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Enhancing Nursing Communication with Patients about HPV and HPV-Vaccination

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Enhancing nursing communication with patients about HPV and HPV-vaccination

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# Table of Contents

Abstract .......................................................................................................................3  
Introduction and Background ...................................................................................4  
Problem, Purpose, and Summary of Plan .................................................................6  
Review of Literature ..................................................................................................7  
Theoretical Framework ...............................................................................................13  
Project Design, Methods, Implementation ...............................................................15  
Description of Implementation Site .........................................................................16  
Pre-intervention Survey .............................................................................................16  
Toolkit and Resource Packet Creation and Delivery ...............................................16  
Assessment of Project Efficacy ...............................................................................18  
Ethics and Human Subjects Protection ....................................................................18  
Results ......................................................................................................................19  
Outcomes ..................................................................................................................20  
Discussion/Interpretations .........................................................................................22  
Suggestions and Future Recommendations .............................................................28  
Conclusion ...............................................................................................................28  
References .................................................................................................................32  
Appendices .................................................................................................................38
Abstract

Background: Human Papillomavirus (HPV) is a common infection, where persistent disease may result in the development of malignancies. Minority populations are at increased risk for developing these cancers. Current guidelines recommend all adolescents receive HPV-vaccination. Patient education plays a critical role in willingness to vaccinate, however despite the availability of print materials, successful HPV-vaccination rates continues to lag behind other adolescent immunizations. Language-congruent interventions in a variety of multimodal implementation strategies have demonstrated efficacy at increasing HPV-vaccination acceptance.

Purpose: This project included an integrative review of literature examining educational strategies aimed at increasing HPV-vaccine acceptance followed by implementation of a toolkit and resource packet detailing concepts critical to unique needs of minority populations aimed at increasing vaccine acceptance. Methods: A toolkit was developed utilizing agency guidelines. A resource packet containing multimedia educational tools was presented. Efficacy of this project was assessed through questionnaires completed pre and post-intervention. Results: Participants felt the toolkit and resource packet were helpful to their practice and positively influenced their ability to provide HPV-education to patients. Yet, one month following the intervention, respondents reported they utilized the information “moderately” or “not at all.” Conclusion: To further examine the efficacy of this toolkit, future distribution of the materials to a larger sample in a variety of settings, including school based health clinics, and to providers who are integral to delivery of HPV-vaccine information would be beneficial.

Keywords: HPV vaccine, HPV immunization, vaccine education, educational intervention, nursing education
Introduction

Background

Human papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the United States and is often asymptomatic. Untreated or persistent infection by certain strains of HPV may lead to malignancies, primarily cervical, oropharyngeal, penile, and anal cancers. While HPV was initially deemed a virus with deleterious effects in women, we now know that men are also at significant risk for developing HPV related cancers as well. HPV causes 17,000 cases of cancer in women and 9,000 cases in men each year (Burden of HPV Cancer, 2015). Despite this prevalence, HPV related cancers are essentially preventable. Current guidelines recommend the two-dose HPV-vaccine series be administered to both adolescent boys and girls beginning at age 11 or 12. This represents a recent change in recommendation which, until October 2016, consisted of a three-shot series. Nationwide four in ten adolescent girls and five in ten adolescent boys remain unvaccinated (HPV vaccine coverage, 2016). Of the adolescents who begin HPV-vaccination, many do not complete the series, having received only a portion of the originally recommended three-shot series. The national vaccination rate for females who have received at least one dose is only 63% and lower in males (50%) (HPV vaccine coverage, 2016). Vaccination rates continue to hover well below the Healthy People 2020 target of 80% (Healthy People, 2016).

The incidence of HPV infection is associated with marked disparities, notably among minority groups resulting in increased healthcare costs, morbidity, and mortality. Cervical cancer incidence is increased in African American women (8.9 per 1,000), Hispanics (9.4 per 1,000), and American Indians and Alaska natives (7.7 per 1,000) compared to 7.5 per 1,000 white women (SEER stat fact sheet, 2013). Additionally, women in certain geographical
locations display increased incidence and mortality from cervical cancer. The highest incidence rates are noted in the Appalachian region, South Atlantic, lower Mississippi valley, and Texas-Mexico border (Horner et al., 2011). Individuals from low socioeconomic status are also disproportionately affected as they are less likely to have health screening tests, may present for healthcare less frequently, and are more likely to engage in behaviors such as risky sexual activity and smoking than those from higher socioeconomic classes. Additionally, they may not speak English well, be unable to coordinate physician appointment times with their work schedules, or be unable to get transportation for health care (CDC, 2014). These barriers alone may decrease opportunities to vaccinate adolescents. Adolescents and parents also self-report barriers to vaccination including the need for additional educational materials about HPV related diseases and HPV-vaccine information such as safety and effectiveness (Guerry et al, 2011; Francis et al 2013).

Patient and family education is associated with increased willingness to vaccinate (Ylitalo et al, 2013; Rahman et al, 2015; Guerry et al, 2011). However, despite availability of educational brochures and online information, vaccination rates continue to be low. Fu and colleagues (2014) conducted a systematic review of the effect of educational interventions on HPV-vaccination acceptance and identify no one type of educational intervention as more effective than another. However, this review highlighted studies primarily evaluating well-educated females with high-literacy levels and of higher socioeconomic status and included only one study in which a culturally-tailored intervention was examined.

It remains uncertain whether specific educational modalities have a greater impact on high-risk populations than others. Tailored educational interventions targeting the unique needs of high risk populations, such as language barriers and cultural differences, have not yet been
evaluated on a large scale. Tailoring education to adolescents’ and parents’ specific needs may increase awareness, acceptance, and subsequent successful vaccine series completion.

Education plays a successful role in increasing the acceptability of HPV-vaccination, yet HPV and related cancers continue to affect a greater proportion of certain populations. Examination of the literature through integrative review is warranted to decrease such disparity. Alternative educational methods may address the unmet needs of high-risk patients by increasing HPV-related knowledge and inclination towards successful vaccination.

**Problem, Purpose & Summary of Plan**

**Problem.**

The risk of future human papillomavirus (HPV) related cancers remains high in individuals unvaccinated against HPV. Minority group populations are at increased risk for developing HPV related cancers. Rates of HPV-vaccination among American adolescents remain low despite national guidelines strongly recommending vaccination. Primary care providers’ recommendation to vaccinate and family education about HPV and vaccine efficacy have a positive impact on a family’s decision to vaccinate.

**Purpose.**

This DNP project sought to evaluate through integrative review whether certain educational modalities were more effective for delivering HPV-vaccine information to at-risk populations, including minority groups. Based on these findings the DNP student provided a pediatric primary care practice with: 1) a toolkit aimed at enhancing provider/patient communication about HPV vaccination; and 2) a resource packet containing alternative educational modalities. Healthcare providers were thus equipped with knowledge, materials, and diverse educational strategies to improve their communication with patients about the HPV-
vaccine.

**Summary of plan.**

The DNP student completed the integrative review and determined the specific implementation practice site needs based on surveys completed by nursing staff at the project site. The resource packet was then tailored to the identified needs of the practice before presentation of the toolkit and resource packet. Efficacy of the toolkit and project were determined by analyzing post-intervention survey questionnaires.

**Review of the Literature**

The cornerstone of this DNP project was an integrative review of literature examining alternative educational modalities for at-risk patients for HPV. *Inclusion criteria:* The review considered studies that included adolescent males and females age 9-18 who are, or will be, eligible for the HPV-vaccine, as well as the parents of these adolescents. *Types of intervention:* This review considered studies that examined educational interventions differing from the standard education about HPV, diseases related to HPV, and the HPV-vaccine. The interventions may occur in medical settings, as well as community settings, such as health centers, and community centers, and patient’s own homes. Comparators for this review were standard care, which includes no tailored educational intervention. *Types of outcomes:* This review considered studies that included the following outcomes: actual HPV-vaccination rate, uptake, completion, as well as HPV-vaccine intention, attitudes, knowledge, and acceptance. *Types of studies:* This review considered both experimental and epidemiological study designs including randomized controlled trials, non-randomized controlled trials, quasi-experimental studies, before and after studies, prospective and retrospective cohort studies, case control studies and analytical cross sectional studies for inclusion. In addition, descriptive
epidemiological study designs including case series, individual case reports and descriptive cross sectional studies were included.

The search strategy aimed to find both published and unpublished studies. Only studies published in English between the years 2010 and 2016 were considered for inclusion in this review. The databases searched included:

- MEDLINE, CINAHL, PsychINFO, PsychARTICLES, ScienceDirect, WileyOnlineLibrary, Virginia Henderson Library of Sigma Theta Tau

- The search for unpublished studies included:

  Google Scholar, New York Academy of Medicine Grey Literature Report

- keywords used:

  HPV vaccine; education; intervention; adolescent; uptake; acceptance

Quantitative data was extracted from papers included in the review, and pooled and grouped according to category of the various educational modalities. The data extracted included specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives. Efficacy of the educational interventions was generalized for purposes of comparison for this review.

The databases keyword search revealed a total of 183 articles. Of these, thirty-nine were identified through analysis of abstracts as applicable to the purposes of this review. Upon further review of each text, seventeen articles met criteria for the review portion of this project. Of the included studies, six were randomized controlled trials, eight were cross sectional studies, one was a case study, one was a prospective cohort study, and one was a quasi-experimental study.
These articles were systematically examined, and data was extracted and synthesized to reveal several themes as described in the following subsections.

**Language or literacy tailored education**

Eight of the examined articles included an English-language alternative as a component to the intervention. Of these, the educational methods differed. Three examined language-specific pamphlets, two DVD videos, one tablet application, one radio segment, one Power Point presentation, and four studies included a language-tailored question and answer session with a healthcare provider as a component to the intervention. Each of these language-specific interventions was associated with an increase in HPV-vaccine intention or acceptability. One cross-sectional study examined use of tablets with language-specific educational multimedia followed by self-persuasion tasks consisting of open-ended vaccination related questions; an 81% HPV-vaccination rate was noted after participation (Baldwin et al., 2016). Foley and colleagues (2015) identified an increased willingness to vaccinate against HPV after non-English speaking participants were exposed to Spanish educational pamphlets, radio segments, and educational sessions at Hispanic community centers. In addition, participants exposed to language specific brochures demonstrated an increase in HPV knowledge and vaccine intention (Obulaney et al., 2016). Ability to understand the educational materials played a key role in decisions about HPV-vaccination. Participants exposed to language-congruent DVDs tailored to specific knowledge gaps of Latino or Korean American parents attained increased knowledge about HPV, improved informed decision making, and decreased perceived decisional conflict compared to parents exposed to CDC vaccination fliers (Valdez et al., 2015). While this was one of the few randomized controlled trials reviewed, this study did not examine actual vaccination uptake or acceptance, and was subject to self-selection bias.
The wording and appearance of educational literature may affect the readability of such documents for certain populations. One study examined the use of a comic book among parents and adolescents as a means of providing HPV education. Parents attained increased knowledge and reported more positive attitudes towards HPV-vaccination after viewing the comic book. Adolescents enjoyed the comic book and reported it as an effective vehicle for learning about HPV (Katz et al., 2014). This method of education may have been more acceptable for a population with lower literacy, or with an aversion to typical informational handouts.

Brueggmann and colleagues (2016) exposed Spanish-speaking mothers to pamphlets outlining “10 easy to understand facts” about HPV. Those who reported comprehension of the information also demonstrated higher HPV-vaccine acceptability ratings.

**Technologies**

Technologies were important to the acceptability of the educational intervention in eleven of the examined studies. Four articles examined use of DVD educational presentations, a tablet, a radio segment, Power Point presentations, an educational website, or a text/email intervention. Appalachian Kentucky women were 2.44 times more likely to complete the three-shot series after exposure to an informational DVD about HPV related disease than women exposed to standard of care in one randomized controlled trial (Vanderpool et al., 2013). Spanish radio segments consisting of announcements focusing on cervical cancer awareness were a component of one intervention that was associated with parent’s greater willingness to have their children vaccinated (Foley et al, 2015). The radio segments were combined with other educational strategies including HPV educational sessions held at community based centers; it remains unclear whether this effect was due to language specific radio segments or a combination of all educational methods.
PowerPoint presentations were associated with an increase in HPV awareness and relation to cervical cancer, as well as increased intention to vaccinate daughters (67% pre-intervention compared to 86% post-intervention) (Li et al, 2015). Parents had higher knowledge self-ratings following PowerPoint presentation in Appalachian North Carolina (Reiter et al, 2011). Spleen and colleagues (2012), completed a cross-sectional study examining a 60-minute PowerPoint presentation and group discussion. One month following the intervention, 100% of participants reported the intervention as helpful, and 44% had initiated vaccination.

Richman and colleagues (2016) conducted a randomized controlled trial to examine the effect of a program consisting of seven text or email HPV educational messages combined with appointment reminders sent to participants. There was no difference between the intervention group and the control group in vaccine uptake as reflected by actual dose completion score. However, knowledge scores were higher in the intervention group.

An HPV infection and vaccination educational website (www.gohealthygirls.org) was developed and piloted with parents of adolescents. The descriptive case report details findings that participants claimed the site was an appealing way to learn about HPV and vaccination (Starling et al, 2014). Unfortunately, this study did not measure actual vaccine intent, but only the ease and appeal of the website.

**Community-based**

Several HPV educational interventions examined studies were delivered as part of community events rather than a singular intervention in a medical setting. One randomized controlled trial examined participants who attended mother/daughter dinners in their Hopi community during which HPV educational presentations were delivered. Participants in the intervention group were more likely to initiate vaccination than those in the control group,
although there was no significant difference between the intervention and control group related to completion of vaccine series (Winer et al, 2016). The examined comic book educational intervention occurred at a YMCA community center in Ohio (Katz et al, 2014).

**Increased education accessibility**

Improved accessibility to educational interventions was a common factor among several of the reviewed studies. The HPV educational website www.gohealthygirls.org allowed participants to access materials from home, and was identified as an appealing way to receive HPV-related education (Starling et al, 2014). Two studies involved directly sending information to participants’ residences which allowed for comfortable and self-paced perusal of information. Tisi and colleagues (2013) mailed educational pamphlets to participants’ homes. A randomized controlled trial focused on multilevel interventions including educational brochure, DVD, vaccine information statements (VIS), and magnet reminders were mailed to participants’ homes (Paskett et al., 2016). This intervention was associated with a small positive impact: 13% of the intervention group received the vaccine compared with 8% of the control group. Another intervention involved educational text messages sent to participants, and those in the intervention group demonstrated higher knowledge scores (Richman et al., 2016). Foley and colleagues (2015) integrated an educational program into the community through monthly education sessions held at Hispanic community centers, and radio segments. The participants in this cross-sectional study were more likely to have knowledge of HPV, vaccination, and be willing to vaccinate their children.

**Interpersonal discussion**

Overwhelmingly, the greatest number of studies included in this review involved the opportunity for interpersonal discussion with a health educator as part of the educational
intervention. Eight studies included either small group discussion, question and answer sessions, or one-on-one counseling as a component to the intervention, or as the sole intervention itself. Participants demonstrated to have increase in knowledge scores as well as increase in vaccination intent after participating in small group informational sessions at a black and minority health fair (Kester et al, 2014). Hispanic participants who received small group education as a supplement to brochure education were more likely to complete the three-vaccine series than a group receiving brochure-education only (Parra-Medina et al, 2015). The combination of language-tailored and small group HPV prevention education in a Hispanic population was associated with increased vaccination intention by 25% following the intervention. While patient-specific vaccine uptake was not measured, HPV-vaccination in the clinic increased from 5.4% to 18% during the intervention period (Obulaney et al, 2016). 100% of participants reported a Power Point and group discussion intervention as “helpful” to their HPV vaccine decisions (Spleen et al, 2012).

The individuals responsible for providing the information during educational sessions filled various roles. In each case, these educators were identified as either nurses, doctors, community health educators, or health professionals.

Theoretical Framework

The Health Belief Model (HBM) (Hochbaum, 1958) suggests that individuals make health related decisions based on their perceptions of risks and benefits of various actions or interventions. Individuals are most likely to take health-promoting behaviors if they believe they are at risk for developing an illness and if they have faith in a particular health-promoting intervention. Concepts influential upon an individuals’ health decision-making are described by six unique constructs. These six constructs of the HBM include: perceived susceptibility,
perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy (Glanz & Bishop, 2010). The HBM provides a framework for why individuals make the decisions they do, and allows the provider to systematically provide education addressing each of the constructs.

The aim of a toolkit is to identify and present critical information to providers which they may, in-turn, utilize to improve clinical care of patients. In this project, the toolkit served to convey the constructs in the HBM as they relate to HPV vaccination, and addressed those constructs when providing health information to patients and families. If healthcare providers deliver education which is grounded in the six constructs of the HBM, the education may have greater influence on families’ decision to vaccinate against HPV. For example, in the realm of “perceived susceptibility,” many individuals misunderstand only females to be susceptible to HPV related diseases because of the cervical cancer risk. The toolkit directly addressed this HBM realm by bringing to providers’ attention the reality of the relation of HPV to oropharyngeal and anal cancers, and citing this point as a key strategy when providing HPV-vaccine education.

As identified through the integrative review, a variety of educational materials and modalities were identified and provided for use in practice through the resource packet. The implementation of the provider toolkit identifying critical teaching points influential to families’ decision-making about HPV-vaccination as well as most effective teaching modalities for high-risk populations is based on the foundation of the HBM. The HBM underpins the development of the toolkit as well because primary care providers assume that patients make healthcare decisions to the best of their ability, based on the information currently available to them (See Table 1)
Table 1
**Health Belief Model Constructs and Toolkit**

<table>
<thead>
<tr>
<th>Construct</th>
<th>Example</th>
<th>How Toolkit Addressed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived Susceptibility</td>
<td>Belief that individual is at risk for contracting HPV</td>
<td>Clearly depict that HPV is spread through both intercourse and oral sex. Both men and women are at risk. Minority populations have increased incidence of HPV-related cancer.</td>
</tr>
<tr>
<td>Perceived Severity</td>
<td>Belief that HPV infection has negative consequences functionally, socially, and/or psychologically</td>
<td>HPV infection may lead to cancers: cervical, anal, oral.</td>
</tr>
<tr>
<td>Perceived Benefit</td>
<td>Belief that receiving HPV-vaccine will protect individual from risks associated with HPV infection</td>
<td>Vaccination before sexual activity may prevent most HPV infections, protect future partners, eliminate need for treatment for HPV-related cancers</td>
</tr>
<tr>
<td>Perceived Barriers</td>
<td>Belief that injection will hurt, or may cause adolescents to be promiscuous</td>
<td>Only minor pain from injection, little risk for sensitivity. No evidence that discussing vaccine may cause adolescents to initiate sexual activity</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>One individual has power to prevent spread of infection</td>
<td>Empower patient to receive first vaccine, and give encouragement to return to complete series.</td>
</tr>
<tr>
<td>Cues to action</td>
<td>Strategies to activate readiness</td>
<td>Provider recommendation of vaccine at same time as other standard 12-year vaccines, importance of vaccination prior to any sexual activity, language-tailored education, small-group informational sessions</td>
</tr>
</tbody>
</table>

**Project Design/Methods/Implementation**

The foundation of this DNP project was an integrative review of literature examining alternative educational modalities for at-risk patients, followed by development of a Toolkit and Resource Packet for implementation in practice. Efficacy of the toolkit’s ability to enhance provider/patient communication about the HPV-vaccine was evaluated after presenting to the practice using a post-intervention survey administered via email. The design and method specifics as related to the implementation site, toolkit, and resource packet development, analysis, and efficacy examination are described in the following sections.
Description of the Implementation Practice Site

The site for implementation of the Toolkit and Resource Packet was a pediatric primary care office in an urban locale north of Boston, MA. The clinic serves a large minority population, with a majority Spanish speaking. This clinic was chosen based on their diverse patient population. Six practice nurses are employed in the facility, and were eligible to participate in this project. Several of the nurses are multi-lingual, allowing them to interpersonally communicate with their patients who may not speak English without the use of translation services.

Stakeholder engagement was initiated by telephone conversation and email discussion. Prior to any implementation at the practice site, a student practicum request agreement was completed by the DNP student, UMass faculty, and nursing administration at the implementation site.

Pre-Intervention Survey

Prior to entering the implementation site, a pre-intervention survey was sent via email to participating nurses (see Appendix). The goal of this survey was to assess importance of vaccination to the nurses’ practice, evaluate their current method of HPV specific patient education, and determine whether certain educational materials were needed. Five quantitative categorical questions were posed and one qualitative question, where respondents could provide descriptive text answers. Analysis of this data was completed by examining each question categorically. Data gathered from the qualitative question was examined for themes.

Toolkit and Resource Packet Creation and Delivery

The aim of the toolkit was to educate providers about key identified concepts and educational modalities critical to families’ decision-making surrounding HPV-vaccination. The
goal was direct, precise delivery of select educational bullet-points and educational modalities deemed influential to families’ decision-making about the HPV-vaccine and in line with the HBM constructs. The presentation and toolkit for dissemination into practice was generated from (a) agency guidelines and fact sheets (e.g. Centers for Disease Control and Prevention, Immunization Action Coalition, American Academy of Pediatrics) specifying recommendations aimed at educating adolescents and families about the HPV-vaccine, and (b) the findings of integrative review. The documents chosen for the toolkit were factual, easy to read, and addressed key points families report as being barriers to HPV-vaccine acceptance.

Simultaneous to this project’s implementation, the Advisory Committee on Immunization Practices (ACIP) released a report detailing a change in recommended dosing schedule from a three-shot series to a two-shot series for individuals younger than 15 years. Because of this recent change, information detailing the updated recommendations about using a two-dose schedule for HPV-vaccination was included in the toolkit as an additional element. The ACIP report was released one month in advance of implementation of the toolkit, thus the complete Morbidity and Mortality Weekly Report detailing this update was included in the toolkit, as well as a verbal presentation of the critical clinical practice changes.

The inclusion of the resource packet in this project was intended to support nurses’ ability to provide education to families using a method tailored to their learning needs. The Resource Packet consisted of a binder of educational resources aimed at targeting a variety of different patients, and as demonstrated to be effective through the integrative review. It was tailored to the “HPV educational needs” as identified in the nurse reported pre-intervention survey. Included in the Resource Packet were a variety of alternative-to-vaccine information statements (VIS) educational modalities, including these handouts in Spanish: one-sheet informational
handouts for less literate individuals, comic books about one Spanish-speaking family’s experience with the HPV-vaccine, and access to an educational video in Spanish. Products were also supplied in English for patients who are English speaking, or for staff who required translation.

Both the Toolkit and Resource packet were presented to participants by verbal in-person presentation by DNP student, with time for question and answer afterwards. In addition to supplying the binder of Toolkit and resources, the nursing director was provided with PDF documents of the materials as well as a web link to the educational videos.

**Assessment of Efficacy of Intervention**

Four weeks following implementation of presentation, toolkit, and resource packet, a post-intervention survey was completed by participants. This six-question survey was intended to assess the effect of the intervention on the nurse’s ability to provide patient-appropriate educational materials. Analysis of this data consisted of systematic breakdown of each question, and categorical assessment of quantitative data. Responses to the qualitative question were examined for themes.

**Ethics and Human Subjects Protection**

Human Subjects screening form was submitted to UMASS IRB and this project was determined not to be considered research under the human subject regulations (see Appendix). Evaluation of current research to determine what practices improves healthcare and this is ethically sound at its core. Summarizing this information for delivery in a toolkit allowed providers access to this information in a clear and concise manner, while allowing them the professional freedom to implement in a way they see fit. There are no ethical risks that have been identified associated with this DNP project.
This project has great ethical implications for health equity. To promote health equity is to provide everyone with the opportunity to attain their best possible health. Inequities are created whenever barriers exist that prevent individuals from accessing care. As this project relates to HPV-vaccination, barriers that may impede vaccination include lack of provider recommendation, need for further education, and provider/patient language incongruence, which can hinder education. According to American Public Health Association Executive Director Georges Benjamin “education is central to be ready to be healthy” (Greenberg, 2015). Evaluating elements essential to effective education about HPV promotes health equity, because it identifies methods providers can utilize to promote health and prevents disease. Evidence based practice reveals that HPV-vaccination prevents disease and is associated with limited risk. Lack of this information is a major limiting factor in a patient’s decision to receive vaccination. By providing this missing education in a method that is easily received by the patient, this barrier is mitigated.

Great disparities exist among diseases related to HPV: they are not evenly spread out amongst the population. Cervical cancer, in particular, affects a disproportionate number of minority women, and those from low socioeconomic classes. Providing information to patients in a clear, concise manner, in a language they understand promotes health equity among groups, and may reduce these known disparities. Providing a more even platform for healthcare delivery promotes ethical practice.

Results

The goal of this project was to improve patient and provider communication regarding the HPV-vaccine. Although an improvement in communication and thus increased patient-awareness of the importance of HPV-vaccination may in-turn increase vaccination rates, this was
not measured as a part of this project and has potential as a focus of future study. Of interest for this project was the perceived importance of HPV-vaccination and education to the nursing staff, any specific educational modalities nurses felt the patient population would benefit from at the project practice, and specific practice needs. The impact of this project on meeting these specific educational needs and providing nurses with tools they can use in practice was assessed using questionnaires and qualitative information obtained during informal discussions.

**Outcomes**

**Pre-intervention survey.**

Of the six nurses employed at the intervention practice, all six completed the pre-intervention survey which focused on daily practices related to HPV education and vaccination at the site. On a scale of one to five (1 - “not very important” to 5 - “very important,”), All six nurses responded that they value HPV-vaccination as “very important” to adolescent health. In addition, all six reported that HPV-vaccination plays a “significant” role in their routine practice. When asked to estimate the percentage of patients who decline HPV-vaccination, 83% of participants estimated 0 - 25% and 17% estimated 75-100% declined HPV-vaccination when offered. In assessing what the practice currently uses for HPV-vaccine education, 100% of the nurses responded “provider explanation,” 67% responded “language-specific literature,” and 17% responded “small group instruction/nurse-provided information.” No participants responded “videos” or “podcasts.” In assessing whether there were specific HPV educational needs at the practice, 100% of nurses responded “language-specific literature,” 33% additionally responded “small group instruction/nurse-provided education,” and 33% responded “videos.” No participants identified “podcasts” as an educational need.
Three participants responded to the qualitative question “please list any barriers you see to HPV vaccination.” Identified barriers by the nurses at their practice included: cultural beliefs; misinformation and “rumors” including parental concern related to the HPV-vaccination encouraging sexual promiscuity, the belief that HPV-vaccination is only for girls, and the worry that risks outweigh benefits; inconsistent provider practice related to initiating the vaccine at 11; and, lack of parent follow through in terms of ensuring the child/adolescent completes the series.

**Post-intervention survey.**

Three of the six participants completed the six question post-intervention survey which focused on the impact of this intervention on the nurses’ ability to provide patient-appropriate HPV educational materials. When asked to rate how helpful the information provided in the toolkit was to the practice, two respondents reported a 4/5 on a Likert scale (1 - “not very helpful” and 5 - “very helpful”). One participant indicated the information was “very helpful.” Two participants responded that the provided information “somewhat” enhanced their ability to provide HPV education to patients, while one respondent indicated it “significantly” enhanced their ability to provide education. 100% of respondents reported that the information introduced them to HPV patient education options that are supplemental to Vaccine Information Statement (VIS) sheets “significantly.” In terms of translation to practice, two nurses have not utilized the information at all to help answer patient’s HPV questions, while one reported utilizing the information a “moderate” amount. All participants thought that HPV-vaccine education was “somewhat” affected by this project.

**Facilitators and barriers.**

Completion of the integrative review was limited only by DNP student time restraints. Acceptance and engagement by the implementation site was limited by practice time constraints,
nurse patient load, and personal interest in the topic of study by the nurses. One time barrier was minimized by offering the surveys by email for completion and the education and toolkit at convenient times without interrupting clinical flow. The toolkit and resource packet were presented at prearranged times in person with time allowed for discussion, and the resources were left at the practice for staff to access when needed, allowing them to peruse at their convenience. Electronic copies of all information were forwarded to participants, aiding in the accessibility of information.

After delivery of the intervention, implementation of specific education suggested in the toolkit required only minor alterations and additions to delivery of information, during patient interactions that would be occurring nonetheless for clinical purposes. In fact, implementation of the resource packet had the potential to save providers’ time, by allowing quick and easy access to appropriate patient-tailored educational materials which may otherwise be time consuming to unearth. No new patients needed to be recruited for this project, nor was patient interaction an element of this project. The minimal financial expenditures in the form of paper supplies for toolkit print-outs were absorbed by the DNP student.

**Discussion/Interpretations**

Through the literature review, a wide variety of educational interventions benefitting at-risk groups were examined. While vaccine acceptability and intention was frequently measured, few studies correlated actual vaccine uptake or vaccination rates following the interventions. Most studies did report that there was an increase in HPV related knowledge, vaccine acceptance, and even vaccine intent following implementation of the interventions. However, there was no way to determine if actual successful vaccination was achieved. Educational
interventions are likely to prove some benefit if the recipient is accepting of the education and feels invested in the topic.

Because of the great variety of educational interventions studied in the relatively few number of articles available, no conclusions can be drawn about certain modalities providing more benefit in comparison to others. However, opportunities for interpersonal communication between patient and provider was a link among many of the studies, an ideal time to address HPV related questions or concerns. While one is unable to directly correlate this provider/patient communication with increased acceptability separate from other educational interventions, it was noted as a common aspect of the effective interventions. Patient/provider communication is the trend that enables nurses to positively influence practice. Nurses play an integral role in the successful immunization of populations, both by direct administration of the vaccine, and by providing education. They provide vaccine education both formally in the clinic and informally in the community. By preparing nurses with streamlined education about patient-reported learning needs, they become well-positioned to deliver this education to families through their daily interactions.

The pre-intervention questionnaire provided information that allowed for the tailoring of the resource packet with specific tools nurses reported they may find helpful to their practice. This element provided some form of control and was intended to maximize the efficacy of the toolkit through not only meeting the identified need, but also by ensuring nurses were engaged and invested in the components of the resource packet. Through this survey, most staff reported a desire for different language-congruent print materials, and several thought videos or small-group nurse led discussion may be helpful. This clear request for alternative educational modalities highlights nurses’ perception of opportunities for improving HPV education, and may
shed insight into the mechanisms that may be most helpful for the diverse patient populations they treat.

Limitations of this project include the small sample which makes interpretation of the impact of this project limited. However, preliminary results showed promise. Of the 50% of participants who responded to the post-intervention survey, they unanimously felt that the information provided through this intervention was helpful to their practice and positively influenced their ability to provide HPV-education to patients. Most notably, respondents reported that this project significantly improved their awareness of HPV-education options that could be provided in addition to the VIS sheets routinely provided to patients in this practice. The composition of patients served at this clinic is comprised of a large percentage of Spanish-speaking individuals, who may directly benefit from the addition of some of these alternative educational strategies. Clinician awareness is a critical component of recommending certain interventions, thus increasing this awareness is likely to increase the incidence with which the interventions are utilized with patients.

In addition to the quantitative information obtained through surveys, qualitative information was obtained through question/answer sessions following implementation of the intervention. Immediately following presentation of the toolkit and resource packet, informal discussions were held to elicit anecdotal information from participants, as well as provide further HPV-specific nursing education as needed. These responses provide further insight into the efficacy of the toolkit, and suggestions for future applications. All six of the participants provided feedback about the perceived usefulness of the tools, as well as suggestions for how to disseminate the data to patients, and other healthcare providers.
The overall consensus among staff about the education toolkit and resource packet was positive, particularly for future applicability of the various language-congruent resources. Overwhelmingly, participants reported that the patient population of the clinic would be especially receptive to certain Spanish handouts provided, highlighting that they may be easier for patients to read and understand than what is routinely offered currently in the clinic. Two staff members commented on the visually appealing one-page informative sheet as being particularly beneficial to families in the practice with limited literacy. Respondents indicated through the post-intervention survey their perception that HPV-vaccine education was “somewhat” affected by this project. Clearly, nurse awareness of different educational strategies was increased, however actual implementation at the patient level was infrequent. The reported “somewhat” degree of efficacy presents opportunity for future examination to determine which specific aspects of HPV-education were realized through this project.

While only two nurses reported via the pre-intervention survey that they would find Spanish videos helpful for patient education, during discussion the nurses unanimously reported their perception that videos may be a helpful tool. One participant did suggest one possible occasion when videos could be utilized: during the time patients are waiting for the providers to come to the exam room. However, she further explained that the need for additional HPV education is typically not realized until after the conclusion of the provider visit. All other participants believed that time constraints in the clinic would prevent utilization of video education. The use and efficacy of videos for teaching thus deserves further study.

Several nurses did comment on their personal sense of limited ability to assess the patient’s need for additional educational resources based on their assumption that the providers frequently supplied as much educational information as the patients needed. There were few
instances where families directed vaccine questions to nurses rather than the provider. In general, the nurses were eager to identify resources their patients would benefit from and willing to present these additional resources to those patients in need; however, they felt that overall patients were accepting of HPV-vaccination after the recommendation by the provider.

Despite the reported belief of the participants for this project being helpful and influential to the practice of providing HPV-education to patients, respondents reported utilizing the information either “moderately”, or “not at all.” It is important to note that the HPV vaccination rate for this clinic is higher than the state average which implies that at some point a majority of patients are being offered vaccination. The reported current practice at this facility is recommendation of the HPV-vaccine equally and in the same way as the other adolescent immunizations. This practice is in-line with evidence-based strategies suggested by the CDC for increasing HPV vaccination rates and implementing best evidence-based recommendations aimed at improving rates. One nurse reported her beliefs that because this community population is generally underserved, the patients are eagerly receptive to the medical care that is offered, thus less likely to decline immunizations that are recommended.

In different clinical settings, standing orders have been implemented as a strategy to improve HPV-vaccination rates. A Standing Order is a protocol enabling assessment of vaccination status and subsequent administration (if needed) without a direct physician’s order. In the case of standing orders, immunizations may be administered during an office visit by nursing staff prior to the patient meeting with the provider. In Massachusetts, LPNs and RNs may administer vaccines under standing orders, and the Massachusetts Department of Public Health provides a model for implementing this in clinic (Commonwealth of Massachusetts, 2017). This strategy may free up physician and Nurse Practitioner time through placing some
the vaccine education responsibilities on nursing staff, who also administer the vaccines. In settings where Standing Orders are in place, it is plausible that the nursing staff may more thoroughly utilize the information presented through this project because of the increased responsibility to provide HPV vaccine education to patients.

During discussion, several participants requested additional information about the recent recommendation change from a three-dose HPV series to two doses. While educational materials were supplied as part of the toolkit, many participants were not aware of the evidence resulting in the recommendation modification. This request for information suggests the need to further educate clinicians about the evidence behind the change in recommendation. Overwhelmingly, participants were optimistic that this recent change will increase vaccine acceptance and successful vaccination rates.

Results from the information obtained through questionnaire and discussion indicates that the toolkit is an effective intervention to raise awareness about various educational mechanisms that can be utilized with different patient populations. The in-person delivery of the material was well-received and effective, allowing for further exploration of the topic, as well as the opportunity for further staff education regarding current immunization guideline changes. Based on the information available, this project had limited sustained effect on the delivery of information, as few nurses reported utilizing the information for patient education one month following implementation. To further examine this toolkit as a method for increasing awareness and improving communication between patients and nurses, this could be implemented across a larger sample and include diverse populations ethnically, racially and socioeconomically. Additionally, implementation of this project in a setting where nursing staff consistently provide more vaccine education could prove beneficial.
Suggestions and future recommendations.

The interest and engagement by the nurses, as well as their contribution about perceived patient preferences for educational interventions demonstrates that nurses play an integral role in educating about HPV-disease and vaccination. Their interest and engagement during the post-intervention discussion sessions clearly depicts an interest in the subject matter, and a willing receptive audience. The wide variety of practice settings and integration of nurses into the community presents the opportunity to promote sustained patient education through first educating this ready and willing audience of health professionals.

This project may be expanded in the future through distribution of the toolkit and resource packet to a variety of clinic settings, including school based health clinics, and to providers who are integral to delivery of HPV-vaccine information. While the DNP student shared the purpose of this project and had informal discussion with several physicians and nurse practitioners at the implementation site, they were not direct recipients of the intervention. Seeking out practices where nurses are the primary educators prior to administration of vaccinations such as settings where Standing Orders are implemented could serve to have a greater impact. Additionally, delivering this toolkit and resource packet directly to the providers who place orders for the vaccine (physicians, nurse practitioners, and physician assistants) may also have beneficial impact.

Conclusion

HPV remains a common sexually transmitted viral infection, affecting an estimated 79 million Americans currently. Despite the availability and recommendations of immunization, rates of HPV-vaccination remain low. The risk of future HPV related cancers is increased for
individuals who remain unvaccinated against HPV, with certain minority populations at increased risk for developing these related cancers.

The purpose of the DNP project was to evaluate the efficacy of educational modalities at providing HPV-vaccine information to at-risk populations, and to provide a toolkit and resource packet aimed at enhancing provider/patient communication about the HPV-vaccine in addition to providing various options for educational strategies.

Through integrative review, the common theme of patient/provider communication was identified as an integral component to effective HPV-education, and nurses were provided with a toolkit and resource packet of various patient educational materials to utilize during their patient education encounters. Through survey questionnaire and informal discussion with participants, the impact of this intervention and toolkit was analyzed. Based on results of the questionnaire and discussion, this toolkit was determined to be an effective way to introduce nurses to a variety of HPV educational materials they may find useful with their patient populations. Nurses were interested and engaged in the topic and invested in identifying educational materials their patients may benefit from. However, participants at the study site infrequently utilized the educational materials with patients one month following intervention which merits further consideration. The project’s impact on patient/provider communication about HPV would benefit from future study specifically implementing the toolkit on a broader scale, in a setting with already identified gaps in staff awareness of alternative educational materials.

Dissemination of this project is multifactorial, and encompasses three settings: the community, with other professionals in practice, and with scholars. While this project directly examined the impact of a toolkit on nurses’ ability to provide alternative educational modalities to high-risk populations, outside of the clinic setting the DNP student educated her local
community on a more basic level. Through informal daily interaction with community members throughout the duration of this project, HPV infection and vaccine education was discussed. A personal observation of friends, colleagues, and parents’ skepticism about the HPV-vaccine and the resulting hesitation to have their children vaccinated inspired the DNP student to pursue this project. Engaging in social conversation with laypersons and networking with community members fosters the education of immediate community members. Involvement in professional conferences and the Massachusetts HPV/cervical cancer awareness coalition presents opportunities to share the results of this project. Dissemination at the community level cannot be trivialized. Conversation increases awareness of the importance of the vaccine, and risks associated with acquiring the disease. Normalizing the conversation about HPV and related cancers may inspire individuals to be comfortable to have further conversation with their healthcare providers. Finally, discussions about the availability of educational materials may inspire people who would benefit from such materials to seek them out, or acquire them for family members.

While completing the project at the implementation site, healthcare professionals including nurses, physicians, and management were impacted. The goal was to increase medical professionals’ awareness of the great variety of alternative educational materials for high-risk HPV individuals, as well as the ease of accessing this information. By increasing providers’ awareness, the hope is they will in-turn use these materials with their patients, who will benefit by an increased understanding of the information. By providing electronic versions of the variety of educational materials, as well as direct access to the videos, the goal was sustainability: allowing staff access to the information, as well as an easy ability to share with others.
Results of the integrative review are important, particularly because it highlights the critical role providers play in educating patients about the HPV vaccine. Because of the limited generalizability of findings to the general population, conducting this project on a larger scale would be suggested prior publication of any resulting information. Further dissemination plans include directly sharing the results from the analysis determining the efficacy of the toolkit and resource packet implementation with leadership from the implementation site. Scholarly dissemination will be further realized through poster presentation during UMass Amherst Nursing Scholar day with student colleagues and academic faculty.
References


Li, J., Kang, L. N., Li, B., Pang, Y., Huang, R., & Qiao, Y. L. (January 01, 2015). Effect of a group educational intervention on rural Chinese women's knowledge and attitudes about human papillomavirus (HPV) and HPV vaccines. *Bmc Cancer, 15*.


ENHANCING HPV-VACCINE COMMUNICATION

Cancer Epidemiology, Biomarkers & Prevention: a Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology, 25, 4, 593-602.


Burlington, MA: Jones & Bartlett Learning
MEMORANDUM

To: Elizabeth Love, College of Nursing
From: Human Research Protection Office
Date: July 28, 2016

Project Title: The Effect of Tailored Education on HPV Vaccine Uptake and Acceptability in Adolescents in Comparison to Standard Education: An Integrative Review and Toolkit for Practice

IRB Number: 16-75

The Human Research Protection Office (HRPO) has evaluated the above named project and has made the following determination:

☐ The activity does not involve research that obtains information about living individuals.

☐ The activity does not involve intervention or interaction with individuals OR does not use identifiable private information.

☒ The current activity is not considered research under the human subject regulations. (Research is defined as "a systematic investigation designed to develop or contribute to generalizable knowledge."

☐ The activity is determined to meet the definition of human subject research under federal regulations and requires submission of applicable materials for IRB review.

For activities requiring review, please see our web pages for more on types of review or submitting a new protocol. For assistance do not hesitate to contact the Human Research Protection Office at 545-3428 for assistance.
Pre-Intervention Survey

1. How valuable do you believe HPV vaccination is to adolescent health?
   1 - Not very important
   2
   3 - Somewhat important
   4
   5 - Very important

2. To what extent is HPV vaccination a routine part of your practice?
   [ ] Not at all
   [ ] Somewhat
   [ ] Moderate
   [ ] Significant

3. What percentage of patients decline HPV vaccination? (estimate)
   [ ] 0-25%
   [ ] 25-50%
   [ ] 50-75%
   [ ] 75-100%

4. What do you currently use for HPV vaccine education? (check all appropriate)
   [ ] Provider Explanation
   [ ] Small group instruction/nurse-provided information
   [ ] Language specific literature
   [ ] Videos
   [ ] Podcasts

5. Are there specific HPV educational needs? (check all appropriate)
   [ ] Small group instruction/nurse-provided education
   [ ] Language specific literature
   [ ] Videos
   [ ] Podcasts

6. Please list any barriers you see to HPV vaccination
Post-Intervention Survey

1. How helpful was the information provided in the toolkit for your practice?

[ ] Not at all
[ ] Somewhat
[ ] Moderate
[ ] Significant

2. To what extent did the information provided enhance your delivery of HPV education to patients?

[ ] Not at all
[ ] Somewhat
[ ] Moderate
[ ] Significant

3. To what extent did the information provided introduce you to HPV patient education options that are alternative to VIS sheets?

[ ] Not at all
[ ] Somewhat
[ ] Moderate
[ ] Significant

4. Have you utilized the provided information to help answer patient’s HPV related questions?

[ ] Not at all
[ ] Somewhat
[ ] Moderate
[ ] Significant

5. Do you think HPV vaccine education was affected at all by this project?

[ ] Not at all
[ ] Somewhat
[ ] Moderate
[ ] Significant

6. Please list any comments or suggestions
Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices

Elaine Minkes, MD, Abelson Kemp, MD, FACP, and Marcia M. MacCartney, MD

Introduction

Vaccination against human papillomavirus (HPV) is re-
mended to prevent HPV infection and HPV-associated diseases, including cervical cancer. Routine vaccination with 9-valent HPV vaccines is recommended for persons aged 9 through 26 years (1). This report provides re-
mendations regarding use of 9-valent HPV vaccines in the 0-, 2-, and 6-month dosing schedules (2DSC) used in the Advisory Committee on Immunization Practices (ACIP) HPV Vaccine Work Group (3). The recommendations of the work group were published in 2015 and 2016 (2, 3). This report includes new recommendations for use of a 2DSC for eligible 9-vaccines and a reminder that HPV vaccination is recommended for persons who initiate the vaccination series at ages 9 through 26 years and for immunocompromised persons.

Background

HPV infections cause cervical, vaginal, and vulvar cancers in women; penile cancer in men; and oropharyngeal and anal cancers as well as genital warts in both men and women (4).

Recommendations for use of vaccines in children, adolescents, and adults are developed by the Advisory Committee on Immunization Practices (ACIP). ACIP is chaired at a federal advisory committee to provide expert advice and guidance to the Director of the Centers for Disease Control and Prevention (CDC) on use of vaccines and related agents for the control of vaccine-preventable diseases in the civilian population of the United States. Recommendations for use of vaccines in children and adolescents are harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American Academy of Ophthalmology and Genitourinary (AOOG). Recommendations for use of vaccines in adults are harmonized with recommendations of AAFP, AAOOG, and the American College of Physicians (ACP). ACIP recommendations approved by the CDC Director become agency guidelines on the date published in the Morbidity and Mortality Weekly Report (MMWR). Additional information about ACIP is available at http://www.cdc.gov/vaccines.

Three HPV vaccines are licensed for use in the United States. All are noninfectious. Quadrivalent and 9-valent HPV vac-
cines (4vHPV and 9vHPV, Gardasil and Gardasil 9, Merck and Sanofi Pasteur, respectively) are recommended for use in females and males aged 9 through 26 years (5). Biologics HPV vaccine (Biologics HPV, Corning/Ingenus/Biogen, Boston, Massachusetts) is licensed for use in females aged through 25 years. All 3 vaccines are approved for use in the United States. The majority of all HPV-associated cancers are caused by HPV 16 or 18, types targeted by all 3 vaccines. Biologics HPV targets against these and additional important HPV types (31, 33, 45, and 52) to which 9vHPV has been approved for administration in a 3-dose series at intervals of 0, 1, 2, and 6 months. In October 2016, after considering new clinical trial results (4), the Food and Drug Administration (FDA) also approved 9vHPV for use in 2-dose series for girls and boys aged through 14 years. In October 2016, ACIP recommended a 2DSC schedule for adolescents initiating HPV vaccination in the age range. This report provides recommendations for use of 2DSC and 3DSC schedules for HPV vaccination.

Methods

During November 2015–October 2016, the ACIP HPV Vaccine Work Group held monthly telephone conferences to 3) review and evaluate the quality of the evidence among immunogenicity, efficacy, and postlicensure effectiveness of a 2DSC versus a 3DSC; and 4) recommend potential changes to the recommendations for use of HPV vaccines made in 2015 and 2016. The work group considered data from clinical trials, pharmacokinetic and toxicologic studies, and evidence from observational studies that included real-world data. The reviewers were 1) a statistician with expertise in vaccine efficacy and immunogenicity, 2) a biologic vaccine expert, 3) a clinician, 4) an expert in epidemiology and infectious disease, and 5) an expert in biologics. A systematic review was conducted to identify clinical trials comparing 2DSC and 3DSC with 9vHPV. The review included studies that included 2DSC with a minimum interval of 6 months (±4 weeks) to a maximum of 12 months. This systematic review included studies that included 2DSC with a minimum interval of 5 months. If the second dose is administered after a shorter interval, it should be readministered after another

Special populations. For children with a history of usual vaccination, many health care providers recommend routine HPV vaccination beginning at age 9-11 years. For men who have sex with men (MSM) (6) ACIP recommends routine HPV vaccination as far as all men, and vaccination through age 26 years for those who were not adequately vac-
munization. For transgender persons, ACIP recommends routine HPV vaccination for all adolescents, and vaccination through age 26 years for those who were not adequately vac-
munization. Medical conditions. ACIP recommends vaccination with 3 doses of HPV vaccine (0-, 2-, 6-month schedule) for females and males aged through 14 years with public or secondary immunity-compromising conditions that might reduce cell-mediated or humoral immunity, such as persons with lymphopenia, complement deficiencies, neutropenia, amegakaryocytic thrombocytopenia, immunodeficiency, or any important or critical health outcomes related to HPV vaccination after 2 doses of 9vHPV, 4vHPV, or 2vHPV, administered a minimum of 12 months apart. If a 2DSC schedule is used, the second dose is administered after a longer interval of 1 year (±4 weeks) to a maximum of 12 months (Table 2). Special populations. For children with a history of usual vaccination, many health care providers recommend routine HPV vaccination beginning at age 9-11 years. For men who have sex with men (MSM) (6) ACIP recommends routine HPV vaccination as far as all men, and vaccination through age 26 years for those who were not adequately vac-
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FACT 1: The HPV vaccine is safe.

Scientists from both the CDC and the FDA continue to monitor and report any adverse events and side effects related to HPV vaccines. Monitoring in 2009 revealed that most side effects related to the vaccine were mild and were similar to those seen with any other vaccine. Several studies from 2011-2015 looking at more than four million women and girls who have received the vaccine show that there is no relationship between HPV vaccines and autoimmune disorders, blood clots, or other serious disorders.

TALKING POINT: More than 200 million doses of vaccine have been distributed worldwide, with more than 80 million doses in the US. While the safety of these vaccines is continually monitored in 80 countries, no safety concerns have been identified. All vaccines have side effects, but reactions caused by HPV vaccines have been mostly mild and similar to those from other vaccines.

FACT 2: The HPV vaccine does NOT cause fertility issues.

Claims of HPV vaccine-induced infertility are anecdotal and not backed by research or clinical trials. The HPV vaccine can actually help protect fertility by preventing gynecological problems related to the treatment of cervical cancer. It’s possible that the treatment of cervical cancer could leave a woman unable to have children. It’s also possible that treatment for cervical pre-cancer could put a woman at risk for problems with her cervix, which could cause premature delivery or other problems.

TALKING POINT: There are no data to suggest that getting the HPV vaccine will have a negative effect on future fertility. In fact, getting vaccinated and protecting against cervical cancer can help protect a woman’s ability to get pregnant and have healthy babies.

FACT 3: The HPV vaccine does NOT contain harmful ingredients.

HPV vaccines contain ingredients that have been proven to be safe. Like the hepatitis B and Tdap vaccines, HPV vaccines contain aluminum, which boosts the body’s immune response to the vaccine. In addition to certain vaccines, aluminum is found in breast milk, infant formula, antacids, and numerous foods and beverages, including fruits and vegetables, seasonings, flour, cereals, nuts, dairy products, and honey. Typical adults ingest 7 to 9 milligrams of aluminum per day, whereas the HPV vaccines contain .225 milligrams of aluminum per dose. These vaccines, like other vaccines for children and adolescents, do not contain thimerosal (a preservative that contains mercury).

TALKING POINT: Given the quantities of aluminum we are exposed to on a daily basis, the quantity of aluminum in vaccines is miniscule. Aluminum-containing vaccines have been used for decades and have been given to more than 1 billion people without problems. In spring 2000, the National Vaccine Program Office reviewed aluminum exposure through vaccines and determined that no changes to vaccine recommendations were needed based on aluminum content. The Global Advisory Committee on Vaccine Safety, part of the World Health Organization, has also reviewed studies and found no evidence of health risks that would require changes to vaccine policy.

FACT 4: The HPV vaccine is necessary, regardless of sexual activity.

Vaccines are for prevention, not treatment, so they only work if given before coming in contact with a virus. Research also shows that younger people create more antibodies to the vaccine than those in their late teens.

Studies have shown that HPV vaccination is not associated with changes in sexual behavior. Age of onset of sexual activity, incidence of STIs, and rates of pregnancy have all been shown to be similar in vaccinated girls compared to unvaccinated girls.

TALKING POINT: People are vaccinated well before they’re exposed to an infection (i.e., measles and the other recommended childhood vaccines). Similarly, they should be vaccinated before they are exposed to HPV. Also, the HPV vaccine produces a higher immune response in preteens than it does in older teens.

HPV is so common that almost everyone will be exposed at some point in their lives. So even if your child delays sexual activity until marriage, or only has one partner in the future, they could still be exposed if their partner has been exposed.

Studies have shown there’s no correlation between receiving the HPV vaccine and increased rates of (or earlier engagement in) sexual activity.

FACT 5: The HPV vaccine is for boys and girls.

Both males and females can get HPV. It’s very common; the CDC estimates that between 80-90% of sexually active people will be infected with at least one type of HPV in their lifetime.

Although cervical cancer is currently the most common type of cancer caused by HPV, persistent infection also causes cancers of the base of the tongue and tonsils. These cancers are becoming more common, especially among men, and may be more common than cervical cancer by 2020. HPV can also cause penile and anal cancers in men. The HPV vaccine provides protection against most of the genital cancers in men caused by HPV infection.

TALKING POINT: HPV vaccination is strongly recommended for boys and girls. Vaccination helps protect boys from getting infected with the most common types of HPV than can cause cancers of the throat, penis, and anus; it also helps prevent most genital warts. In addition, when boys are vaccinated, they are less likely to spread HPV to their current and future partners.

FACT 6: The HPV vaccine is effective and prevents cancer.

In studies that led to the approval of HPV vaccines, the vaccines provided nearly 100% protection against persistent cervical infections with HPV types 16 and 18, plus the pre-cancers that those persistent infections can cause. In addition, a clinical trial of HPV vaccines in men indicated that they can prevent anal pre-cancers caused by persistent infection and genital warts.

HPV-associated cancers can take decades to develop, and the vaccines have not been in use long enough to produce studies comparing cancer rates. Advanced pre-cancers are universally accepted markers for cancers.

TALKING POINT: The vaccine has been proven, through numerous studies, to prevent the cell changes and infections that correspond with multiple HPV-associated cancers.

In addition, population studies in the US and other countries that have introduced the HPV vaccine have shown a significant reduction in abnormal Pap test results and genital warts.

FACT 7: Many parents do not know about the HPV vaccine and benefit from a quality provider recommendation.

Studies have shown many parents (37%) have no prior knowledge about the vaccine before their child’s provider educates them about it. Knowledge varies across racial/ethnic groups, socioeconomic status, and geographic areas.

Studies have also shown that parents value the HPV vaccine equally with other adolescent vaccines. In addition, parents want to prevent cancer in their children.

TALKING POINT: A quality provider recommendation is the single best predictor of vaccination. Recent studies show that a patient who receives a provider recommendation is four to five times more likely to receive the HPV vaccine.

FACT 8: The effectiveness of the HPV vaccine does not decrease over time.

Ongoing studies have found that those who received the vaccine continue to have antibodies to the virus, providing long-term protection against infections and pre-cancers. There is no indication that they will decrease over time, but studies continue.

TALKING POINT: Studies continue to monitor how long the vaccine protects against HPV infections and cancer. Protection has been shown to last at least 15 years with no signs of the protection weakening.
References


Talking to Parents about HPV Vaccine

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 pertussis.” 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.

**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.

**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. If you wait, your child may need three shots instead of two.

**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 recommend we give your child her first HPV shot today.

**Why do boys need HPV vaccine?**

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

**Can HPV vaccine cause infertility in my child?**

There is no known link between HPV vaccination and the inability to have children in the future. However, women who develop an HPV precancer or cancer could require treatment that would limit their ability to have children.

**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 protect your child by having them stay seated after the shot.

**Would you get HPV vaccine for your kids?**

Yes, I gave HPV vaccine to my child (or grandchild, etc.) when he was 11, because it’s important for preventing cancer.

**What vaccines are 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.

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**HPV VACCINE IS CANCER PREVENTION**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

December, 2016 | CS269453B
Human Papillomavirus (HPV) Vaccination Report: Massachusetts

Working Together to Reach National Goals for HPV Vaccination

The Morbidity and Mortality Weekly Report (MMWR)* recently released the 2015 National Immunization Survey-Teen (NIS-Teen) data, which provides national, state, regional, and selected local area estimates of vaccination coverage. As reported in the MMWR, “In 2015, coverage with each HPV vaccine dose increased among males, however, among females, ≥1 dose HPV vaccination coverage increased only modestly, and no change was observed in coverage with ≥2 and ≥3 HPV doses.” As in prior years, coverage with ≥2 HPV vaccine dose was lower than coverage estimates for two other vaccines routinely recommended at age 11–12 years, highlighting ongoing missed opportunities for HPV vaccination when other recommended vaccines are administered. Next year, a revised Healthcare Effectiveness Data and Information Set (HEDIS) measure will be implemented to evaluate receipt of the three recommended vaccines by age 13 years in females and males combined in one composite indicator, ** facilitating health plans’ and providers’ assessment of their performances in administering these vaccines on time to adolescents. See page 2 of this report for 2015 NIS-Teen vaccination coverage, as well as a data summary for Massachusetts.

2016 HPV Vaccine Distribution Trends in Massachusetts

Below are available year-to-date totals of CDC and non-CDC distributed HPV vaccine doses of Gardasil and Gardasil 9 in your state or city. CDC recommends examining vaccine distribution data for trends to approximate recent HPV vaccine administration, as distribution data can inform action in real time to increase vaccination.

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Doses Distributed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan</td>
<td>20,580</td>
</tr>
<tr>
<td>Feb</td>
<td>40,365</td>
</tr>
<tr>
<td>Mar</td>
<td>62,963</td>
</tr>
<tr>
<td>Apr</td>
<td>94,304</td>
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<td>May</td>
<td>102,625</td>
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<tr>
<td>Jun</td>
<td>127,519</td>
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<tr>
<td>Jul</td>
<td>155,520</td>
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<tr>
<td>Aug</td>
<td>186,109</td>
</tr>
<tr>
<td>Sep</td>
<td>214,671</td>
</tr>
<tr>
<td>Oct</td>
<td>230,250</td>
</tr>
<tr>
<td>Nov</td>
<td>268,424</td>
</tr>
<tr>
<td>Dec</td>
<td>288,864</td>
</tr>
</tbody>
</table>

*Note: Gardasil and Gardasil 9 HPV vaccine doses distributed in the United States, are not included in this report.

2015 NIS-Teen HPV Data Summary:

Massachusetts

Compared to estimates from 2014, HPV vaccination coverage in Massachusetts:

- Did not change significantly from 2014 to 2015 among females. There were non-significant increases in ≥1, ≥2, and ≥3 dose coverage among females.
- Did not change significantly from 2014 to 2015 among males. There were non-significant increases in ≥1, ≥2, and ≥3 dose coverage among males.

Visit these CDC-authored publications for information interpreting survey findings:

http://www.cdc.gov/mmwr/volumes/65/wr/mm6533a4.htm?s_cid=mm6533a4_e
http://www.cdc.gov/mmwr/volumes/66/wr/mm6633a3.htm#sthash.COMPAQqZ87U.dpuf

Resources to Increase HPV Vaccination Coverage:

- Get involved with partners, such as the American Cancer Society (ACS). Information on the National HPV Vaccination Roundtable can be found at:
- Visit the latest PreteenVaccine webinar, “Research Project Update: AT1X Program Strategies for Improving HPV Vaccination Rates in the Field”:
  http://www.youtube.com/watch?v=xU7j0AY9lzQ
- Visit TeenAxClear for comprehensive interactive adolescent vaccination coverage data online at:
  https://www.cdc.gov/vaccines/imz-manage/coverage/teenvaccine/index.html

Have questions? Contact us at preteenvaccines@cdc.gov.
Massachusetts HPV Initiative:
Raising HPV Immunization Rates to Prevent HPV-Related Cancers

WHAT YOU NEED TO KNOW ABOUT HPV AND HPV-RELATED CANCERS

- Approximately 79 million people in the US are infected with HPV, and approximately 14 million people in the US will become newly infected with HPV each year.
- The current number of cancers attributable to HPV is rising with an estimated 30,700 each year.
- The 9vHPV vaccine has the potential to prevent 92% of the HPV-attributable cancers.
- Cervical cancer is the most common HPV-associated cancer among women and oropharyngeal cancers are the most common among men.

THE CURRENT PROBLEM
Even though the HPV vaccine can prevent cancer, immunization rates remain very low among female and male adolescents in our state. Missed opportunities for HPV vaccination may result in serious consequences. The CDC, AAP and AAFP recommend that all 11-12 year-olds receive HPV, meningococcal, and Tdap vaccines at the same time.

WHAT CAN PROVIDERS DO?
The most significant factor in parents’ decision to vaccinate their children with HPV vaccine is a strong, routine recommendation from the child’s healthcare provider. Research shows that simply changing the wording used to introduce the HPV vaccine makes a tremendous difference.

HELPFUL STRATEGIES

- Talk about HPV vaccination as cancer prevention. Cancer prevention is important to parents so remind them that certain HPV types can cause not only cervical cancer, but also anal, penile, vaginal, vulvar, and oropharyngeal cancers.
- Recommend the HPV vaccine the same way and on the same day as other vaccines.

“Now that your child is 11, they are due for three vaccines that are really important for all kids their age. They will help protect against meningitis, HPV cancers, and pertussis. We will be giving these at the end of the visit today.”

OTHER RESOURCES
CDC You are the Key to Cancer Prevention Clinician Website: http://www.cdc.gov/hpv/hcp/
MA Chapter, American Academy of Pediatrics (MCAAP) HPV Website: http://mcaap.org/immunization-hpv/

Contact Rebecca Vanucci (rebecca.vanucci@state.ma.us), MDPH Immunization Outreach Coordinator, for more information.
**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 2019, most side effects reported after receiving HPV vaccine were non-serious, including fainting, dizziness, nausea, headache, and pain, swelling, or severe reaction 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 seizure than those who were unvaccinated or who received other vaccines.

- **A 2012 study**
  - Looked at when adverse events occur after 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**
  - Included almost 1 million women found Gardasil was not associated with blood clots or adverse events related to the autoimmune and brain systems.

- **A 2014 study**
  - Included over 1 million women found Gardasil was not associated with headaches or 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 no more likely to develop autism or more autistic 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.

- **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 can provide useful information on vaccine safety, it does not 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 a 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.
  - People should sit or lie down for about 15 minutes after getting a shot. This can help prevent fainting.

- CDC has carefully studied the risk of HPV vaccination.
  - HPV vaccine is recommended to prevent the cancers, but such prevention, as well as side effects, outweigh the risks of possible side effects.

### CDC and FDA provide the Vaccine Adverse Event Reporting System (VAERS)

- **Benefits**
  - **Cervical, vaginal, and vulvar cancer**
  - **Anal cancer in men and women**
  - **Likely penile cancer in men**
  - **Likely oropharyngeal cancer in women and men**

- **Potential Risks**
  - **Pain, redness, or swelling in the arm where the shot was given**

### 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 3 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 vacc

### Related Scientific Articles

- [Arnheim-Dahlström L, Pasternak B, Svanström H, Sparén P, Hviid A. Autoimmune, neurological, and venous thromboembolic adverse events after immunization with quadrivalent human papillomavirus vaccines in Denmark and Sweden: Cohort study.](https://jama.jamanetwork.com/journals/jama/fullarticle/2529329)

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**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.**
Clinician FAQ: CDC Recommendations for HPV Vaccine 2-Dose Schedules

After the October 2016 ACIP meeting, CDC now recommends that 11 or 12 year olds receive 2 doses of HPV vaccine instead of 3. Parents may have questions about this change. This resource helps explain the reasons for changing the HPV vaccine recommendation, and provides tips for talking with the parents of your patients about the change.

What has changed in the new HPV vaccine recommendations?
In October 2016, CDC updated HPV vaccination recommendations regarding dosing schedules. CDC now recommends 2 doses of HPV vaccine for people starting the vaccination series before the 15th birthday. Three doses of HPV vaccine are recommended for people starting the vaccination series on or after the 15th birthday and for people with certain immunocompromising conditions.

CDC continues to recommend routine vaccination for girls and boys at age 11 or 12 years. The vaccination series can be started at age 9 years. CDC also recommends vaccination through age 26 years for females and through age 21 years for males. Males age 22–26 years may be vaccinated.

What is the recommended 2-dose HPV vaccination schedule?
For girls and boys starting the vaccination series before the 15th birthday, the recommended schedule is 2 doses of HPV vaccine. The second dose should be given 6–12 months after the first dose (0, 6–12 month schedule).

Answering parents’ questions: We now recommend 2 doses of HPV vaccine for your son or daughter, instead of 3, if your child starts the series before their 15th birthday. I still recommend your child start the vaccination series by age 11 or 12 years for best protection against HPV. He or she will need a second dose 6–12 months after the first dose.

Who should still receive a 3-dose schedule?
CDC continues to recommend a 3-dose schedule for persons starting the HPV vaccination series on or after the 15th birthday, and for persons with certain immunocompromising conditions. The second dose should be given 1–2 months after the first dose, and the third dose should be given 6 months after the first dose (0, 1–2, 6 month schedule).

Answering parents’ questions: If your child starts the series after his or her 15th birthday or has certain health problems that weaken his or her immune system, he or she will need the 3-dose series. We will give the second dose 1–2 months after the first, and the last dose 6 months after the first dose.

Why did CDC make the recommendation change to a 2-dose schedule?
Over the past year, CDC and the Advisory Committee on Immunization Practices (ACIP) have been reviewing data on 2-dose schedules, including results from studies of HPV vaccines that compared the antibody response after 2 doses and 3 doses. The studies showed that the antibody response after 2 doses given at least 6 months apart to 9–14 year-olds was as good or better than the antibody response after 3 doses given to older adolescents and young adults, the age group in which efficacy was demonstrated in clinical trials.

Answering parents’ questions: CDC and ACIP (a group of experts that make vaccine recommendations) have been reviewing data on 2-dose HPV vaccination schedules for several months. The evidence showed that 2 doses of HPV vaccine given at least 6 months apart in younger adolescents were as good or better than 3 doses. These updated recommendations are an example of using the latest available evidence to provide your child with the best possible protection against serious diseases.

Answering parents’ questions: Since your child received his/her first dose of the HPV vaccine before he/she was 15 years old, we’ll only need to give 1 more dose.

Why is the 2-dose schedule change recommended only for girls and boys age 9–14 years?
ACIP makes recommendations based on the best available scientific evidence. Immunogenicity studies have shown that 2 doses of HPV vaccine given to 9–14 year-olds at least 6 months apart were as good, or better, than 3 doses given to older adolescents and young adults. Studies have not been done to show this in adolescents age 15 years or older.

Answering parents’ questions: The data currently are from scientific studies (clinical trials) that showed that 2 doses of HPV vaccine given at least 6 months apart were as good or better than 3 doses in children 9–14 years of age. Older adolescents haven’t been studied in the same way, so we don’t have information available for that age group. For that reason, the recommendation for number of doses has not been changed for older adolescents.

What is the recommendation for persons with immunocompromising conditions?
CDC recommends 3 doses of HPV vaccine (0, 1–2, 6 months) for immunocompromised people age 9 through 26 years. People whose immune responses might be lower, for example due to HIV infection, cancer, autoimmune disease, or taking immunosuppressant medications, should receive 3 doses to make sure they get the most benefit. However, children with asthma, diabetes, and other conditions that would not suppress immune response to HPV vaccination can receive a 2-dose schedule.

Answering parents’ questions: Even though CDC has recommended just 2 doses of HPV for kids under 15 years, we’ll need to give your child 3 doses because he/she has a health problem that weakens his or her immune system.

If a HPV vaccine series was started with quadrivalent HPV vaccine or bivalent HPV vaccine and will be completed with 9-valent HPV vaccine, what are the intervals for the remaining doses in a 3-dose or 2-dose series?
If the first dose of any vaccine was given before the 15th birthday, vaccination should be completed according to a 2-dose schedule. In a 2-dose series, the second dose is recommended 6–12 months after the first dose (0, 6–12 month schedule). If the first dose of any vaccine was given on or after the 15th birthday, vaccination should be completed according to a 3-dose schedule. In a 3-dose series, the second dose is recommended 1–2 months after the first dose, and the third dose is recommended 6 months after the first dose (0, 1–2, 6 month schedule).

If a vaccination schedule is interrupted, vaccine doses do not need to be repeated.

If a girl or boy received 2 doses of HPV vaccine less than 5 months apart, do they need a third HPV vaccine dose?
Yes. In a 2-dose schedule of HPV vaccine, the recommended interval is 6–12 months, and the minimum interval is 5 months between the first and second dose. If the second dose is given earlier than 5 months, a third dose should be administered.

Answering parents’ questions: The recommended schedule is 2 doses given 6 to 12 months apart. The minimum amount of time between these doses is 5 months. Because your child received 2 doses less than 5 months apart, we’ll need to give your child a third dose.

If someone is age 15 years or older and started the vaccination series at age 11 but only received 1 dose, how many more doses do they need?
This person needs 1 more dose to complete a 2-dose series, which is recommended because the vaccination was started before turning 15 years old. In a 2-dose series, the second dose is recommended 6–12 months after the first dose. In this case, the first dose was given several years ago, so the second dose can be given right away.

Is the 9-valent HPV vaccine approved by FDA for use as a 2-dose schedule?
Yes, in October 2016, FDA approved a 2-dose schedule (0, 6–12 months) of 9-valent HPV vaccine for use in girls and boys age 9–14 years in the United States.

What HPV vaccines are currently available in the United States?
Three HPV vaccines are licensed for use in the United States: 9-valent HPV vaccine, quadrivalent HPV vaccine, and bivalent HPV vaccine. However, after the end of 2016, only 9-valent HPV vaccine will be sold in the United States.