



## ATTITUDES OF ADOLESCENT/YOUNG ADULT WOMEN TOWARD HUMAN PAPILLOMAVIRUS VACCINATION AND CLINICAL TRIALS

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Human papillomavirus (HPV) is the most common sexually transmitted infection. It often inflicts adolescents and young adults shortly after onset of sexual activity. More than 30 types of HPV infect the anogenital area; some HPV types cause cervical cancer in women decades after infection, whereas other types cause genital warts in both men and women within a year after infection. Vaccines are being developed against oncogenic and wart-producing HPV. Knowledge of HPV and attitudes toward HPV vaccination/clinical trial participation among 60 female adolescents and young adults were evaluated. Knowledge of HPV in this group was limited, but almost all participants would be interested in receiving vaccines that prevented cervical cancer and genital warts. Only 30% were likely to participate in an HPV clinical trial that required shots and pelvic examinations. A key motivating factor for clinical trial participation was the potential for a vaccine to help other women.

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## INTRODUCTION

HPV cause cervical cancer and genital warts. HPV is sexually transmitted among adolescents/young adults, and development of a vaccine is being considered as a means to prevent infection. We conducted a survey of 60 adolescent/young adult women on (a) knowledge and concerns about HPV, (b) attitudes toward being vaccinated against HPV, and (c) willingness to participate in a clinical trial of an HPV vaccine. Descriptive presentations of the survey results are given and implications for prevention of HPV infection and disease are discussed.

## BACKGROUND

### HPV

Approximately 30 types of HPV infect the anogenital area and are spread through skin-to-skin contact that occurs during sex (Daley, 1998; International Agency for Research on Cancer [IARC], 1995; Koutsky, 1997). Studies are now detecting HPV DNA in virtually all cervical cancers (Bosch et al., 1995; Daley 1998) and HPV is believed responsible, but undetected, in the remaining cancers. About 20 HPV types cause cervical cancer in women; four of which are responsible for most cases. Type 16 causes about 50% of cervical cancer, Type 18 causes another 20%, and Types 31 and 45 together cause another 15% of cervical cancer cases (Bosch et al., 1995). Two types, HPV-6 and HPV-11, cause virtually all genital warts in both women and men.

### HPV Diseases

#### *Cervical Cancer*

In the United States alone, 13,700 women were diagnosed with cervical cancer in 1998 and 4,900 died from the disease (Landis, Murray, Bolden, & Wingo, 1998). Worldwide, about 500,000 new cases of cervical cancer have been diagnosed (Peto, 1986) and 300,000 women die from this disease annually (IARC, 1995). Cervical cancer is treated by hysterectomy (removal of the uterus). If the cancer has spread beyond the uterus, then aggressive chemotherapy also is required. However, in spite of chemotherapy, 33% of treated women will relapse or die within 5 years following treatment. Cervical cancer is second worldwide among malignancies for causing death among women (IARC, 1995).

Progression to cervical cancer can take 20 or more years from the time of initial HPV infection. Most HPV infections occur during the teenage years or early twenties, whereas cervical cancer typically presents in

women 35 years and older (i.e., Berkow, Beers, & Fletcher, 1997; IARC, 1995).

During progression, cervical tissue transforms to progressively more malignant stages of dysplasia (Berkow et al., 1997; Daley, 1998; IARC, 1995). These precancerous stages can be detected through Pap smear testing of pelvic exam samples. Precancerous tissue is then treated with cryotherapy, laser vaporization, and excision to prevent further transformation into cancer. In the United States, sexually active women and women over 18 years old are advised to have annual Pap smear testing (Berkow et al., 1997). Pap smear testing has reduced cervical cancer incidence by over 50% in the United States and several European countries. However, even under optimal use, the Pap smear detects only 90% of cervical cancers. In the United States, 40% of women do not have regular Pap testing, and in developing countries, Pap testing is not feasible.

### ***Genital Warts***

Genital warts typically occur 1 to 6 months following infection with HPV Types 6 and 11 (Berkow et al., 1997; IARC, 1995). In men, warts occur on the penis and in the anal region. In women they develop on the vulva, vaginal wall, cervix, and skin surrounding the vaginal and anal regions. Warts start as small red swellings and can grow rapidly into large cauliflower-type masses. They cause discomfort and unsightly appearance and can become infected with bacteria. External warts can be removed by cryotherapy or surgery or treated over a period of months by chemicals. Internal warts (i.e., in vagina or urethra) can be mitigated with anticancer drugs such as thiotepa and fluorouracil. No treatment is completely satisfactory; failures are common and genital warts frequently return requiring additional treatments.

### **HPV Transmission**

Unlike other sexually transmitted diseases (STDs), which are spread through body fluids, HPV is spread through skin contact. Thus, condoms may have limited effectiveness against HPV (Koutsky, 1997). Since HPV infection remains subclinical for extended periods, spread is not abated by treatment of (or abstinence from sex during periods of) active disease. This is problematic as HPV is very contagious. Today, HPV is the most common sexually transmitted infection in the United States. Over 1,000,000 new genital HPV infections occur annually in the United States alone (Daley, 1998). HPV strikes populations at low risk for other STDs; 11%–46% percent of university women are found to be infected with HPV (Koutsky, 1997). Most HPV infections occur during the first

few years of sexual activity (late teens and early twenties) (IARC, 1995; Koutsky, 1997).

### **Prevention of HPV Diseases through Vaccination**

Composite prophylactic vaccines against HPV (containing antigens against different HPV types) are being developed to prevent genital warts and cervical cancer (Hines, Ghim, & Jenson, 1998). Different antigens must be placed into the vaccine for each type of HPV against which protection is sought. Current thought (Sherman, Schiffman, Strickler, & Hildesheim, 1998) is that HPV vaccines should cover some or all of six major HPV types: (1) HPV-6 and HPV-11 responsible for virtually all genital wart infections and (2) HPV-16, 18, 33, and 45, responsible for about 50%, 20%, 10%, and 5%, respectively, of cervical cancers in women.

As prophylactic vaccines do not protect those who previously acquired HPV, the ideal time to vaccinate is prior to any sexual activity—adolescence or early adulthood. This is important as it may take three vaccine shots to establish sufficient immunogenicity; the hepatitis B vaccine requires an initial shot and boosters 2 months and 6 months later. While three shots over six months may be unappealing, this must be weighed against the long-term protection against genital warts and cervical cancer.

There is considerable debate on how to formulate HPV vaccines given the limitations on number of different HPV types that can be covered by one vaccine. One option is to combine the four cancer-causing types (16, 18, 31, and 45) together into one vaccine, which would target 85% of cervical cancer but miss warts altogether. This vaccine may have little attraction to men who do not develop cervical cancer. Another option is to combine the two leading cancer types (16 and 18) together with the two wart types (6 and 11) to create a vaccine that simultaneously targets 70% of cervical cancer and 100% of genital warts. Although this vaccine would cover 15% less cancer in women than the previous formulation, it would protect both men and women from 100% of warts. In addition, as men might be more motivated to take a vaccine that covered warts, the protection that men received against oncogenic HPV would prevent them from infecting female sex partners with these HPV types.

### **Acceptability of HPV Vaccines and Testing**

Many issues remain to be clarified about acceptability of an HPV vaccine among adolescent and young adult men and women. Studies of other STD vaccines in development (HIV and genital herpes) indicate that

high rates of acceptability cannot be taken for granted (Liau, Zimet, & Fortenberry, 1998; Rosenthal, Kottenhahn, Biro, & Succop, 1995; Zimet, Fortenberry et al., 1997; Zimet, Liau, & Fortenberry, 1997). As cervical cancer does not occur until later in life, adolescent women may be less concerned about HPV protection than they are about other STDs.

Previous studies in the United States find that knowledge of HPV is limited among adolescents, university undergraduates and even women with abnormal Pap smears referred for further testing (Biro, Rosenthal, Kollar, & Hillard, 1997; Horn, McQuillan, Ray, & Hook, 1990; Jennings, 1997; Jubelirer et al., 1996; Masad, Meyer, & Hobbs, 1997; Ramirez, Ramos, Clayton, Kanowitz, & Moscicki, 1997; Sharp, Dignan, Dammers, Michielutte, & Jackson, 1990). Many women did not understand the purpose of Pap smear testing. No study has evaluated acceptability of an HPV vaccine and participation in a clinical trial of an HPV vaccine.

The optimal study population for such a trial would be adolescent or young adult women just beginning sexual activity. As with many vaccines, it is anticipated that the number of people required for an HPV vaccine trial could be large (i.e., in the thousands or greater). Because of the length of time from infection with HPV to development of cervical dysplasia, HPV vaccine trials could last several years. During this time, women would have to undergo periodic pelvic exams and receive several shots. Willingness and motivation to participate in these trials is important as poor recruitment and high dropout may make it statistically impossible to see any benefit from the vaccine.

## **Objectives of This Research**

In this paper, we evaluate HPV knowledge and priorities, HPV vaccine acceptability, and willingness to participate in an HPV vaccine clinical trial among a group of adolescent and young adult women in the United States.

## **METHODS**

### **Study Population**

A convenience sample of 60 women between 15 and 28 years old was obtained early in September 1998 from four sites at the southern New Jersey Shore: Stone Harbor Beach, Wildwood Beach, Ocean City Boardwalk, and Ocean City Beach. These areas were frequented by young teens and adults. Many women who were accompanied by boyfriends/husbands or families were not appreciative of being approached. As such, the study focused primarily on unaccompanied women or those with female friends

or relatives. Women were asked if they were willing to fill out a survey that took 10–15 minutes and were assured of confidentiality.

## Data Collection

There were two study interviewers. Both had previously conducted surveillance research among adolescent women and were given an orientation on the protocol and specific details concerning participation in the study. The interviewers reviewed the data collection forms and used these to carry out practice sessions, which were directly observed and critiqued.

Survey participants first read a short statement describing a hypothetical vaccine trial to prevent “Human Papillomavirus, a sexually transmitted disease.” It was explained that this trial would last for 3 years and require 2 visits per year each lasting 1–3 hours. At various visits they would receive shots, pelvic exams, have blood drawn, and answer questions about their sexual behavior and overall health care. Participants were asked to role play being a clinical study participant and then assess the feelings they might have after they had just completed the first visit of this clinical study.

The women then answered a series of questions designed to assess knowledge about HPV, concerns about risks of sexual activity, and attitudes toward using an HPV vaccine and participation in an HPV vaccine trial. Questions related to prior and current sexual history were not asked because of concern that such questions would reduce participation in this survey. It took, on average, 20 minutes to complete each questionnaire. This was done in a secluded area where privacy of the woman's answers was ensured. Upon completion of the questionnaire, participants were given a gift certificate and preapproved HPV and STD information from the Rutgers University web site.

## Data Analysis

Data analysis was done with Statistical Analysis Software (SAS, 1997). Statistical comparisons were made with confidence intervals, exact tests, McNemar's tests, and sign tests.

## RESULTS

Demographic characteristics are shown in Table 1. The sample was mostly (96.7%) Caucasian. Most (58.3%) were adults (18–28 years old), and the others were 15–17 years old. About 60% had completed at least some college. When interviewers were restricted to women 18 years or

**Table 1. Demographic characteristics**

Characteristic	Percentage of sample
Age	(Out of 60 responses)
15–17 Years	41.7
18–28 Years	58.3
Ethnicity	(Out of 60 responses)
Caucasian	96.7
African American	3.3
Highest grade completed	(Out of 60 responses)
0–8 years	1.7
9–12 Years	45.0
1–4 Years College	43.3
>4 Years College	10.0
Have significant other (boyfriend or husband)	(Out of 60 responses)
No	52.1
Yes	47.9
Cigarette smoker	(Out of 59 responses)
No	78.0
Yes	22.0
Currently employed and/or a student	(Out of 60 responses)
No	10.0
Yes	90.0
Employment status	(Out of 60 responses)
Not employed	21.7
Working part time	35.0
Working full time	43.3
Student status	(Out of 60 responses)
Not in school	28.3
In school part time	6.7
In school full time	65.0
Had participant heard of HPV before this study	(Out of 60 responses)
No	76.7
Yes	23.3

older, about 90% had completed at least some college. About 50% (35% of those 18 years or older) had a boyfriend or significant other, but only 3.3% had children (data not shown). The vast majority (90%) were employed or went to school. Only 22% were smokers, 97% would use cars for transportation to a study clinic (data not shown), and 70% had lived in the same area for more than 7 years (data not shown).

Only 23.3% had previously heard of HPV; 34.5% of women 18 years or older had heard of HPV versus 8.3% of those 17 years and under ( $P < 0.01$  Exact Test). Most of those who had heard of HPV (14.8%)

had done so at school; 9% had heard of HPV from a doctor and 9% from television (data not shown).

### Concerns about Risks of Sexual Activity

Table 2 shows that among five potentially adverse outcomes of sexual activity (AIDS, cervical cancer, herpes, genital warts, and pregnancy), 86.6% ranked AIDS as their biggest concern. Cervical cancer was ranked second by most (52%) of the participants ahead of herpes, and genital warts was ranked fourth. Participants feared AIDS significantly more ( $P < 0.05$  paired  $t$  test) and herpes significantly less ( $P < 0.05$ ) than cervical cancer, and participants feared herpes significantly more ( $P < 0.05$ ) than genital warts or pregnancy. When asked to directly compare concern about cervical cancer with concern about genital warts, 42.4% were more concerned about cervical cancer, 42.4% were equally concerned about both and 6.8% were more concerned about genital warts.

### Attitudes toward Receiving an HPV Vaccine

Table 3 presents responses to questions about attitudes toward HPV vaccinations. Only 15% would be extremely likely to pay for an HPV vaccine if the costs were not covered by insurance; 31.7% would be either somewhat or extremely unlikely to pay for an HPV vaccine. By a factor of 5 to 1 (83.3% versus 16.7%,  $p < 0.001$ ) women preferred a vaccine that protected against 70% of cancer and 100% of genital warts to one that protected against 85% of cancer but had no protection against genital warts. Almost 70% felt that men should receive a vaccine against oncogenic HPV to protect potential sexual partners even though men did

**Table 2. Participants ( $n = 60$ ) rank of personal concern for 5 potentially adverse outcomes of pregnancy**

Outcome	Rank (1st is most concerned, 5th is least concerned)				
	1st	2nd	3rd	4th	5th
AIDS	86.6%	5.7%	1.9%	5.7%	0.0%
Cervical cancer	2.0%	52.0%	24.0%	8.0%	14.0%
Herpes	2.0%	19.6%	39.2%	23.5%	15.7%
Genital warts	0.0%	7.7%	21.2%	46.2%	25.0%
Pregnancy	14.5%	16.4%	14.5%	14.5%	40.0%

*Note:* The numbers do not add up to 100% in all columns since some participants assigned the same rank to multiple outcomes.



**Table 3. Attitudes toward an HPV vaccine**

Question	Percentage responding
Which type of HPV vaccine participant preferred	(Out of 60 responses)
One that protected against 85% of cervical cancer	16.7
One that protected against 70% of cervical cancer and 100% of genital warts	83.3
When participant felt a woman should receive an HPV vaccine	(Out of 60 responses)
Before becoming sexually active	88.3
After becoming sexually active	5.0
It doesn't matter when	6.7
Did participant feel men should receive a vaccine against oncogenic HPV to protect their sexual partners even though men do not develop cervical cancer?	(Out of 60 responses)
Yes, strongly agreed	68.3
Yes, somewhat agreed	26.7
No, somewhat disagreed	3.3
No, strongly disagreed	1.7
Would participant pay for an HPV vaccine if it was not covered by insurance	(Out of 60 responses)
Extremely likely	15.0
Somewhat likely	53.3
Somewhat unlikely	25.0
Extremely unlikely	6.7

not develop cervical cancer. Almost 80% felt that men should receive a vaccine that protected against genital warts and oncogenic HPV (data not shown). About 90% felt the best time for women and men (data not shown) to be vaccinated against HPV was before becoming sexually active.

### **Attitudes toward Participation in an HPV Vaccine Trial**

Many of these women would not participate in a 3-year HPV vaccine clinical trial under conditions that were likely to exist as described by the interviewers (Table 4). Less than 30% would participate in a trial that required 3 vaccine shots and biannual pelvic exams. The shots and pelvic exams were equal deterrents against participation; 46.7% would participate in a trial requiring 3 shots, while 40% would participate in a trial requiring biannual pelvic exams. Other factors could limit participation in a 3-year HPV vaccine trial. About 35% thought that they might move from their present geographical area within 3 years (data not shown).

**Table 4. Attitudes toward participation in an HPV vaccine trial**

Question	Percent responding
A. Would participant enroll in a clinical trial if	
Trial required 6 pelvic exams over 3 years	(Out of 60 responses)
Yes	40.0
No	48.3
Perhaps	11.7
Trial required 3 vaccination shots	(Out of 60 responses)
Yes	46.7
No	50.0
Perhaps	3.3
Trial required both 6 pelvic exams over 3 years and 3 vaccination shots	(Out of 60 responses)
Yes	28.3
No	65.0
Perhaps	6.7
B. Participant's opinion of potential benefits from enrolling in an HPV clinical trial	
The benefits to women in general a vaccine would have if proven to work in the trial	(Out of 60 responses)
Would not influence her to enroll in a clinical trial	5.0
Would somewhat influence her to enroll in a clinical trial	5.0
Would moderately influence her to enroll in a clinical trial	43.3
Would strongly influence her to enroll in a clinical trial	46.7
Vaccine benefits to participant if the vaccine was effective and participant was randomized to the vaccinated group	(Out of 60 responses)
Would not influence her to enroll in a clinical trial	10.0
Would somewhat influence her to enroll in a clinical trial	20.0
Would moderately influence her to enroll in a clinical trial	33.3
Would strongly influence her to enroll in a clinical trial	36.7
Free medical care that participant would receive from the clinical trial	(Out of 60 responses)
Would not influence her to enroll in a clinical trial	23.3
Would somewhat influence her to enroll in a clinical trial	13.3
Would moderately influence her to enroll in a clinical trial	40.0
Would strongly influence her to enroll in a clinical trial	23.3
A monetary reimbursement from participating in the clinical trial	(Out of 60 responses)
Would not influence her to enroll in a clinical trial	8.3
Would somewhat influence her to enroll in a clinical trial	30.0
Would moderately influence her to enroll in a clinical trial	33.3
Would strongly influence her to enroll in a clinical trial	28.3

*(continued)*

Table 4. (Continued)

Question	Percent responding
C. Participant's opinions of potential detriments from enrolling in a clinical trial of HPV vaccine	
What effect enrolling in the HPV-vaccine trial would have on her free time	(Out of 60 responses)
Would have little or no effect	28.3
Would have some effect	55.0
Would have considerable effect	8.3
Did not know	8.3
What effect enrolling in the HPV-vaccine trial would have on her grades/career	(Out of 60 responses)
Would have no effect or help	56.7
Would hurt	10.0
Don't know	33.3
The pelvic exams for the clinical trial would be physically uncomfortable	(Out of 58 responses)
No	70.2
Yes	29.8
The pelvic exams for the clinical trial would cause embarrassment	(Out of 57 responses)
No	68.4
Yes	31.6
D. Participant's beliefs about attitudes of family and friends toward her enrolling in an HPV clinical trial	
Likely parental opinion of her enrolling in clinical trial for an HPV vaccine	(Out of 57 responses*)
Would approve	35.0
Would neither approve nor disapprove	38.6
Would disapprove	26.3
Likely boyfriend/significant other's opinion of her enrolling in a clinical trial for an HPV vaccine	(Out of 35 responses**)
Would approve	28.6
Would neither approve nor disapprove	60.0
Would disapprove	11.4
Likely opinion of most of her friends toward her enrolling in a clinical trial for an HPV	(Out of 60 responses)
Most would approve	39.7
Most would neither approve nor disapprove	56.9
Most would disapprove	3.4

\*Excludes one woman whose parents were deceased.

\*\*Excludes 23 women without boyfriend/significant other.

About 30% preferred a female pelvic examiner, 5% preferred a man, and 65% had no preference.

Most of these women saw benefits from participation in an HPV vaccine trial. About 95% felt that receiving the vaccine and medical exams in the clinical trials would provide at least some benefit to their own health (data not shown). Almost 47% responded that the potential for a vaccine to benefit women in general would strongly influence them to participate in such a trial. This was statistically greater ( $P < 0.001$ ) than any of the other potential reasons for vaccine trial participation that were asked. By comparison only 23.3% and 28.3%, respectively, stated that free medical care (from study visits) and monetary reimbursement would strongly influence them to participate in a vaccine trial.

Some downsides to participation in an HPV vaccine trial were also expressed. About 10% felt that the study would have considerable effect on their free time. Close to 30% and 35%, respectively, felt that pelvic exams would be uncomfortable and cause embarrassment. Almost 40% of the 14 smokers thought that a nonsmoking policy in the clinic would make a 1–3 hour visit uncomfortable (data not shown).

Pressure from parents and peers may not be a significant factor in limiting clinical trial participation by these women. About one fourth felt their parents would disapprove of the trial with the remainder equally split between “approving” and “neither approving nor disapproving.” Surprisingly, these responses did not differ substantially by age of respondent; 37.5% of those 17 and younger thought their parents would approve of their participation in the trial compared with 32.4% of those 18 and older. Around 90% and 95%, respectively, felt that boyfriend/significant others and at least some of their other friends, respectively, would either approve of or not care about the respondent's participation in the HPV vaccine trial.

## DISCUSSION

HPVs are sexually transmitted and can cause cervical cancer in women and genital warts in both sexes. Vaccines to prevent HPV are currently being developed. Because acquisition of HPV occurs rapidly after initiation of sexual activity and cervical cancer is limited to women, adolescent/young adult women should be vaccinated. Prophylactic HPV vaccines may soon be actively tested in lengthy and demanding clinical trials. The ultimate success of these trials and subsequent efforts to disseminate the vaccine will depend on whether young women are willing to participate in clinical trials for and to use an HPV vaccine. The goals of this study were to evaluate HPV knowledge and priorities, HPV vaccine acceptability, and factors related to participation in an HPV vaccine clinical

trial among a group of adolescent and young adult women in the United States.

The 15–28-year-old women sampled in this survey were almost exclusively Caucasian and most likely middle class. Most of those over 18 were attending college and those under 18 were continuing their education in high school. Most had access to automobile transportation, were employed at least part time, and did not have children. These women had greater education and trust of and access to medical care than would other groups in the United States. There might, however, be less awareness of STDs among this group compared with adolescents from groups more at risk for more widely known STDs.

Knowledge about HPV among this group was limited, with only 8.3% of those 15–17 years old and 34.5% of those 18–28 years old having heard of HPV. Others also have found low knowledge of HPV among American women (Biro et al., 1997; Burak and Meyer, 1997; Horn et al., 1990; Jubelirer et al., 1996; Masad et al., 1997; Najem, Batuman, & Smith, 1996; Nugent & Tamlyn-Leaman, 1992; Ramirez et al., 1997; Sharp et al., 1990). More education on HPV is needed. Women are increasingly at risk for HPV and its consequences starting at late adolescence. Schools need to play a major role in this education, yet only 10% of these women heard about HPV at school.

Concern about cervical cancer was high among this group, ranking below AIDS, but above herpes, genital warts, and pregnancy as an unwanted risk of sexual activity. This undoubtedly reflects that cancer is life threatening and (except for AIDS) the other diseases are not. The level of concern about cervical cancer did not completely dominate that for the other HPV, namely, genital warts. About half of the study participants stated being equally concerned with both diseases, and 7% were more concerned about genital warts. When given a choice of taking a vaccine that protects against 85% of cervical cancer compared with one that protected against only 70% of cervical cancer and 100% of genital warts, by a margin of 5 to 1, women preferred the latter. It may be better for a four-valent HPV vaccine to include both types of HPV that cause genital warts and the two oncogenic types causing 70% of cervical cancer rather than the four leading types of oncogenic HPV that cause 85% of cervical cancer.

Almost 90% felt that a woman should be vaccinated against HPV before becoming sexually active. This bodes well for the chance of an HPV vaccine being accepted by adolescents. Caution is needed as well. Strong objections are likely from those who might feel vaccination of teenage girls against an STD would condone and promote gratuitous sex. Such opposition could delay practical acceptance. Although vaccination of adolescents against hepatitis B is now standard, obtaining acceptance

for this may have been aided in part by the knowledge that hepatitis B could be transmitted nonsexually as well as sexually.

It bodes well that 68% of this sample stated they would be extremely likely or somewhat likely to pay for an HPV vaccine even if insurance did not cover it. However, these are educated middle-class women who may have the means to privately pay for such a vaccine. Still, many of these women may not be willing to pay when faced with an actual choice, and women with lower socioeconomic means may not be able to pay for this. Unless an HPV vaccine were actively promoted as part of a national safe sex campaign that goes beyond just condom use, it is likely that most women would not be vaccinated.

It may be impossible to eliminate an STD by only vaccinating one gender; vaccination of men against oncogenic HPV may be needed. While 95% of women felt men should be vaccinated against oncogenic HPV to prevent transmission of these viruses to subsequent sexual partners, fewer men may hold this attitude. Almost 100% of women felt that men should receive a vaccine against oncogenic HPV if this vaccine would also protect men against genital warts. Although research on attitudes of men is needed to answer this question, inclusion of protection against warts may make an oncogenic vaccine more acceptable to men thus increasing its use by both sexes.

There is not much literature on factors related to willingness of healthy people to participate in medical research toward prevention of a potential future disease and none on factors related to willingness to participate in an HPV vaccine trial. Only 30% of these women would commit to an HPV vaccine trial that required 3 shots and 6 pelvic exams over 3 years. Perhaps even fewer would participate if faced with a real decision that required such a time commitment. Subsequent attrition after the trial begins could also be a problem. For example, 35% had plans to move out of their current geographical area within 3 years. This underscores the difficulty in recruiting for a long-term trial of HPV vaccine. Although recruitment strategies that enroll only women who are likely to remain in a trial for the duration might be considered, restricting a trial to any subgroup of women might draw questions about generalizability of the results to other women.

Among the factors promoting participation in an HPV vaccine trial that we considered here, the potential for a vaccine to help women was the strongest inducement for this group to participate; close to 50% stated this would strongly influence them to participate in a trial. Perhaps emphasis on this issue may be a useful message for recruiting women into an HPV vaccine trial. Although only 29% said that a monetary payment would strongly influence them to participate, the demands and length of such a trial would call for some economic reimbursement for participants. As

with other long-term clinical trials, it is not likely that participation would occur without some monetary compensation to volunteers, particularly for young adolescents with limited sources of income.

Most women did not feel that the trial would have significant impact on their free time or school/career. Close to 30% felt that pelvic exams would be uncomfortable, and 30% felt they would be embarrassing. Many of the younger women would not have had previous pelvic exams, so perhaps some of these perceptions reflect lack of experience. About 25% felt that parents would disapprove of their participation in a vaccine trial, but fewer felt that boyfriends/significant others would disapprove. Both comfort of/embarrassment about pelvic exams and opinions of participant's network members are beyond control of the staff conducting a clinical trial. The best strategy to address these issues may be to make sure that study entrants have fully considered these issues before enrolling. Although this could limit enrollment, it may reduce wasted effort and resources committed to individuals who subsequently drop out of the study.

## CONCLUSION

This study provides a first look at acceptability of an HPV vaccine and willingness to participate in an HPV vaccine trial among mostly middle-class White adolescent and young women. This is perhaps the largest HPV risk group in the United States with many of these women becoming infected with HPV then developing genital warts, beginning to progress toward cervical abnormalities, or both. It is, however, important to note that the findings presented here are based on a convenience sample, which may differ in unknown aspects from other women.

Although knowledge of HPV was low in this group, these women were very concerned about cervical cancer and genital warts. A vast majority believed that women should be vaccinated against HPV before beginning sexual activities. Most preferred a vaccine that protected against genital warts even if its coverage against cervical cancer was reduced. These women also felt that men should be vaccinated against oncogenic HPV, particularly if the vaccine protected against genital warts. Only 30% would participate in a three-year HPV vaccine trial under conditions that would likely exist. One of the main motivations for participating in an HPV vaccine trial was "gender altruism," the potential for the vaccine to help other women.

Increased education of American high school students on HPV may be needed. Although it may not be difficult to convince adolescent women in this group that taking an HPV vaccine before initiating sexual activity is important, convincing their parents and other community members

may be more difficult. If a vaccine against HPV is developed, national health efforts to expand childhood vaccination to adolescent vaccinations may be needed to protect the million of women and men who will contract HPV in the coming years. Further research on HPV knowledge and acceptability of vaccines is needed among all risk groups including men.

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