Effects of Intervention on Orthodox Jewish Knowledge and Intent to Vaccinate Against Human Papillomavirus

Yardena Mandel, BSN, RN

Rutgers, The State University of New Jersey - School of Nursing

DNP Chair:	Dr. Mary Kamienski, PhD, APRN-C, FAEN, FAAN, CEN
DNP Team Members:	Dr. Irina Benenson, DNP, NP-C, CEN
Date of Submission:	May 8, 2018

Table of Contents

Abstract

Purpose

Despite the growing research and clear association between human papilloma virus and cancers, vaccination rates remain low. This is largely due to lack of knowledge, attitudes, and beliefs. This study aimed to assess the impact of providing an educational intervention on human papillomavirus (HPV) knowledge and intent to vaccinate among Orthodox Jews.

Methodology

The project took place in a private residence within an Orthodox Jewish community in northern New Jersey. The project consisted of a one-time ninety-minute educational session presented in a culturally and religiously sensitive manner offered to parents. A convenience sample of 14 Jewish mothers participated. The design of this study consisted of an analysis using a pre and post-test questionnaire to measure knowledge and intent to vaccinate. This project was guided by the Health Belief Model (HBM), which addresses perceived risks, benefits, barriers, susceptibility, and cues to action.

Results

Fourteen mothers (n=14) participated in this project. HPV and cervical cancer knowledge varied. The majority of the participants expressed a desire to have more information prior to making an informed decision on vaccinating their children. Perceived susceptibility was a key determinant preventing parents from vaccinating, due to the beliefs of religious and cultural practices of abstinence prior to marriage, and one life time partner. Mothers also expressed disappointment in the approach to how the vaccine was offered by the practitioners. Overall knowledge measured pre-intervention to post intervention increased by sixty percent. Using Wilcoxon Signed-Rank Test it was determined that the difference in knowledge pre versus post-intervention was statistically significant (p=0.05). Intent to vaccinate increased by a hundred and twenty percent (36% to 79%). A Chi-Square test for independence was performed to analyze intent pre and post-intervention, which was also found to be statistically significant (p=0.02).

Implications for Practice

This project supports the importance to raise parental awareness and knowledge on HPV and the vaccine via a culturally sensitive intervention tailored toward the Orthodox Jewish community to increase vaccination intent. The research findings can be used to expand educational forums, address attached reservations and gain support of healthcare personnel, religious leaders, and the community as a whole.

Keywords: Papillomavirus, HPV, HPV vaccine, sexually transmitted infections, sexually transmitted diseases, Orthodox Jews, Judaism, Israel, health knowledge, attitudes, practice, perception, Health Belief Model, religion, belief, religious beliefs, intent, immunization

Effects of Intervention on Orthodox Jewish

Knowledge and Intent to Vaccinate Against Human Papillomavirus

Introduction

Human papilloma virus (HPV) is a group of infections classified by warts (papillomas) that are transmitted through skin and sexual contact. According to the Centers for Disease Control and Prevention (CDC, 2018), HPV is so prevalent that nearly all males and females will contract at least one type of HPV during their lifetime. It is the most common sexually transmitted disease with more than three million new cases per year. There are more than 100 strains with two (HPV-16 and HPV-18) accounting for over 70% of cervical cancers (WHO, 2018). In addition to cervical cancer, HPV is responsible for penile, anal, and oropharyngeal cancers (CDC, 2018). At present, there are three prophylactic HPV vaccines available on the market to protect against disease. The WHO identifies HPV-related conditions as global health problems and has made the recommendation that HPV be accepted as part of the national vaccination requirements (Weekly epidemiological record, 2017). Despite growing evidence, HPV vaccination acceptance and rates remain low.

Background and Significance

Human Papillomavirus (HPV) is a virus spread from person to person via intimate skin-to-skin contact. It is the most common sexually transmitted infection (STI). HPV is so prevalent, that according to the Centers for Disease Control and Prevention (CDC), nearly all males and females will contract at least one of the types in their lifetime (2018). Seventy-nine million Americans, one in every four, are currently infected with HPV. In some cases, HPV can go away on its own, but for others it results in genital warts, cancers, and death. HPV is responsible for causing cervical, penile, anal, vulvar, vaginal, and oropharyngeal cancers. Roughly fourteen

million Americans are infected with HPV each year, 12,000 women are diagnosed with cervical cancer, and more than 4,000 women have fatal outcomes, despite screenings and treatment. Approximately 19,400 women and 12,100 men are affected by other HPV causing cancers. These numbers are only reflective of the reported cases of people who seek care and the numbers continue to rise (CDC, 2018).

There are over a hundred and fifty related viruses that are collectively classified as human papillomavirus. The name stems from papillomas, which is another word for warts. The infection however can still be transmitted in the absence of visible warts. Two strains, HPV-16 and HPV-18 have been identified as causing over seventy percent of the cervical cancer cases (WHO, 2018). At present, there are three prophylactic HPV vaccines available on the market. One of the available formulations is a 9-valent vaccine (HPV-6, HPV-11, HPV-16, HPV-18, HPV-31, HPV-33, HPV-45, HPV-52, HPV-58), targeted at protecting against 90% of cervical cancers and other anogenital cancers, and 90% of cervical warts (Iversen et al., 2016). The significance of this data and the necessity to vaccinate speaks for itself. HPV vaccination is attainable to prevent cancer.

According to the American Academy of Pediatrics (AAP), the most effective way to safeguard a loved one against HPV is to vaccinate (2018). Vaccination is now recommended as a two-dose series for both males and females 11 to 12 years of age (CDC, 2018). This is in no way a license for kids to engage in early sexual behaviors, it is meant to protect your child prior to this topic even becoming an issue. Additionally, the immune response is better among preteens (CDC, 2018).

HPV vaccination has been available for females since 2006 and in 2011, the recommendation to vaccinate was expanded to males. Despite this health advice, vaccination uptake remains suboptimal (Stokley et al., 2014). According to the Health Information National

Trends Survey (HINTS), *Healthy People 2020* established an 80% vaccination goal for girls between the ages 13-15 and only one third had received all three of the recommended doses. As of 2012, less than seven percent of boys between the ages of 13-17 were fully vaccinated (2014). The major barriers for vaccinations are lack of knowledge, poor attitude, and cultural beliefs.

Knowledge

The studies show that there is low knowledge related to human papillomavirus and vaccination. In a study performed by Gao, Okoror, & Hyner (2016), Chinese international graduate level students had limited awareness and knowledge of HPV infection and its vaccination. Some of the participants were under the erroneous belief that cervical cancer is largely associated with abortion and miscarriage. Few were knowledgeable in HPV, its association with cervical cancer, genital warts, and the HPV vaccine.

In a systematic review performed by Brewer & Fazekas (2007), knowledge about HPV was low overall. In seven studies analyzed, 58% of men and women were not even aware of HPV. Only 21% of participants knew that HPV is common, and 59% understood that a pap test is to screen for HPV. Knowledge that HPV could cause cervical cancer was relatively low. Other studies which reflected greater knowledge of human papillomavirus as a sexually transmitted infection, were still uneducated on its impacts on cancers.

Attitude

According to Trim, Nagji, Elit, & Roy (2012), the oncogenic role of HPV in other cancers aside from cervical is still evolving. As more people gain an understanding of HPV implications in penile, vulvovaginal, oropharyngeal, and anal cancers, vaccination attitudes may shift.

Dempsey, Zimet, Davis, & Koutsky (2006) evaluated the influence of educational materials on HPV vaccination intent and aimed to identify independent factors which affected acceptability. Although the educational materials provided improved knowledge, its affects were minimal on uptake. Attitudes and life experiences were found to show more significant influences on the decision-making process. Attitudes varied across geographic and sociocultural classes. Among understanding of attitudes, were people's perceived susceptibility of disease, perceived severity, perceived benefits of vaccination, and perceived barriers to vaccination. To account for attitudes, individually structured teachings for particular groups of people would offer great benefit.

Religion/Culture

It is due to this variance across cultures and religions that HPV vaccination uptake remains controversial. Religious and cultural beliefs play a significant role in vaccination acceptance. This ranges across different cultures and religions, and religious practices worldwide. For example, among parents who identified themselves as being born-again or evangelical Christian, there was lower vaccine acceptability, in contrast with Catholics and individuals who do not attend religious services regularly (Brewer & Fazekas, 2007).

Attitudes among Jewish mothers in the United Kingdom were found to be more reflective of religion over ethnicity. There was a similar association among mothers from non-Christian religions and vaccine acceptability. Mothers who felt the vaccine contradicted religious beliefs, were less likely to vaccinate their daughters. There was a direct correlation with individuals' level of religious observance and practices, with vaccination intent. Among the beliefs against vaccination was the overall topic of sex and its taboo nature. Discussing such matters was thought to possibly put their youth at disadvantage when it came to arranging marriages. Mothers

questioned the relevance of the vaccine to their children, as the religion firmly believes in avoiding multiple sexual partners, and sex outside of the holy marriage covenant. Others deemed the vaccine to be a religious obligation, as Judaism encourages health protection (Gordon, Waller, & Marlow, 2011).

Problem Statement

Human papillomavirus can be a deadly infection, but there are available prophylactic vaccinations on the market. Despite the growing evidence of HPV, and vaccine availability, uptake remains low. This is largely due to lack of knowledge, attitudes regarding the vaccine, and cultural and religious beliefs. The objective of this project was to enhance knowledge about the virus, and its vaccine, in order to improve intent to vaccinate among Orthodox Jews.

Clinical Question

In Orthodox Jewish parents, would an educational intervention improve knowledge and intent to vaccinate against Human Papilloma Virus (HPV)? (Appendix A).

Needs Assessment

National Level

Despite the growing research and clear association between human papilloma virus infection and cancers, substantial adversary is still being seen globally. There are many reasons why people are opting out of vaccination, from discourse about the concept of vaccination itself, to religious or sexual beliefs, and lack of faith in the benefits of the HPV vaccine over the risks. This is seen cross-culturally and is that much more prevalent among religious, insular communities. According to the CDC (2018), National coverage in 2016 was 60%, indicating that on average six out of every ten parents are choosing to vaccinate their children against human papillomavirus. While the data shows that numbers have been growing, the overall rate remains

low. On the other end, data on the growth rates of cancers continue to rise. Annually, roughly 39,800 new cancers are diagnosed in parts of the body where HPV is found and 31,500 of these cancers are said to be caused by the HPV infection. The five states with the lowest vaccination rates include Tennessee, Mississippi, Alaska, Missouri, and Kansas (CDC, 2018).

State Level

The vaccination rate in New Jersey ranked as the sixth lowest, with only 48% being vaccinated. According to data collected in 2014, 34.5% of females received all three of the vaccine series and 21.2% of the males. It is not a mandated vaccine in the state of New Jersey, but it is highly recommended to prevent against cervical cancer, genital warts, in addition to other anogenital and oropharyngeal cancers. While vaccination rates for completing the series are very low in the state of New Jersey, some of the adolescence are at least getting the first immunization of the series. In this category, 35.5% of boys receive at least one shot. Those statistics rank New Jersey better than sixteen other states (CDC, 2018).

Community Level

British Jewish community.

According to Gordon et al. (2011), there are a few studies that have accounted for HPV vaccination rates among varying minority communities in the United Kingdom (UK). Among the research conducted, there is evidence that religious beliefs served as a significant contributing factor. A survey of 680 mothers showed lower acceptance among non-Christian religious groups. In a similar survey involving 317 parents, those that had "strong religious or cultural views" were less inclined to vaccinate their daughters (Gordon et al., 2011, p. 7351). Both ethnicity and religion were deemed independent factors which played significant roles in vaccination acceptance. The studies in the UK that were performed, considered attitudes in minority

communities. However, these studies examined major ethnic minority groups and did not provide a chronicle of smaller groups, like the British Jewish community (Gordon et al., 2011).

Jewish women historically had low cervical cancer rates. A number of factors are accredited with this finding, including traditional religious habits, such as abstinence from premarital sexual encounters. However, HPV infection rates among Jews has only been performed in Israel, and there is a lack of data in Jewish communities globally. As times are changing, there is greater assimilation and possible changes in sexual behaviors even among the Jewish community. Therefore, the historically low rates may no longer be accurate (Gordon et al., 2011).

The study's aim therefore was to examine HPV vaccination acceptance among the British Jewish community and understand the implications of these results. Reasons for declining the vaccine were largely due to perceived low risks based on cultural/religious beliefs that their daughters were not sexually active and were unlikely to have multiple partners in their lifetime. Other reasons can be grouped as a lack of knowledge regarding the infection, potential disease, and the vaccine itself. Some of the mothers who did accept the vaccine, recognized the increasing acculturation. They admitted while they are hopeful that their daughters would lead religious Jewish lifestyles, they cannot predict or control their daughters' behaviors and it is therefore better to protect them. It was found that while there is general information available to the public regarding HPV, its risks, and benefits of vaccination, culturally specific issues are not addressed. Religious Jewish communities would therefore benefit from tailored education to increase vaccine coverage (Gordon et al., 2011).

Israel Jewish community.

In a study conducted by Bar-Am, Niv, Yavetz, Jaffa, & Peyser (1995), risk factors were analyzed to gain an understanding of the distribution among Israeli Jewish women with various cervical cytological abnormalities. It was found that the causative agents and liable behaviors were virtually identical in both Jewish and non-Jewish populations. At that time there was also found to be a 29.2% increase in prevalence of cervical premalignant lesions among Israeli women. This data is significant and attests to this population's inability to continue to be considered at low risk for the disease.

In a more recent review of literature, conducted by Natan, Aharon, Palickshvili, & Gurman (2011), the prevalence of contracting HPV was found to be lower in Israel, as compared to the rest of the world, but the phenomenon nonetheless affected 500,000 men and women. This accounts for seven percent of the population, which is roughly seven million people. This includes Jews of varying observances, Muslims, and individuals from other demographic backgrounds. Natan & collaborators (2011) examined Israeli mothers' intent to vaccinate and to understand the themes associated with uptake or lack thereof. Of the convenience sample that was used, 82.5% identified themselves as being Jewish. It was found that out of the total population surveyed, approximately 65% of the mothers intended to vaccinate. A large caveat to mothers' intent was behavioral beliefs, level of knowledge and level of religiosity. It was found that the higher levels of religious practices were negatively associated with vaccine acceptance.

New Jersey Jewish community.

There is no current available data on the Jewish community vaccination uptake rates in New Jersey. Based on conversations with doctors serving the Orthodox Jewish community in one of the largest municipalities in New Jersey, the HPV vaccine was not even being offered to

male patients, which accounts for roughly half of the population. Out of cultural sensitivity, the vaccine was then only being offered to some of the parents of the female patients. This decision was made based on who the doctors thought may not be insulted by the topic and speculated that those particular parents were more open to the idea of vaccination. Among the parents approached by the topic, there was still not a hundred percent acceptance.

Based on a conversation had with the dean of one of the girls' high-schools in this same community, HPV knowledge was found to be very low. Although women in the Jewish community see gynecologists regularly both for childbearing purposes and for annual exams, there was a lack of understanding regarding pap smears that are performed. Women were unaware that pap smears are to detect the presence of HPV and screen for potential risks of cervical cancer. The dean does recognize the evolving cultural patterns due to acculturation and reports that this leads to an ongoing transition in practice. She personally could admit to knowing of girls within the community at higher risk.

Through conversations had with other practitioners within the "larger" Jewish community in the tristate area, it was professed that there are unfortunately a number of individuals within the community who seek medical attention for a variety of sexually transmitted infections. Those individuals were regarded highly in the sense that at least they were being treated for their infections, albeit embarrassing and potentially shameful. Although this topic is rarely addressed and sexual practices in general are approached with modesty, the reality is that the Orthodox Jewish community is not spared of these risks.

Reasons for lack of sub-recommended uptake acceptance of this particular preventive vaccine is due to perceived low susceptibility and lack of knowledge. However, with the

changing dynamics, it is imperative that initiatives be made to protect the youth of this seemingly insular community.

Aims and Objectives

The aim of this project was to assess the impact of providing an educational intervention on both HPV knowledge, along with specialized direction accounting for cultural and religious beliefs, to increase parents' intent to vaccinate their children.

Aim

1) Increased intent to vaccinate

Objectives

1) To provide education about HPV, the vaccine, culturally sensitive informational session that addresses the specific needs related to the Orthodox Jewish community.
2) Evaluate knowledge, attitude before and after the intervention and intent to vaccinate.

Review of the Literature

For the purpose of this review a search was conducted with the assistance of a librarian. The keywords and medical subject heading (MESH) terms selected for use in this paper were papillomavirus vaccines, HPV vaccine, Gardasil, Judaism, Orthodox Jews, Ashkenazi, Sephardic, Israel*, Judaism, health knowledge, attitudes, practice, patient acceptance of health care, attitude*, acceptance, perception*, religion, belief*, informed consent, consent, intent, intention, Health Belief Model, immunization and immunisation. Search terms were combined using "AND" and "OR" parameters to include all relevant articles. The investigator searched PubMed, Scopus, CINAHL, and Google Scholar. The reference sections of relevant articles were also examined. The search was not limited by dates, in order not to exclude search results related to this under researched topic. Only articles in English were included. This search identified

1,030 articles, ten were reviewed for this project (Appendix B). Out of ten articles, four were cross-sectional, three were a systematic review, one was a randomized controlled study, one was a quasi-experimental study, and one was a qualitative study. Four studies were performed in the United States, two in Israel, one in Turkey, one in England, and two were International. Methodological quality assessment was performed using the Johns Hopkins Nursing Evidence-Based Practice tool to assign level of evidence. In general, most of the articles were level III and had good quality. Quality was assessed by the primary investigator (PI). Quality was categorized as high if eleven out of twelve criteria were met in the Johns Hopkins Appraisal Tool. Quality was deemed good if seven out of twelve criteria were met. The major limitations were lack of randomization that may induce sample bias and limit assessment of cause-effect relationship. Another limitation of these studies was that they did not use validated tools to assess knowledge, attitudes, and intent to vaccinate.

The majority of the studies used survey instruments to assess knowledge, beliefs, attitudes, and intent to vaccinate. Three studies distributed informational materials, one study had one-on-one interviews and one study had intimate focus groups. In most of the studies, the participants were parents, one was nursing students, and another was graduate level students. Five studies assessed attitudes, two studied knowledge, three analyzed factors, and two assessed intent.

In order to fully understand this disparity, it is important to assess the public's knowledge on the topic at hand. According to Osazuwa-Peters et al. (2017), recommendations were made for males to also receive the HPV vaccine beginning in 2011, as there were growing numbers of HPV-related cancers affecting males. The study aimed to explore the knowledge surrounding HPV and associated cancers. A comparative analysis was performed to understand HPV knowledge based on gender differences. It was found that knowledge among both groups was

very low. Trim, Nagji, Elit, & Roy (2011) performed a systematic review of parental knowledge, attitudes, and behaviors towards the human papillomavirus vaccine. They found that during the Food and Drug Administration (FDA) approval of the HPV vaccine, knowledge and acceptance increased; but over time, awareness, intent, and vaccination rates have declined. This trend correlated with parents' desire for more information and to have their concerns be addressed.

Knowledge served as a key barrier or factor for parents' approval and intent to vaccinate. A number of studies have analyzed parental knowledge, attitudes, and beliefs about the HPV vaccine, but Radisic, Chapman, Flight, & Wilson (2017) decided to take the research a step further to understand the barriers affecting translation of the knowledge gap into acceptance. They found that in order for there to be implemented uptake, programs would need to be geared towards education of susceptibility of disease, address the barriers that are preventing vaccination consent, and promote the benefits of the vaccine. It was also concluded that health care endorsement was associated with a positive response towards the vaccine. Brewer & Fazekas (2007) similarly identified predictors affecting vaccine acceptability through a systematic review. The objective was to improve future program structuring in efforts to increase rates of inoculation. Gordon, Waller, & Marlow (2011) studied the attitudes and beliefs within the British Jewish community. In this particular group, there was a range in knowledge regarding HPV and the vaccine. Poor knowledge was attributed to perceived low susceptibility of the disease due to cultural and religious practices. Attitudes must be explored as a barrier affecting uptake within religious communities. It was concluded that information should be delivered to fit community-specific beliefs and concerns.

Once barriers were recognized, a few studies provided interventions to increase acceptance. Among a study performed by Gao, Okoror, & Hyner (2016) with Chinese

International Students' (CIS), lack of knowledge and the "secret" nature of sexually transmitted infections were barriers to vaccination in this population. CIS perceived HPV similarly to the religious community, as they believed that if they were not engaged in extramarital sexual encounters, HPV was not relevant to them. Teaching was provided via intimate focus groups and informational pamphlets. Education was found to serve as a de-stigmatization tool. To promote further uptake, it was found that it is of great importance to tailor learning in a culturally sensitive manner. Dempsey, Zimet, Davis, & Koutsky (2006) provided parents with an HPV informational sheet to address the knowledge gap barrier. Although knowledge seemed to improve, it had little effect on vaccine acceptance. Instead it was found that personal experiences, beliefs, and perceptions played a bigger role. Consistent with Gao & collaborators' (2016) findings, it is imperative that the gap be closed with more than just facts. It is through personalized teachings which address internal beliefs and concerns.

Finally, bearing all of these factors, knowledge, attitudes, and barriers in mind, is there a means to predict intent to vaccinate? Natan, Aharon, Palickshvili, & Gurman (2011) examined the Theory of Reasoned Action (TRA) to predict intent to vaccinate based on rational actions, attitudes, knowledge, beliefs, and religiosity. Among their findings, having health care professionals provide information, such as nurses, proved to be valuable. This is consistent with Radisic et al. (2017), who reported healthcare endorsement as a convincing tactic. Ben Natan, Mildej, Mitelman, & Vafiliev (2017) echoed shared findings in the significance of the nurses' role. They utilized the Health Belief Model (HBM) as a tool to predict intent to vaccinate. They assessed factors and ascribed perceived benefits of vaccination as the most influential determinant. Guvenc, Seven, & Akyuz (2016) adapted the Health Belief Model into a scale to determine the validity and reliability in using this instrument as a predictive measure of intent to

vaccinate. The HBM can be a valuable asset in planning health education, as it outlines beliefs, which are essential in constructing informational interventions.

It is with this understanding that knowledge is merely one of the factors that needs to be addressed. However, there are beliefs and attitudes which carry significant weight in decision-making for preventive health. This is especially true regarding the sensitive topic of sexual interactions. The purpose of this study was to address the gap in research that may identify multiple barriers including religious, cultural, and health perceptions among the Orthodox Jewish population, in order to increase HPV vaccination uptake.

Theoretical Framework

The theoretical framework was based on the Health Belief Model (HBM) (Appendix C) developed by a group of social psychologists in the United States (U.S.) public Health Service during the 1950s. Drs. Hochbaum, Kegeles, Leventhal, and Rosenstock were largely concerned with prevention, rather than treatment of disease. At that time, there was considerable resistance to take preventive measures or screening tests for early detection of asymptomatic disease. This was evident by failure to accept tuberculosis screening. A phenomenon was noted that decision-making was based on perceived beliefs over the physical environment. There are a number of components that were considered as influences on whether an individual would take action to prevent disease. These factors are based in the persons' beliefs. He would need to believe that he was susceptible to the disease, that the disease was serious in nature and could affect his life, and that by taking action(s), he was at lower risk. The model also had to account for barriers that might prevent action by outweighing benefits (Rosenstock, 1974).

To fully appreciate the HBM, the key terms must be further defined. *Perceived susceptibility* is a person's belief that he is likely to contract the disease or condition. *Perceived*

severity is the belief that by contracting said disease it would seriously affect one's life either through pain, morbidity, mortality, or have social consequences. The *perceived threat* is the multiplied effect of combining the susceptibility and severity. *Perceived benefits* are beliefs about advantages gained through implementing the recommended action. These benefits may be health related, such as not contracting the disease, and/or non-health related such as financial or social gains. *Perceived barriers* are potential obstacles that would prevent a person from taking action. Barriers may include costs, convenience, psychological, or social constraints. *Cues to action* are internal (such as feelings) or external factors (i.e. media) that may influence a person's decision to act. The HBM model makes an assumption that there are "*other variables*," which must be accounted for and may indirectly affect beliefs, such as demographics and psychosocial factors (Glanz, Rimer, & Viswanath, 2015).

The Health Belief Model has repeatedly been used as a framework to predict vaccine acceptance to protect against Human Papilloma Virus (HPV). There are a number of studies that focus on knowledge, beliefs, perceptions, and attitudes regarding the HPV vaccine. It provides a social cognition understanding of decisions about vaccination acceptance. These determinations are made based on beliefs, perceptions, and exposures to *cues to action*. A systematic review analyzed the use of the HBM in acceptance of the HPV vaccine for daughters in the United States and African countries. Radisic, Chapman, Flight, and Wilson (2017) concluded that the HBM framework was a beneficial tool to systematically arrange and understand factors correlated with parental decision of the HPV vaccine.

According to Guvenc, Seven, & Akyuz (2016), HBM can be used as a tool in understanding health behavior and how to encourage change. The HBM provides a valuable guide in structuring health education. Its basis is in motivation and illustrates how a person's

behaviors are rooted in their beliefs. Health prevention or resistance to available care can be understood within this model. In this particular study, the Health Belief Model was adapted to a scale to analyze its construct validity and reliability for human papilloma virus and its vaccine. Based on the findings, the HBM was found to be a good instrument for measuring beliefs toward HPV and its vaccination.

The current use of the HBM framework was to assess the Orthodox Jewish parental intent to vaccinate their children (Appendix D). This particular sect has additional beliefs or cultural influences which may impede vaccine acceptance or cues to action. As this model is based in personal perceptions and beliefs affecting preventive medicine, it was particularly appropriate in this context. Perceived susceptibility may be broken down further to explain why the Orthodox Jewish community may believe that their children are not at risk for contracting HPV; parental knowledge and beliefs regarding the HPV vaccine within the Orthodox Jewish community may be limited, parental beliefs that their children are at low risk of HPV due to lack of premarital sexual activity, and that their children are likely to have one lifetime partner, thereby effectively limiting exposure to infection. Perceived threat would be to understand the disease, its process, and those who are susceptible. Perceived benefits and barriers to change may be accomplished through identifying the knowledge gap of the HPV vaccine, the beliefs of parents regarding the vaccine and cultural beliefs of Orthodox Jewish parents regarding sexual behavior of adolescence. In order to improve vaccination acceptance, an educational session about health promotion, cancer prevention, and HPV vaccine was provided, along with an informational pamphlet to influence cues to action. A pre- & post-test was utilized to assess knowledge and intent to vaccinate. Accounting for modifying factors such as age of parents, religion, and socio-

economic status, along with above described components, analysis was then made on Orthodox Jewish parental intent to vaccinate.

Methodology

The project design of this study was an analysis using a pre and post-test questionnaire to evaluate whether an educational intervention would increase intent to vaccinate against the human papillomavirus (HPV) among Orthodox Jews. This project was guided by the Health Belief Model (HBM), which recognizes perceived risks, benefits, barriers, susceptibility, and cues to action. By acknowledging that there is a gap in parental knowledge regarding the vaccine and barriers which may prevent parental uptake, an educational lecture was provided to address these needs. Studies have been conducted to assess knowledge, attitudes, barriers, and intent among the general population, but prior to this Doctor of Nursing Practice (DNP) project there had not been any research devoted to a religious insular community, such as the Orthodox Jewish population. The importance of directing such an education towards this particular group was the perceived additional barriers related to cultural and religious beliefs.

Setting

An educational lecture was offered in a private residence within an Orthodox Jewish community in northern New Jersey. At this location, parents could feel uninhibited to express themselves freely regarding this sensitive topic. It avoided politics of religious environments, including synagogues and schools. While it did exclude the confounding variables of structured religious environments, it was still offered in the residence of an Orthodox Jewish family, so as to add comfort to the participants in the host being of shared cultural and religious beliefs.

Study Population

The intended population was Orthodox Jewish parents of children who are currently eligible or will become eligible to receive the HPV vaccine. Inclusion criteria were: parents (either male or female) of one or more children, being self-defined as an Orthodox Jew, English-speaking, and at least 18 years of age. Exclusion criteria were: individuals who are younger than 18 years of age, do not speak English, are not parents of one or more children, and do not ascribe themselves as an Orthodox Jew. As there is a need for this subject in the community even prior to suggested age of vaccination, there was not an exclusion factor based on age of children, so as not to limit the parent-body. A demographic survey (Appendix E) was filled out by each participant examining age of parent, age(s) of child(ren), marital status, educational level, upbringing, and profession, upon arriving to the lecture. Participants were reassured that all surveys/questionnaires were both confidential and anonymous. The population sample projection was about 20-25 participants, as a pilot study in this controversial topic. It was hoped that this initial pilot study would offer valuable insight into the knowledge, barriers, and intent to vaccinate against HPV. The aim was that through the study intervention, intent to vaccinate would improve.

Study Interventions

An educational lecture was provided to the Orthodox Jewish community about HPV, and its vaccine. Educational materials including handouts/flyers, and posters (Appendix F & G) made available through the CDC (2018) and AAP (2018) were distributed and prominently displayed during the session. A lecture plan may be viewed in full in Appendix H, which outlines the structure of the event. The educational messages were based on guidelines and handouts from the

CDC, along with the data outlined during the review of literature and conversations with medical professionals serving the Orthodox Jewish community.

Outcome Measures

Knowledge and intent to vaccinate were measured using a pre and post-test (Appendix I & J). The knowledge pre and post-tests were created by Rebecca Epperson, DNP, ARNP (Epperson, 2015), and modified with her approval for the purposes of this study (Appendix K). Intent to vaccinate was a secondary outcome that was examined via a two question de novo tool created by the Principal Investigator (Appendix L).

Benefits/Risks

Subjects benefitted from a culturally sensitive lecture tailor-made for the Orthodox Jewish insular community. The lecturer, who is a member of the Orthodox Jewish community, was able to build rapport as she is aware of the concerns and beliefs of the parent body. Having the Orthodox Jewish background enabled some parents to speak more freely and encouraged more open discussions on the sensitive subject matter of anogenital and oropharyngeal cancers, HPV, and sexually transmitted infections.

A risk to participants was the possibility of loss of anonymity within the conversation, question/answer portion of the forum. All participants maintained discretion and did not use any names of participants outside of the study site. The site itself was a private residence and was not public to people outside of the community. Another possible risk was the potential for a breach in confidentiality, but measures were taken to avoid such a complication. Confidentiality was preserved by using a secure method of data collection, without the collection of any names or identifiers and all data was stored on a password protected computer. Consent forms were not collected as this study only required informed consent and signatures were waived.

Another possible risk to participants was the discomfort of the topic at hand. The subject matter, as it relates to sexual activity is considered a taboo topic within the Orthodox Jewish community. In addition, most parents regardless of denomination or religious affiliation do not want to consider the thought of their children having sexual interactions or acting in a promiscuous manner. This is true of the Orthodox Jewish community and as such had the ability to raise emotional feelings. It was therefore impressed upon the participants that the purpose of this education was to make them prepared for undesired outcomes by protecting their children in advance of any potential health risks.

Subject Recruitment

A convenience sample of parents was recruited through a community-wide e-mail in a northern New Jersey self-defined Orthodox neighborhood, in addition to flyers handed out locally within the community. Email is an effective method to use within this particular community, as it is the standard means of communication to broadcast announcements pertaining to the neighborhood. The email contained a flyer (Appendix M) with the topic, date, and time of the educational seminar. The email also contained a copy of the consent form (Appendix N), in order for parents to have time to consider their interest in participating in this group. Copies of the consent form were available at the site. Parents who participated were asked to fill out a short demographic questionnaire (Appendix A), which included questions about age of parent, age(s), gender(s), and number of children, and whether the parents were raised in Orthodox Jewish homes or chose this lifestyle later in life.

Consent Procedures

As stated above, a copy of the consent form was included in the email for participants to review at their leisure, prior to participation. Consent forms (Appendix N) were distributed at the

onset of arriving to the lecture. Signatures were not collected during the consent process. A waiver of Documentation was distributed from the Rutgers Institutional Review Board (IRB). Subjects were reminded that they can withdraw from the study at any time. The consent form was created using the sample Rutgers IRB template and modified for the purposes of this study.

Subject Costs and Compensation

There was no cost to the subjects. There was also no monetary compensation provided for participation. The Principal Investigator did not receive any financial gain from this project.

Project Timeline

The process of this project began during the spring semester of 2018 with the development of the proposal. The Principal Investigator presented this proposal to the Doctor of Nursing Practice (DNP) Chair and Team Member in May of 2018. Once the proposal received approval from the DNP Chair and DNP Team Member, it was then submitted to the Rutgers institutional review board (IRB) via the online portal for evaluation. After multiple revisions, the proposal gained IRB approval on September 30, 2018, approximately 15 weeks from the time of the initial application submission. Once IRB approval was received, the implementation phase of the project began in the fall semester of 2018. The implementation phase included subject recruitment, and distribution of a demographic survey and pre-test, along with supplemental materials, prior to the educational lecture. The educational seminar was carried out in November of 2018. A post-test was then distributed and completed by the participants. Upon completion of the project implementation, the data was analyzed and recorded. The Principal Investigator presented her findings in January of 2019 (Appendix O).

Resources Needed/Economic Considerations

The preliminary budget for this project consisted of printing costs, rental of a projector, and refreshments. There was no cost for the setting location as it took place in a private residence free of charge. The estimated total cost was assumed to be $300.00. The Principal Investigator assumed all responsibility for the entire cost of the project.

Evaluation Plan

Data Maintenance/Security

All data was collected anonymously. No names or identifiers were collected. It is important to note that the Principal Investigator did not correlate any of the data provided with any particular participant. The anonymous data was then stored on a password protected computer by the Principal Investigator. As signed consent forms were waived, there were no consent forms to store or maintain.

Data Analysis

Demographic data was described using frequencies and percentages (Table 2). Pre and post-test data regarding knowledge was analyzed using the Wilcoxon Signed Rank statistic to determine if there were statistically significant differences. Intent pre and post-intervention was assessed via a Chi-Square Test for Independence to evaluate statistical significance. Statistics were performed using excel.

Results

A total of 14 participants attended the educational seminar. All of the participants were female, mothers, who self-identified as Orthodox Jews. All of the participants had a minimum of two children, with a range of two to eight children per family and an average of 4.5 children per family. Each participant was given an informed consent form, for which signed consent was

waived and then completed a demographic form, pre-test questionnaire, and de novo intent question. At the completion of the informational component, the participants completed a post-test questionnaire along with a de novo intent question to assess whether there was increased knowledge and intent to vaccinate post intervention. The data was reviewed and translated into tables.

The demographic form was completed by 14 anonymous participants, with no identifiers collected. The quantitative data was displayed as frequencies and percentages. The data shows that the majority of participants (n = 7, 50%) were between the ages of 35 to 44 years old. The second largest group (n = 6, 42.86%) were between the ages of 25 and 34 years old. There was one participant (n = 1, 7.14%) between the ages of 45 and 54. In this particular group, there were no participants below the age of 25 or above 54 years of age (Table 2). All of the participants were married. Other demographic information that was collected included participants highest level of completed education. The results demonstrated that the majority of the participants (n = 8, 57.14%) earned master's degrees, (n = 4, 28.57%) earned Bachelor's degrees and two participants (n = 2, 14.29%) have high-school diplomas or general education development (GED) equivalents. Professional categories were collected as well, with 4 participants reporting that they are in the healthcare field (n = 4, 28.57%), three participants identified themselves as being in the education field (n = 3, 21.43%), two in various forms of business (n = 2, 14.29%), and four participants classified their profession as "other" (n = 5, 35.71%). Lastly, data was collected on participants' upbringing. This included three subcategories, participants who were raised Orthodox from birth (Frum from birth), those who became observant of Torah law later in life (Ba'al Teshuvah), and those who converted (Ger). The majority of the participants (n = 11, 78.57%) were raised religious, with the remaining three (n = 3, 21.43%) identifying themselves

as having been brought up as non-observant Jews and later observing the Torah commandments. There were not any participants who converted from another religion.

The pre and post-test included questions regarding HPV knowledge. In the preliminary analysis of the data (Figure 3), it was found that the participants cumulatively answered 50 questions correctly and 48 questions incorrectly during the pre-test evaluation. After the educational session, 80 questions were calculated as correct with a remaining 17 questions answered incorrectly. One participant neglected to answer one of the questions, which accounts for the discrepancy in total number of answers between the pre and post-test. There was a sixty-percent increase in knowledge post-intervention.

The mean score of knowledge pre-intervention was 3.64. The mean score of knowledge post-intervention was 5.64. Meaning that there was an increase in knowledge post-intervention. This difference was statistically significant since Wilcoxon statistics of 6 was less than the critical value of 21 at p=0.05. The difference in knowledge scores was significantly higher post-intervention. Meaning, that the observed increase in mean scores was due to the intervention and not by chance alone (Table 3).

A de novo question of whether the participants intended to vaccinate their children against HPV was also asked. If participants were either undecided or marked off "no" a follow-up question was asked to understand why. Most of the participants (n = 7, 50%) stated that they would be interested in more information prior to making an informed decision on the matter. In the pre-test (Figure 4), the majority of the participants were undecided (n = 8, 57%). Five mothers intended to vaccinate their children against HPV (n = 5, 36%) and one participant (n = 1, 7%) indicated that she would not give her children the vaccine. After the educational intervention (Figure 5), eleven participants (n=11, 79%) were convinced to vaccinate their

children based on the merit of the vaccine and benefit/risk ratio. Two mothers (n = 2, 14%) remained undecided, and one participant did not intend to vaccinate (n = 1, 7%). There was a 120% increase in intent to vaccinate post education (36% to 79%).

Pre-intervention, only 5 participants intended to vaccinate. Post-intervention, there were 11 participants who declared that they will vaccinate. A Chi-square test for independence was performed and found to be statistically significant (p=0.02), meaning that the difference in the intended rate of vaccination increased because of the intervention and not by chance alone (Table 4).

Discussion

This study is the first to explore knowledge and intent to vaccinate against HPV in the New Jersey Orthodox Jewish community. To date, there are no other studies in the United States (U.S.) that reflect this particular population. Studies have been performed in the United Kingdom (UK) and Israel (Gordon, Waller, & Marlow, 2011) to analyze parental attitudes and reasons for accepting or declining vaccination.

All of the participants were self-defined as Orthodox Jews, who are parents, having at least one child. Although the educational seminar was open to both mothers and fathers, the gathering happened to only draw the mothers. There were fathers who expressed interest in attending, but due to childcare needs, only one parent could attend or perhaps some fathers were still at their workplace. While decisions about healthcare are often made in partnership, perhaps some of the mothers attended in place of fathers due to their role in the family, where mothers are more often taking the children for doctor's appointments, over the fathers.

Knowledge and awareness of HPV, the vaccine, and pap smears varied widely among the participants. The majority of the participants who indicated that they were undecided on whether

or not to vaccinate their children, expounded that they would like to know more, prior to making an informed decision on the matter. In the systematic review performed by Trim, Nagji, Elit, & Roy (2012), 13 studies reflected parental desire to have more information about HPV vaccination prior to making an informed decision. This is consistent with the current study that there is a need for increased parental knowledge. While this systematic review analyzed parental knowledge, attitudes, and behaviors, it did not assess knowledge pre and post-educational intervention. In the study conducted by Dempsey, Zimet, Davis, and Koutsky (2006), parental knowledge increased subsequent to receiving an informational sheet, however, despite this improvement in knowledge, there was no statistically significant difference in vaccine acceptability. This may be attributed to the need for more individualized tailored education, which was provided in the current project.

This was also consistent with the research conducted by Gordon et al. (2011), who reported that the mothers were keen to have more information prior to authorizing consent. In that study, mothers expressed that although general information is helpful, it is not specific to their cultural needs. It was suggested that tailored information may be beneficial in promoting vaccine coverage. As HPV relates to sexual encounters, mothers questioned the relevance of the vaccine among the Orthodox Jewish community, citing low risk and susceptibility due to monogamy and the practice of no premarital sex. This is again consistent with the research conducted in the UK, along with a questionnaire dispersed among Israeli women.

According to one of the mothers who remained undecided, she reported that she sees the benefits to giving her children the vaccine, and may decide to do so, but has yet to discuss it with her husband. The other participant who remained undecided, was unable to stay for the duration of the educational session. Although she was quite knowledgeable when it came to HPV and the

vaccine itself, as she is a practicing midwife, she repeatedly inquired as to its necessity for members of our community, questioning the perceived susceptibility due to religious and cultural practices. She was not present to hear the arguments for why it impacts the Orthodox Jewish community. Although cervical cancer rates have historically been lower among Orthodox Jews (Gordon, Waller, & Marlow, 2011), causative agents and liable behaviors were found to be the same across cultures and communities (Bar-Am, Niv, Yavetz, Jaffa, & Peyser, 1995). If data was made available about the prevalence of sexually transmitted diseases, HPV, sexual behavior, or rates of cancer among the Orthodox Jewish communities in the U.S., or more specifically in demographic areas similar to where this intervention took place, it would likely influence perceived susceptibility and the desire to vaccinate.

While the mothers would like to believe that their children are not at risk, they did recognize that times are changing. There is greater acculturation and assimilation. While no one wants to entertain the idea of their child being at risk, the mothers who gathered for the educational session acknowledged that there are things beyond their control. This includes but is not limited to sexual abuse, the inability to predict who our children will marry and what background that individual has, as well as teenagers being teenagers and exploring physiological desires. Prior to the educational session, the main reason for not vaccinating was the belief that "children within our community are not sexually active prior to marriage, so it is unnecessary." This line of thinking is consistent with prior research on this topic. However, parents recognized that there is a clear benefit to risk ratio and even if they deemed their children to be at a low likelihood of susceptibility, they also understood that the severity and threat of cancer is far too great. The mothers appreciated the sense of being able to protect against the disease as a preventive measure even if the exposure risks are low.

It was expressed by a number of the mothers that the single most influencing factor to vaccinate is a strong recommendation from their healthcare provider. Upon completion of the seminar, one mother reported that her boys were not even offered the vaccine. She stated that had she known of the risks to the males, she would have vaccinated her sons and now intends to ask her children's pediatrician to administer the vaccine to her sons. Another mother expressed confusion as to why this is not a mandated vaccine, based on its merit. Parents expressed that they would like to be informed that their child is due to receive three vaccines: HPV, meningitis, and Tdap, which follows the recommended guidelines according to the CDC (2018).

This study aimed at increasing knowledge and intent to vaccinate by means of exploring barriers of HPV vaccination among the Orthodox Jewish community. An analysis of cervical cancer rates, or incidence of HPV among this cohort of people can serve as a tool to boost uptake.

Limitations

The form of sampling utilized was a convenience method. Due to the nature of participant recruitment and the sensitive subject matter, it was difficult to gather a large sample size. As the project aim was to increase knowledge, awareness, and intent to vaccinate, limited information was provided prior to the session as it may have skewed the results of the data. Had too much data been presented prior to measuring the pre-test knowledge, the findings would have been less accurate. The primary investigator therefore faced a "catch 22," where recipients of the flyer via listserv may have read the subject matter and thought that as they do not know what HPV is referring to, it may not have been a topic applicable to them. Others may have believed that since they were aware of what the human papillomavirus is, that the matter is not relevant for them, thereby not attending and ultimately preventing the gain of knowledge and

awareness. The limitations of this study resulted in a smaller sample size. However, the findings support the proposed hypothesis and the need to expand this project to benefit more people.

In order to make the findings more generalizable, further research should be conducted using a randomized sample. Additionally, a prospective study on actual administration of the vaccine would be beneficial.

Other factors which precluded participants from attending the educational session were various conflicting activities scheduled within the community. Unfortunately, it is challenging to find a time with fewer social, religious, and community obligations within this community.

One of the limitations of this project was that the survey was not validated, so the questions were not adequately vetted. Some of the questions therefore did not fully capture insight into what the Principal Investigator intended to gain. This was only appreciated by the Principal Investigator after collecting the data and the structure of some of the wording in the pre and post-test was reviewed. For instance, question number eight asks, "What would be your reasoning for not vaccinating your child?" There were a number of possible answers to choose from, none of which included an option for the participants to state that they did not have reservations of vaccination. It forced whoever filled out the forms to pick one of the options provided, which may have not been an accurate portrayal of the peoples' thought processes.

Implications

The theoretical framework used to guide this project was the Health Belief Model. The HBM was used to gain an understanding of motivation and perceptions which lead to an individual's behavioral pattern. It was through the guide of this framework, that it was determined that a culturally sensitive educational seminar would increase intent to take preventive measures against disease. The research findings support the use of the HBM to

identify predictors of parental intent to vaccinate, address the reservations attached, and serve as motivation to increase compliance with vaccination.

Clinical Practice

The data supports the importance to raise parental awareness and knowledge on HPV and the vaccine. As a number of participants expressed that their decision to vaccinate would largely be guided by practitioner recommendation, it is also essential to stress that need to primary care providers and ancillary medical staff serving the community. Concerns were raised regarding the current practice of physicians serving the Orthodox Jewish community. In an attempt for some of these healthcare providers to be sensitive to families and the desire to discuss matters as they relate to sexual interactions or infection, they are not fully informing parents of the risks, the relevance as it relates to this particular population, and the benefits of vaccinating. One mother reported that upon her child's physician asking if she would like to vaccinate against HPV, it was never mentioned that the vaccine is to prevent against cancer. Informational sessions offered to parent bodies at schools, community gatherings, and religious affiliations, sanctioned by the heads of the community or rabbinical personnel would also encourage vaccination uptake.

Healthcare Policy

Policy changes, such as mandating the vaccine, are recommended. Some participants expressed reservation to vaccinate merely on the basis that the vaccine is optional, which leads room for questioning its necessity. If it truly is as beneficial and necessary based on the data presented, which it is, then it should be required and not suggested. Healthcare providers could benefit from better education on HPV and the vaccine, as misconceptions continue to remain regarding who is susceptible and the associated risks. There are additionally recommendations for healthcare providers on how to best increase HPV vaccination success. One such example,

encouraged by the CDC is for clinicians to offer the HPV vaccine the same way and on the same day as other routine vaccinations are recommended for patients eleven or twelve years of age.

On an international level, as more people become educated on the subject matter and the research made more publicly accessible, hopefully it will gain support within the greater Orthodox Jewish community.

Quality & Safety

This project impacts quality and safety by enhancing knowledge and awareness through education. It is through the enhancement of information that individuals should be empowered to make a healthful decision for their children's future. This is accomplished through means of understanding the impact of this vaccination, HPV transmission rates can be reduced, along with the ultimate goal of reducing rates of cancer. This project further encouraged healthcare providers to play a more engaged role in advocating for the vaccine and engaging their clientele in being more active participants in their healthcare. As there is an overall gain in acceptance of vaccination, primary prevention may be increased, with the aim of avoiding disease altogether and not trying to treat a disease, which may or may not even have an option of remedy.

Education

According to the current data, knowledge is a key barrier to vaccination uptake. Despite the growing research on HPV, the vaccine, and related cancers, the public's understanding of HPV, how it relates to cancer, and the understanding of pap tests as they relate to HPV remains subpar. Although educational materials are made available through a variety of resources including but not limited to the CDC and American Academy of Pediatrics, the research shows that there was minimal positive effect on the use of informational readings on their own. It was therefore found that as attitudes and life experiences played a significant role in decision-making,

education should be tailored towards particular groups. The intervention was therefore geared towards the religious and cultural beliefs of the Orthodox Jewish community. One of the main points echoed by a number of the participants, was the need to understand how this particular disease was relevant to the Orthodox Jewish community. The belief as stated previously is that this particular community is not susceptible due to religious and cultural practice of monogamy and no premarital sex prior to marriage. As the Principal Investigator was from the Orthodox Jewish background, which may have additionally helped build rapport in discussing this sensitive subject matter, these questions were able to be addressed head on. Some of the education that was provided included that although cervical cancer rates are found to be lower among the Jewish community, the causative agents and liable behaviors are found to be the same regardless of the community. Points were raised about domestic, child, and sexual abuse within the community, rape victims from both predators within the community and outside the community, and varying backgrounds of individuals that may or may not account for behaviors which we cannot control. Some of these backgrounds include individuals who convert to Judaism, were not raised religious, but became observant of Torah law later in life, or were raised religious, but have normal physiological needs and may have "transgressed" at some point in their lifetime. Additionally articles were brought to the participants attention about documented cases of sexually transmitted diseases within the community, and undocumented cases as relayed by practitioners who are treating infected persons. A key recommendation that can be given to healthcare personnel is that while stressing the importance of sensitivity to many different cultures, the vaccine itself needs to be desexualized. The vaccine's purpose is to protect against cancer.

Future Research

This DNP project showed that there is increased intent to vaccinate. Future research should determine whether educational interventions improve actual rates of vaccination. Additionally future research may be needed to determine what is the best intervention to increase vaccination rates. Future research could also be performed to determine the risk factors for not vaccinating and what specific targeted intervention should be applied to populations at risk to improve vaccination rates.

Stakeholders

The Primary Investigator assumed responsibility for the entire cost of the project. There was no financial gain for either the Principal Investigator nor any stakeholders. The Principal Investigator does not have any ties to the pharmaceutical companies who produce the HPV vaccine or to any doctors' offices by which it is offered.

Sustainability

There are a number of opportunities for sustainability of the implemented intervention through this DNP project. It is the hope of the Principal Investigator to be able to provide additional educational sessions to inform the public about HPV and its vaccine. This can be done through medical facilities, schools, or even synagogues. This project took place at a unique time where there was a measles outbreak specifically noted among Orthodox Jewish communities in Israel, Europe, and parts of North America, including various locales in the tristate area and on the West Coast. Much conversation was raised with regard to vaccination and education needs. It is unfortunate to have such occurrences which make the public aware of health concerns, but it also drums up interest and propels initiatives in public safety concerns.

Plans for Future Scholarship

The plans for future scholarship of this DNP project include health initiative conferences and publication opportunities, including manuscripts that may be of interest to peer-reviewed journals. As this topic is minimally addressed globally in this particular cohort of people, and to date there are not any research articles in the New Jersey area, it is the hope that the data collected from this project can serve as an initial tool for further investigation. This project served to assess the need for culturally sensitive education tailored towards the Orthodox Jewish community to increase knowledge and intent to vaccinate. As the data supported the benefit of such an intervention, it is the aim of the Principal Investigator to share the findings in order to expand educational forums and gain support of healthcare personnel, religious leaders, school administrators, and the community as a whole.

References

American Academy of Pediatrics (AAP). (2018). *Adolescent sexual health: Human papillomavirus (HPV)*. Retrieved from https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/adolescent-sexual-health/Pages/HPV.aspx

Bar-Am, A., Niv, J., Yavetz, H., Jaffa, A. J., & Peyser, R. M. (1995). Are Israeli women in a low risk group for developing squamous cell carcinoma of the uterine cervix? *Acta Obstetricia et Gynecologica Scandinavica, 74*(6), 472-477. doi:10.3109/00016349509024412

Ben Natan, M., Midlej, K., Mitelman, O., & Vafiliev, K. (2017). Intention of Mothers in Israel to Vaccinate their Sons against the Human Papilloma Virus. *J Pediatr Nurs, 33*, 41-45. doi:10.1016/j.pedn.2017.01.001

Brewer, N. T., & Fazekas, K. I. (2007). Predictors of HPV vaccine acceptability: a theory-informed, systematic review. *Prev Med, 45*(2-3), 107-114. doi:10.1016/j.ypmed.2007.05.013

Centers for Disease Control and Prevention (CDC). (2018). *Human papillomavirus (HPV).* Retrieved from https://www.cdc.gov/hpv/index.html

Dempsey, A. F., Zimet, G. D., Davis, R. L., & Koutsky, L. (2006). Factors that are associated with parental acceptance of human papillomavirus vaccines: a randomized intervention study of written information about HPV. *Pediatrics, 117*(5), 1486-1493. doi:10.1542/peds.2005-1381

Epperson, R. (2015). Increasing human papillomavirus (HPV) immunization uptake: A pilot program. *Frontier Nursing University, 2015*.

Gao, H., Okoror, T. A., & Hyner, G. C. (2016). Focus group study of Chinese international students' knowledge and beliefs about HPV vaccination, before and after reading an informational pamphlet about Gardasil(R). *J Immigr Minor Health, 18*(5), 1085-1092. doi:10.1007/s10903-016-0349-7

Glanz, K., Rimer, B.K., & Viswanath, K. (2015). *Health behavior: theory, research, and practice*. Retrieved from https://ebookcentral-proquest-com.proxy.libraries.rutgers.edu

Gordon, D., Waller, J., & Marlow, L. A. (2011). Attitudes to HPV vaccination among mothers in the British Jewish community: Reasons for accepting or declining the vaccine. *Vaccine, 29*(43), 7350-7356. doi:10.1016/j.vaccine.2011.07.083

Guvenc, G., Seven, M., & Akyuz, A. (2016). Health Belief Model Scale for Human Papilloma Virus and its Vaccination: Adaptation and Psychometric Testing. *J Pediatr Adolesc Gynecol, 29*(3), 252-258. doi:10.1016/j.jpag.2015.09.007

Health Information National Trends Survey (HINTS). (2014). *Preventing cancer through increased human papillomavirus (HPV) vaccine uptake*. Retrieved from https://hints.cancer.gov/docs/Briefs/HINTS_Brief_26.pdf

Iversen, O., Miranda, M.J., Ulied, A., Soerdal, T., Lazarus, E., Chokephaibulkit, K., & … Saah, A.J. (2016). Immunogenicity of the 9-valent HPV vaccine using 2-dose regimens in girls and boys vs a 3-dose regimen in women. *JAMA: Journal of The American Medical Association, 316*(22), 2411.

Natan, M. B., Aharon, O., Palickshvili, S., & Gurman, V. (2011). Attitude of Israeli mothers with vaccination of their daughters against human papilloma virus. *Journal of Pediatric Nursing, 26*(1), 70-77. doi:10.1016/j.pedn.2009.07.006

Osazuwa-Peters, N., Adjei Boakye, E., Mohammed, K. A., Tobo, B. B., Geneus, C. J., & Schootman, M. (2017). Not just a woman's business! Understanding men and women's knowledge of HPV, the HPV vaccine, and HPV-associated cancers. *Prev Med, 99*, 299-304. doi:10.1016/j.ypmed.2017.03.014

Radisic, G., Chapman, J., Flight, I., & Wilson, C. (2017). Factors associated with parents' attitudes to the HPV vaccination of their adolescent sons : A systematic review. *Prev Med, 95*, 26-37. doi:10.1016/j.ypmed.2016.11.019

Rosenstock, I. M. (1974). Historical origins of the health belief model. *Health education monographs, 2*(4), 328-335.

Stokley, S., Jeyarajah, J., Yankey, D., Cano, M., Gee, J., Roark, J., & … Markowitz, L. (2014). Human papillomavirus vaccination coverage among adolescents, 2007-2013, and postlicensure vaccine safety monitoring, 2006-2014--United States. *MMWR: Morbidity & Mortality Weekly Report, 63*(29), 620-624.

Trim, K., Nagji, N., Elit, L., & Roy, K. (2012). Parental knowledge, attitudes, and behaviours towards human papillomavirus vaccination for their children: a systematic review from 2001 to 2011. *Obstetrics and gynecology international, 2012*.

Weekly epidemiological record. (2017). *Weekly Epidemiological Record, 92*(19), 241-268.

World Health Organization (WHO). (2018). Human papillomavirus (HPV) and cervical cancer. Retrieved from http://www.who.int/mediacentre/factsheets/fs380/en/

Appendix A: Clinical Question

In Orthodox Jewish parents, would an educational intervention improve knowledge and intent to vaccinate against Human Papilloma Virus (HPV)?

P: Orthodox Jewish parents
I: Educational seminar
C: Comparison of intent using pre-/post- test
O: Increased knowledge & intent to vaccinate

Appendix B: Review of Literature

Table 1. Table of Evidence

Article	Author, Date	Evidence Type	Sample, Sample Size, Setting	Study Findings that help answer EBP question	Limitations	Evidence Level & Quality
#1	Ben Natan, M., Midlej, K., Mitelman, O., & Vafiliev, K. (2017).	Cross-sectional study	A convenience sample of 200 Israeli mothers of boys between the ages of 5 to 18 (100 Jewish and 100 Arab) completed a questionnaire based on the Health Belief Model (HBM).	Only 14% of the mothers (mostly Arab), vaccinated their sons against HPV. Intent to vaccinate was similar between Arab & Jewish mothers, but the health beliefs of the two sects differed. The HBM was found to explain 68% of mothers' intent to vaccinate and the perceived benefit was the greatest factor affecting intent. The HBM can be used to explain mothers' motivation to vaccinate their sons.	Sampling was based on convenience method, which may make it hard to generalize data. The study refers to mothers' self-report of intent to vaccinate and does not reflect actual vaccination rates.	Research Level III Grade: High
#2	Brewer, N.T., & Fazekas, K.I. (2007).	Systematic Review	28 studies were identified in the United States. Most studies were cross-sectional studies of parents ranging in sample size from 20 to 840. One study used a quasi-experimental design, another	Programs to promote HPV vaccine uptake need to address the high risk of HPV infection, benefits of the vaccine, physicians' recommendation, and concentrate on barriers to vaccine uptake.	The studies had a number of limitations including study design, populations or sample size, and inability to generalize the findings.	Research Level III Grade: High

			used a controlled experimental design, and others used qualitative methods.			
#3	Dempsey, A. F., Zimet, G. D., Davis, R. L., & Koutsky, L. (2006).	Randomized controlled study	A randomized sample of parents or primary caregivers of 1600 children between the ages of 8 to 12 years were enrolled in a 1 year Group Health Cooperative Health Plan in Seattle.	Providing parents with informational content about HPV improved knowledge, but the mean vaccine acceptance rates were calculated to be P =.17, suggesting that those who received the informational intervention were not more inclined to vaccinate. Life experience and attitudes had a greater influence.	Participants were all from the same Washington regional health organization, which is a homogenous sample and may not be applicable to other parent bodies. The survey was self-administered, which did not allow an opportunity for parents to consult medical providers. A vaccine acceptability scale was used to predict parental intent to vaccinate their children. The tool does not provide a scaled measurement to predict vaccination acceptability.	Research Level I Grade: High
#4	Gao, H., Okoror, T., & Hyner, G. (2016).	Quasi experimental study with pre-/post test design	44 Chinese international students (CIS) attending a university in the United States Midwest participated in 10 focus group discussion (5 female & 5 male).	It was found that participants have limited awareness and knowledge about HPV infection and vaccination. Perceived stigma about HPV infection decreased with increased knowledge. HPV	Convenience sample from a larger research university. This data may not be generalized to people of differing cultural and social environments at other universities. The majority of the participants were graduate students, which does not	Research Level III Grade: Good

				vaccine promotion may be beneficial alongside sex education among CIS.	account for younger CIS.	
#5	Gordon, D., Waller, J., & Marlow, L. A. (2011).	Qualitative study, thematic analysis	Face-to-face interviews were conducting with vaccine-accepting (n=10) mothers and vaccine-declining (n=10) mothers. Participants were mothers of girls, from Jewish secondary schools, who had been offered the HPV vaccine. Interviews were conducted between June and September 2010 in the participants' homes	Attitudes to HPV vaccine may result in lower adherence to vaccinate in religious communities. Main reasons attributed with this decision are due to novelty of the HPV vaccine and perceived low susceptibility of HPV due to religious practices. Development of tailored community-specific education about vaccination importance may offer benefits.	The study did not account for different variables within the Orthodox Jewish community (ie. Different attitudes between Hassidic, ultra-orthodox, Ashkenazi/Sephardic, Jews in UK vs other countries, or socio-economic class). There was likely self-selection bias as mothers were invited to participate based on interest. Although the main interviewer was from a Jewish background, mothers may not have felt comfortable to discuss certain aspects due to the sensitive nature of the subject matter.	Research Level III Grade: Good
#6	Guvenc, G., Seven, M., & Akyuz, A. (n.d.).	Cross sectional study	302 nursing students at a nursing school in Turkey from April to May 2013. Participants received 2 simultaneous administrations of the HPV-KS	The HBMS-HPVV was found to be both a valid and reliable instrument to measure Turkish women's beliefs and attitudes about HPV and its vaccination. Knowledge regarding HPV	The HBMS-HPVV tool was found to have good validity and reliability among nursing students, but studies are needed to evaluate attitudes and beliefs of adolescence of varying backgrounds.	Research Level III Grade: High

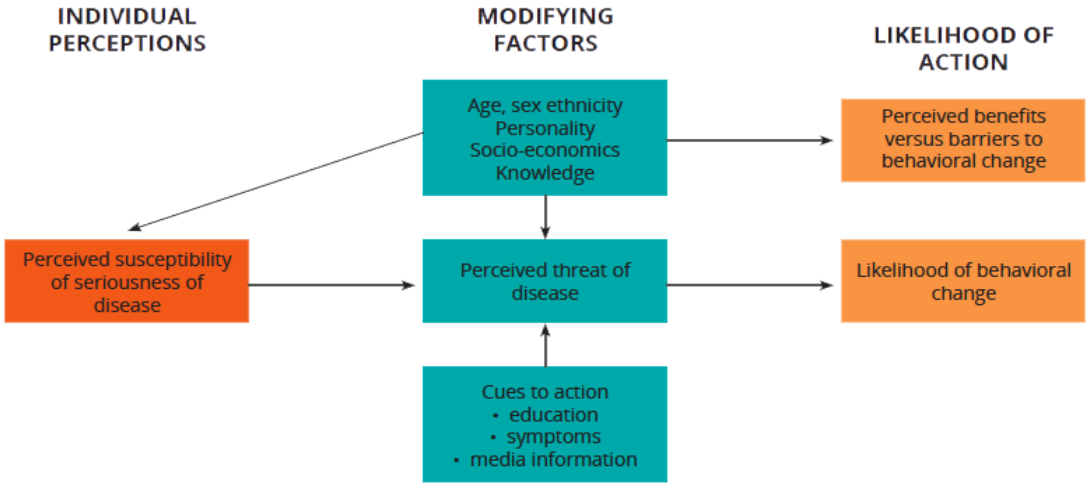
			and HBMS-HPVV with two weeks between tests and retests.	and its vaccination was low and increased knowledge had a positive effect on intent to vaccinate. The HBM strengthens educational interventions for healthcare professionals.	Only attitudes of young women towards the HPV vaccine were evaluated. Health beliefs of men were not evaluated.	
#7	Natan, M.B., Aharon, O., Palickshvili, S., & Gurman, V. (2011).	Cross-sectional study	Convenience sample of 103 mothers of daughters 18 years of age and younger in central Israel. Data was collected via questionnaires during community-based sessions. 103 out of 130 mothers completed the questionnaires (79.2%)	Behavioral beliefs and level of knowledge had a positive effect on mothers' intent to vaccinate their daughters with HPV vaccine. High levels of religious observance negatively impacted mothers' intent to vaccinate. The study also shows the importance of the nurses' role in providing education about the HPV vaccine, especially among religious Jews and Muslim populations.	The sample is a convenience sample and not a randomized sample. There is a high probability of selection bias. The study is limited to central Israel.	Research Level III Grade: High
#8	Radisic, G., Chapman, J., Flight, I., & Wilson, C. (2017).	Systematic review.	N=18 studies included in this review (n=13065 records were identified and then were	HPV vaccine among adolescent males is low. Parental decision to vaccinate was influenced by	The review was inclusive of studies in developed countries, but did not include developing countries and more conservative	Research Level III Grade: High

			narrowed down based on eligibility criteria. Inclusion criteria: studies that addressed factors influencing parental attitudes to vaccination, intent to vaccinate or actual vaccination of adolescent boys (9-18 yrs old) fo7r HPV. Both quantitative and qualitative studies were included of varying settings. Only journal articles based on original research were included.	perceived benefits of the vaccine, perceived risks of sons contracting HPV, and recommendations from healthcare providers. Future projects should address decision to vaccinate through education about infection, benefits of vaccination, and to address perceived barriers.	societies, thus limiting generalizability. Two thirds of the studies were from the United States, further limiting the generalizability. The HBM framework was used to organize the findings, but it did not account for all variables related to the HPV vaccine, so other factors were needed to augment this model.	
#9	Osazuwa-Peters, N., Adjei Boakye, E., Mohammed, K. A., Tobo, B. B., Geneus, C. J., & Schootman, M. (2017).	Cross-sectional study	n=3,677 survey participants aged 18 years and older from the Health Information National Trends Survey (HINTS)	Men had lower knowledge compared to women about HPV and HPV vaccine. Knowledge of both genders was very low regarding cancers associated with HPV. Respondents with lower education reported lower knowledge of HPV and HPV vaccine.	Due to the cross-sectional study design of HINTS, causal inferences cannot be made. The study sample was largely comprised of individuals from higher socioeconomic status, limiting generalizability to the greater population. Bias may have been introduced by wording of the questions utilized in the survey and sampling technique	Research Level III Grade: Good

					in the HINTS data collection.	
#10	Trim, K., Nagji, N., Elit, L., & Roy, K. (2012).	Systematic review	53 studies with publication dates between 2004 and 2011. Total number of parents included n=54,194 from North America, European Union, Asia, and New Zealand/Australia	Parents are looking for greater knowledge and understanding about the HPV vaccine and reassurance of safety from their providers.	The challenge of validating parental responses to the surveys. Data was not collected on actual vaccination rates.	Research Level III Grade: Good

Appendix C: Theoretical Framework: HBM

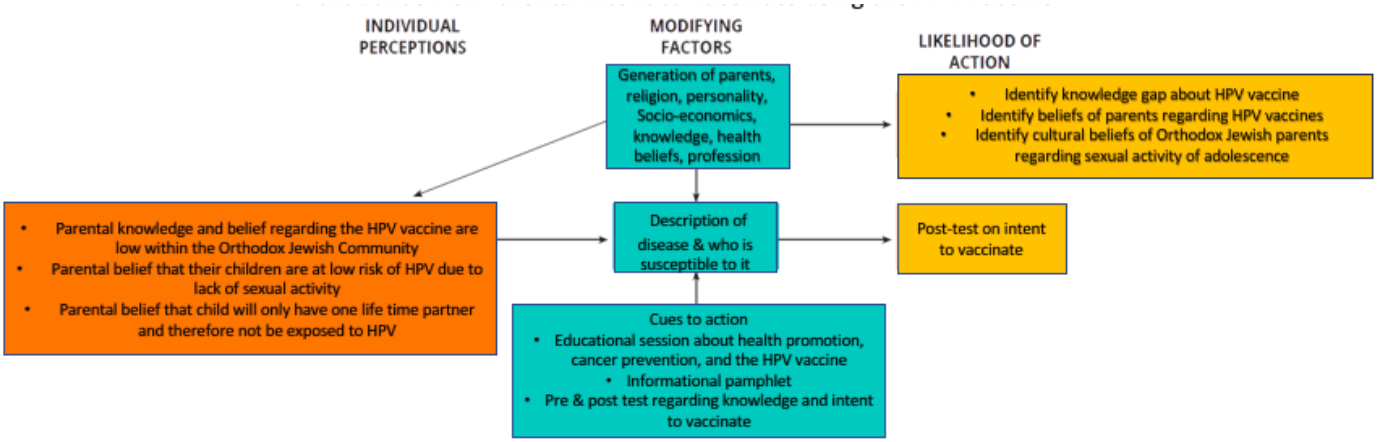
Figure 1. The Health Belief Model (HBM)



(Rosenstock, 1974, p. 334).

Appendix D: Theoretical Framework: Adapted

Figure 2. Orthodox Jewish parental intent to vaccinate using the HPV vaccine



Appendix E: Demographic Survey

Increasing HPV Vaccination Knowledge & Intent Among Orthodox Jews

1. What is your gender?

    Male

    Female

2. Are you an Orthodox Jew (self-defined)?

    Yes

    No

3. Do you have any children?

    Yes

    No

4. If the answer to question #3 is yes, please list their ages and gender below:

    _____

    _____

5. What is your age range?

    18-24

    25-34

    35-44

    45-54

    55-64

- 65 or older

6. What is your highest level of education?
   - Completed high school diploma or equivalent
   - Associates degree
   - Bachelor's degree
   - Masters
   - Doctorate or professional degree

7. Do you attend school or work outside of the Orthodox Jewish community?
   - Yes
   - No
   - N/A

8. What is your profession?
   - Healthcare
   - Education
   - Rabbi
   - Business
   - Other _____

9. What is your marital status (please select all that apply)?
   - Single

- Married
- Divorced
- Widowed
- Re-married

10. What was your upbringing?

- Frum from birth (raised religious)
- Ba'al Teshuvah (became observant of the Torah commandments later in life)
- Ger (convert)

Appendix F: Educational Materials

HPV Vaccine Safety and Effectiveness

HPV vaccination provides safe, effective, and long-lasting protection against cancers caused by HPV.

HPV vaccination prevents cancer

Human papillomavirus (HPV) infects about 14 million people, including teens, each year. While most HPV infections go away on their own, infections that don't go away can lead to certain types of cancer. Every year, 32,500 men and women develop a cancer caused by HPV. **HPV vaccination could prevent more than 90% of these cancers from ever developing.** The vaccine is made from one protein from the virus, and is not infectious, meaning it *cannot* cause HPV infection or cancer.

HPV vaccination is safe for boys and girls

With over 100 million doses distributed in the United States, HPV vaccine has a reassuring safety record that is backed by over 10 years of monitoring and research. All vaccines used in the United States are required to go through years of extensive safety testing before they are licensed. Once in use, public health officials continuously monitor their safety and effectiveness.

Since the Food and Drug Administration (FDA) licensed the vaccine, scientists and vaccine researchers have conducted large research studies to monitor and evaluate safety. These studies show that HPV vaccine is safe and is not associated with any serious safety concerns.

HPV vaccination works

The HPV vaccine works extremely well. Since HPV vaccination was introduced over 10 years ago, infections with HPV types that cause most HPV cancers and genital warts have dropped 71 percent among teen girls. Research has also shown that fewer women are developing cervical precancers (abnormal cells on the cervix that can lead to cancer).

HPV vaccination provides long-lasting protection

Studies suggest that the protection provided by HPV vaccine is long lasting. Studies have followed people who received HPV vaccine for about 10 years, and protection has remained high in those individuals with no evidence of the protection decreasing over time.

HPV vaccination can cause side effects

Like any vaccine or medicine, HPV vaccination can cause side effects. The most common side effects are mild and include pain, redness, or swelling in the arm where the shot is given; dizziness, fainting, nausea, and headache. Fainting after any vaccine, including HPV vaccine, is more common among adolescents. To prevent fainting and injuries related to fainting, anyone receiving HPV vaccine should be seated or lying down during vaccination and remain in that position for 15 minutes after the vaccine is given. **The benefits of HPV vaccination far outweigh any potential risk of side effects.**

HPV vaccination doesn't negatively affect fertility

There is no evidence to suggest that HPV vaccine causes fertility problems. However, not getting HPV vaccine leaves people vulnerable to HPV cancers and precancers. Women who develop a precancer or cancer caused by HPV could require treatment that would limit their ability to have children, such as a hysterectomy, chemotherapy, or radiation. Treatment for cervical precancer could also put a woman at risk for problems with her cervix, which could cause preterm delivery.

How can I get help paying for vaccines?

The Vaccines for Children (VFC) program provides vaccines for children ages 18 years and younger, who are uninsured, Medicaid-eligible, American Indian or Alaska Native. Learn more at

www.cdc.gov/Features/VFCprogram

Last updated JULY 2018

HPV Vaccine for Preteens and Teens

HPV vaccination is recommended at ages 11-12 to protect against cancers caused by HPV infection.

Why does my child need HPV vaccine?

Human papillomavirus (HPV) vaccine protects against cancers caused by HPV infection. HPV is a common virus that infects teens and adults. About 14 million people, including teens, become infected with HPV each year. HPV infection can cause cervical, vaginal, and vulvar cancers in women and penile cancer in men. HPV can also cause anal cancer, cancer of the back of the throat (oropharynx), and genital warts in both men and women.

When should my child be vaccinated?

All kids who are 11 or 12 years old should get two shots of HPV vaccine six to twelve months apart. Getting vaccinated on time protects preteens long before ever being exposed to the virus. People get HPV from another person during intimate sexual contact.

Some children may need three doses of HPV vaccine. For example, adolescents who receive their two shots less than five months apart will need a third dose for best protection. Also, children who start the vaccine series on or after their 15th birthday need three shots given over 6 months. If your teen hasn't gotten the vaccine yet, talk to his/her doctor about getting it as soon as possible.

The best way to remember to get your child all of the recommended doses is to make an appointment for the remaining shots before you leave the doctor's office or clinic.

Is HPV vaccine safe for my child?

HPV vaccination provides safe, effective, and long-lasting protection against cancers caused by HPV. HPV vaccine has a reassuring safety record that's backed by 10 years of monitoring and research.

Like any vaccine or medicine, HPV vaccination can cause side effects. The most common side effects are mild and include pain, redness, or swelling in the arm where the shot was given; dizziness, fainting, nausea, and headache. Fainting after any vaccine, including HPV vaccine, is more common among adolescents.

To prevent fainting and injuries related to fainting, adolescents should be seated or lying down during vaccination and remain in that position for 15 minutes after the vaccine is given. The benefits of HPV vaccination far outweigh any potential risk of side effects.

It is important to tell the doctor or nurse if your child has any severe allergies, including an allergy to latex or yeast. HPV vaccine is not recommended for anyone who is pregnant.

How can I get help paying for these vaccines?

The Vaccines for Children (VFC) program provides vaccines for children ages 18 years and younger, who are uninsured, Medicaid-eligible, American Indian or Alaska Native. Learn more at www.cdc.gov/Features/VFCprogram

Where can I learn more?

Talk to your child's doctor or nurse to learn more about HPV vaccine and the other vaccines that your child may need. You can also find out more about HPV vaccine at

www.cdc.gov/hpv

Last updated JUNE 2018

Talking to Parents about HPV Vaccine

HPV VACCINE
IS CANCER PREVENTION

Recommend HPV vaccination in the **same way** and on the **same day** as all adolescent vaccines. You can say, "Now that your son is 11, he is due for vaccinations today to help protect him from meningitis, HPV cancers, and whooping cough. Do you have any questions?" Remind parents of the follow-up shots their child will need and ask them to make appointments before they leave.

Why does my child need HPV vaccine?

HPV vaccine is important because it prevents infections that can cause cancer. That's why we need to start the shot series today.

How do you know the vaccine works?

Studies continue to prove HPV vaccination works extremely well, decreasing the number of infections and HPV precancers in young people since it has been available.

Why do they need HPV vaccine at such a young age?

Like all vaccines, we want to give HPV vaccine earlier rather than later. Getting the vaccine now protects your child long before they are ever exposed. If you wait until your child is older, he/she may end up needing three shots instead of two.

Why do boys need the HPV vaccine?

HPV vaccination can help prevent future infections that can lead to cancers of the penis, anus, and back of the throat in men.

Are all of these vaccines actually required?

I strongly recommend each of these vaccines and so do experts at the CDC and major medical organizations. School entry requirements are developed for public health and safety, but don't always reflect the most current medical recommendations for your child's health.

Would you get HPV vaccine for your kids?

Yes, I gave HPV vaccine to my child (or grandchild, etc.) when he was 11, because I wanted to help protect him from cancer in the future.

What diseases are caused by HPV?

Some HPV infections can cause cancer—like cancer of the cervix or in the back of the throat—but we can protect your child from these cancers in the future by getting the first HPV shot today.

Is my child really at risk for HPV?

HPV is a very common infection in women and men that can cause cancer. Starting the vaccine series today will help protect your child from the cancers and diseases caused by HPV.

I'm worried my child will think that getting this vaccine makes it OK to have sex.

Studies tell us that getting HPV vaccine doesn't make kids more likely to start having sex. I made sure my child (or grandchild, etc.) got HPV vaccine, and I recommend we give your child her first HPV shot today.

I'm worried about the safety of HPV vaccine. Do you think it's safe?

Yes, HPV vaccination is very safe. Like any medication, vaccines can cause side effects, including pain, swelling, or redness where the shot was given. That's normal for HPV vaccine too and should go away in a day or two. Sometimes kids faint after they get shots and they could be injured if they fall from fainting. We'll have your child stay seated after the shot to help protect him/her.

Can HPV vaccine cause infertility in my child?

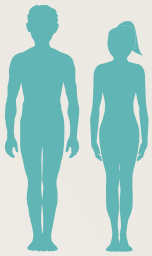
There is no evidence available to suggest that getting HPV vaccine will have an effect on future fertility. However, women who develop an HPV precancer or cancer could require treatment that would limit their ability to have children.

CS269453B
Last updated MAY 2018

HPV VACCINE IS IMPORTANT TO GIVE TO BOYS AND GIRLS

1 HUMAN PAPILLOMAVIRUS (HPV) IS A DANGEROUS VIRUS.

MORE THAN 30,000 PEOPLE IN THE US EACH YEAR ARE DIAGNOSED WITH AN HPV-RELATED CANCER, AND ABOUT 8,000 PEOPLE DIE FROM THESE CANCERS EACH YEAR. HPV VACCINES PREVENT INFECTION, AND CAN PREVENT PRE-CANCERS AND CANCERS.



HPV infects
- The head and neck
- Penis, anus, cervix, vagina and vulva

HPV causes genital warts within a few months after infection

HPV causes cervical pre-cancer within a few years after infection

HPV causes cancers 5-20 years after infection
- Tongue and tonsils: 10,000-12,000 per year
- Cervix: 10,000-12,000 per year
- Anus: 4,000-5,000 per year
- Vagina and vulva: 3,000 per year
- Penis: 700 per year

The vaccine is effective against the HPV types that cause the majority of the cancers, and infections of the head and neck, cervix, vagina and vulva

HPV vaccine prevents genital warts:
Over 90% of genital warts can be prevented

HPV vaccine prevents cervical pre-cancer
Girls who received all required doses of the HPV vaccine by age 14 were **75% less likely** than unvaccinated girls to go on to have a **cervical precancer**

HPV vaccine is expected to prevent cancers:
- 70% of tongue and tonsils cancers
- 85% of cervical cancers
- 80% of anal cancers
- 40% of vaginal and vulvar cancers
- 60% of penile cancers

2 HPV VACCINE HAS BEEN GIVEN TO ADOLESCENTS WORLDWIDE SINCE 2006, AND IT IS VERY SAFE.

Safety is continuously monitored in the United States, Europe, and in over 180 countries around the world. In-depth studies on over 4 million girls and women have not shown any serious side effects following vaccination.

3 HPV VACCINE WORKS BETTER WHEN IT IS GIVEN AT THE RECOMMENDED AGES OF 11-12.

Younger adolescents make more antibodies for each dose of the vaccine that they receive. That is why only 2 doses are necessary when the vaccine is started at the recommended age—3 are needed later. Women who were vaccinated when they were younger went on to develop fewer pre-cancers compared to women who were older when they got the vaccine.

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

This document was supported by the Grant or Cooperative Agreement Number, 5H23IP000952, funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Department of Health and Human Services.

Human Papillomavirus

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. The relationship of cervical cancer and sexual behavior was suspected for more than 100 years and was established by epidemiologic studies in the 1960s. In the early 1980s, cervical cancer cells were demonstrated to contain HPV DNA. Epidemiologic studies showing a consistent association between HPV and cervical cancer were published in the 1990s. The first vaccine to prevent infection with four types of HPV was licensed in 2006.

Human Papillomaviruses

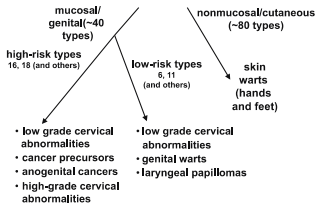
Human papillomaviruses are small, double-stranded DNA viruses that infect the epithelium. More than 120 HPV types have been identified; they are differentiated by the genetic sequence of the outer capsid protein L1. Most HPV types infect the cutaneous epithelium and can cause common skin warts. About 40 types infect the mucosal epithelium; these are categorized according to their epidemiologic association with cervical cancer. Infection with low-risk, or nononcogenic types, such as types 6 and 11, can cause benign or low-grade cervical cell abnormalities, genital warts and laryngeal papillomas. High-risk, or oncogenic, HPV types act as carcinogens in the development of cervical cancer and other anogenital cancers. High-risk types (currently including types 16 and 18, among others) can cause low-grade cervical cell abnormalities, high-grade cervical cell abnormalities that are precursors to cancer, and anogenital cancers. High-risk HPV types are detected in 99% of cervical cancers. Type 16 is the cause of approximately 50% of cervical cancers worldwide, and types 16 and 18 together account for about 70% of cervical cancers. Infection with a high-risk HPV type is considered necessary for the development of cervical cancer, but by itself it is not sufficient to cause cancer because the vast majority of women with HPV infection do not develop cancer.

In addition to cervical cancer, HPV infection is also associated with anogenital cancers less common than cervical cancer, such as cancer of the vulva, vagina, penis and anus. The association of genital types of HPV with non-genital cancers is less well established, but studies support a role for these HPV types in some oropharyngeal cancers.

Human Papillomaviruses (HPV)

- Small DNA virus
- More than 120 types identified based on the genetic sequence of the outer capsid protein L1
- About 40 types infect the mucosal epithelium

Human Papillomavirus Types and Disease Association

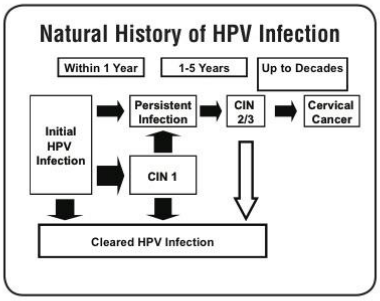


11

Pathogenesis

HPV infection occurs at the basal epithelium. Although the incidence of infection is high, most infections resolve spontaneously. A small proportion of infected persons become persistently infected; persistent infection is the most important risk factor for the development of cervical cancer.

Human Papillomavirus



The most common clinically significant manifestation of persistent genital HPV infection is cervical intraepithelial neoplasia, or CIN. Within a few years of infection, low-grade CIN—called CIN 1—may develop, which may spontaneously resolve and the infection clear.

Persistent HPV infection, however, may progress directly to higher-grade CIN, called CIN2 or CIN3. High-grade abnormalities are at risk of progression to cancer and so are considered cancer precursors. Some high-grade abnormalities spontaneously regress. If left undetected and untreated, years or decades later CIN2 or 3 can progress to cervical cancer.

Infection with one type of HPV does not prevent infection with another type. Of persons infected with mucosal HPV, 5% to 30% are infected with multiple types of the virus.

11

HPV Clinical Features

- Most HPV infections are asymptomatic and result in no clinical disease
- Clinical manifestations of HPV infection include:
  - anogenital warts
  - recurrent respiratory papillomatosis
  - cervical cancer precursors (cervical intraepithelial neoplasia)
  - cancer (cervical, anal, vaginal, vulvar, penile, and oropharyngeal cancer)

Clinical Features

Most HPV infections are asymptomatic and result in no clinical disease. Clinical manifestations of HPV infection include anogenital warts, recurrent respiratory papillomatosis, cervical cancer precursors (cervical intraepithelial neoplasia), and cancers, including cervical, anal, vaginal, vulvar, penile, and oropharyngeal cancer.

Laboratory Diagnosis

HPV has not been cultured by conventional methods. Infection is identified by detection of HPV DNA from clinical samples. Assays for HPV detection differ considerably in their sensitivity and type specificity, and detection is also affected by the anatomic region sampled as well as the method of specimen collection.

Several HPV tests have been approved by the Food and Drug Administration (FDA) and detect 13-14 high-risk types (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68). Test results are reported as positive or negative for any of the types; some tests specifically identify HPV 16 and 18. These tests are approved for triage of Papanicolaou (Pap) test results (ASC-US, atypical cells of undetermined significance) and in combination with the Pap test for cervical cancer screening in women 30 years of age and older. The tests are not clinically indicated nor approved for use in men.

Epidemiologic and basic research studies of HPV generally use nucleic acid amplification methods that generate type-specific results. The polymerase chain reaction (PCR) assays used most commonly in epidemiologic studies target genetically conserved regions in the L1 gene.

The most frequently used HPV serologic assays are virus-like particle (VLP)-based enzyme immunoassays. However, laboratory reagents used for these assays are not standardized and there are no standards for setting a threshold for a positive result.

Medical Management

There is no specific treatment for HPV infection. Medical management depends on treatment of the specific clinical manifestation of the infection (such as genital warts or abnormal cervical cell cytology).

Epidemiology

Occurrence

HPV infection occurs throughout the world.

HPV Epidemiology

- Reservoir
  - Human
- Transmission
  - Direct contact, usually sexual
- Temporal pattern
  - None
- Communicability
  - Presumed to be high

Reservoir

Viruses in the papillomavirus family affect other species. Humans are the only natural reservoir of HPV.

Transmission

HPV is transmitted by direct contact, usually sexual, with an infected person. Transmission occurs most frequently with sexual intercourse but can occur following nonpenetrative sexual activity.

Studies of newly acquired HPV infection demonstrate that infection occurs soon after onset of sexual activity. In a prospective study of college women, the cumulative incidence of infection was 40% by 24 months after first sexual intercourse. HPV 16 accounted for 10.4% of infections.

Genital HPV infection also may be transmitted by nonsexual routes, but this appears to be uncommon. Nonsexual routes of genital HPV transmission include transmission from a woman to a newborn infant at the time of birth.

Temporal Pattern

There is no known seasonal variation in HPV infection.

Communicability

HPV is presumably communicable during the acute infection and during persistent infection. This issue is difficult to study because of the inability to culture the virus. Communicability can be presumed to be high because of the large number of new infections estimated to occur each year.

Human Papillomavirus

11

HPV Disease Burden in the United States

- Anogenital HPV is the most common sexually transmitted infection in the US
  - estimated 79 million infected
  - 14 million new infections/ year
- Common among adolescents and young adults

Risk Factors

Risk factors for HPV infection are primarily related to sexual behavior, including lifetime and recent sex partners. Results of epidemiologic studies are less consistent for other risk factors, including young age at sexual initiation, number of pregnancies, genetic factors, smoking, and lack of circumcision of male partner.

Disease Burden in the United States

Anogenital HPV infection is believed to be the most common sexually transmitted infection in the United States. An estimated 79 million persons are infected, and an estimated 14 million new HPV infections occur annually with half of these in persons 15-24 years.

The two most common types of cervical cancer worldwide, squamous cell carcinoma followed by adenocarcinoma, are both caused by HPV. The CDC and National Cancer Institute's United States Cancer Statistics Working Group reports that from 2005 through 2009 there were annual averages of 12,595 cases and 3,968 deaths due to cervical cancer. HPV is believed to be responsible for nearly all of these cases of cervical cancer. HPV types 16 and 18 are associated with 70% of these cancers.

In addition to cervical cancer, HPV is believed to be responsible for 90% of anal cancers, 71% of vulvar, vaginal, or penile cancers, and 72% of oropharyngeal cancers.

Population-based estimates, primarily from clinics treating persons with sexually transmitted infections, indicate that about 1% of the sexually active adolescent and adult population in the United States have clinically apparent genital warts. More than 90% of cases of anogenital warts are associated with the low-risk HPV types 6 and 11.

About 8 billion dollars are spent annually on management of sequelae of HPV infections, primarily for the management of abnormal cervical cytology and treatment of cervical neoplasia. This exceeds the economic burden of any other sexually transmitted infection except human immunodeficiency virus.

Prevention

HPV Infection

HPV transmission can be reduced but not eliminated with the use of physical barriers such as condoms. Recent studies demonstrated a significant reduction in HPV infection among young women after initiation of sexual activity when their partners used condoms consistently and correctly.

Abstaining from sexual activity (i.e., refraining from any genital contact with another individual) is the surest way to prevent genital HPV infection. For those who choose to be sexually active, a monogamous relationship with an uninfected partner is the strategy most likely to prevent future genital HPV infections.

Cervical Cancer Screening

Most cases and deaths from cervical cancer can be prevented through detection of precancerous changes within the cervix by cervical cytology using the Pap test. Currently available Pap test screening can be done by a conventional Pap or a liquid-based cytology. CDC does not issue recommendations for cervical cancer screening, but various professional groups have published recommendations. Cervical cancer screening recommendations were revised in 2012 after the U.S. Preventive Services Task Force (USPSTF) and a multidisciplinary group, including the American Cancer Society (ASC), American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society for Clinical Pathology (ASCP) reviewed new evidence. Previously, recommendations varied by organization. Since 2012, all organizations have recommended that screening should begin at age 21 years. While there are slight differences in other aspects of the recommendations, all groups recommend screening in women aged 21 to 65 years with cytology (Pap test) every 3 years. For women aged 30 to 65 years who want to lengthen the screening interval, screening can be done with a combination of cytology and HPV testing ("co-testing") every 5 years.

Cervical Cancer Screening

- Revised in 2012
- Screening should begin at age 21 years
- Screen women 21 to 65 years of age with Pap test every 3 years
- Co-testing (Pap and HPV testing) every 5 years in women 30 to 65 years of age

The use of HPV vaccine does not eliminate the need for continued Pap test screening, since 30% of cervical cancers are caused by HPV types not included in the vaccine.

Human Papillomavirus Vaccine

Characteristics

Three HPV vaccines are licensed in the United States. The vaccines are non-infectious subunit vaccines. The antigen for the vaccines is the L1 major capsid protein of HPV, produced by using recombinant DNA technology. L1 proteins self-assemble into noninfectious, nononcogenic units called virus-like particles (VLP).

Quadrivalent HPV (HPV4) vaccine (Gardasil, Merck) was approved by the FDA in June 2006. The vaccine is approved for females and males 9 through 26 years of age. Each 0.5-mL dose of HPV4 contains 20 micrograms HPV 6 L1 protein, 40 micrograms HPV 11 L1 protein, 40 micrograms HPV 16 L1 protein, and 20 micrograms HPV 18 L1 protein. The vaccine antigen is adsorbed on alum adjuvant.

Human Papillomavirus Vaccine

- HPV L1 major capsid protein of the virus is antigen used for immunization
- L1 protein produced using recombinant technology
- L1 proteins self-assemble into virus-like particles (VLP)
- VLPs are noninfectious and nononcogenic

Human Papillomavirus

HPV Vaccines

- HPV4 (Gardasil, Merck)
  - approved for females and males 9 through 26 years of age
  - contains types 16 and 18 (high risk) and types 6 and 11 (low risk)
- a 9-valent vaccine licensed in December 2014
- HPV2 (Cervarix, GlaxoSmithKline)
  - approved for females 9 through 25 years of age
  - contains types 16 and 18 (high risk)

11

The vaccine also includes sodium chloride, L-histidine, polysorbate 80, and sodium borate. HPV4 does not contain a preservative or antibiotic. The vaccine is supplied in single-dose vials and syringes. A 9-valent vaccine (Merck) was approved by the FDA in December 2014.

Bivalent HPV (HPV2) vaccine (Cervarix, GlaxoSmithKline) was approved by the FDA in October 2009. The vaccine is approved for females 9 through 25 years of age. HPV2 is not approved for males. The L1 antigen is adsorbed onto aluminum hydroxide. The unique adjuvant system, AS04, is composed of 3-O-desacyl-4'-monophosphoryl lipid A (MPL) adsorbed onto aluminum hydroxide. Each 0.5-mL dose contains 20 micrograms of HPV type 16 L1 protein and 20 micrograms of HPV type 18 L1 protein. HPV2 does not contain a preservative or antibiotic. It is available in 2 types of prefilled syringes.

Immunogenicity and Vaccine Efficacy

HPV vaccines are highly immunogenic. More than 99% of recipients develop an antibody response to HPV types included in the respective vaccines 1 month after completing the three-dose series. However, there is no known serologic correlate of immunity and no known minimal titer determined to be protective. The high efficacy found in the clinical trials to date has precluded identification of a minimum protective antibody titer. Further follow-up of vaccinated cohorts may allow determination of serologic correlates of immunity in the future.

Both HPV vaccines have been found to have high efficacy for prevention of HPV vaccine type–related persistent infection, CIN 2/3 and adenocarcinoma in-situ (AIS). Clinical efficacy for HPV4 against cervical disease was determined in two double-blind, placebo-controlled trials. In women 16 through 26 years of age vaccine efficacy for HPV 16 or 18–related CIN 2/3 or AIS was 97%. HPV4 efficacy against HPV 6, 11, 16 or 18–related genital warts was 99%.

HPV2 efficacy was evaluated in two randomized, double-blind, controlled clinical trials in females aged 15 through 25 years. In the phase III trial, efficacy against HPV 16 or 18-related CIN 2/3 or AIS was 93%.

HPV4 was evaluated in men 16 through 26 years and found to have 88% efficacy against vaccine type genital warts. Among men who have sex with men (MSM), efficacy against anal intraepithelial neoplasia grade 2 or 3 (AIN2/3) was 75%.

Although high efficacy among persons without evidence of infection with vaccine HPV types was demonstrated in clinical trials of both HPV vaccines, there is no evidence of

efficacy against disease caused by vaccine types with which participants were infected at the time of vaccination (i.e., the vaccines had no therapeutic effect on existing infection or disease). Participants infected with one or more vaccine HPV types prior to vaccination were protected against disease caused by the other vaccine types. Prior infection with one HPV type did not diminish efficacy of the vaccine against other vaccine HPV types.

The duration of protection following HPV vaccine is not known. For both vaccines a subset of participants have been followed for more than 60 months with no evidence of waning protection. Study populations will continue to be followed for any evidence of waning immunity.

HPV Vaccine Efficacy

- High efficacy among females without evidence of infection with vaccine HPV types
- No evidence of efficacy against disease caused by vaccine types with which participants were infected at the time of vaccination
- Prior infection with one HPV type did not diminish efficacy of the vaccine against other vaccine HPV types

Vaccination Schedule and Use

ACIP recommends vaccination of females with HPV2 or HPV4 for prevention of cervical cancers and precancers. HPV4 is recommended also for prevention of genital warts. ACIP recommends routine vaccination at age 11 or 12 years with HPV4 or HPV2 for females and with HPV4 for males. The vaccination series can be started beginning at age 9 years.

HPV4 and HPV2 are each administered in a 3-dose series. The second dose should be administered 1 to 2 months after the first dose and the third dose 6 months after the first dose. Vaccination also is recommended for females aged 13 through 26 years and for males aged 13 through 21 years, who have not been previously vaccinated or who have not completed the 3-dose series. For immunocompromised males (including HIV infection) and men who have sex with men, ACIP recommends routine vaccination with HPV4, as for all males, through 26 years of age for those who have not been vaccinated previously or who have not completed the 3-dose series. Males aged 22 through 26 years without these risk factors may be vaccinated as well. HPV2 is neither licensed nor recommended for males.

HPV Vaccination Recommendations

- ACIP recommends routine vaccination at age 11 or 12 years with HPV4 or HPV2 for females and HPV 4 for males
- The vaccination series can be started as young as 9 years of age
- Vaccination also recommended for females 13 through 26 years of age
- Vaccination also recommended for males 13 through 21 years of age
- All immunocompromised males (including HIV infection) and MSM through 26 years of age should be vaccinated
- Males aged 22 through 26 years may be vaccinated

If females or males reach age 27 years before the vaccination series is complete, the second and/or third doses of vaccine can be administered after age 26 to complete the vaccination series.

Prevaccination assessments (e.g., Pap testing or screening for high-risk HPV DNA, type-specific HPV tests, or HPV antibody) to establish the appropriateness of HPV vaccination are not recommended.

Ideally, vaccine should be administered before potential exposure to HPV through sexual contact; however, persons who may have already been exposed to HPV should be

Human Papillomavirus

11

HPV Vaccination Schedule

- Routine schedule is 0, 1 to 2, 6 months
- An accelerated schedule using minimum intervals is not recommended
- Series does not need to be restarted if the schedule is interrupted
- Prevaccination assessments not recommended
- No therapeutic effect on HPV infection, genital warts, cervical lesions

vaccinated. Sexually active persons who have not been infected with any of the HPV vaccine types will receive full benefit from vaccination. Vaccination will provide less benefit to persons if they have already been infected with one or more of the HPV vaccine types. However, it is not possible for a clinician to assess the extent to which sexually active persons would benefit from vaccination, and the risk of HPV infection may continue as long as persons are sexually active. Pap testing or screening for HPV DNA or HPV antibody is not recommended prior to vaccination at any age.

Both HPV vaccines are administered in a three-dose series of intramuscular injections. The second and third doses should be administered 1 to 2 and 6 months after the first dose. The third dose should follow the first dose by at least 24 weeks. The third dose need not be repeated as long as it was administered at least 16 weeks after the first dose and at least 12 weeks after the second dose. An accelerated schedule for HPV vaccine is not recommended.

There is no maximum interval between doses. If the HPV vaccine schedule is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be given as soon as possible, and the second and third doses should be separated by an interval of at least 12 weeks. If only the third dose is delayed, it should be administered as soon as possible.

Whenever feasible, the same HPV vaccine should be used for the entire vaccination series. No studies address interchangeability of HPV vaccines. However, if the vaccine provider does not know or have available the HPV vaccine product previously administered, either HPV vaccine can be used to complete the series to provide protection against HPV 16 and 18. For protection against HPV 6 or 11-related genital warts, a vaccination series with fewer than 3 doses of HPV4 might provide less protection than a complete 3-dose HPV4 series.

HPV vaccine should be administered at the same visit as other age-appropriate vaccines, such as Tdap and quadrivalent meningococcal conjugate (MCV4) vaccines. Administering all indicated vaccines at a single visit increases the likelihood that adolescents and young adults will receive each of the vaccines on schedule. Each vaccine should be administered using a separate syringe at a different anatomic site.

As mentioned, prevaccination assessments (e.g. Pap testing or screening for high-risk HPV DNA, type-specific HPV tests, or HPV antibody) to establish the appropriateness

of HPV vaccination are not recommended at any age. HPV vaccination can provide protection against infection with HPV vaccine types not already acquired. Therefore, vaccination is recommended through the recommended age for females regardless of whether they have an abnormal pap test result, and for females or males regardless of known HPV infection.

Women should be advised that the vaccine will not have a therapeutic effect on existing HPV infection, genital warts or cervical lesions.

A history of genital warts or clinically evident genital warts indicates infection with HPV, most often type 6 or 11. However, these persons may be infected with HPV types other than the HPV4 vaccine types, and therefore they may receive HPV4 vaccine if they are in the recommended age group. Persons with a history of genital warts should be advised that data do not indicate HPV4 vaccine will have any therapeutic effect on existing HPV infection or genital warts.

Because HPV vaccines are subunit vaccines, they can be administered to persons who are immunosuppressed because of disease or medications. However, the immune response and vaccine efficacy might be less than that in persons who are immunocompetent. Women who are breastfeeding may receive HPV vaccine.

Contraindications and Precautions to Vaccination

A severe allergic reaction (e.g., anaphylaxis) to a vaccine component or following a prior dose of HPV vaccine is a contraindication to receipt of HPV vaccine. Anaphylactic allergy to latex is a contraindication to bivalent HPV vaccine in a prefilled syringe since the tip cap contains natural rubber latex. A moderate or severe acute illness is a precaution to vaccination, and vaccination should be deferred until symptoms of the acute illness improve. A minor acute illness (e.g., diarrhea or mild upper respiratory tract infection, with or without fever) is not a reason to defer vaccination.

HPV Vaccine Contraindications and Precautions

- Contraindication
  - severe allergic reaction to a vaccine component or following a prior dose
- Precaution
  - moderate or severe acute illnesses (defer until symptoms improve)

HPV vaccine is not recommended for use during pregnancy. The vaccine has not been causally associated with adverse pregnancy outcomes or with adverse effects on the developing fetus, but data on vaccination during pregnancy are limited. Pregnancy testing before vaccination is not needed. However, if a woman is found to be pregnant after initiation of the vaccination series, the remainder of the series should be delayed until after completion of the

Human Papillomavirus

HPV Vaccination During Pregnancy

- Initiation of the vaccine series should be delayed until after completion of pregnancy
- If a woman is found to be pregnant after initiating the vaccination series, remaining doses should be delayed until after the pregnancy
- If a vaccine dose has been administered during pregnancy, there is no indication for intervention
- Women vaccinated during pregnancy may be reported to the respective manufacturer

HPV Vaccine Adverse Reactions

- Local reactions (pain, redness, swelling)
  - 20%-90%
- Fever (100°F)
  - 10%-13%*
- No serious adverse reactions associated with either vaccine

*similar to reports in placebo recipients

pregnancy. No intervention is indicated. Women known to be pregnant should delay initiation of the vaccine series until after delivery.

Pregnancy registries for both HPV2 and HPV4 have been terminated. However, vaccination with either vaccine during pregnancy may still be reported to VAERS or to the manufacturer: GlaxoSmithKline at 1-888-825-5249 (for HPV2), or Merck at 1-877-888-4231 (for HPV4).

Adverse Reactions Following Vaccination

The most common adverse reactions reported during clinical trials of HPV vaccines were local reactions at the site of injection. In prelicensure clinical trials, local reactions, such as pain, redness or swelling were reported by 20% to 90% of recipients. A temperature of 100°F during the 15 days after vaccination was reported in 10% to 13% of recipients of either vaccine. A similar proportion of placebo recipients reported an elevated temperature. Local reactions generally increased in frequency with increasing doses. However, reports of fever did not increase significantly with increasing doses. No serious adverse events have been associated with either HPV vaccine based on monitoring by CDC and the Food and Drug Administration.

A variety of systemic adverse reactions were reported by vaccine recipients, including nausea, dizziness, myalgia and malaise. However, these symptoms occurred with equal frequency among both vaccine and placebo recipients.

Syncope has been reported among adolescents who received HPV and other vaccines recommended for this age group (Tdap, MCV4). Recipients should always be seated during vaccine administration. Clinicians should consider observing recipient for 15 minutes after vaccination.

Vaccine Storage and Handling

HPV vaccines should be maintained at refrigerator temperature between 35°F and 46°F (2°C and 8°C). Manufacturer package inserts contain additional information and can be found at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093830.htm. For complete information on best practices and recommendations please refer to CDC's Vaccine Storage and Handling Toolkit, http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf.

Acknowledgment

The editors thank Drs. Lauri Markowitz and Elizabeth Unger for their assistance in updating this chapter.

Selected References

American College of Obstetricians and Gynecologists. Human papillomavirus vaccination. ACOG committee opinion No. 467. *Obstet Gynecol* 2010;116:800–803.

CDC. Human papillomavirus vaccination. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2014;63(No. 5):1-30.

CDC. Quadrivalent human papillomavirus vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2007;56 (No.RR-2):1–24.

CDC. FDA licensure of bivalent human papillomavirus vaccine (HPV2, Cervarix) for use in females and updated HPV vaccination recommendations from the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2010;59(No. 20):626-9.

CDC. Recommendations on the use of quadrivalent human papillomavirus vaccine in males – Advisory Committee on Immunization Practices (ACIP), 2011. *MMWR* 2011;60 (No. 50):1705-8.

Dunne E, Markowitz L. Genital human papillomavirus infection. *Clin Infect Dis* 2006;43:624–9.

Koutsky LA, Kiviat NB. Genital human papillomavirus. In: Holmes KK, Sparling PF, Mårdh PA, et al, eds. *Sexually Transmitted Diseases*. 3rd ed. New York: McGraw-Hill;1999:347-59.

Moyer VA. Screening for cervical cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2012;156:880-91, W312.

Saslow D, Solomon D, Lawson HW, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *American Journal of Clinical pathology* 2012; 137:516-42.

Satterwhite CL, Torrone E, Meites E, et al. Sexually Transmitted Infections Among US Women and Men: Prevalence and Incidence Estimates, 2008. *Sex Transm Dis*. 2013;40:187-93

Schiller JT, Lowy DR, Markowitz LE. Human papillomavirus vaccines. In: Plotkin SA, Orenstein WA, Offit PA, eds. *Vaccines*. 6th ed. China: Saunders 2012:235-256.

Human Papillomavirus

Trottier H, Franco E. The epidemiology of genital human papillomavirus infection. *Vaccine 2006*;24(suppl1):51–15.

U.S. Cancer Statistics Working Group. United States Cancer Statistics; 1999-2009 Incidence and Mortality Web-based Report. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2013. Available at: www.cdc.gov/uscs.

Winer R, Hughes J, Feng Q, et al. Condom use and the risk of genital human papillomavirus infection in young women. *N Engl J Med* 2006;354:2645–54.

Winer R, Lee S, Hughes J, et al. Genital human papillomavirus infection incidence and risk factors in a cohort of female university students. *Am J Epidemiol* 2003;157: 218-26.

11

The HPV Vaccine Schedule

The number of recommended doses is based on the age at the 1st dose.

- 2–dose series: Children starting the series **before** their 15th birthday
  (unless they are immunocompromised, then give a 3-dose series)
- 3–dose series: Children starting the series **on or after** their 15th birthday

Ages for Vaccination

- Minimum age: 9 years
- Routine age: 11-12 years
- Recommended through age 26 years for females and through age 21 years for males if not vaccinated previously.

  Males age 22-26 years may be vaccinated. Also recommended through age 26 years for immunocompromised and men who have sex with men.

Population	# of doses	Routine schedule	Minimum intervals
Started series at age 9 through 14 years, except immunocompromised persons	2	0, 6 to 12 months	5 months between doses
Started series at age 15 through 26 years, and immunocompromised persons (any age)	3	0, 1 to 2, 6 months	4 weeks between doses 1-2 12 weeks between doses 2-3 5 months between doses 1-3

3 doses of HPV vaccine are recommended for persons with immunocompromising conditions that might reduce cell-mediated or humoral immunity. Examples include:

- B lymphocyte Ab deficiences
- HIV infections
- Transplantation
- Immunosuppresive therapy
- T lymphocyte complete or partial defects
- Malignant neoplasm
- Autoimmune disease

The 2-dose series is enough for persons with **conditions that don't affect HPV immunity**. Examples include:

- Asthma
- Asplenia
- Diabetes mellitus
- Sickle cell disease
- Chronic granulomatous disease
- Chronic disease of liver, lung, kidneys
- Heart disease
- CNS barrier defects (eg, cochlear implant)
- Complement & persistent complement component deficiency

- ACIP has not recommended routine additional vaccination with 9vHPV for persons who have completed a 3-dose series of another HPV vaccine, but this is likely to be safe. Additional vaccination with 9vHPV may not be covered by insurance.
- Prolonged intervals: If the vaccination series is interrupted, the series does NOT need to be restarted.
- Too short intervals
  - In a 2-dose series: If the 2nd dose is given <5 months after the 1st, a 3rd dose should be administered at least 12 weeks after the 2nd dose and at least 5 months after the 1st dose.
  - In a 3-dose series: If a vaccine dose is given at less than the minimum interval, it should be re-administered after another minimum interval has been met.
- HPV vaccine may be administered starting at age 9. Do not delay beyond age 9 for children with a history of sexual assault.
- Pregnancy testing is not needed before HPV vaccination. HPV vaccination is not recommended during pregnancy, but there is no evidence that it poses harm. If a woman is found to be pregnant after starting the series, no intervention is needed; delay the remaining doses until after the pregnancy.
- For more information, see https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6549a5.pdf

Scheduling Human Papillomavirus (HPV) Vaccination

Test yourself – Test your staff

For each of the following cases, jot down *how many more doses of HPV vaccine are needed* and then, check your answers below.

Case 1
- Visit: On his 15th birthday
- Previous doses: None

Case 2
- Visit: Age 13 years
- Previous doses:
  1. 4vHPV given at age 12 years
  2. 9vHPV given 6 months later
- Medical history: Sickle cell disease

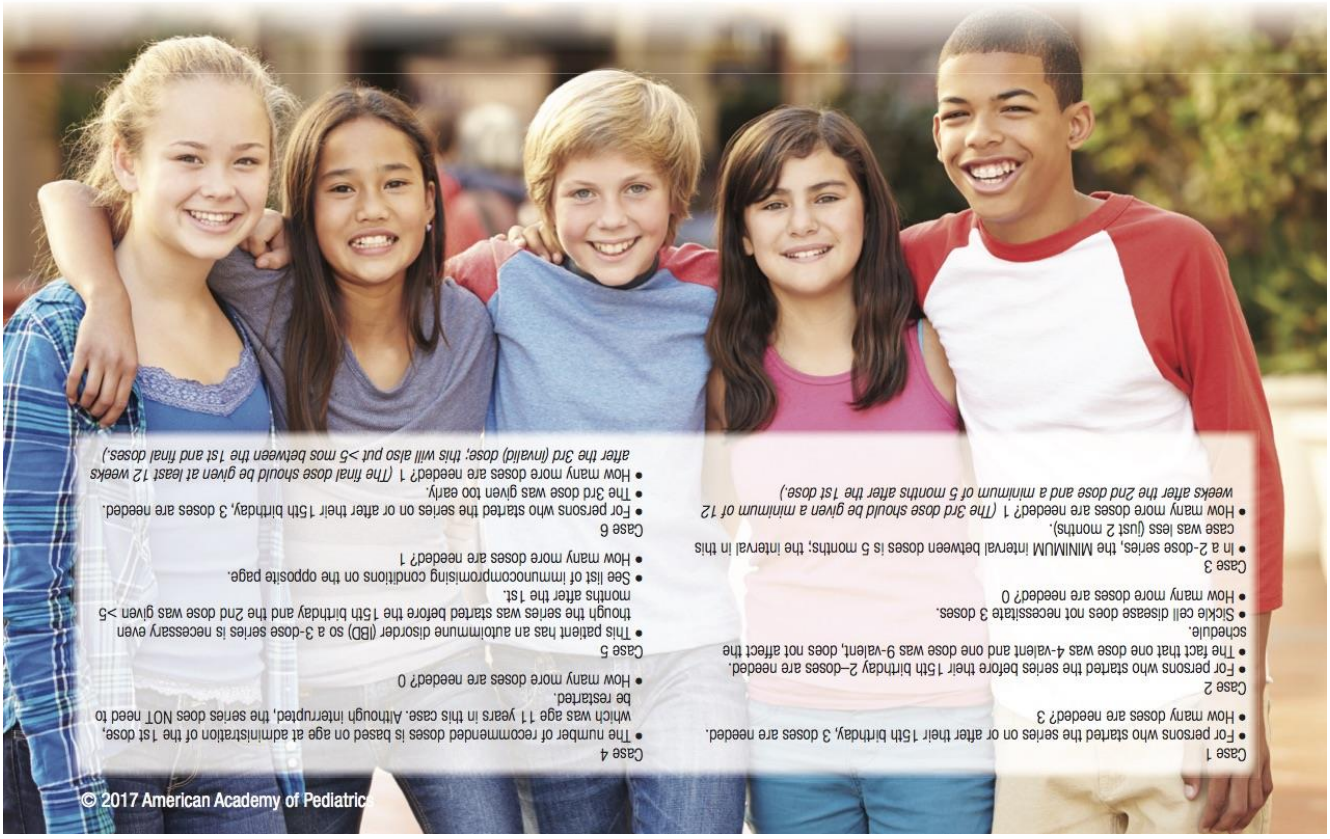
Case 3
- Visit: Age 13 years
- Previous doses:
  1. 4vHPV given at age 11 years
  2. 9vHPV given 2 months later

Case 4
- Visit: Age 15 years
- Previous doses:
  1. 4vHPV given at age 11 years
  2. 4vHPV given at age 13 years

Case 5
- Visit: Age 11 years
- Previous doses:
  1. 4vHPV given at age 9 years
  2. 9vHPV given at age 10 years
- Medial history: IBD

Case 6
- Visit: Age 15 years
- Previous doses:
  1. 9vHPV given on 15th birthday
  2. 9vHPV given 2 months later
  3. 9vHPV given 2 months after 2nd dose

For a free online interactive version of this sheet, see http://bit.ly/2seXMT0.



Case 1
• For persons who started the series on or after their 15th birthday, 3 doses are needed.
• How many doses are needed? 3

Case 2
• For persons who started the series before their 15th birthday 2–doses are needed.
• The fact that one dose was 4-valent and one dose was 9-valent, does not affect the schedule.
• Sickle cell disease does not necessitate 3 doses.
• How many more doses are needed? 0

Case 3
• In a 2-dose series, the MINIMUM interval between doses is 5 months; the interval in this case was less (just 2 months).
• How many more doses are needed? 1 *(The 3rd dose should be given a minimum of 12 weeks after the 2nd dose and a minimum of 5 months after the 1st dose.)*

Case 4
• The number of recommended doses is based on age at administration of the 1st dose, which was age 11 years in this case. Although interrupted, the series does NOT need to be restarted.
• How many more doses are needed? 0

Case 5
• This patient has an autoimmune disorder (IBD) so a 3-dose series is necessary even though the series was started before the 15th birthday and the 2nd dose was given >5 months after the 1st.
• See list of immunocompromising conditions on the opposite page.
• How many more doses are needed? 1

Case 6
• For persons who started the series on or after their 15th birthday, 3 doses are needed.
• The 3rd dose was given too early.
• How many more doses are needed? 1 *(The final dose should be given at least 12 weeks after the 3rd (invalid) dose; this will also put >5 mos between the 1st and final doses.)*

INFORMATION FOR PARENTS

| DISEASES and the VACCINES THAT PREVENT THEM |

HPV Vaccines Are Safe For Your Child

09/09/2015 CS256663B

HPV vaccines are very safe. CDC has carefully studied the risks of HPV vaccination. The benefits of HPV vaccination, such as prevention of cancer, far outweigh the risks of possible side effects.

HPV vaccines are safe and recommended for girls and boys at age 11 or 12

Human papillomavirus (HPV) is a common virus that affects men and women. HPV can cause cancers of the cervix, vagina, and vulva in women; cancer of the penis in men, and cancers of the anus and throat in men and women.

HPV vaccination is recommended for girls and boys at ages 11 or 12.There are three HPV vaccines approved by the Food and Drug Administration (FDA) and recommended by the Centers for Disease Control and Prevention (CDC) to protect against HPV and the cancers it can cause.

Like all vaccines used in the United States, HPV vaccines are required to go through years of safety testing before they are approved by the FDA. CDC and FDA closely monitor vaccines to make sure they are safe even after they are available to the public.

HPV vaccines have good safety records. Studies have shown that each HPV vaccine is very safe, and careful safety monitoring has not shown any problems.

The safety of HPV vaccines was tested in thousands of volunteers before the vaccines were approved

	How many people was it tested in?	When was it approved?	Who is it recommended for?
Gardasil	More than 29,000 volunteers	2006	Girls and boys at age 11 or 12
Cervarix	More than 30,000 volunteers	2009	Girls age 11 or 12
Gardasil 9	More than 15,000 volunteers	2014	Girls and boys at age 11 or 12 years

Like any vaccine or medicine, HPV vaccines can cause side effects

Some people have mild side effects after getting the HPV vaccine. Common side effects include:

- Pain, swelling, or redness in the arm where the shot was given
- Fever
- Headache or feeling tired
- Nausea, vomiting, diarrhea, or stomach pain
- Muscle or joint pain

Talk with your doctor about any health concerns before vaccination

If your child is scheduled for HPV vaccination, tell your doctor about any severe allergies. Some children should not get some HPV vaccines, including:

- Children who have ever had a life-threatening allergic reaction to any ingredient of an HPV vaccine, or to a previous dose of HPV vaccine
- Children who have an allergy to yeast (Gardasil and Gardasil 9)
- Children who have an allergy to latex (Cervarix)

HPV vaccines are safe for children who are mildly ill – for example, with a low-grade fever of less than 101 degrees, a cold, runny nose, or cough. Children with a moderate or severe illness should wait until they are better.

DEPARTMENT OF HEALTH & HUMAN SERVICES USA

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

AMERICAN ACADEMY OF FAMILY PHYSICIANS STRONG MEDICINE FOR AMERICA

American Academy of Pediatrics DEDICATED TO THE HEALTH OF ALL CHILDREN™

HPV vaccines don't cause HPV infection or cancer

HPV vaccines cannot cause HPV infection or cancer. In fact, HPV vaccines are very effective at protecting against HPV types that cause cancers.

HPV vaccines don't cause any fertility problems

Some parents have been concerned that HPV vaccines might make their child unable to have children in the future. However, HPV vaccines do not cause any fertility problems.

In fact, *not* getting HPV vaccination leaves boys and girls at risk for cancers caused by HPV. A girl who develops cervical cancer later in life due to HPV infection may require serious treatments that could leave her unable to have children. HPV vaccination can prevent these complications.

Fainting can happen after any medical procedure, including HPV vaccination

Some people, especially teens, faint after getting vaccinated. To prevent fainting and related injuries, people receiving HPV vaccines should sit or lie down during vaccination, then remain seated for 15 minutes after the shot. People should tell the doctor or nurse if they're feeling dizzy, faint, or light-headed.

Seek medical care if your child has a reaction

If your child is having a severe allergic reaction or other health emergency, call 9-1-1 or go to the nearest hospital.

Look for any signs or symptoms that concern you, like signs of a severe allergic reaction, very high fever, or behavior changes. These would start a few minutes to a few hours after the shot is given.

Signs of a severe allergic reaction can include:

- Hives
- Swelling of the face and throat
- Difficulty breathing
- A fast heartbeat
- Dizziness
- Weakness

After seeing a doctor, you should report the reaction to the Vaccine Adverse Event Reporting System (VAERS). CDC and FDA use this system to track possible vaccine side effects. Your doctor can file this report, or you can do it yourself through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

The Centers for Disease Control and Prevention, American Academy of Family Physicians, and American Academy of Pediatrics strongly recommend children receive all vaccines according to the recommended schedule.

INFORMATION FOR PARENTS

| DISEASES and the VACCINES THAT PREVENT THEM |

HPV Vaccine is Safe — (Gardasil)

04/08/2016 CS256663A

What are HPV Vaccines?

HPV vaccines protect against certain cancers caused by human papillomavirus (HPV) infection. HPV infection can cause cervical, vaginal, and vulvar cancers in women and penile cancer in men. HPV can also cause anal cancer, throat (oropharyngeal) cancer, and genital warts in both men and women. There are currently three HPV vaccines available for use in the United States. This fact sheet summarizes what we know about the safety of Gardasil, one of the available HPV vaccines.

How Do I Know HPV Vaccine is Safe?

As with all approved vaccines, CDC and the Food and Drug Administration (FDA) closely monitor the safety of HPV vaccine to identify **adverse events** and **side effects**. Pre-licensure clinical trials and data collected after the vaccine was made available show that it is very safe.

Adverse event: a health problem that happens after vaccination that may or may not be caused by a vaccine.

Side effect: a health problem that has been shown to be linked to a vaccine by scientific studies.

What Are the Side Effects?

HPV vaccine is very safe, and it is effective at protecting against some HPV types that cause cancer. Vaccines, like any medicine, can have side effects. Many people who get HPV vaccine have no side effects at all. Some people report having very mild side effects, like a sore arm from the shot. The most common side effects are usually mild.

Common Side Effects of HPV Vaccines

- Pain, redness, or swelling in the arm where the shot was given
- Fever
- Headache or feeling tired
- Nausea
- Muscle or joint pain

Understanding HPV Vaccine Safety Studies and Monitoring

It is important to understand the following when reading about HPV vaccine safety studies:

Anyone can report side effects and adverse events.
CDC and FDA maintain a vaccine safety monitoring system called the Vaccine Adverse Event Reporting System (VAERS). VAERS accepts reports from anyone, including doctors, patients, and parents. While VAERS provides useful information on vaccine safety, the data have limitations. It is generally not possible to use VAERS to determine whether a vaccine caused an adverse event.

HPV vaccine has many of the same, mild side effects as other vaccines.
Common, mild side effects reported during HPV vaccine safety studies include pain in the arm where the shot was given, fever, dizziness and nausea. These are similar to side effects seen with other vaccines.
Some preteens and teens might faint after getting the HPV vaccine or any shot. People should sit or lie down for about 15 minutes after getting a shot. This can help prevent fainting.

CDC has carefully studied the risks of HPV vaccination.
HPV vaccination is recommended because the benefits, such as prevention of cancer, far outweigh the risks of possible side effects.

Benefits	Potential Risks
Cancer Prevention	Chance of fainting
Cervical, vaginal, and vulvar cancer in women	Pain, redness, or swelling in the arm where the shot was given
Anal cancer in men and women	
Likely penile cancer in men	
Likely oropharyngeal cancer in women and men	

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
CDC CENTERS FOR DISEASE CONTROL AND PREVENTION
AMERICAN ACADEMY OF FAMILY PHYSICIANS STRONG MEDICINE FOR AMERICA
American Academy of Pediatrics DEDICATED TO THE HEALTH OF ALL CHILDREN™

What Do the Studies Say?

Scientists at CDC and FDA continuously monitor the safety of HPV vaccine. While monitoring activities help identify possible side effects and adverse events, they do not prove the side effects were caused by Gardasil.

- Monitoring by CDC and FDA in 2009 revealed most side effects reported after receiving HPV vaccine were non-serious, including: fainting; dizziness; nausea; headache; and pain, swelling, or redness in the arm where the shot was given.

Formal studies have also looked at whether or not specific adverse events can be linked to Gardasil:

- A 2011 study found women and girls who received Gardasil were no more at risk of allergic reactions, anaphylaxis (severe allergic reaction), Guillain–Barré Syndrome (GBS), stroke, blood clots, appendicitis, or seizures than those who were unvaccinated or who received other vaccines.
- A 2012 study that looked at when adverse events occur found Gardasil may be associated with skin infections where the shot is given during the two weeks after vaccination and fainting on the day the shot is received.
- A 2013 study that included almost 1 million girls found Gardasil was not associated with blood clots or adverse events related to the autoimmune and brain systems.
- A 2014 study that included over 1 million women found Gardasil was not associated with venous thromboembolism, also called VTE or blood clots.

Several studies have shown that there is no relationship between Gardasil and autoimmune disorders:

- A 2012 study and a 2014 study both found women and girls who received the Gardasil shot were not more likely to develop autoimmune disorders than those who were unvaccinated.
- A 2015 study found women and girls who received Gardasil were not more likely than those who were unvaccinated to develop multiple sclerosis (MS) or other similar diseases.

Gardasil is not recommended during pregnancy. However, some women may receive the Gardasil shot before realizing they are pregnant. There have been several studies that found pregnant women who received Gardasil did not experience any problems:

- A 2015 study found no safety concerns for pregnant women who received Gardasil, or for their babies.
- The Gardasil Pregnancy Registry, maintained by the manufacturer, received many reports of pregnant women who were vaccinated, and found no evidence that the vaccine affects fertility, pregnancy, or the health of the baby.

Related Scientific Articles

Arnheim-Dahlström L, Pasternak B, Svanström H, Sparén P, Hviid A. Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: Cohort study. *BMJ*. 2013 Oct;347:f5906.

Chao C, Klein NP, Velicer CM, Sy LS, Slezak JM, Takhar H, et al. Surveillance of autoimmune conditions following routine use of quadrivalent human papillomavirus vaccine. *J Intern Med*. 2012 Feb; 271(2):193-203. Epub 2011 Nov.

Gee J, Naleway A, Shui I, Baggs J, Yin R, Li R, et al. Monitoring the safety of quadrivalent human papillomavirus vaccine: Findings from the Vaccine Safety Datalink. *Vaccine*. 2011 Oct; 29(46):8279-84.

Grimaldi-Bensouda L, Guillemot D, Godeau B, Benichou J, Lebrun-Frenay C, Papeix C, et al. Autoimmune disorders and quadrivalent human papillomavirus vaccination of young female subjects. *J Intern Med*. 2014 Apr; 275(4):398-408. Epub 2013 Nov 22.

Klein NP, Hansen J, Chao C, Velicer C, Emery M, Slezak J, et al. Safety of quadrivalent human papillomavirus vaccine administered routinely to females. *Arch Pediatr Adolesc Med*. 2012 Dec; 166(12):1140-8.

Macartney KK, Chiu C, Georgousakis M, Brotherton JM. Safety of human papillomavirus vaccines: A review. *Drug Saf*. 2013 Jun; 36(6):393-412.

Markowitz LE, Dunne EF, Saraiya M, Chesson HW, Curtis CR, Gee J, et al. Human papillomavirus vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 63(RR05);1-30

Moro PL, Zheteyeva Y, Lewis P, Shi J, Yue X, Museru OI, et al. Safety of quadrivalent human papillomavirus vaccine (Gardasil®) in pregnancy: Adverse events among non-manufacturer reports in the Vaccine Adverse Event Reporting System, 2006-2013. *Vaccine*. 2015 Jan; 33(4): 519-22.

Scheller NM, Pasternak B, Svanström H, Hviid A. Quadrivalent human papillomavirus vaccine and the risk of venous thromboembolism. *JAMA*. 2014 Jul;312(2):187-8.

Scheller NM, Svanström H, Pasternak B, Arnheim-Dahlström L, Sundström K, Katharina Fink K, et al. Quadrivalent HPV vaccination and risk of multiple sclerosis and other demyelinating diseases of the central nervous system. *JAMA*. 2015 Jan; 313(1):54-61.

Slade BA, Leidel L, Vellozzi C, Woo EJ, Hua W, Sutherland A, et al. Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. *JAMA*. 2009; 302(7):750-7

The Centers for Disease Control and Prevention, American Academy of Family Physicians, and American Academy of Pediatrics strongly recommend children receive all vaccines according to the recommended schedule.

HPV

also known as *Human Papillomavirus*

As parents, you do everything you can to protect your children's health for now and for the future. Today, there is a strong weapon to prevent several types of cancer in our kids: the HPV vaccine.

HPV and Cancer

HPV is short for Human Papillomavirus, a common virus. In the United States each year, there are about 17,500 women and 9,300 men affected by HPV-related cancers. Many of these cancers **could be prevented with vaccination.** In both women and men, HPV can cause anal cancer and mouth/throat (oropharyngeal) cancer. It can also cause cancers of the cervix, vulva and vagina in women; and cancer of the penis in men.

For women, screening is available to detect most cases of cervical cancer with a Pap smear. Unfortunately, there is no routine screening for other HPV-related cancers for women or men, and these cancers can cause pain, suffering, or even death. **That is why a vaccine that prevents most of these types of cancers is so important.**

More about HPV

HPV is a virus passed from one person to another during skin-to-skin sexual contact, including vaginal, oral, and anal sex. HPV is most common in people in their late teens and early 20s. Almost all sexually active people will get HPV at some time in their lives, though most will never even know it.

Most of the time, the body naturally fights off HPV, before HPV causes any health problems. But in some cases, the body does not fight off HPV, and HPV can cause health problems, like cancer and genital warts. Genital warts are not a life-threatening disease, but they can cause emotional stress, and their treatment can be very uncomfortable. About 1 in 100 sexually active adults in the United States have genital warts at any given time.

HPV vaccination is recommended for preteen girls and boys at age 11 or 12 years

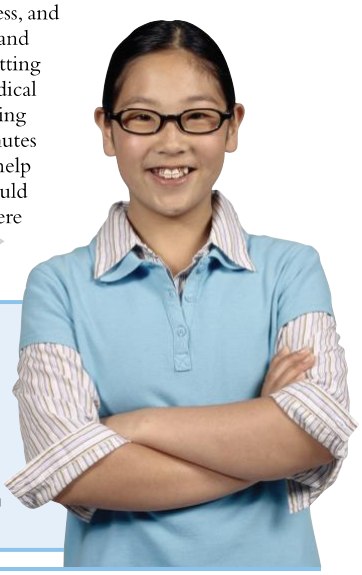
All preteens need HPV vaccination so they can be protected from HPV infections that cause cancer. Teens and young adults who didn't start or finish the HPV vaccine series also need HPV vaccination. Young women can get HPV vaccine until they are 27 years old and young men can get HPV vaccine until they are 22 years old. Young men who have sex with other men or who have weakened immune systems can also get HPV vaccine until they are 27.

HPV vaccination is a series of shots given over several months. The best way to remember to get your child all of the shots they need is to make an appointment for the remaining shots before you leave the doctor's office or clinic.

Is the HPV vaccine safe?

Yes. HPV vaccination has been studied very carefully and continues to be monitored by CDC and the Food and Drug Administration (FDA). No serious safety concerns have been linked to HPV vaccination. **These studies continue to show that HPV vaccines are safe.**

The most common side effects reported after HPV vaccination are mild. They include pain and redness in the area of the arm where the shot was given, fever, dizziness, and nausea. Some preteens and teens may faint after getting a shot or any other medical procedure. Sitting or lying down for about 15 minutes after getting shots can help prevent injuries that could happen if your child were to fall while fainting.



Why does my child need this now?

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

CS HCVG15-PTT+111 12/16/2016

DISTRIBUTED BY:

Serious side effects from HPV vaccination are rare. Children with severe allergies to yeast or latex shouldn't get certain HPV vaccines. Be sure to tell the doctor or nurse if your child has any severe allergies.

Help paying for vaccines

The Vaccines for Children (VFC) program provides vaccines for children ages 18 years and younger who are uninsured, Medicaid-eligible, or American Indian/Alaska Native. Learn more about the VFC program at **www.cdc.gov/Features/VFCprogram/**

Whether you have insurance, or your child is VFC-eligible, some doctors' offices may also charge a fee to give the vaccines.

Jacquelyn's story: "I was healthy—and got cervical cancer."

When I was in my late 20's and early 30's, in the years before my daughter was born, I had some abnormal Pap smears and had to have further testing. I was told I had the kind of HPV that can cause cancer and mild dysplasia.

For three more years, I had normal tests. But when I got my first Pap test after my son was born, they told me I needed a biopsy. The results came back as cancer, and my doctor sent me to an oncologist. Fortunately, the cancer was at an early stage. My lymph nodes were clear, and I didn't need radiation. But I did need to have a total hysterectomy.

My husband and I have been together for 15 years, and we were planning to have more children. We are so grateful for our two wonderful children, but we were hoping for more—which is not going to happen now.

The bottom line is they caught the cancer early, but the complications continue to impact my life and my family. For the next few years, I have to get pelvic exams and Pap smears every few months, the doctors measure tumor markers, and I have to have regular x-rays and ultrasounds, just in case. I have so many medical appointments that are taking time away from my family, my friends, and my job.

Worse, every time the phone rings, and I know it's my oncologist calling, I hold my breath until I get the results. I'm hopeful I can live a full and healthy life, but cancer is always in the back of my mind.

In a short period of time, I went from being healthy and planning more children to all of a sudden having a radical hysterectomy and trying to make sure I don't have cancer again. It's kind of overwhelming. And I am one of the lucky ones!

Ultimately I need to make sure I'm healthy and there for my children. I want to be around to see their children grow up.

I will do everything to keep my son and daughter from going through this. I will get them both the HPV vaccine as soon as they turn 11. I tell everyone—my friends, my family—to get their children the HPV vaccine series to protect them from this kind of cancer.

What about boys?

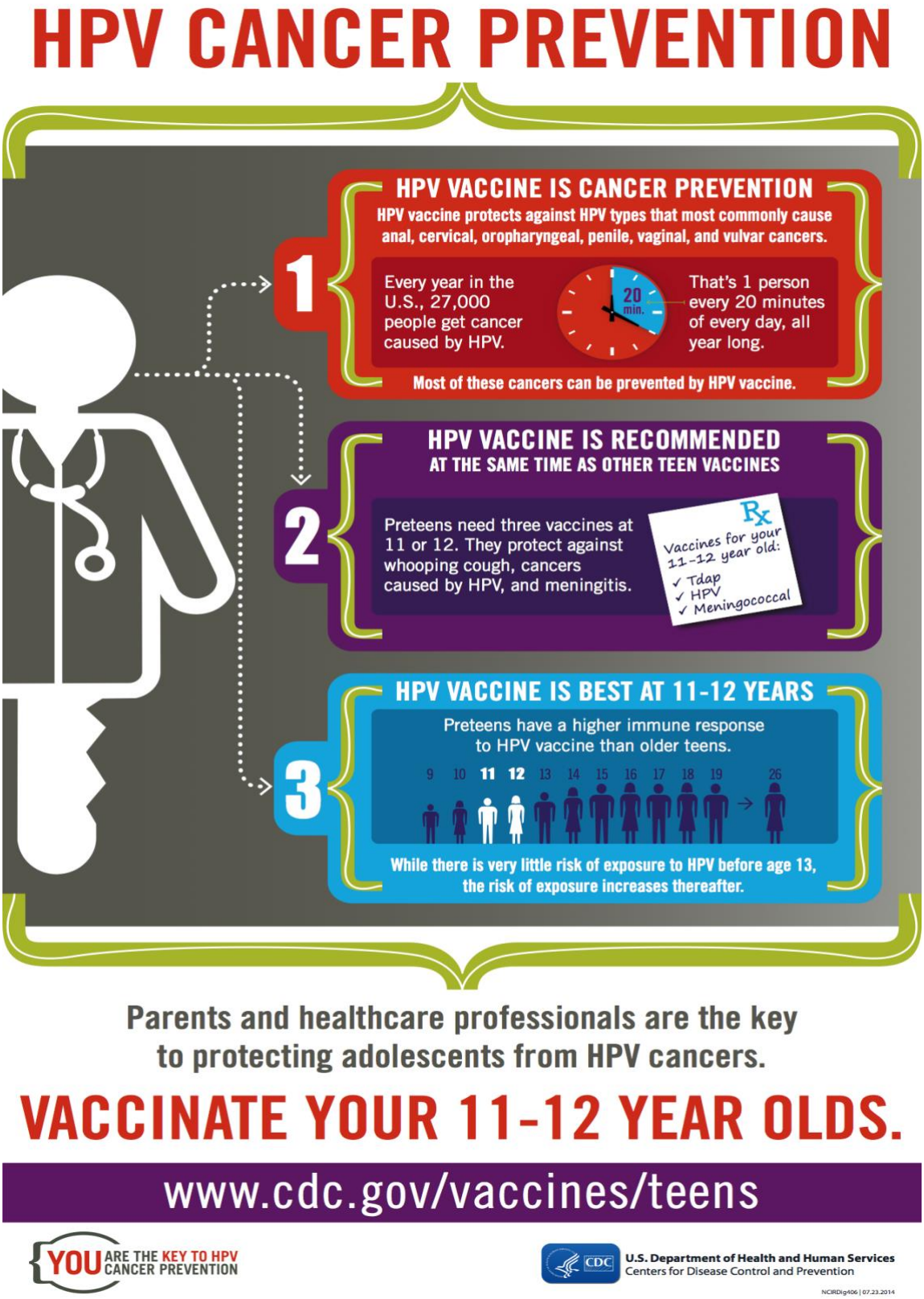
HPV vaccine is for boys too! This vaccine can help prevent boys from getting infected with the types of HPV that can cause cancers of the mouth/throat, penis and anus. The vaccine can also help prevent genital warts. HPV vaccination of males is also likely to benefit females by reducing the spread of HPV viruses.

Learn more about HPV and HPV vaccine at **www.cdc.gov/hpv**

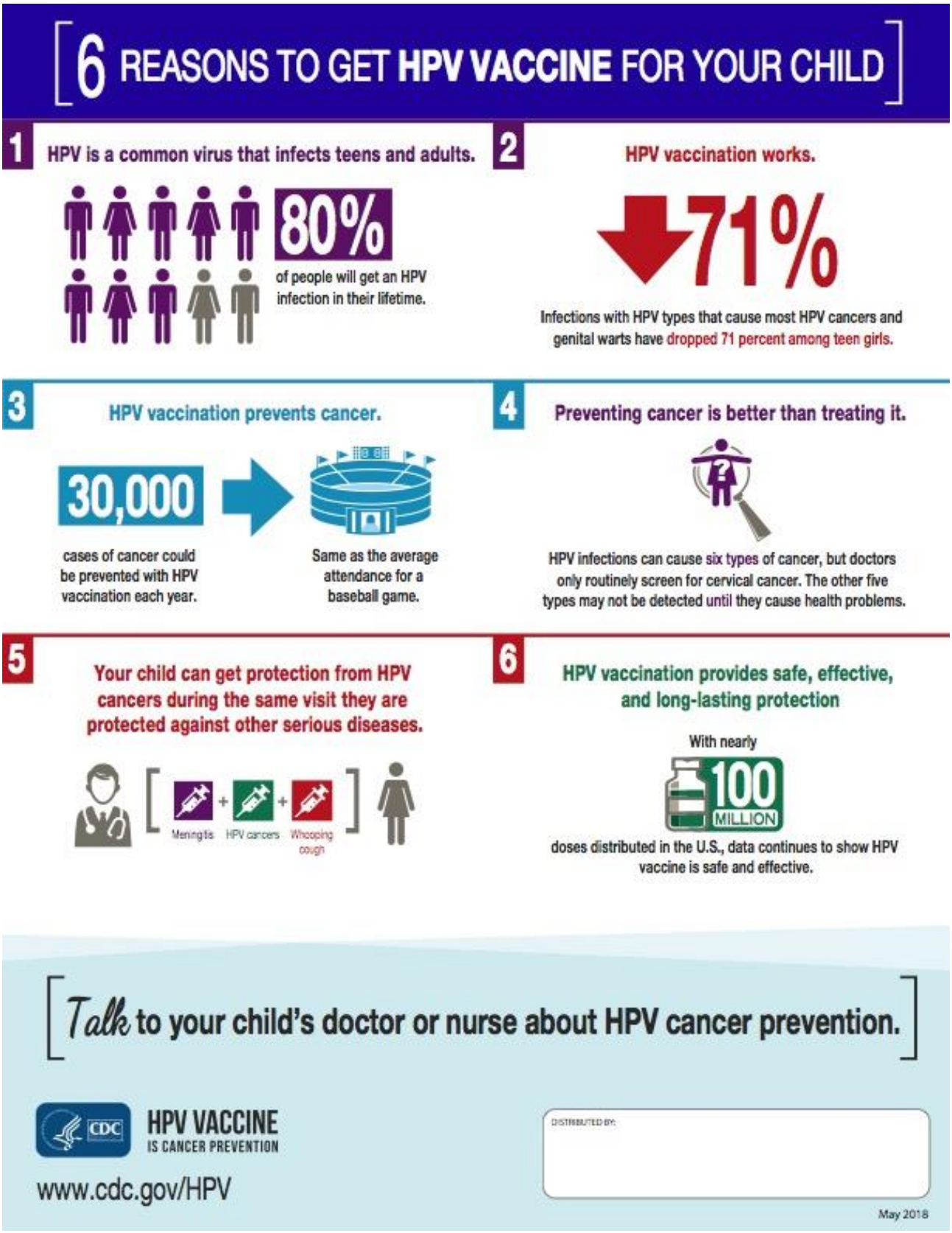
For more information about the vaccines recommended for preteens and teens:
800-CDC-INFO *(800-232-4636)*
www.cdc.gov/vaccines/teens

Appendix G: Promotional Images

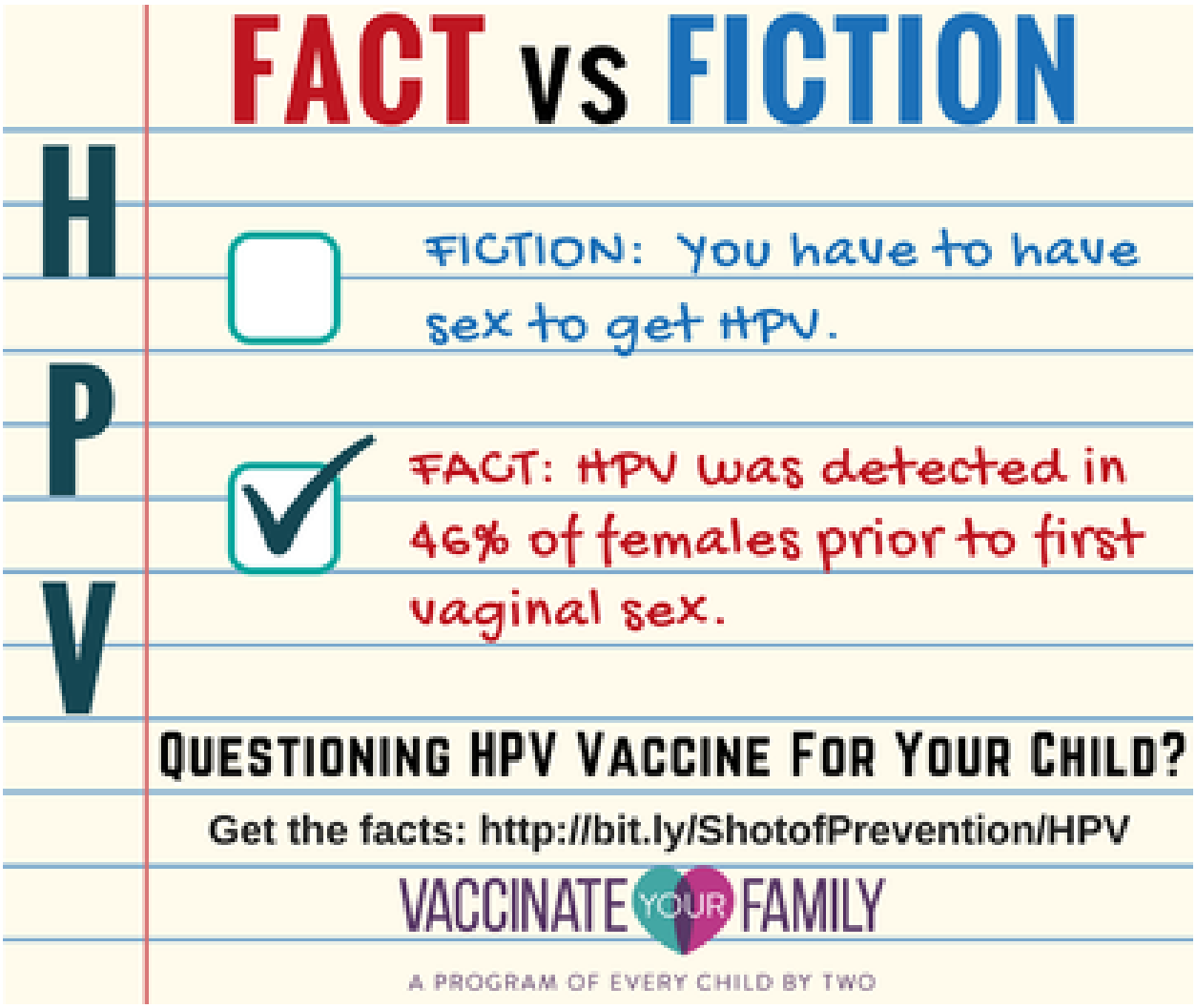
Poster



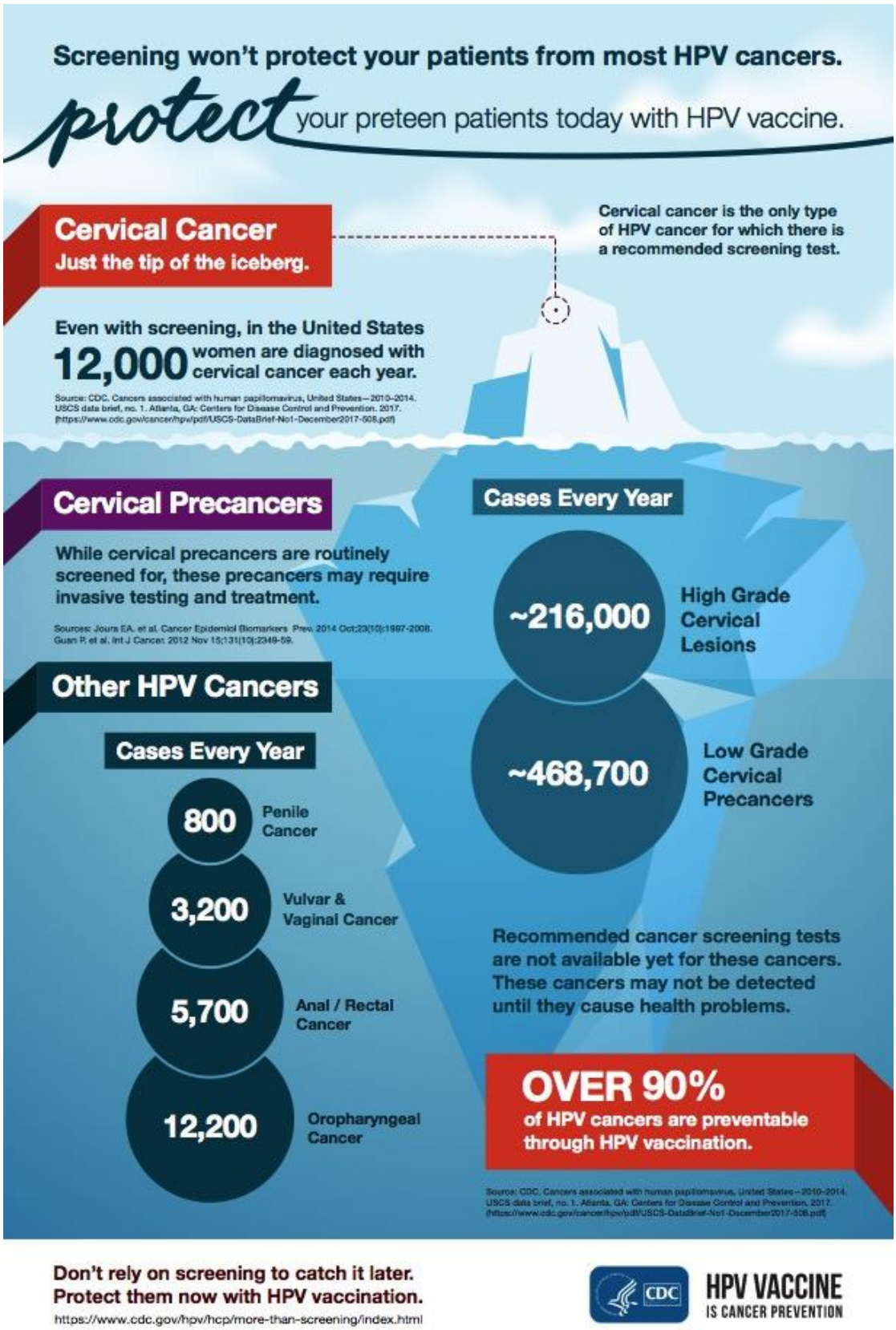
Poster


6 REASONS TO GET HPV VACCINE FOR YOUR CHILD
1
HPV is a common virus that infects teens and adults.
80%
of people will get an HPV infection in their lifetime.
2
HPV vaccination works.
71%
Infections with HPV types that cause most HPV cancers and genital warts have dropped 71 percent among teen girls.
3
HPV vaccination prevents cancer.
30,000
cases of cancer could be prevented with HPV vaccination each year.
Same as the average attendance for a baseball game.
4
Preventing cancer is better than treating it.
HPV infections can cause six types of cancer, but doctors only routinely screen for cervical cancer. The other five types may not be detected until they cause health problems.
5
Your child can get protection from HPV cancers during the same visit they are protected against other serious diseases.
Meningitis
HPV cancers
Whooping cough
6
HPV vaccination provides safe, effective, and long-lasting protection
With nearly
100 MILLION
doses distributed in the U.S., data continues to show HPV vaccine is safe and effective.
Talk to your child's doctor or nurse about HPV cancer prevention.
CDC
HPV VACCINE
IS CANCER PREVENTION
www.cdc.gov/HPV
DISTRIBUTED BY:
May 2018

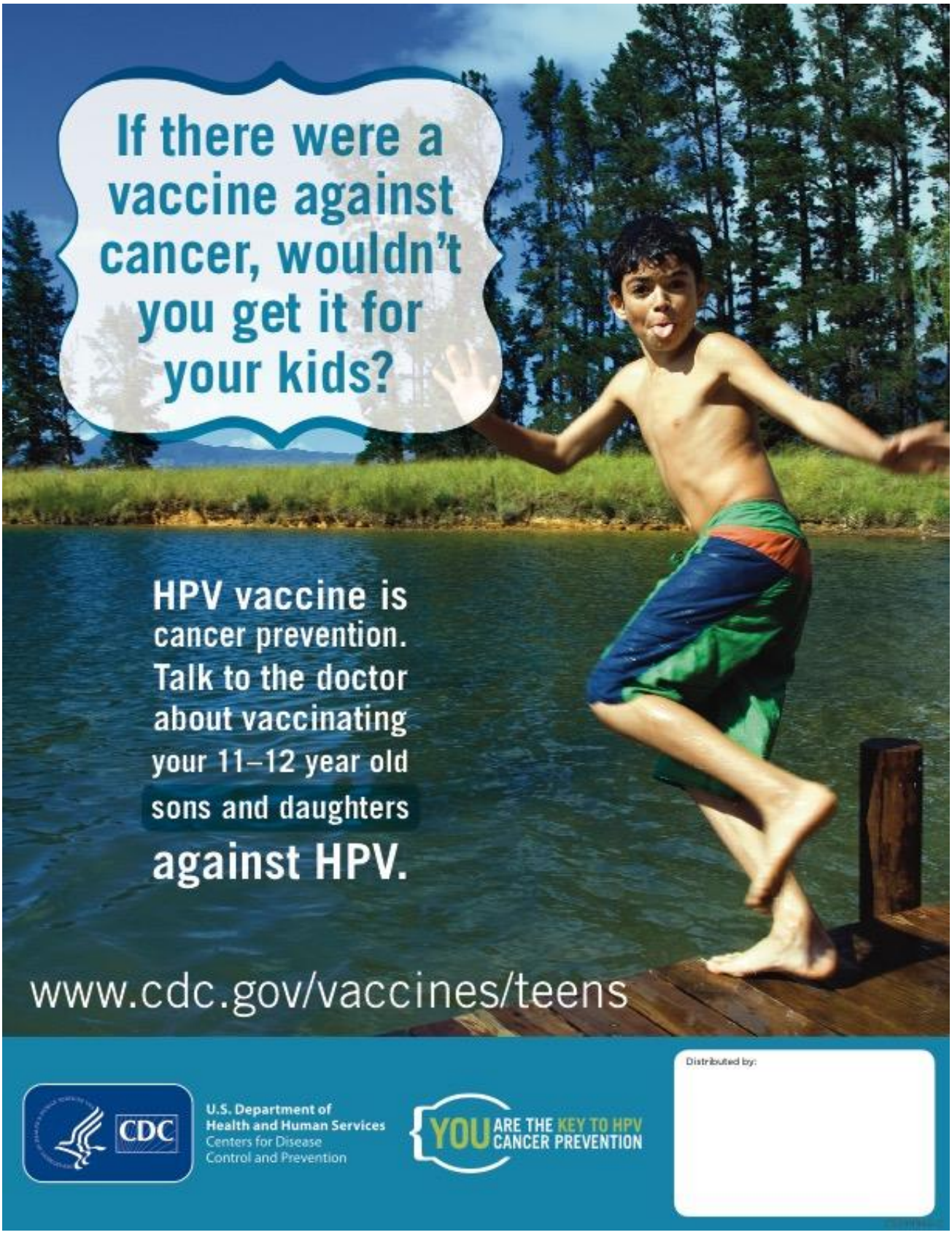
Poster


FACT vs FICTION
H
P
V
FICTION: You have to have sex to get HPV.
FACT: HPV was detected in 46% of females prior to first vaginal sex.
QUESTIONING HPV VACCINE FOR YOUR CHILD?
Get the facts: http://bit.ly/ShotofPrevention/HPV
VACCINATE YOUR FAMILY
A PROGRAM OF EVERY CHILD BY TWO

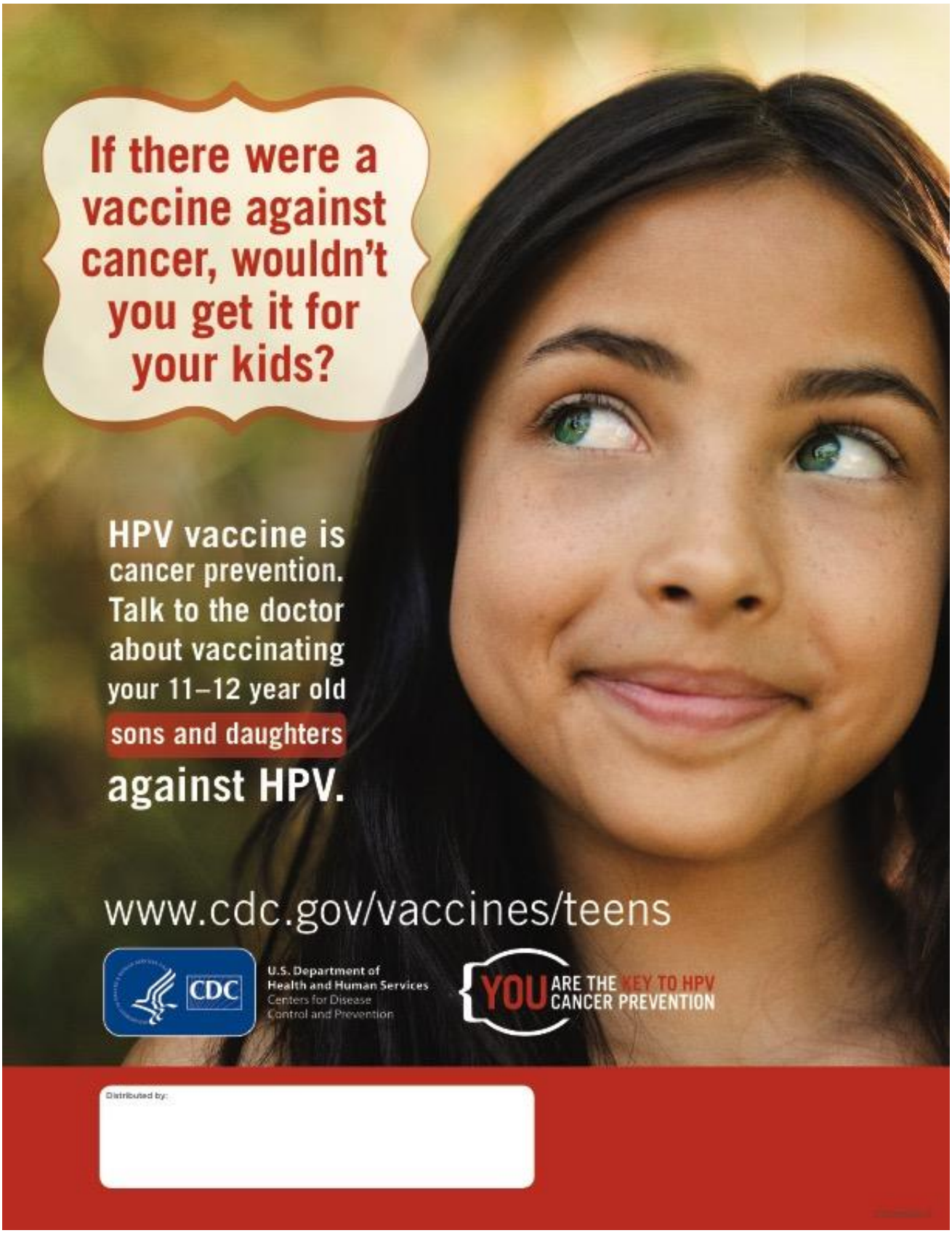
Poster


Screening won't protect your patients from most HPV cancers.
protect your preteen patients today with HPV vaccine.
Cervical Cancer
Just the tip of the iceberg.
Cervical cancer is the only type of HPV cancer for which there is a recommended screening test.
Even with screening, in the United States
12,000 women are diagnosed with cervical cancer each year.
Source: CDC. Cancers associated with human papillomavirus, United States—2010–2014. USCS data brief, no. 1. Atlanta, GA: Centers for Disease Control and Prevention. 2017. (https://www.cdc.gov/cancer/hpv/pdf/USCS-DataBrief-No1-December2017-508.pdf)
Cervical Precancers
While cervical precancers are routinely screened for, these precancers may require invasive testing and treatment.
Sources: Joura EA, et al. Cancer Epidemiol Biomarkers Prev. 2014 Oct;23(10):1997-2008. Guan P, et al. Int J Cancer. 2012 Nov 15;131(10):2349-59.
Cases Every Year
~216,000 High Grade Cervical Lesions
~468,700 Low Grade Cervical Precancers
Other HPV Cancers
Cases Every Year
800 Penile Cancer
3,200 Vulvar & Vaginal Cancer
5,700 Anal / Rectal Cancer
12,200 Oropharyngeal Cancer
Recommended cancer screening tests are not available yet for these cancers. These cancers may not be detected until they cause health problems.
OVER 90%
of HPV cancers are preventable through HPV vaccination.
Source: CDC. Cancers associated with human papillomavirus, United States—2010–2014. USCS data brief, no. 1. Atlanta, GA: Centers for Disease Control and Prevention, 2017. (https://www.cdc.gov/cancer/hpv/pdf/USCS-DataBrief-No1-December2017-508.pdf)
Don't rely on screening to catch it later.
Protect them now with HPV vaccination.
https://www.cdc.gov/hpv/hcp/more-than-screening/index.html
CDC
HPV VACCINE
IS CANCER PREVENTION

Poster


If there were a vaccine against cancer, wouldn't you get it for your kids?
HPV vaccine is cancer prevention. Talk to the doctor about vaccinating your 11–12 year old sons and daughters against HPV.
www.cdc.gov/vaccines/teens
CDC
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
YOU ARE THE KEY TO HPV CANCER PREVENTION
Distributed by:

Poster


If there were a vaccine against cancer, wouldn't you get it for your kids?
HPV vaccine is cancer prevention. Talk to the doctor about vaccinating your 11–12 year old sons and daughters against HPV.
www.cdc.gov/vaccines/teens
CDC
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
YOU ARE THE KEY TO HPV CANCER PREVENTION
Distributed by:

Poster


You're not opening the door to sex.
You're closing the door to cancer.
HPV vaccine is cancer prevention.
Talk to your child's doctor about vaccinating your 11–12 year old against HPV.
www.cdc.gov/vaccines/teens
Distributed by:
CDC
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
YOU ARE THE KEY TO HPV CANCER PREVENTION

Appendix H: Lecture Plan

An Educational Intervention

Time	Activity
15 minutes	Welcome • Consent • Pre-test • Distribution of educational materials
5 minutes	Introduction of the Instructor: Yardena Mandel, BSN, RN Briefing: • Aim/Purpose of lecture • Objectives
40 minutes	Education: • HPV • Vaccine • Statistics Identify barriers to acceptance Address cultural beliefs
15 minutes	Question & Answer session
10 minutes	Closing and Post-test questionnaire
Total time: 1hr 25mins	

Appendix I: Knowledge Pre-test

Increasing HPV Vaccination Knowledge & Intent Among Orthodox Jews

1. The HPV vaccine is routinely suggested for which individuals?
    a) Male and female adolescents at the 11 or 12 year old visit
    b) Female only at the 13 year old well child visit
    c) Males only at the 11 and 12 year old visit
    d) Females only at the 11 and 12 year old visit

2. How many new cases of HPV are expected to occur each year
    a) 14,000
    b) 14,000,000
    c) 140,000
    d) 1,400,000

3. Which recommendation would be the most compelling for you as a parent?
    a) Be informed that your child is due to receive three scheduled vaccines: HPV, MCV4, and Tdap.
    b) Be informed about the mandatory vaccines required for school attendance and be asked if you would like your child to get the HPV vaccine.
    c) Be offered to have your child vaccinated at the 11 or 12 year old checkup or wait until the child is older.
    d) For the practitioner to confide that he vaccinated his own children against HPV.

4. Which three educational points are important to understand about the HPV vaccine:
    a) HPV vaccine prevents STD's, is most effective when started after sexual activity, and it is important to get all 3 shots on time
    b) HPV vaccine is a cancer prevention vaccine, it is most effective when given to 11 and 12 years olds, and it is important to get both shots (2)
    c) It is important to get at least 1 of 3 shots, HPV vaccine is a cancer prevention vaccine, and it should be started after sexual activity
    d) HPV vaccine prevents genital warts, it should be started at 11 and 12 years of age, and it is most important to get the first shot in the series

5. Why is the HPV vaccination recommended to be given to 11 and 12 year olds?
    a) The HPV vaccine provides the strongest immune response when given at that age
    b) It is convenient to give with other required vaccines for school
    c) It is more ideal to be vaccinated prior to first sexual encounter
    d) Both A and B
    e) Both A and C

6. What is the single most influencing factor to vaccinate?
    a) A strong recommendation by the healthcare provider
    b) Strong recommendations from friends and family to get the vaccination
    c) Strong recommendation from your child's school
    d) Reading about the vaccine in a brochure or on posters

7. Why do boys need the HPV vaccine?
    a) HPV vaccination can help prevent future infections that can lead to cancers in males
    b) Males can be carriers and infect females, but are otherwise unaffected by the infection
    c) Males who are vaccinated may be protected against infection, but HPV does not cause cancers in male
    d) HPV related cancers in males are easily screened and can be treated at an early stage

8. What would be your reasoning for not vaccinating your child?
    a) Children within our community are not sexually active prior to marriage, so it is unnecessary
    b) It is not a mandatory vaccine, and therefore is unnecessary
    c) The vaccine is relatively new, so long-term effects are not yet known
    d) Vaccinating our children, may provide a green light for our children to engage in sexual promiscuity
    e) Our community is not at risk of HPV related cancers
    f) Acceptance of the vaccine could lead to community disapproval

9. What are the major safety concerns related to the HPV vaccine?
    a) HPV vaccines may render the patient infertile
    b) HPV vaccines can cause HPV infection or cancer

c) HPV vaccination can cause brain swelling and cognitive decline

d) HPV vaccination may cause mild side effects including: pain, swelling and redness at the vaccination site, fever, nausea, and headache

10. Which three educational points are important to understand about HPV, cervical cancer, and pap smears:

a) HPV is a sexually transmitted infection and pap smears are performed to prevent HPV or cervical precancerous cells

b) HPV is the infection which can cause cervical cancer and pap smears are routinely performed to screen for the presence of HPV and precancerous cervical cells

c) As pap smears detect the presence of HPV and cervical cancer, they are unnecessary until a woman becomes sexually active

d) As pap smears are routinely performed during annual exams to detect the presence of cancer, the HPV vaccine is unnecessary

Appendix J: Knowledge Post-test

Increasing HPV Vaccination Knowledge & Intent Among Orthodox Jews

1. The HPV vaccine is routinely suggested for which individuals?
    a) Male and female adolescents at the 11 or 12 year old visit
    b) Female only at the 13 year old well child visit
    c) Males only at the 11 and 12 year old visit
    d) Females only at the 11 and 12 year old visit

2. How many new cases of HPV are expected to occur each year
    a) 14,000
    b) 14,000,000
    c) 140,000
    d) 1,400,000

3. Which recommendation would be the most compelling for you as a parent?
    a) Be informed that your child is due to receive three scheduled vaccines: HPV, MCV4, and Tdap.
    b) Be informed about the mandatory vaccines required for school attendance and be asked if you would like your child to get the HPV vaccine.
    c) Be offered to have your child vaccinated at the 11 or 12 year old checkup or wait until the child is older.
    d) For the practitioner to confide that he vaccinated his own children against HPV.

4. Which three educational points are important to understand about the HPV vaccine:
    a) HPV vaccine prevents STD's, is most effective when started after sexual activity, and it is important to get all 3 shots on time
    b) HPV vaccine is a cancer prevention vaccine, it is most effective when given to 11 and 12 years olds, and it is important to get both shots (2)
    c) It is important to get at least 1 of 3 shots, HPV vaccine is a cancer prevention vaccine, and it should be started after sexual activity
    d) HPV vaccine prevents genital warts, it should be started at 11 and 12 years of age, and it is most important to get the first shot in the series

5. Why is the HPV vaccination recommended to be given to 11 and 12 year olds?
    a) The HPV vaccine provides the strongest immune response when given at that age
    b) It is convenient to give with other required vaccines for school
    c) It is more ideal to be vaccinated prior to first sexual encounter
    d) Both A and B
    e) Both A and C

6. What is the single most influencing factor to vaccinate?
    a) A strong recommendation by the healthcare provider
    b) Strong recommendations from friends and family to get the vaccination
    c) Strong recommendation from your child's school
    d) Reading about the vaccine in a brochure or on posters

7. Why do boys need the HPV vaccine?
    a) HPV vaccination can help prevent future infections that can lead to cancers in males
    b) Males can be carriers and infect females, but are otherwise unaffected by the infection
    c) Males who are vaccinated may be protected against infection, but HPV does not cause cancers in male
    d) HPV related cancers in males are easily screened and can be treated at an early stage

8. What would be your reasoning for not vaccinating your child?
    a) Children within our community are not sexually active prior to marriage, so it is unnecessary
    b) It is not a mandatory vaccine, and therefore is unnecessary
    c) The vaccine is relatively new, so long-term effects are not yet known
    d) Vaccinating our children, may provide a green light for our children to engage in sexual promiscuity
    e) Our community is not at risk of HPV related cancers
    f) Acceptance of the vaccine could lead to community disapproval

9. What are the major safety concerns related to the HPV vaccine?
    a) HPV vaccines may render the patient infertile
    b) HPV vaccines can cause HPV infection or cancer

c) HPV vaccination can cause brain swelling and cognitive decline

d) HPV vaccination may cause mild side effects including: pain, swelling and redness at the vaccination site, fever, nausea, and headache

10. Which three educational points are important to understand about HPV, cervical cancer, and pap smears:

a) HPV is a sexually transmitted infection and pap smears are performed to prevent HPV or cervical precancerous cells

b) HPV is the infection which can cause cervical cancer and pap smears are routinely performed to screen for the presence of HPV and precancerous cervical cells

c) As pap smears detect the presence of HPV and cervical cancer, they are unnecessary until a woman becomes sexually active

d) As pap smears are routinely performed during annual exams to detect the presence of cancer, the HPV vaccine is unnecessary

Appendix K: E-mail Correspondence for Pre/Post-test Approval

Dr. Becky Epperson DNP, ARNP
Doctor of Nursing Practice at Western Washington Medical Group

HPV research

Dear Dr Epperson,

I am a DNP student at Rutgers University in Newark, NJ. For my DNP project, I am trying to assess if an educational intervention will increase HPV intent to vaccinate within the Orthodox Jewish community. I am writing to ask you for permission to use your knowledge pretest & post-test surveys about HPV, or utilize some of the relevant questions that would pertain to my particular study.

Thank you for your time. I look forward to being in touch.

Best wishes,
Yardena Mandel, BSN, RN

Hi Yardena, thanks for reaching out! You are welcome to use the pre test and post test surveys or any of the questions off of them. Best of luck. Feel free to reach out any time.

Dr Rebecca Epperson, DNP, ARNP, FNP-C

6:56 PM

Appendix L : De Novo Intent Questionnaire

Increasing HPV Vaccination Knowledge & Intent Among Orthodox Jews

1. Do you **intend** to vaccinate your child(ren) against HPV?

   - ☐ Yes
   - ☐ No
   - ☐ Undecided

2. If the answer to question #1 is no or undecided, please state your reason below:

   _____

   _____

Appendix M: Recruitment Flyer

RUTGERS
School of Nursing

PARTICIPANTS NEEDED

DOCTOR OF NURSING PRACTICE GRADUATE RESEARCH STUDY:

Increasing HPV Knowledge & Intent to Vaccinate Among Orthodox Jews

Can a Simple Vaccine Really Help Prevent Cancer???

Please Join us for a 90-minute Educational Event Where we Discuss the HPV Vaccine and How to make the Best Decisions for our Children

A pre- and post-test questionnaire will be administered

WHEN??? Tuesday, November 20th, 2018 at 8:30pm

WHERE??? 88 Reid Ave., Passaic, New Jersey, 07055

Join us for a confidential, anonymous, and culturally sensitive research study

By: Yardena Mandel, BSN, RN

Principal Investigator

yym1@sn.rutgers.edu/yardena25@gmail.com

~ Light refreshments will be served ~

Appendix N: Consent Form

RUTGERS
School of Nursing

I. SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Increasing HPV Vaccination Knowledge & Intent Among Orthodox Jews
Principal Investigator: Yardena Mandel, BSN, RN, Rutgers University School of Nursing

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the Study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

Yardena Mandel is the Principal Investigator (PI) of this research study.

Yardena Mandel may be reached at [redacted] or via email at yym1@sn.rutgers.edu

The study PI, Yardena Mandel will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Who might benefit financially from this research?

There is no financial gain to stakeholders, the Principal Investigator, or Rutgers University from this project.

Why is this study being done?

The aim of this study is to assess the impact of providing an educational intervention on both HPV knowledge and intent to vaccinate among Orthodox Jews.

Why have you been asked to take part in this study?

You have been asked to participate in this study because you are a parent of one or more children, self-defined as an Orthodox Jew, above the age of 18, and are English speaking.

Who may take part in this study? And who may not?

Inclusion criteria include: parents (either male or female) of one or more children, being self-defined as an Orthodox Jew, English-speaking, and at least 18 years of age.
Exclusion criteria include: individuals who are younger than 18 years of age, do not speak English, are not parents of one or more children, and do not ascribe themselves as an Orthodox Jew.

How long will the study take and how many subjects will participate?

The educational lecture is a one-time session, which will take approximately 90 minutes. The population sample projection is about 20-25 participants, as a pilot study.

What will you be asked to do if you take part in this research study?

After completing the informed consent, you will be asked to fill out a demographic survey and knowledge pre-test about HPV. You will then be provided with educational materials and participate in an educational seminar. Upon completion of the educational intervention, you will then complete a post-test and two question tool on intent to vaccinate.

What are the risks and/or discomforts you might experience if you take part in this study?

The potential risks involved in this study, include the possibility of loss of anonymity during the question/answer portion of the forum, but participants will be urged to maintain discretion and not use any names of participants outside of the study site. The site itself is a private residence and will not be made public to people outside of the community.

Another possible risk to participants is the discomfort of the sensitive subject matter of the human papillomavirus and participation involvement in this controversial topic within the Orthodox Jewish community. If you feel uncomfortable with a question, you can skip that question or withdraw from the study altogether. If you choose to opt out of the study at any time prior to completing the survey, your answers will NOT be recorded.

Are there any benefits for you if you choose to take part in this research study?

The benefits of taking part in this study may be increased knowledge about HPV, HPV vaccine and increased parental intent to vaccinate children among the Orthodox Jewish community. However, it is possible that you might receive no direct personal benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?

There are no alternative treatments available. Your alternative is not to take part in this study.

Will there be any cost to you to take part in this study?

There is no cost for participating in this study.

Will you be paid to take part in this study?

You will not be paid for your participation in this research study.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

All data will be collected anonymously. No names or identifiers will be collected. The anonymous data will be stored on a password protected computer by the Principal Investigator. The signed consent forms and data will be maintained by the Rutgers facility in a secured location within the university at 65 Bergen Street SSB 1130. The consent forms will be destroyed six years after completion of the project in accordance with the Rutgers University policy.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

Who can you call if you have any questions?

If you have any questions about taking part in this study, please contact Yardena Mandel via e-mail at yym1@sn.rutgers.edu.

This research project has been reviewed according to Rutgers University IRB procedures for research involving human subjects.

If you have any questions about your rights as a research subject, please contact the IRB Director at (973)-972-3608 Newark.

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

By beginning this study, you acknowledge that you have read this information and agree to participate in this research, with the knowledge that you are free to withdraw your participation at any time without penalty.

Appendix O: Project Timeline

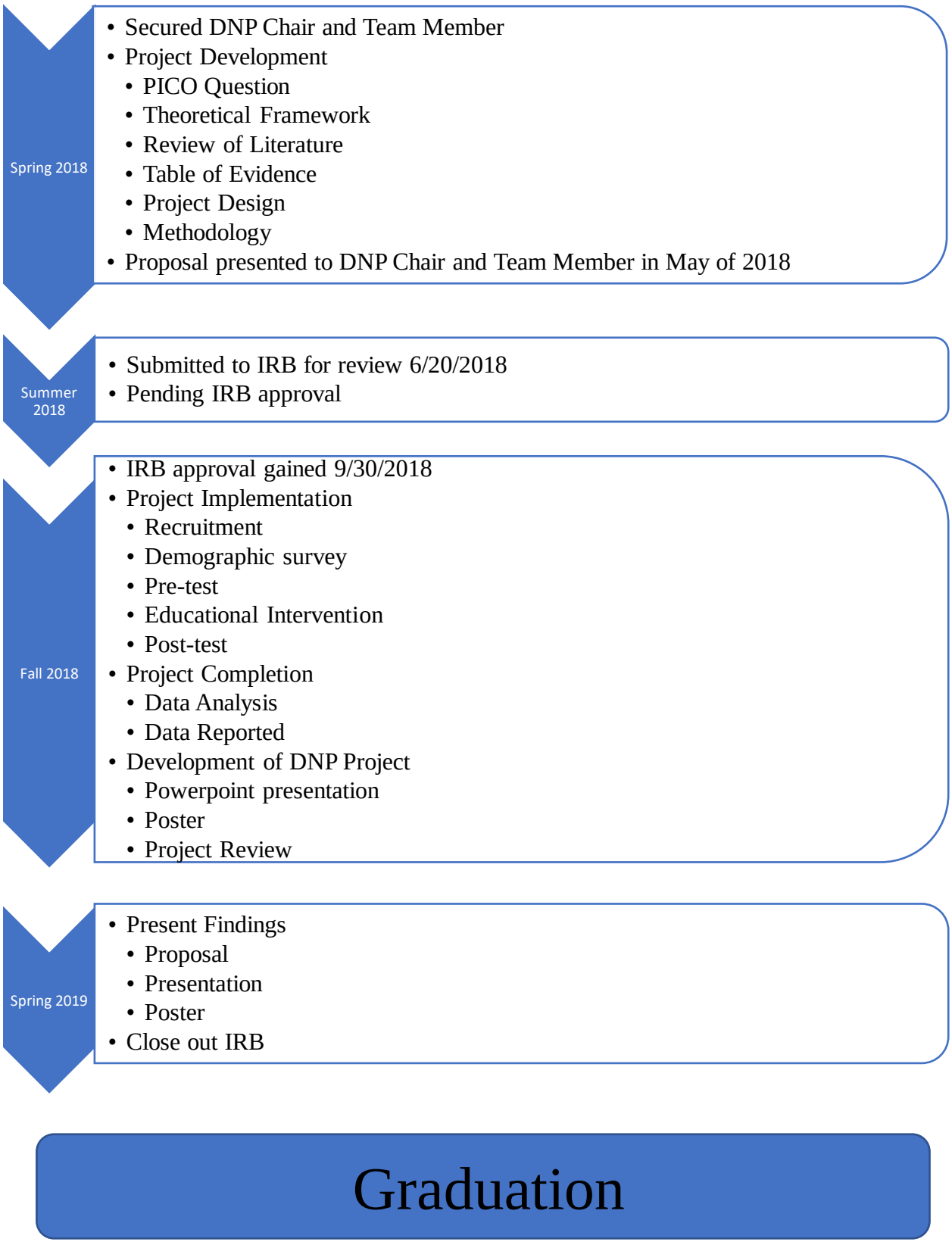


Table 2: Demographics

Table 2

Demographics

Characteristics	Frequency	%
Gender		
Female	14/14	100.00%
Male	0/14	0.00%
Orthodox Jew (self-defined)		
Yes	14/14	100.00%
No	0/14	0.00%
Children?		
Yes	14/14	100.00%
No	0/14	0.00%
Age by range		
18-24	0/14	0.00%
25-34	6/14	42.86%
35-44	7/14	50.00%
45-54	1/14	7.14%
55-64	0/14	0.00%
65 or older	0/14	0.00%
Highest level of education		
High school diploma/equivalent	2/14	14.29%
Associate's degree	0/14	0.00%
Bachelor's degree	4/14	28.57%
Masters	8/14	57.14%
Doctorate or professional	0/14	0.00%
School/work outside community		
Yes	6/14	42.86%
No	7/14	50.00%
N/A	1/14	7.14%
Profession		
Healthcare	4/14	28.57%
Education	3/14	21.43%
Rabbi	0/14	0.00%
Business	2/14	14.29%
Other	5/14	35.71%
Marital status		
Single	0/14	0.00%
Married	14/14	100.00%
Divorced	0/14	0.00%
Widowed	0/14	0.00%
Re-married	0/14	0.00%
Upbringing		

Frum from birth (raised religious)	11/14	78.57%
Ba'al Teshuvah	3/14	21.43%
Ger (convert)	0/14	0.00%

Figure 3: Frequency of Correct Answers

Figure 3. *Frequency of Correct Answers*

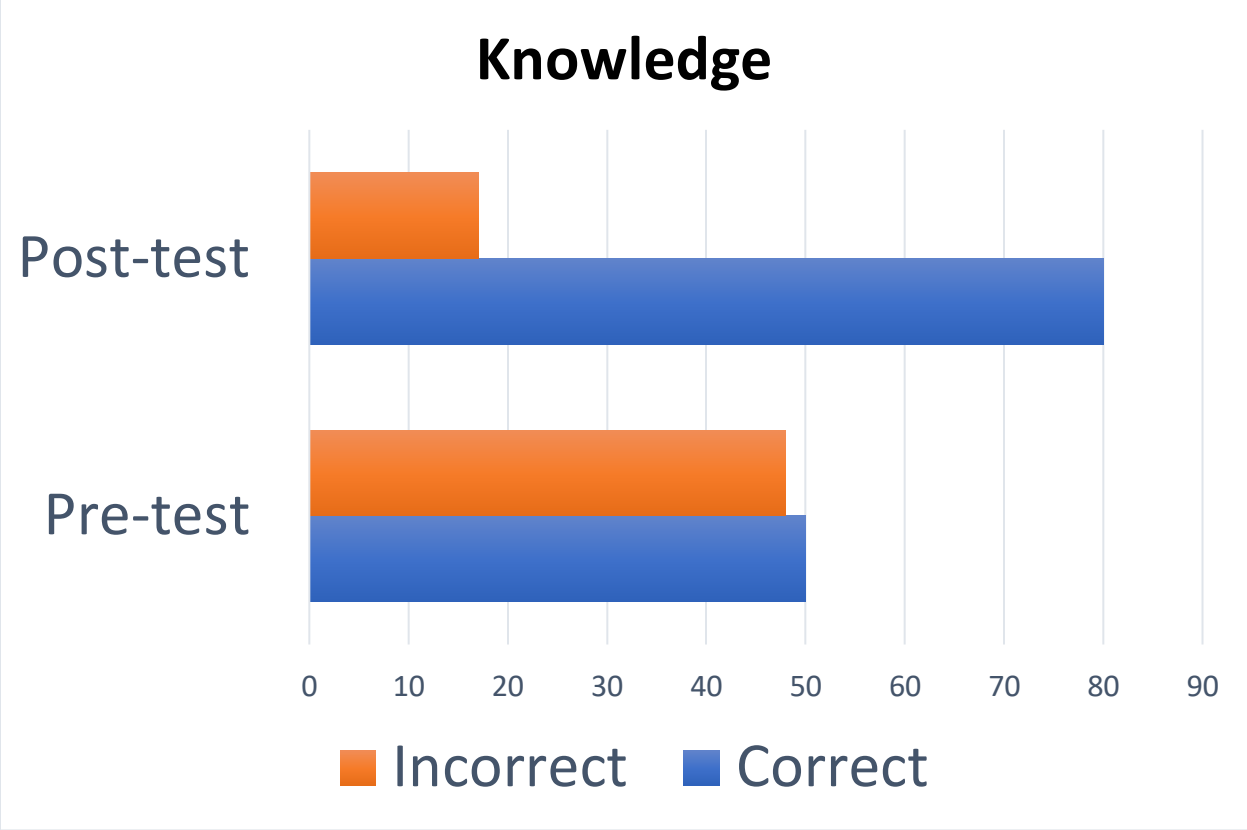


Table 3

Knowledge Pre & Post-Intervention

Mean pre	Mean post	Wilcoxon Signed Rank	p-value
3.64	5.64	6	< 0.05

Figure 4: Intent Pre-test

Figure 4. *Frequency of Pre-test Intent*

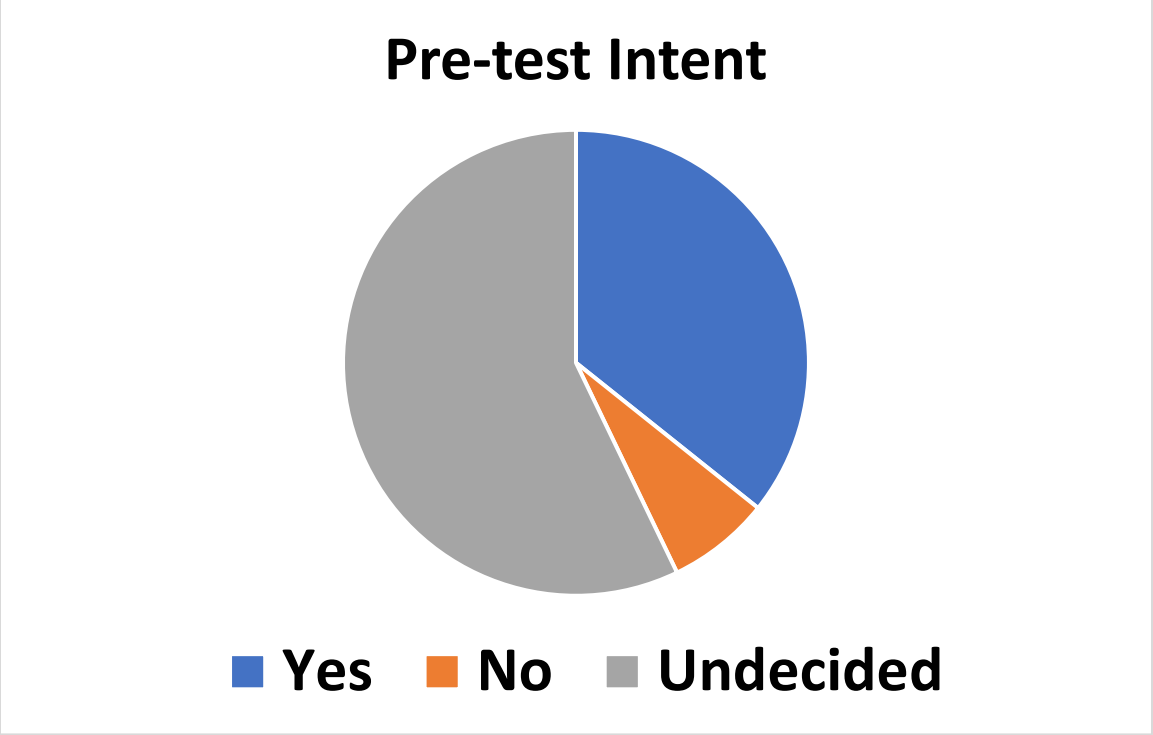


Table 4. *Frequency of Pre-test Intent*

	Intent	Percentages
Yes	5	36%
No	1	7%
Undecided	8	57%

Figure 5: Intent Post-test

Figure 5. *Frequency of Post-test Intent*

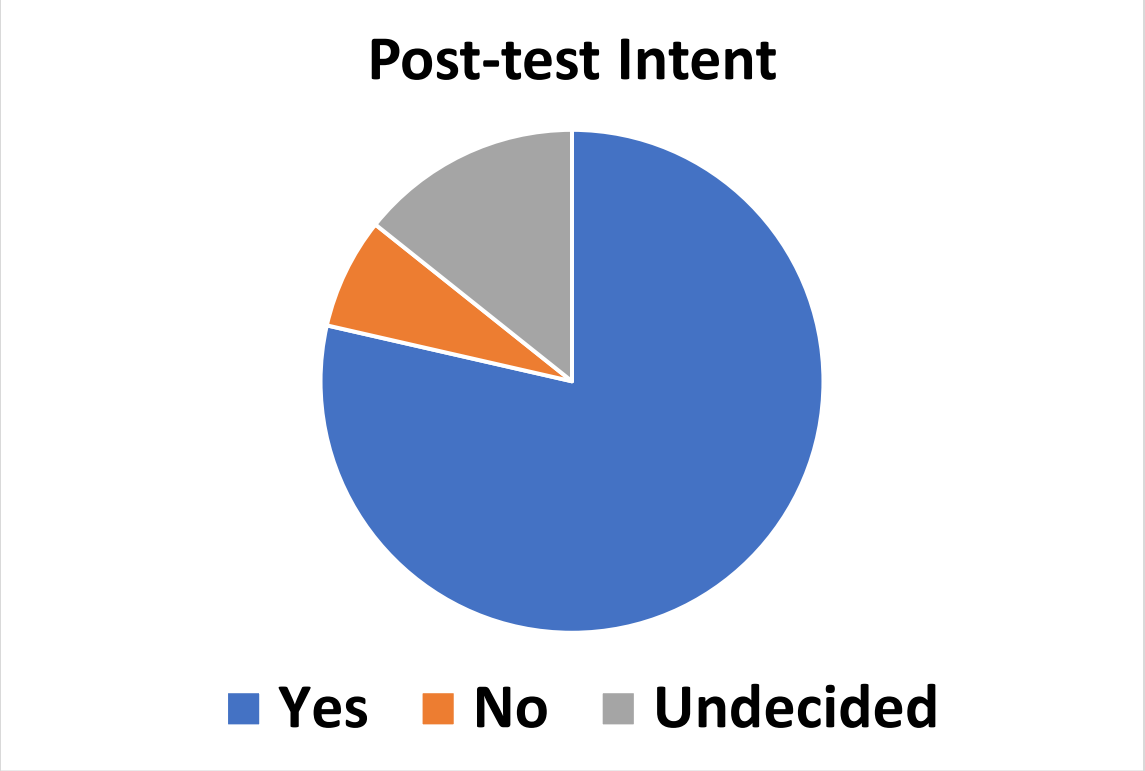


Table 5. *Frequency of Post-test Intent*

	Intent	Percentages
Yes	11	79%
No	1	7%
Undecided	2	14%

Table 6

Comparison of Pre & Post-test Intent

	Yes	No/Undecided	Total
Pre	5	9	14
Post	11	3	14

Table 7

Percent Difference Chi-Square

	Pre	Post	*P* value
	5	11	0.02