2019

Increasing HPV vaccine uptake through implementation of an HPV protocol

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INCREASING HPV VACCINE UPTAKE THROUGH IMPLEMENTATION OF AN HPV PROTOCOL

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A DNP PROJECT

Submitted in partial fulfillment of the requirements for the Degree of Doctor of Nursing Practice to The School of Graduate Studies of The University of Alabama in Huntsville

HUNTSVILLE, ALABAMA
2019

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DNP PROJECT APPROVAL FORM

Submitted by Amy Beck in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

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ABSTRACT
The School of Graduate Studies
The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice College: Nursing

Name of Candidate: Amy Beck

Title: Increasing HPV Vaccine Uptake through Implementation of an HPV protocol

Abstract

Purpose

To implement a protocol that aligns with the current HPV guidelines by offering HPV education and provider recommendation to parents of adolescents to increase the uptake of HPV vaccination.

Methods

An HPV protocol was implemented to parents of adolescents ages 11-17 years. Instruments were used to identify vaccine hesitant parents, vaccination status after protocol implementation was tracked over a six-week period, and educational materials were used to ensure parental understanding of the HPV vaccine. HPV vaccination uptake was compared to the same time period from the previous year to trend for increase in uptake of the vaccine.

Results

Data collected from the clinic vaccination log during the same six-week time period in 2018 identified that four adolescents were vaccinated with the HPV vaccine. In 2019 while the HPV protocol was implemented, twenty-four adolescents were vaccinated with the HPV vaccine.

Conclusions

Implementation of an HPV vaccine protocol is an effective way to ensure completion of vaccine series, and eliminate missed clinical opportunities by providing standing vaccine orders

and incorporating reminders and recalls to ensure completion of vaccine series. Every missed clinical opportunity to vaccinate a child increases the chances of genital warts and cancers as a result of infection with HPV, and leads to lower rates of HPV vaccination.

Key words: protocol, uptake

TABLE OF CONTENTS

Page

SECTION II: DNP PROJECT PRODUCT

Identification of the Problem

Human papillomavirus (HPV) is the most frequently occurring sexually transmitted disease in the United States (Cipriano, Scoloveno, & Kelly, 2017). Each year roughly 14 million Americans receive a diagnosis of HPV infection, half of which are between the ages of 15-24 years (Fuller & Hinyard, 2017). The HPV vaccine has the potential to prevent morbidity and mortality from HPV related cancers, including cervical, vaginal, penile, anal, and oropharyngeal (Daley et al., 2017). However, compared to other recommended vaccines, the acceptance and uptake of the HPV vaccine has been slower than other recommended adolescent vaccines (McLean et al., 2017). Among adolescents, healthcare provider recommendation is one of the most influential and consistent predictors of HPV vaccination (McRee, Gilkey, & Dempsey, 2014). The role of the healthcare provider is to ensure proper education in all adolescent patients and their parents on the importance of receiving the HPV vaccine to decrease morbidity and mortality related to the most common sexually transmitted disease. In order to provide appropriate HPV education and increase vaccine uptake, providers and clinical staff must review current clinical guidelines and educational materials, develop educational handouts and teaching techniques appropriate for their clinical setting, and implement HPV vaccine protocols. The objectives of this project were to: increase vaccine uptake through implementation of HPV protocol; teach medical staff how to implement protocol; and increase knowledge and awareness of HPV vaccine in parents and adolescents. The PICOT question for this quality improvement project was: For parents of adolescents, does providing HPV education and provider recommendation, as compared to not providing education and provider recommendation, increase uptake of the HPV vaccine of the parent's adolescent?

Review of Evidence

A comprehensive literature review was conducted to evaluate current evidence of implementing HPV vaccine protocols in the outpatient setting, the impact of education on HPV vaccine intent, and the significance of strong provider vaccine recommendation. The online databases searched included CINAHL, OVID, and PubMed. Key words of the search included HPV, HPV education, vaccine recommendation, and vaccination intent. The total number of articles retrieved during the search was 156. Parameters used to narrow the search to 62 articles included English language, articles published within the past five years, with and without abstract, and peer-reviewed. Fourteen articles were identified and included in this paper.

Current Clinical Guidelines

HPV is the most frequently occurring sexually transmitted disease in the United States, accounting for a prevalence rate of approximately 79 million infections (Cipriano, Scoloveno, & Kelly, 2017). Current HPV guidelines published by the Advisory Committee on Immunization Practices (ACIP) for adolescents include routine vaccination for ages 11-12 years, with schedules available for catch-up vaccinations and special populations. In the United States acceptance and utilization of the HPV vaccine have been slower than other recommended adolescent vaccines (McLean et al., 2017). According to the 2016 National Immunization Survey-Teen (NIS-Teen), coverage with one or more doses of the HPV vaccine was approximately 65% among females and 56% among males. Coverage with three or more doses among females and males was 43% and 32%, respectively (Boyd, Phillips, Schoenberger, & Simpson, 2018). Every missed clinical opportunity to vaccinate a child increases the chances of genital warts and cancers as a result of infection with HPV, and leads to lower rates of HPV vaccination.

Importance of Immunization

The HPV infection is a major public health concern (McGhee et al., 2017). Immunization not only decreases the incidence of adverse health outcomes related to the disease but also provides herd immunity for reducing the prevalence of HPV in the general population. Diseases caused by HPV affect women and men, causing cervical, vaginal, penile, anal, and oropharyngeal cancers, as well as genital warts. HPV passes through sexual contact without any signs or symptoms that the disease was transmitted. Most HPV infections are silent, asymptomatic, and do not cause symptoms or disease until years later. Given the high prevalence of the infection, any sexually active person is at risk of contracting HPV (Han et al., 2017). There is no cure, despite increasing knowledge about the benefits of HPV vaccinations. Furthermore, there are no screening tests currently available to detect HPV in men (McGhee et al., 2017). To date, the best defense against HPV is through education and vaccination (Han et al., 2017).

Barriers to Immunization

Barriers to HPV vaccination occur at the level of the patient/parent and provider (Cartmell et al., 2018). At the patient/parent level, vaccine barriers include: lack of recommendation by the provider, lack of knowledge about the vaccine and HPV-related diseases, value conflicts about vaccinating an adolescent against a sexually transmitted infection, disbelief that the vaccine is essential, and concerns about vaccine safety and costs. All of the patient/parent vaccine barriers can be eliminated if providers take the time to address HPV questions and concerns at every adolescent visit, provide up-to-date education verbally and in written form through educational handouts, provide a strong provider recommendation, and familiarize self and staff with available local vaccine programs for the uninsured. A high-quality

provider recommendation with a strong endorsement for same-day vaccination and an emphasis on cancer prevention is associated with decreased parental refusal, increased series initiation, and the delivery of subsequent doses (Kornides, Fontenot, McRee, Panozzo, & Gilkey, 2018). At the provider level, barriers include: lack of understanding about HPV-related diseases, safety concerns, concerns about vaccine reimbursement, personal attitudes, discomfort talking to parents and children about a topic related to sexual behavior, concerns about parental resistance, lack of vaccine reminder and recall systems, and lack of time during visits to provide education about the vaccine. The provider level barriers are the responsibility of the provider to identify and eliminate. Providers must stay up-to-date on current HPV clinical guidelines in order to address all patient and parent concerns during office visits. To ensure completion of vaccine series, implementation of an HPV vaccine protocol is an effective way to eliminate missed clinical opportunities by providing standing vaccine orders and incorporating reminders and recalls to ensure completion of vaccine series.

Conceptual Framework

Lewin's Theory of Planned Change

To increase the use of the HPV vaccine as recommended by current Advisory Committee on Immunization Practices (ACIP) guidelines, theory informed implementation interventions are urgently needed (Garbutt et al., 2018). Kurt Lewin developed the Theory of Planned Change to ensure successful change (Barrow & Toney-Butler, 2017). The Theory of Planned Change includes the following three change stages: Unfreezing (identifying that change is needed); Moving (initiating the change); Refreezing (establishing change as the new normal). In healthcare, using best practices obtained from change theories such as Lewin's can improve the odds of success and improve practice outcomes (Barrow & Toney-Butler, 2017). All healthcare

providers play an important role in ensuring successful change for their patients. The Theory of Planned Change can be applied to increase HPV vaccine uptake in adolescents. To implement change in vaccine uptake, health care providers must understand that HPV immunization rates are low and determine ways to change this issue in clinical practice (unfreezing phase). Once it is determined that change must be made, healthcare providers must find ways to implement parental and adolescent education which leads to vaccine acceptance (moving phase). In this phase, providers can supply each patient/parent with educational materials on HPV and the vaccine, discuss the need for vaccination during routine visits, and provide strong provider recommendation when discussing the vaccine. After providers have determined which educational practices lead to higher uptake of the vaccine, new protocols should be implemented to continue effective change (refreezing phase). Implementing Lewin's Theory of Planned Change in offices that provide healthcare services to adolescents can lead to positive change when the appropriate steps are followed, thus leading to an increased uptake of the HPV vaccine. Increased uptake of the vaccine leads to decreased incidence of HPV infection and related illnesses/cancers, leading to positive health outcomes. Healthcare providers can decrease the gap of unvaccinated adolescents by using the Theory of Planned Change as a guide when implementing new protocols for HPV vaccination in adolescents.

DNP Project Development

The purpose of this project was to provide HPV education and provider recommendation to parents of adolescents, increasing intent for HPV vaccination. This was done by implementing an HPV protocol to parents of adolescents ages 11-17 years. Instruments were used to identify vaccine hesitant parents, vaccination status after protocol implementation was

tracked, and educational materials were used to ensure parental understanding of the HPV vaccine.

Setting

This project took place at a rural, nurse practitioner-run primary care/walk-in clinic in Somerville, Alabama. At the clinic, adolescents have the ability to seek well-child primary care visits, as well as sick visits. Routine adolescent vaccines are available in the clinic. Appointments are available for well-child visits, and sick-visits are walk-in based.

Participants

The participants in this project include parents of adolescents ages 11-17 years old that visit the clinic. Participants were male and female of all races, 18 years of age and older. Parents of adolescents that have not initiated the vaccine series, or have initiated but not completed the series, were included. Exclusion criteria includes parents of adolescents who have previously completed the HPV vaccine series.

Instruments

Demographics

The demographic survey was developed by the principal investigator (PI) in order to collect statistics on the population sample. The survey collected data on participant gender, age, educational level, total number of children, and if children are up-to-date on all vaccinations. (See appendix A).

The Parent Attitudes about Childhood Vaccines (PACV) Survey Tool

The Parent Attitudes about Childhood Vaccines (PACV) Survey Tool is an instrument used to identify vaccine-hesitant parents (VHP) (Opel et al., 2014). The survey is self-administered and reads at a sixth grade level. It contains fifteen questions and can be completed

in less than five minutes. The PACV is scored by assigning a numeric score of two for items answered with a hesitant response, a score of one for items answered with a response of unsure, and a score of zero for items answered with a non-hesitant response. Item scores are then summed into one total score that is converted into a scale ranging from 0-100. Surveys that score greater than fifty percent identify VHP. The survey is implemented before well-child visits to determine what educational information the healthcare provider needs to focus on in order to gain the parents trust of the HPV vaccine. The PACV survey allows the provider to implement individualized shared decision making during the visit based off of the survey results. (See appendix B).

Vaccination Status After Protocol Implementation Log

The vaccination status after protocol implementation log was designed to record the number of HPV vaccines declined and accepted during the project. The log collected the following data: participant number, vaccine administered-reminder card for second dose given, vaccine declined, agreed to vaccinate at a later time-followed through, agreed to vaccinate at a later time-did not follow through. (See appendix C).

Appointment Reminder Card

The appointment reminder card was given to participants who chose to vaccinate their child the same day as the visit. The name of the participant's child was recorded on the reminder card, along with the date and time of the visit for the second dose of the vaccine. (See appendix D).

Procedure

A quality improvement project designed to increase rates of HPV vaccination was conducted to determine if the HPV protocol causes change. Approval from The University of

Alabama in Huntsville's Institutional Research Board was granted before the implementation of the project (See appendix E). The PACV survey was completed by the parent, and the results evaluated by the PI or RA before the visit. Once the survey was completed, educational materials were given to patients and their parents. They were allowed time to read over the educational material handouts before the PI or RA entered the exam room to ensure any questions or concerns are addressed during the office visit. The PI or RA addressed all of the information on the educational material while providing HPV education during the visit. If the participant agreed to HPV vaccination of their adolescent, they were told to let the medical assistant know that they desire vaccination before leaving the clinic. Vaccination acceptance or refusal was documented for every participant. Participants who accepted vaccination received a reminder card for the second dose of the vaccine before leaving the office.

Educational materials

The educational material discussed HPV facts and statistics obtained from the Centers for Disease Control and Prevention (CDC), highlight the important role the vaccine plays in cancer prevention, and provide vaccine schedules and guidelines. Two educational material handouts were given to the participants to review. (See appendix F).

Data Analysis

Data collected from the clinic vaccination log, along with answers to the PACV and demographic survey, were entered into Microsoft Excel to be analyzed. Frequencies and percentages were captured and analyzed.

Application to Practice

Current HPV guidelines are published by the ACIP. Unfortunately, these guidelines are not implemented as standard practice in every clinic. Due to this lack of HPV guideline

implementation in the United States, acceptance and utilization of the HPV vaccine have been slower than other recommended adolescent vaccines (McLean et al., 2017). By implementing a protocol to ensure all adolescent patients and their parents receive HPV education along with a strong healthcare provider vaccine recommendation, it is expected that HPV vaccine uptake will increase. Increasing vaccine uptake in adolescents decreases the incidence of HPV related cancers and diseases throughout their lifetime. The HPV vaccine is a mechanism of cancer prevention. It is currently the only vaccine proven to prevent cancer. It is the responsibility of healthcare providers and their staff to ensure current HPV clinical guidelines are implemented in their clinics in order to decrease the incidence of HPV. A barrier of project completion is the lack of provider involvement. This may occur due to staffing shortages or time constraints in the clinic. Implementing the protocol during adolescent office visits is the only way to ensure missed clinical opportunities do not occur.

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SECTION II: DNP PROJECT PRODUCT

Professional Journal Selection

Scope of Journal

"*The Journal of Adolescent Health* is a multidisciplinary scientific Journal, which seeks to publish new research findings in the field of Adolescent Medicine and Health ranging from the basic biological and behavioral sciences to public health and policy. We seek original manuscripts, review articles, letters to the editor, commentaries, and case reports from our colleagues in Anthropology, Dentistry and Oral Health, Education, Health Services Research, International Health, Law, Medicine, Mental Health, Nursing, Nutrition, Psychology, Public Health and Policy, Social Work, Sociology, Youth Development, and other disciplines that work with or are committed to improving the lives of adolescents and young adults."[1] (See appendix G for author guidelines).

Aims of Journal

"The Journal is the official publication of the Society for Adolescent Health and Medicine (SAHM), a multidisciplinary organization committed to improving the health and well-being of adolescents. One of the Society's primary goals is the development, synthesis, and dissemination of scientific and scholarly knowledge unique to the health needs of adolescents. To meet this goal, the Society established the *Journal of Adolescent Health* in 1980."[1]

Increasing HPV Vaccine Uptake Through Implementation of an HPV Protocol

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Abstract

Purpose

To implement a protocol that aligns with the current HPV guidelines by offering HPV education and provider recommendation to parents of adolescents to increase the uptake of HPV vaccination.

Methods

An HPV protocol was implemented to parents of adolescents ages 11-17 years. Instruments were used to identify vaccine hesitant parents, vaccination status after protocol implementation was tracked over a six-week period, and educational materials were used to ensure parental understanding of the HPV vaccine. HPV vaccination uptake was compared to the same time period from the previous year to trend for increase in uptake of the vaccine.

Results

Data collected from the clinic vaccination log during the same six-week time period in 2018 identified that four adolescents were vaccinated with the HPV vaccine. In 2019 while the HPV protocol was implemented, twenty-four adolescents were vaccinated with the HPV vaccine.

Conclusions

Implementation of an HPV vaccine protocol is an effective way to ensure completion of vaccine series, and eliminate missed clinical opportunities by providing standing vaccine orders and incorporating reminders and recalls to ensure completion of vaccine series. Every missed clinical opportunity to vaccinate a child increases the chances of genital warts and cancers as a result of infection with HPV, and leads to lower rates of HPV vaccination.

Human papillomavirus (HPV) is the most frequently occurring sexually transmitted disease in the United States.[2] Each year roughly 14 million Americans receive a diagnosis of HPV infection, half of which are between the ages of 15-24 years.[3] The HPV vaccine has the potential to prevent morbidity and mortality from HPV related cancers, including cervical, vaginal, penile, anal, and oropharyngeal.[4] However, compared to other recommended vaccines, the acceptance and uptake of the HPV vaccine has been slower than other recommended adolescent vaccines.[5] Among adolescents, healthcare provider recommendation is one of the most influential and consistent predictors of HPV vaccination.[6] The role of the healthcare provider is to ensure proper education in all adolescent patients and their parents on the importance of receiving the HPV vaccine to decrease morbidity and mortality related to the most common sexually transmitted disease. The purpose of this project was to implement a protocol that aligns with the current HPV guidelines by offering HPV education and provider recommendation to parents of adolescents to increase the uptake of HPV vaccination. Instruments were used to identify vaccine hesitant parents, vaccination status after protocol implementation was tracked, and educational materials were used to ensure parental understanding of the HPV vaccine. We sought to investigate if providing HPV education and provider recommendation during office visits, as compared to not providing education and provider recommendation, would increase uptake of the HPV vaccine of the parent's adolescent?

Methods

Setting

The setting for this project was a rural, nurse practitioner-run primary care/walk-in clinic in the southeast. At the clinic, clients have the ability to seek primary care visits, as well as sick visits. Routine adolescent vaccines are available at the clinic. Appointments are available for

primary care visits, and sick-visits are walk-in based. Approximately 100 clients visit the clinic per week.

Sample

The sample for this project included parents of adolescents ages 11-17 years old that visit the clinic. The sample included males and females of all races, 18 years of age and older. Parents of adolescents that have not initiated the vaccine series, or have initiated but not completed the series, were included. Exclusion criteria includes parents of adolescents who have previously completed the HPV vaccine series.

Measures

The demographic survey collected data from the sample that included: gender, age, educational level, total number of children, and if children are up-to-date on all vaccinations. (See appendix A).

The Parent Attitudes about Childhood Vaccines (PACV) Survey Tool is an instrument used to identify vaccine-hesitant parents (VHP) (Opel et al., 2014). The survey is self-administered and reads at a sixth grade level. It contains fifteen questions and can be completed in less than five minutes. The PACV is scored by assigning a numeric score of two for items answered with a hesitant response, a score of one for items answered with a response of unsure, and a score of zero for items answered with a non-hesitant response. Item scores are then summed into one total score that is converted into a scale ranging from 0-100. Surveys that score greater than fifty percent identify VHP. The survey is implemented before well-child visits to determine what educational information the healthcare provider needs to focus on in order to gain the parents trust of the HPV vaccine. The PACV survey allows the provider to implement

individualized shared decision making during the visit based off of the survey results. (See appendix B).

The vaccination status after protocol implementation log was designed to record the number of HPV vaccines declined and accepted during the project. The log collected the following data: participant number, vaccine administered-reminder card for second dose given, vaccine declined, agreed to vaccinate at a later time-followed through, agreed to vaccinate at a later time-did not follow through. (See appendix C).

The appointment reminder card was given to participants who chose to vaccinate their child the same day as the visit. The name of the participant's child was recorded on the reminder card, along with the date and time of the visit for the second dose of the vaccine. (See appendix D).

Procedure

A quality improvement project designed to increase rates of HPV vaccination was conducted to determine if the HPV protocol causes change. Approval from an Institutional Research Board was granted before the implementation of the project (See appendix E). The PACV survey was completed by the parent, and the results evaluated before the visit. Once the survey was completed, educational materials were given to patients and their parents. They were allowed time to read over the educational materials before the provider entered the exam room to ensure any questions or concerns are addressed during the office visit. The provider addressed all of the information on the educational material handouts while providing HPV education during the visit. The educational materials discussed HPV facts and statistics obtained from the Centers for Disease Control and Prevention (CDC), highlight the important role the vaccine plays in cancer prevention, and provide vaccine schedules and guidelines. Two educational

handouts were given to the participants to review (See appendix F). A strong recommendation for HPV vaccination with an emphasis on cancer prevention was given during each visit. If the participant agreed to HPV vaccination of their adolescent, they were told to let the medical assistant know that they desire vaccination before leaving the clinic. Vaccination acceptance or refusal was documented for every participant. Participants who accepted vaccination received an appointment reminder card for the second dose of the vaccine before leaving the office.

Data analysis

Descriptive statistics were used to analyze demographic data, PACV scores, and identification of VHP. Data were entered into Microsoft Excel to be analyzed. Frequencies and percentages were captured and analyzed to trend uptake of the HPV vaccine during the initiation of the protocol, as well as vaccine uptake prior to initiating the protocol during the same time period the previous year.

Results

Fourteen individuals did not meet criteria due to their child already having completed the vaccine series. The final sample size was twenty-four. The majority of participants were female (7%, n=17) and seven (29%) were male. Participants reported their age to be between 18 and 25 (13%, n=3), five participants (21%) reported their age to be between 26 and 33, nine participants (36%) reported age between 34 and 41, four participants (17%) reported age to be between 42 and 49, three participants (13%) reported age to be between 50 and 57, and zero participants reported their age above 57 years old. The majority of participants were white (75%, n=18), five were Hispanic or Latino (21%), while one participant (4%) reported other. Participants reported highest degree obtained as follows: 17% (n=4) less than high school diploma, 25% (n=6) high school diploma, 21% (n=5) some college but no degree, 8% (n=2) associate's degrees, 25%

(n=6) bachelor's degrees, 4% (n=1) master's degree, and zero participants reported having a doctorate. Participants reported the number of children they have as follows: 8% (n=2) one child, 38% (n=9) two children, 38% (n=9) three children, 8% (n=2) four children, and 8% (n=2) five or more children. The majority of participants reported their children were up-to-date on vaccinations (92%, n=22), while 8% reported their children were not up-to-date (See Table 1).

Of the twenty-four participants who consented, twenty were initiating the HPV vaccine series and four were continuing the HPV series that had been initiated previously but had not received the next recommended dose. In 2019 while the HPV protocol was implemented, twenty-four adolescents were vaccinated with the HPV vaccine. PACV scores ranged from zero to 87, although four parents were identified as VHP with scores that range from 50 to 87 (See Table 2). See Table 3 for frequencies and percentages of responses to the PACV survey. Data collected from the clinic vaccination log during the same six-week time period in 2018 identified that only four adolescents were vaccinated with the HPV vaccine.

Discussion

Implementation of an HPV vaccine protocol is an effective way to ensure completion of vaccine series, and eliminate missed clinical opportunities by providing standing vaccine orders and incorporating reminders and recalls to ensure completion of vaccine series. By implementing a protocol to ensure all adolescent patients and their parents receive HPV education along with a strong healthcare provider vaccine recommendation, it is expected that HPV vaccine uptake will increase. This was demonstrated in the project implemented in a rural, nurse practitioner ran clinic. The HPV immunization rate over six weeks increased from four adolescents receiving the vaccine in 2018, to twenty-four receiving the vaccine in 2019 during implementation of the HPV protocol. This demonstrates an increase in adolescent vaccination

due to providing HPV education and strong recommendation for same-day vaccination. A high-quality provider recommendation with a strong endorsement for same-day vaccination and an emphasis on cancer prevention is associated with decreased parental refusal, increased series initiation, and the delivery of subsequent doses.[7] Unfortunately, HPV guidelines published by the ACIP are not implemented as standard practice in every clinic. Due to this lack of HPV guideline implementation in the United States, acceptance and utilization of the HPV vaccine have been slower than other recommended adolescent vaccines.[4] Every missed clinical opportunity to vaccinate a child increases the chances of genital warts and cancers as a result of infection with HPV, and leads to lower rates of HPV vaccination.

Limitations of Project

Limitations of this project include lack of time to implement the protocol due to time constraints in the clinic. Staffing issues led to inability to implement the protocol. Also, the project was constrained to a six-week time period. Additionally, the project was implemented during the summer where typically the patient volume is lower in this rural clinic.

Future Considerations

Increasing vaccine uptake in adolescents decreases the incidence of HPV related cancers and diseases throughout their lifetime. The HPV vaccine is a mechanism of cancer prevention. It is currently the only vaccine proven to prevent cancer. It is the responsibility of healthcare providers and their staff to ensure current HPV clinical guidelines are implemented in their clinics in order to decrease the incidence of HPV. Failing to implement the protocol during every adolescent visit leads to missed clinical opportunities that can result in a decrease in HPV vaccine uptake.

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Tables

Table 1: Participant Demographics

Table 1 Participant Demographics (n=24)	*n*	%
Gender		
Female	17	71
Male	7	29
Age		
18-25 years	3	13
26-33 years	5	21
34-41 years	9	36
42-49 years	4	17
50-57 years	3	13
58-65 years	0	0
Over 65 years	0	0
Ethnicity		
White	18	75
Hispanic or Latino	5	21
Black or African American	0	0
Native American or American Indian	0	0
Asian/Pacific Islander	0	0
Other	1	4
Highest level of education completed		
Less than high school diploma	4	17
High school diploma	6	25
Some college, but no degree	5	21
Associates degree	2	8
Bachelor's degree	6	25
Master's degree	1	4
Doctorate	0	0
How many children do you have		
1	2	8
2	9	38
3	9	38
4	2	8
5 or more	2	8
Are all of your children up-to-date on vaccinations		
Yes	22	92
No	2	8

Table 2: PACV Survey Identification of VHP

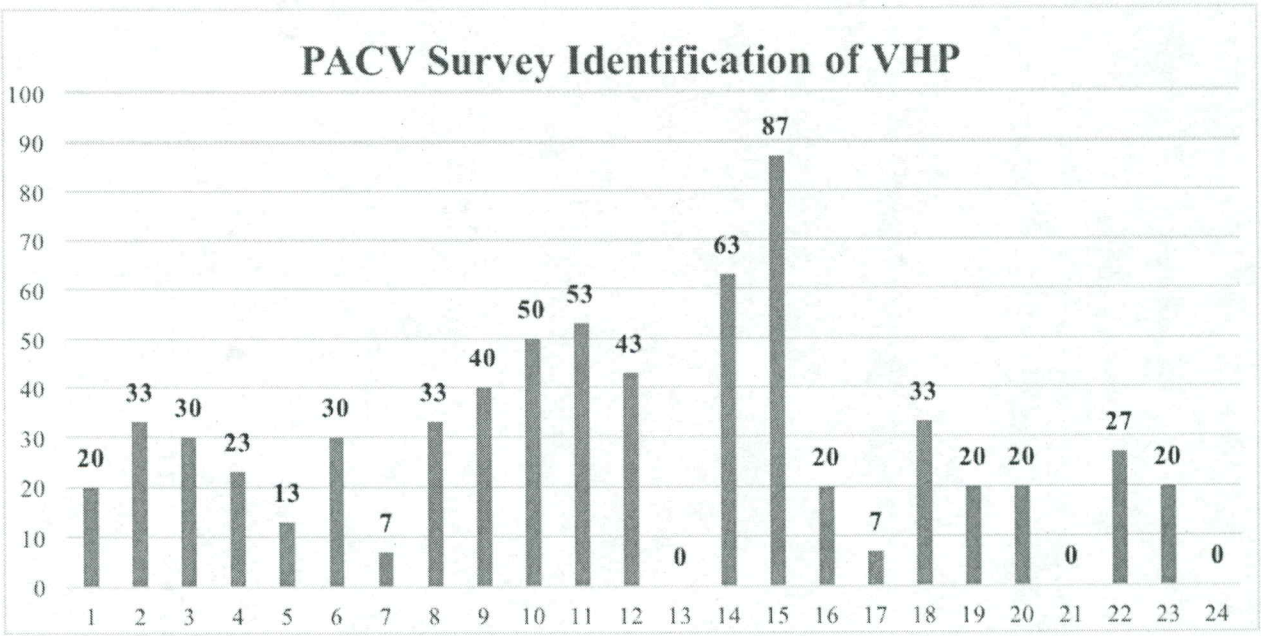


Table 3: PACV Survey

PACV Survey		*n*	%
Have you ever delayed having your child get a vaccine for reasons other than illness or allergy?			
	Yes	5	21
	No	18	75
	Unsure	1	4
Have you ever decided not to have your child get a vaccine for reasons other than illness or allergy?			
	Yes	3	13
	No	20	83
	Unsure	1	4
How sure are you that following the recommended shot schedule is a good idea for your child?			
	0	4	17
	1	0	0
	2	0	0
	3	0	0
	4	1	4
	5	3	13
	6	1	4

	7	2	8
	8	1	4
	9	2	8
	10	10	42
Children get more shots than are good for them:			
	Strongly agree	9	38
	Strongly disagree	15	62
I believe that many of the illnesses that shots prevent are severe:			
	Strongly agree	24	100
	Strongly disagree	0	0
It is better for my child to develop immunity by getting sick than to get a vaccine:			
	Strongly agree	2	8
	Strongly disagree	22	92
It is better for my child to get fewer vaccines at the same time:			
	Strongly agree	15	63
	Strongly disagree	9	37
How concerned are you that your child might have a serious side effect from a vaccine?			

	Not at all concerned	6	25
	Very concerned	18	75
How concerned are you that any one of the childhood vaccines might not be safe?			
	Not at all concerned	9	37
	Very concerned	15	63
How concerned are you that a vaccine might not prevent disease?			
	Not at all concerned	11	46
	Very concerned	13	54
If you had another infant today, would you want him/her to get all the recommended vaccines?			
	Yes	20	83
	No	0	0
	Unsure	4	17
Overall, how hesitant about childhood vaccines would you consider yourself to be?			
	Not at all hesitant	14	58
	Very hesitant	10	42
I trust the information I received about vaccines:			
	Strongly agree	23	96

	Strongly disagree	1	4
I am able to openly discuss my concerns about shots with my healthcare provider:			
	Strongly agree	24	100
	Strongly disagree	0	0
All things considered, how much do you trust your child's healthcare provider?			
	0	0	0
	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	1	4
	6	0	0
	7	2	8
	8	4	17
	9	0	0
	10	17	71

Appendix A

Demographic Survey

Please select the answer that applies to you:

1. What is your gender?
   - ☐ Male
   - ☐ Female
   - ☐ Other
2. What is your age?
   - ☐ 18-25
   - ☐ 26-33
   - ☐ 34-41
   - ☐ 42-49
   - ☐ 50-57
   - ☐ 58-65
   - ☐ Over 65
3. What is your ethnicity?
   - ☐ White
   - ☐ Hispanic or Latino
   - ☐ Black or African American
   - ☐ Native American or American Indian
   - ☐ Asian/Pacific Islander
   - ☐ Other
4. What is the highest level degree or level of school that you have completed?
   - ☐ Less than high school diploma
   - ☐ High school diploma or GED
   - ☐ Some college, but no degree
   - ☐ Associates degree
   - ☐ Bachelor's degree
   - ☐ Master's degree
   - ☐ Doctorate
5. How many children do you have?
   - ☐ 1
   - ☐ 2
   - ☐ 3
   - ☐ 4
   - ☐ 5 or more
6. Are all of your children up-to-date on vaccinations?
   - ☐ Yes
   - ☐ No

Appendix B

Parent Attitude about Childhood Vaccines Survey

Please select the answer that applies to you:

1. Have you ever <u>delayed</u> having your child get a vaccine for reasons other than illness or allergy?

- ☐ Yes
- ☐ No
- ☐ Unsure

2. Have you ever <u>decided not to</u> have your child get a vaccine for reasons other than illness or allergy?

- ☐ Yes
- ☐ No
- ☐ Unsure

3. How sure are you that following the recommended shot schedule is a good idea for your child? Please circle your answer.

0 1 2 3 4 5 6 7 8 9 10

4. Children get more shots than are good for them:

- ☐ Strongly agree
- ☐ Strongly disagree

5. I believe that many of the illnesses that shots prevent are severe:

- ☐ Strongly agree
- ☐ Strongly disagree

6. It is better for my child to develop immunity by getting sick than to get a vaccine:

- ☐ Strongly agree
- ☐ Strongly disagree

7. It is better for my child to get fewer vaccines at the same time:

- ☐ Strongly agree
- ☐ Strongly disagree

8. How concerned are you that your child might have a serious side effect from a vaccine?

- ☐ Not at all concerned
- ☐ Very concerned

9. How concerned are you that any one of the childhood vaccines might not be safe?

- ☐ Not at all concerned
- ☐ Very concerned

10. How concerned are you that a vaccine might not prevent disease?

- ☐ Not at all concerned
- ☐ Very concerned

11. If you had another infant today, would you want him/her to get all the recommended vaccines?

- ☐ Yes
- ☐ No
- ☐ Unsure

Appendix B

12. Overall, how hesitant about childhood vaccines would you consider yourself to be?

- ☐ Not at all hesitant
- ☐ Very hesitant

13. I trust the information I receive about vaccines:

- ☐ Strongly agree
- ☐ Strongly disagree

14. I am able to openly discuss my concerns about shots with my healthcare provider:

- ☐ Strongly agree
- ☐ Strongly disagree

15. All things considered, how much do you trust your child's healthcare provider? Please circle your answer:

0 1 2 3 4 5 6 7 8 9 10

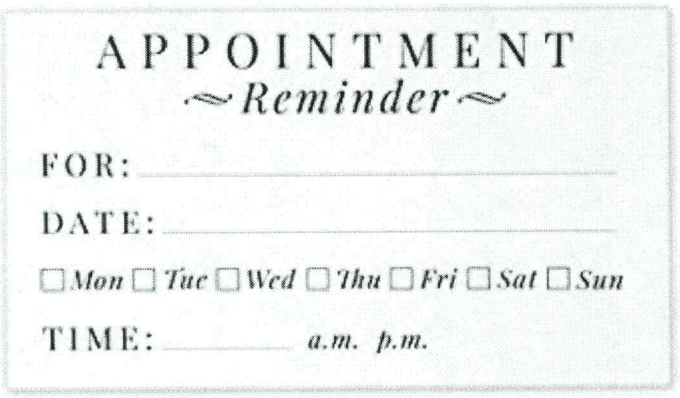
Appendix C

Vaccination Status After Protocol Implementation Log

Participant Number	Vaccine administered, reminder card for second dose given	Vaccine declined	Agreed to vaccinate at a later time, followed through	Agreed to vaccinate at a later time, did not follow through

Appendix D

Appointment reminder card



Appendix E

Institutional Review Board Approval Letter

THE UNIVERSITY OF
ALABAMA IN HUNTSVILLE

__ Expedited (see pg 2)
_X_ Exempted (see pg 3)
__ Full Review
__ Extension of Approval

Date: 19 June 2019

PI: Amy Beck
PI Department: College of Nursing
The University of Alabama in Huntsville

Dear Amy,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal titled: *Increasing HPV Vaccine Uptake through Implementation of HPV Protocol* and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with these institutions Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g. a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB's decision, please contact me.

Sincerely,

Ann L. Bianchi

Ann L. Bianchi
IRB Chair
Associate Professor, College of Nursing

Appendix E

Expedited:

☐ Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Exempt

☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research is not FDA regulated and does not involve prisoners as participants.

X☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interviews, or observation of public behavior ı in which information is obtained in a manner that human subjects cannot be identified directly or through identifiers linked to the subjects and any disclosure of the human subject's responses outside the research would NOT place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior if (a) the human subjects are elected or appointed public officials or candidates for public office, or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs;(iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. The protocol will be conducted pursuant to specific federal statutory authority; has no statutory requirement for IRB review; does not involve significant physical invasions or intrusions upon the privacy interests of the participant; has authorization or concurrent by the funding agency and does not involve prisoners as participants.

☐ Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. The research does not involve prisoners as participants.

1 Surveys, interviews, or observation of public behavior involving children cannot be exempt.

Appendix F

Educational Materials

DISEASES and the VACCINES THAT PREVENT THEM
Updated December 2016

HPV

also known as *Human Papillomavirus*

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

HPV and Cancer

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

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

More about HPV

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

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

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

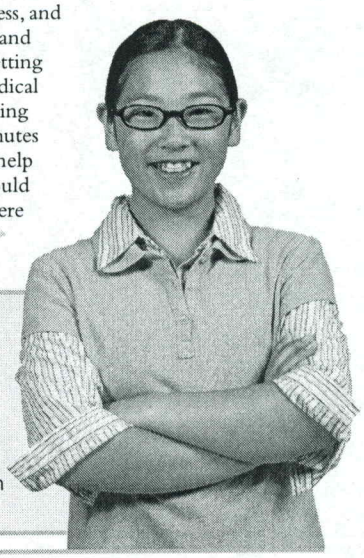
All preteens need HPV vaccination so they can be protected from HPV infections that cause cancer. Teens and young adults who didn't start or finish the HPV vaccine series also need HPV vaccination. Young women can get HPV vaccine until they are 27 years old and young men can get HPV vaccine until they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

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

Is the HPV vaccine safe?

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

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

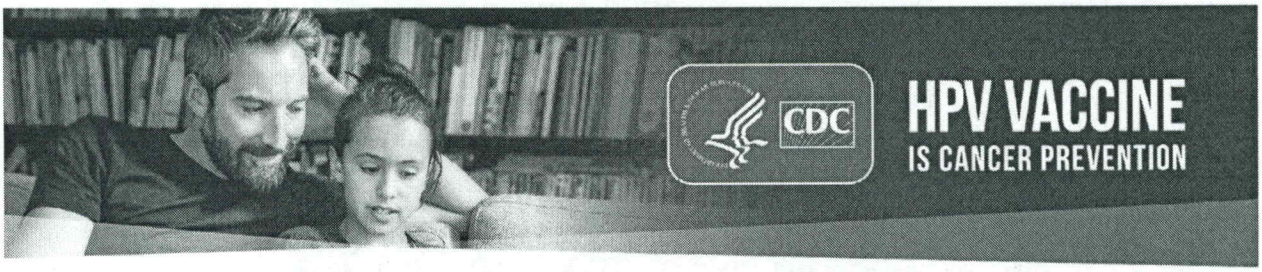


Why does my child need this now?

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

DISTRIBUTED BY:

Appendix F



HPV Vaccine for Preteens and Teens

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

Why does my child need HPV vaccine?

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

When should my child be vaccinated?

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

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

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

Is HPV vaccine safe for my child?

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

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

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

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

How can I get help paying for these vaccines?

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

Where can I learn more?

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

www.cdc.gov/hpv

Last updated JUNE 2018