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Encouraging Human Papillomavirus Vaccine Uptake: A Healthcare Improvement Project

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Abstract

Problem: Human papillomaviruses are the causative agents of >95% of cervical cancers, most oropharyngeal and anogenital cancers, yet the vaccination status of the population remains critically low despite Gardasil9 offering robust protection against HPV-related disease.

Methods: This quality improvement project utilized a descriptive, observational design to assess the effect of the HPV Encouragement Bundle, a two-step intervention to improve HPV vaccine uptake. Quantitative data was collected via retrospective chart review to assess the effect of the intervention on first-dose administration of Gardasil9 (series initiation), as well as overall Gardasil9 vaccine uptake.

Results: Following implementation, Gardasil9 first dose uptake increased from 0% to 8.45%, and overall Gardasil9 uptake increased from 0.8% to 12.68%, in pre- and post-intervention groups, respectively. A Chi-square test of independence was performed to examine the relationship between intervention groups and Gardasil9 administration. A statistically significant relationship was established between intervention groups and Gardasil9 administration, with alpha value of .05, $\chi^2(1) = 14.19$, $p < .001$. Persons in the post-intervention group were more likely to be administered a dose of Gardasil9.

Implications for practice: Widespread use of the HPV Encouragement Bundle is a cost-effective, inclusive intervention that could be used to improve Gardasil9 vaccine uptake.

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Human papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the United States (US), with an estimated 80% of the population acquiring HPV infection during their lifetime (Pingali et al., 2021; Piróg et al., 2022). Human Papillomaviruses infect the epithelial cells of the skin, oral, and genital mucosa. While most infections are asymptomatic and resolve spontaneously, persistent HPV infection is the causative agent of most anogenital warts and multiple malignancies which include but are not limited to the anogenital region, breasts, esophagus, and neck (Arbyn et al., 2018; Pingali et al., 2021). It is estimated that HPV causes approximately 70% of oropharyngeal cancers, 90% of anogenital cancers, and upwards of 95% of cervical cancers which represents about 5% of the cancer burden in the US (Araldi et al., 2018; Pingali et al., 2021). There exist 40 well-studied viral strains of HPV that are strongly associated with malignancy and of those, 12 strains are considered high-risk for cancer development, and two strains are associated with most HPV-related cancers (Araldi et al., 2018; Pingali et al., 2021).

Although HPV is responsible for a significant disease burden in both male and female populations, screening and preventative measures are highly gendered (Portnoy et al., 2020). Males are not routinely screened for, nor is there an FDA (Food & Drug Administration)-approved test for HPV in males (Fontham et al., 2020; Lieblong et al., 2019). The Papanicolaou or Pap smear, with a positive predictive value of 88.7%, has been the gold standard for HPV and cervical cancer screening in females and people with cervixes (Cheng et al., 2020; Smith et al., 2018). The Pap smear surveils a sample of cells taken from the cervix for abnormal or precancerous cytology, as well as the presence of

HPV, and while it remains an effective screening tool in early cancer detection, it does nothing to prevent initial disease burgeon (Cheng et al., 2020; Hirth, 2018). Additionally, although HPV-related diseases are similarly prevalent in transgender male populations as they are in cisgender populations, transgender males are less likely to receive cervical cancer screening in their lifetime than cisgender females (Dhillon, et al., 2020). While screening measures such as Pap smears, remain integral for HPV surveillance and early cancer detection in people with cervixes, no routine screening measures are employed in male-identifying populations, and they are lacking within the transgender male community (Arbyn et al., 2018; Cheng et al., 2020; Dhillon, et al., 2020). Reasonably, then, timely HPV inoculation may be the only line of defense between cis- and transgender male populations and HPV-related disease.

Gardasil9 is the only HPV vaccine licensed in the US (Solimen et al., 2021). It has indications for use in female persons, ages nine through 45 for the prevention of HPV infection related to cancerous and precancerous lesions of the anus, cervix, head, neck, oropharynx, vagina, vulva, and anogenital warts (Saslow et al., 2021; Soliman et al., 2021). Additionally, it is indicated for use in male populations, ages nine through 45 for the prevention of HPV infection related cancerous and pre-cancerous lesions of the anus, head, neck, oropharynx, and anogenital warts (Saslow et al., 2021; Soliman et al., 2021).

The Advisory Committee on Immunization Practices (ACIP), and the Center for Disease Control and Prevention (CDC) recommend routine HPV vaccination as early as 9 to 12 years of age for all children, and “catch-up,” vaccination for persons up to 26 years of age and the vaccine is most efficacious in preventing HPV infection and sequelae if administered before a patient becomes sexually active and therefore potentially exposed

to the virus (Drolet et al., 2019; Muthukrishnan et al., 2022). Shared clinical decision making between the healthcare provider and the patient is recommended to determine whether vaccine administration after the age of 26 will be beneficial to the individual patient, as cost-benefit analysis does not support routine vaccination of all older patients, and vaccination may or may not be clinically or cost effective, depending on individual behaviors and risk factors (Kim et al., 2021).

Population based studies demonstrate the efficacy of HPV vaccination in infection prevention, HPV-related disease, and HPV endemicity. A systematic review and meta-analysis by Drolet et al. (2019) looked at population-level impacts of HPV vaccination and found the prevalence of HPV 16 and 18 (strains of the greatest risk for cervical cancer) decreased by 83% among fully vaccinated females ages 13 to 19 years, and 66% among fully vaccinated females ages 20 to 24 years. Regarding HPV strains 31, 33, and 45 (strains of high risk for cervical cancer) vaccination decreased infection rates by 54% in females ages 13 to 19 (Drolet et al., 2019). New diagnoses of anogenital warts decreased by 67% in females, and 48% in males, ages 15 to 19 years old (Drolet et al., 2019). Furthermore, diagnoses of moderately graded cervical squamous intraepithelial neoplasms (CIN2+) decreased by 51% and 31% among screened females ages 15 to 19, and 20 to 24, respectively (Drolet et al., 2019).

A Cochrane systematic review by Arbyn et al. (2018) echoed high-certainty evidence that HPV vaccines prevent cervical precancer in females ages 15 to 26, moderate-certainty evidence that HPV vaccines reduce CIN2+ in older females ages 24 to 45 years old and found no increased risk of serious adverse effects. Cheng et al.

(2021) found that in addition to a reduction in HPV-related diseases, effects of herd immunity were observed among young males and older females who were HPV-vaccinated. In addition, recent literature indicates that antibodies induced by Gardasil9 can transfer across the placenta, potentially conferring fetal immunity to HPV (Guevara et al., 2018).

Cervical cancer screening is recommended for persons with cervixes beginning at age 21, through 65 years old, and the United States Preventative Service Task Force (USPSTF) offers screening options for cervical cancer; a Pap smear every three years, or a combined testing method called "co-testing" every five years, which includes a Pap smear and testing for high-risk strains of human papillomavirus (hrHPV) (Curry et al., 2018). Significantly, between the years 1987 and 2018, the Centers for Disease Control and Prevention (CDC) found the percentage of patients ages 18 and older who reported having a Pap smear in the last three years had steadily decreased from 74.1% to 68.1%, signaling missed opportunities in cancer detection and disease prevention (*National Center for Health Statistics*, 2019). As cervical cancer screening rates decline, HPV vaccination offers primary preventative protection against HPV-related diseases, providing coverage to those who are outside age or gendered parameters for HPV screening, such as males, younger or older females, and those who will not receive screening due to lack of access to care.

Although ACIP considers inoculation against human papillomavirus (HPV) part of routine childhood and adolescent vaccine scheduling for males and females, the most recent National Immunization Survey (NIS) from 2020 indicates that the status of adolescents up to date on HPV vaccinations remains low when compared to other routine

vaccinations (Hirth, 2018; Pingali et al., 2021). Pingali et al. (2021) estimated the percentage of adolescents up to date with HPV vaccinations in 2020 to be 58.6%, which is lower than other routine vaccination rates, such as Tetanus, Diphtheria, Pertussis (Tdap) (90.1%), Meningococcal conjugates (MenACWY) (89.3%), Measles, Mumps, Rubella (MMR) (90%), and Hepatitis B (HepB) (90%). Healthy People 2030, which establishes national standards for preventative health efforts, set a target goal for 80% of adolescents to be up to date on their HPV vaccination, however the most recent from the Office of Disease Prevention and Health Promotion (N.d.) data indicates that only 54.5% of adolescents met this goal.

At a federally qualified healthcare center (FQHC) in rural Illinois, an opportunity existed to improve HPV vaccination rates in patients ages nine through 26. The evidence-based framework utilized for this project was the Institute for Healthcare Improvement (IHI) Model for Change, and the Plan Do Study Act (PDSA) cycle used to iterate the intervention. The purpose of this project was to implement an HPV Encouragement Bundle that improved the rate of HPV vaccine initiation. The encouragement bundle consisted of two parts; (1) an educational handout and (2) a strong, verbal provider recommendation to vaccinate against HPV. The handout elucidated themes encountered in the literature search, such as common misconceptions, misinformation, and hesitations regarding HPV vaccine uptake and was administered to every patient that visited the clinic. Then, in clinically appropriate patients, the healthcare provider was instructed to offer a strong, verbal recommendation to vaccinate against HPV. The aim of this project was to increase the number of patients who initiated the HPV vaccine series by 10% over a 12-week period. The primary outcome measure of

interest for this project was the number of patients who initiated the HPV vaccine series over a 12-week period. A process measure of interest was the number of patients/caregivers who received the HPV Encouragement Bundle. The project question was: In persons ages nine through 26 who present for medical care at a regional FQHC, what is the effect of the HPV Encouragement Bundle on HPV vaccination rates over a 12-week period?

Review of Literature

A literature search was performed to explore factors contributing to the widespread unsuccessfulness of contemporary HPV vaccination efforts. To conduct the literature search, the Cochrane Library, PubMed, Medline, and CINAHL databases were accessed. Key search terms and phrases included *hpv vaccine, hpv vaccination, human papillomavirus vaccine, human papillomavirus,* and *cervical cancer.* Boolean operators AND and OR were used. Initially, 17,464 publications were generated using the key search terms and phrases. A refined search was conducted by applying inclusion and exclusion criteria. Inclusion criteria incorporated literature published between the years 2017 and 2022, English language publications, and works defined as "scholarly" or "peer reviewed." Three different age filters were applied which included: 0-18 years, 13-18 years, and 19-44 years. Exclusion criteria included literature published in languages other than English, studies with a population of focus older than 45 years of age, and publications that did not have full-text links. Publications before the year 2017 were excluded, with exception for seminal references. After inclusion and exclusion criteria were applied, deduplication was performed and a total of 211 publications resulted. Of the refined search results 21 publications were selected for review.

The influence of the "provider recommendation to vaccinate" is frequently cited as a facilitator, as well as a barrier, to HPV vaccination. According to Hirth (2018), caregivers who did not receive a strong recommendation from a clinician were twice as likely to report they did not intend to vaccinate their child. A meta-analysis and systematic review by Oh et al. (2021) found a provider's communication and/or recommendation to vaccinate had robust, positive associations with vaccine initiation, completion, and follow-through, regardless of patient age or gender. A cross-sectional study of adults ages 18 to 35 by Muthukrishnan et al. (2022) did not significantly associate a provider recommendation with "vaccine intention[s]", however, more than half of the study population (53.1%) indicated that their clinician had never recommended the HPV vaccine to them. From the perspective of the patient research establishes the redundant association between a strong provider recommendation to vaccinate and vaccine uptake (Hirth, 2018; Muthukrishnan et al., 2022; Oh et al, 2021). Conversely, Osaghae et al. (2022) investigated how provider recommendations influenced HPV vaccination rates from the perspective of the healthcare provider and found that despite disruptions to routine healthcare services during the Coronavirus disease 2019 (COVID19) pandemic, a strong provider recommendation to vaccinate was still associated with vaccine acceptance.

Regarding vaccine intention, hesitancy and rejection, multiple themes were encountered. A Cochrane review by Cooper et al. (2021) explored factors that influenced caregiver attitudes and practices surrounding routine childhood vaccinations and found that the decision to vaccinate depended on a variety of social, economic, and personal beliefs. In high-income countries where neoliberal ideology predominates, healthcare

decisions are generally appreciated as personal matters of individual choice, risk, and responsibility (Cooper et al., 2019). While many vaccine programs in the US may focus on public health benefits or generalized risks as potential motivators to vaccinate, they fail to emphasize individual risks and benefits. This approach may reduce acceptance of routine vaccinations as it does not effectively appeal to the prevailing cultural logic and could help to explain growing vaccine hesitancy among the US population.

A Cochrane review authored by Kaufman et al. (2018), assessed the effect of face-to-face and educational interventions on the status of routine childhood vaccination rates. Outcome measures such as vaccination status, parental knowledge, attitudes, and intentions surrounding vaccination were explored. They found low-to-moderate certainty evidence suggesting face-to-face education may improve a child's vaccination status, their caregiver's knowledge, and intentions to vaccinate (Kaufman et al., 2018). Recommendations from both Cooper et al. (2019) and Kaufman et al. (2018) align, suggesting that vaccine intentionality involves a complex consideration of a wide variety of factors. While both reviews call for more high-quality research to assess the effects of individual interventions on vaccine uptake, they establish a solid bedrock from which to build successful vaccine campaigns – with focus on face-to-face interventions that effectively appeal to prevailing cultural ideologies.

Today, although HPV vaccination is considered part of routine childhood vaccine scheduling for all children, there remains a problematic disparity between vaccine uptake in females versus males, with male populations falling behind (Hirth, 2018; Piróg et al., 2022; Muthukrishnan et al. 2022). Misinformation and confusion, perpetuated by gendered vaccine marketing and a lack of parity in HPV screening can help explain

different rates of HPV vaccine uptake when comparing varied patient populations (Cooper et al., 2019). The link between HPV and cervical cancer has been long-established, as has the link between HPV and penile and anal cancers in males. Yet, the Gardasil vaccine was initially licensed and marketed only for use in females. The initial, unisexual offering of HPV vaccination, the paucity of HPV screening in males, and the lack of an FDA-approved test for HPV in males continually reinforces the narrative that HPV is a female burden, marginalizing males, and LGBTQIA+ groups while needlessly placing the burden of HPV detection and prevention onto the shoulders of female patients (Hirth, 2018; Piróg et al., 2022; Portnoy et al., 2020). Although HPV vaccine uptake is increasing in cisgender male populations, there are spectral disparities in vaccine uptake within LGBTQIA+ communities regarding HPV vaccine uptake (Hirth, 2018). Piróg et al. (2022) describes several studies which demonstrate that females who have sex with females, as well as transgender men with cervixes, believed they did not need HPV vaccination, and concordantly, both populations had lower rates of vaccination when compared with cisgender, heterosexual females. Jaiswal et al. (2020) evaluated similar findings, indicating that males who have sex with males had low knowledge regarding HPVs, and had a highly gendered perception of HPVs only affecting females. A Cochrane systematic review by Abdullahi et al., 2020 offered high-certainty evidence that offering health education increased vaccine uptake when compared to usual practice, which is logically congruent with the idea that misinformation or confusion surrounding HPV vaccination may contribute to poor vaccine uptake. Inclusive, medically accurate information is needed to address rampant misconceptions regarding HPV prevalence, risk factors, and prevention for all patients, as males and LQBTQIA+ groups are less likely to

be screened for or informed of their risk of HPV-related disease, or the benefits associated with vaccination.

Despite being the most prevalent STI in the US, patient's perceived risks of HPV infection may also not reflect the statistical reality of disease prevalence. Barnard et al., (2020) conducted a cross-sectional survey, exploring perceived risks regarding HPV infection in college-aged students. Of the diverse sample of students, less than a quarter of the respondents believed they were likely to contract HPV in their lifetime, despite the universally high lifetime probability of HPV acquisition (Barnard et al., 2020; Pírog et al., 2022). In a similar study by McBride et al., (2017), over 70% of participants were knowledgeable about the cervical cancer risks of HPV infection but had low knowledge regarding other HPV-related diseases such as genital warts, anal warts, and other cancers ($\leq$ 32%). Low intention to vaccinate was associated with ideas such that the HPV vaccine was not safe or necessary to prevent disease (Muthukrishnan et al. 2022).

There exists a vast spectrum of barriers that contribute to poor HPV vaccine uptake, regardless of the readily available, high-certainty evidence that administration is without risk of serious adverse outcomes and offers robust protection against a significant disease burden (Arbyn et al., 2018). Rampant misinformation regarding HPV-related disease and vaccines can help explain low rates of vaccine uptake compared to other routine vaccines, creating an opportunity for patient education and empowerment regarding their health. The provider is in a unique and privileged position to influence and improve vaccine uptake, and awareness of the power their recommendation holds could lead to a dramatic reduction in HPV-related diseases and the possibility of herd immunity or disease eradication in the not-so-distant future.

Methods

Design

This observational, quality improvement project utilized the Institute for Healthcare Improvement's Plan-Do-Study-Act (PDSA) Model for Improvement.

Setting

This project took place at a Federally Qualified Health Center (FQHC) in Illinois, 10 miles northeast of a midwestern metropolitan area.

Sample

The primary investigator collected data from a convenience sample of patient ages 9 to 26 who sought specialty medical care from obstetrics and gynecology (OBGYN) department within the FQHC. Retrospective data was collected via the electronic medical record (EMR) regarding the number of patients who initiated their HPV vaccination series from September 7, 2022, through November 30, 2022. Prospective was collected via the EMR regarding the number of patients who initiated their HPV vaccination series from January 18, 2023, through April 12, 2023. Patient protected information was de-identified, and patient identity was protected by utilizing a unique, alphanumeric identifier.

Procedures

This QI (Quality Improvement) project was implemented and evaluated by the primary investigator. Patient-facing staff received education regarding HPV-related disease, vaccine risks, benefits, alternatives, and the current state of HPV vaccine uptake, including the common barriers and facilitators discussed in this literature review. Patient facing staff was educated on the HPV Encouragement Bundle, which included two parts;

the administration of the educational handout coupled with a strong provider recommendation to vaccinate. The education handout was administered upon rooming all patients receiving care and was offered in English and Spanish languages. The pamphlet was scientifically accurate and contained plain language addressing the following topics:

- HPV-related disease, endemicity, and communicability
- the indications, safety, and efficacy of Gardasil 9
- correction of common misconceptions regarding HPV vaccination and HPV-related disease

Healthcare providers were educated on the efficacy of the strong provider recommendation to vaccinate and were encouraged to use their best clinical judgement to recommend HPV-vaccination in medically appropriate patients.

Data Collection/Analysis

All data was extracted via retrospective chart review. Patient data extracted during the first PDSA cycle (January 18, 2023, through April 12, 2023) was compared against data from the proceeding months (September 7th, 2022, through November 30th, 2022) and descriptive statistics were run using Intellectus Statistics.

Approval Process

Formal approval was obtained from the participating clinic's site manager on October 10, 2022. Approval for this project was sought from the University of Missouri – St. Louis Institutional Review Board prior to implementation.

Results

Demographics

The sample included 267 female patients, ages nine to 26 years, with a mean age of 21 years (SD = 3.47). The most frequently observed race was Black or African American (*n*=130, 48.69%), followed by White (*n*=120, 44.94%), Spanish American Indian (*n*=7, 2.62%), and American Indian (*n*=2, 0.75%). Eight patients (3%), declined to provide racial demographic information. Ethnically, the sample most frequently observed identified as Not Hispanic or Latinx (*n*=222, 83.15%), followed by Hispanic or Latinx/Spanish (*n*=26, 9.74%), Latin American/Latin/Latinx (*n*=5, 1.87%), and Mexican (*n*=4, 1.50%). Ten patients (3.75%) declined to provide ethnic demographic information. (See Table 1, Appendix)

HPV Vaccination Uptake

A retrospective chart review of patients who received OB-GYN care at the FQHC during the pre-intervention period of September 7, 2022, and November 30, 2022, revealed 125 unique patients between the ages of nine and 26 who received care. Of those patients, one patient (0.80%) received a dose of the Gardasil9 vaccine, thought it was not the patient's first dose. During the post-intervention period of January 18, 2023, through April 12, 2023, a retrospective chart review revealed that of patients of ages nine to 26, 142 unique patients received care in the OB-GYN clinic and of those patients 18 (12.68%) received the Gardasil9 vaccine, however, only 12 of those 18 received their first dose, initiating the Gardasil9 series.

The primary outcome measure of this project was the number of patients who initiated the Gardasil9 series in the 12-week intervention period. As there were no

patients who received a first dose of Gardasil9 in the pre-intervention group, it created a challenge in assessing statistical significance as there was no true comparator group. However, a Chi-square Exact Test of Independence was performed using data including overall Gardasil9 uptake to examine whether the intervention group variable and vaccine administration variable were independent related, which revealed alpha value of 0.05, $\chi^2(1) = 14.19$, $p < .001$, suggesting that the intervention groups and vaccine administration variables had a robust, statistically significant relationship (see Table 3, Appendix). It can be assumed, then, that the HPV Initiation Bundle was associated with an increase in overall Gardasil9 vaccine uptake. In the 12-week intervention period wherein all patients ages 9-26 received the HPV intervention bundle, uptake of Gardasil9 first doses increased by 8.45%, and overall Gardasil9 uptake (regardless of first dose or subsequent dose) increased by 11.88%.

Discussion

The project purpose, to increase overall Gardasil9 vaccine uptake, was met through this initiative as evidenced by an 11.88% absolute increase in Gardasil9 uptake over a 12-week period. A statistically significant relationship was established between intervention group and vaccine administration variables with an alpha value of 0.05, $\chi^2(1) = 14.19$, $p < .001$, however the study was limited in establishing relationship between the intervention groups and Gardasil9 first dose administration. The project aim, to increase first dose Gardasil9 uptake by 10% in a 12-week period, therefore, was not met, as first dose Gardasil9 uptake increased 8.45% during the post-intervention period.

The strengths of this project were the culturally appropriate use of English and Spanish language versions of the educational handout, the affordability of project

materials, and the time-efficient methodology of a handout (versus face-to-face education). Weaknesses of this project include a lack of parity of representation in the male versus female patients, inaccessibility for patients with visual impairments, inaccessibility for patients who are unable to read, and a lack of feedback regarding patient's attitudes and knowledge ascquisition surrounding the educational handout. Recommendations for future PDSA cycles include utilization of the HPV Encouragement Bundle in other clinical areas (Family Medicine, Internal Medicine, Pediatrics) to assess whether it is effective in increasing Gardasil9 vaccine series initiation, as well as vaccine uptake, with more diverse patient populations. A longer data-collection period may be helpful in gathering larger samples so that more detailed statistical analyses may be performed to assess the effects of the HPV Encouragement Bundle.

Finally, it must be acknowledged that this project was piloted in an OB-GYN that mostly serves patients with cervixes or female-identifying patients for convenience and preliminary research purposes. There exists a demanding need for expansive, inclusive education regarding HPV and the Gardasil9 vaccine.

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Appendix

Table 1

Patient Demographics for Race and Ethnicity

Variable	*n*	*%*
Race		
Black or African American	108	40.45
White	120	44.94
African American	22	8.24
Patient Declined	8	3.00
Mexican American Indian	2	0.75
Spanish American Indian	7	2.62
Missing	0	0.00
Ethnicity		
Not Hispanic or Latino	222	83.15
Patient Declined	10	3.75
Hispanic or Latino/Spanish	26	9.74
Mexican	4	1.50
Latin American/Latin, Latino	5	1.87
Missing	0	0.00

Note. Due to rounding errors, percentages may not equal 100%.

Table 2

Patient Ages

Variable	*M*	*SD*	*n*	SE_M	Min	Max	Skewness	Kurtosis
Age	20.95	3.47	267	0.21	12.00	26.00	-0.24	-0.98

Note. '-' indicates the statistic is undefined due to constant data or an insufficient sample size.

Table 3

Observed and Expected Frequencies

	Dose Administered				
Intervention Group	No	Yes	χ^2	*df*	*p*

Pre	124[116.10]	1[8.90]	14.19	1	< .001
Post	124[131.90]	18[10.10]			

Note. Values formatted as Observed [Expected].