



Use of patient navigators to increase HPV vaccination rates in a pediatric clinical population

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ABSTRACT

A patient navigator (PN) program was implemented in pediatric clinics to increase uptake of the human papillomavirus (HPV) vaccine. The purpose of this study is to examine the impact of this program. All visits between April 1, 2013 and December 31, 2017 for 9–17 year old patients at 3 program and 5 non-program clinics were examined using electronic medical records. These dates included patient visits before and after program initiation (February 1, 2015). Visits including 1 dose of the HPV vaccine were assessed as a proportion of total visits for each month. Multivariable binary logistic regression was used to examine the odds of HPV vaccination across time, between program and non-program clinics, and age group. A total of 128,051 visits by 21,395 patients were examined. HPV vaccines were administered during 12,742 visits (10.0%). Odds of HPV vaccination during visits by 13–17 year olds was greater than during visits by 9–12 year olds in the pre-intervention period (odds ratio [OR]: 1.12, 95% confidence interval [CI]: 1.04–1.19). However, this association changed during the intervention period, with odds of HPV vaccination among visits by 13–17 year olds lower compared to visits by 9–12 year olds (OR: 0.78, 95% CI: 0.75–0.82). The odds of HPV vaccination were elevated among 9–12 year olds in program clinics as compared to 2014, the year before the program was implemented. Having on-site PNs can increase the frequency of HPV vaccination in pediatric clinics, particularly among patients 9–12 years of age.

1. Introduction

Human papillomavirus (HPV) vaccination can reduce HPV-related cancers significantly if a high proportion of the population receives the vaccine before exposure to the virus (Stern and Roden, 2019). To achieve this, the Advisory Committee on Immunization Practices (ACIP) recommends vaccination at 11–12 years of age, although it is permitted as young as age 9 and up to age 45 (Petrosky et al., 2015). Unfortunately, uptake and completion of the vaccine among adolescents have been poor in the US, particularly in regions where cervical cancer rates are high and screening rates are low (Kish et al., 2016; Walker et al., 2018). Only a few states currently mandate the vaccine for school enrollment, and those that do have liberal opt-out options that have led to vaccination rates similar to states without mandates

(Perkins et al., 2016). Due to the widespread lack of a school mandate, the responsibility for gaining HPV vaccine acceptance has fallen largely to healthcare providers, who may have reservations about offering it to their young patients or may not communicate about the vaccine effectively with parents (Allison et al., 2016; Dempsey and Human, 2018). Interventions have been developed to help this situation, but they are largely limited to educating health providers or patients or providing reminder texts. Although educating health providers is an important component of any program, it may not be enough to improve HPV vaccination among pediatric patients by itself (Fu et al., 2014; Kharbanda et al., 2011; Matheson et al., 2013; Kang et al., 2018).

To address low HPV vaccination rates at the University of Texas Medical Branch (UTMB), a patient navigator (PN) based program was implemented in 2015 in three pediatric clinics as part of a broader

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program to also educate pediatric health providers. PNs were utilized to inform patients about the availability of the HPV vaccine as well as to schedule appointments for additional doses in selected clinics. This intervention was evidence-based as PNs have been shown to increase cancer prevention practices, including HPV vaccination (Berenson et al., 2018, 2016; DeGroff et al., 2017; Marshall et al., 2016).

We have previously reported that HPV vaccine series completion rates among 9–17 year old pediatric patients are high at 93% of initiators in this program (Berenson et al., 2018). We have also found that patients and providers accept and appreciate the PN program intervention (Berenson et al., 2018; Hirth et al., 2019). However, prior reports did not evaluate the change in vaccination rates among the clinic population. Here, we examine the relative impact of education provided to healthcare providers, as well as education combined with the PN program among patients visiting program clinics by evaluating electronic medical records of patient visits before and after program initiation and comparing vaccination between program and non-program clinics.

2. Methods

As part of an HPV education program administered in all clinics, providers and clinic staff attended a lecture or in-service that lasted < 1 h explaining the program and need to encourage HPV vaccination, particularly among 11–12 year olds. These sessions also included the fact that children could be vaccinated as young as 9 years old.

In addition to the education services, PNs were utilized at 3 clinics to assist providers in identifying patients who were not fully vaccinated. The on-site PN informed parents of their 9–17 year old children's eligibility for the HPV vaccine and provided information about the vaccine's purpose and safety. If the parent decided to vaccinate their child, the PN obtained consents, ensured that future appointments were scheduled, and provided reminders by phone or text for future appointments (Berenson et al., 2018). They also helped coordinate vaccination visits with other medical appointments for convenience to the family (Berenson et al., 2018). The HPV vaccine was further discussed by providers with patients who remained unsure about whether they wanted to vaccinate their children, as well as with those who wanted to ask further questions. Providers also gave recommendations for vaccination to patients who declined. The PN program included patients 9–17 years of age who resided in two Texas counties (Galveston and Brazoria) and attended a program pediatric clinic administered by the University of Texas Medical Branch (UTMB) during the period assessed. One PN was assigned to work on-site in each of these clinics. Details of this program have been previously reported (Berenson et al., 2018).

To assess whether the PN program impacted vaccination rates, patient visits between April 1, 2013 and December 31, 2017 were examined at three program and five non-program pediatric clinics in the UTMB system. Non-program clinics consisted of one clinic that served more patients with urgent care needs, but the other 4 clinics were mainly primary care pediatric clinics, similar to program clinics, although they had a smaller patient volume. However, all clinics accepted both primary and urgent care visits. Algorithms were used to identify visits of patients 9–17 years of age before and after program initiation on February 1, 2015. The pre-program period included April 1, 2013 through January 31, 2015. The program period included February 1, 2015 through December 31, 2017. All visit types, including urgent care visits, were included, as PNs were instructed to approach all age-eligible patients. Urgent care visits were often coded concurrently with other visit types. Further, the HPV vaccine can be given to children with mild illnesses, such as diarrhea or mild upper respiratory tract infection. The UTMB Institutional Review Board approved all methods for this study.

We examined records of all visits to the selected pediatric clinics for patients 9–17 years of age. Since we did not collect identifying

information, such as patient ID, all analyses were conducted using visits as the denominator, with the exception of individual patient count. Information about race/ethnicity, age, type of visit, date of visit, gender, and clinic visited were included in the dataset for each visit. To determine if the PN-based program increased the number of visits that included HPV vaccination among younger adolescent patients, we grouped visits into two patient age groups: 9–12 and 13–17 years of age. The age cutoffs were determined by defining the younger age to include those recommended to receive the HPV vaccine (11–12 years old) and younger. The program also included patients in the catch-up age group of 13–17 years old, so those adolescents were included in the older age group. For race/ethnicity, we used “white” as the referent category, as white patients have been shown in the literature to be less likely to initiate the vaccine than other racial/ethnic groups, but more likely to complete the series after initiating (Hirth, 2019). Further, racial/ethnic minorities have a heavier disease burden and poorer outcomes from HPV related cancers (Musselwhite et al., 2016; Yoo et al., 2017; Megwalu and Ma, 2017; Lenze et al., 2019), and thus, it is important to consider whether the program is equitable for minority patients.

2.1. Statistical analyses

Proportions of monthly visits that included HPV vaccination were calculated across time, from the pre-program period through the program period. To visualize the PN-based program's effects, we graphed the proportion of visits that included HPV vaccination according to age group and according to whether PNs were onsite at a clinic (program clinics had onsite PNs and non-program clinic did not have onsite PNs). Since UTMB medical faculty and staff who did not work in the program clinics participated in HPV education programs and PNs scheduled follow-up appointments at convenient UTMB locations, we anticipated finding some effect in clinics without on-site PNs. Binary logistic regression was used to examine time effects for HPV vaccination, with comparisons between the pre-program period and the program period, by year, after controlling for month, which was not shown as it would have added much data to the tables, but was not relevant to focal associations that were examined. Because the outcome was between 10% and 20% prevalence, and all odds ratios were between 0.5 and 2.5, we used logistic regression to estimate the associations in this study (Zhang and Yu, 1998). The dependent variable was binary, indicating whether a visit included HPV vaccination or did not include HPV vaccination. This method was used because strong seasonal variations in vaccination and significant autocorrelation effects in the interrupted time period analyses, we chose a less complicated and easier to interpret model to present our results. The referent year for the full models was 2014, because it was the only full 12-month period examined that did not include the PN-based program. Binary logistic regression was used to compare program clinic and non-program clinics in the pre-program period and the program period. Analyses included models stratified by clinic participation status, and then again by clinic participation status and patient age group. Sensitivity analyses were conducted with urgent care visits removed. All statistical calculations were done using SAS statistical software version 9.4 (Cary, NC).

3. Results

During the 3 year program, 452 health professionals attended the educational lectures. Across the entire time period examined, 21,395 patients 9–17 years of age visited at least one of the 8 clinics included in these analyses, for a total of 128,051 visits during the time examined. HPV vaccines were administered during 12,742 of those visits (10.0%). Of the 128,051 clinic visits, 41.4% were attended by non-Hispanic white patients, 34.5% Hispanic, 22.0% Black, and 2.1% by patients identifying as other races/ethnicities, such as Asian, American Indian, and Pacific Islander. Males made 50.1% of visits, while females made

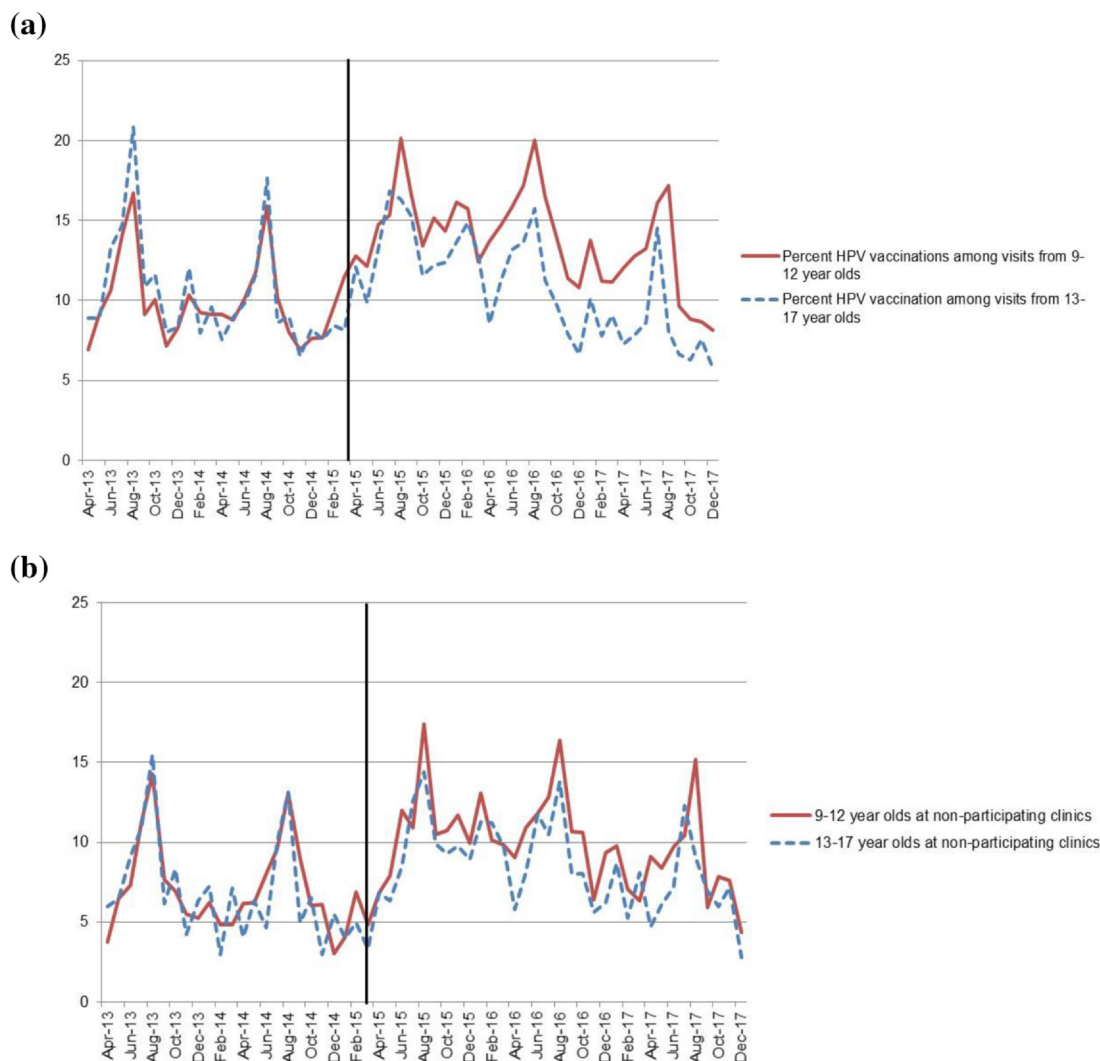


Fig. 1. Proportion of clinic visits with HPV vaccination over time. a) The proportion of total clinic visits that included HPV vaccination varied from April 2013 to December 2017 with greater increase among 9–12 year olds (solid red line) than 13–17 year olds (blue dashed line). The difference between the younger and older patients was more pronounced in program clinics where patient navigators worked (c) than in non-program clinics (b). (d) HPV vaccination visits were more common among 9–12 year olds at program clinics than non-program clinics. Solid/Red lines: 9–12 year olds; dashed/blue lines: 13–17 year olds. Solid vertical bar indicates time of program inception. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

49.9% of visits. HPV vaccination (10.0% and 10.0% of all visits, respectively) did not differ by gender ($p < 0.05$). A total of 17,805 visits out of 128,051 were coded as urgent care visits.

During the pre-program period, 9–12 year old patients appeared to receive HPV vaccination as frequently as 13–17 year old patients (Fig. 1a). During the program period, overall HPV vaccination as a proportion of visits increased, especially among 9–12 year olds. Although this pattern occurred to a lesser extent in non-program clinics (Fig. 1b), more patient visits included HPV vaccination in program clinics (Fig. 1c). Moreover, increases in HPV vaccination among 9–12 year olds were strongest at program clinics (Fig. 1d). Among 13–17 year olds, vaccination as a proportion of visits was initially high at program clinics (Fig. 1e). During the program period in the 13–17 year olds, HPV vaccination remained higher in program clinics initially, but appeared more similar to non-program clinics during the last 18 months of data collection (Fig. 1e).

Interactions between age group and intervention period ($p < 0.001$) as well as those between intervention period and program participation status ($p < 0.01$) were significant (data not shown). The three-way interaction between intervention date, age group, and program site was also significant ($p < 0.001$, data not shown). As these

interactions were significant, we determined that it would be appropriate to stratify analyses according to program period, as well as by age group and program site. Models examining the association between program participation status and HPV vaccination were examined by program period, after controlling for month and race/ethnicity (Table 1). Program clinics had significantly higher odds of HPV vaccination during clinic visits as compared to non-program clinics in both pre-program and program periods (Model 1). Program clinics had elevated odds of HPV vaccination in both pre-program and during the program period. However, the odds of HPV vaccination occurring among 13–17 year olds were elevated in the pre-program period compared to 9–12 year olds. This association was reversed among 13–17 year olds in the program period, with 13–17 year olds having lower odds of HPV vaccination during a clinic visit in the program period compared to 9–12 year olds (Model 2).

Four models stratified by age group and program participation status revealed that visits by 9–12 year olds to program clinics had increased odds of HPV vaccination during the program period as compared to 2014 (Table 2, model 1). Older patients (13–17 year olds) in program clinics, however, only experienced a small increase in odds of HPV vaccination during clinic visits in 2015, compared to 2014

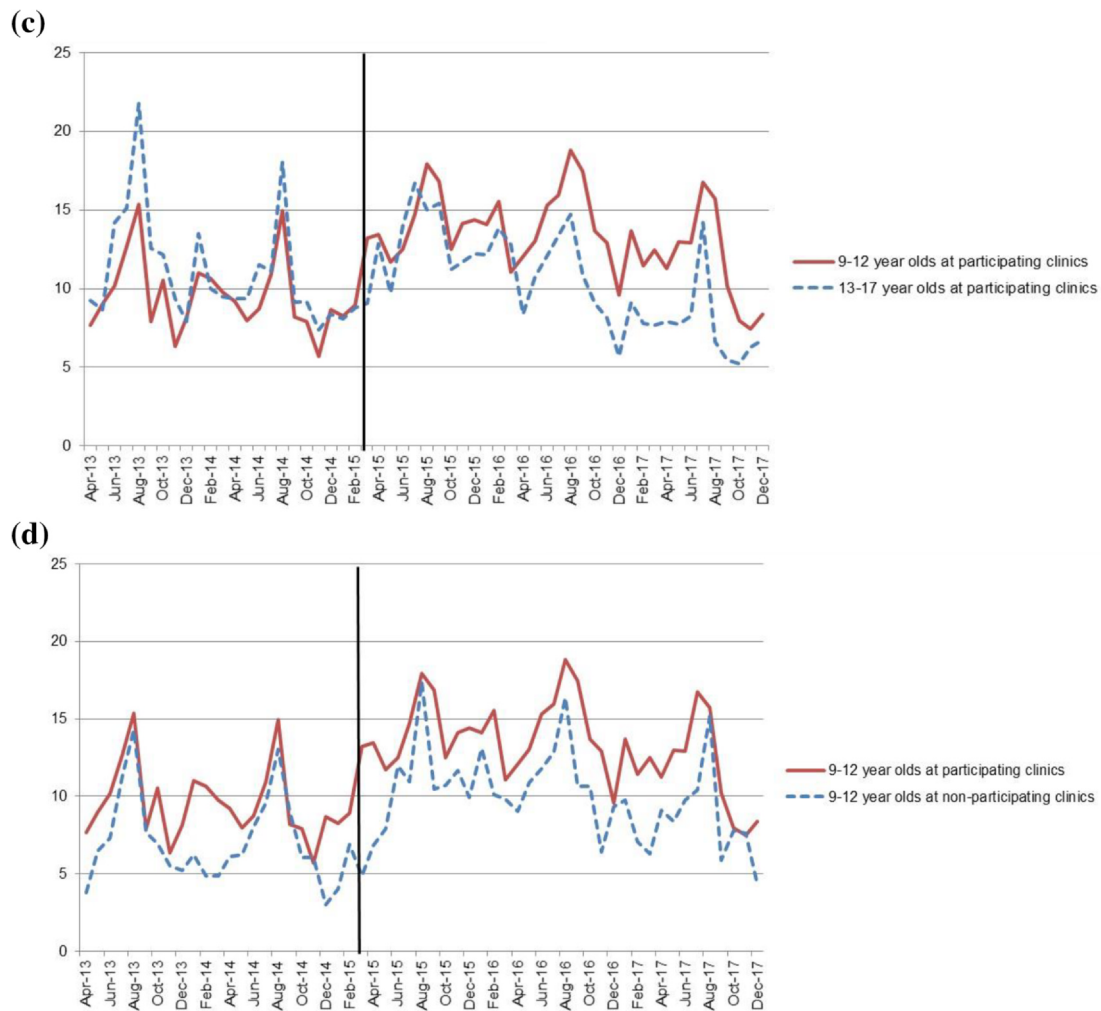


Fig. 1. (continued)

(model 2). By 2017, the odds of HPV vaccination during clinic visits in the older age group were smaller compared to 2014 (model 2). Non-program clinics also experienced an increase in odds of HPV vaccination during clinic visits in the program period. Although the effect was greater for 9–12 year olds (model 3), those 13–17 years of age had greater odds of receiving an HPV vaccination during 2015 and 2016 visits at non-program clinics compared to 2014 (model 4).

Compared to visits by white patients, the odds of HPV vaccination during patient visits were greater among 9–12 year old black, Hispanic, and other racial groups in both program and non-program clinics. Increased odds of HPV vaccination were also observed among 13–17 year old patients of “other” racial groups at both program and non-program clinics compared to white patients.

Sensitivity analyses that were conducted after removing urgent care

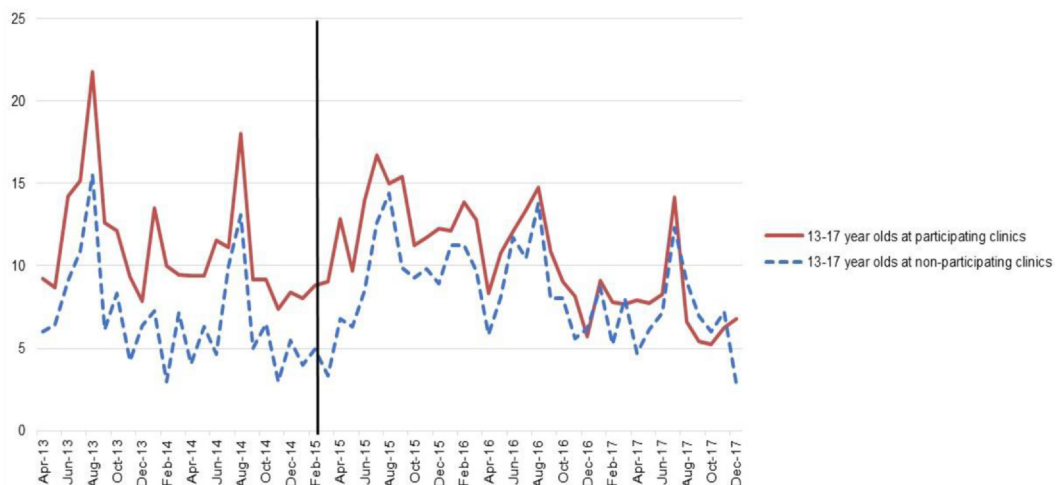


Fig. 1. (continued)

Table 1
Logistic regression examining association between clinic participation status and HPV vaccination during clinic visits, by intervention period (N = 127,962 clinic visits).

	Model 1* Pre-program (2013–2014)	Model 2* Program period (2015–2017)
Race/ethnicity, by visit	OR (95% CI)	OR (95% CI)
Black	1.28 (1.18–1.40)	1.28 (1.21–1.36)
Hispanic	1.18 (1.10–1.28)	1.30 (1.24–1.37)
White	Reference	Reference
Other	1.22 (0.97–1.55)	1.64 (1.43–1.90)
Clinic type		
Program clinics	1.52 (1.42–1.63)	1.36 (1.30–1.42)
Non-program clinics	Reference	Reference
Age group		
9–12 year olds	Reference	Reference
13–17 year olds	1.12 (1.04–1.19)	0.78 (0.75–0.82)

* All models controlled for month. OR = odds ratio; 95% CI = 95% confidence interval.

visits from the data revealed that there was only one significant change from the results presented in the paragraphs above. Patient demographics were similar in sensitivity analyses. The only difference in results was in the analyses comparing program and non-program clinics. In those sensitivity analyses, the odds of HPV vaccination during a visit were lower in the post-program period for program clinics (OR: 0.91, 95% CI: 0.87–0.95) as compared to non-program clinics, likely reflecting the low proportion of visits coded as urgent care visits in the program clinics as compared to the non-program clinics.

4. Discussion

It appeared that provider education was effective, as HPV vaccination was shifted to occurring more frequently among 9–12-year-old patients at both program and non-program clinics from 13 to 17 year olds in the program period. Although an increase in odds of vaccination occurred during the program period among both age groups, the increase in HPV vaccination among 9–12 year olds was an important change to age at vaccination observed before the intervention. The shift is especially notable, as there was a change in ACIP recommendations from three to two doses for patients ≤14 years of age in late 2016 (Meites et al., 2016). As our methods in this study count individual vaccine doses, this change makes our program’s effects appear slightly weaker among the younger age group as compared to the older group, who continued receiving 3 doses if they initiated after age 14. In addition, the reduction of vaccine doses likely contributed to the reduction in the percent of visits in which the HPV vaccine was administered among 9–12 year olds observed in the figure. We could not determine

the independent effects of the PNs on HPV vaccination, as they had the option to send patients to non-program clinics for follow-up doses if it was more convenient for the patients.

Although HPV vaccination is recommended for patients 11–12 years of age, providers have reported a preference for offering the HPV vaccine to older adolescents and young adults (Meites et al., 2016; Vadaparampil et al., 2011). Further, parents have reported preferring to wait until their children are older as some feel that earlier HPV vaccination will make their children think they are permissive about engaging in sexual behaviors at an early age (Hirth et al., 2019; Brown et al., 2017; Madhivanan et al., 2016). However, exposure to HPV may occur prior to vaccination when parents wait until their children are older, as sexual debut may occur earlier than parents realize (Berenson and Croisant, 2017; Demarteau et al., 2013; Mollers et al., 2015). In addition, the vaccine induces a stronger immunologic response when administered to younger patients and only 2 doses are required if administered before 15 years of age (Meites et al., 2016). Thus, there are several benefits to administering the vaccine at the recommended age of 11–12 years.

Education of providers to encourage vaccinating adolescents at a younger age is an important strategy to increase HPV vaccination and shift vaccination to the recommended age. One recommendation is that providers should have mandatory trainings, with a combination of clinical discussions and courses that offer Continuing Education credits (Attia et al., 2018). However, our study shows that limited education can potentially increase HPV vaccination frequency among young adolescents, as both program and non-program clinics had elevated HPV vaccination rates after the program started. Other education programs aimed at increasing provider recommendation and quality have also had a positive effect on HPV vaccination in other clinics (Krantz et al., 2018; Rand et al., 2018; Perkins et al., 2015). However, our program included only short lectures, which were repeated to ensure that all new providers would learn about the vaccination strategies in the pediatric clinics.

We found there was a reduction in the odds of HPV vaccination during the last year of the program, particularly among visits by 13–17 year olds. Further, HPV vaccination as a proportion of visits in this age group in program clinics became similar to that in non-program clinics. This is likely due to saturation of HPV vaccination among patients, as vaccination increased significantly in the first two years of the program. Saturation in this group is also due to the strong increase in HPV vaccination among patients before they reached 13 years of age (likely due to our program), and the lag time after which those same patients aged into the 13–17-year-old group. Since the program was focused only on patients from two counties visiting the pediatric clinics during this evaluation period, those patients would have been vaccinated during previous visits, leading to the decrease observed in the last year of the program.

Table 2
Logistic regression demonstrating association between time and HPV vaccination during a clinic visit (N = 127,962 clinic visits).

	Model 1* Program clinics, 9–12 year olds	Model 2* Program clinics, 13–17 year olds	Model 3* Non-program clinics, 9–12 year olds	Model 4* Non-program clinics, 13–17 year olds
Year**	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
2013	1.04 (0.92–1.17)	1.20 (1.06–1.36)	1.04 (0.89–1.20)	1.28 (1.07–1.51)
2014	Reference	Reference	Reference	Reference
2015	1.46 (1.32–1.62)	1.17 (1.04–1.30)	1.43 (1.26–1.63)	1.35 (1.16–1.58)
2016	1.56 (1.41–1.72)	1.05 (0.94–1.17)	1.66 (1.47–1.88)	1.47 (1.27–1.70)
2017	1.25 (1.13–1.38)	0.69 (0.61–0.78)	1.24 (1.10–1.41)	1.10 (0.94–1.28)
Race/ethnicity, by visit				
Black	1.42 (1.30–1.54)	0.91 (0.82–1.01)	1.70 (1.54–1.87)	1.09 (0.96–1.23)
Hispanic	1.64 (1.53–1.76)	1.05 (0.96–1.14)	1.21 (1.10–1.32)	1.02 (0.91–1.14)
White	Reference	Reference	Reference	Reference
Other	1.42 (1.14–1.77)	1.46 (1.13–1.88)	1.62 (1.27–2.07)	1.63 (1.26–2.13)

* All models controlled for month. OR = odds ratio; 95% CI = 95% confidence interval.

** 2013 and 2014 were pre-program years. 2015, 2016, and 2017 were years that the HPV vaccination program was implemented.

We found that odds of HPV vaccination were elevated among clinic visits by non-whites in the 9–12-year-old group, after controlling for month, and program clinic in the program period. This is consistent with a recent report that educated white parents are less likely to accept HPV vaccination than racial/ethnic minorities, and our results indicate that this may be particularly true among the younger adolescents for whom the vaccine is recommended (Warner et al., 2017). Although HPV vaccination among black adolescents was initially lower than whites in the U.S., recent initiation rates among racial/ethnic minorities have been similar or greater than white adolescents (Burdette et al., 2017; Spencer et al., 2019; Hirth et al., 2018). Increased HPV vaccination among young females from ethnic groups that have high rates of cervical cancer, such as Black and Hispanic, is promising for reducing previously observed disparities (Hirth, 2019; Islami et al., 2019). Programs such as this PN-based intervention can contribute significantly to reducing future disparities in development of HPV-related cancers by increasing initiation and completion of the vaccine series. In particular, the PNs in this program spoke both Spanish and English, which likely contributed to higher vaccination odds during clinic visits among Hispanic patients.

Although non-program clinics in this study had a lower proportion of visits that included HPV vaccination compared to program clinics, they still achieved an increase, particularly among the 9–12 year olds. This may have been the result, in part, of educating providers and staff about HPV vaccination. However, clinics with on-site PNs performed better. Although one concern about PN-based programs may include cost of PN salaries, these employees are not as expensive as licensed clinical personnel, such as nurses. Further, PNs are very cost effective compared to the cost of screening for and treating HPV-related cancers. Care related to HPV infection has been estimated to cost \$8 billion annually, including significant costs for testing for and treating dysplasia, cancer, genital warts, and recurrent respiratory papillomatosis (Chesson et al., 2012).

A strength of this study was that it reviewed records of all visits from patients in the program's targeted age range. The evaluation was limited, however, by the inability to randomize clinics because the PN-based program was set up as an intervention to improve HPV vaccination rates. Further, some of the increase in HPV vaccination visits to the non-program clinics could have resulted from patients being scheduled at those clinics by PNs working to find the most convenient clinic for each patient. The type of visit may have affected vaccination rates, as vaccination may have been less likely, for example, during urgent care visits. In addition, we could not determine the impact of improved provider knowledge. However, there were very clear effects that occurred right after the start date of the program that are unlikely to be due to other factors alone. While sensitivity analyses which eliminated urgent care visits changed some results of this study, we presented the data with urgent care visits included. We did this because it appeared that clinics did not code patient visits similarly across clinics, as several urgent care visits also included codes for primary care or other encounter types. Very few visits were characterized as urgent care visits in the program clinics (< 1% of all urgent care visits) which indicate variations in coding practices by clinic, as those clinics accept urgent care visits as well as primary care. Further, some visits were coded as having more than one purpose. Eliminating urgent care visits from the study data made it difficult to determine whether a visit was primarily for urgent care and would have introduced selection bias if these visits had not been included in the analyses.

In conclusion, having on-site PNs can increase the frequency of HPV vaccination in pediatric clinics, particularly among patients 9–12 years of age. These findings and our prior report on a 93% completion rate among project participants suggest that the services provided by PNs were important to increasing HPV vaccination among younger adolescents attending pediatric clinics and could be a highly effective tool for administering this important vaccine at the recommended ages.

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CRediT authorship contribution statement

Abbey B. Berenson: Funding acquisition, Project administration, Resources, Writing - original draft, Writing - review & editing, Conceptualization. **Jacqueline M. Hirth:** Formal analysis, Investigation, Methodology, Writing - original draft, Writing - review & editing, Conceptualization. **Yong-Fang Kuo:** Methodology, Validation, Writing - review & editing. **Jonathan M. Starkey:** Data curation, Methodology, Writing - review & editing. **Richard E. Rupp:** Conceptualization, Methodology, Writing - review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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