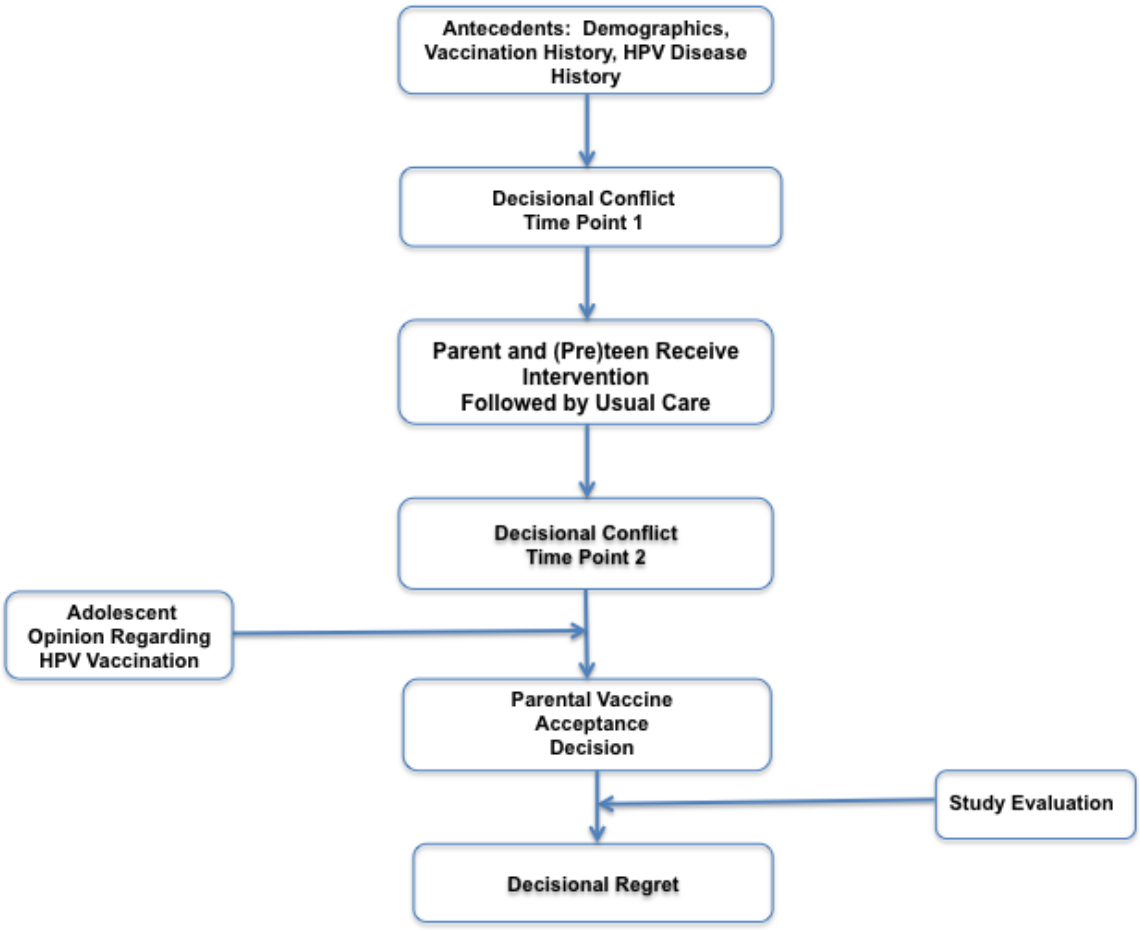

Figure 3.1 Study Schema

Setting

The study was conducted in a primary care pediatric office in a mixed suburban/rural community in northern Virginia. The primary care office was established twenty years ago and has an active patient base of approximately 60,000. The practice currently supports four pediatricians and three nurse practitioners. There are typically five providers seeing patients at any one time. The practice accepts patients from newborn to twenty-one years of age.

Intervention

Description and initial development. In phase 1, the intervention, developed by the PI, was a two-part decision aid. Part 1 of the decision aid provided factual information to the parent/child dyad about HPV related disease and the HPV vaccine (see Appendix B). This information was designed to expand on information included in the HPV Gardasil Vaccine Information Sheet (CDC, 2013). Part 2 of the decision aid was a decisional balance sheet to encourage the parents to think about and prioritize the potential perceived advantages and disadvantages of a child receiving the HPV vaccination for themself and for their child. The PI designed a balance sheet for personal decision making that was adapted from a 4-cell balance sheet of benefits and risks, for how they may affect oneself and how they may affect others, developed by Irving Janis (1959) and further supported by Janis and Mann (1977) in their book entitled, *Decision Making: A Psychological Analysis of Conflict, Choice, and Commitment* (see Appendix B). The balance sheet was designed to allow parents/guardians to consider the pros and cons of decision options with respect to personal objectives and values related to the HPV vaccination. The value statements content included on the balance sheet were derived from the literature and social media. The balance sheet also allowed space for parents to write in any other benefits or risks that applied to them but were not already on the sheet. After the pros and cons were considered, the participants were asked to prioritize these value statements that were most important to them and were used to guide discussion with their healthcare provider.

The decision aid was assessed at an 8th graded reading level according to the Flesch-Kincaid Grade Level test. The purpose of the decision aid was to reduce parental decisional conflict and regret regarding HPV vaccination initiation for their child. The process for the dyad was to utilize the key components of the decision aid interactively with the nurse interventionist (PI) and the usual health care provider to facilitate communication and informed, shared decision making (see Table 3.1). The target audience was defined as parent or guardian/child or adolescent dyads when the child/adolescent was 11 to 17 years of age, who had not initiated the HPV vaccination series, and who were medically eligible to receive the HPV vaccine. In accordance with two authoritative bodies, the CDC (2013) and the Advisory Committee on Immunization Practices (ACIP) [2015], medical contraindications were aligned with the current guidelines that included: 1) an immediate hypersensitivity to yeast; 2) pregnancy; or

3) delaying initiation of the vaccine in anyone, who was acutely moderately or severely ill, until they were feeling well.

Table 3.1

Key Components of "A Decision Aid for Those Considering the HPV Vaccine"

Component	Content elements	Process
Decision clarification	Focuses on what decision has to be made, when it has to be made, the stage of decision making and the dyad's thinking.	The interventionist verifies that the parent and child understand that they will be accepting or not accepting the HPV vaccination at this visit for the study and that the intervention is an interactive process that includes both the parent and the child.
Decision exploration and support	Informational support and guidance with follow up questions permitting ongoing assessment of knowledge. The adolescent's participation may offer decisional support to the parent.	The interventionist provides content using an HPV information sheet (Part 1 of the Decision Aid) which is reviewed with opportunity for questions and clarification from both the parent and adolescent.
Knowledge expectations and values related to HPV vaccination	Content using a 4-cell decisional balance sheet (Part 2 of the Decision Aid) personalizes the information to address the individual's culture and values.	Part 2 of the Decision Aid is used to assist the parent in identifying perceived risks and benefits of HPV vaccination to the parent and child using an interactive process and within the context of personal value statements for self and others. A decision is reached for acceptance or not of the HPV vaccine for the adolescent at this visit.

Content selection. The PI chose specific content areas for the decision aid based on parental feedback gleaned from the literature review 1 and 2 discussed in Chapter 2. Specifically, information was included to address items shown in Table 3.2.

IPDAS criteria. The decision aid was developed with the guidance of the international quality criteria of the International Patients Decision Aid Standards (IPDAS) as a guideline (Elwyn et al., 2009). Not all IPDAS criteria were met with this decision aid alone because it was used in conjunction with usual care that included the CDC HPV Gardasil Vaccine Information Sheet. Care was taken not to duplicate information that was detailed in the CDC HPV Gardasil Vaccine Information Sheet that is given to all parents considering the HPV vaccine for their child. The two-part decision aid satisfied 31 of the 50 (62%) applicable IPDAS criteria (Elwyn et al., 2009). With

regard to content, 10 of the 23 (43%) criteria were met. Statistical data were covered in the CDC Gardasil Vaccine Information Sheet; thus, event rates and probabilities were not included in the decision aid. For the development process criteria, 14 of the 20 (70%) criteria were met. All seven of the criteria in the effectiveness domain were met.

Table 3.2

Parent Perceived Gaps in Information

Content Area	Literature Reference
Information about HPV and the vaccine	Allen et al., 2010; Bair et al., 2008; Dempsey et al., 2009; Hughes et al., 2011; Oldach & Katz, 2012; Morales-Campos et al., 2012; Reiter et al., 2013; Woodhall et al., 2007; Yeganeh, Curtis, & Kuo, 2010
Information regarding the recommended age for vaccination	Alexander et al., 2012; Bair et al., 2008; Constantine & Jerman, 2007; Dempsey et al., 2006; Dempsey at al., 2009; Hughes et al., 2011; Odach & Katz, 2012; Sanders et al., 2012
Information regarding vaccine safety	Allen et al., 2010; Alexander et al., 2012; Dempsey et al., 2009; Gowda et al., 2012; Hughes et al., 2011; Oldach & Katz, 2012; Reiter et al., 2013; Woodhall et al., 2007; Yeganeh et al., 2010
Information about who should receive the vaccine	Dempsey et al., 2009; Hughes et al., 2011; Reiter et al., 2013
Concerns about encouraging adolescents' sexual debut	Alexander et al., 2012
CDC guidelines on HPV prevention/vaccination	Markowitz et al., 2007; CDC, 2008; CDC, 2011

Expert review. A panel of five experts (two female pediatricians, two male pediatricians and one female nurse practitioner) reviewed and gave feedback related to the 2-part HPV vaccination decision aid shown in Appendix C**.** The expert panel was asked to report their evaluation using a survey with 9 items and return within 2 weeks. Changes were made to the decision aid base on their comments and recommendations shown in Appendix C.

Participant review. The development process of the decision aid went through several iterative steps. In phase 1, the decision aid included an information sheet for parents and adolescents, ages 11-17 years, and a one page decisional balance sheet (a 4-cell decisional balance sheet with risks and benefits for self and others) adapted with permission from Hollen et al. (2012) simplified version of the original Janis and Mann (1977) balance sheet for clinical settings. This decisional balance sheet is used to assist the parent/adolescent dyad in considering their personal values and beliefs while making the vaccination decision (see Appendix B). The parent and child/adolescent independently evaluated their respective decision aid using the Parent Study Evaluation

form and the Child/Adolescent Study Evaluation form, designed by the PI (see Appendix A).

Final intervention. In phase 2, a separate decision aid was developed for children/adolescents, ages 11-14 years, after considering verbal feedback from parents, children/adolescent participants and written feedback from the children/adolescents using the Child/Adolescent Study Evaluation Form (see Appendix B). The original HPV information sheet was modified for this younger group so that, unlike the version provided to parents and older adolescents, it did not discuss transmission of the virus and was assessed at a 6th grade reading level according to the Flesch-Kincaid Grade Level Test. Information was also updated on the original informational decision aid for parents and now targeted for adolescents, ages 15-17 years, which remained at an 8th grade reading level. Specifically, this additional information included those individuals with suppressed immune systems or human immunodeficiency virus (HIV) who were now advised to receive the HPV vaccine because the latest research demonstrated immunogenicity and safety of the quadrivalent human papillomavirus vaccine in this population (Kojic et al., 2014). These decision aid modifications will be discussed in greater detail in Chapter 4.

Underpinning decision theory. The purpose of the decision aid was to reduce parental decisional conflict when deciding whether to vaccinate their child/adolescent against HPV and later decisional regret. The initial conceptualization for the intervention was to enhance parental decision making related to HPV vaccination based on the conflict model of decision making, now considered a theory, by Janis and Mann (1977). Janis and Mann (1977) defined *decisional conflict* as the result of uncertainty about accepting or rejecting a given course of action. This conflict is considered a source of stress to the individual. The degree of stress is important in determining whether this stress is beneficial in the decision-making process or whether it hampers quality decision making and leads to decisional regret.

According to the theory, five basic assumptions relate the degree of stress to the type or style of decision making that is likely to occur. The first assumption is that stress occurs when there is a risk of not attaining an important goal. The more important the goal is to the individual, the greater the degree of stress. When the goal is of little importance, there is no stress and the decision maker is not motivated to consider options carefully or give the decision full and sustained attention. A sense that there is little risk to the individual or that the consequences are minor, the decision pattern is one of *un-conflicted inertia* or adherence to their decision not to act or take protective measures.

The second assumption is that stress occurs when a situation arises that causes an individual to consider a new course of action. This level of stress creates arousal or attention to the situation. The degree of stress also depends on how committed the individual is to stay on the original course of action. A highly committed individual will experience higher levels of stress that discourages them from switching positions or courses of action. An individual who is aroused by the importance of the goal and

perceives a risk, while being more open to changing their course of action will vigilantly begin seeking more information. If the individual perceives a risk and the consequences of not taking protective action to be serious compared to the risk of taking the protective action, *unconflicted change* may occur and stress decreases. If the individual perceives risk, and the possibility or definite risks in taking the protective action, increased stress may occur.

The third assumption is that loss of hope in finding a better solution than the least objectionable solution leads to extreme stress. A *defensive avoidance* style is likely to occur and important information will be ignored while wishful rationalizations are accepted as accurate. Behaviors consistent with defensive avoidance include: 1) a lack of interest in the problem, 2) failure to search for a solution, 3) passing the buck or relying on outside agents who promise a more acceptable solution rather than expert information, and 4) bolstering or generating new thoughts or beliefs to reduce stress.

The fourth assumption is that decision making under pressure of time, increases stress. In this situation, cognition is impaired and panic ensues. The individual may feel a sense of helplessness and hopelessness. Cognitive functioning is diminished due to a highly emotional state. A *hypervigilant* style of decision making occurs and the individual makes a decision without considering all of the alternatives and consequences often ending in post-decisional regret.

The fifth assumption is that a moderate level of stress is beneficial and allows one to engage in the situation, give sustained attention to the information at hand and to be vigilant in considering all of the alternatives and consequences in order to make a decision. The individual perceives that a risk is present, but has low confidence in the recommended protective course of action or perceives this action as potentially risky. Finally, this individual believes that there is time to search for potential alternatives, more information, or additional advice. This *vigilance* style occurs when there is a challenging threat at hand and the decision maker expects to find a satisfactory solution to the problem or situation.

As the theorists explain, high quality decision making results in high decisional satisfaction and low decisional regret based on vigilant information processing. In this study the theory was used to guide the study design and development of the intervention to assess the influence of a decision aid with a balance sheet on the outcomes of reduced decisional conflict, vaccine acceptance and the absence of decisional regret.

Sample/sampling plan. The sample consisted of 80 willing parents/guardians and their children, ages 11-17 years, who were coming into the pediatric office for scheduled well exams and had not begun the HPV vaccination series. Inclusion criteria included the following: 1) child/adolescent was accompanied by a parent/guardian; 2) child/adolescent was 11 to 17 years of age; 3) child/adolescent had not begun the HPV vaccination series; and 4) parent/child dyad was able to understand spoken English. Exclusion criteria included: 1) child/adolescent was ill; 2) child/adolescent was developmentally unable to assent to participation in the study; 3) child/adolescent was

medically not a candidate for vaccination; and 4) patient was currently a patient of the study principal investigator (PI). Data from all enrolled participants, using Modified Intention-to-Treat (MIT), defined as those with baseline data, were used and included in the results.

The screen failure rate was expected to be very low (~5%), as most adolescents on the clinic roster would meet the inclusion criteria at the time of their routine visit. Dropout or withdrawal rates were also expected to be low and were estimate to be ~5% (or four cases), because with the exception of a follow-up phone call that addressed the exploratory aim, the data collection took place in one day and at one sitting.

As part of the sampling plan, the office nurse identified potential study participants by screening their immunization record and asked the parent if they would be interested in hearing about a decision support study related to HPV vaccination. If the parent agreed to hear about the study, the PI approached the parent to further explain the study. If the parent agreed to participate in the study, the PI obtained written parental consent and written assent from the child/adolescent as well.

Demographics. Although the pediatric practice draws patients from several surrounding counties, the majority of patients in the practice come from the county where the practice is located. In this county, approximately 91 percent of the population is a high school graduate or higher, 33 percent of the population has a Bachelor's degree or higher, the median household income during 2009-2013 was $88,409 and 50% of the population is female (U.S. Census Bureau, 2015). Data from the U.S. Census Bureau (2015) reported the total population estimate as 68,248 in this catchment area (2015). Population estimates by race/ethnicity according to the U.S. Census Bureau (2015) are shown in Table 3.3.

Table 3.3

2014 Population Estimates by Race/Ethnicity Category

Race	Percentage
White alone (2014)	87.3
Black or African American alone (2014)	8.2
American Indian and Alaska Native alone (2104)	0.5
Asian alone (2014)	1.5
Native Hawaiian and Other Pacific Islander alone (2104)	0.1
Two or More Races (2014)	2.4
Hispanic or Latino (2104)	7.2
White alone, not Hispanic or Latino (2104)	81

Power analysis

Power analysis for this pilot study was obtained using nQuery Advisor 7.0 as well as Cohen's (1988) convention and the help of a School of Nursing statistician (V. Rovnyak). The effect size of the change in Decisional Conflict Scale (DCS) in women considering preventive hormone therapy who received a decision support intervention was reported as 0.92 (O'Connor, 1997). According to Cohen's (1988) convention, with just a medium effect size of 0.50, a sample size of just 64 participants per group would be needed for a two-tailed paired t-test with a significance level of 0.05 and power of 0.80. For a chi-square test of a 2x2 table with parent accepted the vaccination (Yes/No) vs. parent has decisional conflict (Yes/No) and with a significance level of 0.05, a medium effect size of .30 would require a sample size of 87 participants. For a logistic regression model, Harrell's (2001) sample size guideline requires at least 10-20 cases in the smaller outcome group per model predictor for the fitted model to be reliable. In this pilot study, acceptance of the vaccination is the outcome variable, so for a logistic regression model with three predictors, at least 30 vaccinations and at least 30 rejections of the vaccination would be needed.

Instruments and Timing of Administration

Eight instruments were used for data collection in this study as seen in Appendix A. Consented adults/guardians and assented children/adolescents were asked to independently complete forms described below.

1. **Demographic Form**. A demographic form developed by the PI for demographic descriptors and information that may be associated with HPV vaccine acceptance based on the literature was completed by each parent/guardian.

2. **Decisional Conflict Scale (DCS) - Baseline**. Prior to the decision aid intervention, parents were asked to complete the DCS for baseline data. The DCS was developed by Annette O'Connor (1997) to evaluate the presence of uncertainty in making a choice, the presence of modifiable factors contributing to the uncertainty and perceived lack of information, unclear values and inadequate social support. The scale is written at an eighth grade reading level. The constructs of the scale were developed based on the conflict theory of decision making (Janis & Mann, 1977). According to Janis & Mann (1977) *decisional conflict* is a state of uncertainty due to opposing sentiments regarding accepting or rejecting a particular course of action. O'Connor (1997) developed the DCS (items 1-12) to assess for decisional conflict at baseline or pre-intervention decisional conflict by measuring two dimensions: 1) uncertainty or the degree to which the decision maker is clear about what to do, and 2) factors contributing to the uncertainty. Uncertainty is measured using items 1-3. Factors contributing to the uncertainty are measured using three components: 1) feeling uninformed about options, risks and benefits (items 4,5,6); 2) feeling uncertain about which

are more important, the risks or the benefits (items 7,8,9); and c) feeling unsupported while making this decision (items 10,11,12). This 12-item scale is scored according to responses along a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Total scores and subscale scores consider a decision they are about to make. A total score of 1 indicates low decisional conflict; a score of 5 indicates high decisional conflict. Decisional conflict was defined as a total score of greater than 2.0 .

3. **Decisional Conflict Scale (DCS) Time point 2.** Following the intervention, parents were asked to complete the DCS for time point 2 or post-intervention. The post-intervention DCS assessed for decisional conflict at the time vaccination decision was made. The DCS at time point 2 or post-intervention is an expanded version of DCS at baseline. The DCS at time point 2 or post-intervention includes three dimensions that total 16 items. It includes the two dimensions from the DCS at baseline (items 1-12) and adds a third dimension a perceived effective decision-making subscale, which measures the decision maker's perceptions that: a) their decision is informed; b) their decision is consistent with their personal values; c) that they anticipate following through with the decision; and d) that they are satisfied with their decision (items 13, 14, 15, 16). The 16-item scale is scored according to responses along a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). A total score of 1 indicates low decisional conflict; a score of 5 indicates high decisional conflict. Study norms indicate that a score of 2.0 or less is associated with acceptance of an intervention (O'Conner, 1995).

   The DCS has been adjusted to an 8th grade reading level by the developer. It is feasible, taking only 5 to 10 minutes to complete. It was tested in 1995 on two groups of health science students (N = 45 + 106), in health employees at a teaching hospital and a visiting nurse agency (N = 115) and in patients with known cardiac or pulmonary disorders (N = 283) for decision making related to flu vaccine acceptance (O'Connor, 1995).

   The two student groups were offered the influenza vaccine and asked for their intention or decision to be immunized. Responses were categorized as accept, reject or delay. They were given the DCS (Items 1-16) to complete. The students were tested again two weeks later. Stability as a measure of reliability was assessed using test/retest. There was no statistically significant difference between test and retest scores (O'Connor, 1995). The test-retest correlation coefficient was 0.81 (O'Connor, 1995). Internal consistency was evaluated using Cronbach's alphas for the two student studies with alpha coefficients ranging from 0.78 to 0.92. and from 0.58 to 0.92 for the subscales (O'Connor, 1995).

   Construct validity was supported using the known-groups approach comparing DCS scores with the decisions or stated intentions indicating they had accepted, rejected or were uncertain regarding influenza vaccine acceptance (O'Connor, 1995). The DCS also has normative data with more than 1,000 individuals who were evaluated during the process of making preventative decisions about

immunization and breast cancer screening (O'Connor, Pennie & Dales, 1992; Osoba, Lippman & Boyd, 1992).

4. **Adolescent Opinion Regarding the HPV Vaccination.** After the intervention, the child/adolescent was asked to complete this 2-item form developed by the PI to indicate whether they thought vaccination against HPV was important and whether they would like to receive the vaccination.

5. **Parent Response Sheet.** Following the intervention, the parent was made aware of the adolescent's opinion concerning HPV vaccination. The parent was asked to complete the 5-item Parents Response Sheet developed by the PI to indicate how important and how influential the child's opinion regarding vaccination was on their vaccination decision. The parent was also asked to report the primary reason for accepting or declining vaccination.

6. **Parent Study Evaluation Form.** After the vaccination decision, the parent was asked to complete the 9-item Parent Study Evaluation Form developed by the PI to assess the feasibility and acceptability of the intervention.

7. **Child/Adolescent Study Evaluation Form.** After the child had given their opinion regarding HPV vaccination, the child/adolescent was asked to complete this 9-item form developed by the PI to assess the feasibility and acceptability of the intervention.

8. **Decision Regret Scale.** The Decision Regret Scale (DRS) was developed by O'Connor (1996) to measure distress or remorse after a health care decision. The 5-item Likert-type rating scale was designed to assess the experience of regret after a health-related decision was made. The PI utilized the DRS to assess for parental decisional regret during a brief phone call two weeks after the vaccination decision. The parent/guardian was asked to respond to the statement "It was the right decision." The item responses were strongly agree=1, agree=2, neither agree nor disagree=3, disagree=4 or strongly disagree=5. The negative emotion of regret is captured using the 5-item scale according to modern regret theory (Bell, 1982). *Regret* is defined as a sense of loss or a negative emotion that evokes a sense of responsibility for having caused an unfavorable outcome that would not have occurred had an alternative decision been made (Bell, 1982; Zeelenberg et al., 1998). Items 2 and 4 were reverse coded, so that a higher number indicates more regret. To facilitate use of the scale with other scales that use a 0 to 100 point scoring system, the scores from the DRS scale were converted to a 0-100 scale by subtracting 1 from each item and multiplying by 25. To obtain final scores, the item scores were summed and averaged.

   The Decision Regret Scale has been successfully tested in several different study population related to health care decision making. Decisional regret was studied 9 months after women (N= 177) had decided whether or not to choose hormone replacement therapy (O'Connor, Tugwell & Wells, 1998). Another

study used the scale to assess regret related to breast cancer treatments with a population of women (N = 200) in Canada, three to three and a half years after selecting their treatment (Strull, Lo & Charles, 1984). A third study utilized the instrument to assess decisional regret in males (n = 5) three months after deciding on treatment options for prostate cancer; completion time was less than 1 minute with fewer than 1 per 500 responses missing (Brehaut, 2003). Psychometric properties were obtained on a combined sample from these three studies.

For reliability testing, internal consistency of the DRS in these 3 groups using Cronbach's alpha ranged from 0.81 to 0.92. The hormone replacement group (N = 177) and the breast cancer group (N = 200) were used to evaluate support for construct validity for the scale using relationship testing (Brehaut et al., 2003). In that study, higher regret scores correlated substantially with unfavorable outcomes and lower rated quality of life for both groups. Further support for construct validity using known-groups was obtained when those in the hormone replacement group who participated less in their decision making and instead relied on the health care provider to make the decision, had higher regret score, $F(2, 171) = 3.72$, $p = 0.03$. The regret scale discriminated between patients in the breast cancer group who reported feeling positively, negatively or mixed about their treatment decision. Analysis of variance and appropriate post hoc tests corroborated that those with positive feelings concerning their treatment decision also had significantly lower regret scores. Higher regret scores were associated with later decisions to change treatment options.

Procedures

This study was given approval by the Institutional Review Board at the University of Virginia. The office nurse asked the parent if they would be interested in hearing about the HPV decision study if their child was 11 to 17 years of age and had not begun the HPV vaccination series. The PI approached the parent to explain the study in greater detail if they indicated to the office nurse that they would like to hear more about the study. If inclusion and exclusion criteria were met and the parent indicated that as a dyad they were interested in the study, the PI explained the study to both the parent and the child/adolescent and the parent was permitted to preview the information sheet that their child would be reading. If the parent gave written consent to participate in the study, and gave permission for their child to assent, the child/adolescent was asked whether or not they wished to participate in the research. The child/adolescent also gave written assent as a participating minor. The PI continued as the nurse interventionist and administrator of the battery of measures.

Procedures for the consented/assented participant dyad were as follows:

1. Collection of demographic data using the Demographic Form was completed by the parent.
2. Parental decisional conflict related to HPV vaccination was assessed pre-intervention using the Decisional Conflict Scale-Baseline (items 1-12).
3. A two-part educational intervention was provided using a decision aid for HPV vaccination in an interactive format that included the PI, the parent and the child/adolescent (see Table 2).
    a. Phase 1:
        i. Part 1: "What can you do to prevent human papillomavirus (HPV)?" for parents and child/adolescents.
        ii. Part 2: Balance Sheet for Personal Decision Making was given to parents.
    b. Phase 2:
        i. Part 1: "What can you do to prevent human papillomavirus (HPV)"? for parents and adolescents ages 15-17 years or "A decision aid for those considering the HPV shot" for children/adolescents 11-14 years of age.
        ii. Part 2: Balance Sheet for Personal Decision Making was given to parents.
4. The healthcare provider gave usual care for the child/adolescent that included vaccine recommendations and counseling.
5. Parental decisional conflict related to HPV vaccination was assessed post-intervention using the Decisional Conflict Scale-Time 2 (items 1-16).
6. Post-intervention HPV vaccine acceptance was assessed using the Adolescent Opinion Regarding HPV Vaccination Form.
7. The importance and influence of the child's opinion to the parent, the parent vaccination decision, and permission to call in two weeks to assess for decisional regret was obtained using the Parent Response Sheet.
8. The feasibility and acceptability of the intervention was assessed using two study evaluation forms that were completed by the parent using the Parent Study Evaluation Form and the child using the Child/Adolescent Study Evaluation Form.
9. The parental vaccination decision was obtained by medical chart review.
10. Parental decisional regret was assessed by phone at least two weeks after the vaccination decision using the Decision Regret Scale if permission was given.

Data Analysis

Several methods of descriptive and inferential statistics were utilized to interpret the data as shown in Table 3.4**.** SPSS version 21 was used to analyze the data.

Table 3.4

Analyses Methods

Specific Aims	**Analytic Methods**
Primary Aims: 1. To determine the feasibility and acceptability of implementing a short primary care, office-based, decision aid (cognitive-behavioral skills intervention) for a parent/child dyad deciding whether to accept HPV vaccination. The feasibility and acceptability of the study will be evaluated on the following criteria: 1.1 Describe the proportion of the total number of eligible patient dyads (those satisfying the inclusion and exclusion criteria) that will be consented and enrolled within the specified 9-month accrual period. 1.2 Describe the proportion of participants (parents and children separately) who found the intervention helpful in the decision-making process and acceptable (ease of use and length of time for completion).	Descriptive statistical analysis 1.1 Frequency, proportion 1.2 Frequency, proportion
Secondary Aims: 2. To gather preliminary data for: 2.1 Describing the frequency of decisional conflict in parents scheduled to obtain the recommended HPV vaccine for their child in a primary care pediatric practice. 2.2 Testing the hypothesis that parental post-intervention decisional conflict will be less than parental pre-intervention decisional conflict. 2.3 Testing the hypothesis that there will be a difference between the proportion of parents with decisional conflict who accept the HPV vaccine and the proportion of parents with no decisional conflict who accept the HPV vaccine. 2.4 Testing the hypothesis that factors affecting parental vaccine acceptance include the adolescent's opinion regarding HPV vaccination, whether any children in the family have already received the HPV vaccine (Yes/No), and a personal or family history of HPV related disease, in addition to parental decisional conflict	2.1 Frequency, percentage, mean, standard deviation 2.2 Two-tailed t-test 2.3 Chi-square 2.4 Frequencies, proportions, chi-square, logistic regression
Exploratory Aim 3. To gather preliminary data for: 3.1 Describing the frequency of parental decisional regret 2 weeks post-vaccination decision.	3.1 Frequency, proportion

Chapter 4

RESULTS

The primary outcome of this pilot study to assess a decision aid for HPV vaccination for parents and their children or adolescents addressed the following specific aim:

Specific aim 1. To determine the feasibility and acceptability of implementing a short primary care, office-based decision aid (cognitive-behavioral skills intervention) for a parent/child dyad deciding whether to accept HPV vaccination. The feasibility and acceptability of the study will be evaluated on the following criteria:

1.1 Describe the proportion of the total number of eligible patient dyads (those satisfying the inclusion and exclusion criteria) that will be consented and enrolled within the specified 9-month accrual period.

For assessing feasibility of implementing the intervention, 80 participant dyads were consented/assented and enrolled out of 91 dyads who were approached and satisfied the inclusion and exclusion criteria. Enrollment (N=80 parent/child dyads) was completed in five months. The enrollment rate for eligible participants was 88%.

The ages of enrolled parents/guardians ranged from 29 to 70 years of age, with a median age of 45 years. The majority of the parent participants were Caucasian, had at least some college education, had a family income of greater than $60,000 and had a child who had private insurance coverage. Parents who declined participation in the study reported the following reasons for declining: 1) mom had an infant with her and did not feel she could pay attention to the study; 2) mom stated she is on a tight schedule to return to work and does not want to be delayed; 3) dad stated he did not feel comfortable making decisions pertinent to the study; 4) six mothers and one father reported that they were not interested in talking about HPV and/or the vaccine; and 5) one mother could not state a reason for declining.

Five potential participants who met initial screening criteria for age and vaccination status were ineligible to participate for the following reasons: 1) three adolescents, all 17 years of age, came alone to the appointment with no parent or guardian; 2) one parent did not read or understand spoken English; and 3) one child was at the appointment with his grandfather who was not the legal guardian. Among the 80 enrolled adolescents, 40 were male and 40 female using a convenience sample from the clinic roster. There were 69 participants (86.3%) from 11 to 14 years of age and 11 participants (13.7%) from 15 to 17 years of age.

For assessing acceptability of the intervention, the pilot testing consisted of an early phase (Phase 1) and a revision phase (Phase 2) to address the specific aim as follows:

1.2 Describe the proportion of participants (parents and children separately) who found the intervention helpful in the decision-making process and acceptable (ease of use and length of time for completion)

Phase1. Early pilot testing of the intervention for acceptability was conducted using the first 11 participants, all of whom were 11-14 years old. Feedback from these seven female participants and four male participants were reviewed. Of the 11 participants, seven were 11 years of age, two were 13 years and two were 14 years of age. The PI considered verbal feedback from parents, children/adolescents as well as the completed participant Child/Adolescent Study Evaluation Forms (see Appendix A). Study evaluation item responses "agree" and "strongly agree" indicated acceptability. Responses such as "undecided", "disagree" or "strongly disagree" were considered potentially concerning; those given by the 11 children/adolescents are shown in Table 4.1.

Table 4.1

Study Evaluation Responses of Concern for the Decision Aid Intervention, from Early Child/Adolescent Participants (n=11)

Assessment Item	Acceptability	Age/Gender	n
The Decision Aid was Easy to Read	Undecided	11yr/Female	1
	Disagree	11yr/Female	1
The Decision Aid was Easy to Use	Undecided	14yr/Female	1
The Decision Aid was Helpful in Making a Decision Today	Undecided	11yr/Female	2
	Undecided	13yr/Male	1
The Time Needed to Review the Decision Aid was Acceptable	Undecided	11yr/Female	1
	Disagree	11yr/Male	1

Although most of the eleven children/adolescents reported that the decision aid was easy to read (n=9) and easy to use (n=10), three of children/adolescents were undecided as to whether the decision aid was helpful. Observation by the PI and asking clarifying questions to check understanding revealed that the children/adolescents were having difficulty understanding the language used in the decision aid, specifically the meaning of key terms. Parent feedback validated the concern when one mother stated that she had not yet talked to her daughter about the content in the decision aid and questioned whether she would understand the content. The daughter stated that she had a "general idea" what the decision aid was talking about. Another mother, who was a reading teacher for the 6th grade level said that, in her opinion, most of the kids in the 11-13 year old age group would not understand the meaning of certain words used in the decision aid such as "genitals" or "immune response". The PI's advisor for this study was made aware of this concern that the younger pre-teen/early adolescent population did not understand the decision aid. It was decided that the PI would cease to enroll children 11-14 years of age until a new decision aid was developed and reviewed by the

Institutional Review Board (IRB). The study continued to enroll 15-17 year old participants, and all of these received the original decision aid. The decision aid was revised for the 11-14 year old participants.

Phase 2. The revised decision aid for this age group of 11-14 years was called "A decision aid for those considering the HPV shot" (see Appendix B). The modified version was written on a 6th grade reading level according to the Flesch-Kincaid Grade Level test and did not include information related to transmission of the virus. Five parents of the 11-14 year old children, who had previously consented to participate in the study, were asked to evaluate the modified decision aid. Two of the mothers that were asked to participate had previously stated that they did not think their child would fully understand the original decision aid. All five of the parents who were asked completed the evaluation of the new decision aid for 11-14 year olds, and there was 100 percent acceptance (see Appendix D). The revised decision aid was approved by the IRB. After IRB approval was received, enrollment of the 11-14 year old age group was resumed.

Using the final revised versions per age groups, 62 of the 80 participating parents (77.6%) found the decision aid helpful in the decision-making process while 59 of the 80 participating parents (74%) found the intervention helpful in the decision-making process and acceptable (ease of use and length of time for completion). There were no missing data.

As explained above for the younger age group, eight of the first 11 children/ adolescents (73%), who were all 11-14 years old, responded that the revised decision aid was helpful for making the decision, although there is some evidence that they may not have understood what it said. Fifty-eight additional 11-14 year olds were given the revised decision aid. In this enlarged group, forty-two (73%) found the revised decision aid acceptable, 34 (59%) found the revised decision aid helpful and 26 (45%) found it both helpful in the decision-making process and acceptable.

Out of the eleven older participants aged 15-17 years, all of whom received the original decision aid, 8 (83%) found the intervention helpful in the decision-making process and acceptable. There were no missing data.

The secondary outcome of this pilot study to assess a decision aid for HPV vaccination for parents and their children or adolescents addressed the following specific aim:

Specific aim 2. To gather preliminary data for:

2.1 Describing the frequency of decisional conflict in parents scheduled to obtain the recommended HPV vaccine for their child in a primary care pediatric practice.

Decisional conflict was defined by a total score of greater than 2.0 using the Decisional Conflict Scale (DCS). According to O'Connor (1995), the scale norms indicate that individuals with a total DCS score of 2.0 or less tend to make a decision to

accept a treatment or intervention after being informed whereas, those with scores greater than 2.0 tend to decline or delay their decision. Fifty-four parents (67.5%) scored greater than 2.0 at baseline using the DCS. Twenty-six parents (32.5%) scored 2.0 or less at baseline. Baseline total scores for the DCS were normally distributed with a mean score of 2.57 as seen in Table 4.2. All subscale scores were also normally distributed

Table 4.2

Baseline Decisional Conflict Scores (N=80 parents/guardians)

Scale Components	**Mean**	**Standard deviation**
Total DCS Score	2.57	0.99
Subscale score	**Mean**	**Standard deviation**
Uncertainty	2.84	1.30
Uninformed	2.52	1.08
Unclear values	2.57	1.11
Unsupported	2.20	0.87

The frequency of baseline decisional conflict defined as scores greater than 2.0 are shown in Table 4.3.

Table 4.3

Frequency of Parental Baseline Decisional Conflict (DCS > 2.0)

Scale Components	**Frequency (N=80)**	**Percentage**
Total DCS Score	54	67.5
Subscale score	**Frequency**	**Percentage**
Uncertainty	47	58.8
Uninformed	49	61.3
Unclear values	46	57.5
Unsupported	35	43.8

For the hypothesis testing of the decision aid, the specific aim was as follows:

2.2 Testing the hypothesis that parental post-intervention decisional conflict will be less than parental pre-intervention decisional conflict.

A two-tailed paired t-test was used to compare the mean DCS score at baseline (pre-intervention) and the mean DCS score at Time point 2 (post-intervention). The total DCS scores at Time point 2 or post-intervention were less than the baseline or pre-intervention scores by an average of 0.68 points as shown in Table 4.4. Pre-and post-intervention total scores were significantly correlated ($p < 0.001$).

Table 4.4

Descriptive Statistics for Parental Decisional Conflict Pre-and Post-Intervention

DCS Score	N	Mean	Std. Deviation
Pre-intervention	80	2.57	0.99
Post-intervention	80	1.89	0.64

The null hypothesis of the paired t-test was rejected. There was strong evidence that the decision aid intervention significantly decreased parental decisional conflict regarding HPV vaccination for their child (t= 8.68, $p < 0.001$). The total DCS scores decreased an average of 0.68 points (95% confidence interval, 0.53, 0.83) after receiving the decision aid intervention. The standard deviation of the difference in scores was 0.699. The effect size of 0.97 is considered large by Cohen (Cohen, 1988).

Descriptive statistics for the parental subscale scores of the decisional conflict scale are shown in Table 4.5. Pre- and post-intervention subscale scores were assessed using paired *t*-tests.

Table 4.5

Descriptive Statistics for Decisional Conflict Subscale Scores

Subscale Score	N	Pre-intervention Mean and Std. Deviation	Post-intervention Mean and Std. Deviation
Uncertainty	80	2.84 ± 1.30	2.25 ± 1.04
Uninformed	80	2.52 ± 1.08	1.85 ± 0.68
Unclear Values	80	2.57 ± 1.11	1.88 ± 0.73
Unsupported	80	2.20 ± 0.87	1.67 ± 0.60

Pre- and post-intervention subscale scores were significantly correlated as shown in Table 4.6.

Table 4.6

Paired Samples Parental DCS Subscale Correlations (N=80)

Subscale score	**Correlation**	***p* value**
Pre-intervention Uncertainty Post-intervention Uncertainty	.727	.000
Pre-intervention Uninformed Post-intervention Uninformed	.599	.000
Pre-intervention Unclear Values Post-intervention Unclear Values	.552	.000
Pre-intervention Unsupported Post-intervention Unsupported	.713	.000

Using two-tailed paired *t*-tests, the parental DCS subscale scores for (a) *Uncertainty,* $t(79) = 3.71$, $p < 0.001$; (b) *Uninformed*, $t(79) = 6.85$, $p < 0.001$; (c) *Unclear Values*, $t(79) = 6.65$, $p < 0.001$; and (d) feeling *Unsupported,* $t(79) = 5.16$, $p < 0.001$, were significantly decreased post-intervention. The subscale scores for *Uncertainty* decreased from 1.59 ± 0.50 to 1.40 ± 0.49 for an average of 0.19 points, 95% CI [0.09, 0.29]. The subscale scores for feeling *Uninformed* decreased from 2.52 ± 1.08 to 1.85 ± 0.68 for an average of 0.66 points, with a 95% CI, [0.47, 0.86] after the decision aid intervention. The subscale scores for *Unclear Values* or feeling unclear about the value they place on the pros and cons of the decision decreased from 2.57 ± 1.11 to 1.88 ± 0.73 for an average of 0.69 points, 95% CI [0.48, 0.90] after the decision aid intervention. The subscale score for feeling *Unsupported* decreased from 1.44 ± 0.50 to 1.16 ± 0.37 for an average of 0.28 points, 95% CI [0.17, 0.38]. In summary, decisional conflict subscale scores for the 80 parent participants decreased in all of the subscales.

For the hypothesis testing of the decision aid, the additional specific aim was as follows:

> 2.3 Testing the hypothesis that there will be a difference between the proportion of parents with decisional conflict who accept the HPV vaccine and the proportion of parents with no decisional conflict who accept the HPV vaccine.

The Chi-Square test was used to assess the differences of HPV vaccine acceptance and parental decisional conflict post-intervention. Overall, 29 of the 80 parents (36.3%) accepted the HPV vaccine for their child. Parents were then grouped according to whether they had post-intervention decisional conflict (DCS > 2) or no post-intervention decisional conflict (DCS ≤ 2). As expected, the vaccine acceptance rate was much higher for the 47 parents without post-intervention decisional conflict (n=26, 55.3%) than it was for the 33 parents with post-intervention decisional conflict (n=3, 9.1%) as shown in Table 4.7. A Pearson chi-square test of the independence of the variables was significant ($x^2(1,80) = 17.93$, $p < 0.001$).

Table 4.7

Parental Acceptance of HPV Vaccine vs. Post-Intervention Parental Decisional Conflict

	Accepted HPV Vaccine		**Total**	***p*-value***
	No	**Yes**		
Post-Intervention Decisional Conflict (DCS > 2)	30	3	33	< .001
	90.9%	9.1%	100.0%	
No Post-Intervention Decisional Conflict (DCS ≤ 2)	21	26	47	
	44.7%	55.3%	100.0%	

*Pearson chi-square test

For the final portion of hypothesis testing of the decision aid, the specific aim was as follows:

> 2.4 Testing the hypothesis that factors affecting parental vaccine acceptance include the adolescent's opinion regarding HPV vaccination (Yes=agree, or strongly agree/ No=undecided, disagree or strongly disagree), whether any children in the family have already received the HPV vaccine (Yes/No), and a personal or family history of HPV related disease (Yes/No), in addition to parental decisional conflict.

The data were analyzed using binary logistic regression: multivariate. The dependent variable, parental vaccine acceptance, was dichotomous (accept/decline). According to the power analysis, at least 30 parents to accept the vaccine and at least 30 parents to decline the vaccine were needed. In this study, 29 parents accepted the vaccine while 51 declined the vaccine, which was deemed enough to permit three predictors in the logistic model. Categorical independent variables were assessed for frequency as seen in Table 4.8.

Table 4.8

Frequency Table for Categorical Independent Variables (N=80)

Variable	**Category**	**Frequency**	**Percentage**
Adolescent Opinion about Vaccination	Accepted	24	30
	Declined	56	70
Previously Vaccinated Child(ren) against HPV	Yes	19	23.8
	No	61	76.3
Personal/Family History of HPV	Yes	4	5
	No	76	95

Because there were only four families with a history of HPV, that variable was not included as a predictor in the logistic model. Due to the low occurrence, the model would not be reliable if it were included.

Bivariate analysis of the remaining two categorical variables with the dependent variable, parental vaccination decision was conducted as shown in Table 4.9. As expected, both tests were highly significant, $p < 0.01$, indicating a significant relationship between the parental vaccination decision and the adolescent vaccination decision and between the parental vaccination decision and whether the parent had previously

accepted HPV vaccination for another child or children in the family. There were no missing data.

Table 4.9

Chi-Square Tests

Variables	Pearson Chi-Square	df	*p* value	Fisher's Exact Sig.
Parental Vaccination Decision * Adolescent Opinion about Vaccination	7.235	1	.007	.011
Parental Vaccination Decision * Child Previously Vaccinated	11.160	1	.001	.002

Logistic regression was carried out on the probability of adolescent vaccination, with three predictors in the model: having previously vaccinated a child against HPV, parental decisional conflict post-intervention and adolescent opinion about vaccination. The model was significant ($p < 0.001$, Nagelkerke $R^2 = 0.446$). All three predictors made statistically significant contributions to the model. Their effects are presented in Table 4.10.

Table 4.10

Binary Logistic Regression for Parental Vaccination Decision (N=80)

Variable	B	S.E.	*p* value	O.R.	C.I. (lower)	C.I. (upper)
Child Previously Vaccinated	2.169	0.734	0.003	8.746	2.075	36.866
Parental DCS Score Post-Intervention	-1.799	0.545	0.001	0.165	0.057	0.481
Adolescent Opinion about Vaccination	-1.591	0.642	0.013	0.204	0.058	0.717

Alpha=0.05

Controlling for differences in parental decisional conflict post-intervention and adolescent opinion about vaccination, the estimated odds of the adolescent receiving the HPV vaccine (i.e., the parent chooses vaccination) are 8.75 times greater if other children in the family received the HPV vaccine previously (p=0.003; OR=8.75; CI, 2.075-36.866). Holding other variables constant, for every increase of 1 unit of parental decisional conflict post-intervention, the estimated odds of the adolescent receiving the HPV vaccine were reduced by a factor of .165 (p=.001; OR=0.165; CI, 0.057-0.481). Holding other variables constant, the estimated odds of the adolescent receiving the

HPV vaccine were reduced by a factor of 0.204 when the adolescent's opinion on vaccination expressed rejection instead of acceptance (p=0.013; OR=0.204; CI, 0.058-0.717).

A post-hoc analysis of reasons parents chose to accept the vaccine is shown in Table 4.11.

Table 4.11

Parent Reported Primary Reasons for HPV Vaccine Acceptance (N=29)

Reason for vaccine acceptance	**N**	**%**
Protection from HPV related disease	23	79.3
Healthcare provider recommendation	4	13.8
Benefits outweigh the risks	2	6.9

A post-hoc analysis of reasons parents chose to decline the vaccine is shown in Table 4.12.

Table 4.12

Parent Reported Primary Reasons for Declining HPV Vaccination (N=51)

Reason for declining vaccination	**N**	**%**
Child is not at risk due to age, lifestyle or not sexually active	12	23.5
Concern for vaccine safety / side effects	11	21.6
Want more information	9	17.6
Undecided	4	7.8
Child does not want to get a shot	3	5.9
Getting other vaccines that day	3	5.9
Wants to talk about with spouse	2	3.9
Risks outweigh benefits	2	3.9
No explanation	2	3.9
Vaccine is not required	1	2.0
Not sure of insurance coverage	1	2.0
Weak provider recommendation	1	2.0

Specific Aim 3. Of the specific aims, a final exploratory aim is as follows:

3. To gather preliminary data for describing the frequency of parental decisional regret 2-weeks post-vaccination decision.

Parental decisional regret was assessed by telephone using the Decision Regret Scale two weeks after the vaccination decision was made. The scores were converted to a 0-100 scale by subtracting 1 from each item score then multiplying by 25. The item scores were then averaged to produce a Decision Regret Scale score (0 = no regret; 100 = high regret. Data were missing from nine participants. Four participants were not reached by telephone after three attempts. Five participants declined follow up at the time of the initial encounter. Descriptive statistics using the Decision Regret Scale are shown in Table 4.13. The majority of parents (44; 62 %) reported no decisional regret. The distribution of parental decisional regret are shown in Figure 2. The boxplot below in Figure 4.2 represents highly skewed data with a median of 0 and a few outliers.

Table 4.13

Descriptive Statistics for Parental Decisional Regret

N	71
IQ 1	0.00
Median	0.00
IQ 3	15.00

Decision regret scores were assessed comparing parents who vaccinated with parents who declined vaccination. The median regret score for parents who declined vaccination (N=44) was 0 with an interquartile range (IQR= 0-20). The median regret score for parents who accepted HPV vaccination (N=27) was 0 (IQR=0-0). The Mann-Whitney *U*-test was significant (p=0.015), concluding that parents who declined HPV vaccination for their child experienced significantly more decisional regret than parents who accepted HPV vaccination.

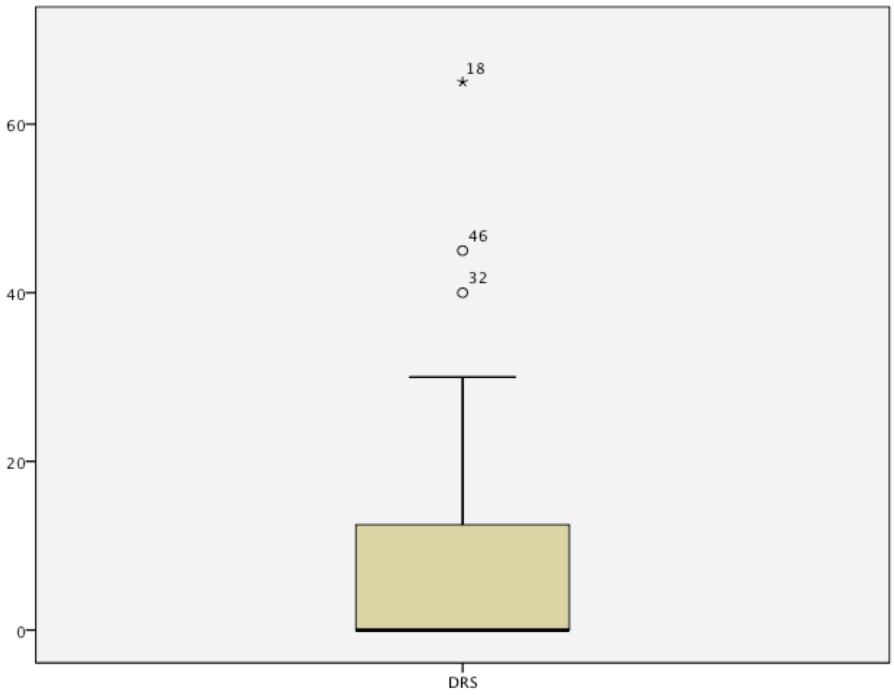

Figure 4.2 Boxplot of the Distribution of Parental Decision Regret Scale Scores (N = 71)

Chapter 5

DISCUSSION

The number of female and male adolescents receiving the HPV vaccine has been disappointingly low compared to vaccine uptake of other adolescent vaccines (CDC, 2014a). This pilot study strove to assess the frequency of parental decisional conflict regarding HPV vaccination, the feasibility and acceptability of an interactive decision aid intervention, and the effect of a decision aid used interactively with the parent/child dyad on the parents' decisional conflict and regret.

Feasibility and Acceptability

This study adds to the existing body of knowledge assessing the feasibility and acceptability of decision aids regarding HPV vaccination with a parent/child dyad in a primary care setting at the actual time of vaccine recommendation by the healthcare provider. The healthcare providers recommended HPV vaccination to all of the participant dyads at their routine healthcare visit.

Recruitment and enrollment. Study findings support the feasibility of enrolling parent/child or parent/adolescent dyads in a study utilizing a decision aid related to HPV vaccination. The desired number of participant dyads was easily enrolled in the study over a 5-month period; this was four months less than the original time allotted. This included a 3-week pause in enrollment of 11-14 year old participants while the original decision aid was revised and resubmitted to the Institutional Review Board (IRB) for approval.

The majority (7 out of 11; 64%) of parents who declined participation did not want to discuss HPV or the HPV vaccination. A lack of desire for additional information could indicate that: 1) additional information may conflict with their established ideas or opinions of which they are not conflicted, and do not wish to vaccinate against HPV; 2) they feel sufficiently informed, are not conflicted and intend to vaccinate; or, 3) they are conflicted and are choosing not to seek additional information while deciding not to vaccinate or to delay vaccination.

Acceptance of the decision aid. The majority of parents (74%) and older adolescents (83%) found the decision aid to be helpful in the decision-making process regarding HPV vaccination and acceptable (ease of use and length of time for completion), although the sample size of older adolescents was small (n=11). Feedback from the first eleven participants who were all 11-14 years of age and who received the original decision aid (Phase1) indicated that it was generally easy to read and easy to use. Yet, it was apparent there was a health literacy problem with the original decision aid for the younger age group from multiple sources used in this pilot study (observation, probing questions for the PI, feedback from parents and study evaluation feedback).

To support acceptability of the decision aid after the revision in Phase 2, the majority (42 out of 58; 73%) of young aged adolescents reported that the decision aid was easy to use and that there was enough time to read

the information. The revised decision aid was helpful in the decision-making process according to slightly more than half (59%) of the younger adolescent participants. Slightly less than half (45%) of the younger adolescents, ages 11 to 14 years old, found the revised decision aid both helpful in the decision-making process and acceptable. This result suggests that finding the decision aid *acceptable* and finding the decision aid *helpful* may not be highly correlated. Fewer of the younger adolescents perceived the decision aid to be helpful compared to parents and older adolescents, which may be due to the very general information that was provided for this age group about HPV related disease and the vaccination. This may also be a reflection of their lack of confidence or comfort making this decision due to a lack of or limited prior experience with taking responsibility in health-related decision making. Maturity, confidence and cognition may also influence their preference for involvement in decision making. Increasing age and developmental level are reported in the literature as factors that promote adolescent participation in the decision-making process in other health related contexts (Coyne & Gallagher, 2011; Geller et al, 2003; Green et al., 2012; Griffloen et al., 2012; Herbert et al., 2013; Miller, 2009, Squitieri et al., 2013; Taylor et al., 2010).

Parental Decisional Conflict

Approximately two-thirds (67.5%) of the parents reported feeling conflicted about the HPV vaccination decision for their child at baseline (pre-intervention). This finding is consistent with other studies reporting that some parents express doubt or uncertainty when deciding about vaccine acceptance for their child (Gust et al., 2008; Hughes et al., 2011; McRee et al., 2010). Primary subscale components that contributed to decisional conflict at baseline in descending order of frequency included: 1) feeling uninformed; 2) feelings of uncertainty; 3) feeling unclear about their values when making this decision; and 4) feeling unsupported. This finding is consistent with the literature that identifies a perceived lack of knowledge as a major barrier to HPV vaccination (Allen eta l., 2010; Bair et al., 2008; Dempsey et al., 2009; Hughes et al., 2011; Morales-Campos et al., 2012; Oldach & Katz, 2012; Reiter et al., 2013; Woodhall et al., 2007; Yeganeh, et al., 2010). Less than half (43.8%) of parents reported feeling unsupported. Feeling uncertain had the highest DCS score of the subscale components.

Total decision conflict scores and all subscale scores decreased significantly after the decision aid intervention. Based on scale norms, a meaningful difference in decision conflict scores may be defined as 0.4 to 0.5 of a standard deviation (O'Conner, 1995). The standard deviation of the paired differences in this study were 0.699 indicating that the decision aid with usual care produced a meaningful difference in reducing parental decisional conflict. This decision aid provided two components in an interactive process: 1) factual information that supplemented the CDC HPV Gardasil Vaccine Information Sheet to increase knowledge, and 2) encouraged the parent to consider the risks and benefits of HPV vaccination for themself and for their child through a decisional balance sheet. The helpfulness of decision aids in decision making is likely multifaceted and may be helpful to individuals differently. The decrease in decisional conflict post-intervention in this study is consistent with the underpinning theory of the study by Janis and Mann (1977) and study findings by Parayre et al. (2014) who found that uncertainty or decisional conflict can result from a perceived lack of decisional support, including a lack of adequate and accurate information as well as consideration of one's personal values and preferences. Similar to findings by Holman et al. (2014),

83.4 % of parents reported that this decision aid served as a useful intervention to improve communication between the parent, child and healthcare provider. However, less than half (45.1%) of adolescents reported that the decision aid helped them to communicate with their healthcare provider. This finding may be important for illuminating a failure to communicate or include adolescents in the discussion or decision-making process and should be explored further.

In this study of 80 parents, decisional conflict subscale scores for uncertainty, feeling uninformed, making a decision with unclear values and feeling unsupported decreased significantly post-intervention. Decision aids have been reported to decrease decisional conflict in other studies by promoting parental participation in the decision-making process, improving parental perceptions of feeling informed, decreasing anxiety and facilitating communication with the health care provider (O'Connor, 1995; Wallace et al, 2006; Wroe et al., 2005). Moreover, these results are in agreement with a Cochrane systematic review of decision aids for people making decisions related to healthcare treatment or screening (Stacey et al., 2014).

Vaccine Acceptance

As expected, vaccine acceptance rates were much higher in parents without decisional conflict post-intervention (55.3%) compared to those with decisional conflict (9.1%). This finding is consistent with earlier studies using the decision conflict scale (DCS) that found DCS scores greater than 2 were associated with declining or delaying treatment or an intervention (O'Connor, 1995). Nearly all (90.9%) of parents with DCS scores greater than 2 declined the HPV vaccine for their child. Parents with DCS scores of 2 or less vaccinated their child just over 50% of the time. These findings suggest that parental decisional conflict is significantly associated with non-acceptance of the HPV vaccine, although a substantial number of parents (n=21; 44.7%) declined vaccination that were not conflicted in their decision.

In 1999, the World Health Organization (WHO) established the Strategic Advisory Group of Experts (SAGE) on immunizations to provide guidance to the WHO on vaccine and immunization related issues (World Health Organization [WHO], 2015). The SAGE Working Group on Vaccine Hesitancy was established in 2012 specifically to address *vaccine hesitancy* that was defined as a delay in acceptance or refusal of vaccination despite the availability of vaccination services (MacDonald & the SAGE Working Group on Vaccine Hesitancy, 2015; Schuster, Eskola, Duclos, the SAGE Working Group on Vaccine Hesitancy, 2015). Vaccine hesitancy is complex and occurs on a continuum (Hickler, Guirguis, & Obregon, 2015). Vaccination delay may include vaccine refusal with continued consideration by the parent, acceptance of some vaccines while refusing others, as well as alternative scheduling of recommended or required vaccines. Hickler et al. (2015) report that globally, vaccine hesitancy occurs for reasons that are highly variable and context specific.

In the post-hoc analysis of this study, consistent with the information from Hickler et al. (2015), parents gave a variety of reasons for declining the HPV vaccine for their child.

Parents reported declining the HPV vaccine most often because they did not feel their child was at risk and due to concerns regarding vaccine safety and side effects. This feedback suggests that parents associate recommendations for HPV vaccination with sexual activity. Parents who declined vaccination because they felt their child was not at risk may be overlooking the information related to immune responses to HPV vaccination. Studies have demonstrated that antibody levels are highest when the HPV vaccine is given before 15 years of age (Petaja et al., 2011). This point may need to be strengthened or clarified to encourage vaccination prior to age 15 years.

Parents frequently voiced concerns about side effects and potential long-term adverse effects of vaccination. Even after discussion of what is known in the side effect profile, parents voiced concerns about what may not be known. This finding is consistent with previous research showing that people avoid unknown or ambiguous risks, have a heightened or exaggerated perception of unknown risks, and have a preference for known probabilities (Ellsberg, 1961; Rode, Cosmides, Hell, & Tooby, 1999). For the health care provider, discussing what is not known is a challenge. Blaisdell, Gutheil, Hootsmans, & Han (2015) interviewed eight focus groups with 42 vaccine hesitant parents. Parents in the focus groups reported a sense of ambiguity over vaccine safety due to a perceived insufficient information, conflicting or changing information and a lack of credibility on the part of information sources or healthcare providers who some feel may follow pharmaceutical or government recommendations without proper scrutiny of the information (Blaisdell et al., 2015). Parents with ambiguity of vaccine-associated risks often maximized the perceived risk of vaccine harm, minimized the perceived susceptibility of the vaccine preventable illness, and minimized the perceived severity of the vaccine preventable illness (Blaisdell et al., 2015).

There was substantially better consensus among parents regarding reasons for accepting HPV vaccination. Overwhelmingly, 79.3% of parents reported accepting the HPV vaccine for their child to protect them against HPV related disease. Only 13.8% of parents reported provider recommendation as the primary reason for vaccinating. These findings are somewhat different from earlier reports in the literature that identified a desire to protect their child and provider recommendation as primary reasons parents vaccinated with similar frequency. This latter finding may suggest that parents perceive their decision to be more autonomous when they are given more information for decision making or jointly determined when a shared decision-making style is utilized rather than a paternalistic style. This finding is consistent with previous studies reporting an increase in patient engagement in the decision-making process when decision aids are utilized compared to usual care (Coylewright et al., 2014; LeBlanc et al., 2015).

As expected, a history of having other children in the family previously vaccinated against HPV was significantly associated with parental HPV vaccine acceptance. This may not only suggest a general acceptance of vaccines but also, positive experiences with the HPV vaccine. Parents were more likely to decline the HPV vaccine if the adolescent indicated that they did not want to receive the vaccine. Specifically, 41 parents (73.2%) declined the HPV vaccine when the adolescent did not indicate that they would like to receive the vaccine. This finding may indicate that

healthcare providers need to educate adolescents more about HPV related disease, the vaccine and address their individual concerns.

Parental Decisional Regret

The majority of parents (62%) did not report any decisional regret after their vaccination decision. Three parents as outliers were identified who expressed significant decisional regret. Two of the three parents who expressed regret had declined HPV vaccination for their child:

1) One parent, who declined vaccination and had the highest level of decisional regret, indicated that she wanted to discuss HPV vaccination with her husband. It may be that she was hoping her husband would support a decision of vaccination at another time. If her husband's feelings differed from her own, she may feel regret that she missed an opportunity to vaccinate her daughter and now is in disagreement with someone whose opinion she values. This concept falls under the construct of *cues to action* related to advise from others in the health belief model. Rather than the likely anticipated cue to action from her husband that she was hoping for, she now is faced with a barrier or discordance with her husband's opinion. She may feel that she has failed to protect her child from disease.

2) The second parent that expressed decisional regret and who did not vaccinate, indicated that she declined vaccination due to perceived lack of information. This parent may have gained additional knowledge since the vaccination visit or received feedback from someone whose opinion she valued that caused her to feel regret. She may be feeling regretful for not taking the opportunity to protect her child. She may feel a lack of concordance with her own value system for not vaccinating. If this parent normally vaccinates her child(ren) against other diseases, she may feel that her decision to decline vaccination went against her previously held values.

3) The third parent who expressed decisional regret accepted HPV vaccination for her child. This parent reported vaccinating her child to protect her future health. There were no adverse events reported post-vaccination for this child. It may be that the mother had gained new knowledge that concerned her or that she was given disapproval by someone important to her for her vaccination decision.

Overall, post-decisional regret was absent or low, considering there were only a few cases reported. Although the frequency was low in this small scale pilot study, parental decisional regret in parents who have chosen not to vaccinate should be explored further.

Historical Events During Study

Two historical events may have been threats to validity for this study. A heightened awareness of controversy surrounding vaccines and non-vaccinators amidst a measles outbreak and the development of an expanded HPV vaccine were potential external threats to the validity of this single arm study.

Measles outbreak. An outbreak of measles in Orange County California involving at least 40 people began in December 2014 and was declared over in April 2015 (California Department of Public Health, 2016). This outbreak occurred just prior to the onset of this study. The measles outbreak drew great media attention to the impact that non-vaccinated individuals can have on public health. The outbreak stimulated passionate debate again about mandatory vaccination policies, threats to the health of the public by non-vaccinators and the rights of individuals.

Study site policy change. This study was conducted at a primary care pediatric practice that decided to take a stand on this issue and instituted a policy that they would no longer accept patients whose parents did not follow the vaccination requirements established in the state of Virginia. The partners of the practice chose not to include the HPV vaccine in this policy because the "opt out" clause was so generous. Patients who were already established patients at the office were notified of the policy change and parents who maintained a decision not to vaccinate were given thirty days to establish themselves elsewhere. It is difficult to determine what, if any, impact this event may have had on the results of this study. It may have encouraged some to engage in conversation and learn more about the HPV vaccine. The controversy may have been a barrier to communication or to accepting new information for others. Conversely, the controversy may have encouraged discussion or vaccine acceptance due to the public health implications of the outbreak.

Gardasil 9. The FDA licensed the Gardasil 9 vaccine for females 9 to 26 years of age, and for males 9 to 15 years of age in December, 2014 (Kirby, 2015). This study was conducted from April, 2015 to September, 2015. The practice where this study was conducted was not stocking or using this vaccine at the time of this study. Vaccine delay or declining the 4-valent Gardasil may have occurred if a parent wanted their child to receive the 9-valent Gardasil. This was never given as a reason for declining in this study, but the development of this expanded vaccine had the potential to influence parents' decision making.

Study Limitations

Single arm study. The single arm study design limits the interpretation of results, and has greater threats to validity because there is no control arm. Using a single arm design, the true effect of the intervention or interactive decision aid cannot be determined due to the possible effect of confounding variables. Confounding variables may include the effect of having been offered the vaccine previously and the difference in "usual care" by different providers. These variables were not controlled for in this single arm study. Additionally, the sample was racially and ethnically homogeneous and was limited to a single geographic area.

Rapidly evolving information. Information related to HPV related diseases, and cancers continue to evolve. Research related to vaccine information, safety and efficacy is ongoing. Studies to assess long-term safety and efficacy continue, while new studies are being developed to include different populations including immunocompromised individuals. It was challenging to provide a decision aid with accurate and up-to-date information.

Conclusion

Overall, the participants reported the interactive decision aid was helpful in the decision-making process and acceptable (ease of use and length of time for completion). Parents and older adolescents found the decision aid to be more helpful in the decision-making process compared to the younger adolescents. The latter finding may reflect the experience of being a novice in health-related decision making.

The results of this study demonstrated evidence that parents have decisional conflict regarding HPV vaccination for their child as reported in the media, the literature, and by the World Health Organization. This study also demonstrated preliminary evidence that an interactive decision aid for HPV vaccine used with the parent/child dyad decreases parental decisional conflict. This finding is in line with results from a 2011 Cochrane Review of 86 studies that reported that the use of decision aids improves patient knowledge, provides a more accurate perception of involved risks, decreases decisional conflict and encourages care that is consistent with one's values (Stacey et al., 2011).

The presence of decisional conflict post-intervention was overwhelmingly associated with non-acceptance of the HPV vaccine. Most importantly, 55.3% of parents with no decisional conflict after the decision aid vaccinated their child compared to 9.1% of parents with decisional conflict. Yet, parents who reported no decisional conflict post-intervention declined vaccination for their child almost half (44.7%) of the time. Nonetheless, there is greater consensus among parents choosing to vaccinate against HPV than among parents declining vaccination. This finding is consistent with the SAGE Working Group on vaccine hesitancy (WHO, 2014).

Parental decisional regret may be more frequent in parents who decline vaccination than in those that accept vaccination. This is an important finding considering the findings of Brehaut et al. (2003) who reported post-decisional regret was associated with an increase in changes of reversible decisions.

In summary, these findings suggest that decision aids are a useful intervention to facilitate and improve communication, advance knowledge, reduce parental decisional conflict and promote vaccine acceptance. This decision aid also focused on an intervention using informed, shared decision making, as recommended in a recent Institute of Medicine Report as a means of improving care by partnering with health care

providers (Institute of Medicine [IOM], 2014). In addition to the Institute of Medicine emphasizing shared decision making, these findings are in line with the goals of the Affordable Care Act to improve health outcomes, decrease costs, and provide health care that is compatible with the patients' values (Lee & Emanuel, 2013).

Implications for Research and Practice

More research is warranted with larger samples. A follow-up study using a control group may give additional information about the impact of the decision aid on parental decisional conflict. A randomized control trial would reduce population bias through randomization while a control group would elucidate the effect of the decision aid on parental decisional conflict related to HPV vaccination compared to usual care and/or an additional intervention. The reasons for parental non-acceptance of the vaccine were highly variable, indicating the need for targeted communication and personalized interventions to address specific concerns of the intended audience about HPV vaccination. Additionally, parents may be more aware of the benefits of HPV vaccination; but, parental concerns remain about the safety of the vaccination and potentially unknown risks.

Engaging and involving stakeholders, specifically the adolescent population, may prove to be very important in reducing parental decisional conflict related to HPV vaccination. Further research is needed to assess adolescents' concerns regarding HPV vaccination such as concerns for painful immunizations. Age appropriate interventions for improving communication with adolescents, increasing awareness and education of adolescents regarding HPV are needed as their opinion may influence parental decision making.

Lastly, additional studies to understand the reasons parents experience decisional regret are needed to move this public health concern forward toward resolution. It was unexpected and interesting that two of the three outliers expressing significant parental decisional regret declined vaccination. Implications for practice suggest that even if parents have declined vaccination previously, they may change their decision at the next opportunity. This finding suggests the need for ongoing discussions about vaccines at every patient encounter; however, due to time being perceived as a barrier for many busy practices, further study is warranted as well.

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Summary of Appendices

Appendix A Instruments

Demographic Form
Decisional Conflict Scale (DCS) Baseline
Decisional Conflict Scale (DCS) Time point 2
Adolescent Opinion Regarding the HPV Vaccination
Parent Response Sheet
Parent Study Evaluation Form
Child/Adolescent Study Evaluation Form
Decision Regret Scale

Patient ID _____

Today's Date _____

Demographic Form

1. Parent's Age (fill in age)…….. ☐☐
2. The number of years of schooling the parent has completed (check appropriate box):
   - Did not finish high school…… ☐
   - GED or High school graduate…..... ☐
   - Some college……..... ☐
   - College Graduate…….. ☐
3. Assigned race/ethnicity (check appropriate box):
   - Caucasian…….. ☐
   - Black or African American……... ☐
   - Latino (Puerto Rican, Cuban, Dominican, etc.)…….. ☐
   - West India (Haitian, Jamaican etc.)..…… ☐
   - Asian or Asian American…….. ☐
   - Native American……... ☐
   - Other: _____
4. Annual household income (check appropriate box):
   - < less than $15,000…… ☐
   - $15,000– $29,0000…… ☐
   - $30,000-$60,000……..…. ☐
   - >$60,000…….. ☐
5. Child Health Insurance (check the appropriate box):
   - None reported……..... ☐
   - Private…… ☐
   - Public…….. ☐
   - Other/don't know…… ☐

Patient ID _____

Today's Date _____

Demographic Form

6. Your child's age (fill in age)…… ☐☐

7. What is your child's gender? (check appropriate box) Male… ☐ Female... ☐

8. How many children do you have? (fill in number)…… ☐☐

9. How many of your children have received the human papillomavirus HPV) vaccine? (fill in number)…… ☐☐

10. Have you or anyone in your family had an HPV related infection or disease? (check appropriate box) Yes... ☐ No... ☐

Thank you!!

Patient ID: _____

Today's Date: _____

Decisional Conflict Scale (DCS) – Baseline

You may be advised by your health care provider to vaccinate your child against human papillomavirus (HPV) today. After considering the HPV vaccine for your child today, you may or may not decide to have your child get the HPV vaccine today.

Please indicate if you agree or disagree with the following:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. This decision is easy for me to make…….	☐	☐	☐	☐	☐
2. I'm sure what to do in this decision……	☐	☐	☐	☐	☐
3. It's clear to what choice is best for my child……..	☐	☐	☐	☐	☐
4. I'm aware of the options I have in this decision……..	☐	☐	☐	☐	☐
5. I feel I know the advantages of each option……	☐	☐	☐	☐	☐
6. I feel I know the disadvantages of each option……...	☐	☐	☐	☐	☐
7. I am clear about <u>how important</u> the advantages are to me in this decision…….	☐	☐	☐	☐	☐
8. I am clear about <u>how important</u> the disadvantages are to me in this decision…….	☐	☐	☐	☐	☐
9. For the main options I am considering, I am clear about which is <u>more</u> important to me (the advantages or disadvantages)……	☐	☐	☐	☐	☐
10. I am making this choice without any pressure from others…….	☐	☐	☐	☐	☐
11. I have the right amount of support from others in making this choice……...	☐	☐	☐	☐	☐
12. I have enough advice about the options……..	☐	☐	☐	☐	☐

Source: O'Connor, A. M., Copyright, 1993; Revised, 1999

Patient ID: _____

Today's Date: _____

Decisional Conflict Scale (DCS) – Time 2

After meeting with your health care provider, you have been asked to decide whether or not you will vaccinate your child against human papillomavirus (HPV) today.

Please indicate if you agree or disagree with the following:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. This decision is easy for me to make……..	☐	☐	☐	☐	☐
2. I'm sure what to do in this decision…….	☐	☐	☐	☐	☐
3. It's clear to what choice is best for my child……...	☐	☐	☐	☐	☐
4. I'm aware of the options I have in this decision……..	☐	☐	☐	☐	☐
5. I feel I know the advantages of each option……	☐	☐	☐	☐	☐
6. I feel I know the disadvantages of each option……...	☐	☐	☐	☐	☐
7. I am clear about <u>how important</u> the advantages are to me in this decision……..	☐	☐	☐	☐	☐
8. I am clear about <u>how important</u> the disadvantages are to me in this decision……...	☐	☐	☐	☐	☐
9. For the main options I am considering, I am clear about which is <u>more</u> important to me (the advantages or disadvantages)……..	☐	☐	☐	☐	☐
10. I am making this choice without any pressure from others……...	☐	☐	☐	☐	☐
11. I have the right amount of support from others in making this choice……..	☐	☐	☐	☐	☐
12. I have enough advice about the options…….	☐	☐	☐	☐	☐
13. I feel I have made an informed choice……...	☐	☐	☐	☐	☐
14. My decision shows what is important to me……..	☐	☐	☐	☐	☐
15. I expect to stick with my decision……..	☐	☐	☐	☐	☐
16. I am satisfied with my decision……..……	☐	☐	☐	☐	☐

Patient ID: _____

Today's Date: _____

Adolescent Opinion Regarding the HPV Vaccination

Please state your opinion regarding the HPV vaccination
(you may or may not agree with your parent's point of view)

Please indicate if you agree or disagree with the following:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. I believe vaccination against human papilloma virus (HPV) is important to protect me from disease later in my life……..……	☐	☐	☐	☐	☐
2. I would like to receive the HPV vaccine today……..……	☐	☐	☐	☐	☐

Patient ID: _____

Today's Date: _____

Parent Response Sheet

1. How important is your child's opinion regarding vaccination to you?

   ☐ Not at all

   ☐ Somewhat

   ☐ Very

   ☐ Extremely

2. Are you aware of your child's opinion regarding vaccination today?

   ☐ Yes

   ☐ No

3. If yes, did your child's opinion regarding vaccination influence your final decision regarding HPV vaccination today?

   ☐ Not at all

   ☐ Somewhat

   ☐ Very

   ☐ Extremely

4. Did you decide to vaccinate your child against HPV today?

   ☐ Yes

   ☐ No

5. Please tell us the **primary** reason you decided to accept or decline the HPV vaccine today.

6. May the researcher contact you by phone in two weeks for a 5 minute follow-up interview about how you feel about your decision today?

   ☐ Yes

   ☐ No

   The best phone number to reach me is_____

   (This number will not be used for **any other** purpose and **will not** be given out to anyone)

   The best day and time to reach me is _____

Participant ID#_____

Today's date _____

Parent Study Evaluation

1. The decision aid was **easy to read**.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

2. The decision aid and balance sheet was **easy to use.**

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

3. The **time needed** to review the decision aid **was acceptable**.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

4. The **decision aid was helpful** in making a decision today.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

5. The decision aid encouraged me to **talk about my personal values** when making this decision.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

6. The decision aid **helped me communicate** with my health care provider.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

7. I would advise other patients to use the decision aid to help in making informed decisions.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

8. Please write what you liked most about the decision aid.

9. Please write how the decision aid could be improved.

Participant ID#_____

Today's date_____

Child/Adolescent Study Evaluation

1. The decision aid was **easy to read**.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

2. The decision aid and balance sheet was **easy to use.**

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

3. The **time needed** to review the decision aid **was acceptable**.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

4. The **decision aid was helpful** in making a decision today.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

5. The decision aid encouraged me to **talk about my personal values** when making this decision.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

6. The decision aid **helped me communicate** with my health care provider.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

7. I would advise other patients to use the decision aid to help in making informed decisions.

   Strongly disagree_____ Disagree _____ Undecided_____ Agree_____ Strongly agree_____
   1 2 3 4 5

8. Please write what you liked most about the decision aid.

9. Please write how the decision aid could be improved.

Participant ID _____

Todays date

_____

Decision Regret Scale (DRS)

Thank you for agreeing to talk with me over the telephone two weeks after the office visit with your child. Regarding your decision to vaccinate or not to vaccinate your child against human papillomavirus (HPV), please respond to the following statements.

1. It was the right decision.

   1=Strongly Agree 2=Agree 3=Neither agree or disagree 4=Disagree 5=Strongly disagree

2. I regret the choice that was made.

   1=Strongly Agree 2=Agree 3=Neither agree or disagree 4=Disagree 5=Strongly disagree

3. I would go for the same choice if I had to do it all over again.

   1=Strongly Agree 2=Agree 3=Neither agree or disagree 4=Disagree 5=Strongly disagree

4. The choice did my child a lot of harm.

   1=Strongly Agree 2=Agree 3=Neither agree or disagree 4=Disagree 5=Strongly disagree

5. The decision was a wise one.

   1=Strongly Agree 2=Agree 3=Neither agree or disagree 4=Disagree 5=Strongly disagree

Appendix B **Intervention Phase 1**

Part 1: Decision Aid: "What can you do to prevent Human Papillomavirus (HPV)"?

Part 2: Balance Sheet for Personal Decision Making: Vaccinating Against HPV

Intervention Phase 2

Part 1: Decision Aid: "What can you do to prevent Human Papillomavirus (HPV)? for ages 15-17 years and parents
A decision aid for those considering the HPV shot (Ages 11-14 years)

Part 2: Balance Sheet for Personal Decision Making: Vaccinating Against HPV

Patient ID: _____
Today's Date: _____

What can you do to *prevent Human Papillomavirus (HPV)?*

A decision aid for those considering the HPV vaccine

- **Today you will be asked to accept or decline HPV vaccination for your child.**
- **Please use this decision aid interactively with your child and the study nurse as part of the decision-making process.**

What is human papillomavirus?

- Human papillomavirus (HPV) is a virus that can cause certain cancers and genital warts in males and females.
- The virus is most often spread from person to person during intimate or sexual contact.
- Often, the body fights off the virus on its own, like when you have a cold, but sometimes it causes warts or changes to the cells in the body that become cancer cells.

What are your options *to decrease your risk* of getting/spreading HPV?

- Take the HPV vaccine before you become intimate with others.
- You can decrease your risk by minimizing the number of intimate partners you have.
- Use condoms during sexual activity.
- The only way to be **certain** not to be infected with HPV is to never have intimate relations with anyone.

What other health factors may affect your choice? (Check any that apply to you)

You should not get the HPV vaccine if:

- You have a severe allergy to yeast.

You should wait to get the HPV vaccine at a later time if:

- You are pregnant.
- You are currently sick with a serious illness.
- Your immune system is not working properly at this time (due to certain medications, or an illness).

What other HPV disease and vaccine facts may affect your choice? (Check any that apply to you).

- Pre-teens and early adolescents (ages 11-15) have a better immune response to the vaccine compared to older adolescents.
- We do not know how long the vaccine lasts, although studies are ongoing.
- Genital warts can be treated with medicine but usually come back.
- Genital warts do not turn into cancer.
- Warts in the reproductive tract of females can be passed to the throat and airways of the baby during childbirth.
- Females 21 years and older still need PAP smears to monitor for cervical cancer because the HPV vaccine does not prevent 30% of cervical cancers.
- The HPV vaccine prevents seventy percent of cervical cancers.
- Since the vaccine was licensed in 2006, the Center for Disease Control reports there have been no serious side effects related to the HPV vaccine.
- The vaccine prevents but does not cure infections that have already occurred.
- Studies have consistently found no support for suggestions that the vaccine is associated with increased sexual activity (Aujo et al., 2014; Mattebo et al., 2014; Rysavy et al., 2014).

UNIVERSITY of VIRGINIA SCHOOL of NURSING

Patient ID: _____

Today's Date: _____

Balance Sheet for Personal Decision Making: Vaccinating Against Human Papillomavirus (HPV)

Instructions:

- In the box, please **check** statements important to you for this decision. Be sure to identify these for yourself and for your child. If there are other areas of importance, please write them in.
- Please review again and **star** those statements MOST important to you.
- If any statement is not clear to you, be sure to ask the researcher.

Parent: *I understand that my child's health care provider has recommended that my child receive a vaccine against human papillomavirus (HPV). If I decide to have my child vaccinated, what are the benefits and risks? What matters most to me?*

Gains/Losses	***Benefits (+)***	***Risks (-)***
For myself	1) I will have relief knowing that my child is protected against HPV. 2) My child may be grateful to me for preventing them from having a potentially life threatening disease. 3) People may be pleased that I am helping prevent the spread of disease to others. 4) My child may ask me questions about sexually transmitted diseases. 5) Other **benefits** for myself?	1) I will feel guilty if my child has an adverse reaction to the vaccine. 2) My child may be upset with me for agreeing to give a painful injection. 3) People may think I am a bad parent because they may assume my child is sexually active. 4) Others, whose opinion matters to me, may not agree with my decision. 5) I will have to bring my child in for two more doses. 6) My child may ask me questions about sexually transmitted diseases. 7) Other **risks** for myself?

Participant ID #_____ Date_____

Page 2: Balance Sheet for Personal Decision Making:
Vaccinating Against Human Papillomavirus (HPV)

Gains/Losses	Benefits (+)	Risks (-)
For my child	1) My child may avoid getting HPV related diseases and cancers. 2) My child may avoid getting genital warts. 3) My child may become more informed about sexually transmitted diseases. 4) Other **benefits** for my child.	1) My child may have an adverse reaction to the vaccine. 2) My child will feel pain at the time of the injection. 3) My child will have to receive a total of three doses to complete the series. 4) People may think my child is sexually active. 5) My child may become sexually active because he/she has received the vaccine. 6) Other **risks** for my child.

(Adapted with permission from the DecisionKEYS by Hollen et al., 2012)

Patient ID:
Today's Date:

What can you do to prevent Human Papillomavirus (HPV)?

(For ages 15-17 years)

A decision aid for those considering the HPV vaccine

➢➢ Today you will be asked to accept or decline HPV vaccination for your child.
➢➢ Please use this decision aid interactively with your child and the study nurse as part of the decision-making process.

What is human papillomavirus?

- Human papillomavirus (HPV) is a virus that can cause certain cancers and genital warts in males and females.
- The virus is most often spread from person to person during intimate or sexual contact.
- Often, the body fights off the virus on its own, like when you have a cold, but sometimes it causes warts or changes to the cells in the body that become cancer cells.

What are your options to decrease your risk of getting/spreading HPV?

- Take the HPV vaccine before you become intimate with others.
- Use condoms during sexual activity.
- You can decrease your risk by minimizing the number of intimate partners you have.

What other health factors may affect your choice? (Check any that apply to you)

You should not get the HPV vaccine if:

- You have a severe allergy to yeast.

You should wait to get the HPV vaccine at a later time if:

- You are pregnant.
- You are currently sick with a serious illness.

What other HPV disease and vaccine facts may affect your choice? (Check any that apply to you)

- Pre-teens and early adolescents (ages 11-14) have a better immune response to the vaccine compared to older adolescents.
- The vaccine prevents but does not cure infections that have already occurred.
- We do not know how long the vaccine lasts, although studies are ongoing.
- Since the vaccine was licensed in 2006, the Centers for Disease Control and Prevention report there have been no serious side effects related to the HPV vaccine.
- Genital warts can be treated with medicine but usually come back and need retreatment.
- Genital warts do not turn into cancer.
- Warts in the reproductive tract of females can be passed to the throat and airways of the baby during childbirth.
- The HPV vaccine prevents seventy percent of cervical cancers.
- Females 21 years and older still need PAP smears to monitor for cervical cancer because the HPV vaccine does not prevent 30% of cervical cancers.
- Studies have consistently found no support for suggestions that the vaccine is associated with increased sexual activity (Aujo et al., 2014; Mattebo et al., 2014; Rysavy et al., 2014).

By Joyce Apted, PhD(C), CPNP, RN

Patient ID: _____
Today's Date: _____

A decision aid for those considering the HPV shot (Ages 11-14 years)

- **Today your doctor or nurse practitioner might say you should get this shot.**
- **Please read this information as you think about getting this shot.**

What is human papillomavirus (HPV)?

- Human papillomavirus (HPV) is a virus that sometimes causes certain cancers and skin infections in males and females.
- Often, the body fights off the virus on its own, like when you have a cold, but sometimes it causes skin infections called warts that keep coming back or become certain types of cancers.

What are some reasons you should not get the shot today?

You should not get the HPV shot today if:

- You have an allergy to something in the vaccine or shot (your parent will know this information)
- Your body is not very strong right now due to certain medicines or sickness.

What other facts may affect your choice in getting the shot today?

- The shot works best for kids who are 11 or 12 years old compared to older kids, especially older than 15 years of age.
- The shot can prevent you from getting the virus; but it cannot make you better if you already have the virus.
- We do not know of anything bad that happens to people who get this shot.

By Joyce Apted, PhD(C), CPNP, RN

UNIVERSITY of VIRGINIA SCHOOL of NURSING

Patient ID: _____

Today's Date: _____

Balance Sheet for Personal Decision Making: Vaccinating Against Human Papillomavirus (HPV)

Instructions:

- In the box, please **check** statements important to you for this decision. Be sure to identify these for yourself and for your child. If there are other areas of importance, please write them in.
- Please review again and **star** those statements **MOST** important to you.
- If any statement is not clear to you, be sure to ask the researcher.

Parent: *I understand that my child's health care provider has recommended that my child receive a vaccine against human papillomavirus (HPV). If I decide to have my child vaccinated, what are the benefits and risks? What matters most to me?*

Gains/Losses	***Benefits (+)***	***Risks (-)***
For myself	1) I will have relief knowing that my child is protected against HPV. 2) My child may be grateful to me for preventing them from having a potentially life threatening disease. 3) People may be pleased that I am helping prevent the spread of disease to others. 4) My child may ask me questions about sexually transmitted diseases. 5) Other **benefits** for myself?	1) I will feel guilty if my child has an adverse reaction to the vaccine. 2) My child may be upset with me for agreeing to give a painful injection. 3) People may think I am a bad parent because they may assume my child is sexually active. 4) Others, whose opinion matters to me, may not agree with my decision. 5) I will have to bring my child in for two more doses. 6) My child may ask me questions about sexually transmitted diseases. 7) Other **risks** for myself?

Participant ID #_____ Date_____

Page 2: Balance Sheet for Personal Decision Making:
Vaccinating Against Human Papillomavirus (HPV)

Gains/Losses	Benefits (+)	Risks (-)
For my child	1) My child may avoid getting HPV related diseases and cancers. 2) My child may avoid getting genital warts. 3) My child may become more informed about sexually transmitted diseases. 4) Other **benefits** for my child.	1) My child may have an adverse reaction to the vaccine. 2) My child will feel pain at the time of the injection. 3) My child will have to receive a total of three doses to complete the series. 4) People may think my child is sexually active. 5) My child may become sexually active because he/she has received the vaccine. 6) Other **risks** for my child.

(Adapted with permission from the DecisionKEYS by Hollen et al., 2012)

Appendix C Expert Review

Evaluation of the Decision Aid by an Expert Panel (N=5)

Evaluating question	Not relevant	Somewhat relevant	Quite relevant	Very relevant
1. How *relevant* is the information in this decision aid on the topic of human papillomavirus (HPV) and the HPV vaccine?				*****
2. How *relevant* did you find the decision aid in increasing knowledge related to HPV and the HPV vaccine?			*	****
3. How *relevant* did you find the decision aid for HPV vaccination in considering the values of the individual making the decision?			***	**
Evaluating question	Not appropriate	Somewhat appropriate	Appropriate	Very appropriate
4. Did you find the length of the decision aid *appropriate* to cover the content of interest well for both individuals of the dyad?			****	*
5. How *appropriate* did you find the reading level of the decision aid for the target population?			*****	
6. How *appropriate* did you find the content of the decision aid for the target population?			***	**
Evaluating question	Not clear	Somewhat clear	Clear	Very clear
7. How *clear* did you find the wording in the decision aid?		***	**	
8. How *clear* did you find the instructions for the decision aid?			*****	
9. How *clear* did you find the overall information in the decision aid?			****	*

Expert Panel (N=5) Comments and Recommendations for Part 1 of Decision Aid

Reviewer comments	Response/Changes made
Reviewer 1 a. In the decision aid, intimate is used and may be construed differently by different people. b. Under the *Waiting to get vaccine at a later time,* what does "none of above applies" mean?	a. The word "sexual" was added to clarify the term "intimate". b. "None of the above" option has been deleted.
Reviewer 2 a. I think this is very well done. I was a bit confused about how you are using the balance sheet and the decision aid. The decision aid the way I read it has 2 different parts-the first part informational, the 2nd is gathering information about reasons one would or would not receive the vaccine? I wonder if individuals will be frustrated with having to fill both out? Perhaps there needs to be more instructions on the decision aid... b. I also wonder about addressing the differences in why someone will or will not get the injection based on gender (do boys elect not to get it for different reasons than females)-but you may be able to sort that out with your study. And finally, I wonder if people don't get it because it is not required for school enrollment.	a. The informational decision aid addresses factual information. The balance sheet addresses value laden considerations for the dyad to consider. Information alone has not been effective as a decision aid. People's values play a significant part in their decision making and are included along with the factual part of the decision aid. b. Vaccine acceptance and non-acceptance will be assessed in the study as well as their reasoning in the decision-making process.
Reviewer 3 a. In the section *You should wait to get the HPV vaccine at a later time if:* "None of the above applies" is confusing. b. Where it says, "Females still need PAP smears" you may want to add "for ages 18 years of age or older". Where it says, "The HPV vaccine prevents seventy percent of cervical cancer", you may want to differentiate between Gardasil and Cervarix.	a. The 'None of the above" option will be deleted. b. The recommendation of the American College of Obstetrics and Gynecology recommend that women 21 years and older should begin having PAP smears. This age will be added. Both Gardasil and Cervarix offer protection from HPV 16 and 18, which prevent 70% of cervical cancer. Additionally, the CDC VIS sheet included in the decision aid will only be for Gardasil.
Reviewer 4 You use the term "intimate" in the decision aid, but you mean sexual intercourse. This might be misunderstood by younger teens.	The word "sexual" was added to clarify the term intimate.
Reviewer 5 No recommendations for change.	

Appendix D Evaluation of New Decision Aid For 11-14 Year Olds

Parent (N=5) Evaluations for "A decision aid for those considering the HPV shot"

Evaluation Item	Evaluation Score
The information is appropriate for the child's/adolescent's needs	Strongly agree ***** Agree Neutral Disagree Strongly disagree
The information is easy for them to understand	Strongly agree ***** Agree Neutral Disagree Strongly disagree
The information should appeal to their age group and not offend them or their parents	Strongly agree ***** Agree Neutral Disagree Strongly disagree
The reading level of this handout is appropriate	Strongly agree ***** Agree Neutral Disagree Strongly disagree
The length of this handout is appropriate	Strongly agree ***** Agree Neutral Disagree Strongly disagree