Get the Message! HPV Vaccination Recommendations

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Author Testimony

Submitting this assignment confirms this is the sole work of the author as required by the student

code of conduct.

Abstract

Background: Each year in the USA, 35,900 cancers are caused by the human papillomavirus (HPV). These cancers are preventable with the successful completion of the 2-dose HPV vaccination series at 11-12 years of age. There is an association with a strong and consistent provider recommendation and an increase in HPV vaccination rates.

Local problem: The Oregon Health Authority reports that 65% of 13-year-olds in our county have started the 2-dose series while only 37% have completed it.

Methods: Providers and clinical staff were observed before and after an educational presentation during 11-year and 12-year well child visits using a data collection tool to code the quality of their vaccine recommendations.

Interventions: The educational presentation shared preliminary data, a review of current literature, and HPV recommendation quality factors.

Results: The quality of clinical staff recommendation improved from a medium of zero to two out of five. The vaccine refusal rates increased from 21.1% to 33.3%. There was a significant association between higher quality of recommendation and higher rate of vaccine refusal. **Conclusions:** A brief education on high-quality HPV vaccine recommendation improves quality of clinical staff's recommendations while increasing refusals. Future quality improvement

project may consider interventions other than education.

Get the Message! HPV Vaccination Recommendations

The human papillomavirus (HPV) is a common virus that most people (80%) will contract in their lifetime (Centers for Disease Control and Prevention [CDC], 2019b). Those that are infected with HPV can usually clear it on their own, but for some it leads to cancers, precancers, and/or warts. Each year in the U.S. about 35,900 cancers of the throat, cervix, anus, vulva, penis, and vagina are caused by the HPV virus (CDC, 2019b). These cancers are preventable with the successful completion of the HPV vaccination series. Centers for Disease Control and Prevention (CDC) recommends the HPV vaccination for all children aged 11-12 years old (CDC, 2019c). This is provided in a 2-dose series, 6-12 months apart. HealthyPeople.gov 2020 objective is for 80% of children by 13-15 years of age will have completed the HPV vaccination series (CDC - National Center for Immunization and Respiratory Diseases, 2018). The Oregon Health Authority reports that 65% of 13-year-olds in our county have started the 2-dose series while only 37% have completed it (Oregon Health Authority, 2020). There are similar rates in our practice. In the literature, there is an association with a strong and consistent provider recommendation and an increase in HPV vaccination rates (Brewer et al., 2017; Finney Rutten et al., 2017; Sturm et al., 2017). By age 13, young adolescents are advised to have completed four immunizations (TDaP, 2 doses of HPV, and Meningococcal) (CDC, 2021). However, in our practice 37.7% of 13-year-olds have completed these with noted lag in HPV rates. The purpose of this quality improvement project was to assess provider's and staff's communication style and its correlation to HPV vaccination rates for 11and 12- year-olds in this Pacific Northwest primary care pediatric practice.

Literature Review

Several professional organizations have evidence-based provider toolkits and resources available: the American Academy of Pediatrics, the American Cancer Society, The American College of Obstetricians and Gynecologists, the CDC, the Advisory Committee on Immunization Practices, and Vaccines.gov, to name a few. Many of these discuss the important role of a provider in increasing HPV vaccination rates. They advise strong and consistent messaging starting at 9-11 years old. A review of literature was conducted in 2020 using a combination of subject headings and keywords in PubMed, CINAHL, and Scopus databases to further support this advice (Appendix A). The PICO question was: "Does a strong and consistent recommendation from a pediatric provider increase HPV vaccination rates in 11-15-year-olds?" Two-hundred-sixty-one manuscripts were screened first by title, then by abstract (n=64), then by complete manuscript review (n=14), ending with ten chosen manuscripts. Manuscripts were included of any study design in the US, if the target population is children 11-15 years of age, if pediatric provider make the recommendations for HPV vaccine, include HPV vaccination rates, take place in primary care setting (pediatric specialty and family medicine). Manuscripts were excluded if study was not available in English, abstract only available, children outside of 11-15 age range, adult population was discussed, the recommendation was from an obstetrics provider, or other setting. Using the resources provided by the CDC for "same day, same way" recommendation combined with the literature review, five factors to a quality recommendation were identified as basis for this project.

Consistently Recommend to All Eligible Children

Studies have shown that a consistent clinician recommendation is associated with higher rates of immunization by 12 years old (Finney Rutten et al., 2017; Rahman et al., 2017; Reno et

al., 2018). The good news is that providers self-report consistently recommending HPV vaccine 62.2%-79% of the time (Finney Rutten et al., 2017). Additionally half of surveyed parents said that more than one health care team member recommended the vaccination; this group was twice as likely to initiate the series (Fontenot et al., 2018). Reinforcing provider and health care team member's consistent recommendation may be key to boosting vaccination rates (Chuang et al., 2017; Fontenot et al., 2018).

Use the Presumptive Style

Announcement- or presumptive-style recommendations are "brief statements that assume parents are ready to vaccinate" (Brewer et al., 2017). Training of providers in this style has been associated with increased quality of providers' recommendations and in some cases with increased HPV vaccination rates (Brewer et al., 2017; Gilkey et al., 2015; Kempe et al., 2019; Sturm et al., 2017). Providers self-report using this style 42%-78.2% of the time, but audio recordings of a small group of providers showed that only 14.7% actually used this style (Kempe et al., 2019; Reno et al., 2018; Sturm et al., 2017). However, when presumptive style was used, same-day vaccination rate was 73% (Sturm et al., 2017). This large variance between self-report and audio recording may be in part due to self-report bias, over-representing a positive attribute, or response bias, providers answering in the way they think the surveyor intends.

It is important to recommend same day vaccination without delay (CDC, 2019d; Finney Rutten et al., 2017; Kempe et al., 2019). Nevertheless, it is common to hear providers offer a delay or even recommend against the vaccine (Dang et al., 2020). In fact almost 1 in 4 parents received a recommendation against receiving the vaccine (Fontenot et al., 2018). Twenty-four to sixty-five percent of providers offered a delay in vaccination which increases parental hesitancy and decreases the rate of same-day vaccination to as little as 6% (Fontenot et al., 2018; Gilkey et al., 2015; Sturm et al., 2017).

List HPV Vaccine in the Middle

Providers can normalize the vaccines for parents by recommending HPV vaccine in the middle of other vaccines (Brewer et al., 2017; CDC, 2019a). It is suggested not to separate the HPV vaccine recommendation from other vaccines due that day as it fuels parental hesitancy (Sturm et al., 2017).

State Brief Purpose of Vaccines

The healthcare team members need to help families make informed decisions while not adding to parental hesitancy. Phrases such as "HPV Vaccine is Cancer Prevention" (Centers for Disease Control and Prevention, 2019d) are recommended. Recommending the HPV vaccine as prevention against warts, precancers, and cancers results in higher acceptance rates (Finney Rutten et al., 2017; Gilkey et al., 2015).

Strongly Recommend

A strong recommendation can be defined as saying "I strongly recommend..." or it is "very/extremely important..." (Finney Rutten et al., 2017; Gilkey et al., 2015). Strong recommendations are frequently associated with parental acceptance or less refusal of the HPV vaccine (Finney Rutten et al., 2017; Kempe et al., 2019). However, sometimes this association is not statistically significant, as in Sturm et al. (2017). This may be due to site/population variance or changing attitudes over time. Providers have reported strongly recommending the HPV vaccine 66%-85% of the time for all 11- and 12-year-olds (Finney Rutten et al., 2017; Kempe et al., 2019; Sturm et al., 2017). While a fair percentage, this is an area for quality improvement. In summary, a high-quality recommendation using these five factors looks like this: Based on your child's age, they are due for Tdap, HPV, Meningococcal, and Flu vaccines. These protect against tetanus, diphtheria, whooping cough, warts, precancers, cancers, meningitis, and influenza. I strongly recommend getting all of these done today.

While the literature is clear on what to say and how to say it, it is inconsistent on how teams are adopting the recommendation in practice. Literature relies on self-reported data regarding language use in the visits, with the exception of Gilkey et al. (2015) which stands out from the group by analyzing audio recordings. To add to this gap in the literature, vaccination discussions during visits were coded by an observer in real time.

This project aimed to implement quality consistent messaging for HPV vaccinations, thereby increasing adherence to best practice standards and creating consistency among the healthcare team. Due to the strong association between a high-quality recommendation and HPV vaccination acceptance rates, we predicted vaccination rates would increase as the quality of the recommendation increases. This project is framed by The Model for Improvement and Plan, Do, Study, Act cycles (Langley et al., 2009).

Methods

Setting

This project took place at an urban pediatric primary care clinic as part of a large community-based hospital system in the Pacific Northwest. Pediatricians and nurse practitioners see patients who are roomed by nurses and medical assistants. This practice trains medical students, residents, and nurse practitioner students regularly. The author met with primary care director of the site to form a mutually acceptable project. This practice does annual quality improvement projects and has chosen to focus on HPV vaccination this year to meet a Coordinated Care Organization (CCO) incentive metric.

Sample Population

Providers and clinical staff were observed during 11-year and 12-year well child visits using a data collection tool (Appendix B). These visits included routine HPV vaccination based on CDC's adolescent vaccine schedule (CDC, 2021). Exclusion criteria includes patients that have already completed the HPV vaccination series and/or are outside the age range for the project. Providers, nurses, medical assistants, and patients were assigned a number in order of appearance for thirty-nine visits. The project was submitted to two institutional review boards (IRBs) (site of project and student's academic medical center) and had determined this project to be non-research/exempt from IRB oversite (Appendix D).

Intervention

Procedures

The quality improvement project had three PDSA cycles (PDSA-1, PDSA-2, and PDSA-3) and included observations by a single observer and an educational session. The education took place at the end of PDSA-1 (Appendix C). During PDSA-1, to collect baseline quality scores, the providers and clinical staff were blinded to the intent, only knowing it was part of this year's quality improvement project. The observer was introduced to the patient and family as a nurse practitioner learning from the nurses and doctors that day and verbal permission to observe the visit was obtained. Provider schedules were checked frequently in the electronic health system to see when the target visits were scheduled and matched them with the observer's schedule. Thereby not every visit during the project's six-month timeline was able to be observed.

The educational presentation to providers and clinical staff revealed the nature of the project and shared preliminary data. A review of current literature and recommended style for recommending HPV vaccination to families was presented. Video examples were attempted to be shown but audio did not function. Links to examples were emailed out. Two handouts were provided as reminders of how to recommend HPV vaccinations for PDSA-2. During PDSA-2 it was identified that a more specific script was needed. PDSA-3 posted such a script and observations continued (see Appendix C).

Measures

The observer used a printed data collection tool (Appendix B) that includes definitions and descriptions of the five quality factors from the literature. This tool collected demographics, years in practice (providers and clinical staff), typical daily patient load (provider only), and insurance type (patient only). It also described the order of vaccines recommended, and the provider and clinical staff's style and strength of recommendation. Additional content was tracked if they mention the HPV vaccine purpose: cancer prevention, precancer prevention, wart prevention or other content. It noted patient's acceptance and declination and why. The observation tool was reviewed by content experts, however, is not validated. The tool was piloted during the first visit observation for ease of use. No changes were made, and the tool was used throughout. Data from this tool was entered into an electronic spreadsheet for future data analysis. Accuracy was maintained during observations by having a quick one-page tool with definitions to ensure the observer was coding correctly as heard. Data was double-checked for accuracy when transferred from paper to electronic spreadsheet.

Cumulative performance rates on completion of HPV vaccination by age 13 is tracked by the clinic's vaccine coordinator already. This was displayed on a run chart on the quality

improvement bulletin board in the clinic. Daily updated run charts during PDSA-2 and -3 were shared here as well. These showed quality scores by visit for clinical staff and providers separately, as well as acceptance/declination by visit.

Results

The demographics are summarized in Table 1. The overall clinic HPV vaccination initiation and complete rates of those turning 13 during the project are in Figure 1. The overall clinic-wide initiation and completion rates of HPV vaccine did not significantly change during the project. The run charts are displayed as Figure 2. The quality of provider recommendation was unchanged at medium of three out of five possible. The quality of clinical staff recommendation improved from medium of zero to two out of five. The summed quality of provider and clinical staff recommendation improved from three to five out of ten. The vaccine refusals increased from 4/19 (21.1%) to 3/11 (30.0%) to 3/9 (33.3%) in PDSA-1, -2, and -3, respectively.

Table 1

Demographics		Providers	Clinical Staff	Patients
Age (average in years)		42.6	34.8	11.6
Gender				
	F 1	1000/		
	Female	100%	90.9%	61.5%
	Male	_	Q 1%	38 5%
	Wiate	-	9.170	30.370
Race				
	Asian	28.6%	-	2.6%

Demographics of Participants

Black	-	-	41.0%	
Latinx	14.3%	18.2%	28.2%	
White	71.4%	81.8%	28.2%	
Other	-	-	7.7%	
Years in Practice (average)	8.1	10.3	-	
Daily Patient Load	11.3	-	-	
Insurance				
Private	-	-	17.9%	
Public	-	-	82.1%	

Figure 1:

HPV Vaccination Rates by Quarter of Those Turning 13 During That Period



Outcomes

Figure 2

Run Charts – Provider Quality Scores (top), Clinical Staff Quality Scores (middle), and Observed Vaccination Reception (bottom) Across the Project







These results differ in comparison to the recommendations of the current literature which state: "Care team members in higher performing clinics were more likely to describe vaccination as a team effort rather than solely the provider's responsibility;" "Clinicwide HPV vaccination training may help align interests so that clinic support staff and clinicians are giving the same consistent timely message around HPV vaccination to all families;" and "Healthcare teams should consider clinical in-service trainings to ensure that all members of the team are

educated about HPV and HPV vaccination, as well as understand the importance of building a comprehensive communication strategy that promotes multiple opportunities to provide HPV vaccine recommendations to patients and families." (Chuang et al., 2017; Dang et al., 2020; Fontenot et al., 2018). The suggestion in the literature that the whole care team may help at improving rates was not supported in our case.

There may be multiple reasons for the differences between observed and anticipated outcomes. The small sample size chosen by convenience sampling reduced equal matching of pre- and post-data. It is possible that we did not perform the change with enough patient encounters to reach the goal of five quality points. There was also some resistance to change among clinical staff reported to the observer but not formally measured, which might explain a part of the lower quality scores. The COVID-19 pandemic has increased vaccine hesitancy and reduced childhood vaccination rates broadly, which may have been a factor here as well (Santoli et al., 2020).

The costs are similar to usual clinic practices for the well child visits, vaccines, vaccine storage and administration. There may be a negligible increase in office supply consumption for observation tool, display charts, and ink. The time spent by the observer is unpaid as a student. There are no changes to provider and clinic staff compensation.

Limitations

Some limitations include small scale of the quality improvement project at a single site, using a unvalidated tool to measure quality factors, relying on observer to accurately document words said vs. using audio recording device, and a technology failure in playing audio during intervention education. We attempted to mitigate these limitations. The small scale was chosen for convenience sampling as well as low-risk-high reward calculation. The observation tool based on the evidence with examples cited on the form itself. The use of audio recording may alter behavior even more than having an observer. We did not have a secure way to capture and protect audio files. Education video examples where shared via email after technology failed to play with sound during meeting. The observer missed three clinical staff's interactions with patients due to overlapping scheduled observations (n=1) and clinical staff forgetting to notify the observer when entering the room (n=2).

Conclusions

A brief education on high-quality HPV vaccine recommendation improves quality of clinical staff's recommendations. This approach at educating staff was effective at causing change. However, the findings for the clinical staff went counter to what we expected. The vaccine recommendation quality improved, but the vaccine acceptance rate did not improve as expected. In fact, for clinical staff, there is a small significant association between higher quality of recommendation and higher rate of vaccine refusal.

Implications for Practice

This project is a useful contribution to the literature as the outcomes do not reflect current suggestions regarding staff participation in HPV vaccine recommendation. This project relied on student and volunteer hours for observation and analysis so sustainability would rely on paid staff to complete future quality improvement initiatives. After the project showed that clinical staff recommendations caused an increase in refusal, the group decided to abandon the addition of clinical staff recommendation of HPV vaccine and leave it for the providers. Time may be saved at this site by eliminating training for clinical staff to deliver a quality HPV vaccine recommendation. The focus can shift to providers and how to create improvements in quality of provider recommendation in the future. The next PDSA cycle may include repeat provider-only

education with working technology to show video examples. It may also include a provider attitude survey on recommending HPV vaccine using all five quality factors, due to any hesitancy still present in the provider regarding HPV vaccination. If these results persist in future quality improvement projects, it may be useful to consider alternatives, other than provider education. Further quality improvement and research may also be required to assess effect of clinical staff recommendation on acceptance and initiation rates of other vaccinations and procedures as well.

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Appendix A

Search Terms for PICO Question

Population

("adolescent"[MeSH Terms] OR "child"[MeSH Terms] OR child OR children OR boy OR boys OR girl OR girls OR teenager OR teen OR adolescent OR adolescence OR youth)

AND

Intervention

((("Patient Education as Topic"[Mesh] OR "Health Education"[Mesh] OR "parents/education"[Mesh] OR patient education OR parent education OR education OR health education OR recommendation) AND ("Pediatricians"[Mesh] OR "Nurse Practitioners"[Mesh] OR "Physician Assistants"[Mesh] OR "Physicians, Family"[Mesh] OR family physician OR physician assistant OR nurse practitioner OR pediatrician))

AND

Outcome

(("Papillomavirus Vaccines"[Mesh] OR "papillomaviridae"[MeSH Terms] OR "papilloma"[MeSH Terms] OR HPV OR "wart virus" OR condyloma OR papilloma OR papillomavirus OR verruca OR papillomaviridae) AND ("vaccination"[MeSH Terms] OR "immunization"[MeSH Terms] OR vaccinate OR vaccinated OR vaccination OR immunize OR immunized OR immunization OR immunise OR immunised OR immunisation OR prophylaxis)))

Appendix B

Observational Tool: Consistent Messaging on HPV vaccine

#	<u>11</u>
	· · · · · · · · · · · · · · · · · · ·
Degree	Age
CMA	
RN	Sex
Other	
Years in Practice	Race/Ethnicity
	Black/African American
Age	White/Caucasian
	Asian
Sex	Pacific Islander
	Native American
Race/Ethnicity	Latinx
Black/African American	Other
White/Caucasian	Insurance
Asian	Private
Pacific Islander	Public
Native American	Self-pay
Latinx	Recention
Other	Accepts
Recommend (in what order?)	Declines
HPV	W/hy?
TD ₃ P	
Meningococcal	
Style	
Presumptive	
Conversational	
Strength	
Strong	
Moderate	
Weak	
Against	
Offers delay	
Content	
Cancer prevention	
Precancer prevention	
Wart prevention	
Other	
	CMA RN Other Years in Practice Age Sex Race/Ethnicity Black/African American White/Caucasian Asian Pacific Islander Native American Latinx Other Recommend (in what order?) HPV Recommend (in what order?) HPV TDaP Meningococcal Style Presumptive Conversational Strength Strong Moderate Weak Against Offers delay Content Cancer prevention Precancer prevention Wart prevention Other

Presumptive - announces child is due for vaccinations, confidently as if presuming client will get the shots today

Conversational - leads with asking parents about the vaccines, discuss benefits and risks, asking and answering questions, end with recommendation for vaccination Strength Definitions: (Sturm et al., 2017) Strong – uses words like I "highly" "definitely" or "strongly" recommend Moderate – no strong words as above but states I/we recommend

Weak - passively states "it is recommended" "professional organizations recommend"

Against- makes a recommendation not to vaccinate

Offers delay - says does not have to be given today

Appendix C



Appendix D

IRB Approvals

RE: [EXTERNAL] Re: DNP student interested in immunization as project

Newton, Paul W :LRI Research < PWNEWTON@LHS.ORG>

Tue 9/22/2020 4:40 PM

To:Kelley Davis <daviskel@ohsu.edu>;

Cc:Bianchini, Cindy LSO Clinical Practice Support <CBIANCHI@LHS.ORG>; Stallings, Valerie L :LRI Research <VStallin@LHS.ORG>;

1 attachments (963 KB)

Kelley Davis Project.pdf;

Hi Kelley,

I agree with Cindy that this project is exempt QI and does not required IRB oversight. Approved as exempt.

Thanks

Paul

Paul Newton, JD, CIP Senior Research Regulatory Specialist Research Administration Legacy Research Institute 1225 NE 2nd Ave Portland, OR 97232 Phone (503) 413-5355 pwnewton@lhs.org

From: Bianchini, Cindy :LSO Clinical Practice Support <CBIANCHI@LHS.ORG> Sent: Tuesday, September 15, 2020 4:58 PM To: Newton, Paul W :LRI Research <PWNEWTON@LHS.ORG> Subject: FW: [EXTERNAL] Re: DNP student interested in immunization as project

Hi Paul,

I have attached Kelley Davis' project details and the other documents. Can you please approve as QI? Let me know if you need anything else or if you have questions. Hope you are well!

Thank you,

Cindy Bianchini, DNP, RN, NPD-BC, CNOR(E) RN Residency and Academic Relations Program Director Legacy Health 2801 N. Gantenbein Office 3072 Portland, OR 97227

STUDY00022169 is not human research

eirb@ohsu.edu

Mon 10/5/2020 10:48 AM

To:Kelley Davis <daviskel@ohsu.edu>;

Template:IRB_T_Post-Review_NotHumanResearch



Notification of Not Human Research Determination

To:	Kelley Davis
Link:	STUDY00022169
P.I.:	Sharon Norman
Title:	Improving HPV vaccination rates
Description:	The committee reviewed this submission and assigned

Description: The committee reviewed this submission and assigned a determination of Not Human Research. For additional details, click on the link above to access the project workspace.

Oregon Health & Science University	VA Portland Health Care System
Research Integrity Office	Research and Development Service
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