


Barriers to Human Papillomavirus Vaccine Series Completion among Insured Individuals in an Integrated Healthcare Setting

Infectious Diseases: Research and Treatment
Volume 14: 1–8
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DOI: 10.1177/11786337211018712



Aruna Kamineni¹, Paula R Blasi¹, Gabrielle D Gundersen¹,
Malia Oliver¹, John B Dunn¹, Denise A Galloway²
and Margaret M Madeleine³

¹Kaiser Permanente Washington Health Research Institute, Seattle, WA, USA. ²Human Biology Division, Fred Hutchinson Cancer Research Center, Seattle, WA, USA. ³Public Health Sciences Division, Fred Hutchinson Cancer Research Center, Seattle, WA, USA.

ABSTRACT

INTRODUCTION: Infection with certain types of human papillomavirus (HPV) can lead to cervical cancer as well as other cancers in both men and women. However, the requirement for multiple doses may limit the vaccine's effectiveness for cancer prevention. We conducted a pilot study to investigate barriers to HPV vaccine series completion among members of an integrated healthcare system with clinical documentation of only 1 dose.

METHODS: We surveyed parents or legal guardians of 11-17-year-old girls (n=10) and boys (n=18), as well as 18-31-year-old women (n=20) and men (n=9), about their reasons for not completing the HPV vaccine series.

RESULTS: Most participants (70.2%) were non-Hispanic white. Among parents of children, commonly reported barriers to HPV vaccine series completion included not being aware or informed of the need for additional doses (28.6%), as well as the inconvenience of returning for additional doses (17.9%). Concerns about the HPV vaccine or vaccines in general were more common among parents of girls (30.0%) compared with parents of boys (16.7%). Among adults, barriers to HPV vaccine series completion included the inconvenience of returning for additional doses (31.0%), not being aware or informed of the need for additional doses (10.3%), and forgetting (10.3%).

CONCLUSION: Our findings suggest that clinicians and healthcare systems can play a greater role in promoting awareness of the multiple-dose requirement, addressing vaccine concerns, and increasing opportunistic vaccination in a variety of settings. Increasing these efforts may facilitate HPV vaccine completion and increase its effectiveness in cancer prevention.

KEYWORDS: HPV, human papillomavirus, vaccine, completion, barriers, survey

RECEIVED: September 22, 2020. **ACCEPTED:** April 29, 2021.

TYPE: Original Research

FUNDING: The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the National Cancer Institute of the National Institutes of Health (grant number U54CA163261-04S1); Kaiser Permanente Washington Health Research Institute Development Fund; and Fred Hutch Institutional Support.

DECLARATION OF CONFLICTING INTERESTS: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

CORRESPONDING AUTHOR: Aruna Kamineni, Kaiser Permanente Washington Health Research Institute, 1730 Minor Ave. Ste. 1600, Seattle, WA 98101, USA.
Email: Aruna.S.Kamineni@kp.org

Introduction

Persistent infection with oncogenic types of human papillomavirus (HPV) causes virtually all cervical cancers and can also cause oropharyngeal, vulvar, anal, vaginal, and penile cancers.^{1,2} Available in the United States since 2006, HPV vaccines are safe, highly efficacious in preventing HPV infections and associated precancers, and highly immunogenic.³ Current recommendations focus on delivering 2 doses 6 months apart for 9–14 year-olds or 3 doses at 0, 1–2, and 6 months for those aged 15 years or older.⁴ Vaccination before exposure improves prophylaxis, but HPV vaccination among adolescents remains suboptimal at 71.5% for ≥ 1 dose and 54.2% for series completion.⁵ Coverage remains below the Healthy People 2020 goal of 80% vaccinated.⁶ The requirement for multiple doses is a barrier to HPV vaccination and may limit its effectiveness in cancer prevention.^{7,8}

We conducted a pilot study to better understand reasons for noncompliance with vaccine series completion among members of an integrated healthcare system with clinical documentation

of only 1 dose of HPV vaccine. Previous studies have largely relied on self-reported immunization history, which has been shown to be inaccurate,⁹ or shared immunization history with study participants.^{8,10} We sought to use more objective clinical information in a setting in which insurance coverage and vaccine cost were not barriers. Our purpose was to: (1) describe challenges experienced by insured individuals who initiate HPV vaccination but do not complete the recommended dosing regimen and (2) highlight potential opportunities to promote vaccine series completion in an integrated healthcare setting to improve protection from HPV-associated disease.

Methods

Setting

Our study was conducted within Kaiser Permanente Washington (KPWA), a healthcare system that provides coverage to approximately 710 000 Washington State residents.



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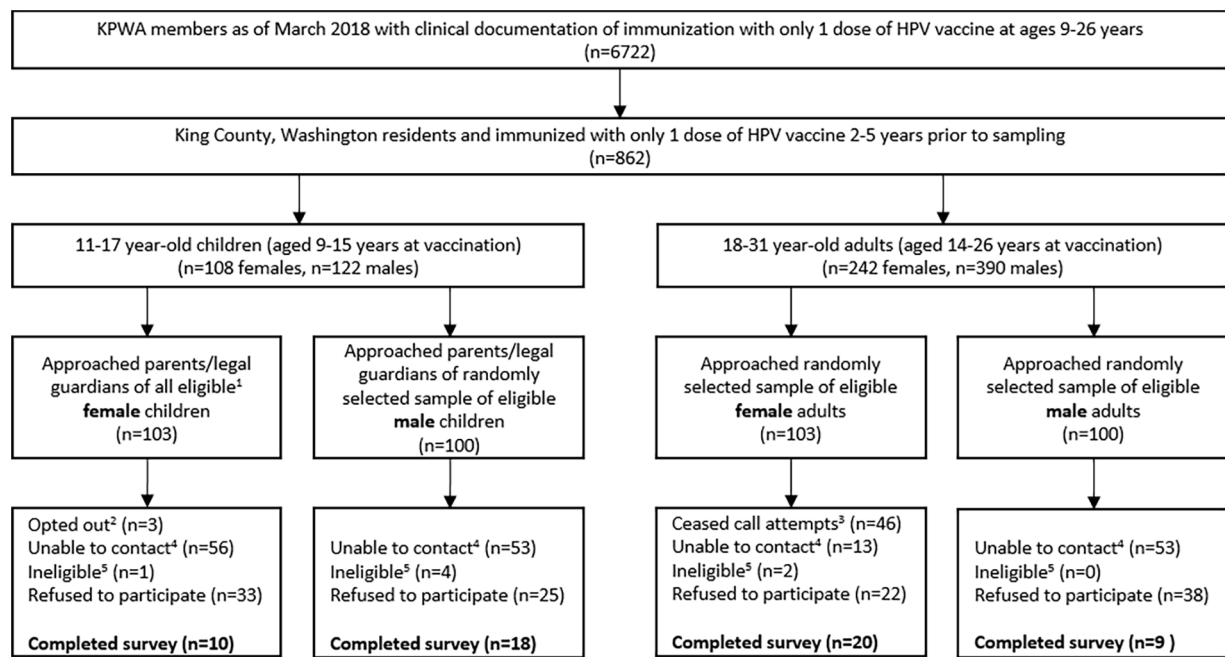


Figure 1. Study population flow diagram.

Abbreviations: KPWA, Kaiser Permanente Washington; HPV, human papillomavirus.

^aOnly 1 sibling from households with same-sex sibling pairs was eligible if both were minors at time of sampling, but both were eligible if at least 1 was an adult. Two were ineligible as minor female siblings and 3 were ineligible due to reaching majority age prior to the conclusion of the survey period.

^bOpted out of further contact prior to phone call.

^cCeased further call attempts because target participation in this group was met.

^dIndividuals were not able to be contacted by phone or passively refused to participate.

^eIneligible due to language barrier or physical/mental challenges.

KPWA exchanges immunization data bi-directionally with the Washington State Immunization Information System (IIS) registry. KPWA clinical information systems include provider-administered and patient-reported immunizations, immunization records identified through claims from non-KPWA providers, and IIS data, enabling comprehensive capture of vaccination history on members. The KPWA Institutional Review Board approved study activities.

Study population and sample selection

Among KPWA members (patients insured by KPWA and paneled to a KPWA Medical Center for primary care) as of March 2018, we identified individuals with clinical documentation of immunization with only 1 dose of HPV vaccine between ages 9 and 26 years ($N=6722$, Figure 1). We further restricted eligibility to King County, Washington residents and those who had been immunized 2-5 years prior to sampling. Eligible individuals ($n=862$) comprised 2 groups of potential survey participants: (1) parents of 11-17 year-old children (aged 9-15 at vaccination; $n=108$ females, $n=122$ males); and (2) 18-31 year-old adults (aged 14-26 at vaccination; $n=242$ females, $n=390$ males). We selected all girls who remained eligible throughout the survey period ($n=103$), randomly selected 103 women for parity with the number of eligible girls, and randomly selected 100 boys and 100 men to approach for the survey.

Data collection

Electronic administrative and clinical data to identify and characterize eligible individuals were obtained with a waiver of consent. Potential participants were contacted via a mailed letter and invited to participate in a 10-minute telephone survey. No monetary incentive was provided. Those who consented to survey participation when called by a trained study interviewer were queried about reasons for noncompliance with the vaccine series and sociodemographic characteristics. Participants who reported that they or their child had received all recommended doses were not asked about barriers to series completion. Study interviewers attempted to contact individuals until a total of 20 in each age and sex stratum completed surveys or the selected pool of potential participants was depleted.

We developed an 11-item survey informed by literature on HPV vaccination barriers.¹⁰⁻¹² Vaccination measures included confirmation of receipt of HPV vaccine (yes, no, don't know), confirmation of number of doses received (1, 2, 3, or not sure), and location of HPV vaccine administration (KPWA clinic or other). Participants who reported receiving fewer than the recommended doses were asked to describe reasons for not completing the vaccine series; response options were open-ended. Interviewers immediately captured each participant's response by selecting from the following pre-defined categories: refusing another dose, having problems with the first dose, not thinking additional doses were needed, doctor not telling

participant additional doses were needed, having concerns about the HPV vaccine, and the inconvenience of coming back to the doctor's office for additional doses. Interviewers also had a free-text field to enter reasons that did not fit into the pre-defined categories. Sociodemographic measures included race, ethnicity, household income, and education level of immediate family. Responses were recorded using WinCATI software or via direct data entry.

Analysis

We calculated frequencies of race/ethnicity, vaccination characteristics, primary care encounters in the previous 12 and 24 months, and flu vaccination history separately for eligible individuals and survey participants. Race/ethnicity information provided in the survey was used when it was not available from administrative data. We also calculated frequencies of participant-reported reasons for not completing the vaccine series, including responses that fit into pre-defined response categories ($n=43$) and those captured in free-text fields ($n=12$). Two pre-defined response options (not thinking additional doses were needed, doctor not telling participant additional doses were needed) were combined into a single category (not being informed additional doses were needed) due to overlapping responses. One study team member (PRB) reviewed the 12 free-text responses and assigned each to an existing response category or created a new category to characterize the free-text response. For example, the free-text response "I don't know enough about it and I'm not comfortable with my child getting it" was assigned to the pre-defined category of "I have concerns about the HPV vaccine," and we created a new category ("I forgot about the additional doses") to capture free-text responses such as "I lost track," and "I just don't remember if I got them or not." Two additional team members (AK and GDG) reviewed the categorizations of free-text responses and made independent determinations; discrepancies were resolved by consensus. Survey responses were analyzed in Excel and other data were analyzed using SAS software (v9.4).

Results

Nearly 30% ($n=121$) of those approached actively refused to participate in the survey (Figure 1). The most common refusal reasons were not being interested (65.3%), not having time (18.2%), refusing additional HPV vaccinations (9.9%), and having privacy concerns (8.3%). Refusal reasons were similar across age and sex strata (data not shown). Among those contacted and confirmed eligible, participation varied by group (23.3% for parents of girls; 41.9% for parents of boys; 47.6% for women; and 19.1% for men). We met our target of 20 survey participants only for women.

There were no meaningful differences in distributions of race/ethnicity, years since vaccination, and vaccine valency across age and sex strata of eligible individuals (Table 1). Most women (66.9%) had initiated HPV vaccination after age 21,

whereas most men (80.8%) had initiated at age 21 or younger. The proportions of girls, boys, and men with at least 1 primary care encounter in the previous 12 months were similar (34.9%, 35.3%, and 39.7%, respectively). A greater proportion of women (62.7%) had a primary care encounter in the previous 12 months. Receipt of flu vaccine in the previous year was low across all groups, with the highest proportion among women (27.1%). Survey participants were more likely to be non-Hispanic white (70.2%) compared to eligible individuals with known race/ethnicity (55.3% non-Hispanic white), but we observed no other meaningful differences between eligible individuals and survey participants.

Most survey participants (77.2%) reported the highest level of education attained by a member of their immediate family as a bachelor's degree or higher, and most (78.6% of parents of children and 58.6% of adults) had an annual family income of \$50 000 or more (data not shown). When participants were asked about their reasons for not completing the HPV vaccine series, parents of boys more frequently reported not being informed that additional doses were needed compared with parents of girls (38.9% vs 10.0%, respectively) (Table 2). We observed similar sex differences among parents reporting the inconvenience of returning for multiple doses (22.2% of parents of boys vs 10.0% parents of girls). However, parents of girls more frequently expressed concern about the HPV vaccine or vaccines in general compared to parents of boys (30.0% vs 16.7%, respectively). Among adult men, the most common reason for noncompliance was the inconvenience of coming back for additional doses (44.4%). Among adult women, the most common reasons for noncompliance were the inconvenience of coming back for additional doses (25.0%), believing they had received all recommended doses (20.0%), and not being informed that additional doses were needed (15.0%).

Discussion

Reasons for noncompliance with HPV vaccine series completion among our sample of insured patients in an integrated healthcare setting varied by age and sex, with more parents of boys citing a lack of awareness about the need for additional doses, and more parents of girls citing concerns about the HPV vaccine or vaccines in general. Among adults, commonly reported barriers included the inconvenience of returning for additional doses and believing all recommended doses had been received. Our findings are consistent with prior research showing that barriers to HPV vaccine series completion include a lack of awareness or clinician recommendation about the need for multiple doses.^{8,11} Barriers specific to parents include safety concerns about the vaccine.¹¹ Our study shows these informational barriers exist even in a predominantly white population with access to health insurance and health care. Most individuals eligible for our study were similarly behind on flu vaccination, suggesting that this population may not prioritize immunization and may need additional or more targeted outreach.

Table 1. Characteristics of Kaiser Permanente Washington members with clinical documentation of immunization with a single human papillomavirus vaccine (HPV) dose, stratified by age and sex.

CHARACTERISTIC	11-17YEAR-OLDS				18-31YEAR-OLDS			
	FEMALES		MALES		FEMALES		MALES	
	ELIGIBLE ^a POPULATION (N=108)	SURVEY PARTICIPANT (N=10)	ELIGIBLE ^a POPULATION (N=122)	SURVEY PARTICIPANT (N=18)	ELIGIBLE ^a POPULATION (N=242)	SURVEY PARTICIPANT (N=20)	ELIGIBLE ^a POPULATION (N=390)	SURVEY PARTICIPANT (N=9)
N (%) ^b	N (%) ^b	N (%) ^b	N (%) ^b	N (%) ^b	N (%) ^b	N (%) ^b	N (%) ^b	
Race/ethnicity								
Non-Hispanic White	43 (49.4)	7 (70.0)	60 (57.1)	13 (72.2)	124 (55.6)	14 (70.0)	193 (56.1)	8 (88.9)
Non-Hispanic Black	14 (16.1)	1 (10.0)	13 (12.4)	2 (11.0)	22 (9.9)	1 (5.0)	34 (9.9)	1 (11.1)
Hispanic	4 (4.6)	1 (10.0)	5 (4.8)	1 (5.6)	21 (9.4)	1 (5.0)	28 (8.1)	0 (0.0)
Asian/Pacific Islander	17 (19.5)	1 (10.0)	13 (12.4)	1 (5.6)	42 (18.8)	3 (15.0)	59 (17.2)	0 (0.0)
Native American/Alaskan Native	0 (0.0)	0 (0.0)	2 (1.9)	0 (0.0)	2 (0.9)	1 (5.0)	1 (0.3)	0 (0.0)
Other/Multi-racial	9 (10.4)	0 (0.0)	12 (11.4)	1 (5.6)	12 (5.4)	0 (0.0)	29 (8.4)	0 (0.0)
Unknown	21	0	17	0	19	0	46	0
Age at first HPV vaccine dose (years)								
9-10	4 (3.7)	1 (10.0)	3 (2.5)	0 (0.0)	–	–	–	–
11-12	79 (73.1)	4 (40.0)	90 (73.8)	15 (83.3)	–	–	–	–
13-14	22 (20.4)	4 (40.0)	26 (21.3)	1 (5.6)	10 (4.1)	3 (15.0)	8 (2.1)	0 (0.0)
15-17	3 (2.8)	1 (10.0)	3 (2.5)	2 (11.1)	32 (13.2)	2 (10.0)	112 (28.7)	2 (22.2)
18-21	–	–	–	–	38 (15.7)	3 (15.0)	195 (50.0)	4 (44.4)
22-26	–	–	–	–	162 (66.9)	12 (60.0)	75 (19.2)	3 (33.3)

(Continued)

Table 1. (Continued)

CHARACTERISTIC	11-17 YEAR-OLDS				18-31 YEAR-OLDS			
	FEMALES		MALES		FEMALES		MALES	
	ELIGIBLE ^a POPULATION (N = 108)	SURVEY PARTICIPANT (N = 10)	ELIGIBLE ^a POPULATION (N = 122)	SURVEY PARTICIPANT (N = 18)	ELIGIBLE ^a POPULATION (N = 242)	SURVEY PARTICIPANT (N = 20)	ELIGIBLE ^a POPULATION (N = 390)	SURVEY PARTICIPANT (N = 9)
N (%) ^b	N (%) ^b	N (%) ^b	N (%) ^b	N (%) ^b	N (%) ^b	N (%) ^b	N (%) ^b	
Years since vaccination								
2	17 (15.7)	3 (30.0)	9 (7.4)	2 (11.1)	11 (4.5)	0 (0.0)	16 (4.1)	1 (11.1)
3	48 (44.4)	4 (40.0)	63 (51.6)	8 (44.4)	85 (35.1)	3 (15.0)	123 (31.5)	5 (55.6)
4	29 (26.9)	3 (30.0)	33 (27.1)	6 (33.3)	80 (33.1)	7 (35.0)	140 (35.9)	2 (22.2)
5	14 (13.0)	0 (0.0)	17 (13.9)	2 (11.1)	66 (27.3)	10 (50.0)	111 (28.5)	1 (11.1)
Vaccine valency								
2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
4	53 (49.1)	3 (30.0)	67 (54.9)	10 (55.6)	186 (76.9)	19 (95.0)	308 (79.0)	6 (66.7)
9	55 (50.9)	7 (70.0)	55 (45.1)	8 (44.4)	55 (22.7)	1 (5.0)	82 (21.0)	3 (33.3)
Ambulatory primary care encounter in 24 months prior to sampling date ^c	56 (52.8)	5 (62.5)	55 (46.2)	9 (60.0)	178 (75.4)	12 (85.7)	200 (51.3)	7 (77.8)
Ambulatory primary care encounter in 12 months prior to sampling date ^c	37 (34.9)	4 (50.0)	42 (35.3)	6 (40.0)	148 (62.7)	7 (50.0)	155 (39.7)	6 (66.7)
Flu immunization (in 365 days prior to sampling date) ^c	15 (14.2)	1 (12.5)	23 (19.3)	3 (20.0)	64 (27.1)	4 (28.6)	74 (19.0)	3 (33.3)

^aKing County, Washington residents with clinical documentation of immunization with single human papillomavirus dose, 2-5 years prior to March 8, 2018 (sampling date).

^bColumn percents that do not sum to 100 are due to rounding.

^cExcludes 11 survey participants who refused consent for collection of information on ambulatory primary care encounter history and flu vaccination history (n = 2 girls; n = 3 boys; n = 6 women).

Table 2. Reasons^a for not receiving additional human papillomavirus (HPV) vaccine doses among children and adults with clinical documentation of receipt of only 1 dose, 2-5 years prior to March 2018.

	PARENTS OF 11-17 YEAR-OLDS				ADULTS AGED 18-31 YEARS			
	FEMALE CHILDREN (N=10) 11 RESPONSES		MALE CHILDREN (N=18) 19 RESPONSES		FEMALE ADULTS (N=20) 24 RESPONSES		MALE ADULTS (N=9) 9 RESPONSES	
	N	%	N	%	N	%	N	%
I believe (my child has/I have) received all recommended doses	2 ^b	20.0	1 ^c	5.6	4 ^d	20.0	0	0.0
(My child refuses/I refuse) to get another dose	1	10.0	1 ^e	5.6	1 ^f	5.0	0	0.0
(My child/I) had a problem with the HPV vaccine	1 ^g	10.0	2 ^e	11.1	1 ^f	5.0	0	0.0
I was not informed that more doses were needed	1	10.0	7	38.9	3 ^h	15.0	0	0.0
I have concerns about the HPV vaccine	2 ^g	20.0	2	11.1	0	0.0	0	0.0
I have concerns about vaccines in general	1	10.0	1	5.6	1	5.0	0	0.0
It is inconvenient to come back for additional doses	1	10.0	4	22.2	5 ^h	25.0	4	44.4
I forgot about the additional doses ⁱ	0	0.0	1	5.6	2	10.0	1	11.1
Additional doses were contraindicated due to illness ⁱ	1	10.0	0	0.0	0	0.0	0	0.0
(My child is/I am) afraid of needles ⁱ	0	0.0	0	0.0	2	10.0	0	0.0
I do not believe my (child has/I have) risks ⁱ	0	0.0	0	0.0	0	0.0	1	11.1
(My child/I) had a change in insurance coverage ⁱ	0	0.0	0	0.0	1	5.0	0	0.0
I don't know	1	10.0	0	0.0	2	10.0	3	33.3

^aRespondents could provide multiple reasons for not receiving additional HPV vaccine doses.

^bParents of 2 female children reported that their child received all 3 doses and indicated that 1 or more of these doses were delivered at a Kaiser Permanente Washington clinic. Medical record review confirmed that 1 child received a second dose post-sampling/prior to survey, but did not find evidence of any additional HPV vaccinations.

^cPrior to conclusion of the survey period, 1 male child received all recommended HPV vaccine doses (2 doses were delivered prior to age 15; 1 was received prior to sampling and 1 was received post-sampling/prior to survey).

^dOne adult female reported receiving all 3 doses at a non-Kaiser Permanente Washington clinic. The remaining 3 adult females also reported receiving all 3 doses but could not recall where they had received the vaccinations. Medical record review did not find evidence of any additional HPV vaccinations, although records were incomplete for 2 participants.

^eOne parent of a male child reported 2 reasons: child refusing to get another dose; and child having problems with the HPV vaccine.

^fOne adult female reported 2 reasons: refusing to get another dose; and having problems with the HPV vaccine.

^gOne parent of a female child reported 2 reasons: child having a problem with the HPV vaccine; and having concerns about the HPV vaccine.

^hOne adult female reported 2 reasons: not being informed that more doses were needed; and it is inconvenient to come back for additional doses.

ⁱNew response category created based on reasons captured in free-text field of survey (all other response categories were pre-defined).

Study limitations and strengths

Study limitations include a low participation response and small sample size, which precluded us from examining non-compliance reasons by race/ethnicity. Findings may not be generalizable to populations who are uninsured, on Medicaid, non-white, or who lack a medical home. Seven (12.3%) survey participants reported believing they had received all recommended HPV vaccine doses. Two participants had completed the series after being sampled and before survey participation, but medical record review found no evidence of additional doses for others. High levels of inaccuracy between actual HPV vaccination status and self-reported status have been observed.⁹ Unique strengths of our study include use of multiple data sources, including the state immunization registry, to comprehensively capture HPV vaccination history, objective assessment of vaccination status rather than reliance on self-report, and nondisclosure of vaccination status to survey participants to measure their recall. Furthermore, our study adds nuance to the existing literature with its focus on a population that was insured, had a medical home, and received care in an integrated healthcare setting—the lack of these characteristics has been reported as barriers to HPV vaccine series completion.⁸

Implications for practice

The collective evidence suggests that both healthcare systems and clinicians can play a greater role in promoting HPV vaccine series completion. This could include expanding efforts to educate patients about the cancer-prevention benefits of HPV vaccination and the need for multiple doses, while also addressing parents' safety concerns. Clinicians could use CDC toolkits to help them present the HPV vaccine to target-age children and their parents.¹³ Healthcare systems could also provide cues to action through electronic health record prompts for clinicians and reminder letters, emails, phone calls, or text messages for patients.^{14,15} A robust reminder/recall system would provide a safety net for gaps in communication. Prior research shows that knowledge about HPV, awareness of the need for multiple doses, and clinician recommendations are associated with completion of the HPV vaccine series,^{12,16,17} and interventions to increase knowledge about HPV and HPV vaccination have increased acceptance of the vaccine.¹⁸

Another commonly reported barrier to completing the HPV vaccine series in our study was the inconvenience of returning for additional doses. Healthcare systems could address this barrier by providing opportunities for HPV vaccination in settings outside of traditional primary care, such as school-based health centers, pharmacies, retail clinics, and mobile immunization clinics,^{8,19} while also facilitating and encouraging opportunistic vaccinations. Healthcare systems

and clinicians can also encourage timely vaccination prior to age 15, when only 2 doses are needed.

Conclusion

Although data on 1- and 2-dose effectiveness are beginning to emerge,²⁰⁻²² the clinical and public health impact of incomplete dosing is unclear, and data on the long-term protection conferred by incomplete dosing are not yet available. Until the evidence supports a recommendation for fewer doses, interventions to increase HPV vaccine series completion are needed to optimize the effectiveness of this vaccine in preventing HPV-related cancers.

Acknowledgements

The authors thank Julia P. Anderson, M.A. and the KPWHRI Survey Research Program interviewers for deployment of the survey, and Danielle L. Katsman for administrative assistance.

Author Contributions

Conception and design: AK, GDG, DAG, MMM. Acquisition, analysis, and/or interpretation of data: AK, PRB, GDG, MO, JBD, MMM. Writing, review, and/or revision of the manuscript: AK, PRB, GDG, MO, JBD, DAG, MMM.

Ethics approval and consent to participate

Study activities were approved by the Kaiser Permanente Washington Institutional Review Board (1152987). Survey data were obtained from study participants with verbal consent. All other study data were obtained with a waiver of consent.

ORCID iD

Aruna Kamineni  <https://orcid.org/0000-0002-0763-989X>

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