



Published in final edited form as:

J Adolesc Health. 2007 August ; 41(2): 119–125.

Effective Strategies for HPV Vaccine Delivery: The Views of Pediatricians

Abbigail M. Tissot, M.A.^{1,5}, Gregory D. Zimet, Ph.D.², Susan L. Rosenthal, Ph.D.³, David I. Bernstein, M.D. M.S.⁴, Caitlin Wetzel¹, and Jessica A. Kahn, M.D. M.P.H.¹

1 Division of Adolescent Medicine, Department of Pediatrics, Cincinnati Children's Hospital Medical Center and the University of Cincinnati College of Medicine, Cincinnati, OH

2 Division of Adolescent Medicine, Department of Pediatrics, Indiana University, Indianapolis, IN

3 Division of Adolescent and Behavioral Health, Department of Pediatrics, University of Texas, Medical Branch at Galveston, Galveston, TX

4 Division of Infectious Diseases, Department of Pediatrics, Cincinnati Children's Hospital Medical Center and the University of Cincinnati College of Medicine, Cincinnati, OH

5 Ms. Tissot is now in the Department of Psychology, Kent State University, Kent, OH

Abstract

Purpose—Pediatricians will play a critical role in human papillomavirus (HPV) vaccine delivery. The objectives of this research were to examine pediatricians' views about key issues related to HPV vaccine delivery and identify their strategies for effective vaccine delivery.

Methods—A diverse sample of practicing pediatricians was recruited from a three-state region using a purposeful sampling strategy. Participants completed in-depth, semi-structured interviews. Qualitative data were analyzed using framework analysis.

Results—The mean age of the 31 participants was 47 (range 30-78) years, 17 (55%) were female, 9 (29%) black, and 4 (13%) Latino. Participants noted that cultural issues, including a family's religious and ethnic background, were important considerations when recommending an HPV vaccine. Almost all participants believed that vaccination should be universal rather than targeted, but opinions regarding legislative mandates for vaccination varied. Those in favor of mandates cited their potential to maximize the public health impact of immunization, while those opposed noted that HPV is not transmitted casually and were concerned about limited data on the long-term safety and efficacy of HPV vaccines. Pediatricians noted that specific strategies for effective vaccine delivery would be needed for an STI vaccine targeted toward adolescents, especially considering the poor public understanding of HPV. These included provision of HPV vaccines in alternative settings, guidance for pediatricians as to how to address parental concerns, and specific educational initiatives.

Conclusions—The views of pediatricians, who have extensive experience administering vaccines to children and adolescents, will be valuable as HPV vaccine delivery strategies are designed.

Corresponding Author Jessica A. Kahn, M.D. M.P.H. Division of Adolescent Medicine, MLC 4000, Cincinnati Children's Hospital Medical Center 3333 Burnet Avenue, Cincinnati, OH 45229 Phone 513-636-8587 Fax 513-636-1129 jessica.kahn@cchmc.org

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Keywords

pediatrician; immunization; human papillomavirus; delivery; strategy; sexually transmitted infection; mandate; qualitative

Introduction

Genital human papillomavirus (HPV) infection is a highly prevalent sexually transmitted infection (STI) that may cause respiratory and anogenital warts, cervical cancer, and other anogenital cancers.[1] Safe and effective vaccines to prevent HPV infection recently have been developed,[2,3] and in 2006 one of these vaccines was approved for use by the U.S. Food and Drug Administration. The Advisory Committee on Immunization Practices (ACIP) has recommended immunization of all 11- to 12-year-old girls, as well as 13- to 26-year-old girls and women not previously immunized.[4]

Pediatricians will play a key role in HPV vaccine delivery, because girls in the age group targeted for vaccination are very likely to visit a pediatrician. In addition, a pediatrician's recommendation for immunization is a powerful influence on parents' and adolescents' decisions about vaccination.[5,6] Given their critical role in HPV vaccine delivery and their extensive clinical experience administering vaccines to children and adolescents, pediatricians' views concerning effective HPV vaccine delivery strategies will be valuable as public health initiatives for HPV vaccination are designed and implemented.

Two previous studies have examined pediatricians' attitudes about HPV vaccines and identified factors associated with their intention to recommend HPV vaccines; each involved a survey mailed to a national sample of pediatricians.[7,8] Although these studies provided important information about pediatricians' personal intentions, they did not focus on practical issues surrounding effective vaccine delivery. In addition, the quantitative methods used did not allow investigators to identify the full range of pediatrician views about strategies for effective vaccine delivery, or to explore the rationale underlying these views. Therefore, we designed a qualitative study to accomplish two objectives. The first was to examine pediatricians' attitudes about the key issues surrounding HPV vaccine delivery, including cultural considerations related to HPV vaccine delivery, targeted vs. universal approaches to vaccination, and legislative mandates for HPV vaccination. The second objective was to identify pediatricians' suggested strategies for effective vaccine delivery, including clinical and public health initiatives to increase vaccination rates and strategies to meet the educational needs of providers, parents, and adolescents.

Methods

Participants were pediatricians with active clinical practices in a three-state region (Ohio, Indiana, and Kentucky) surrounding the Greater Cincinnati metropolitan area. Pediatricians were recruited using a purposeful sampling strategy to achieve representation of those who were of varying gender, race and ethnicity and those who practiced in different settings (Table). The majority of these pediatricians refer to the regional children's hospital if their patients need hospital admission or subspecialty care. We achieved one of the primary endpoints of our analysis, informational redundancy, after 31 pediatricians were recruited, representing 72% of the 43 initially contacted.[9] The study was approved by the hospital's Institutional Review Board.

Two research coordinators conducted study visits at pediatricians' practices during the summer of 2005. Pediatricians provided written informed consent and then completed a brief survey

assessing sociodemographic characteristics, practice characteristics, and experience with adolescent patients. Participants then individually participated in 30 to 60 minute semi-structured interviews conducted by one research coordinator, while the second research coordinator took detailed field notes. The interviewer began by providing a brief, standardized introduction to HPV vaccines in development. She first told participants that there were two HPV vaccines in development that would likely be licensed shortly and targeted towards preadolescents or early adolescents. She then explained that one was a quadrivalent vaccine targeting types 6, 11, 16 and 18, which could prevent approximately 70% of cervical cancer and 90% of genital warts, and that the other was a bivalent vaccine targeting types 16 and 18 which could prevent approximately 70% of cervical cancer. Pediatricians were then asked a series of open-ended questions concerning their attitudes about HPV vaccine delivery. Participants were asked specifically for their opinions about cultural considerations related to HPV vaccination, targeted vs. universal strategies for vaccination, mandated vaccination for school enrollment, and components of successful delivery programs, including suggestions for clinical and public health initiatives to increase vaccination and the design of educational resources for patients, parents, and pediatricians. Participants were compensated \$50 for their time.

Interviews were audiotaped and transcribed, and transcripts and field notes were cleaned and edited by the research team. The team used Framework Analysis, a multi-step collaborative method for analyzing qualitative data, to reach consensus regarding data interpretation. Details of this method are described in Ritchie et al.[10] and our previous articles.[11,12]

Results

Cultural considerations related to HPV vaccination

Virtually all participants agreed that cultural considerations were important when recommending HPV vaccines, given that these are STI vaccines targeted toward preadolescents, but differed in their interpretation of the term “cultural.” Most understood cultural to mean religious or other beliefs, race, ethnicity, or socioeconomic status. Approximately half of the participants discussed parental religious beliefs that could affect acceptance of an HPV vaccine. Some believed that it would be difficult to address the concerns of parents belonging to “fundamentalist religious groups that are very anti-sexual behavior” or other religious communities characterized by conservatism about sexuality. One participant noted that Muslims in her community were “culturally more modest in terms of how they approach sexual issues ... you'd see that in conservative Christian cultures as well.” These parents “might feel that if you give [their child] that vaccine, they're almost condoning that behavior.” Participants discussed a variety of other belief systems (e.g. holistic, naturopathic) that could lead parents to fear or reject vaccination and affect pediatricians' recommendations for the HPV vaccine: “I have some [parents] that don't want any vaccinations ... those I would not even broach the subject with.”

Participants who discussed the importance of considering cultural beliefs that might be more prevalent in specific racial or ethnic groups were virtually all African-American or Latino. Two providers noted that African-American parents may mistrust the medical establishment and therefore be reluctant to accept vaccination in general. One noted: “Well, I think that African-American people are not very trusting when it comes to medicine. They don't trust doctors, and the reason is that doctors haven't been nice to them. And they did the Tuskegee study...and *everybody* remembers it.” Others noted that certain racial or ethnic groups may be more cautious specifically about new vaccines: “I think that African-Americans are less accepting of new vaccines. You know, it's just that *distrust*.” On the other hand, some pediatricians perceived African-American parents as being more open than other parents to discussions of sexuality and STI prevention, and thus potentially more accepting of HPV

vaccines. Participants also noted the importance of being sensitive to the beliefs of specific ethnic or cultural groups for whom it may not be culturally acceptable to discuss sexuality openly; for example, Indian, Asian, and Latino populations. Two participants noted that congruence of race or ethnicity between the provider and family may enhance acceptance of a provider's recommendation for an HPV vaccine.

Approximately one-third of the pediatricians noted that socioeconomic factors would be relevant to HPV vaccine delivery. Participants generally agreed that parental income or education level would be positively correlated with adolescent receipt of the HPV vaccine, because these parents 1) were more likely to be informed about HPV vaccines, and thus to request the vaccine or agree with the pediatricians' recommendation; 2) could afford the vaccine if not covered by insurance, and 3) tended to trust the "medical establishment" with respect to recommendations for new vaccines because "the more affluent you are, the more you're a part of society." In contrast, several participants pointed out that those parents who oppose vaccination tend to be highly educated. Furthermore, some participants noted that a bias on the part of the physician or parent that "rich, white, suburban kids" are unlikely to be sexually active could lead to lower vaccination rates in these populations: such parents "may not want the HPV vaccine because [they think their children] aren't at risk for developing HPV."

Targeted vs. universal strategies for HPV vaccination

The great majority of participants believed that HPV vaccination should not be targeted toward specific populations, but instead recommended universally. The primary rationale was that all sexually active adolescents and adults are susceptible to HPV infection and its sequelae: "I don't think that any one racial or ethnic group has a monopoly on developing cervical cancer." Others noted that the vaccine should be equally safe and effective in all adolescents, and that it would be difficult to determine which individuals or groups would be at risk for HPV. The few pediatricians who supported targeted vaccination believed that certain groups of adolescents were at particularly high risk for HPV or cervical cancer, including urban adolescents, racial and ethnic minorities, homosexual males, or low-income adolescents. One noted: "Well, you know, we try not to be judgmental, but we *know* there are certain populations where sexual activity with multiple partners is more common, more prevalent ... we treat them frequently for various STDs."

Legislative mandates for HPV vaccination

Pediatricians' views regarding whether HPV vaccination should be mandated for school enrollment varied: approximately one-third believed the vaccine should be mandated, one-third disagreed with mandated vaccination, and the remaining one-third were unsure but believed that mandates were unlikely in the near future. Pediatricians who agreed with mandated vaccination cited the public health benefits of universal vaccination, noting that mandates are the most effective and "only realistic modality" to ensure widespread uptake and realization of the potential health benefits of HPV vaccines: "I would be all for requiring vaccines, because it's a public health issue. And I would certainly think that we could really impact significantly on a serious public health problem." Some noted that mandated vaccination would have the benefit of ensuring vaccination among those who traditionally have limited access to vaccination: "realistically, that's how you're going to get those patients who fall under the system to get vaccinated." Yet, even pediatricians who supported mandated vaccination noted that legislation for mandated vaccination should not be introduced until adequate data regarding safety, efficacy, and cost-effectiveness were available.

Pediatricians who were opposed to mandated HPV vaccination cited two primary reasons: first, the lack of long-term data regarding vaccine efficacy and safety, and second, the fact that HPV is sexually transmitted while existing mandated vaccines generally target infections that are

transmitted casually (e.g. by respiratory routes) in schools. “The only mandates we currently have for vaccines in our country are for infectious diseases spread in a school setting. It would not be a school issue or a public health issue, but more of an individual issue.” Other concerns were mandating vaccination in the absence of insurance coverage, anticipated opposition from specific groups, and beliefs about parental and adolescent autonomy with respect to decisions about vaccination: “I can *never* see this being a requirement, it's going to have to be something people make their own decision about.”

A subset of pediatricians was unsure whether HPV vaccines should be mandated, but believed that legislation was highly unlikely in the near future, primarily due to “cultural conservatism” about adolescent sexuality: “I'm pretty sure some groups are going to start saying, ‘you're just making it easy for them to have sex. If you don't have sex, you don't need to have the vaccine.’” In addition, participants pointed out that typically there is a several-year time lag between FDA approval and mandated vaccination, as data about long-term safety and efficacy accrue and as providers and the public become more educated about and comfortable with the vaccine.

Clinical and public health strategies to increase vaccination

Pediatricians identified a number of strategies that they believed were critical for effective future implementation of HPV vaccination. These included 1) maximizing ease of vaccine administration; 2) implementing office-based procedures and policies to optimize vaccine uptake, 3) ensuring broad access to vaccines, 4) ensuring endorsement of vaccination by influential organizations, and 5) addressing the educational needs of providers, parents, and patients. The majority of participants suggested general strategies related to ease of vaccine administration, including developing vaccination schedules involving a minimal number of injections, developing options for oral or nasal administration, utilizing less painful injection systems, and combining HPV with other vaccines targeted towards early adolescents (i.e., meningococcal and tetanus/diphtheria/pertussis vaccines) to decrease the number of necessary injections. Office-based procedures and policies to optimize vaccine uptake included screening charts to check for eligibility, computerized recall or reminder systems, informational mailers, required annual check-ups, and vaccinating during sports physicals or urgent care visits so as to avoid “missed opportunities” for vaccination. Many participants focused on the difficulty ensuring universal access to a vaccine targeted toward adolescents, suggesting that widespread vaccine uptake would require that HPV vaccines be offered by a broad spectrum of providers and in non-traditional settings, such as school-based health clinics and public health clinics (including STI and family planning clinics. Several believed that including the HPV vaccine in the early childhood immunization schedule, instead of during adolescence, would enhance both uptake and acceptability.

A number of pediatricians emphasized the importance of vaccine recommendations for providers from influential organizations, particularly the AAP and CDC: “A strong endorsement by the CDC and FDA and by the AAP, then we're talking business here.” Others discussed the importance of health care provider recommendations, which are driven in large part by professional organization endorsement, for parental acceptance: “if the doctors feel very confident about it being something [the adolescent] needs to do and the parents look at you because you've seen them all these years, they're more likely to do it.”

Finally, participants noted that given the availability of an STI vaccine in the context of a low level of knowledge about HPV among providers and the general public, addressing the educational needs of health care providers and families would be critical to maximizing vaccine acceptance and uptake. Participants noted that large-scale initiatives to raise public awareness were needed to provide vaccine-specific information (e.g. related to vaccine safety and efficacy) as well as general information about HPV (e.g. HPV transmission, its link to cervical cancer, and other strategies for cervical cancer prevention). Several discussed the primary

importance of educating physicians, who then could educate parents and adolescents: “I think if the physicians are well informed and understand what it's there for and how it's going to work, then they have a higher likelihood of having their parents and patients accept the vaccine. So, step one is to educate the physicians.”

Strategies to meet educational needs related to HPV vaccines

Participants provided numerous practical suggestions for meeting the educational needs of providers and families related to HPV vaccines. Participants themselves generally preferred lectures (i.e., grand rounds) and written materials (i.e., informational sheets, policy statements from professional organizations) from trusted sources. Preferred sources of information for lectures and seminars included local experts; e.g. pediatric infectious disease specialists, and preferred sources of information for written and on-line materials included professional and public health organizations. On-line educational activities, websites containing information and recommendations, CD-ROMs, and e-mail were mentioned by fewer participants. Participants suggested that the most important information for providers about *HPV* would be data concerning *HPV* prevalence, a description of *HPV*-related diseases and their health impact, and susceptibility to *HPV* in one's patient population. Key information for providers about *HPV vaccines* included data concerning vaccine safety and efficacy, duration of immunity, contraindications, and the potential public health and economic benefits of vaccination. Participants also suggested including specific strategies for introduction, especially guidance as to how to discuss vaccination to parents and patients in a culturally sensitive manner. One stated: “Give me some tips, give me some tools, give me some techniques, give me some ‘what's worked for other docs,’ give me some specific scenarios, some specific openings. How do I raise the issue with the young 26-year-old mom who got pregnant when she was 16, and she's here with her 8- or 9-year-old daughter ... give me some ‘how to’ stuff.”

In terms of educational resources for patients and parents, participants recognized the multiplicity of ways in which medical information is accessed, and described a wide range of potential sources of information about *HPV* and *HPV vaccines*. These included written materials available in the office, educational videos that could be shown during an office visit, school-based sexuality education, reliable internet-based materials, other media (television, radio, magazines), and peer education. Adolescent exposure to information about *HPV* and *HPV vaccines* outside of the office setting was seen as essential. Participants specifically noted the importance of comprehensive school-based education on reproductive health, including prevention of STIs, because of the impossibility of providing such education during a brief office visit. Participants generally agreed that separate written materials should be developed for adolescents and parents. Several suggested that adolescent-specific materials include graphic images of *HPV*-related disease to emphasize the relevance of infection for teens. Participants noted that materials should aim to increase perceived risk by focusing on the severity of consequences and stressing that all sexually active adolescents are susceptible to *HPV* infection, to contend with adolescent developmental issues that could present barriers to vaccination such as beliefs about invulnerability and lack of future orientation. On the other hand, participants suggested that parental materials focus on the role of *HPV vaccines* in cervical cancer prevention, though they should not omit the fact that *HPV* is an STI. They believed that parental materials should emphasize the risk of *HPV* infection to all adolescents, in this case to overcome parental denial that their child would be at risk for infection. Pediatricians also suggested inclusion of information critical to parental decision-making about vaccination, including vaccine safety, efficacy, and side effects.

Discussion

In this study, we examined pediatricians' views about key issues surrounding HPV vaccine delivery and identified their strategies for effective vaccine delivery, including practice-based and public health initiatives and strategies to meet educational needs. Qualitative methods allowed us to identify a broad range of views on HPV vaccine delivery and to understand the rationale underlying specific beliefs and suggested strategies.[13]

Provider awareness of families' cultural or religious beliefs, particularly those related to vaccines and adolescent sexuality, clearly will be important as they recommend HPV vaccines to girls and their parents. While participants in this study acknowledged the importance of cultural sensitivity in discussing HPV vaccines with specific populations, they tended to focus on the anticipated difficulty and frustration associated with such discussions. Few participants described specific approaches they might use in the future when recommending HPV vaccines. Having the skills needed to address cultural or religious beliefs that may impact acceptance of HPV vaccination will be essential for successful vaccine delivery. Providers may benefit from educational initiatives that help them acquire the skills needed to address adolescent sexuality in general, and HPV vaccination specifically, with different racial, ethnic, religious, or cultural groups. As one participant noted, "cultural competence is more important than cultural sensitivity."

Although participants acknowledged that HPV prevalence may vary in different adolescent populations, most supported universal vaccination, which in fact is consistent with current ACIP recommendations. However, the belief among a small subset of participants that certain adolescents who are at particularly high risk for HPV should be targeted for vaccination may represent a barrier to implementation of universal recommendations. Strategies to overcome this barrier would include emphasizing universal recommendations and educating pediatricians about the high prevalence of HPV in all sexually active adolescents.

In contrast to the general support for universal vaccination, there was no consensus among participants as to whether HPV vaccines should be mandated for school entry. Legislation for mandated HPV vaccination has been introduced recently in a number of states and has been the subject of intense media coverage and debate. Participants in this study identified several key issues that they believed should be resolved before mandating HPV vaccination. Their views were expressed *prior to* the introduction of legislation and related media coverage, and the fact that the key issues they raised were not adequately discussed or resolved before legislation was introduced may explain in part the current controversy about mandates. One of the fundamental issues in the current debate, which was articulated clearly by pediatricians in this study, is whether the economic, public health, and individual health benefits of HPV vaccination outweigh the potential risks.[14,15] Some participants pointed out that vaccination could ensure access to vaccination among groups who otherwise might not receive the vaccine, and also tend to be at relatively high risk for developing cervical cancer.[16] They were cognizant of the potential for universal access to reduce the existing racial disparities in cervical cancer.[17,18] However, others cautioned that cost-effectiveness and long-term safety and efficacy data must be available in order to weigh the public health benefits against these possible risks; this issue has been raised often in the current national debate. Although participants raised the issue that HPV infection is not transmitted casually in the school setting, they did not discuss the fact that vaccines caused by other pathogens that are not transmitted casually are mandated for school enrollment in many states; e.g. hepatitis B and tetanus vaccines. Rather, pediatricians sensed that mandating HPV vaccines for school entry would represent a new paradigm for vaccine-related legislation. Finally, participants discussed the critical importance of public education campaigns and financing mechanisms before legislative mandates are passed. Instituting school mandates without a coexisting financial plan for

providing the vaccine to those who cannot afford vaccination could result in parents choosing to request a vaccine exemption for their child. Laws in most states allow parents to opt out of vaccination for religious, philosophical, or other personal beliefs. This could lead inadvertently to an increase in opt-out rates for other vaccines.

Participants provided a broad array of strategies for HPV vaccine delivery programs, based on their extensive experience vaccinating children and adolescents. Many of these strategies have been shown to be effective in promoting vaccination in general, such as implementing practice-based procedures to maximize vaccination rates and ensuring sufficient vaccine supply and affordability.[19-22] However, pediatricians made it clear that specific strategies would be particularly important in the context of a vaccine targeted towards adolescents, against an STI, and against a disease that is not well understood among many pediatricians and the general public.[23,24] These included enhancing access to vaccination by providing HPV vaccines in alternative settings, addressing specific educational needs related to HPV and HPV vaccines, and providing pediatricians with guidance as to how to address the specific concerns that parents might have about an STI vaccine. Of note, pediatricians' anticipation of negative parental reactions is not completely supported by research on parental HPV vaccine acceptability: parents generally support vaccination of their preadolescent and adolescent children.[6,25-27] Nevertheless, it will be important to formulate strategies to address effectively the concerns of the minority of parents who find vaccination unacceptable.

Participants delineated a number of strategies to meet the considerable educational needs of providers as well as parents and adolescents. Although providers in this study preferred lectures and written materials by trusted sources, electronic resources may be particularly helpful given the time constraints faced by many pediatricians and the fact that local experts may not be available in all practice locations. Educational initiatives might focus on increasing pediatricians' comfort with the use of electronic resources. Pediatricians emphasized the importance of educating the public about HPV and HPV vaccines through multiple venues, including effective school-based sexuality education. They also suggested that written materials for parents and adolescents should aim to increase perceptions of risk for HPV and overcome denial in both adolescents and parents. These findings may be helpful to professional and public health organizations as they design strategies for effective HPV vaccine implementation in the U.S.

Two possible limitations of qualitative research are inadequate descriptive or interpretive validity. In order to maximize descriptive validity, we audiotaped interviews, asked a typist not involved in data collection or analysis to transcribe them, and used standardized but open-ended questions. In order to achieve interpretive validity, we asked participants to clarify or elaborate when a response was unclear and followed specific procedures for data interpretation involving multiple investigators. However, we were unable to bring the findings back to study participants to validate our interpretations. Qualitative research is sometimes criticized because the study populations are not representative or because findings may not be generalizable to other populations. However, study samples in qualitative studies are chosen in order to achieve the goals of the study (e.g., to characterize provider strategies), not to be representative of a population. In addition, the results are not meant to be generalizable; instead, the results are meant to allow for generalizations from or about cases, and to contribute to the theoretical understanding of an issue.[13] Finally, the information about HPV vaccines that was provided as an overview prior to the interview may have biased responses.

In conclusion, the views of pediatricians, who have extensive experience in caring for adolescents and administering vaccines, will be extremely valuable in the design of practice-based strategies for effective HPV vaccine delivery. Consideration of clinician opinions before designing public health strategies or introducing legislation may help to prevent outcomes such

as the current controversy over legislative mandates for HPV vaccination, which could have the unintended effect of decreasing vaccine uptake.

Acknowledgements

Support: Dr. Kahn was supported by grant #K23 AI50923 from the National Institute for Allergy and Infectious Diseases.

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Table

Study sample characteristics.

	N (%)	Mean (standard deviation)
Age (years)		46.9 (11.8)
Gender		
Female	17 (55)	
Male	14 (45)	
Race		
White	18 (58)	
Black/African American	9 (29)	
Asian American	2 (7)	
American Indian/Alaskan Native	1 (3)	
Multiracial	1 (3)	
Ethnicity		
Latino	4 (13)	
Type of clinical practice		
Primary care pediatrics	19 (61)	
Medicine/pediatrics	4 (13)	
Subspecialty care pediatrics	4 (13)	
Academic primary care pediatrics	2 (6)	
In training	2 (6)	
Practice setting		
Urban	15 (48)	
Suburban	15 (48)	
Rural	1 (3)	
Professional memberships		
American Academy of Pediatrics	19 (61)	
Ambulatory Pediatric Association	5 (16)	
Other	7 (23)	
Number of preadolescents and adolescents seen per week in practice		
9-12 year-olds		
1-10	2 (7)	
11-25	9 (29)	
26-49	11 (36)	
≥ 50	9 (29)	
13-15 year-olds		
1-10	9 (19)	
11-25	11 (36)	
26-49	9 (29)	
50-74	5 (16)	