ORIGINAL PAPER



Parent-reported Barriers and Parental Beliefs Associated with Intentions to Obtain HPV Vaccination for Children in a Primary care Patient Population in Minnesota, USA

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Accepted: 18 February 2023 / Published online: 15 March 2023 © The Author(s), under exclusive licence to Springer Science+Business Media, LLC, part of Springer Nature 2023

Abstract

Human papillomavirus (HPV) vaccine uptake among adolescents remains suboptimal in the US. The COVID-19 pandemic posed new challenges to increase HPV vaccination rates. To characterize parent-reported barriers to obtain HPV vaccination for their children and to identify psychosocial factors associated with parents' intention to vaccinate their children for HPV, we administered parent surveys between April 2020 and January 2022 during a randomized pragmatic trial assessing the impact of evidence-based implementation strategies on HPV vaccination rates for adolescent patients at six Mayo Clinic primary care practices in Southeast Minnesota. A total of 342 surveys were completed (response rate 34.1%). Analyses were focused on parents of unvaccinated children (n=133). The survey assessed the main reason the child did not receive the HPV vaccine, parental beliefs about the vaccine, and the parent's intention to vaccinate the child for HPV in the next 12 months. Frequently reported awareness and access barriers to HPV vaccination included not knowing the child was due (17.8%) and COVID-19 related delay (11.6%). Frequently reported attitudinal barriers include the belief that the child was too young for the vaccine (17.8%) and that the vaccine is not proven to be safe (16.3%). Injunctive social norm (Adjusted-OR=3.15, 95%CI: 1.94, 5.41) and perceived harm beliefs (Adjusted-OR=0.58, 95%CI: 0.35, 0.94) about the HPV vaccine were positively and negatively associated with HPV vaccination intention, respectively. Our findings suggest that continued efforts to overcome parental awareness, access, and attitudinal barriers to HPV vaccination are needed and underscore the importance of utilizing evidence-based health system-level interventions.

Keywords Papillomavirus Vaccines; Health Knowledge · Attitudes · Practice; COVID-19 · "Patient Acceptance of Health Care" · Vaccination Hesitancy

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Introduction

Human papillomavirus (HPV) causes nearly all cervical cancers and many cancers of the vagina, vulva, penis, anus, rectum, and oropharynx. [1] Based on data from 2014 to 2018, an estimated average of 36,500 new cases of HPV-attributable cancers are diagnosed in the US each year, with 21,400 among females and 15,100 among males. [1] Most HPV-attributable cancers are caused by persistent highrisk HPV infections, which can be prevented by the HPV vaccine. [2–7] The Advisory Committee on Immunization Practices recommends routine HPV vaccination at age 11–12 years and catch-up HPV vaccination for all persons through age 26 years. [8] Despite compelling evidence on the effectiveness and safety of the HPV vaccine to prevent



cancer, less than 60% of adolescents aged 13–17 years are up-to-date on HPV vaccination according to data from the 2020 National Immunization Survey-Teen. [9].

Lack of provider recommendation, inadequate awareness and knowledge of HPV and the HPV vaccine, and overestimation of parental vaccine hesitancy among providers have been identified as major barriers to HPV vaccine initiation and completion. [10–14] Additionally, HPV vaccine related beliefs have been shown to influence parental decisionmaking regarding obtaining HPV vaccine for their children. Higher perceived effectiveness of HPV vaccine has been associated with greater HPV vaccination acceptance and intentions to vaccinate, while concerns about vaccine safety and potential harms have been associated with lower HPV vaccination acceptance and intentions to vaccinate. [15–18] Social norms and parental views on sexuality have also been found to influence parental HPV vaccination acceptance and intentions to vaccinate. [19-21] Since March 2020, the COVID-19 pandemic has emerged as an additional barrier to routine vaccine uptake among adolescents in the US. Recent studies showed that the administration rates of routine adolescent vaccines, including the HPV vaccine, declined significantly in the US during COVID-19 and it may require a sustained increase in vaccination uptake over multiple years to reverse the long-term public health and economic impact caused by this disruption. [22, 23]

Due to low HPV vaccination rates in the local population, [24] a multilevel intervention leveraging evidence-based implementation strategies to increase HPV vaccination rates was developed and implemented in an empaneled Mayo Clinic primary care patient population. The pragmatic trial, currently underway, aims to evaluate the impact of the multilevel intervention and is expected to be completed by of March 31, 2024. [25] Throughout the trial we have conducted surveys to evaluate parent-reported barriers and other potential factors that may be associated with HPV vaccine initiation and completion, outcomes that will be measured at the end of the trial using patients electronic medical record data. This current analysis reports findings from survey data and will be used to inform adaptations to the implementation strategies of the parent/patient-facing components of the multilevel intervention. Identifying and understanding parental knowledge, attitudes, and behaviors that influence HPV vaccination is critical for informing adaptations to improve HPV vaccine initiation and completion, particularly among those who remain unvaccinated following exposure to reminders and recalls and their providers' strong recommendations with specific information regarding the vaccines and how to get them.

Methods

Study Design

The parent/guardian survey was administered as part of the impact evaluation of a stepped-wedge cluster randomized pragmatic trial assessing the impact of evidence-based implementation strategies (reminder-recall intervention, audit feedback reports and provider tool kit) on HPV vaccination rates for female and male empaneled patients aged 11 and 12 years at six Mayo Clinic primary care practices in Southeast Minnesota. The investigators have published the protocol elsewhere (ClinicalTrials.gov Identifier: NCT03501992). [25] Starting April 2019, at the beginning of each calendar month, the clinical practice sites that are randomly assigned to the reminder-recall intervention sent reminder-recall communications in the format of mailed letters to the parent or legal guardian of the patients who were due for HPV vaccination. The reminder-recall communication listed the vaccines for which the child was due and provided a quick response (QR) code and a website address (URL) for accessing further information about the vaccines due. The reminder-recall communication also urged parents to vaccinate their child as soon as possible and described the availability of convenient nurse visits, availability of vaccines at express care sites, and provided phone numbers for scheduling appointments. The letter also described the availability of measures available to make the injections less painful. The study received ethical approval from the Mayo Clinic Institutional Review Board.

Data Collection

For the impact evaluation, parents and guardians of children who were empaneled to the sites randomized to the reminder-recall intervention were mailed a paper survey one year after the reminder-recall communications were sent. Surveys were intended to evaluate parent awareness of and response to the reminder-recall intervention. The initial survey packet included a \$2 bill as compensation for participants' time. A reminder survey was sent 1 month after the initial mailing to non-respondents. As of January 2022, a total of 1,004 surveys were sent and 342 completed surveys were returned, resulting in a response rate of 34.1%.

Measures

The survey measured the parent/guardian awareness of the reminder-recall intervention, assessed whether they used the QR code and/or the URL to access further information



about the vaccines due, and asked whether they scheduled an appointment for the child to receive the HPV vaccine, and the type of appointments scheduled. Additionally, the survey assessed the child's HPV vaccination status in the last 12 months, the main reason the child did not receive the HPV vaccine, and the parent/guardian's intention for the child to receive the HPV vaccine in the next 12 months if currently unvaccinated.

Parent/guardian's beliefs about the HPV vaccine were measured through five items modified from the Carolina HPV Immunization and Attitudes and Beliefs Scale [26– 28] using 5-point Likert scales (1=Strongly disagree to 5 = Strongly agree). The items and associated psychosocial constructs were as follows: "Most people who are important to me would support getting the HPV vaccine for my child" (injunctive social norm), "Other parents in my community are getting their children the HPV vaccine" (descriptive social norm), "The HPV vaccine might cause lasting health problems" (perceived harm), "I don't have enough information about the HPV vaccine to decide whether to give it to my child" (uncertainty), and "The HPV vaccine is effective in preventing several cancers" (effectiveness). General vaccine confidence was measured with three items adapted from the Vaccination Confidence Scale [29, 30] using 5-point Likert scales (1 = Strongly disagree to 5 = Strongly agree), including "Vaccines are necessary to protect the health of children who are the age of my child" (necessity), "Vaccines do a good job in preventing the diseases they are intended to prevent" (effectiveness), and "Vaccines are safe" (safety).

The survey also measured the demographic characteristics of the child and the parent/guardian, including sex, race, and ethnicity of the child and parent/guardian, parent/guardian's marital status, education level, and employment status, and the family's housing status.

Data Analysis

We focused our analyses on parents/guardians who reported that their child has not received the HPV vaccination in the last 12 months. We summarized the main reasons the children did not receive the HPV vaccine. Descriptive statistics and polychoric correlation were used to examine the distribution of and the correlations between the vaccine related beliefs. Due to high correlations between the general vaccine confidence items, a confirmative factor analysis (CFA) was conducted on the three items, and factor scores (i.e., estimated values for the latent variable) were generated from the CFA model to represent participants' general vaccine confidence. Ordinal logistic regression was used to assess the bivariate associations between parent/guardian's intention for their child to receive the HPV vaccine in the next 12 months (primary outcome variable) and HPV

vaccine related beliefs and general vaccine confidence. Multivariable ordinal logistic regression was used to examine the associations between HPV vaccination intention and all vaccine related beliefs, adjusting for child and parent/guardian demographic characteristics including the sex of the child and parent/guardian age, sex, employment status, and education level. Statistical analyses were conducted in R (version 3.6.2). [31] P-values < 0.05 were considered statistically significant.

Results

Table 1 summarizes child and parent/guardian demographic characteristics. The majority of children were non-Hispanic (98.5%), white (93.3%), and male (56.5%). According to their parents/guardians, over half (59.9%) of the children received the HPV vaccine in the last 12 months. Most of the parents/guardians were non-Hispanic (99.1%), white (93.3%), female (86.3%), have a bachelor's degree or higher (78%), married/partnered (89.4%), employed (88.1%), and own their family home (94.7%). The results reported hereafter are based on data from parents who reported that their child has not received the HPV vaccination in the last 12 months (n = 133). The demographic characteristics of child and parent/guardian did not differ by self-reported HPV vaccination status (all p-values>0.05).

Table 2 summarizes the frequency of parents' reports of the main reasons their child did not receive the HPV vaccine in the last 12 months. Most reported reasons fell into two categories: awareness and access barriers (41.8%) and attitudinal barriers (55.8%). Parents reported awareness and access barriers to HPV vaccine. These included being unaware that the child was due (17.8%), delay in vaccination because of the COVID-19 pandemic (11.6%), and lack of time or failure to remember the need to vaccinate (6.2%). Parents also reported attitudinal barriers to HPV vaccination, including the belief that the child is too young for the vaccine (17.8%), concerns about vaccine safety (16.3%), and the belief that the vaccine is not necessary for their child (6.2%).

Table 3 summarizes the distribution of vaccine related beliefs. Regarding HPV vaccine related beliefs, over half of our participants reported perceiving positive injunctive and descriptive social norms regarding HPV vaccination (59.1% and 47.7% reported agreement). However, an equal portion (47.7%) of participants reported they neither agreed nor disagreed with the descriptive social norm that "Other parents in my community are getting their children the HPV vaccine." Over half (65.6%) of participants affirmed that they believed in the effectiveness of the HPV vaccine. A minority of participants expressed concern about potential



Table 1 Sample characteristics

	Total	Child is unvacci	
	N (%)	N (%)	p-value b
Total	342	133 (38.9)	
Sex of child			0.575
Female	147 (43.5)	55 (41.4)	
Male	191 (56.5)	78 (58.6)	
Missing	4		
Child race/ethnicity			0.483
White	299 (88.7)	115 (87.1)	
Person of color	38 (11.3)	17 (12.9)	
Missing	5	1	
Parent/guardian type			0.317
Mother	295 (86.3)	112 (84.2)	
Father	46 (13.5)	20 (15)	
Grandparent	1 (0.3)	1 (0.8)	
Parent/guardian age (in years)			
Mean (SD)	43.5 (5.02)	43.41 (5.54)	
Median [Min-Max]		43 [28–73]	
Missing	10	5	
Sex of parent/guardian			0.513
Female	296 (86.5)	113 (85)	
Male	46 (13.5)	20 (15)	
Parent/guardian race/ethnicity			0.283
White	317 (93)	120 (90.9)	
Person of color	24 (7)	12 (9.1)	
Missing	1	1	
Parent/guardian marital status			0.590
Married/Unmarried couple	304 (89.4)	117 (88)	
Single/Divorced/Widowed	36 (10.6)	16 (12)	
Missing	2	0	
Parent/guardian education			> 0.999
Less than bachelor's degree	75 (22)	29 (21.8)	
Bachelor's degree	143 (41.9)	56 (42.1)	
Postgraduate	123 (36.1)	48 (36.1)	
Missing	1	0	
Housing			0.458
Own home	324 (94.7)	124 (93.2)	
Rent home	18 (5.3)	9 (6.8)	
Parent/guardian employment	` /	. /	0.230
Employed	295 (88.1)	109 (85.2)	
Unemployed/retired	40 (11.9)		
Missing	7	5	

^a Self-reported child HPV vaccination status was missing for 4 participants.

harm and uncertainty about the HPV vaccine, with 27% of participants reporting agreement with the statement that the HPV vaccine may cause lasting health problems and 26.5% reporting that they do not have enough information about the vaccine. Regarding vaccines in general, most participants were affirmative of their necessity (89.5%), effectiveness (93.9%), and safety (82.6%). Over half (61.4%)

Table 2 Parental barriers to their child's receipt of HPV vaccine in the last 12 months (n = 133)

last 12 months $(n = 133)$	
Main reason child did not receive HPV vaccine in the last 12 months	N (%)
Awareness and access barriers to HPV vaccine:	
I did not know that my child was due for the HPV	23
vaccine	(17.8)
I delayed HPV vaccine because of COVID-19	15
	(11.6)
I do not have time/ forgot about it/ it is not a priority	8 (6.2)
My child will get the HPV vaccine at their next health- care visit	5 (3.9)
My child's healthcare provider did not recommend the HPV vaccine	3 (2.3)
Sub-total	54
	(41.8)
Psychological barriers to HPV vaccine:	
My child is too young for the HPV vaccine	23
	(17.8)
I believe the HPV vaccine is not proven safe	
	(16.3)
I believe my child will not need the HPV vaccine	8 (6.2)
The HPV vaccine goes against our family's values	6 (4.7)
I need more information about the HPV vaccine	4 (3.1)
My child will decide whether to get the HPV vaccine	3 (2.3)
My child had too many vaccines/ want to space out vaccines	3 (2.3)
I had concerns about encouraging sexual activity if my child received the HPV vaccine	2 (1.6)
I worry about the side effects of the HPV vaccine	2 (1.6)
Sub-total	72
	(55.8)
Other reasons	3 (2.4)
Total	129
Missing	4

of participants reported that their child "likely" or "very likely" will receive the HPV vaccine in the next 12 months.

Table 4 summarizes the associations between HPV vaccination intention and vaccine related beliefs and child and parent/guardian demographic characteristics. All vaccine related beliefs were statistically significantly associated with HPV vaccination intention in bivariate analyses. However, in the multivariable analysis, only injunctive social norm ("Most people who are important to me would support getting the HPV vaccine for my child") and perceived harm ("The HPV vaccine might cause lasting health problems") remained significantly associated with HPV vaccination intention after adjusting for child and parent/ guardian demographic characteristics. Participants who perceived a higher (versus lower) level of injunctive social norm reported higher intention to get the HPV vaccine for their child during the next 12 months (Adjusted-OR = 3.15, 95%CI: 1.94–5.41), while participants with a higher (versus lower) level of perceived harm reported lower intention to



^b P-values were obtained from Fisher's exact test.

Table 3 Vaccine related beliefs and intention for child to receive the HPV vaccine in the next 12 months

	Strongly Some disagree what disa	Some what disagre		ier agree	Some what agree N (%)	Strongly agree N (%)
	N (%)		N (%)			
Beliefs about HPV vaccine						
Most people who are important to me would support getting the HPV vaccine for my child	12 (9.1)	12 (9.1)	30 (22	7)	37 (28)	41 (31.1)
The HPV vaccine might cause lasting health problems	29 (21.8)	27 (20.3)			26 (19.5)	10 (7.5)
I don't have enough information about the HPV vaccine to decide whether to give it to my child	41 (31.1)	34 (25.8)	22 (16	5.7)	22 (16.7)	13 (9.8)
Other parents in my community are getting their children the HPV vaccine	3 (2.3)	3 (2.3)	63 (47	7.7)	42 (31.8)	21 (15.9)
The HPV vaccine is effective in preventing several cancers	2 (1.5)	5 (3.8)	38 (29.0)		48 (36.6)	38 (29.0)
General vaccine confidence						
Vaccines are necessary to protect the health of children who are the age of my child	2 (1.5)	5 (3.8)	7 (5.3)		34 (25.6)	85 (63.9)
Vaccines do a good job in preventing the diseases they are intended to prevent	1 (0.8)	4 (3.0)	3 (2.3)		44 (33.3)	80 (60.6)
Vaccines are safe	2 (1.5)	7 (5.3)	14 (10	0.6)	50 (37.9)	59 (44.7)
Intention for child to receive the HPV vaccine in 12 months	Not likely at		Not too likely	Somew	hat likely	Very likely
	N (%)		N (%)	N (%)		N (%)
	36 (27.2)		15 (11.4)	33 (25)		48 (36.4)

get the HPV vaccine for their children (Adjusted-OR = 0.58, 95%CI: 0.35–0.94).

Discussion

Our study provides important insights regarding barriers to HPV vaccination in a Southeast Minnesota adolescent primary care population in the midst of the COVID-19 pandemic. Our results showed that awareness and access barriers were encountered by nearly half of the parents of children due for the HPV vaccine who did not receive it during in the 12 months since receiving the reminder-recall communication. Notably, 20% of the parents of unvaccinated children reported that they did not know their children were due for the vaccine or did not receive a provider recommendation about the vaccine. This finding suggests a need for continuing health system-level efforts to improve HPV vaccine awareness among parents through evidencebased interventions. Patient reminder and recall systems, including telephone calls, text messages, mailed letters, and postcards, have been shown to improve adolescent vaccine uptake. [32] In consideration of the COVID-19 pandemic, reminder and recall communication should mention the safety measures clinics are taking to prevent COVID-19 infection to reduce parents' safety concerns. High-quality provider recommendations strongly endorsing the HPV vaccine, emphasizing cancer prevention, and recommending same-day vaccination, has also been shown to be positively associated with HPV vaccine uptake and negatively associated with HPV vaccine refusal and delay. [13] Intervention strategies such as provider communication tool-kit and role modeling by champions may enhance provider self-efficacy in delivering high-quality recommendation and normalize this communication practice throughout the health system.

Our results highlighted the need to improve the availability of HPV vaccine and to make it easier to access for busy parents. Previous research showed that standing orders, point-of-care reminders, and provider active choice prompts are promising interventions to help ensure that every health care encounter is used to promote vaccination. [33-36] Additionally, pharmacies have been suggested as promising alternative settings outside of primary care to provide HPV vaccination for adolescents because they are highly accessible and have well-established immunization infrastructure. [37] However, policy, reimbursement, and care coordination challenges still need to be resolved to make pharmacybased vaccination an effective strategy to increase HPV vaccination uptake. [38] In light of the COVID-19 pandemic, co-administration of COVID-19 vaccine and other routine vaccines has been advocated to facilitate catch-up vaccination of adolescents and rapid uptake of the COVID-19 vaccine. [39].

Over half of the parents of unvaccinated children reported psychological barriers to HPV vaccine, including the perception of their children being too young for



Table 4 Factors associated with parental intention for child to receive HPV vaccine in the next 12 months a

-	Bivariate OR (95% CI)	Adjusted OR (95% CI)
Beliefs about HPV vaccine		
Most people who are important to me would support getting the HPV vac-	4.62	3.15
cine for my child	(3.17, 7.05)	(1.94, 5.41)
The HPV vaccine might cause lasting health problems	0.31	0.58
	(0.22, 0.43)	(0.35, 0.94)
I don't have enough information about the HPV vaccine to decide whether	0.68	1.10
to give it to my child	(0.53, 0.86)	(0.75, 1.62)
Other parents in my community are getting their children the HPV vaccine	1.97	1.05
	(1.33, 2.97)	(0.60, 1.83)
The HPV vaccine is effective in preventing several cancers	3.39	1.84
	(2.24, 5.27)	(0.91, 3.82)
General vaccine confidence (factor score)	3.65	1.26
	(2.33, 5.93)	(0.69, 2.34)
Child and parent demographics		
Sex of child		
Female	Reference	Reference
Male	1.32	0.97
	(0.7, 2.48)	(0.42, 2.16)
Parent/guardian age (in years)	0.98	0.93
	(0.92, 1.04)	(0.85, 1.01)
Sex of parent/guardian		
Female	Reference	Reference
Male	1.36	2.10
	(0.58, 3.26)	(0.65, 7.15)
Parent/guardian employment		
Employed	Reference	Reference
Unemployed/Retired	0.78	1.01
	(0.31, 1.96)	(0.31, 3.37)
Parent/guardian education	Reference	, , ,
Less than bachelor's degree	0.78	1.46
	(0.35, 1.74)	(0.51, 4.25)
Bachelor's degree	Reference	Reference
Postgraduate	1.31	0.51
6	(0.64, 2.67)	(0.20, 1.29)

^a Results from ordinal logistic regression; HPV vaccination intention coded as 1=Not likely at all, 2=Not too likely, 3=Somewhat likely, 4=Very likely.

the HPV vaccine and HPV vaccine safety concerns as the most frequently reported barriers. When parents were asked about their vaccine safety related beliefs specifically, most of them reported high confidence in the safety of vaccines in general, but a sizable minority reported believing the HPV vaccine might cause lasting health problems and a third were ambivalent about it. Additionally, while almost all participants agreed that vaccines in general are effective in preventing the diseases they are intended to prevent, only about two-thirds of participants agreed that the HPV vaccine is effective in preventing several cancers. The level of safety and effectiveness concerns for HPV vaccine identified in our study sample were similar to a 2019 national panel survey on the prevalence and characteristics of parental hesitancy for HPV vaccine. [40] The contrast between higher concerns for HPV vaccine versus minimal concerns for vaccines in general echoes previous research as well. [41] A study based on data from the 2015 to 2018 National Immunization Survey found a 80% increase in the proportion of parents who refused the HPV vaccine for their children due to safety concerns while data from the national vaccine safety surveillance system showed that the HPV vaccine adverse event reporting rate per 100,000 doses distributed decreased from about 45 to under 30 from 2015 to 2018. [42] These findings suggest an urgent need to identify and implement effective intervention strategies to increase parental confidence in the safety and effectiveness of the HPV vaccine. Previous research has shown that focusing on presenting scientific evidence of vaccine safety and effectiveness alone is unlikely to change minds and rebuttal of vaccine misperceptions can backfire. [43–46] Leveraging findings from psychological and communication science



^b Results from multivariable ordinal logistic regression.

is necessary to better understand the psychological mechanisms of vaccine hesitancy and to develop effective means to address it. [47, 48]

Regarding associations between parental beliefs and HPV vaccination intention, injunctive social norm ("Most people who are important to me would support getting the HPV vaccine for my child") and perceived harm of the HPV vaccine ("The HPV vaccine might cause lasting health problems") remain positively and negatively associated with HPV vaccination intention in the next 12 months, respectively, after adjusting for other vaccine related beliefs and parent and child demographic characteristics. These results suggest that having a trusted figure whose opinions are highly valued by the parents to deliver the message that the HPV vaccine is safe may be the key to move the HPV vaccine hesitant parents in our sample toward willingness to vaccinate. To use this finding to inform intervention design, further understanding of whose opinions are valued by these parents is needed. For parents who value the opinions of their children's health care provider, high-quality provider recommendation may be effective in fostering HPV vaccination intention. For parents who do not value the opinions of their children's health care provider, identifying pro-HPV vaccine opinion leaders in their social network and getting these opinion leaders on board to communicate the safety of HPV vaccine will be critical.

Our study has limitations. First, the cross-sectional design does not allow us to draw conclusions about causality of the observed associations. Second, we relied on self-reported data rather than objective measures of HPV vaccination status, which may contain misreporting due to inaccuracies in participants' memory or tendency to provide socially desirable responses. Third, our study sample was from an empaneled Mayo Clinic primary care patient population in Southeast Minnesota, therefore the findings may not be generalizable beyond this context. However, findings on the breadth of parent-reported barriers to HPV vaccination in the midst of COVID-19 pandemic and the associations between parental vaccine beliefs and HPV vaccine intention are relevant to populations beyond our region and may be of more general interest. Finally, our response rate is relatively low, thus our findings' generalizability may be impacted by non-response bias.

Conclusion

Our research identified primary barriers to HPV vaccination in a Southeast Minnesota adolescent primary care population in the midst of the COVID-19 pandemic and highlighted the associations between parental social norm and perceived harm beliefs about HPV vaccine and HPV

vaccination intention. These findings suggest that continued efforts to overcome parental awareness, access, and psychological barriers to HPV vaccination are needed and underscore the importance of utilizing evidence-based health system-level interventions.

Acknowledgements We sincerely thank Gregory D. Jenkins, MS and the Mayo Clinic Survey Research Center staff for their dedicated work and contributions on survey data collection and management.

Funding This work was supported by the National Cancer Institute of the National Institutes of Health under Grant R01CA217889.

Competing Interests Dr. Jacobson has served on safety review committees for Merck & Co for 2 post licensure studies of human papillomavirus vaccine safety and on an external data monitoring committee for Merck & Co for a series of prelicensure trials of a novel pneumococcal vaccine. The other authors report no competing interests.

Data Availability The dataset analyzed in the current study are not publicly available because they are part of research in progress but are available from the corresponding author upon reasonable request.

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