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## Perceived Need for a Parental Decision Aid for the HPV Vaccine: Content and Format Preferences

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### Abstract

The human papillomavirus (HPV) is a precursor of cervical cancer. In 2006, the Federal Drug Administration licensed a vaccine to protect against four types of HPV. Three years postlicensure of the vaccine, HPV vaccination is still fraught with controversy. To date, research suggests that contrary to popular notions, parents are less concerned with controversies on moral issues and more with uncertainty regarding because long-term safety of a drug is resolved after licensure. This study was designed to understand whether mothers from diverse ethnicities perceive a need for a decision support tool. Results suggest that the design of a culturally tailored decision support tool may help guide parents through the decision-making process.

### Keywords

HPV vaccine; decision aid preferences; ethnicity

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The human papillomavirus (HPV) is the most common sexually transmitted disease (Centers for Disease Control and Prevention [CDC], 2008). The estimated prevalence rate of HPV in sexually active women is 40% (Dunne et al., 2007), and 65% in men (Nielson et al., 2007). HPV is a precursor of cervical, anal, and penile cancers and genital warts. HPV strains 16 and 18 are recognized as precursors of 70% of cervical and anal cancers and 30% to 40% of penile cancers. Two low-risk HPV strains, 6 and 11, are associated with 90% of genital warts (Muñoz, Castellsague, de Gonzalez, & Gissmann, 2006). In 2006, the U.S. Food and Drug Administration (FDA) licensed a quad-valent vaccine to protect against HPV types 16, 18, 11, and 6 (CDC, 2009a). The vaccine is given in a three-dose series over the course of 6 months. The CDC recommends the vaccine for girls between the ages of 11 and 12 years, before the initiation of sexual intercourse, and vaccination can start as young as 9 years. The vaccine was recently licensed for boys and young men aged 9 to 26 years (CDC, 2009a). These age recommendations place parents at the forefront of the decision making process. The bulk of the research on HPV vaccination decisions has explored determinants of vaccine acceptability in girls.

The vaccine was only recently approved for boys. A recent literature review on acceptance of the HPV vaccine for males indicates that parental acceptance of the vaccine ranges from 66% to 100% and that this variation depends on the ethnicity of the parent (Liddon, Hood, Wynn, & Markowitz, 2010). Research, however, is yet to explore the perceived effect that vaccinating boys may have on decisions about vaccinating girls. The approval of the vaccine for boys may normalize vaccination and consequently facilitate the decision to vaccinate girls.

Although survey research has documented high levels of vaccine acceptability for girls in parents (Brewer & Fazekas, 2007), recent estimates indicate that only 18% of teenage girls have received the three-dose series (CDC, 2009b). Greater uptake of the HPV vaccine could reduce the 11,000 new cases of cervical cancer that occur yearly in the United States (American Cancer Society, 2009). It could also reduce the monetary burden imposed on society which ranges between \$181.5 million and \$363 million annually (Brody, 2007).

After the FDA's approval of the vaccine, several states introduced legislation to make the vaccine mandatory for all 9-year-old girls (Belluck, 2007). However, constituents perceived these state mandated efforts as controversial and emotional (Charo, 2007). For example, the Texas governor's executive order that would have made the vaccine mandatory was overturned (Blumenthal, 2007). Even though most of these state initiatives provided the option to opt out, controversy was stirred. Objections fueling the controversy surrounding state initiated efforts can be characterized as stemming from two fronts: moral and vaccine safety.

In terms of moral objections to compulsory vaccination, some conservative groups in the United States and around the world voiced a concern that vaccination may lead to sexual disinhibition (Vamos, McDermott, & Daley, 2008). However, when it comes to the actual decision making of parents, research to date indicates that the proportion of parents who would object to the vaccine on moral grounds is low (Constantine & Jerman, 2007; Davis, Dickman, Ferris, & Dias, 2004; Zimet et al., 2005; for a review, see Brewer & Fazekas, 2007). Research, however, has consistently indicated that a powerful predictor of vaccine acceptance is perceived vaccine safety (Constantine & Jerman, 2007; Dempsey, Zimet, Davis, & Koutsky, 2006; De Soto, 2007).

Even though the results of clinical trials, which included more than 21,000 females around the world, indicated that the vaccine is safe (Villa et al., 2005), parents' concerns reflect what experts identify as "the still unresolved issue" (Dempsey & Freed, 2008, p. 308) of the vaccine's long-term safety. Experts contend that even though the vaccine has been approved for use, the result of long-term safety monitoring will determine whether mandatory vaccination programs should be implemented (Dempsey & Freed, 2008; Hildesheim, Markowitz, Hernandez Avila, & Franceschi, 2006; Paavonen & Lehtinen, 2008). According to the CDC's Vaccine Adverse Event Reporting System, to date, 7% of the self-reported adverse events were considered serious. However, after careful examination, the CDC concluded that common patterns could not be identified among vaccine recipients to suggest that the vaccine was the cause of the adverse event (CDC, 2008). Despite these conclusions,

for parents, the issue of vaccine safety contributes heavily to their willingness to vaccinate their children and consequently is an issue that needs to be addressed.

In addition to these moral and safety concerns, parents consistently state a need to be guided by a physician. A physician's recommendation consistently emerges as a strong predictor of vaccine acceptance (Brewer & Fazekas, 2007; Conroy et al., 2009; Reiter, Brewer, Gottlieb, McRee, & Smith, 2009). Unfortunately, although parents perceive a need for a physician's guidance, research also suggests that parental concerns negatively influence physicians' willingness to recommend the vaccine (Kahn et al., 2005). In addition, structural factors such as time constraints or language barriers may prevent physicians from providing the level of guidance that parents may currently need.

Predictors of vaccine acceptance suggest that decisions to vaccinate are fraught with uncertainty, especially regarding safety concerns. Therefore, the time may be appropriate to aid the decision-making process of parents with a decision support tool. Decision support tools are also known as decision aids (DAs). DAs are tools designed to help patients systematically consider the consequences (risks and benefits) of the possible outcomes of health related decisions (O'Connor et al., 1999). The primary aim of a DA is to reduce decisional conflict and instill decision-making skills (O'Connor, Graham, & Visser, 2005). DAs provide balanced information regarding the possible outcomes of options. Therefore, DAs are particularly helpful when there is uncertainty surrounding the outcomes of health decisions (Jackson, Cheater, & Reid, 2008). Research has documented the benefits of DAs in reducing decisional conflict, anxiety, the proportion of people who remain undecided, and promoting more realistic expectations (O'Connor, Leagre, & Stacey, 2003). The development of a DA to guide HPV vaccination decisions could serve to facilitate health care practitioners' guidance by engaging parents in the decision and weigh the pros and cons of vaccination prior to or during consultation.

DAs have been used in the past to guide the decision of parents' to vaccinate their children against other diseases such as measles, mumps, and rubella (MMR; Wallace, Leask, & Trevena, 2006). Research has shown vaccination DAs to be effective in guiding parents through options that are fraught with controversy such as the purported link between the MMR vaccine and autism, which although research does not support, parents still cite as a concern (McIntyre & Leask, 2008). In the context of the MMR vaccine, Wallace et al. (2006) developed a DA that included side-by-side information about the risks associated with the diseases and potential risks associated with the vaccine in easy to grasp numerical and graphical form. Moreover, questions that reflected common concerns such as the link between MMR and autism were answered. A key feature of the MMR DA was the presentation of advantages and disadvantages of vaccination and associated probabilities. Results of the evaluation of the DA indicated that there were significant differences in the proportion of individuals who were undecided pretest compared with posttest. Moreover, individuals who reported a positive attitude toward vaccination posttest reported feeling well informed (Wallace et al., 2006).

Research to date indicates that ethnicity plays a role in the initiation of vaccination (Chao, Velicer, Slezak, & Jacobsen, 2010). Consequently, our goal was to understand whether

ethnicity of the parent influenced perceived need for a decision support tool. Secondly, we wish the perceived effect that vaccinating boys may have on the decision to vaccinate girls.

The principles defined by the Cochrane Review of Decision Aids (O'Connor et al., 2009) guided our formative inquiry. These principles are based on the empirically supported notion that individuals who are prepared to participate in health decisions that entail scientific uncertainty—by being involved in weighing benefits and harms—will improve risk perceptions of benefits and harms, will increase their participation, and will experience reduced difficulty with the decision.

## METHOD

The study was approved by the Medical College of Wisconsin Institutional Review Board. To participate, women had to be the parent or legal guardian of a girl between the ages of 7 to 19 who had not received the HPV vaccine, and be receiving WIC program services at one of four Health Department clinics in Milwaukee, Wisconsin. These recruitment sites were selected to obtain a heterogeneous sample with respect to income and education. The ethnic distribution of participants within clinics was heterogeneous.

To ensure that each respondent had a basic knowledge of HPV mothers read a brochure with CDC information about HPV, the HPV vaccine, and risks and benefits associated with vaccination. All study materials were available in English and Spanish. Brochures were pilot tested for acceptability and comprehension among two convenience samples consisting of health care practitioners experts in vaccination ( $N = 10$ ) and parents from three diverse ethnic groups ( $N = 15$ ). The sample used to pilot test materials did not participate in the survey.

A bilingual researcher approached potential participants and after obtaining verbal consent administered the screening questionnaire to check for eligibility. Participants who were deemed eligible were asked to volunteer to participate. Parents who volunteered to participate received a survey packet and the researcher gave them the choice to self-administer the questionnaire or to have it read. Surveys were administered on a one-to-one basis.

To understand perceived need for a DA across ethnic groups, mothers from three ethnicities were presented with information about the possibility of developing a computerized decision support tool designed to help them navigate the uncertainties associated with vaccinating their preadolescent daughters against HPV. Specifically, we assessed the perceived need for a DA, perceptions of utility, content, and format preferences. To understand the effect that an HPV vaccine for boys would have on vaccination decisions for girls, we surveyed mothers' opinions about vaccinating boys and its effect on easing the decision to vaccinate girls. At the time of data collection however, the vaccine had not been approved for boys and was presented to mothers as a hypothetical possibility.

## Participants

Participants were 150 mothers from three ethnic groups: Hispanic, non-Hispanic White, and African American (50 per ethnic group). Mothers reported a mean age of 33.72 years ( $SD = 7.95$ ). The mean number of children reported was 3.38 ( $SD = 1.42$ ) and the mean age of daughters was 10.94 years ( $SD = 4.01$ ).

## Measures

All mothers answered a demographic questionnaire that assessed ethnicity, age, years of education, insurance, and employment status. In addition, mothers answered the following questions in the order described.

**Vaccination intentions**—Vaccination intent was assessed with the following item: “Do you intend to vaccinate your daughter?” Response options were “yes,” “no,” and “undecided.”

**Attitudes toward vaccinating boys**—Participants were asked to convey their agreement with the following three items: “Do you think that an HPV vaccine should also be available for boys?,” “Do you believe that vaccination decisions would be easier if both boys and girls could be vaccinated?,” and “How do you evaluate the idea that the vaccine be available for boys?” Response options for the first item were “yes” and “no,” and for the last two items options ranged from 1 = *not at all* to 7 = *very much*.

### **Decision support tool format preferences and perceptions of utility**—

Participants were surveyed about their format preferences for a web-based interactive decision aid. Participants read the following statement:

When we are faced with a health decision for ourselves or our loved ones it is normal to feel anxious or uncertain. In response to this situation, the Medical College of Wisconsin may develop an interactive computer program designed to help you to carefully consider the different aspects that are important to think about when trying to make a decision about whether or not to vaccinate your daughter against the human papillomavirus (HPV). If a program is developed, it would be made available to you at no cost. You could sit down in front of a computer, in private, and select the information that you think is most relevant to your decision. The program would be designed to help you make up your mind. At the end, it could also help you to reduce anxiety and uncertainty related to the vaccination decision.

After reading this paragraph, participants were asked, “If a computer program is developed to help you make a decision, and it is provided to you free of charge, would you consider using it?, consider it helpful? Response choices were “yes” and “no.” In addition, participants were asked language of preference (i.e., English, Spanish, other), and whether they would like to see personal narratives about how other people (e.g., other parents) have decided, information about the risks associated with vaccination, effectiveness of the vaccine, and general information about HPV. Response choices were “yes” and “no.”

**Vaccination-related concerns**—Participants also answered the following open-ended item: “Imagine that you are going to make the decision RIGHT NOW to vaccinate your

daughter. In the following blank space please write all the issues, worries, concerns, and other things that cross your mind.”

**Decision-making guidance needs**—Participants were asked to report any other type of information and any other type of guidance that would help them make a decision to vaccinate by answering the following open-ended questions: “What other information would help you make a decision?,” and “What other type of guidance would help you to make a decision?”

### Data Analyses

We computed chi-square analyses and analysis of variance (ANOVA) to compare proportions and ethnic group means, respectively. We conducted a content analysis to investigate emergent themes in answers to the open-ended item assessing vaccination related concerns. Responses ranged from one word to several sentences. A coding scheme was developed after all the responses had been read.

## RESULTS

Table 1 presents the demographic characteristics by ethnic group. Chi-square analyses of demographics across ethnic groups revealed statistically significant differences in insurance status ( $\chi^2 = 49.42$ ,  $df = 6$ ,  $p < .001$ ) and education level ( $\chi^2 = 24.89$ ,  $df = 8$ ,  $p < .01$ ). No significant differences on vaccination intentions emerged by ethnic group; therefore, results on intentions are presented in aggregate form. In all, 66% of mothers expressed intention to vaccinate, 29% were undecided, and 5% expressed they did not have an intention to vaccinate.

Regarding opinions about vaccinating boys, no significant differences by ethnic group were detected in the proportion of mothers who agreed that the vaccine should be made available for boys (80% of Hispanics, 85% of non-Hispanic White, and 82% of African Americans). Moreover, no significant mean differences were detected in mothers' attitudes about vaccinating boys ( $M_{\text{Hispanic}} = 5.94$ ,  $SD = 1.89$  vs  $M_{\text{non-Hispanic White}} = 5.76$ ,  $SD = 1.75$  vs  $M_{\text{African American}} = 5.92$ ,  $SD = 1.99$ ) nor in the perception that vaccination decisions would be easier if boys were vaccinated ( $M_{\text{Hispanic}} = 5.80$ ,  $SD = 1.98$  vs  $M_{\text{non-Hispanic White}} = 4.89$ ,  $SD = 2.31$  vs  $M_{\text{African American}} = 5.58$ ,  $SD = 2.23$ ).

Across the groups, the majority of mothers indicated that they would like the DA to include information about vaccine effectiveness, safety, and general information about HPV. Chi-square analyses of preferences across ethnic groups revealed statistically significant differences in the desire to see personal narratives of how other parents' have decided ( $\chi^2 = 5.62$ ,  $df = 2$ ,  $p = .06$ ). A larger proportion of Hispanic and African American mothers, when compared with non-Hispanic White mothers, conveyed a preference for inclusion of personal narratives. Moreover, 68% of Hispanic mothers would prefer a DA in Spanish compared with 77% of African American and 88% of non-Hispanic White mothers who would prefer it in English ( $\chi^2 = 82.07$ ,  $df = 4$ ,  $p < .001$ ).

Regarding responses to the open-ended item assessing vaccination related concerns, 98% of participants provided a response. Participants concerns clustered around the following four themes: vaccine safety and effectiveness, anticipated positive emotional experiences about having made the decision to vaccinate, concerns about the way the child would handle the vaccination experience, and concerns related to sexual dis-inhibition.

### **Concerns About Vaccine Safety and Effectiveness**

In total, 47% of non-Hispanic White mothers, 41% of Hispanic mothers, and 37% of African American mothers expressed concerns related to vaccine safety and effectiveness. Safety- and effectiveness-related concerns are reflected in this response of a non-Hispanic White mother:

If I vaccinated my daughter I would be concerned knowing that the vaccine is new and not a lot is known about it. I still would be concerned about side effects. How it would affect her menstrual cycle, fertility if she decides to have a family in the future and other side effects. I would still keep in mind that she could still get STDs (warts) or cervical cancer, although if she got the shot the risk is lowered.

Another African American mother stated her response in terms of the questions that she still has about the possible reactions of her daughter's body to the vaccine.

Will she live longer?, Would she gain or loss weight?, Will there be any side effects in the future?, Does this make you go blind?, Will this affect her body in the future?, Will she be able to have children?

### **Other Concerns**

A total of 60% of African American mothers conveyed concerns not related to the vaccine itself. Of these, 29% expressed preoccupation with the way their daughter would react to the vaccination experience, and 20% specifically conveyed a preoccupation with making sure that their daughter understands the pros and cons of the vaccine so that a false sense of protection is not instilled. The following responses of two African American mothers illustrate these concerns:

I worry about how she would deal with getting the shot. Her own worry. How should I explain to her or talk to her about it.

I worry that my daughter truly understands pro and cons of vaccine.

### **Anticipation of Emotion**

Regarding the anticipation of emotional experiences related to having made the decision to vaccinate, 31% of Hispanic mothers, 25% of African American mothers, and 21% of non-Hispanic White mothers expressed anticipated relief once their daughter is vaccinated. Most of the anticipated emotional experiences related to the thought of protecting daughters. One Hispanic mother stated, "I would feel peace of mind because one day she will begin to have sexual relations and hopefully she will be protected."



### Concerns Related to Sexual Disinhibition

Contrary to public debate about the vaccine, the proportion of mothers who expressed concerns related to sexual disinhibition, for example, that vaccination would lead to early initiation of sexual intercourse or engagement in more sexual relations was uniformly low (3% of Hispanics, 6% of African American, and 7% of non-Hispanic White).

Concerning mothers' opinions about other types of information that would help them make a decision, 33% of non-Hispanic White mothers, 12% of African American mothers, and 8% of Hispanic mothers expressed that they would like to see statistical facts about vaccine side effects and explicit recommendations about the correct age to vaccinate. In all, 57% percent of Hispanic mothers, 37% of African American mothers, and 33% of non-Hispanic White mothers conveyed a need for more information.

In terms of other type of guidance needs, high proportions across the groups identified the need for a physician's guidance (91% of Hispanic, 80% of African American, and 71% of non-Hispanic White).

## DISCUSSION

The purpose of our study was to understand whether ethnicity influenced mothers' perceived need for a DA to help guide them through the vaccination decision. The first finding that supports our hypothesis that a DA would be helpful is that ~30% of mothers were undecided after reading information about HPV. This result is consistent with prior research findings, which suggest that providing didactic information about HPV alone is not sufficient to change intentions to vaccinate (Dempsey et al., 2006). The second finding is that the majority of mothers uniformly reported that they would use a DA and conveyed that a DA would indeed help them in the decision-making process. In terms of opinions about the influence that vaccinating boys would have on the decision to vaccinate girls, the majority of mothers agreed that vaccination decisions would be easier if boys could be vaccinated. This finding may indicate that interventions presenting the vaccine as appropriate for children of both genders rather than a vaccine only for girls may facilitate vaccination acceptance among parents of girls.

Regarding ethnic differences, interesting differences emerged across the groups in terms of DA format preferences. When compared with non-Hispanic White and African American mothers, a larger proportion of Hispanic mothers conveyed a preference for the inclusion of personal narratives about how other parents have decided.

Analysis of emergent themes in answers to the question assessing anticipated worries and concerns after a decision to vaccinate had been made indicates that more non-Hispanic White mothers voiced a concern over vaccine safety and effectiveness. This finding may imply that trust in the long-term safety monitoring system needs to be addressed. Interestingly, and in contrast with non-Hispanic White mothers, the majority of African American mothers expressed a concern over the physical and emotional reaction of their daughters to the vaccination experience. In contrast, a larger proportion of Hispanic mothers



indicated that the thought of having made the decision would lead them to experience relief because their daughters would be protected.

Although an equally high proportion of mothers across ethnic groups reported the need to see information about vaccine safety, effectiveness, and HPV, non-Hispanic White mothers conveyed the need to see specific information about the proportion of girls who have experienced negative side effects whereas African American and Hispanic mothers simply conveyed a need to see “more information” to make a decision.

Our findings suggest that the vaccination decision would be facilitated by the development of a DA designed to guide parents in weighing what is currently known about the vaccine and the probability of negative side effects. In addition, our results seem to suggest format preferences vary by ethnicity. In our study, African American mothers indicated that the decision support tool may be more helpful if it is designed to provide structural guidance in how to convey their decision to others involved in the decision in this case, their daughters. Hispanic mothers indicated that the inclusion of personal narratives illustrating how other parents' have decided may be helpful.

The implications of our results for culturally tailoring the DA need to be interpreted cautiously. Our study explored content and format preferences with a limited number of prespecified questions. In addition, some of the questions had Likert-type response options, which may have restricted the preferences of participants to a few options. Approaching the design of the DA from a qualitative perspective may yield a richer variety of content preferences. In addition, developing the DA following an iterative process may be particularly helpful to culturally adapt the DA more precisely.

As in previous studies, a high proportion of mothers identified the need to be guided through the vaccination decision by a physician. Our findings suggest that the development of a decision support tool would facilitate the work of physicians and other health care practitioners by providing guidance to parents before or during their consultation and thus lay the groundwork for a better informed decision-making process.

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**TABLE 1**

## Demographic Variables Across Ethnic Groups

<i>Variable</i>	<b>Ethnic Group</b>					
	<b>Hispanic</b>		<b>Non-Hispanic White</b>		<b>African-American</b>	
	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
Employment Status						
Employed	35	70	37	75	32	64
Unemployed	12	24	12	24	15	30
Retired	3	6	—	—	3	6
Insurance Status						
Don't have	22	44	4	8	2	4
Medicaid or State	20	40	29	59	38	76
Private	8	16	16	32	10	20
Education						
Grade 0-12	41	82	28	57	20	40
Technical School	3	6	2	4	4	8
1-3 Years College	3	6	11	22	21	42
Bachelors Degree	3	6	7	14	4	8
Postgraduate	—	—	1	2	1	2

NOTE. Some proportions do not add to 100% due to missing data.