

Original article

## Availability of Human Papillomavirus Vaccine at Medical Practices in an Area with Elevated Rates of Cervical Cancer

Sami L. Gottlieb, M.D., M.S.P.H.<sup>a,\*</sup>, Noel T. Brewer, Ph.D.<sup>b</sup>, Jennifer S. Smith, Ph.D.<sup>b</sup>,  
Katie M. Keating, M.P.H.<sup>b</sup>, and Lauri E. Markowitz, M.D.<sup>a</sup>

<sup>a</sup>Division of STD Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

<sup>b</sup>UNC Gillings School of Global Public Health, University of North Carolina, Chapel Hill, North Carolina

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#### Abstract

**Purpose:** To assess availability of human papillomavirus (HPV) vaccine at medical practices in an area with elevated cervical cancer rates.

**Methods:** During July–November 2007, we conducted a telephone survey of staff at medical practices providing outpatient care to 9- to 26-year-old females in four North Carolina counties with elevated cervical cancer rates. We assessed availability of HPV vaccine and concerns about its provision.

**Results:** Staff from 71 of 96 eligible practices completed a full interview. Overall, 62% of these practices had HPV vaccine available to patients (family practice, 74%; pediatrics, 75%; obstetrics–gynecology, 64%; internal medicine, 15%). In multivariate analysis, practice characteristics that independently predicted a lower likelihood of carrying HPV vaccine were having at least 50% African-American patient population (odds ratio [OR] 0.19, 95% confidence interval [CI] 0.06–0.63) and providing only privately purchased (and no state-supplied) vaccines (OR 0.19, 95% CI 0.06–0.63). HPV vaccine nonproviders were significantly more likely than HPV vaccine providers to report “large” concerns about the up-front costs of purchasing HPV vaccine (52% vs. 27%,  $p < .05$ ) and late reimbursement (33% vs. 14%,  $p < .05$ ).

**Conclusions:** Approximately 1 year after its introduction, HPV vaccine was available at three-quarters of family practice and pediatrics practices, two-thirds of obstetrics–gynecology practices, and few internal medicine practices in an area with elevated cervical cancer rates. Practices’ concerns about cost and reimbursement have implications for accessibility of HPV vaccine to those who need it most. Published by Elsevier Inc. on behalf of Society for Adolescent Medicine.

**Keywords:** Human papillomavirus; HPV vaccines; Adolescent health services

The quadrivalent human papillomavirus (HPV) vaccine has been shown to be highly efficacious in preventing persistent infection and disease related to HPV types 16 and 18, which are responsible for 70% of invasive cervical cancers, and HPV types 6 and 11, responsible for most genital warts [1,2]. This vaccine was licensed by the U.S. Food and Drug Administration in June 2006, and soon thereafter the Advisory Committee on Immunization Practices (ACIP) recommended

routine HPV vaccination for 11 and 12 year-old girls and “catch-up” vaccination for 13- through 26-year-olds who have not previously received it [3,4]. HPV vaccine holds great promise for reducing the burden of cervical cancer and other HPV-related disease in the United States; however, broad availability and uptake of the vaccine will be important, especially in communities with the highest cervical cancer rates.

Cervical cancer rates vary in the United States; communities with large racial or ethnic minority populations tend to be at highest risk [5]. Because such communities are often medically underserved, adolescents with the greatest need for the HPV vaccine may be least likely to receive it. During mid-2007, we assessed HPV vaccine uptake in an area of North

\*Address correspondence to: Sami L. Gottlieb, M.D., M.S.P.H., Division of STD Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS E-02, Atlanta, GA 30333.

E-mail address: [sgottlieb@cdc.gov](mailto:sgottlieb@cdc.gov)

Carolina with elevated cervical cancer rates, and found that only 10% of girls aged 10 to 18 had initiated HPV vaccine [6]. A fundamental first step in fostering HPV vaccine uptake in these communities is ensuring that HPV vaccine is available at medical practices where adolescents might seek care. Thus, to better understand vaccine delivery in this population, we studied availability of HPV vaccine, and potential barriers to its availability, at medical practices serving adolescent girls and young women in the same region of North Carolina with elevated cervical cancer rates.

## Methods

We conducted a telephone survey of all medical practices serving adolescent girls and young women in the four rural North Carolina counties in which we evaluated HPV vaccine initiation [6]. To select these counties, we identified 11 that met predefined inclusion criteria of: (1) annual cervical cancer incidence rates greater than 10 cases/100,000 women, 1993–2003, and mortality rates greater than 4 deaths/100,000 women, 1994–2004; (2) at least 20% African-American residents; and (3) at least 1,500 girls in the targeted age range. We narrowed the potential list to eight eligible rural counties that clustered in the same region of southeastern North Carolina, and then randomly selected the four study counties: Duplin, Harnett, Sampson, and Wayne (combined population 336,481). Mean annual cervical cancer incidence rates in these counties ranged from 10.8 to 13.9 cases/100,000 women and mortality rates from 4.2 to 6.5 deaths/100,000 women (personal communication, North Carolina State Center for Health Statistics, 2006), substantially higher than annual U.S. rates in a similar time frame (incidence, 8.6 cases/100,000; mortality, 2.9 deaths/100,000) [7].

The survey was conducted July to November 2007, approximately 1 year after HPV vaccine was licensed and first recommended [3], 5 months after final ACIP recommendations were published [4], and 6 months after HPV vaccine became available through the Universal Children's Vaccine Distribution Program (UCVDP). UCVDP is North Carolina's program to distribute vaccines through the federally funded Vaccines for Children (VFC) program, which provides vaccines at no cost primarily to uninsured and Medicaid-eligible children and adolescents [8]. Although North Carolina also uses state funds to supplement the VFC entitlement to provide vaccines for all underinsured, non-VFC-eligible children, state funds were not available for HPV vaccine in 2007.

To locate eligible medical practices, we first identified physicians with active medical licenses registered with the North Carolina Medical Board who listed a primary specialty of pediatrics, family or general practice, internal medicine, obstetrics–gynecology, or public health. Second, we obtained lists of medical facilities enrolled in UCVDP from the Immunization Branch of the North Carolina Department of Health and Human Services. Finally, we obtained lists of county medical service providers from health departments in

each of the four study counties. Inclusion criteria for practices were providing outpatient medical services and serving any female patients aged 9 through 26 years.

Two trained interviewers called practices, determined eligibility, and asked to speak with a staff member who knew about HPV vaccine availability and logistical issues around its provision. The main outcome was HPV vaccine availability, defined as a “yes” response to the question, “Has your practice or clinic provided doses of the HPV vaccine to any patients?” or, for those that had not yet provided any doses, a “yes” response to, “Do you currently have the HPV vaccine in stock?” We also assessed a variety of practice characteristics. The primary specialty of each practice was determined by the stated specialty of the greatest number of clinicians in the practice. Clinicians were defined as physicians, nurse practitioners, or physician assistants. We also asked how much each of 10 potential barriers to HPV vaccine provision had been a concern to their practice. Response options were “not a concern,” “a small concern,” and “a large concern.” Medical practice staff that did not have time to participate in the full interview had the option of a short interview consisting of only the two main outcome questions. The University of North Carolina institutional review board approved the study protocol.

Bivariate associations were evaluated with chi square tests, or with Fisher exact tests when any expected cell size was less than 5. Multivariate logistic regression was used to examine predictors of HPV vaccine availability at medical practices, using a forward selection process. All variables that were associated with HPV vaccine availability at  $p \leq .10$  in bivariate analyses were considered in the model, except for “adolescent vaccine provision,” given its collinearity with the outcome variable. Data were analyzed using SAS version 9.1 (Cary, NC). All statistical tests were two tailed, with a critical alpha of .05.

## Results

### *Practice characteristics*

We identified 105 distinct medical practices in the four study counties. Nine were excluded because they did not provide outpatient care or did not see any 9- to 26-year-old females. Of the remaining 96 practices, 4 could not be contacted and 2 refused participation. Staff from 71 practices completed the full interview (response rate 74%, 71/96). Study respondents were primarily nurses (51%) or office managers (18%); 21 interviews required speaking to more than one staff person. Staff from another 19 practices just answered questions about HPV vaccine availability; thus, 90 practices completed at least the short interview (response rate 94%, 90/96).

Characteristics of medical practices completing the full interview are shown in Table 1. The majority (72%) were private practices, and 28% were Federally Qualified Health Centers ( $n = 15$ ) or public health clinics ( $n = 5$ ). The most common primary specialty of clinicians was family or

Table 1  
Proportion of study practices with HPV vaccine available, according to practice characteristics

	n	HPV vaccine available <sup>a</sup> N (%)	p-value
Total	71	44 (62%)	
Type of facility			.06
Private practice	51	28 (55%)	
Federally Qualified Health Center or public health clinic	20	16 (80%)	
Main service provided			.17
Primary care	53	34 (64%)	
Family planning, women's health, or STD care	8	5 (62%)	
Vaccination services	2	2 (100%)	
Other, including subspecialty care	5	1 (20%)	
Primary specialty of practice clinicians <sup>b</sup>			<.01
Family practice	34	25 (74%)	
Pediatrics	8	6 (75%)	
Internal medicine	13	2 (15%)	
Obstetrics and gynecology	11	7 (64%)	
Size of practice—number of clinicians			<.01
1	19	6 (32%)	
2	20	11 (55%)	
3–4	21	18 (86%)	
≥ 5	10	8 (80%)	
Number of patients seen in 1 week			.03
< 100	16	7 (44%)	
101–150	18	10 (56%)	
151–250	11	9 (82%)	
> 250	20	17 (85%)	
Percentage of patients aged 9–18 years <sup>c</sup>			<.01
< 10%	23	9 (39%)	
10–24%	15	13 (87%)	
≥ 25%	33	22 (67%)	
Percentage of African-American patients			<.01
< 50%	43	34 (79%)	
≥ 50%	28	10 (36%)	
Percentage of patients with private insurance			.66
< 25%	17	11 (65%)	
25–49%	27	18 (67%)	
50–74%	16	10 (62%)	
> 75%	11	5 (45%)	
Percentage of patients with Medicaid or North Carolina Health Choice			.43
< 25%	16	12 (75%)	
25–49%	22	12 (55%)	
≥ 50%	33	20 (61%)	
Percentage of patients who are uninsured			.80
< 10%	28	16 (57%)	
10–24%	23	15 (65%)	
≥ 25%	20	13 (65%)	
Type of vaccines provided at practice <sup>d</sup>			
Childhood vaccines			<.01
Yes	43	34 (79%)	
No	23	10 (43%)	
Adolescent vaccines (e.g., MCV4, Tdap)			<.01
Yes	46	37 (80%)	

(Continued)

Table 1  
Proportion of study practices with HPV vaccine available, according to practice characteristics (Continued)

	n	HPV vaccine available <sup>a</sup> N (%)	p-value
No	20	7 (35%)	
Adult vaccines			.19
Yes	56	36 (64%)	
No	10	8 (80%)	
Vaccine financing <sup>d</sup>			<.01
Privately purchased vaccine only	24	10 (42%)	
UCVDP with/without privately purchased vaccine <sup>e</sup>	42	34 (81%)	

STD = sexually transmitted disease; MCV4 = meningococcal conjugate vaccine; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine; UCVDP = Universal Children's Vaccine Distribution Program, North Carolina's program to distribute vaccines that are federally funded through the Vaccines for Children program.

<sup>a</sup> Includes four practices that had stocked HPV vaccine, but had not yet provided any doses.

<sup>b</sup> Primary specialty could not be determined for two vaccination clinics, two practices with equal numbers of clinicians in more than one specialty, and two practices with missing data on clinician specialty.

<sup>c</sup> Six practices reported providing no care to girls 9 to 18 years of age: four internal medicine, one family practice, and one public health clinic.

<sup>d</sup> Among the 66 practices that provided any vaccines.

<sup>e</sup> Only three practices reported providing only UCVDP vaccine and not purchasing any vaccine privately; another two practices reported participating in UCVDP but did not provide any information on whether they also purchased private vaccine.

general practice (51%), and just over half of the practices (n = 39) included only one or two clinicians. Staff from 47% of the practices reported that less than half of their patients had private insurance.

Sixty-six practices reported that they provided either childhood, adolescent, or adult vaccines. Overall, 36% provided privately purchased vaccines only, and 64% provided UCVDP-supplied vaccines, with or without privately purchased vaccine. Only three practices reported providing only UCVDP vaccine and not purchasing any vaccine privately.

#### HPV vaccine availability

HPV vaccine was available at 44 (62%) of 71 practices completing the full interview; 40 had provided doses of HPV vaccine, and an additional 4 had HPV vaccine in stock but had not yet provided any doses. HPV vaccine availability was similar when considering all 90 practices that completed either the short or full interview, with 53 (58%) having HPV vaccine available.

HPV vaccine availability at study practices (n = 71) is shown according to practice characteristics in Table 1. HPV vaccine was available at 55% of private practices and 80% of Federally Qualified Health Centers and other public health clinics (p = .06). The majority of family practice (74%), pediatrics (75%), and obstetrics–gynecology (64%) practices had HPV vaccine available to patients, but few

internal medicine practices carried it (15%,  $p < .01$  vs. other specialty types). Practices with fewer clinicians and those seeing fewer patients in 1 week were less likely to have HPV vaccine available, as were practices in which half or more of the patient population was African American ( $p < .03$  for each). Reported health insurance status of patients was not significantly associated with availability of HPV vaccine. However, practices using only privately purchased vaccines were less likely to provide HPV vaccine than those using UCVDP-supplied vaccines with or without privately purchased vaccines (42% vs. 81%,  $p < .01$ ).

In multivariate analysis, two practice characteristics independently predicted a lower likelihood of carrying HPV vaccine: serving a patient population that was at least 50% African American (odds ratio [OR] 0.19, 95% confidence interval [CI] 0.06–0.63), and providing only privately purchased (and no UCVDP state-supplied) vaccines (OR 0.19, 95% CI 0.06–0.63).

#### *HPV vaccine charges and insurance coverage*

Data about HPV vaccine charges were available for 30 of 31 practices that had provided UCVDP-supplied HPV vaccine to patients. The median charge reported for one dose of UCVDP-supplied HPV vaccine, including administration and office fees to a patient paying out of pocket, was \$14 (range: \$0–\$68). Overall, 37% reported that they did not charge anything, 43% reported they charged between \$10 and \$19, and 20% reported they charged \$20 or more. Thirty practices had provided doses of privately purchased HPV vaccine, and 27 answered a question about charges. The median charge for one dose of privately purchased HPV vaccine, including administration and office fees, was \$164 (range: \$120–\$256). One practice reported charging \$120 per dose, 41% reported charging between \$135 and \$159, 33% reported charging between \$160 and \$184, and 22% reported charging \$185 or more.

Of respondents from 38 practices who answered a question about the proportion of privately insured girls that were covered for the HPV vaccine, staff from 10 practices did not know. Of the remaining 28, only 6 (21%) reported that all of their privately insured patients were covered for the HPV vaccine; 13 (46%) reported that over half but not all patients were covered, and 9 (32%) reported that less than half of their patients were covered.

#### *Reminder and recall systems*

Few practices offering HPV vaccine reported flagging charts or having another system in place to identify patients eligible for their first dose of the vaccine (9/44, 20%). However, 59% of practices reported reminding patients to come in for their second and third doses, for example, by mailing reminder cards or making phone calls. In addition, 52% reported having a system in place to remind providers to give patients their second and third doses. Eleven (28%)

of the 40 practices that had already administered doses of HPV vaccine reported they had had problems with patients not returning for follow-up doses.

#### *Concerns about HPV vaccine provision*

The largest reported concerns about HPV vaccine provision, for both HPV vaccine providers and nonproviders, were too high a cost to patients, inadequate reimbursement, high up-front costs of ordering and stocking the vaccine, and the burden of determining insurance coverage (Figure 1). Practices that did not have HPV vaccine available were significantly more likely than those that did to have large concerns about the high up-front costs of ordering and stocking the vaccine and late reimbursement ( $p < .05$  for each). The differences in large concerns between HPV vaccine providers and nonproviders related to the burden of determining insurance coverage and vaccine expiring before use did not reach statistical significance.

## **Discussion**

HPV vaccine has the potential to greatly reduce the burden of cervical cancer and other HPV-related disease where the vaccine is widely available and delivered broadly, and it is especially important in areas at highest risk for HPV-related morbidity and mortality. In our survey of medical practices in an area with elevated cervical cancer rates, HPV vaccine was available at 62% of practices serving adolescent girls and young women approximately 1 year after HPV vaccine introduction and 6 months after release of the vaccine through the state UCVDP program. To our knowledge, this is the first study assessing availability of HPV vaccine across all medical practices serving a defined population. Although HPV vaccine availability was promising at this time point, it leaves ample room for improvement. HPV vaccine was still not available at practices where a sizable number of girls and young women may receive care.

HPV vaccine was available at three-quarters of practices at which the primary specialty of clinicians was either family practice or pediatrics. Although the number of pediatrics practices was relatively small in the study counties, we did not find that pediatricians were much more likely to carry HPV vaccine than family practitioners, as has been observed soon after introduction of several childhood vaccines [9–11]. Few internal medicine practices had the vaccine; however, 64% of obstetrics–gynecology practices offered it. This suggests that obstetrician–gynecologists, who have not traditionally been vaccine providers but have been supportive of HPV vaccination efforts [12], have quickly put systems in place to make HPV vaccine available. Improved availability of HPV vaccine at obstetrics–gynecology practices will be important for “catch-up” vaccination efforts. Females aged 18 to 21 years access healthcare much more often than do younger adolescents, and over one-third of their visits are to obstetrician–gynecologists [13].

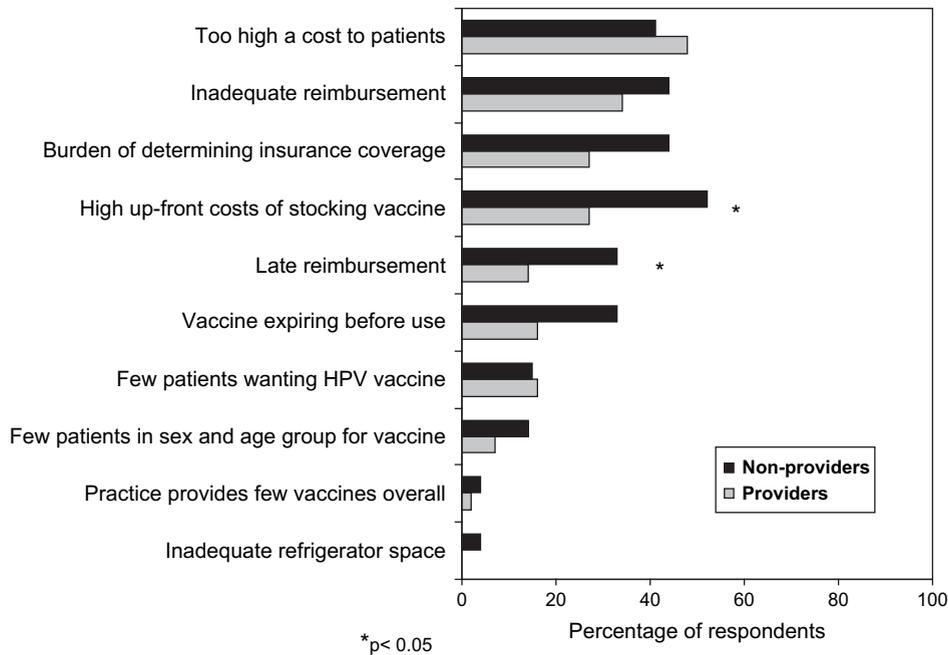


Figure 1. Proportion of practices reporting “large” concerns about HPV vaccine provision, among HPV vaccine providers (n = 44) and nonproviders (n = 27).

Medical practices serving primarily African-American patients were significantly less likely to have HPV vaccine available; almost two-thirds of such practices did not have HPV vaccine. Having a higher proportion of African American patients may be an indicator of providing care in a more resource-constrained setting. Potential missed opportunities to vaccinate African-American adolescent girls and women are particularly worrisome given existing large racial disparities in cervical cancer incidence and mortality rates, with African-American women more than twice as likely to die of cervical cancer than non-Hispanic white women [5]. However, we cannot directly determine where community African-American females are going to access HPV vaccine. Of note, interviews with parents of adolescent girls in the same four rural counties and a neighboring urban county during the same time period did not identify racial disparities in early uptake of HPV vaccine, nor in intentions to vaccinate among those whose daughters had not yet been vaccinated [6]. Continued efforts are needed to ensure that all adolescent girls, and especially those at highest risk of cervical cancer, have equal access to HPV vaccine.

We also found striking differences in HPV vaccine availability related to how vaccines were financed in the practices. Practices providing only privately purchased vaccines were much less likely to have HPV vaccine available than those providing state-supplied UCVDV vaccine. Mode of vaccine financing has been found to be a barrier to vaccine delivery in other studies [14–16]. Differences in vaccine availability by mode of vaccine financing may be explained in part by the concerns about HPV vaccine provision reported by study respondents. Similar to a previous analysis of overall concerns (both small and large) from this study [17], we found that the largest concerns reported by all practices were high

cost to patients, inadequate reimbursement, and the burden of determining insurance coverage. In addition, we found that practices that did not have HPV vaccine available were significantly more likely to have large concerns about up-front costs of purchasing vaccine and late reimbursement. These concerns may represent a barrier to HPV vaccine availability and may explain, in part, why smaller practices were much less likely to offer the vaccine than larger practices, as they may be less able to support this up-front investment.

Although concerns related to cost and reimbursement have been reported for other vaccines [14,15,18], they may be particularly likely to serve as barriers to implementation of HPV vaccine, the most expensive vaccination series (\$360 wholesale) ever to be universally recommended by the ACIP [19]. Only 20% of practice staff reported that all of their privately insured patients were covered for HPV vaccine. In the past, for example with introduction of pneumococcal conjugate vaccine, some physicians delayed vaccine implementation until insurance coverage was more uniform, so as not to give vaccine to some patients while withholding it from others [9]. In a study of a new rotavirus vaccine, the major reason given by providers for delaying implementation was waiting to see if insurers would cover the vaccine [15]. Even when an insurer covers the vaccine, reimbursement may not cover additional costs to the practice for buying and administering the vaccine [20]. A recent study has shown wide variation across practices in reimbursements for vaccine and administration fees paid by insurers [21]. This may be one reason that the majority of practices we surveyed charged well above the \$120 wholesale vaccine cost to patients paying out of pocket.

The concerns raised by study respondents may limit the extent to which HPV vaccine is being offered and provided

to eligible patients, even if it is theoretically available in a given practice. In addition, we found that most practices lacked a system to identify eligible adolescents for HPV vaccine, and many lacked patient recall systems. Because these simple strategies are proven effective at raising vaccination rates [22–24], the low proportion of reminder and recall systems suggests a ready target for intervention, in addition to the need to increase overall availability of the vaccine. Although there may be missed opportunities for vaccinating eligible patients at practices that have HPV vaccine available, all opportunities are missed at practices that do not carry it.

Our study has several limitations. First, we evaluated HPV vaccine availability in an area of North Carolina with elevated cervical cancer rates, and thus our findings may not be generalizable outside the Southeast or in other types of communities. Second, we conducted our assessment relatively early after HPV vaccine introduction; availability of the vaccine at these medical practices may still be evolving. Finally, we did not assess provider opinions that may influence vaccine provision, such as discomfort discussing an adolescent vaccine for a sexually transmitted infection or perceived lack of parental acceptance, as these issues have been addressed elsewhere [25,26]. Rather, we focused on overall HPV vaccine availability and the structural and logistical factors that may affect it.

Our survey of medical practices in four counties with elevated cervical cancer rates provides a snapshot of HPV vaccine availability approximately 1 year after the vaccine was introduced. Although HPV vaccine availability was promising, further efforts are needed to broaden availability of HPV vaccine in communities with the greatest need for it. Differences in availability by practice characteristics and concerns about cost and reimbursement have implications for accessibility of HPV vaccine to adolescent girls and young women at highest risk for cervical cancer. Our findings suggest that participation of additional practices in the Vaccines for Children program, structural changes to improve uniformity and ease of determining insurance coverage, and policies to lessen the burden of up-front and administrative costs may all help overcome potential obstacles to HPV vaccine availability. Additionally, efforts to increase availability of HPV vaccine at practices serving predominantly African-American populations are critical to ensure that existing racial disparities in cervical cancer rates are not widened.

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