# Vaccination against Human Papilloma Virus infection in male adolescents: Knowledge, attitudes, and acceptability among parents in Italy

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Abbreviations: CI, confidence intervals; HPV, human papilloma virus; OR, odds ratio.

**Objectives:** To elicit information about parents' knowledge, attitudes, and acceptability toward HPV infection and vaccination of male adolescents in Italy; to identify subgroups of this population who exhibit poor knowledge about prevention of HPV infection and reveal negative attitudes toward HPV vaccination in relation to their male sons.

**Study design**: Data were collected via self-administered anonymous questionnaire from 1021 parents of males aged 10 to 14 y who were recruited from a random sample of public secondary schools in the South of Italy.

**Results**: Three-quarters (72.6%) reported that the vaccine is a preventive measure for HPV infection and 55.8% that condom use reduces the risk of HPV infection. A high education level, abundant sources of information about HPV infection received from physicians, and knowledge about HPV infection were factors significantly associated with high level of knowledge about preventive measures for HPV infection. 71% revealed their intentions to vaccinate their sons, and this intention was significantly associated with perceived benefits both for HPV vaccination for girls and for childhood recommended vaccinations as well as a need for additional information about HPV vaccination. 53.7% of the eligible parents reported that their daughters had been vaccinated against HPV.

**Conclusion**: Results of the study suggest that the risk of acquiring HPV infection and HPV-related diseases is sorely underestimated. Knowledge on the benefits of adolescents' HPV vaccination in cancer prevention in both sexes should be improved to maximize uptake of HPV vaccination.

#### Introduction

Immunization to prevent infection with high-oncogenic Human Papilloma Virus (HPV) types represents the most promising strategy for prevention of one of the most common sexually transmitted infections worldwide.<sup>1,2</sup> Vaccination can reduce the substantial health and economic burden of HPV-associated diseases, such as cervical intraepithelial neoplasia (CIN), cervical and other cancers, genital warts, and recurrent respiratory papillomatosis (RRP). Numerous published studies have concluded that HPV vaccination is highly efficacious and cost-effective in preadolescent girls.<sup>3-5</sup> In Italy, the Ministry of Health has introduced HPV vaccination in the national immunization program, and it is provided free for girls aged 11 or 12.

An emerging issue of great importance for future HPV policy and use is male immunization. Although cervical cancer is clearly the predominant HPV-related cancer in the developing world, where screening is uncommon and treatment is often unavailable, Gillison and colleagues<sup>6</sup> point out that noncervical HPV-related cancers may surpass within a decade the incidence of cervical cancer within a decade in the United States and other industrial countries with effective screening. This prospect should cause reframing of the issue of HPV immunization, broadening it from primarily a cervical cancer–prevention effort in women to an effort to control HPV-related cancers and genital lesions in both women and men.<sup>7</sup>

Recently, clinical trials have shown the HPV quadrivalent vaccine to be 86% effective at preventing vaccine type persistent infection in males aged 16–26,<sup>8,9</sup> and, on the basis of recent data, the Food and Drug Administration (FDA) licensed the quadrivalent HPV vaccine for preventing anal precancerous lesions in males.<sup>10</sup> In October 2011, the CDC Advisory Committee on Immunization Practices (ACIP) recommended routine

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immunization of boys who are 11 or 12 y old with the quadrivalent vaccine to help prevent anal cancer caused by HPV types 16 and 18, anal dysplasia and precancerous lesions caused by HPV types 6, 11, 16, and 18, and genital warts caused by HPV types 6 and 11. ACIP also recommended the quadrivalent vaccine for males who are 13 to 21 y of age who have not previously been vaccinated.11 Male HPV vaccination reduces the risk of incident and persistent infection by vaccine HPV types, thus, the assumption that transmission will also diminish seems reasonable. Vaccinating boys is expected to facilitate the eradication of the cervical cancer, to reduce the transmission of the virus, to increase herd immunity, and to contribute to the prevention of HPV associated diseases in both genders.<sup>12</sup> So, in addition to the direct benefit that HPV vaccination will provide to male recipients, a population benefit to unvaccinated members of both sexes through herd immunity seems likely.<sup>13</sup>

Widespread acceptance of HPV vaccine is likely to provide enormous public health benefits;<sup>14,15</sup> it is extremely important to gather data on HPV infection and vaccination. Such questioning has already taken place: several studies mainly address vaccine acceptability among parents of female adolescents,<sup>16-20</sup> female adolescents and young women,<sup>21-23</sup> and health care workers,<sup>24-26</sup> but very little research has targeted male adolescents.<sup>27-29</sup>

The primary aim of this study is to elicit information about parents' knowledge, attitudes, and acceptability toward HPV infection and vaccination of male adolescents in Italy; to identify subgroups of this population who exhibit poor knowledge about prevention of HPV infection and reveal negative attitudes toward HPV vaccination in relation to their male sons. Moreover, this study attempts to determine and understand parents' education needs regarding HPV vaccination. These data may be helpful to adequately characterize acceptability for all the groups that may benefit from the HPV vaccine.

# Results

Of the 1021 parents that were approached, a total of 566 agreed to participate, an effective response rate of 55.4%. Almost 2-thirds of the respondents were mothers, the mean age was 42.9 years, the vast majority was married (92.9%), 75.2% had a high school education or higher, 69.7% were employed and more than half had 2 children.

Four hundred and 19 (74%) subjects reported knowing about HPV, and when we investigated their knowledge closely about the HPV infection, the preventive measures and HPV vaccination, the frequencies of those who answered correctly varied considerably (**Table 1**). Indeed, the vast majority (89.7%) knew that the infection is primarily transmitted through sexual intercourse, and 77.3% knew that it is related to both sexes, whereas 16.5% and 1.9% believed that it is related to women only and men only, respectively. Three-quarters (72.6%) reported that the vaccine is a preventive measure for HPV infection and 55.8% that condom use reduces the risk of HPV infection, whereas other preventive measures, such as reducing the number of sexual partners and late start of sexual activity were less frequently  $\ensuremath{\textbf{Table 1.}}$  Knowledge about Human Papillomavirus (HPV) of the study population  $^{a,b}$ 

Knowledge about HPV infection	N (%)
Physicians	208 (49.6)
Other	211 (54.4)
HPV is transmitted by sexual intercourse	376 (89.7)
Risk of HPV infection is related to both sexes	324 (77.3)
Preventive measures for HPV infection <sup>c</sup>	
Specific vaccination (true)	304 (72.6)
Condom use (true)	234 (55.8)
Reducing number of sexual partners (true)	76 (18.1)
Late start of sexual activity (true)	40 (6.7)
Other contraceptives than condoms (false)	12 (2.9)
Knowledge about HPV vaccination	N (%)
Sources of information about the HPV vaccination	
Physicians	193 (59.6)
Other	131 (40.4)
Availability of HPV vaccine	324 (77.3)
HPV vaccine prevents <sup>c</sup>	
Cervical cancer (true)	299 (71.4)
Condyloma acuminata (true)	87 (20.8)
Anal cancer (true)	85 (20.3)
Prostate cancer (false)	72 (17.2)
Oral cancer (true)	45 (10.7)
Don't know	11 (2.9)
HPV vaccine in Italy is available only for girls	209 (64.5)

<sup>a</sup>The number of participants responding to these questions is related to 419 subjects (74% of total sample) who stated to have knowledge about HPV. <sup>b</sup>The numbers that do not add to 419 are due to missing or not applicable data for the variable.

<sup>c</sup>Multiple responses allowed.

acknowledged. More than half (64.5%) knew that a vaccine is available in Italy for girls only, whereas 28.4% and 1.2% believed that it is available for both sexes and for boys only, respectively. Among those who know that the HPV vaccine has been approved in Italy (57.1%), 63.8% knew the appropriate age for starting the immunization. 71.4% knew that it is able to prevent the development of cervical cancer, but only 6.5% correctly indicated all investigated HPV-related vaccine-preventable diseases (cervical, anal, and oropharyngeal cancers and condyloma acuminate).

When asked about their main source of information about HPV infection and vaccines, 49.6% and 59.6% claimed physicians, respectively. A vast majority (84.6%) felt they needed more information.

The results of the logistic regression analysis revealed that the following factors were significantly associated with a higher level of knowledge about preventive measures for HPV infection: having a higher education level (OR = 1.55; 95% CI 1.12–2.16), having received information about HPV infection from physicians (OR = 1.71; 95% CI 1.12–2.61), knowledge that HPV is transmitted by sexual intercourse (OR = 5.83; 95% CI 1.95–17.44), and that risk of HPV infection is related to both genders (OR = 1.98; 95% CI 1.15–3.42) (Model 1 in Table 2).

Table 3 presents parents' attitudes toward vaccination for their sons. Subjects were asked about the perceived benefits of vaccinations within the childhood immunization program and

Table 2.	Logistic	regression	models	results
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Variable	OR	SE <sup>a</sup>	95% CI	Р
Model 1. Knowledge about modes of prevention of HPV infection				
Log-likelihood = $-251.13$ , $\chi^2 = 58.15$ , $p < .001$				
Knowledge that HPV is trasmitted by sexual intercourse	5.83	3.26	1.95–17.44	0.002
Highest education level	1.55	0.26	1.12-2.16	0.009
Physicians as source of information about HPV infection	1.71	0.37	1.12-2.61	0.013
Knowledge that risk of HPV infection is related to both sexes	1.98	0.55	1.15-3.42	0.014
Knowledge that HPV vaccine is available	1.68	0.48	0.96-2.94	0.069
Married	1.89	0.91	0.73-4.84	0.187
Parents'age	0.97	0.02	0.93-1.02	0.226
Mother respondent	1.29	0.33	0.78-2.14	0.321
Model 2. Positive attitudes of parents toward HPV vaccination for their son(s)				
Log-likelihood = $-195.12$ , $\chi^2 = 79.28$ , p < .001				
Perceived benefits of HPV vaccine in girls	1.49	0.14	1.24-1.79	<.001
Perceived benefits of vaccinations within the childhood immunization program	1.28	0.13	1.05-1.55	0.014
Need of additional information about HPV vaccination	2.24	0.75	1.16-4.32	0.016
High level of perceived risk of HPV infection in their children	1.11	0.07	0.99-1.25	0.064
Married	3.35	2.55	0.76-14.86	0.112
Lower number of children	0.79	0.13	0.57-1.10	0.162
Knowledge that HPV vaccine is available	1.53	0.48	0.84-2.82	0.168
Knowledge about modes of prevention of HPV infection	1.45	0.39	0.85-2.45	0.171
Willingness to inform their children about HPV infection	2.78	2.11	0.63-12.30	0.178
Lower education level	0.79	0.16	0.53–1.17	0.239

<sup>a</sup>Standard Error.

the perceived risk for their children for contracting HPV infection, with a mean total score, on a scale from 1 to 10, of 8.9 (SD:  $\pm$  1.6) and 8.1 (SD:  $\pm$  2.3), respectively. Similarly, the parents expressed positive attitudes for HPV vaccination of their daughters with a mean total score of 8.9 (SD:  $\pm$  1.6).

Subjects were asked about their belief toward the utility of HPV vaccination for their sons and whether they would consider it in the future, and 71% expressed an intention to vaccinate their sons. The most common reasons for parents in this instance were to reduce infection in both genders (70.8%), to protect their sons against cancer (45.7%), and females from cervical cancer (36.4%). Overall, 27.4% and 1.4% of the participants said that they would refuse or had doubts about HPV vaccination for their sons, respectively. The main reasons for refusal were fear of side effects (67.1%), uncertainty about efficacy (31.6%) or utility (21.9%) and belief that vaccination would encourage unprotected sexual intercourse and that condom use was preferable as protection against HPV infection (20.6%). Multiple logistic regression was used to examine the attitudes of parents toward HPV vaccination for their sons, and the adjusted ORs are presented in Table 2. The intentions of respondents toward vaccination were significantly associated with perceived benefits of HPV vaccine in girls (OR = 1.49; 95% CI 1.24-1.79) and of vaccinations included within the childhood immunization program (OR = 1.28; 95% CI 1.05-1.55), and the need for more information about HPV vaccination (OR = 2.24; 95%) CI 1.16–4.32) (Model 2 in Table 2).

Almost all participants (95%) believe it would be useful to inform both sons and daughters about HPV infection and prevention, and that information should be provided mainly by pediatricians or primary care physicians (92%), teachers (59.1%), or parents (54.1%). The most common reasons for not informing their children about HPV infection were the beliefs that it is not an interesting subject for children (57.1%) and that it will excite the curiosity for sex (35.7%).

The children of 98.6% of all participants had received at least one vaccination within the childhood immunization program. More than half (53.7%) of those parents who had daughters between the ages of 12 and 18 reported that their daughters had undergone HPV immunization, and the main reasons for not accepting the vaccination were that the vaccination had not been proposed to them (37.3%) or had been actively discouraged (23.5%) by health authorities. Overall, parents have difficulties discussing issues related to sexuality and sexually transmitted diseases, since only 23% and 15.9%, respectively, discussed those issues always or frequently (Table 4).

#### Discussion

Over the past several years, much of the focus of information regarding HPV infection and HPV-associated diseases has been directed at young women and parents of girls. As a result, a context of poor overall knowledge about HPV infection, disease, and transmission related to males has been generated. Many other important research questions remain unexplored regarding male HPV vaccination, and the evaluation of decision making among parents. In this survey, therefore, we assembled current information about knowledge and attitudes regarding HPV infection, modes of transmission, preventive measures and acceptability of vaccination among parents of male adolescents in Italy. The information gathered can be used to guide public health professionals in developing interventions to increase vaccine uptake.

	N (%)
Positive attitudes toward HPV vaccination for their sons (565) <sup>a</sup>	402 (71.2)
Reasons for vaccinating your son against HPV (407) <sup>a, b</sup>	
Reducing infection in both sexes	288 (70.8)
Protecting males from cancers	186 (45.7)
Protecting females from cervical cancer	148 (36.4)
Willingness to receive all effective vaccines	78 (19.2)
Protecting males from genital warts	73 (17.9)
Recommended by pediatrician/family physician	73 (17.9)
The vaccine is required/provided by the Ministry of Health	61 (15)
Experiences of cancer in family	36 (8.8)
Other	5 (1.2)
Reasons for not having your son vaccinated against HPV (155) <sup>a, b</sup>	
Fear of side effects	104 (67.1)
Doubtful efficacy	49 (31.6)
Doubtful utility	34 (21.9)
Vaccination will encourage unprotected sexual intercourse/the condom is preferable	32 (20.6)
Vaccination is not suitable for males/vaccination for girls is enough	27 (17.4)
Contrary to many vaccinations	15 (9.7)
It would be better that children make their own decisions	12 (7.7)
He is too young	10 (6.5)
Other	13 (8.4)
Positive attitudes to inform their children about HPV infection (564) <sup>a</sup>	536 (95)
Reasons for not informing their children about HPV infection (28) <sup>a, b</sup>	
This is not an interesting subject for children	16 (57.1)
It will excite curiosity for sex	10 (35.7)
The parents make decisions for their children	2 (7.1)
Other	2 (7.1)
Sources of information about HPV prevention (538) <sup>a, b</sup>	
Pediatrician/family physician	495 (92)
Teachers	318 (59.1)
Parents	291 (54.1)
Other physician	17 (3.2)
Mass media	10 (1.9)

<sup>a</sup>In brackets the number of parents responding and/or eligible to the question <sup>b</sup>Multiple responses allowed

Parents have gaps of knowledge concerning HPV infection and its prevention by means of vaccination, as well as about HPV-related diseases. Moreover, they underestimate the risk of HPV infection in males. The fact that parents, who are key decision makers in the health-related issues of their children, are not cognizant concerning HPV infection and prevention, is alarming, and strategies aimed at increasing their awareness on this topic need to be urgently employed.

As expected, the higher the education level of the parent, the higher the level of knowledge about prevention of HPV infection, and when a physician represented the source of information about HPV infection, there was again a significant association. This latter finding demonstrates that physicians are key components of successful HPV vaccination program: by initiating a conversation with patients about their concerns, clarifying misunderstandings, and recommending the vaccine, they may be uniquely persuasive in addressing all perceived barriers. It is well known that unfounded rumors and misinformation, in particular, may severely impede immunization efforts,<sup>7</sup> and healthcare professionals, properly trained, should handle the communication of evidence-based information to the public.<sup>30</sup>

Indeed, earlier published findings from 2 previous studies conducted by some of us in similar arenas of argument, have reported significant associations between correct knowledge, positive attitudes and appropriate behaviors on vaccinations in the elderly in a large majority of physicians,<sup>31</sup> that was also associated with high recommendation of influenza vaccination to older patients attending primary care physicians.<sup>32</sup> The prime opportunities to increase adolescent vaccination rates will be in assessing systemic and structural barriers that retard the implementation of effective ways to encourage health care professionals to offer routine but strong recommendations for all adolescent platform vaccines.

Our results suggest that parents have positive attitudes toward male HPV vaccination; likewise, 2 previous review articles report generally high acceptability of HPV vaccination in men, but also warn that parents, as well as healthcare providers, typically viewed female vaccination as a higher priority.<sup>33,34</sup> Numerous potential barriers to HPV vaccination have been identified, including fear of side effects and doubtful efficacy/utility. This supposition is of great concern, since current contrafactual data indicate its tolerability and safeness. This negative attitude, to some extent, seems

Table 4. Reported behavior related to vaccination adherence for the prevention of children major infectious diseases

	N (%)
Child/children received at least one vaccination within the childhood immunization program (564) <sup>a</sup>	556 (98.6)
Skipped at least one session of the childhood immunization program (557) <sup>a</sup>	52 (9.3)
Daughter aged 12–16 y received the HPV vaccination (120) <sup>a</sup>	65 (53.7)
Reasons for having not performed the HPV vaccination (44) <sup>a, b</sup>	
The vaccine has not been proposed	19 (37.3)
The vaccine was discouraged	12 (23.5)
The vaccine is dangerous/ineffective	11 (21.5)
The vaccine is expensive	2 (3.9)
The vaccination has not been in use long enough	2 (3.9)
Other	5 (9.9)
Discuss with children about issues related to sexuality (565) <sup>a</sup>	
Sometimes	295 (52.2)
Never	97 (17.2)
Frequently	92 (16.3)
Only if they have problems	43 (7.6)
Always	38 (6.7)
Discuss with children about sexually transmitted diseases (565) <sup>a</sup>	
Sometimes	270 (47.8)
Never	155 (27.4)
Frequently	61 (10.8)
Only if they have problems	50 (8.8)
Always	29 (5.1)
Having discussed with children about HPV after receiving this questionnaire (564) <sup>a</sup>	347 (61.5)

<sup>a</sup>In brackets the number of parents responding and/or elegible to the question. <sup>b</sup>Multiple responses allowed.

to interfere with the real-world implementation of these intentions, since parental consent is required for minor children, and perceived effectiveness of the vaccines is significantly associated with vaccine acceptability.<sup>35</sup> Moreover, findings that parents who perceived benefits of HPV vaccine in girls and being in favor of vaccinations in general are more prone to vaccinate their sons, suggest that future efforts to improve rates of vaccination may benefit by featuring the advantages of vaccination.

Particularly notable was the discovery that some reasons against vaccination derived from its lack of recommendation or active discouragement by health professional. Recent research looked at different ways of presenting vaccine information to parents and showed that current public health communications about vaccines may not be effective.<sup>36</sup> Scientific evidence for many people is not sufficient, and the most convincing way for health care providers to present evidence on vaccines should be determined. More studies on pro-vaccine messaging are needed. Moreover, it is of concern that less than one-quarter of parents discuss frequently/always with children about sexual behavior. It could indicate an analogous concern about discussing the vaccine's purpose, since many parents have hesitated to vaccinate their children against HPV over fears that doing so might give their teen license to have sex. Parents should help adolescents to realize that HPV vaccine does not protect against sexually transmitted infections and that practicing safe sex, including the use of a condom, is needed.

Our study has potential limitations. First, it is cross-sectional; claims to association only, but not causation, can be made about the independent variables and the different outcomes. Second, the data are self-reported and thus subject to response bias, particularly when dealing with questions of a sensitive nature, such as sexually transmitted diseases or topics related to sexuality, and this bias may have inhibited honest responses. Also the positive response toward HPV vaccination may be related to social desirability. Guarantees were proffered to all respondents that data collection would be protected by confidentiality and anonymity. Efforts were made to minimize this problem as the questionnaire was self-administered and the participants could complete it in private. Third, our sample was not representative of the general Italian population, since recruitment was limited to one Italian region. However, we are confident that our findings are representative at least of the Southern regions. Even with these potential limitations, however, this research involved a welldesigned survey, data were produced using a rigorous methodology, and the random sampling strengthens the representativeness.

In conclusion, the study results suggest that the risk of acquiring HPV infection, or of developing HPV-related diseases, is underestimated due to the lack of knowledge about HPV. Uptake of HPV vaccination may be maximized by improving general knowledge and attitudes toward the safety and efficacy of childhood vaccinations, highlighting cancer prevention as a benefit of HPV vaccination for adolescents<sup>37</sup> and challenging false beliefs that HPV vaccines are not relevant for men.<sup>35</sup>

## Methods

The target population comprised parents of males aged between 10 and 14 y. Seven public secondary schools were randomly selected in the geographic area of the Calabria region, in the South of Italy, and a random sample of 1021 parents of male students was invited to participate.

Prior to the enrollment, a meeting with the headmaster of each school was arranged to present the project and to obtain permission and to encourage collaboration in the study. Then, the research team members provided a description of the study to the randomly recruited male students attending to the selected schools, and delivered a formal letter addressed to the parents and a questionnaire. The letter described the aims of the study, explained that participation in the survey was voluntary and confidential, and that the team was available for further clarification when necessary. The completed questionnaires were returned by students to their teachers within a week of their distribution, and were collected from the schools by members of the research team.

The questionnaire was designed to collect information concerning socio-demographic characteristics (age, marital status, education, employment status, number, age and sex of children), knowledge (i.e. definition and modes of infection transmission, preventive measures), attitudes and beliefs (i.e., opinions about the perceived benefits of vaccination in girls, willingness of parents toward HPV vaccination for their sons, willingness to inform their children about HPV infection), and behavior related to adherence to vaccination for the prevention of major infectious diseases of children. Finally, sources of vaccine information were investigated.

Questions exploring knowledge on HPV infections and prevention, as well as on diseases correlated to HPV infections were in a yes/no answer format and in a closed ended format.

Items regarding parents' attitudes were measured on a 10point Likert scale with a score ranging from 1 to 10. The responses for the 2 questions about perceived benefits of vaccinations within the childhood immunization program and of HPV vaccine in girls were recorded as 1 for not at all and 10 for high utility; for the perceived risk of HPV infection in their children, 1 for no risk at all and 10 for very high perceived risk. Questions on willingness of parents toward HPV vaccination for their sons and to inform their children about HPV infection were in a yes/ no answer format. The respondents were also asked to report reason(s) for willingness or unwillingness toward HPV vaccination for their son(s) and for not informing their children about HPV infection.

In the section on behaviors, parents were asked to indicate the vaccinations within the childhood immunization program that their children received and, in parents of girls aged 12–18 years, if their daughter received the HPV vaccination and, when appropriate, detailed reason(s) for not having performed the HPV

vaccination; the frequency of discussing with their children about issues related to sexuality and sexually transmitted diseases were measured on a 5-point Likert scale ranging from 'never' to 'always'.

The questionnaire was pilot tested on 18 parents before initiation of the survey.

The study protocol was ratified by the Institutional Ethical Committee ('Mater Domini' Hospital of Catanzaro, Italy) (15/ 12/2011).

## Statistical analysis

Multivariable logistic regression models were performed using a stepwise procedure to assess the independent predictors of the following outcomes of interest: knowledge about modes of prevention of HPV infection (having correctly identified at least 2 modes of HPV prevention = 1, all others = 0) (Model 1); positive attitudes of parents toward HPV vaccination for their son(s) (no = 0, yes = 1) (Model 2). The following explanatory variables were included in both models: age in years (continuous), respondent parent (father = 0, mother = 1), marital status (married =0, other = 1), education level (none = 0, primary school = 1, secondary school = 2, high school = 3, university degree = 4), number of children (continuous), need of additional information about HPV vaccination (no = 0, yes = 1), sources of information about HPV infection (physicians = 1, other = 0), knowledge on modes of transmission of HPV (correct answer = 1, other = 0), knowledge that both sexes are at risk of HPV infection (correct answer = 1, other = 0), knowledge that HPV vaccine is available (correct answer = 1, other = 0). The following variables were also included in Model 2: knowledge about modes of prevention of HPV infection (having correctly identified at least 2 modes of HPV prevention = 0, all others = 1), perceived benefits of vaccinations included in the childhood immunization program (continuous), perceived risk of HPV infection in their children (continuous), perceived benefits of HPV vaccine in girls (continuous), and willingness to inform their children about HPV infection (no = 0, yes = 1).

The significance level for variables entering the logistic regression models was set at 0.2 and for removing at 0.4. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated; all reported P values are 2-tailed. The data were analyzed using the Stata software program, version  $11.^{38}$ 

## Disclosure of Potential Conflicts of Interest

There were no potential conflicts of interest.

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