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HPV Knowledge and Time to Complete Vaccination Among Vulnerable Female Youth

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Abstract

Objective—To examine the association of human papillomavirus (HPV) HPV knowledge on the time to completion of the 3-dose quadrivalent vaccine series in an inner-city population of adolescent females at high risk for infection.

Study design—We prospectively followed 139 females aged 14-20 years enrolled in a vaccine surveillance study in New York City over a period of at least 24 months. Participants were given a 30-item true or false survey on HPV at enrollment and ranked according to the number of correct responses. Multivariate Cox regression was used to examine the association between level of HPV knowledge and time to completion (in days) of vaccine dose1-3, dose1-2 and dose2-3.

Results—Overall time to completion of the 3-dose vaccine ranged from 158 days to 1114 days. Participants in the high knowledge group (top quartile) were significantly more likely to complete the 3-dose series earlier (HR=1.69, 95% CI 1.03-2.77; $p=0.04$), in particular doses 2 to 3 (HR=1.71, 95% CI 1.02-2.89; $p=0.04$), than those with low-to-moderate knowledge (bottom three quartiles).

Conclusions—These findings suggest that HPV knowledge is associated with shorter time to complete the 3-dose HPV vaccine series. Educational campaigns at time of vaccination may be important to improve vaccine adherence.

The quadrivalent human papillomavirus vaccine (qHPV; Gardasil®, Merck & Co., Inc., NJ) is highly effective in preventing anogenital HPV infection, warts, and precancerous lesions in females who test negative for the HPV types targeted by the vaccine and are highly

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compliant with the 3-dose vaccination schedule.¹⁻³ Since the approval of the vaccine in 2006, coverage with 1 dose of any HPV vaccine among adolescent females has remained low, with only 57% of girls aged 13-17 receiving the vaccine and 38% completing all three doses.⁴ Although a number of countries have approved reduced dose schedules for HPV vaccination in adolescents, it is unlikely this will be adopted in the US soon while both the quadrivalent and bivalent vaccines remain licensed for 3 doses. Moreover, per the recent World Health Organization Report from the Global Advisory Committee on Vaccine Safety,⁵ the 3-dose schedule remains necessary if immunization is initiated after the 15th birthday. Additional studies, however, are needed to further determine the effectiveness of alternate dosing schedules and regimens for different age groups. Until a long-term immunological threshold of disease protection is well established, full and timely completion of the series continues to be a desirable public health goal. Geometric mean antibody titer levels in girls aged 9-13 and found they were higher in those receiving 3 versus 2 doses, suggesting that completion may be advantageous⁶. On the other hand, evidence from trials indicate that vaccine efficacy is maintained after just 2 doses,⁷ and after longer intervals of up to 24 months for a 3-dose regimen.^{8,9}

Vaccine completion rates for the three recommended doses among those who have already received the first dose are lower among blacks and Hispanics compared with whites nationally,¹⁰ with even greater disparities observed among the uninsured and disadvantaged. After controlling for insurance type, a study of 8,069 young women attending an urban clinic between 2006-2010 found black teenagers ages 14-17 who initiated the qHPV series were less likely to complete than white or other ethnicity teenagers,¹¹ suggesting that removing financial barriers among uninsured teens of ethnic minority background is only a first step in achieving vaccine adherence.

Diffusion theory applied to newly approved vaccination programs proposes that because initiation is a focus at early stages of vaccine uptake, with full and on-schedule completion (ie, by 7 months) subsequently becoming an important focus as programs expand and gain acceptance.¹² As nationwide vaccination efforts advance from initiation to completion, it is critical to identify modifiable factors that may facilitate completion in clinical settings serving vulnerable teens. This identification is important because, even though evidence from trials support moving to a two-dose vaccine schedule, which would improve compliance, little is known about the long-term consequences of partial or delayed adherence on vaccine effectiveness.^{6,7}

Research to date has focused primarily on vaccine initiation, with a few studies observing significant associations between limited knowledge of HPV and decreased acceptability of the vaccine.¹³⁻¹⁸ In an effort to expand current literature, we assessed level of knowledge about HPV transmission, treatment, consequences, vaccine efficacy, and prevention in prospectively followed ethnic minority adolescents receiving the 3-dose qHPV vaccine at a large urban adolescent health center in New York City.

METHODS

The current study included 139 participants between 14-20 years of age enrolled in a longitudinal HPV vaccine surveillance study^{19,20} at the Mount Sinai Adolescent Health Center (MSAHC) in NYC from October 2007 to February 2012. MSAHC is an urban health center providing comprehensive care that is confidential and free of charge, including administration of the qHPV vaccine. Women eligible for the main study i) were between 12-19 years of age at time of consent; ii) had ever engaged in vaginal intercourse; and iii) intended to get or had already received the qHPV vaccine. At time of analysis, 709 participants had enrolled in the main study, of which the majority had already initiated or completed the vaccine series. Because this study focused on the time course of vaccine completion, only participants receiving the first vaccine dose at the time of the baseline visit (vaccine naïve) were included. Pregnant females, or those who had terminated a pregnancy within four weeks of enrollment, were excluded. One vaccine naïve participant was later excluded because she was erroneously vaccinated earlier than the minimum recommended schedule.

Participants were informed about the study by research staff and written informed consent was collected from all participants prior to enrollment. The study was approved by the Institutional Review Board of the Icahn School of Medicine at Mount Sinai. Prior to receiving the vaccine, participants completed a self-administered paper and pencil questionnaire consisting of multiple items assessing demographic characteristics, risk behaviors for HPV acquisition, and HPV knowledge. At the conclusion of the baseline visits, or shortly thereafter at a subsequent visit, dose1 of the vaccine was given and the vaccination receipt date was recorded in the electronic medical record. Participants were scheduled to receive dose2 and dose3 according to the intervals recommended by the U.S. Advisory Committee on Immunization Practices (ACIP) at the time of the study: dose 1-2=28 days, dose 2-3=84 days, and dose 1-3=168 days. However, vaccines were still administered at the shortest recommended intervals if participants presented to the clinic outside of study visits. The study took place under optimum vaccination conditions including appointment reminders, follow-up of participants to reschedule missed appointments via a phone call and approaching them during clinic appointments outside of study visits.

The primary outcomes of this analysis were time (in days) to completion of doses 1-3, 1-2, and 2-3 of the qHPV vaccination series following the administration of dose1. Subjects were followed until they completed the 3-dose series or withdrew from the study. For those subjects who were lost to follow-up before vaccine completion, a participating physician (JN) reviewed the New York Citywide Immunization Registry (CIR) and recorded dates for vaccine doses that were received elsewhere.

Assessment of HPV Knowledge

A self-administered HPV knowledge survey comprised of 30 items was scored as true/false/not sure covering general aspects of HPV transmission, treatment, consequences, vaccine efficacy, and prevention. Questions included were similar to those found in a recently validated general HPV knowledge scale.²¹ Responses to items were dichotomized

into either correct or incorrect/not sure: participants were given one point for a correct response and zero for an incorrect/not sure response. The total knowledge score (ranging from 0-30) reflects the number of correct responses (Chronbach $\alpha = 0.89$). Participants with missing data in four items or fewer were given a zero for that individual item ($n=11$). Those missing more than four items were excluded from the main analyses ($n=4$).

Covariates

Information regarding demographics and sexual practices also was assessed by self-report questionnaire. Demographic characteristics included: (1) age measured in years (range 12-20 years); (2) ethnicity/race categorized using The National Longitudinal Study of Adolescent Health (Add Health) guidelines (<http://cpc.unc.edu/projects/addhealth/data/code/race>), which integrate ethnicity and race into three ethnic/race groups: Hispanic, Non-Hispanic Black/African American, and Other (White, Asian, Native American, Other); (3) socioeconomic status (SES) dichotomized by assigning participants a score of one (low SES) if they responded positively to ever receiving any of the following: welfare assistance, food stamps, Medicaid, WIC, free lunch or those who reported 'often not having enough to eat' in the past year or zero for all other participants (not low SES); and (4) current school attendance (yes/no).

Sexual practices assessed included: (1) age at vaginal, anal, or oral sexual debut (11-14, 15 and 16 years); (2) recent (in the past six months) number of sexual partners (0-1, 2, and 3 partners); (3) recent (in the past six months) condom use (never/rarely, sometimes and mostly/always); (4) history of sexually transmitted diseases including chlamydia (yes/no); and (5) history of genital warts (yes/no).

Statistical Analyses

ANOVA/Chi square statistics were used to examine bivariate associations of demographic factors and sexual practices by level of HPV knowledge. To account for the minimum interval periods allowed between doses (during which an individual would not be eligible to receive the next dose), time to vaccination was modeled starting after 30 days for dose1-2, 90 days for dose2-3 and 150 days for dose1-3. Subjects withdrawn from the study or lost-to-follow up, for which qHPV completion dates were unknown ($n=21/139$; 14.3%), were censored at study withdrawal date ($n=10$) or date of last CIR review (4th September 2014; $n=11$).

The probability of time to completion of dose1-3 (in days) by HPV knowledge was examined using Kaplan-Meier survival curves. Only participants with HPV knowledge data ($N=135$) contributed to the analyses. Bivariate Cox regression analyses were used to identify significant covariates while adjusting for HPV knowledge. Covariates that changed the HPV knowledge estimates by 10% or more were included as confounders in the final regressions. Multivariable Cox regression models were used to examine the association of HPV knowledge on time to completion of the vaccine doses. The proportional hazards assumption was tested using the Schoenfeld Test and was satisfied on all the models. Statistical analyses were conducted using SPSS version 20 and STATA SE version 12 software.

RESULTS

At baseline, participants had a mean (SD) age of 17.9 (± 1.4) years, 67.4% were over 17 years of age, 55% identified themselves as Hispanic, 53% were of low socioeconomic status and 82% attended school or college. The mean number of recent sexual partners was 1.7 (± 1.3), with 61% having 0-1 recent partner. Consistent (mostly/always) recent condom use was reported by 53%.

Table I describes the individual items contained in the HPV knowledge measure and the percent of correctly endorsed responses for each item. The mean (SD) HPV knowledge score was 19.9 (± 6.4) with a range of 0 to 30, with over half (52.2%) answering correctly 70% of items. Correct responses for individual items ranged from 92.8% of participants who knew HPV causes some types of cervical cancer to only 33.6% who knew that HPV is not cured by antibiotics. More participants answered correctly on topics related to HPV disease outcome, vaccine availability, and transmission via sexual partners; fewer participants answered correctly on questions related to HPV prevalence, treatment, and cure.

Days to Vaccine Completion and HPV Knowledge Group

The distribution of the total HPV knowledge scores in quartiles by time to completion (in days) is seen in Table II. The median time to completion (in days) among those in the lowest three quartiles varied little (between 240-258 days), and the median time for those in the top quartile was 210 days. To increase power in our bivariate and Cox regression analyses, we collapsed subjects into two HPV knowledge groups: 1) a low-moderate level group comprised of the bottom three quartiles [$n=106$; 75 percentile with a mean (SD) of 17.87(± 5.69) correct answers], and 2) a high level group comprised of the top quartile [$n=29$; >75 percentile with a mean of 27.59 (± 1.35) correct answers].

Subject Characteristics by HPV Knowledge Group

Bivariate analyses showed that older vs. younger subjects [t -test $p < .05$] and those with positive history of genital warts [χ^2 $p < .01$] were more likely to be classified in the high knowledge rather than the low-moderate group. The two HPV knowledge groups (low-moderate vs. high) were similar with regards to ethnicity/race, SES, school attendance, age at sexual debut, recent sexual partners, recent condom usage, and history of Chlamydia (Table III).

Full, Partial, and On-schedule Vaccine Completion

Over the course of the study period, 92.1% (128/139) completed two doses; 92.2% (118/128) of those who completed dose2 went on to complete dose3. Median times to completion of dose 1-3, dose 1-2 and dose 2-3 were: 233 days (range: 158-1114), 76 days (range: 46-1012) and 140 days (range: 87-513), respectively. On-schedule completion (defined as receiving all 3 doses by 7 months using a 28-day count) was accomplished by 31.1% (37/118) of those who completed the series.

Time to Vaccine Completion by HPV Knowledge Group

The Figure shows Kaplan-Meier survival probabilities depicting the median number of days to complete the qHPV 3-dose series by knowledge group of the HPV knowledge measure (log-rank $p=0.04$). After adjusting for age and number of recent sexual partners, the high knowledge group was almost twice as likely to complete the 3-dose series earlier (and on schedule) compared with those in the low-moderate group (HR 1.69, 95% CI 1.03-2.77; $p=0.04$). Similarly, the high HPV knowledge group was almost twice as likely to complete doses 2-3 (HR 1.71, 95% CI 1.02-2.89; $p=0.04$).

DISCUSSION

Although studies have found that HPV knowledge may increase vaccination uptake/initiation,^{15, 22} the impact of higher knowledge on shorter time to vaccine completion has remained inconclusive. Taking advantage of fewer implementation barriers afforded by the high-resource context in which this vaccination protocol took place, the positive associations between higher HPV knowledge level and vaccination adherence were supported for two of the three outcome measures (time to completion of dose 1-3 and dose 2-3).

The information gained in this study supports health education campaigns encouraging greater understanding of HPV transmission and risk factors among vulnerable sexually active adolescent patients. Educational efforts are emerging, but rigorous studies assessing effectiveness of educational interventions are needed.²³ Fortunately, compared with the prevaccine era,^{24,25} HPV awareness seems to be improving; 94% of our adolescent sample had heard of HPV compared with 33% of adult women in 2004.²⁶ Advanced knowledge about HPV, however, may still be lacking. For example, although 71% in this study knew that HPV is a sexually transmitted disease, only 34% knew that HPV cannot be cured by antibiotics. Additionally, 49% erroneously believed the vaccine protects against all types of HPV. This finding is similar to a 2010 study conducted with 1800 college females²⁷ where 44-51% of respondents erroneously believed that the qHPV was almost 100% effective in preventing all types of HPV infection.

The finding that higher HPV knowledge is associated with a reduction in time to vaccine completion from dose 2-3 (but only marginally from dose 1-2) may be related with a longer interval required between dose 2-3 reflecting more opportunities for continued HPV-related education to enhance adherence. In this study 85% completed the three doses, which approaches the high rate (>95%) found in the vaccine efficacy trials involving low-risk young adult women.¹⁻² Very few participants ($n=11$) received only a single dose; and from those who completed two doses, only six failed to finish the series. Our on-schedule completion (3 doses by 7 months) is shown by 31% of the sample representing about a two-fold improvement from previous studies. For example, in a retrospective chart review²⁸ of 3,297 female patients between ages of 9-26 years who initiated qHPV at an urban hospital-based clinic, only 14% completed by 7 months and 28% by 12 months.

Taken together, these findings are remarkable accomplishments given the low and delayed completion rates observed for other high risk youth and speaks to what is attainable under optimum vaccination conditions. Given the inverse association between healthcare cost and

adherence rates,²⁹ the first step in improving vaccination is to eliminate access barriers to initiation. Previously identified barriers to vaccination uptake include infrequent healthcare visits, missed opportunities for vaccination, and lack of health insurance.^{30,31} Coverage of the cost of vaccination has been found to be the strongest predictor of qHPV initiation.³⁰⁻³³ For those without insurance, the out-of-pocket expense for qHPV can be upward of \$360 (\$120/dose) plus the cost of the medical visit. Cost was not a factor in initiating vaccination in this study as participants received the vaccines free of cost, thus removing this initial key barrier.

There are a number of limitations that should be noted. Data collected was based on a small sample of adolescent patients participating in a prospective HPV vaccine surveillance study at a free medical clinic. Although the study context removed access barriers, it limited study generalizability and findings may not easily translate to other healthcare settings serving high-risk youth. Even though the association between HPV knowledge and time to completion was significant, the difference was relatively small and represented approximately one month (35 days over a median of >200 days for both groups). The clinical significance of the one month shorter adherence remains unknown and needs further elucidation. Content items on the HPV knowledge survey such as dimensionality and wording effects were not addressed in this study; the survey took place at only one time point (prior to vaccination). Selection bias may have been introduced from lost-to-follow-up and withdrawal subjects although this was not observed between the two knowledge groups. Despite these limitations, research findings provide promising evidence that higher HPV knowledge prior to vaccination is associated with closer adherence, and points to patient education as an effective component to augment effective vaccination initiatives.

Given the relatively low rates of timely qHPV completion in the United States, effective strategies in clinic may be critical to promote closer adherence to vaccination schedules. Studies have shown that acceptance of the vaccine is higher when health care providers recommend the vaccine.³¹ Clinicians should also emphasize that HPV infection is common, can be asymptomatic, and has limited treatment options. They should also highlight the safety and benefits of timely HPV vaccination for adolescent health promotion. Furthermore, clinicians should inform their patients at the first vaccination visit that additional vaccines are needed and adhering to time frames are important: verifying the patient knows exactly how many and when future doses are needed; and providing ongoing HPV education at multiple occasions (e.g., during acute care visits) and not limited to preventative care or adolescent well visits.

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Abbreviations

HPV	human papillomavirus
qHPV	quadrivalent human papillomavirus vaccine (types 6, 11, 16, and 18)
MSAHC	The Mount Sinai Adolescent Health Center
ACIP	Advisory Committee on Immunization Practices
CIR	New York Citywide Immunization Registry
SES	socioeconomic status

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FIGURE 1.
Time to completion of the qHPV series by HPV knowledge group (N=135)

TABLE 1

Correctly endorsed responses to the HPV knowledge measure

Individual Items	% Correct
1. Some HPV types cause cervical cancer. (T)	92.8
2. There is a vaccine that can protect against some types of HPV. (T)	92.1
3. You can get HPV from vaginal sex. (T)	88.5
4. You can get HPV from having sex with many partners. (T)	86.9
5. HPV goes away after a girls' period. (F)	82.5
6. You can get HPV from having sex only one time in your life. (T)	81.8
7. You can always tell if someone has HPV. (F)	81.8
8. You can get HPV from performing oral sex. (T)	79.9
9. You can get HPV from having sex with only one person. (T)	79.6
10. HPV goes away by washing the area with soap and water. (F)	79.6
11. You can get HPV from performing anal sex. (T)	77.7
12. You can get HPV from receiving anal sex. (T)	73.2
13. You can have HPV and go your whole life without having symptoms. (T)	73.0
14. HPV goes away if you stop having sex. (F)	71.5
15. HPV is a sexually transmitted disease. (T)	70.5
16. You can get HPV from receiving oral sex. (T)	69.1
17. HPV is the virus that can cause genital warts. (T)	65.5
18. HPV goes away with surgery. (F)	63.5
19. If you use a condom you definitely will not get HPV. (F)	61.2
20. HPV goes away with a cream or ointment. (F)	59.1
21. You can get HPV from sharing clothes with someone who has it. (F)	56.2
22. If you are diagnosed with HPV, you will definitely have it for the rest of your life. (F)	56.2
23. Higher risk of HPV spread if you had sex with a partner who has genital warts. (T)	52.6
24. Not many people have (or had) HPV. (F)	52.5
25. Most sexually active people will have HPV some time in their lives. (T)	50.4
26. There is a vaccine that can protect against all types of HPV. (F)	48.9
27. HPV goes away on its own. (T)	43.1
28. You can get HPV by using your hand to touch the genitals of someone who has it. (T)	37.4
29. HPV goes away with other medications besides antibiotics. (F)	36.5
30. HPV goes away with antibiotics. (F)	33.6

T=true; F=false

TABLE 2

Median days to completion of qHPV series by level of HPV knowledge

HPV Knowledge Measure	Median (range) days to complete the qHPV series		
Quartile	Dose 1-3 [*] (N=135)	Dose 1-2 [*] (N=135)	Dose 2-3 [*] (N=126)
Lowest quartile	245(158-749)	75(46-589)	140(98-422)
2 nd quartile	258(166-1114)	91(55-1012)	148(87-341)
3 rd quartile	240(177-518)	74(49-218)	136(107-399)
Highest quartile	210(161-737)	68(46-224)	132(111-513)
Mean(SD)	279.0(±13.2)	107.4 (±9.4)	171.5(±7.2)

* ACIP Recommendations for minimal doses; 1-3=168 days; 1-2=28 days, 2-3=84 days.

TABLE 3

Demographics and sexual practices by HPV knowledge group

Characteristic	HPV Knowledge Group		<i>p</i> -value ^c
	Low-Moderate (n=106)	N (%) ^a High (n=29)	
Age, years (mean, SD)	17.7 (1.4)	18.4 (1.2)	0.02
Ethnicity/race ^b			0.99
Hispanic	57 (54.3)	16 (55.2)	
African American	36 (34.3)	10 (34.5)	
Other	12 (11.4)	3 (10.3)	
Low SES	50 (47.2)	14 (48.3)	0.95
School attendance	85 (80.2)	22 (75.9)	0.42
Sexual practices			
Age at sexual debut ^b			0.61
11-14 years	35 (33.3)	10 (34.5)	
15 years	27 (25.7)	5 (17.2)	
16 years	43 (41.0)	14 (48.3)	
Recent number of sexual partners			0.20
0-1 partners	68 (64.2)	14 (48.3)	
2 partners	25 (23.6)	8 (27.6)	
3 partners	13 (12.3)	7 (24.1)	
Recent condom usage ^b			0.19
Never/rarely	17 (16.3)	6 (20.7)	
Sometimes	28 (27.0)	12 (41.4)	
Mostly/always	59 (56.7)	11 (37.9)	
History of chlamydia	29 (27.4)	5 (18.5)	0.25
History of genital warts	4(3.7)	5(20.0)	0.01

^a based on N=135 (four participants were excluded due to incomplete data).^b N may vary based on missing data^c *p*-values are based on χ^2 statistics for categorical variables and t-test tests for continuous variables.