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Impact of HPV Vaccine Availability on Uptake

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Introduction

Despite widespread support for the human papillomavirus (HPV) vaccine and high acceptability rates¹, HPV vaccine uptake has remained low since the Food and Drug Administration (FDA) approval of Gardasil® in 2006. By the end of 2009, only 44% of females age 13 to 17 had initiated the HPV vaccine series and 27% had received the full three doses². Even fewer young adults 19 to 26 years old have initiated HPV vaccination, with some estimates at less than 10% for receipt of at least one dose³.

Gardasil®, and the more recently approved Cervarix®, have the potential to drastically reduce the prevalence of HPV, the most common sexually transmitted infection, which infects 44.8% of 20 to 24 year old females in the United States⁴. In addition, vaccination against HPV could prevent a majority of the 12,200 cervical cancers, 3,900 vulvar cancers, and 2,300 vaginal cancers estimated to develop in the United States in 2010⁵. Widespread use of the HPV vaccine can result in significant savings in health care expenditures, but is generally considered cost-effective only with high population level uptake⁶. In addition, data suggests that achieving high vaccine coverage among females is more cost effective than adding male vaccination⁷, supporting the examination of factors related to vaccine uptake in various female populations.

Several studies have attempted to identify factors influencing HPV vaccine uptake, with the ultimate goal of improving vaccination rates⁸⁻²⁰. One influence that has emerged is vaccination opportunity. Females presenting for a health care visit^{8, 9, 12}, specifically a preventive maintenance visit¹² where the vaccine is available, are more likely to initiate HPV vaccination, indicating that increased availability of the vaccine should result in increased uptake. To test this hypothesis, we studied the impact of Gardasil® availability on vaccine uptake at two Planned Parenthood Mid and South Michigan (PPMSM) health centers, four years after the FDA approved Gardasil®.

Consistent with Planned Parenthood's mission to "provide comprehensive reproductive and complementary health care services"²¹, PPMSM began carrying Gardasil® for 19 to 26 year

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old female patients starting May 1, 2010 in two of its largest sites. Prior to May 1, 2010, organizational protocols encouraged PPMSM clinicians to recommend the HPV vaccine to females, but required that patients seek out primary care providers or the county health departments to receive the vaccine. After May 1, 2010, PPMSM clinicians gained the ability to offer the vaccine in addition to the recommendation.

Purpose

The primary objective of this study was to evaluate the impact of HPV vaccine availability on uptake among 19 to 26 year old female PPMSM patients. Specifically, the objective was to compare uptake before and after the vaccine became available at two PPMSM health centers, four years after the vaccine became publicly available elsewhere. The secondary objective was to explore clinic level variables other than availability that may have influenced uptake.

Methods

Study design

The study was an observational study reflecting the reality of introducing Gardasil® in two reproductive health centers without the strict controls of a clinical trial. Data was collected from two large, urban, outpatient PPMSM health centers serving a largely uninsured, low-income patient population. Each health center employs one main clinician (nurse practitioner, nurse midwife, or physician's assistant) with other clinicians providing patient services as needed.

A pre-post observational study design following a single group of patients over a two year time period was developed to study the impact of the newly available (at PPMSM) HPV vaccine. Participants' vaccination status was assessed at two annual exams. During the first annual exam, prior to the May 1, 2010 clinical availability of Gardasil® at PPMSM, participants had the opportunity to discuss the recommended HPV vaccine but had to receive it elsewhere. During the subsequent annual exam, after May 1, 2010, participants who were unvaccinated had the opportunity to receive Gardasil® at the clinic visit.

Data for the first three months of PPMSM Gardasil® availability, May 1, 2010 to July 31, 2010, was collected by chart review of all qualifying participants between May and August of 2010. The "Notice of Health Information Privacy Practices" provided to all participants at registration served as informed consent for the research. The study was approved by the University of Michigan Institutional Review Board, Planned Parenthood Mid and South Michigan, and Planned Parenthood Federation of America.

Participants

Inclusion criteria for participants reviewed included 1) female sex, 2) between the ages of 19 and 26, and 3) attended an annual exam between May and July 2010, and an annual exam within the previous two years, at either of the two PPMSM health centers. The inclusion criteria was designed to reflect 1) the FDA's approval of Gardasil® for 9 to 26 year olds, 2) the Advisory Committee on Immunization Practices' recommendation for routine HPV vaccination of all females, and 3) PPMSM's policy to offer Gardasil® to only 19 to 26 year old females.

Data sources/measurement

All data was collected through review of the electronic medical records at PPMSM. No personally identifiable information was collected and no participants were contacted. The components of the electronic medical records were developed for clinical use by PPMSM

and are updated periodically using input for improvement from all clinicians. Clinic information and self-reported demographic information was gathered from the electronic medical record and measured as indicated in Tables 1 and 2.

The primary outcome for this analysis was HPV vaccine uptake, specifically self-reported or PPMSM clinician administered series initiation. Uptake was defined as receipt of at least one dose of HPV vaccine, even though the regimen consists of a series of three doses. Series completion was not considered for the purposes of this study.

Some parts of the electronic medical record were updated by PPMSM between the two annual exams due to periodic revision of the patient history form, and therefore differ slightly in format. To measure HPV vaccine uptake among participants prior to vaccine availability at PPMSM, participants were asked in the patient history form, "Please indicate which vaccines you have received: ...HPV/Gardasil __1 __2 __3 __unsure" at the first annual exam. This was revised to, "Please indicate which vaccines you have received: ... HPV/Gardasil x 3 shots __yes __no __unsure" by the second annual exam. Participants who marked yes or any of the numbered injections were considered to have initiated vaccination. Those who marked no or unsure were considered to be unvaccinated. To measure HPV vaccine uptake at PPMSM after it became available there, clinician documentation of the visit note was reviewed. If the visit included documentation of vaccine administration, the patient was considered vaccinated at PPMSM.

The provider was considered to have recommended the vaccine if she checked "__vaccine discussion and/or recommendations" on the patient history form to indicate her recommendation and was considered not to have recommended the vaccine if the prompt remained blank.

Statistical methods

Data was evaluated using PASWStatistics 18.0. Descriptive statistics for the sample were calculated. Following the sample statistics, subgroup descriptive statistics were calculated including those who received vaccination at PPMSM and those who remained unvaccinated. Any data missing for an individual variable is indicated in the results. Fisher's exact test was used to calculate statistical significance between those who received vaccination at PPMSM and those who remained unvaccinated.

Results

Participants

Of the 344 19 to 26 year old females who received annual exams between May 1, 2010 and July 31, 2010, 171 (49.7%) also received an annual exam within the previous two years and were included in the analyses.

Characteristics of the study population

Demographic characteristics of the study population are shown in Table 1. Overall, the mean age of participants was 23.0 (SD=2.0) years and the average household income was \$18,977.0 (SD=\$13,938.3). Most of the 171 participants were single (89.5%) and white (62.6%). A majority of the participants were uninsured (71.3%), while 21.6% had private insurance and 7.0% had public insurance. Of the 37 participants with private insurance, 11 did not use their insurance at PPMSM, often because it was not accepted at PPMSM or the insurance had high deductibles, but they were still considered to be privately insured for the purpose of this study. Most participants (73.1%) had no other sources of health care.

Descriptive clinic characteristics of the study population are shown in Table 2. Participants were evenly divided between the two health centers, with 92 (53.8%) participants seen in health center “A” and 79 (46.2%) seen in health center “B”. Most participants (76%) were seen by two clinicians, while the remaining six clinicians saw 24% of the participants. Despite the PPMSM protocol indicating that clinicians should recommend and/or offer the HPV vaccine, fewer than half (38.9%) of all participants who were unvaccinated had a clinician-documented recommendation for HPV vaccination at the second annual exam. This differed almost entirely by individual clinician, with some clinicians consistently recommending the vaccine and others consistently not recommending the vaccine. Provider recommendation was statistically significant (Fisher’s exact test p -value = 0.006) between those who received the HPV vaccine at the annual exam and those who did not. A total of 15.2% ($n=26$) of participants received a report of an abnormal Papanicolaou (Pap) smear at the second annual exam.

HPV vaccine uptake

Eleven percent ($n=19$) of the 171 participants indicated they were already vaccinated. Upon availability of Gardasil® at PPMSM during the second annual exam, nine (5.9%) of the 152 participants who did not indicate they were already vaccinated received the HPV vaccine at PPMSM. Thus, the vaccination rate increased from 11% to 16% in the overall population.

Between the first and second annual exam, when Gardasil® was not available at PPMSM, three individuals indicated they received the vaccine elsewhere, by changing their response on the patient history form from unvaccinated at the first annual exam to vaccinated at the second annual exam. Interestingly, four others reversed their vaccination status, changing their response from vaccinated at the first annual exam to unvaccinated at the second annual exam, possibly due to the change in wording of the questionnaire.

Almost all of the nine participants who received the vaccine at the second annual exam were single (88.9%, $n=8$), white (88.9%, $n=8$), and non-Hispanic (88.9%, $n=8$). Two-thirds ($n=6$) who became vaccinated were uninsured, taking advantage of the Merck Vaccine Patient Assistance Program, and one-third ($n=3$) had private insurance. One third ($n=3$) had an abnormal Pap smear result at the second visit. All of the vaccines were given by just two of the eight clinicians. One clinician, who saw 39.2% ($n=67$) of the participants, gave 55.6% ($n=5$) of the vaccines and the second clinician, who saw 9.9% of the participants, gave 44.4% ($n=4$) of the vaccines.

Discussion

Key results

In this study of patients attending annual exams at two PPMSM health centers, 5.9% became vaccinated upon availability of the HPV vaccine in the health center, a small number overall, but an increase from the 11.1% who were already vaccinated. We hypothesized that increasing the availability of the HPV vaccine, so that participants could receive it when they were already at their annual exam rather than having to make a separate trip to another provider, would substantially improve HPV vaccine uptake. Any additional patient vaccinated can be considered an improvement, especially on an individual level. However, the additional six percent of participants who were vaccinated as a result of vaccine availability at the clinic visit does not provide the large-scale increase necessary for population level changes that would result in significant reduction in disease.

Other influences are likely contributing to the low uptake. One of the most important influences on HPV vaccine uptake observed in other populations is provider recommendation^{8, 10, 11, 13, 14, 19, 20}. However, fewer than half of the participants at PPMSM

reported receiving the clinician recommendation, which may have influenced the observed level of uptake.

Cost and insurance coverage has been found to significantly influence vaccine uptake in other populations^{3, 8, 10, 12} and likely contributed to low vaccine uptake in this study. In our study's largely uninsured, low-income population, two thirds of the participants who received HPV vaccination at the second visit utilized the Merck Vaccine Patient Assistance program for free Gardasil® despite the additional \$30 injection fee charged by PPMSM. Still, the additional \$30 injection fee may make vaccination financially unfeasible for many people. Those participants with public health insurance had to seek vaccination outside of PPMSM as Medicaid does not reimburse PPMSM for the vaccine. Even those with private insurance may not have vaccine coverage and would have to pay the full cost of \$160 per dose for the three dose series.

Limitations

One limitation of the study is the use of self-reported measures, especially vaccination status. Young adults may have difficulty remembering if they received the HPV vaccine, or even what the HPV vaccine is, and we had no means of confirming self-reported vaccination status. The patient history form referred to the vaccine in two different forms, using both the name of the vaccine (Gardasil) and the virus (HPV), intended to help improve the likelihood of an accurate response. Self-reported demographic information, especially annual household income, may also be vulnerable to bias as the health centers' visit fees for uninsured participants are determined by patient household income, thereby providing an incentive for participants to underreport income.

Additional limitations include history and maturation as a result of time between annual exams. Also, participants had one to two years after their first annual exam to receive the vaccine elsewhere, while participants had only one visit to receive the vaccine at the second annual exam before they were measured. Participants may have chosen to return to the health centers for vaccination after the second annual exam, but this time period was not included in measurement.

Another limitation of the study is that 11.1% of participants had already been vaccinated before the vaccine became available at PPMSM. The remaining participants may have been inherently less likely to become vaccinated, as they had not done so in the previous four years. Additional vaccine uptake in this age group four years after Gardasil's® FDA approval may be limited.

Finally, the primary investigator of this study is employed as a per diem nurse practitioner at the two PPMSM health centers and her visits are included in the analysis to provide a complete and accurate reflection of the data. Her visits represented a small percentage of the total participant population, but may be considered by some to be a limitation to the study.

Generalizability

The ability to generalize results of the study to other reproductive health centers, specifically non-Planned Parenthood reproductive health centers, may be limited. The study took place at two PPMSM health centers, using regularly updated protocols approved by a national organization with resources that may not be available to other reproductive health centers. As part of a network of 880 Planned Parenthood health centers serving three million patients in the United States each year however, the settings may be generalizable across a large portion of the population. Furthermore, two clinics were chosen instead of a single site in order to decrease the chance that the results are specific to a single location.

Selection bias within PPMSM was avoided by using all participants who received annual exams during the defined study time period rather than a sample of the population. However, only participants who received regular annual exams at PPMSM were used, and not participants presenting for other types of visits, or even participants utilizing PPMSM for a single annual exam. Therefore, this cohort may represent a population more active in preventive health care, and perhaps less able to access care at other non-Planned Parenthood sites.

Wide disparities in HPV vaccine uptake have surfaced among states, likely resulting from differences in approaches to cost coverage and accessibility. Massachusetts, for example, achieved 69% vaccination coverage in 2009 while Mississippi lagged behind at 23%². Michigan's HPV vaccination rates are below the national average with 39% of adolescent females initiating the series². State policy influences were controlled in the study by using only clinic data from Michigan, thus results must be interpreted within this context.

Implications

In this study of participants accessing annual exams at two PPMSM health centers, we found that improving availability of the HPV vaccine, while helpful, is not sufficient to substantially improve uptake of the vaccine. Nurse practitioners must also address issues of accessibility, including cost and provider recommendation. Future research that focuses on evaluating interventions for improving cost and provider recommendation in organizations that provide HPV vaccination on site may be helpful to improve HPV prevention for patients.

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Table 1**Demographic Characteristics of Participants (n=171)**

	All Participants (n=171)	Participants Who Received HPV Vaccine at clinics (n=9)	Participants Who Remained Unvaccinated (n=143)
Mean age in years (SD)	23.0 (2.0)	23.1 (1.9)	23.1 (1.9)
Mean annual household income (SD)	\$18,977.0 (\$13, 938.3)	\$16,288.4 (\$8,339.0)	\$19,136.34 (\$14,442.30)
Insurance			
Uninsured	71.4% (n=122)	66.7% (n=6)	70.6% (n=101)
Private	21.6% (n=37)	33.3% (n=3)	21.7% (n=31)
Public	7.0% (n=12)	0	7.7% (n=11)
Race			
White	62.6% (n=107)	88.9% (n=8)	61.5% (n=88)
Black/African American	21.6% (n=37)	0	23.8% (n=34)
Other	8.8% (n=15)	11.1% (n=1)	7.0% (n=10)
More than one	2.9% (n=5)	0	3.5% (n=5)
Asian	2.3% (n=4)	0	2.1% (n=3)
Native Hawaiian/Pacific Islander	0.6% (n=1)	0	0.7% (n=1)
Native Indian/Alaskan Native	0	0	0
Missing	1.2% (n=2)	0	1.4% (n=2)
Hispanic origin			
No	91.2% (n=156)	88.9% (n=8)	91.6% (n=131)
Yes	8.2% (n=14)	11.1% (n=1)	7.7% (n=11)
Missing	0.6% (n=1)	0	0.7% (n=1)
Marital status			
Single	89.5% (n=153)	88.9% (n=8)	88.1% (n=126)
Unknown	5.8% (n=10)	11/1% (n=1)	6.3% (n=9)
Married	4.1% (n=7)	0	4.9% (n=7)
Separated	0.6% (n=1)	0	0.7% (n=1)
Divorced	0	0	0
Widowed	0	0	0
Have non-PPMSM health care providers			
No	49.1% (n=84)	88.9% (n=8)	46.2% (n=66)
Yes	18.1% (n=31)	0	19.6% (n=28)
Missing	32.8% (n=56)	11.1% (n=1)	34.3% (n=49)

SD=standard deviation.

Table 2

Clinic Characteristics of Participants (n=171)

	All Participants (n=171)	Participants Who Received HPV Vaccine at clinics (n=9)	Participants Who Remained Unvaccinated (n=143)
Clinic visited			
A	53.8% (n=92)	11.1% (n=1)	56.6% (n=81)
B	46.2% (n=79)	88.9% (n=8)	43.4% (n=62)
Provider seen			
A	39.2% (n=67)	55.6% (n=5)	37.0% (n=53)
B	36.8% (n=63)	0	40.5% (n=58)
C	9.9% (n=17)	44.4% (n=4)	8.5% (n=12)
D	5.3% (n=9)	0	4.9% (n=7)
E	2.9% (n=5)	0	3.5% (n=5)
F	2.3% (n=4)	0	1.4% (n=2)
G	1.8% (n=3)	0	2.1% (n=3)
H	1.8% (n=3)	0	2.1% (n=3)
Provider recommended vaccine			
No	53.2% (n=91)	11.1% (n=1)	62.9% (n=90)
Yes	33.9% (n=58)	77.8% (n=7)	35.7% (n=51)
Not applicable (vaccinated)	11.1% (n=19)	not applicable	not applicable
Missing	1.8% (n=3)	11.1% (n=1)	1.4% (n=2)
Abnormal Papanicolaou smear at exam			
No	83.6% (n=143)	66.7% (n=6)	85.3% (n=122)
Yes	15.2% (n=26)	33.3% (n=3)	14.0% (n=20)
Missing	1.2% (n=2)	0	0.7% (n=1)