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Improving HPV Vaccination Series Initiation Rates and Compliance Among Indigent Women in South Texas, Ages 19-26, Through Provider Recommendation and Additional Clinic Funding: a Quality Improvement Project

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IMPROVING HPV VACCINATION SERIES INITIATION RATES AND COMPLIANCE
AMONG INDIGENT WOMEN IN SOUTH TEXAS, AGES 19-26, THROUGH PROVIDER
RECOMMENDATION AND ADDITIONAL CLINIC FUNDING: A QUALITY
IMPROVEMENT PROJECT

by

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Abstract

The purpose of this quality improvement project was to increase human papillomavirus vaccination series initiation rates among indigent women, ages 19-26, at a clinic in South Texas. The human papillomavirus is a sexually transmitted infection that has been associated with multiple types of cancers. Each year, approximately 6.2 million cases of the human papillomavirus infection are diagnosed; as many as 75% of all new infections occur among females 18-26 years of age. The human papillomavirus vaccination has a high efficacy in regards to cancer prevention, preventing as many as 76% of cancers with only one dose. The project included educating clinic staff about human papillomavirus vaccination guidelines, finding a funding source for the human papillomavirus vaccine and developing a protocol for aligning the providers with current guidelines and screening patients to identify vaccine eligible women. The population served at this clinic was primarily Hispanic (84%), 22 years of age, used no contraceptive methods (62%), was single (92%), with a high school diploma (56.9%). Before initiation of the project, random chart audits of 50 human papillomavirus vaccination eligible women indicated that only one out of 50 received the human papillomavirus vaccination. During the project cycle, 21 of the 50 human papillomavirus vaccination eligible women received at least 1 dose of the vaccination, indicating clinical and statistical significance. The interventions implemented were effective in improving adherence to guidelines and improved vaccination rates by 40%. Stakeholder commitment to the project ensures sustainability.

Key Words: *Human Papilloma Virus, vaccination, indigent health, women, cancer*

Context of This Study

The human papillomavirus (HPV) is a sexually transmitted infection that has been associated with multiple types of cancers, most notably, cervical cancer (Hopfer, 2011). This pervasive infection has also been linked to vulvar, vaginal, penile, anogenital, and oropharyngeal cancer, as well as genital warts in both sexes (Centers for Disease Control and Prevention [CDC], 2014). Approximately 6.2 million cases of the human papillomavirus infection are diagnosed annually among females and males (Rosenthal et al., 2011). While HPV occurs in both sexes, as many as 75% of all new HPV infections annually occur among females 18-26 years of age (Hopfer, 2011). Multiple studies have revealed a persistent inequality with regard to HPV vaccination rates in those who reside in the Southern United States, are considered socioeconomically disadvantaged, are Hispanic or another minority race/ethnicity, lack insurance coverage, are married, have less than a high school education, do not have a usual place of care, have not received other recommended vaccinations, have delayed or foregone healthcare, or are greater than 18 years of age (Lu, O'Halloran, & Williams, 2015; Rahman, Islam, & Berenson, 2015; Schmidt & Parsons, 2014). Current practices at the clinical site where this quality improvement project took place, when compared to the national standardized clinical guidelines established by the Advisory Committee on Immunization Practices (ACIP), in regards to HPV vaccination, are not being met.

Statement of the Problem

Currently, in the United States, HPV infections have been cited as the most common STI, with over 200 strains that have been examined (National Cancer Institute, 2015). Approximately 14 million new infections of HPV occur annually, with an estimated 80%-90% of females and males, who are sexually active, contracting at least one strain of HPV at some point during their

lifetime (National Cancer Institute, 2015; CDC, 2014). Roughly, 50% of these infections will be with a high-risk strain of HPV (National Cancer Institute, 2015). High-risk strains of HPV have been associated with approximately 5% of all cancer cases globally (National Cancer Institute, 2015). In the United States, high-risk strains of HPV have been linked to 3% of all cancer cases among females (National Cancer Institute, 2015).

Background and Significance

According to the National Cancer Institute (2015), infection with HPV strains 16 and 18 causes essentially all cases of cervical cancer. The burden caused by the HPV infection includes pre-cancers to cervical lesions (CDC, 2014). Cervical cancer accounts for approximately 70% of all cases of cancer (National Cancer Institute, 2015). Cancer of the anus is caused by HPV at a rate of 95%; of these cases HPV strain 16 is responsible (National Cancer Institute, 2015). An estimated 70% of cancers of the oropharyngeal structures (throat, soft and hard palate, tongue, and tonsils) are caused by infection with HPV (National Cancer Institute, 2015). Currently, half of the cancers caused in the oropharyngeal structures in the United States, are associated with HPV strain 16 (National Cancer Institute, 2015). Infection with HPV also has been shown to cause vaginal cancers, vulvar cancers, and penile cancers; many of these have been linked to HPV strain 16 (National Cancer Institute, 2015). The estimated percentage of cases caused by HPV are 65%, 50%, and 35%, respectively (National Cancer Institute, 2015).

According to the CDC (2014), the introduction of the Gardasil 9-valent vaccination has been shown to be cost-effective, despite the cost of \$13.00 more per dose, when compared to the bi-valent, and quadrivalent vaccinations. According to Jit, Brisson, Portnov, and Hutubessy (2014), in a study conducted in 179 countries, vaccinating a cohort composed of 58 million girls, age 12, showed the HPV vaccination to be cost-effective by preventing an estimated 690,000

cases of cervical cancer, and 420,000 deaths during their lifetime, at a net cost of \$4 billion U.S. dollars (Jit et al., 2014). Most of girls in the study were in primarily low or middle income countries (Jit et al., 2014). The study showed evidence for the HPV vaccination, that with every quality adjusted life year, costs were found to be less than the gross domestic product per head in 87% of these countries (Jit et al., 2014).

Despite ample information displaying the safety and efficacy of the HPV vaccination, a severe deficit in vaccination initiation and completion is seen in women between the ages of 18-26 (Schmidt & Parsons, 2014). The HPV vaccination, Gardasil 9, has a 98% efficacy against cervical cancer, 100% efficacy against vulvar and vaginal cancer, 100% against anal cancer, 75% efficacy against genital warts, and an overall 99% efficacy in females according to a study cited on Merck Vaccines (2015) website. As much as 76% to 100% efficacy can be noted with just one dose of the HPV vaccination (Kreimer, 2011).

Assessment

A hospital-based family health center in South Texas was the site for implementation of this evidence-based quality improvement project related to increasing the HPV vaccination rates in women, 19-26 years of age, and providers' adherence to the CDC and ACIP clinical guidelines. The staff involved in this project included the providers (1.0 physician, 1.0 family nurse practitioner), three licensed vocational nurses, two front office clerks, two medical assistants, the medical records personnel, and a registered nurse, who holds the office manager position.

The South Texas based clinic currently provides care to approximately 7,000 patients annually, and treats patients 18 years of age and older. From March 2016 to March 2017, approximately 300 women, ages 19 to 26, were treated at the clinic.

A May 2017 microsystem assessment indicated the clinic has a high percentage of women who are at an increased risk for acquiring HPV based on their history and physical examination results documented in the electronic health record. As of the present, only 2% of women in the 19-26 age range have initiated the HPV vaccination series according to a pre-intervention chart audit of 100 women seen within the last year. However, according to Bennett et al. (2015), guidelines presented by the ACIP, since 2007, recommend initiating the HPV vaccination series on girls ages 11-12, and implementing the catch up series for females, ages 13-26. The aim of this quality improvement project was to improve rates the of the HPV vaccination series initiation from 2% to 30% in indigent women serviced at the clinic, ages 19-26, in a 10 week period between June 2017 and August 2017. Currently, evidence-based benchmark data on HPV vaccination uptake in women ages 19-26 is limited.

While the majority of the patients spoke Spanish as their primary language, many were bilingual, and a small percentage spoke only English. Of the providers, the nurse practitioner speaks fluent Spanish, while the physician utilizes a translator. Fortunately, for the clinic, many of the staff members, including two licensed vocational nurses, two medical assistants, the office manager, and front desk clerks, all spoke fluent Spanish.

Most of the women who received care at this clinic were of lower socioeconomic class, with as many as 51% of these individuals earning a household income of less than \$34,999 a year (Acosta et al., 2014). The mean age of the pre-intervention group was 22.30 years of age. Of the sample size, there were 11 women who were 19 years of age, 12 who were 20 years of age, 14 who were 21 years of age, 17 who were 22 years of age, 8 who were 23 years of age, 13 who were 24 years of age, 13 who were 25 years of age, and 12 who were 26 years of age.

The top two payer sources of the pre-intervention chart audit was the Nueces County Hospital District (NCHD) at 84% and Medicaid, at 14%. Nearly 84% of these women identified as themselves as Hispanic. The pre-intervention chart audit also identified 62% of women were up-to-date with their annual pap smears, 62% used no form of contraception, 18% have a history of a STI, 30% have a history of an abnormal pap smear, 86% are single, and 54% have a high school diploma, or equivalent. 96% of these women identified as heterosexual.

Due to funding, the clinic did not routinely vaccinate women ages 19-26, who are at risk for acquiring the HPV strains prevented by the vaccination.

Organization's Readiness for Change

Upon review of the CDC and ACIP guidelines, and the results provided from the May 2017 microsystem assessment with key stakeholders, it was determined that the family health center was not aligned with the CDC and ACIP guidelines. Prior to review of the clinical guidelines, the clinic's providers were not aware of the age range for the HPV catch-up series for vaccination; they were also not aware of a way to obtain funding to provide the HPV vaccinations, at little to no cost to the clinic or their patients. Following review of the guidelines for HPV vaccination, it was determined that due to the high-risk population, an algorithm and protocol to align the clinic with the current clinical guidelines was needed. All clinic providers and staff expressed eagerness to engage in a project to implement the latest evidence-based CDC and ACIP guidelines for HPV vaccination in the clinic as a mechanism of improving the standard and quality of patient care.

Collaborating with the providers and the office manager, an algorithm was designed and established to identify women who were at risk for acquiring HPV, and could receive the HPV vaccination. The evidence from the appraisal was shared with the providers, citing that a strong

recommendation in favor of the HPV vaccination appeared to be the best approach to increasing vaccination rates.

Costs of the HPV vaccination appeared to be the primary barrier to increasing HPV vaccination rates at this clinic. However, a funding source, the Merck Patient Vaccine Assistance Program, appeared to be a low cost solution to improving acquisition of the vaccine. The program requires the clinic to purchase the first 10 vaccinations, fill out a Merck Patient Vaccine Assistance application on each patient who can receive the vaccination, and then the application is either approved or denied. Once 10 patients have been approved, the program replenishes the 10 vaccines at no cost to the clinic. This will continue as long as the clinic wishes to participate in the program, and as long as a patient application is faxed and approved by Merck. Qualifications to participate include patients who do not have any form of health insurance, and make less \$48,240 for a household of one (household income and those living in the household was adjusted, as income increases and occupants in the household increases). Due to the type of population serviced at the indigent health center, it was determined that the majority of patients who meet the criteria for vaccination, would qualify for the program.

Buy-in from the office manager, providers, and clinic staff was received openly, as it was a benefit for all involved. By increasing the women vaccinated, an increased number of nurse visits were scheduled for vaccination. An increase in nurse visits for the clinic was reflected in overall visit numbers, assisting the clinic to meet their annual goal of patients seen per year.

Project Identification

Purpose

The purpose of this evidence-based quality improvement project was to increase HPV vaccination series initiation rates among indigent women in South Texas, ages 19-26, through

provider recommendation, clinic funding, and provider adherence to the Centers for Disease Control and Prevention and The Advisory Committee on Immunization Practices guidelines, thereby improving the quality of care provided.

Objectives

The objectives of this evidence-based project to improve the quality of care provided were to:

1. Increase HPV vaccination series initiation rates and compliance from the pre-intervention rate of 2% to 30% by the completion of the 10th week of project implementation.
2. Increase clinic funding for the HPV vaccination by participating in the Merck Patient Vaccine Assistance Program for the Gardasil 9-valent vaccination.
3. Appropriately train staff on the process and procedures of the Merck Patient Vaccine Assistance Program, as well as the current guidelines established by the CDC and ACIP.
4. Increase the amount of times the providers provide a strong recommendation in favor of the HPV vaccination to female patients, between 19-26 years of age, and have not received any doses of the vaccination, or have not completed the vaccination series (3-doses).

Anticipated Outcomes

By meeting the above stated objectives, the outcome of increasing the rate of HPV vaccination initiation and compliance from a pre-intervention rate of 2% to 30% by the completion of the 10th week of the project's implementation, occurred. Additional outcomes included the HPV vaccination being readily available in the office, as more funding was available to stock the vaccination. As a result of improved vaccination rates, women who

received the HPV vaccination will have a decreased morbidity and mortality rate, secondary to HPV and potential cancers. The overall outcome of this evidence-based quality improvement project was to increase the percentage of indigent women in South Texas, ages 19-26, who receive the HPV vaccination from 2% to 30%, as well as increased clinician adherence and compliance to the CDC and ACIP guidelines. The clinic aligned with Healthy People 2020 goals (2014) for increasing immunization rates, thereby directly reducing preventable, infectious diseases.

Summary and Strength of the Evidence

Numerous research studies were appraised to identify the best methods of increasing HPV vaccination rates in women, ages 19-26 years of age, who have access to health care through indigent services, as well as increasing the providers' knowledge and adherence to the CDC and ACIP guidelines. The information which yielded the best evidence was synthesized, utilized to devise a system to increase HPV vaccination rates, and was then implemented.

Physician recommendation has a substantial influence on individuals initiating the HPV vaccination series (Vadaparampil et al., 2014). According to Rosenthal et al., (2011), receiving a strong physician recommendation to initiate the HPV vaccination series could result in up to a four-fold greater likelihood of vaccination. In another study by Ylitalo, Lee, and Mehta (2013), with a sample size of 9,274, greater than half of the study population who received a strong physician recommendation were almost five times as likely to initiate the HPV vaccination series. Furthermore, the strong association between physician recommendation and vaccination initiation translated across all races and ethnicities (Ylitalo et al., 2013). According to Ylitalo et al. (2013), after receiving a strong physician recommendation in favor of the HPV vaccination, both non-Hispanic Whites, as well as those who identify as White, were equally likely to obtain

vaccination. Women, ages 19-26, who had discussed uptake of the HPV vaccination with their health care provider, and received a strong recommendation, were significantly more likely to receive the vaccination (Rosenthal et al., 2011).

Current evidence suggests that other strategies are needed to increase and improve HPV vaccination uptake (Rosenthal et al., 2011). There is a lack of evidence detailing effective interventions to improve HPV vaccination coverage in women, ages 19-26. However, multiple studies suggest focusing on the patient, the health care provider's attitude towards HPV vaccination, health insurance status, marital status, education level, race and ethnicity, as well as current or prior infection with HPV (Bennett et al., 2015; Hopfer, 2011; Lu et al., 2015; Patel et al., 2012; Rosenthal et al., 2011; Wilson et al., 2016). Furthermore, many studies lack participation of the minority populations, individuals of lower socioeconomic class, those who are uninsured, have not completed a college degree, and are of 19-26 years of age (Bennett et al., 2015; Hopfer, 2011; Lu et al., 2015; Patel et al., 2012; Rosenthal et al., 2011; Wilson et al., 2016).

Methods

Project Intervention

A pre-intervention chart audit was performed on 100 patients who meet the criteria for vaccination, seen in the clinic between March 2016 to March 2017. The data obtained reflected that of the women who could receive the vaccination, only 2% had been vaccinated, and completed the 3 dose series.

Prior to implementation, a one-on-one educational session was conducted with each provider and staff member on the current guidelines of administering the HPV vaccination, the eligibility criteria for the catch-up series, the target population (ages 19-26, as the Merck Patient

Vaccine Assistance Program will not cover women younger than 19), the background, significance, and implications of HPV and its vaccination. Each provider and staff member was given a copy of the current CDC and ACIP guidelines, as well as an algorithm of eligibility and screening criteria to use as a resource during the project's implementation (see Appendix A). A copy of the Merck Patient Vaccine Assistance Program was also given to providers and staff members in English (see Appendix B) and Spanish (see Appendix C), so that all staff would be familiar with the application, and understand how to properly complete the forms. Staff was also given an educational flyer with information about HPV and statistics obtained from The American College of Obstetricians and Gynecologists (ACOG) (2017). The obtained flyer was free for public use, and was identified within a tool kit promoting the HPV vaccination (see Appendix D). Prior to implementation of the new HPV vaccination protocol, an additional one-on-one educational session was conducted with providers and staff discussing the different roles and responsibilities to be completed during the project's implementation.

Starting the day before project implementation, medical records personnel placed a Merck Patient Vaccine Application in each female patient's chart who was identified between 19-26 years of age. The provider portion of the application was pre-filled out, and the application was placed in the chart according to provider, and whether the patient spoke English or Spanish. The application was completed, along with the patient's routine registration packet. Once the application was completed, it was then given to the medical assistant during patient intake. The medical assistant surveyed the quality improvement tab in the Athena EHR system to check and see if the patient had received the HPV vaccination and how many doses, and would then confirm this information with the patient during intake. The medical assistant also assessed for pregnancy status, as well as allergies to yeast, or a reaction to a previous dose of the HPV

vaccination. If no contraindications were identified, the medical assistant would place a "vaccine eligible" tab in front of the patient's paper chart, which housed the super bill. The provider was then provided with the application, so a signature could be obtained. The medical assistant then faxed the application to Merck.

Approval from Merck took approximately 10-30 minutes, so the sooner the application was faxed, the greater the chance of the patient receiving the vaccination during their visit. When the providers entered the examination rooms for the patient visits, they reassessed for contraindications to the HPV vaccination, if previous doses had been received, and then provided a strong recommendation in favor of the receiving the HPV vaccination. If the application was approved, no contraindications were noted, and the patient was eligible for the vaccination, the vaccination was then administered.

Post-administration, the providers wrote either a diagnosis of administered immunization: Gardasil 9-valent in the EHR, along with clicking the quality improvement tab in the EHR, and specifying the dates of vaccination administration, or wrote, "patient declined Gardasil vaccination," and then provided the patient with educational materials. In the event where the application was approved, but the patient had to leave, or the office was out of vaccinations, the applications were held for a total of 30 days; The patient was then scheduled for a nurse visit and received the vaccination at a later date. Patients were scheduled for nurse visits to receive subsequent doses of the HPV vaccination, or when the clients declined the HPV vaccination, they were told if they change their mind, to call and schedule a nurse visit for the vaccination.

A list was kept of females who had initiated the vaccination series, but did not schedule a nurse visit for when their next dose would be due. The licensed vocation nurses then called and scheduled these women prior to when their next dose was due.

Following implementation of the new HPV vaccination protocol, all patients ages 19-26 years of age, who entered the office during the 10 weeks of project implementation, were included in the post-intervention data and analysis. There were a total of 50 patients seen at the clinic during the 10 week implementation duration. All patients were tracked throughout each step of the protocol, from the first week of implementation, through the tenth week and the project's end.

Prior to the initiation of this quality improvement project, the proposed plan was submitted to both the University of the Incarnate Word's Institutional Review Board (IRB), as well as the Christus Health IRB for approval. The project was approved by exempt review, as it was determined to be less than minimal risk to those participating, and no known physical, emotional, psychological, or economic risk for the individual participating.

Organizational Barriers and/or Facilitators

Throughout the project's implementation, multiple obstacles were faced with the implementation of the new protocol. Barriers included failure to screen patients, fluctuations with the patient population seen due to provider's absence during the implementation period, patient misconceptions, patients previously having received the HPV vaccination, and EHR charting not reflective of this, as well as missing vaccination doses and receiving these in a timely fashion. The first dose of clinic vaccinations received were short two doses, which were needed for the initial ten. The initial clinic-purchased vaccinations to begin the project were received June 5, 2017. The licensed vocational nurses and the office manager made daily calls to the manager of the hospital's pharmacy to retrieve the missing doses. Vaccinations were delivered July 7, 2017. Multiple opportunities were missed to administer patient vaccinations during this time.

The first week, medical personnel did not include the Merck application on all patients who were eligible. Reinforcement and clarification was provided, which improved the problem.

Other problems identified included the medical assistants not filling out the form in its entirety, and incorrectly. Additional education and reinforcement was provided.

Some patient misconceptions occurred, as some did not see a need for the vaccination, did not want an injection, or had a knowledge deficit regarding the HPV vaccination. Most patients, once provided educational material, and the knowledge that this vaccination helps prevent cervical cancer, were eager to obtain vaccination status. Other misconceptions included a patient's lack of knowledge if they'd previously received the vaccination during childhood, and did not have their immunization card available.

Facilitators to the implementation of the quality improvement project included a strong rapport with staff, eagerness to take on a new role and responsibility, staff empowerment through knowledge, and providing staff with an opportunity to empower patients through education. Furthermore, consideration was taken to consider the clinic staff's input in regards to how to successfully implement this project. The clinic staff was familiar with the processes and procedures of contacting and scheduling patients for visits, and follow-ups, which assisted in smoothly implementing the project. Furthermore, as other vaccinations are given at the clinic, the staff is familiar with the process of obtaining consent, administering vaccinations, and tracking the vaccinations administered.

A major facilitator of this project was the clinic and staff's buy-in. By increasing patient visits with either the nurse or provider, and the overall volume of patients seen, clinic numbers are increased. This helped the clinic to maintain or increase yearly funding. Over the last few

years, the clinic has not met the annual numbers needed to maintain or increase funding, so funding to provide care to high acuity patients has decreased.

Another facilitator of this project was the ease and timeliness of working with the Merck Patient Vaccine Assistance Program. This will be a large contributing factor to the sustainability of this project once the implementation period is over.

Results

From June 2017 to August 2017, 50 women were identified who were eligible to receive the HPV vaccination. Of these women, 13 received the HPV vaccination, 1 was not approved by the Merck Patient Assistance Vaccination Program, 23 were unable to receive the vaccination due to the vaccine being out of stock, 8 were previously vaccinated, but it had not been documented in the EMR, and 5 women refused the vaccination. The pre-intervention group also consisted of 50 women.

A Fisher's Exact Test was conducted on each of the pre-intervention and post-intervention variables. The test results indicated the two groups did not differ significantly in age, marital status, insurance, race, UTD on pap smear, contraceptive method used, history of a STI, or level of education. Equivalency between the pre and post-intervention groups were found.

Descriptive Characteristics of Pre and Post-Intervention Groups

Characteristics of Pre and Post-Intervention Groups	Pre-Intervention (<i>n</i> = 50)	Post-Intervention (<i>n</i> = 50)	<i>p</i> - value
Age (Mean), SD	22.30, 2.288	22.82, 2.179	<i>p</i> = .706
Marital Status	86% Single	92.2% Single	<i>p</i> = .098
Insurance	84% NCHD	90.2% NCHD	<i>p</i> = .160
Race	84% Hispanic	84.3% Hispanic	<i>p</i> = .124
UTD on Pap Smear	62%	70.6%	<i>p</i> = .345
Contraceptive Method?	62% use no method	54.9% use no method	<i>p</i> = .386
History of a STI	18%	19.6%	<i>p</i> = 1.00
Education Level (High School Diploma)	54%	56.9%	<i>p</i> = .316

A chi-square analysis was conducted to determine significance between the pre-intervention and post-intervention groups. The percentage of patients receiving one or more doses of the HPV vaccination were found to differ significantly between the pre-intervention and post-intervention groups. Pearson Chi-Square = 22.744, *df* = 1, *p* < 0.001.

Table 2

Chi-Square Analysis

Statistical Test	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	22.744 ^a	1	.000	.000	.000	
Continuity Correction ^b	20.502	1	.000			
Likelihood Ratio	26.967	1	.000	.000	.000	
Fisher's Exact Test				.000	.000	
Linear-by-Linear Association	22.519 ^c	1	.000	.000	.000	.000
N of Valid Cases	101					

A contingency table analysis was completed with the Chi-Square Statistic to test for a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 10.89 statistical significance. The analysis reflects results which are both statistically and clinically significant. In the pre-intervention group, 2% of individuals were receiving the HPV vaccination. In the post-intervention group, 40% of women seen received one or more doses of the HPV vaccination.

Table 3

Contingency Table Analysis of HPV Vaccination Doses

Pre/Post Intervention		No Doses of HPV Vaccination	1 or More Doses of HPV Vaccination Received	Total
Pre-Intervention	Count	49	1	50
	% within pre/post intervention	98%	2.0%	100%
Post-Intervention	Count	30	20	50
	% within pre/post intervention	60%	40%	100%
Total	Count	79	21	100
	% within pre/post intervention	79%	21%	100%

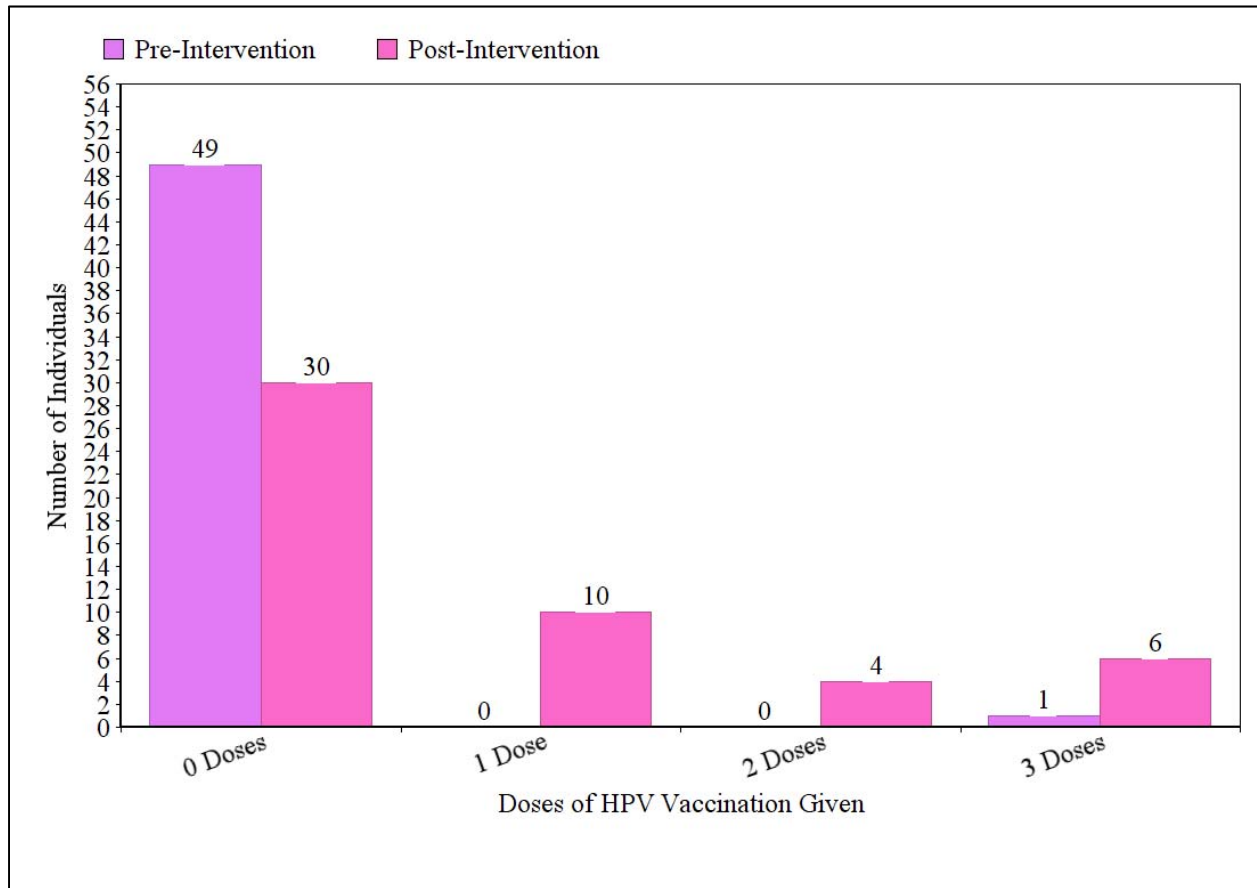


Figure 1. Pre-Intervention versus post-intervention HPV vaccination rates.

The provider's adherence to recommending the vaccination, and documenting the recommendation, or the patient's refusal of the HPV vaccination in the EMR system, increased from 0% to 100%.

Discussion

The purpose of this quality improvement project was to increase the HPV vaccination rate among indigent women 19-26 years of age, and increase provider adherence to the ACIP and CDC guidelines. During the ten-week implementation phase, an increase of 2% pre-intervention to 40% post-intervention was noted. During this time, many women were able to receive one or two doses of the HPV vaccination. These percentages are now more closely related to national

estimates. Within the United States, approximately 21% of HPV vaccine eligible 19-26 year-old women have initiated vaccine uptake (Marchand, Glenn, & Bastani, 2012). However, results yielded from this quality improvement indicated that many women who may benefit from receiving the HPV vaccination, have not received it (Marchand et al., 2012).

The setting where this project took place at serves the indigent population; however, it is considered a hospital-based clinic, and therefore, does not qualify to participate in the Adult Safety Net Program, nor the Vaccines for Children Program. Funding was the main obstacle throughout this endeavor. Many eligible women who received the vaccination were unaware it existed, was needed, or could be given at a younger age. Furthermore, consistent access to the vaccine was a dilemma.

This project was made possible by educating the clinic's office manager, and providers, on the Merck Patient Vaccine Assistance Program, and the benefits it could have for the patients seen in the clinic. By participating in this cost-assistance program, the clinic was required to purchase and stock 10 doses of the HPV vaccination. Merck then provided the Gardasil vaccination to the clinic for low-income adults through the Patient Vaccine Assistance Program. This clinical setting was fortunate enough to afford to stock these initial 10 vaccines. Without this, this strategy would not have been viable.

Furthermore, provider recommendation played a large role in increasing the number of women initiating the HPV vaccination. Prior to this intervention, the providers were not recommending the HPV vaccination; however, post-intervention, 50 out of 50 charts reflected documentation from the clinic's providers that they had recommended, and given educational material regarding the HPV vaccination. By recommending the vaccination, rather than offering it, research has shown that this simple intervention has had marked increases in HPV vaccine

uptake.

Other research has shown that younger age was a predictor of greater vaccine uptake (Marchand et al., 2012). The mean age in both the pre-intervention and post-intervention groups of this study who initiated vaccine uptake was 22 years of age.

Limitations

The main limitation was the lack of time for the project's implementation. The project implementation period was 10 weeks, which is enough time to receive one vaccination, and maybe a second. The overall volume of patients in the target age range (19-26), as well as the eligibility screening rates may have been affected by fluctuations in the clinic's providers' schedules, as well as multiple office staff members and providers on vacation during this time frame. Furthermore, due to the timing of implementation (summer), the Merck Patient Vaccine Assistance representative for Texas was unable to deliver the next shipment of the Gardasil-9 vaccinations to the clinic within the project's implementation time frame, as this individual was on vacation at this time.

Recommendations

Though adherence and compliance rates were increased to levels that were both clinically and statistically significant, more improvements can be made. The clinic should continue to utilize the Merck Patient Vaccine Assistance Program, ensuring that all women who are able to receive the HPV vaccination receive it. Further recommendations would be to include a longer implementation period, not taking place during summer months when providers and patients may be on vacation. Comparing the rates of vaccination in the Summer months to the rates during the Spring and Fall may be an additional way to increase vaccination compliance and adherence.

Lastly, following up with the Merck Patient Assistance Vaccination Program frequently may ensure HPV vaccinations are delivered to the clinic in a timely fashion.

Implications for Practice

There were 1/50 (2%) patients given the HPV vaccination in the pre-intervention patient population. Of the patients screened for eligibility during the project implementation, there were 20/50 (40%) given one or more doses of the HPV vaccination. The results of this QI project demonstrated that by training staff and providers on the most up-to-date guidelines, and utilizing patient assistance programs, HPV vaccination rates in indigent women ages 19-26 can increase. Based on these results, one could conclude that other primary care practices who offer services to the indigent population could benefit from screening women who may be eligible for the HPV vaccination, provider recommendation, utilizing the Merck Patient Vaccine Assistance Program, and administering the vaccination.

Other clinics, such as women's and men's health clinics, gynecologists office, college health centers, and specialty clinics of this nature could also benefit by implementing a HPV vaccination protocol, and utilizing the Merck Patient Vaccine Assistance Program.

The advanced practice registered nurse is in a unique position to offer insight, oversight, and assist in implementing measures which may increase patient outcomes and quality of care. In this circumstance, implementing the CDC and ACIP's guidelines to screen and vaccinate women who are eligible to receive the HPV vaccination, has the potential to significantly impact individuals who are at an increased risk for acquiring the human papillomavirus and cervical cancer. A cornerstone of the advanced practice registered nurse's education focuses on health promotion, disease prevention, and patient education. By utilizing and implementing a protocol to properly screen women who may be eligible for the HPV vaccination, and providing a strong

recommendation in favor of the vaccination, the advanced practice registered nurse has the potential to decrease rates of cancer, and improve the health and quality of lives of their patients, families, and communities.

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Appendix A.

HPV Vaccination Screening Eligibility Protocol

For ALL female patients:

- 1.) Is the patient between 19-26 years of age? If yes, continue to item 2.
- 2.) Has the woman received any doses of the HPV vaccination? Ask patient, and check quality tab in Athena.
- 3.) If **NO**, ask about allergies to yeast. If no allergies to yeast, continue to step 4.
- 4.) Have patient complete Merck Patient Vaccination Assistance Application, and fax application to Merck, 1-800-528-2551.
- 5.) *****REMIND PROVIDER TO RECOMMEND THE HPV VACCINATION*****
- 6.) If **YES**, how many doses has patient received? If 3 doses, stop. If less than 3 doses, continue.
- 7.) Has patient ever had an allergic reaction to the HPV vaccination? If no, continue to step 8.
- 8.) Have patient complete Merck Patient Vaccination Assistance Application, and fax application to Merck, 1-800-528-2551.
- 9.) *****REMIND PROVIDER TO RECOMMEND THE HPV VACCINATION*****

***GUIDELINES* (CDC, 2014; CDC, 2015)**

The three-dose series should be given to those persons who initiate the vaccine at > 15 years of age, as well as individuals who are immunocompromised. The schedule of the 3-dose series is: a vaccination given at the initial visit, one given two months after the first vaccination, and one given six months after this. The HPV 'catch-up' series should be initiated on persons 13-26 years of age.

**For this project: only screen women ages 19-26.*

**Other names for the HPV vaccination include: Gardasil, Gardasil 9, Gardasil 9 valent, Cervarix, Gardasil bivalent, Gardasil quadrivalent.*

Appendix B.

Merck Patient Vaccine Assistance Application - English

MERCK VACCINE PATIENT ASSISTANCE PROGRAM APPLICATION

IMPORTANT: A dose of Merck vaccine should not be administered until after the Merck Vaccine Patient Assistance Program provides a confirmation number.

SECTION 1: Applicant Information (Patient should complete all information in Section 1.)

Form fields for Patient's First Name, Last Name, Address, City, State, ZIP, Phone, Date of Birth, Gender, Medicare insurance, and household income.

Please read the Applicant Declarations and Applicant Authorization and sign each section to indicate your agreement.

Applicant Declarations

I verify that the information provided in this application is complete and accurate and that without enrollment in the Merck Vaccine Patient Assistance Program I would not be able to afford this vaccine.

Patient's Original Signature: _____ Date: _____

Applicant Authorization

I authorize the Merck Vaccine Patient Assistance Program and its administrators to obtain and disclose information from my prescribing physician and other information as necessary to complete the application process.

Patient's Original Signature: _____ Date: _____

Appendix B. Continued - Merck Patient Vaccine Assistance Application - English

Patient First, Last Name: _____

SECTION 2: Licensed Prescriber Information *(Healthcare provider should complete Sections 2 and 3.)*

First, Last Name: _____

Practice/Clinic Name: _____

Address: _____

City: _____ State: _____ ZIP: _____

Note: The address you provide above is where Merck will ship the replacement dose.

Type of Licensed Prescriber: Physician Nurse Practitioner Physician Assistant Certified Nurse Midwife
State License Number: # _____ (must be active and valid)
 Is this patient seeing you at a public practice, (ie, one that is wholly owned and operated by the government)?
 Yes No

Office Contact Person: _____

Phone Number: _____ Fax Number: _____

I have a Merck Direct Account. Account Number: # _____
 I don't have a Merck Direct Account.

SECTION 3: Vaccine Information

Merck Vaccine Product Name: Gardasil 9 **NDC Number: #** _____

If GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], indicate: Dose 1 Dose 2 Dose 3

Have you administered this dose? Yes No

To be completed after application is approved by a Merck Vaccine Patient Assistance Program Representative.
Confirmation Number: # _____
Date of Administration: ____/____/____ **Merck Vaccine Lot Number: #** _____
IMPORTANT: The confirmation number is valid for **30 days**. If the vaccine dose is not administered to the eligible patient within 30 days following when it was granted, then the patient must submit a new application. The office must provide the date of administration and lot number to the Merck Vaccine Patient Assistance Program for all approved doses of vaccine in order for replacement product to be provided.

Merck will replace the doses of vaccine administered to approved patients via quarterly shipments to the licensed prescriber.
[Notes: Merck retains the right to select either prefilled syringes or vials for replacement doses which may or may not be the same as what was administered to approved patients. M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live) and PNEUMOVAX®23 (Pneumococcal Vaccine Polyvalent) are not available in single-dose units; therefore, these vaccines can be shipped only when the minimum threshold is reached.]

Licensed Prescriber Declarations

I verify that the information provided on this application is complete and accurate. I understand that the patient must be part of the population for which the administered vaccine is indicated and I certify that this vaccine is medically indicated for this patient. I understand that the patient must qualify financially and meet the program criteria to be eligible for assistance. The product administered to the above patient on the date(s) above will be considered a donation to the patient from the Merck Vaccine Patient Assistance Program. I also understand that the product I receive is not a sample, but a replacement of product I previously purchased. I understand that I will not receive any reimbursement from Merck & Co., Inc., whether for administration fees or otherwise. I will not seek reimbursement for administration of vaccine from any public payer. Additionally, reimbursement for the cost of the product administered to the above patient on the date(s) above has not been sought and will not be sought from any source. I understand that Merck & Co., Inc., reserves the right to conduct periodic audits of the records, excluding patient-identifiable data (unless the auditor enters into an appropriate relationship with the facility to protect an individual's medical privacy), of all entities receiving replacement of inventory in connection with the Merck Vaccine Patient Assistance Program. I accept that reasonable notice will be granted and audits will be conducted during regular business hours. I represent and warrant that this facility has obtained all applicable authorizations, consents, and notices necessary to comply with all federal and state laws and regulations relating in any way to medical and/or health privacy including but not limited to the HIPAA Privacy Rule, codified at 45 C.F.R. Parts 160 and 164, as amended from time to time. My signature below confirms that the vaccine product will be provided free of charge to this individual. I verify that to the best of my knowledge the information set forth in this application is complete and accurate. I agree to retain a copy of this form in the facility's records and to make it available to the Internal Revenue Service upon request.

Licensed Prescriber's Original Signature: _____

Date: _____

(No stamps accepted)

Appendix C.

Merck Patient Vaccine Assistance Application - Spanish

SOLICITUD DEL PROGRAMA DE ASISTENCIA A PACIENTES DE VACUNAS DE MERCK
IMPORTANTE: No debe administrarse una dosis de vacuna Merck antes de que el Programa de Asistencia a Pacientes de Vacunas de Merck proporcione un número de confirmación. Esto incluye dosis subsiguientes en una serie de dosis múltiples, ya que se requiere hacer una nueva solicitud por cada dosis. En caso de que se administren dosis de vacunas antes de enviar una solicitud y/o recibir un número de confirmación, no se enviarán las sustituciones.

SECCIÓN 1: Información del solicitante (El paciente debe llenar toda la información de la Sección 1.)

Nombre del paciente: _____ Residente de EE.UU.* Sí No

Apellido: _____ Apt. N.º: _____

Dirección: _____ Ciudad: _____ Estado: _____ C.P.: _____

Teléfono: _____ Fecha de nacimiento: _____ Sexo: Masculino Femenino

M M D D A A A A

¿Tiene usted seguro de Medicare? Sí No

Beneficiarios de Medicare solamente: ¿Tiene usted Medicare Parte D? Sí No

¿Tiene usted alguna otra cobertura de seguro médico de cualquier tipo (pública o privada)? Sí No

Ejemplos: Medicaid, beneficios de veteranos, organización de mantenimiento de la salud (HMO), organización de proveedores preferidos (PPO), plan médico universitario, seguro federal o estatal o programa de asistencia médica

¿Está usted cubierto por el plan de seguro médico de otra persona? Sí No

¿Es usted reclamado como dependiente en la declaración de impuestos de otra persona? Sí No

Ingreso anual bruto actual del hogar: \$ _____

Número de personas que dependen de los ingresos del hogar (incluso el solicitante): _____

* Usted no tiene que ser ciudadano de EE.UU.

Por favor, lea las **Declaraciones del Solicitante** y la **Autorización del Solicitante** y firme cada sección para indicar su conformidad.

Declaraciones del Solicitante

Confirmando que la información ofrecida en esta solicitud es completa y exacta y que sin la inscripción en el Programa de Asistencia a Pacientes de Vacunas de Merck no podría sufragar el costo de esta vacuna. Reconozco que mi elegibilidad para este programa y cualquier asistencia del programa terminará si el programa llega a estar en conocimiento de cualquier fraude o si esta vacuna ya no es indicada para mí. Reconozco que Merck & Co., Inc., se reserva el derecho de modificar, en cualquier momento y sin previo aviso, los criterios de elegibilidad para este programa o de modificar o suspender éste o cualquier programa. Reconozco que el llenar esta solicitud no garantiza que reuniré los requisitos para este programa. Asimismo confirmo que no buscaré reembolso ni crédito para esta vacuna de ninguna compañía de seguros, organización de mantenimiento de la salud o programa gubernamental. Si soy miembro del plan Medicare Parte D, no procuraré que esta vacuna y cualquier costo relacionado con la misma sea cobrado como parte de mis gastos o costos de bolsillo de medicamentos de receta.

Firma original del paciente: _____ Fecha: _____

Autorización del Solicitante

Autorizo al Programa de Asistencia a Pacientes de Vacunas de Merck y a sus administradores, a obtener y divulgar información de mi médico prescriptor y cualquier otra información según sea necesario para llevar a cabo el proceso de solicitud o verificar la exactitud de cualquier información proporcionada en la solicitud y con los fines de proporcionar servicios mediante este programa. Asimismo autorizo al programa y sus administradores a usar y divulgar a Medicare, mi plan y sus contratistas mi información médica personal respecto a esta receta para los fines de la coordinación de beneficios y verificación de las declaraciones hechas por mi médico y por mí en relación con mi inscripción en el programa. Reconozco que mi nombre, dirección y cualquier otra información que me identifique personalmente provista en esta solicitud sólo estará disponible para Merck, sus compañías afiliadas y sus subcontratistas, excepto según yo lo autorice o sea requerido por la ley. La función de Merck, sus compañías afiliadas y sus subcontratistas se limitará a las labores administrativas, que incluyen la entrada de datos y la verificación de la exactitud e integridad de la información de elegibilidad y de inscripción contenida en este formulario de solicitud. Reconozco que Merck no es responsable de la comprobación o verificación de la información contenida en la Sección 2. En lo que respecta a esta solicitud, reconozco que solamente el prescriptor autorizado será responsable por la información contenida en la Sección 2. Asimismo reconozco que puedo recibir una copia de esta autorización y que, salvo que cambie mi decisión más temprano, mi autorización vencerá a los 15 meses posteriores a la fecha de firma de abajo.

Firma original del paciente: _____ Fecha: _____

06/2017 1:56 PM FAX +9158491037

Appendix C. Continued - Merck Patient Vaccine Assistance Application - Spanish

Patient First, Last Name: _____

SECTION 2: Licensed Prescriber Information *(Healthcare provider should complete Sections 2 and 3.)*

First, Last Name: _____

Practice/Clinic Name: _____

Address: _____

City: _____ State: _____ ZIP: _____

Note: The address you provide above is where Merck will ship the replacement dose.

Type of Licensed Prescriber: Physician Nurse Practitioner Physician Assistant Certified Nurse Midwife
State License Number: # _____ (must be active and valid)
 Is this patient seeing you at a public practice, (ie, one that is wholly owned and operated by the government)?
 Yes No

Office Contact Person: _____

Phone Number: _____ Fax Number: _____

I have a Merck Direct Account. Account Number: # _____
 I don't have a Merck Direct Account.

SECTION 3: Vaccine Information

Merck Vaccine Product Name: Gardasil 9 **NDC Number: #** _____

If GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], indicate: Dose 1 Dose 2 Dose 3

Have you administered this dose? Yes No

To be completed after application is approved by a Merck Vaccine Patient Assistance Program Representative.
Confirmation Number: # _____
Date of Administration: ____/____/____ **Merck Vaccine Lot Number: #** _____
IMPORTANT: The confirmation number is valid for **30 days**. If the vaccine dose is not administered to the eligible patient within 30 days following when it was granted, then the patient must submit a new application. The office must provide the date of administration and lot number to the Merck Vaccine Patient Assistance Program for all approved doses of vaccine in order for replacement product to be provided.

Merck will replace the doses of vaccine administered to approved patients via quarterly shipments to the licensed prescriber. *[Notes: Merck retains the right to select either prefilled syringes or vials for replacement doses which may or may not be the same as what was administered to approved patients. M-M-R®11 (Measles, Mumps, and Rubella Virus Vaccine Live) and PNEUMOVAX®23 (Pneumococcal Vaccine Polyvalent) are not available in single-dose units; therefore, these vaccines can be shipped only when the minimum threshold is reached.]*

Licensed Prescriber Declarations

I verify that the information provided on this application is complete and accurate. I understand that the patient must be part of the population for which the administered vaccine is indicated and I certify that this vaccine is medically indicated for this patient. I understand that the patient must qualify financially and meet the program criteria to be eligible for assistance. The product administered to the above patient on the date(s) above will be considered a donation to the patient from the Merck Vaccine Patient Assistance Program. I also understand that the product I receive is not a sample, but a replacement of product I previously purchased. I understand that I will not receive any reimbursement from Merck & Co., Inc., whether for administration fees or otherwise. I will not seek reimbursement for administration of vaccine from any public payer. Additionally, reimbursement for the cost of the product administered to the above patient on the date(s) above has not been sought and will not be sought from any source. I understand that Merck & Co., Inc., reserves the right to conduct periodic audits of the records, excluding patient-identifiable data (unless the auditor enters into an appropriate relationship with the facility to protect an individual's medical privacy), of all entities receiving replacement of inventory in connection with the Merck Vaccine Patient Assistance Program. I accept that reasonable notice will be granted and audits will be conducted during regular business hours. I represent and warrant that this facility has obtained all applicable authorizations, consents, and notices necessary to comply with all federal and state laws and regulations relating in any way to medical and/or health privacy including but not limited to the HIPAA Privacy Rule, codified at 45 C.F.R. Parts 160 and 164, as amended from time to time. My signature below confirms that the vaccine product will be provided free of charge to this individual. I verify that to the best of my knowledge the information set forth in this application is complete and accurate. I agree to retain a copy of this form in the facility's records and to make it available to the Internal Revenue Service upon request.

Licensed Prescriber's Original Signature: _____

Date: _____

(No stamps accepted)

Appendix D.

The HPV Vaccine is a Lifesaver Flyer

The HPV VACCINE is a LIFESAVER

THE HPV VACCINE COULD PREVENT ABOUT 28,500 CASES OF HPV-ASSOCIATED CANCER EACH YEAR

CANCER PREVENTION
 HPV vaccination can protect against the types of HPV that cause **81%** of cases of cervical cancer

EFFECTIVE AGAINST MULTIPLE TYPES OF CANCER
 HPV vaccination also protects against the infections that can cause cancer of the vagina, vulva, anus/rectum, throat, and penis

PROTECTIVE
Make sure everyone in your family who needs the HPV vaccine gets it!
11 or 12 years (Target Age)
 Most effective for girls and boys when received early in adolescence
Younger than 27 years (Catch-up Age)
 Provides protection for women and men even if sexual activity has begun

SAFE
Millions of people have received the HPV vaccine without serious adverse effects

The HPV VACCINE is...

GET THE FACTS

- HPV IS A VERY COMMON INFECTION, AND 79 MILLION AMERICANS ARE CURRENTLY INFECTED
- HPV VACCINATION IS NOT LINKED TO MORE OR EARLIER SEXUAL ACTIVITY
- HPV VACCINE IS GIVEN IN A SERIES OF TWO OR THREE SHOTS OVER SEVERAL MONTHS, DEPENDING ON YOUR AGE
- IT IS STILL IMPORTANT TO BE SCREENED FOR CERVICAL CANCER STARTING AT AGE 21 YEARS
- IN ADDITION TO CANCER PREVENTION, THE HPV VACCINE ALSO PROTECTS AGAINST GENITAL WARTS IN MALES AND FEMALES

Abbreviation: HPV, human papillomavirus.

MORE INFORMATION?
 ASK YOUR OB-GYN, VISIT WWW.IMMUNIZATIONFORWOMEN.ORG/HPV, OR SCAN THIS CODE

The American College of Obstetricians and Gynecologists
 WOMEN'S HEALTH CARE PHYSICIANS

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