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Qualitative Responses to a National Physician Survey on HPV Vaccination

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Introduction

Human papillomavirus (HPV) is a sexually transmitted virus that causes virtually all cervical cancers. In 2011, an estimated 12,700 women were newly diagnosed with cervical cancer in the United States [1]. Although not a necessary cause, HPV also is responsible for a substantial number of vulvar, vaginal, penile, anal, and oropharyngeal cancers [2–4]. More than 40 of the 100+ types of HPV infect the genital area [5]. HPV types 16 and 18 are associated with an estimated 22,000 cancers annually in the United States, of which about 7,000 occur in males [6]. Non-oncogenic HPV types cause more than 90% of genital warts [7]; although benign, genital warts are a source of psychosocial distress [8] and itching or other physical discomfort can result from treatment [9].

In June 2006, a quadrivalent HPV vaccine, Gardasil®, became available for females ages 9–26 years, with routine vaccination recommended for ages 11–12 [10]. This vaccine confers immunity against the HPV types that most commonly cause cervical cancer (16, 18) and genital warts (6, 11). The U.S. Food and Drug Administration (FDA) later licensed the HPV vaccine for use in males ages 9–26 in October 2009 [11]. Within a week of FDA approval, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) issued a permissive recommendation, meaning that providers may recommend the HPV vaccine to male patients at their discretion [11]. At the same time, the FDA approved Cervarix®, a bivalent vaccine offering protection against HPV types 16 and 18, for use only in females [12]. The ACIP's revised recommendation for routine HPV vaccination for males was published in December 2011 [7].

Despite availability, HPV vaccination rates remain suboptimal. Estimates for 2011 show about 53% of 13- to 17-year-old females received 1 dose and 35% received 3 doses, with even lower percentages observed for males (8% and 1%, respectively) [13]. Numerous studies have documented the importance of physician recommendation and support on uptake of HPV vaccination by parents on behalf of their adolescent sons and daughters [14, 15]. However, there are few qualitative reports of physicians' attitudes, concerns, and what motivates behaviors regarding HPV vaccine in adolescents, particularly males, from physicians in diverse practice settings and various geographic locations in the United States [16–18].

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Similar to a prior study completed by our team where we analyzed qualitative comments from a 2009 national survey of physicians regarding HPV vaccine recommendation [19], the current study presents comments from a second survey conducted in 2011. As with the prior survey, the primary objective of the qualitative analysis of free responses was to identify HPV vaccine recommendation, beliefs, and practices among U.S. physicians. A secondary objective was to explore comments specific to male HPV vaccination. Analyses of these free text responses may uncover previously unknown or unaccounted for influences on HPV vaccine recommendation among U.S. physicians.

Methods

In April 2011, a quantitative survey assessing physicians' knowledge, attitudes, and HPV vaccination practices was distributed among a national sample of U.S. primary care physicians, including Family Physicians (FPs), Pediatricians (Peds), and Obstetricians/Gynecologists (OBGYNs). A stratified random sample of physicians selected from the American Medical Association Physician Masterfile (n = 1541) was mailed a study packet, which included the survey, a \$25 cash honorarium, and a prepaid envelope to return the survey or incentive if the physician declined participation. A waiver of consent was obtained from the University of South Florida Institutional Review Board. Survey methods are described in greater detail elsewhere (Vadaparampil et al., under review). The end of the survey provided a section labeled "additional comments/suggestions" followed by several lines for text. All comments provided in this free text space and in the survey margins were collected and analyzed. Participants were asked to respond to the survey by July 15, 2011, but late surveys were accepted. The last survey included in the current study was completed September 5, 2011.

Data Analysis

Qualitative comments from the end of the survey and survey margins were imported into ATLAS.ti 5 (Hapburg, Germany) and were organized according to the question with which they were associated. Comments such as 'thank you,' 'no comment,' or 'good survey' were excluded due to lack of analytic specificity and value. Included comments were then analyzed using a combination of grounded theory and content analysis. Two independent reviewers, MR and DM, reviewed all handwritten comments throughout the survey and noted similar issues and language for initial inductive codes. These codes were collapsed and placed into broader categories based on content and thematic saturation. Categories were then reviewed to develop subcategories of comments that diverged from the originating pattern. Final decisions on comments that spanned across multiple subcategories were discussed with a third reviewer, GQ, and consensus was reached.

Results

Of 928 completed surveys from eligible respondents, 134 participants provided 142 comments included in the analysis (Figure 1). Of these comments, 65 were from Peds, 46 from FPs, and 31 from OBGYNs. The majority of physicians providing comments practiced in a private office (71%), followed by an ambulatory care clinic of a hospital/medical center (7%), health maintenance organization clinic (5%), community health center (5%), university/college student health service (4%), and other settings (8%). About 16% of physicians reported a solo practice, 46% practiced in a small group (2–5 physicians), and the remainder practiced in a group of 6 or more physicians. Over half of physicians reported practicing in a suburban setting (54%), followed by urban (28%) and rural (13%) settings. Physicians represented the major U.S. census regions: northeast (17%), midwest (22%), south (31%), and west (26%).

Analysis of the comments resulted in four overall categories: 1) the survey process, 2) personal strategy for discussing HPV vaccine, 3) clinical practice guidelines preference, and 4) barriers to vaccine administration. Categories and their associated subcategories, along with exemplary quotes, are presented in Table 1.

Survey Process

Responses pertaining to the survey process were primarily from OBGYNs, followed by FPs and Peds. The majority of physicians in this category commented on their personal experience completing the survey. A quarter of physicians specifically mentioned their appreciation for the brevity and simplicity of the survey format. The remaining comments pertained to the upfront cash incentive enclosed in each study packet. Some physicians appreciated the directness of the cash incentive, while a few objected to the use of cash.

Personal Strategies

Physicians commented on their personal strategy of recommending and/or discussing the HPV vaccine with patients and families. Peds and FPs equally provided the majority of comments, with only one comment from an OBGYN. Physicians stated they usually recommend the HPV vaccine directly to the family, utilize secondary sources such as brochures, or believe vaccination to be a private matter and advised families to discuss amongst themselves. Additionally, some physicians specified they used an electronic tracking system to indicate when a patient should be offered the vaccine as well as reminders to complete the vaccine series across multiple visits.

Clinical Practice Guidelines

Physicians who commented about the clinical practice guidelines associated with the HPV vaccine were largely OBGYNs, followed by Peds. No FP commented about HPV vaccine policies. The majority of physicians criticized the lack of clarity among policy recommendations for the HPV vaccines, Cervarix® and Gardasil®, and cited the need for uniform policies. Some physicians referred to their preferred professional organization for guidelines including the CDC, American Academy of Pediatrics (AAP), and the American College of Obstetrics and Gynecology (ACOG).

Barriers to Vaccine Administration

The majority of survey comments pertained to vaccine administration barriers. Some physicians did not feel their role was to provide HPV vaccination, and stated it should be pursued through another specialty or health care setting such as the health department. Interestingly, a Ped respondent stated clinic policy is to refer HPV vaccination to OBGYNs, while an OBGYN said they refer to Peds for the vaccine. Few physicians expressed a personal objection to the vaccine.

Some physicians stated the need for more information on vaccine safety and efficacy to feel comfortable administering it. A few physicians commented that parents' main objections involved safety concerns. A few indicated that parents feared that vaccinated children would be more inclined to behave promiscuously and these perceptions also served as a barrier to vaccination. The next majority response was about the barrier of timing or situation, such as if the patient was too ill. Some physicians also discussed their discomfort with recommending the vaccine to the younger age groups. The multiple clinic visits required to receive follow-up shots was also mentioned by some as creating a barrier for vaccine series completion. However, the foremost-cited barrier to HPV vaccination was cost. About 32% of the total sample that provided comments indicated that insurance companies do not always cover this vaccine, particularly for males.

Male Vaccination

A secondary study objective was to explore comments specific to male HPV vaccination. Twenty-six comments were specific to males, with 17 physicians stating they *do not* recommend the vaccine to males. The majority of these comments were provided by private practice FPs; no OBGYNs commented that they do not recommend the vaccine to males. Many comments specific to male patients focused on lack of insurance coverage/reimbursement: “The failure of major insurance carriers to cover HPV vaccine for males is a significant barrier to HPV immunization” (Ped). Although insurance coverage was the primary issue raised, one Ped remarked about vaccine safety: “Awaiting more long term safety studies before immunizing boys since they are not at risk for cervical cancer directly.”

Discussion

The current study provides important insights into physician participation in survey research as well as their perspectives on HPV vaccination. Given consistently low response rates on mailed physician surveys [20], reviewing physicians’ optional comments about the survey experience will inform future research endeavors. The demand on physicians for their time coupled with relatively low survey response rates also placed increased value on comments provided as it was apparent that HPV vaccination is an issue about which physicians wanted their voices heard. The majority of physicians appreciated the survey brevity, acknowledging that the study team valued their time. Some physicians also provided suggested revisions for words/questions that they found confusing, suggesting that these providers were attending to the survey content/questions. Similar to the analysis of written comments from the 2009 survey [19], the majority of physicians were compelled to explain the impact of an upfront cash incentive, and some said they would not have completed the survey without it. This is supported by other studies of physician participation in survey research that indicate a direct relationship between response rate and upfront monetary incentives [21–23].

In this study, some physicians sought to make the study team aware that clarity in guidelines is lacking for HPV vaccination, specifically regarding which vaccine brand, Cervarix® or Gardasil®, to use for females. The major professional organizations representing the specialties included in this study all provide clinical practice guidelines based on recommendations from the CDC’s ACIP regarding patient ages to vaccinate [10]. Since the time of this survey, these organizations have even updated these guidelines to include the more recent recommendations for males [24, 25], for whom only Gardasil® is approved. Yet a small number of physicians in the current study highlighted the absence of guidelines regarding the preferred vaccine brand for administration to female patients [24, 25]. Gardasil® offers protection against genital warts, but Cervarix® has been shown to offer greater cross-protection against oncogenic HPV types 31 and 45 [26, 27]. One physician in our study noted the desire to carry both vaccine brands and “would lean toward giving women the Cervarix and males Gardasil.” Carrying both brands may not be an option for some physicians as suggested by data from our quantitative survey showing that about 45% of physicians agreed that the upfront cost of purchasing private stock HPV vaccine was a barrier to immunizing patients against HPV (Vadaparampil et al., under review). Without guidelines from professional organizations, physicians are left to decide whether to offer a vaccine that offers greater protection against cervical cancer for females or a vaccine that can be administered to both male and female patients that offers protection against non-oncogenic HPV types.

Many physicians offered their personal methods for discussing the HPV vaccine, despite whether these methods were in agreement with the recommendations. Some indicated a more directive approach that may leave little opportunity for a discussion about pros and

cons of vaccination. The majority of physicians commented on barriers to discussing, referring, and administering HPV vaccine. Among physicians who provided comments in this subcategory, there is a clear need for role clarification among providers. Although some variation in practice patterns is expected and appropriate, assumptions that it is another specialist's responsibility may reduce the number of patients who are ultimately vaccinated [28, 29]. Physicians in the current study also indicated they may refer patients to other clinical settings such as the health department [19]; however, it is unknown how many patients are actually vaccinated in this scenario.

Safety and efficacy issues, particularly for male patients, were cited as another barrier to discussion. One physician noted that the vaccine is not effective because it only protects against certain types of HPV, therefore a patient may still acquire HPV and encouraging vaccination is of no value. Both vaccine brands confer immunity against the two types of HPV responsible for 70% of cervical cancers, with some additional cross-protection against other HPV types [27]. Obtaining additional insight into physicians' perceived efficacy and acceptable levels of protection may be warranted.

Some physicians also noted parental concerns about vaccine safety and efficacy, which coincides with recent literature assessing parental perceptions of HPV vaccine [30–32]. Some parents may not receive pertinent clinical trial information on the safety and effectiveness for both males and females [33, 34] or have prevailing concerns about vaccine side effects [31]. In a qualitative study of 20 adolescent-mother-clinician triads, one theme that emerged was parental delay of vaccination due to concerns about safety and efficacy [32]. One mother cited the lack of long-term data on immunity. Although HPV vaccine is relatively new and long-term data are limited, the vaccine is effective only if it is received prior to HPV infection. Furthermore, adolescent preventive visits decline after age 11 [32, 35]; thus, delaying vaccination could further reduce overall vaccine efficacy if an adolescent does not present for vaccination until they are older and the onset of sexual activity is more likely to have occurred. Given that parents are primary decision-makers in children's healthcare, it is imperative to be aware of their perceptions of the HPV vaccine, and to be prepared to educate families.

It is well-established that physicians lack time during office visits and often must prioritize discussion topics [36, 37]. Physicians in this study echoed these constraints as barriers to recommending the HPV vaccine. Physicians noted that they are more likely to recommend the HPV vaccine during well child visits than during illness visits, which coincides with the literature [37]. Because the HPV vaccine is not scheduled to be administered to patients until early adolescence, physicians must ensure that enough time is carved out of a standard clinic visit for this discussion, and many physicians explain the time is not there. On the other hand, early vaccination is an opportunity to promote healthy activities by encouraging long-term, protective behaviors [38] and ultimately reduce the number of illness visits.

The largest majority of physicians commented on the high cost of the vaccine and lack of reimbursement as the primary barrier to discussion and administration. Despite four survey questions that attended to the issue of financial barriers, respondents clearly wanted to emphasize the importance of this obstacle. The addition of males to the HPV vaccination schedule has surpassed the cost-effectiveness threshold [39], largely due to the lack of insurance coverage and the need for many to purchase this expensive vaccine out-of-pocket, or apply for no-cost administration at health departments with a sliding scale fee schedule. A small percentage of physicians specifically stated that they do not discuss the HPV vaccine with males due to lack of insurance coverage, which indicates that physicians' own perceptions of a family's ability to pay for the vaccine may prevent this discussion from occurring. Unfortunately, an absence of physician recommendation is linked to lack of HPV

vaccine uptake among boys [40] and physicians may be missing an opportunity to make parents aware that the vaccine is available for boys. More research is needed to assess the effect of vaccine cost on physician recommendation now that the ACIP has recommended routine vaccination of boys and vaccines are to be covered without cost-sharing through the Patient Protection and Affordable Care Act [41].

In light of the ACIP's permissive recommendations for male HPV vaccination at the time our survey was conducted [11], we were interested in learning about physicians' experiences with vaccinating male patients. The quantitative survey asked physicians to report the frequency with which they recommended the HPV vaccine to male patients. Few physicians reported consistently (>75% of the time) recommending HPV vaccine to male patients aged 11–12 (10.8%), 13–17 (12.9%), and 18–26 years (13.2%) (Malo et al., in preparation). It appears that physicians may have wanted to use the free text space to elaborate on why they do not recommend HPV vaccination more frequently for male patients. As mentioned earlier, the majority of comments pertaining to male vaccination cited lack of insurance coverage as a reason for not recommending or administering HPV vaccine; however, one physician reported: “Awaiting more long term safety studies before immunizing boys since they are not at risk for cervical cancer directly.” Given that about 85% of all HPV-associated anal cancers are caused by HPV-16 [42] and non-oncogenic HPV types cause genital warts, an HPV vaccine can directly benefit males. It is possible that some physicians could benefit from information to this effect, including the psychosocial consequences of HPV infection [8].

Although this study provides important insight into physicians' experiences and perceptions that may have otherwise been unknown, the findings should be viewed in light of several limitations. First, only 14% of survey participants provided comments; these physicians may represent those with the strongest opinions about HPV vaccination. Conversely, they also may represent those with experiences that deviate from other physicians and thus highlight important issues to address. Second, these comments were derived from a quantitative survey that assessed physicians' recommendation of HPV vaccine and therefore this study was not designed to gather in-depth qualitative data. Despite limitations in study design, a variety of themes were identified. Third, although the survey was conducted among a nationally representative sample, the findings may not be transferable to other physicians given the small sample of physicians who provided comments. Finally, this study was conducted prior to the ACIP's routine recommendation of HPV vaccine for males; consequently, perceptions about insurance for male vaccination may have changed since the study was conducted.

Conclusions

HPV vaccination has the potential to significantly impact the health of a generation of adolescents in the U.S. Physicians play a key role in this effort and should be regularly queried about their experiences and concerns regarding vaccination. The current study demonstrates that physicians are developing various approaches to vaccine delivery within the context of their clinical practice and are particularly attuned to specific vaccination issues including clinical practice guidelines and barriers to administration. Future research should focus on examining current physician perspectives now that the ACIP recommends routine HPV vaccination for males and consequently more insurers should cover vaccine costs for male patients.

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Figure 1.
Flow Diagram from National Survey Study to Identify Subset of Physicians who Provided Written Comments

Table 1

Sample Quotes by Subcategory

Category	Subcategory	Example Quotes
Survey Process	Experience completing the survey	<i>'Thank you for the efficient format of the survey. It shows the value you placed on my time...' –FP</i> <i>'This was a good survey! ...And I hate these :)' –OBGYN</i> <i>'Appreciate...the simplicity of the survey...should ensure a high percentage response.' –OBGYN</i>
	Cash incentive	<i>'I am donating the \$25 to a local charity. It is a shame you send to pay for us to participate.' –Ped</i> <i>'How clever you enclose \$25 CASH instead of check for survey. Most of time I would have destroyed the check and survey.' –OBGYN</i>
Personal Strategy for Discussing HPV Vaccine	Recommends to family directly	<i>'I find parents very receptive to the vaccinations and we are far aggressive about the recommendations.' –Ped</i> <i>'I say [to parents] "If you don't trust [your daughter's] future husband, whom you've never met, you need to get the vaccine."' –Ped</i>
	Relies on secondary sources (brochures, commercials)	<i>'I do give out the CDC HPV handout in my office to these parents.' –Ped</i> <i>'I find journals and package inserts the best place to find information. Less bias.' –FP</i>
	HPV vaccination is a private matter	<i>'I do not provide HPV vaccines in my office. I tell parents to go home and have an open, honest talk with their daughters about their expectations of the young woman's sexuality and sexual health...' –Ped</i>
	Reminder system	<i>'We plan to incorporate EHR so reminder systems will help to increase completion of 3 part series.' –Ped</i> <i>'Persons checking in for anything in the system are advised by the nurse on immunizations that are flagged...' –FP</i>
Clinical Practice Guidelines	Expressed need for national/international accepted policy	<i>'I would like to use Cervarix based on higher efficacy against [cancer]-producing HPV strains, but both of my community's gynecologists prefer Gardasil, so that is what I am using – for now. I'll change my practice if there are strong national recommendations to do so.' –OBGYN</i> <i>'We have both vaccines in the office. I use either depending on patient education information. I hope studies would show clearly I to use over the other.' –OBGYN</i>
	Preferred organization's guidelines	<i>'I follow new ACOG guidelines.' –Ped</i> <i>'I follow AAP & CDC rec[ommendation]s.' –Ped</i>
Barriers to Vaccine Administration	Role uncertainty	<i>'I work only part-time, ~3 hours/wk.' –Ped</i> <i>'I refer to one of my gyn colleagues.' –Ped</i> <i>'I'm a gynecologist I send them to the PED or give an Rx.' –OBGYN</i>
	Safety/efficacy	<i>'Awaiting more long term safety studies before immunizing boys since they are not at risk for cervical cancer directly.' –Ped</i> <i>'Just learning about male HPV vaccine.' –Ped</i> <i>'Parents are not informed – lack information. Or they have heard stories of Adverse Reactions.' –FP</i>
	Timing/situation	<i>'Too many things to discuss, unfortunately no financial motivation to make this issue more important than any other.' –OBGYN</i> <i>'I discuss the vaccine with most adolescent males but don't encourage it as strongly as female pts.' –Ped</i>
	Cost	<i>'Most boys do not receive vaccine due to poor insurance coverage in SC. This causes the physicians to not recommend it as often.' –Ped</i> <i>'I will recommend HPV to my male patients when insurances cover it. I have had my own teenage sons vaccinated, at my own expense. Insurance is the greatest barrier...' –Ped</i> <i>'Would definitely use more if reimbursement were not an issue. Unwilling to spend additional office staff time to ensure reimbursement.' –OBGYN</i>

Category	Subcategory	Example Quotes
		<i>'...Insurance may cover the cost slightly (ever so – if the insurance doesn't reject the claim as they routinely do with all claims...) more but my staff man power hours for this is significant...' – OBGYN</i>