Research Article

HPV Vaccine Acceptance in a Clinic-based Sample of Women in the Rural South

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ABSTRACT

Background: *Human papillomavirus (HPV) is a very common sexually transmitted infection linked to cervical disease. Vaccines for some types of HPV were in development at the time of the study.* ***Purpose:*** *The study examined HPV vaccine acceptability among underserved women in a rural region of the southeastern U.S. with high rates of cervical cancer for development of future educational interventions.* ***Methods:*** *A clinic-based sample of women (aged 18-64; ASCUS or higher and tested for HPV DNA) completed a telephone interview (response rate = 78%).* ***Results:*** *Among participants who had ever heard of HPV (n=108), 81% were "very likely" to get the vaccine and 72% would have their daughter vaccinated. These participants desired information about vaccine safety (100%), efficacy (100%), side effects (100%), clinician recommendation (96%), cost (94%), and composition of the vaccine (94%). Cost was identified as the main barrier (55%). Among a subset of participants who reported HPV positivity (n=49), younger age, being single, and high HPV knowledge level were associated with specific types of desired information before getting the HPV vaccine.* ***Discussion:*** *Similar to previously reported vaccine acceptability studies, acceptance among participants in this rural region of the south was also high. Participants also desired more information about the vaccine.* ***Translation to Health Education Practice:*** *Public health educational efforts must address health education issues related to vaccine acceptability and increase HPV knowledge and understanding.*

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BACKGROUND

Genital human papillomavirus (HPV) infection is a very common sexually transmitted infection (STI) in the United States (US).[1] Persistent high-risk HPV infection is necessary, but not sufficient to cause the most common types of invasive cervical cancer.[2-6] Most genital HPV infections are transient and are resolved by a healthy immune system within nine months to a year.[7] However, the financial and psychosocial burden associated with cervical dysplasia and cervical cancer as a result of genital HPV infection is high.[8, 9]

Two HPV vaccines (Cervarix™ by GlaxoSmithKline, Rixensart, Belgium and Gardasil® by Merck & Company, Rahway, NJ, United States) have undergone testing.[10] Results show the HPV vaccines to be highly efficacious in preventing short-term mark-

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ers of cervical disease and genital warts.[10-15] Merck & Company, Inc. recently (June 2006) received FDA licensure for its HPV vaccine, Gardasil®, which is a prophylactic, quadrivalent vaccine for two types of high-risk HPV (16 and 18) and two types of low-risk HPV (6 and 11).[16] These types are responsible for 90% of genital warts worldwide and found in 70% of cervical cancers.[10, 17] The CDC Advisory Committee on Immunization Practices (ACIP), which issues recommendations on vaccine administration in the U.S., recently recommended that the newly licensed vaccine be routinely given to girls when they are 11-12 years old.[16] The ACIP recommendation also allows for vaccination of girls beginning at nine years of age and catch up doses in females 13-26 years old.[16]

Recommendations for administering the vaccine to adolescent girls and young women have changed the target audience for cervical cancer prevention and control efforts to include parents, adolescents and pediatricians, in addition to gynecologists and primary care providers, who have been involved for years in cervical cancer screening efforts.[18] The success of HPV vaccines lies in the acceptability of the vaccine by the target audience as well as the ability of the public health and medical systems to deliver the vaccine effectively, which is a continued source of discussion.[15, 19-30] In South Carolina, rates of cervical cancer are high and innovations, such as HPV vaccines, have the potential to decrease mortality in the long term.[31, 32]

Recent findings have shown relatively high levels of acceptance of HPV vaccines pre- and post-approval of the first vaccine, Gardasil®.[26, 33-43] Acceptance of existing vaccines appears to be determined, in part, by: (1) health beliefs (e.g., perceived susceptibility to the disease, beliefs about disease severity, confidence in the benefits of immunization and minimization of the potential barriers to immunization); (2) vaccine characteristics (e.g., efficacy, safety); and (3) barriers to obtaining vaccination (e.g. cost, transportation problems, ability to link to resources).[26, 42, 43] Public health strategies can be applied to address these influences on HPV vaccine acceptability; therefore, these factors are applicable in HPV vaccine educational programs and cervical cancer prevention messages. In addition, messages must be culturally-appropriate and literacy-appropriate to resonate with underserved populations of women who are at increased risk of cervical cancer.[18, 44]

PURPOSE

Intention to capitalize on an innovation, such as the HPV vaccine, to prevent a disease outcome presents an opportunity to explore factors affecting acceptance. Health behavior theories and models, such as the theory of planned behavior and diffusion of innovations, examine intention and receptivity to innovation.[45, 46] Prior to the approval and clinical availability of an HPV vaccine, this study examined vaccine acceptability by virtue of future intention among women seeking care at partnering primary care clinics in a rural region of South Carolina. This study was to identify salient issues regarding a potential vaccine's acceptability and intended uptake, desired information and potential barriers. It was part of a multi-site CDC-funded study to measure the impact of an HPV diagnosis on women and guide development of HPV educational messages. Results from the vaccine acceptability portion of the study in South Carolina are reported here.

METHODS

Participants were identified and approached for participation in this study by health care providers at seven federally-funded, primary health care clinics in a rural region of South Carolina. The clinics are located in a region where the population is poor (e.g., 23% of families with children are below federal poverty level), has low educational attainment (e.g., 19% have less than 9th grade), is approximately 42% minority (predominantly African American), and has low levels of literacy (e.g., 73% at the lowest two levels of literacy).[47-49] The state of South Carolina ranks third highest in cervical cancer incidence and eighth highest in cervical cancer mortality nationally.[31, 50] This rural region of South Carolina has the highest cervical cancer incidence rate, 15.27 per 100,000, of all nine state health regions.[31, 50]

Health care professionals (most commonly nurses) at each of the participating clinics determined eligibility. Women were eligible to participate if they were between the ages of 18-64 years, English speaking with no cognitive impairments, had received an abnormal Pap result and been tested for HPV within the previous 120 days, and had been informed of their test results by clinic staff. Health care professionals at the clinics informed eligible women about the study by in person or telephone contact. Informed consent was obtained in person from interested, eligible women. The names and contact information of eligible women who provided informed consent were transferred to a contracted, professional survey research firm to conduct a telephone interview. The study was approved by the Institutional Review Boards at the CDC, University of South Carolina, and participating clinics.

Between September 2003 and January 2005, 206 participants completed a telephone interview about their knowledge, beliefs and experiences with abnormal Pap test results and HPV (Table 1). Trained interviewers at the professional survey firm contacted women within 30 days of the woman's consent to participate in the phone interview. The average time to complete the interview was 23.4 minutes (SD=6.6). Each participant received a money order for $10 and a thank-you letter by mail upon completion of the interview.

Measures

A questionnaire of 88 items was developed based on formative research and consultation with other investigators involved in the CDC initiative.[51, 52] The questionnaire included items on participant characteristics, HPV knowledge, sexual history, emotional health, spirituality, and vaccine acceptability and intended future uptake, which is the focus of this manuscript. Results from previous research conducted with this population revealed that about half of the women who were high-risk HPV-positive were unaware of their HPV status, despite having been in-

formed of their test results at the clinic they attended.[52] To avoid asking women who were unaware of their HPV-positive status questions about HPV, a series of initial screening questions was included to determine if the woman had ever heard of HPV, was aware of having had an abnormal Pap test result, and could recall being told by her health care provider that she had HPV. Only participants who reported "Yes" to having ever heard of HPV (n=108; 52% of total sample) were asked four vaccine acceptability topic areas related to "self"-acceptability (future intention to get the vaccine), "parent"-acceptability (future intention to vaccinate a child), HPV vaccine information needs, and potential barriers to getting the HPV vaccine. The four topic areas were:

• Self-acceptability: How likely is it that you would get a vaccine that prevents some HPV infections? (4-point scale: very likely, somewhat likely, somewhat unlikely, very unlikely).

• HPV vaccine information needs: What would you want to know about the HPV vaccine before you made a decision to get the vaccine? ("Yes," "No," "Don't Know" to 10 items).

• Potential barriers: What do you think would stop you from getting the HPV vaccine? ("Yes," "No," "Don't Know" to 8 items).

• Parent-acceptability: If you are a parent or became a parent of a daughter, how likely is it that you would have your teenage daughter vaccinated against HPV? (4-point scale: very likely, somewhat likely, somewhat unlikely, very unlikely).

Data Analysis

Descriptive statistics were used to analyze participants' HPV vaccine acceptability (SAS® Statistical Software 9.1, Cary NC). After descriptive analyses, bivariate associations between participant characteristics and the four vaccine items were examined. Chi square (χ^2) analyses were conducted to determine the associations between each of the four vaccine items and participant characteristics (Table 1). Next, bivariate associations between participant characteristics and the four vaccine items were examined among a subsample of participants who self-reported HPV positive and reported ever hearing of HPV (n=49).

RESULTS

Participant Characteristics

Of 265 women who signed the informed consent form to participate, 78% (n=206) completed the telephone interview, 18% (n=37) could not be reached within the specified time period of 30 days, 8% (n=16) could not be reached due to non-working phone numbers, 2% (n=4) did not participate for other reasons, and <1% (n=2) refused and decided not to participate. The main focus of this analysis is on the 108 participants who had previously heard of HPV and answered the vaccine-related items on the questionnaire.

Participants reported their age, race, ethnicity, relationship status, education level, health insurance status, and HPV status and answered 18 true/false items on HPV infection. Participants were characterized as "high HPV knowledge" if they answered 10 or more items correctly and "low HPV knowledge" if they answered 9 or fewer correctly. Table 1 provides descriptive information for the 108 participants who had previously heard of HPV.

Descriptive Results

In response to the self-acceptability question, "How likely is it that you would get a vaccine that prevents HPV infection?," 81% (n=86) of women indicated that they would be very likely to get the vaccine, 11% (n=12) somewhat likely, 5% (n=5) somewhat unlikely, and 3% (n=3) unlikely.

In response to the "parent"-acceptability question, "If you are a parent or became a parent of a daughter, how likely is it that you would have your teenage daughter vaccinated against HPV?," 72% (n=78) of participants indicated that they would be very likely to have their daughter vaccinated, 12% (n=13) somewhat likely, 5% (n=5) somewhat unlikely, 6% (n=7) unlikely, and 5% (n=5) don't know.

Participants responded to a list of 10 types of information they might want prior to making a decision about getting an HPV vaccine (Table 2). The top three pieces of information, desired by 100% (n=108) of the women responding were: "how safe it is," "how it works" and "what the side effects are."

Participants responded to a list of eight potential barriers to getting the vaccine (Table 3). The top barrier to getting a vaccine (55%; n=59 of women responding) was cost.

Results from Bivariate Analyses

Results from the bivariate analyses for the women who had ever heard of HPV (n=108) examining the associations between vaccine items of which there were six total and six participant characteristics, including overall HPV knowledge, showed no statistically significant associations. Results from the bivariate analyses examining the associations between six participant characteristics and the 11 items from the four vaccine topic areas in participants who both self-reported HPV positive and reported ever hearing of HPV (n=49) showed two statistically significant associations regarding desired information about the HPV vaccine. Regarding what participants would want to know before getting the vaccine, younger participants (aged 18-29; 82.1%) were significantly more likely to answer "yes" to "if family thinks you should get it" (χ^2=14.749; P=0.0006) than those in other age groups (33.3% for aged 30-50; 16.7% for aged 51-64). Results among younger participants (aged 18-29; 32.1%) also showed borderline significance "if friends think you should get it" (χ^2=9.267; P=0.0547) than those in other age groups (26.7% for aged 30-50; 0.0% for aged 51-64). Additionally, participants who were "single" (85.7%) were significantly more likely to answer "yes" to "if family thinks you should get it" (χ^2=11.912; P=0.0026) than those in other relationship status categories (30.8% for "married"; 43.8% for "other"). Finally, participants with "high" HPV knowledge scores (97.0%) were more likely to answer "yes" to "what the vaccine is made of" (χ^2=6.599; P=0.0369) than those with "low" HPV knowledge scores (82.4%).

Table 1. Characteristics of Participants

	Total Sample (n=206)		Ever Heard of HPV (n=108)*	
Characteristic	n	%	n	%
Age				
18-29	56	27	40	38
30-50	91	44	42	40
51-64	59	29	24	23
Race				
African American	139	67	70	65
Caucasian	59	29	37	34
Other race	8	4	1	1
Relationship Status				
Single/Never Married	58	28	35	32
Never Married Living with Partner	17	8	8	7
Married	73	35	37	34
Separated/Divorced	44	21	23	21
Widowed	14	7	5	5
Level of Education				
Less than High School	83	40	33	31
High School Diploma	63	31	33	31
Some College/College Degree	60	29	42	39
Ever Heard of HPV*				
Yes	108	52	108	100
No	98	48	0	0
HPV Status (Clinic-Reported)				
High-risk positive	60	29	39	36
Low-risk positive only	14	7	10	9
No HPV	102	50	43	40
Unknown	30	15	16	15
HPV Status (Self-Reported)				
Positive	50	24	49	46
Negative	156	76	58	54
HPV Knowledge*				
High (10-18 correct)			57	53
Low (0-9 correct)			51	47

* Only the 108 participants who have ever heard of HPV were asked the HPV knowledge items.
† Please note that some percentages may not equal 100 due to rounding.

DISCUSSION

The findings from this study showed high levels of "self"- and "parent" acceptability and intended uptake of an HPV vaccine among this clinic-based sample of women in rural South Carolina. Little has been reported about HPV vaccine acceptability among women living in rural regions to date. Participants reported a desire for information about a vaccine, such as safety, efficacy and side effects, and stated that cost would be a major potential barrier to getting the vaccine. Therefore, public health educational efforts should include desired information as participants expressed interest in learning more from health care providers and other trusted sources, such as family members or friends. Study findings have implications that are generally consistent with previously published research on HPV vaccine acceptability (both pre- and post-availability of the vaccine).[15, 19-26 27-30, 42, 53]

As previously documented, cervical cancer is a prime candidate for an immunization program.[30, 54] The primary public health goals behind the HPV vaccine are to reduce the incidence of cervical cancer and its precursor lesions, thus also reducing cervical cancer mortality. Widespread acceptance of HPV vaccines is likely to lend enormous health benefits by decreasing morbidity and mortality associated with the specific types of HPV included in the vaccine.[19] Savings in health care expenditures (including treatments for genital warts), pre-invasive cervical lesions, and cervical cancer would also be considerable.[8, 9, 30, 55]

Addressing noted barriers to accessing the vaccine and providing necessary educational information will be essential to facilitating the uptake of the vaccine, as shown in this study. Barriers, such as cost, may be more prominent in rural populations due to geographic isolation and limited access to preventive health care services. As such, public health planning efforts should be mindful of barriers specific to rural populations. Further, given the relatively low levels of HPV knowledge among participants, attention to reading grade level of messages and format of materials are important to facilitate informed decision making.

Limitations

This study has several limitations. The observed associations were not much different from chance findings. Information on HPV vaccine acceptability was gathered from a clinic-based sample of adult women in a rural region of South Carolina in a hypothetical context before an HPV vaccine was available. In addition, the study sample may have been biased favorably to an HPV vaccine because they had experiences with cervical dysplasia and HPV. The participants were from a clinic-based sample of women who had already accessed care, received cervical cancer screening, and some had

Table 2. Desired Information about HPV Vaccine among Participants Who Have Ever Heard of HPV (n=108)†

What would you want to know about the HPV vaccine before you made a decision to get the vaccine?	Yes		No		Don't Know	
	n	%	n	%	n	%
How safe it is	108	100	0	0	0	0
How well vaccine works	108	100	0	0	0	0
What the side effects are	108	100	0	0	0	0
If health care provider thinks you should get it	104	96	3	3	1	1
How much it costs	102	94	5	5	1	1
What the vaccine is made of	101	94	5	5	2	2
If other people are getting it	82	76	25	23	1	1
If it hurts	81	75	25	23	2	2
If family thinks you should get it	51	47	57	53	0	0
If friends think you should get it	21	19	86	80	1	1

† Please note that percentages may not equal 100 due to rounding.

Table 3. Barriers to Getting HPV Vaccine among Participants Who Have Ever Heard of HPV

What do you think would stop you from getting the HPV vaccine?	Yes		No		Don't Know	
	n	%	n	%	n	%
How much it costs to get the vaccine	59	55	41	38	8	7
You don't think it will work	24	22	67	62	17	16
Fear of needles	14	13	93	86	1	1
Fear of vaccines	12	11	91	84	5	5
Going back for two shots over 4-6 months	10	9	93	86	5	5
No time off to go to clinic	9	8	96	89	3	3
Transportation to the clinic	8	7	97	90	3	3
What people would think of you if you got it	2	2	105	97	1	1

heard of HPV. There are also limitations to reaching an underserved population by telephone, which may have influenced response rates. Finally, because the currently available prophylactic vaccine is recommended for females in a limited age range (ages 9-26), one of the questions, "How likely is it that you would get a vaccine that prevents HPV infection?" must be considered hypothetical for the majority of participants in the study, whose ages ranged from 18 to 64 years. However, in the future, the age range of the prophylactic vaccine may be expanded, and therapeutic vaccines may be introduced which will be applicable to women outside the age range of 9-26 years.

TRANSLATION TO HEALTH EDUCATION PRACTICE

Participants from this rural region of South Carolina reported that they desired specific information about the vaccine before making a decision to get it. Additionally, previous research with this population showed that their own health care provider is their most trusted source of information.[51] This finding underscores the importance of health care providers' recommendations as part of health educational strategies. Based on these findings, there seems to be a critical need for appropriate training for health care providers to develop skills to communicate effectively with patients about HPV and an HPV vaccine.[18] This might be especially true for providers who serve women with low income and low literacy levels residing in rural areas with high cervical cancer incidence and mortality rates.

This study also identified several potential barriers to obtaining the vaccine. Among underserved women, cost is often a prohibitive factor affecting health care seek-

ing behavior.[32, 42, 56, 57] In this study, consistent with the literature, cost emerged as the most often-reported potential barrier. Manufacturers and providers, then, must consider methods for limiting cost, especially because those most affected by cervical cancer are often those with low income levels.[32] In this case, these are the same women who may be initiating vaccination for their daughters. Health educators must also be cognizant of cost as a factor. When communicating about the HPV vaccine, it will be essential to address cost and provide key linkages to free and reduced cost vaccination for those who desire vaccination for themselves and/or their daughters.

Participants in this study indicated high levels of vaccine acceptability and intentions for future uptake. Before making a decision to be vaccinated, the majority of participants desired information about an HPV vaccine, with the main themes being safety, efficacy, side effects, health care provider recommendation, cost, and the composition of the vaccine. Cost was identified as a major barrier to getting an HPV vaccine. Additionally, the influence of family was important for younger and/or single women in making a decision about whether to get the vaccine. Both of these factors must be considered in public health educational efforts promoting the HPV vaccine. To be effective in achieving the goals of the HPV vaccine, public health educational efforts must address issues related to HPV vaccine acceptability and increase general HPV knowledge and understanding among all stakeholders, including patients and the general public, physicians, pharmacists and nurses. Engaging in these public health educational strategies will assist with future medical technological developments in the HPV field, and allow those most at risk and affected by cervical cancer to benefit from an HPV vaccine.

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