

Original article

Potential Barriers to HPV Vaccine Provision Among Medical Practices in an Area with High Rates of Cervical Cancer

Katie M. Keating, M.P.H.^a, Noel T. Brewer, Ph.D.^{a,*}, Sami L. Gottlieb, M.D., M.S.P.H.^b, Nicole Liddon, Ph.D.^b, Christina Ludema^a, and Jennifer S. Smith, Ph.D., M.P.H.^a

^a*School of Public Health, University of North Carolina, Chapel Hill, North Carolina*

^b*Division of STD Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia*

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Abstract

Purpose: Potential barriers to widespread vaccination of adolescent girls against human papillomavirus (HPV) infection are poorly understood. We provide an overview of potential barriers to provision of HPV vaccine and empirical data on the concerns of medical practices that may inhibit HPV vaccine provision.

Method: We conducted phone interviews with medical practices in rural areas in southeastern North Carolina with high rates of cervical cancer to assess 10 potential concerns about HPV vaccine provision.

Results: Concerns most commonly reported by medical practices (N = 71) were inadequate reimbursement (68%), high cost of the vaccine to patients (66%), and burden of determining insurance coverage (66%). Practices that were not providing the vaccine reported more concerns about HPV vaccine provision on average than practices providing the vaccine (6.0 vs. 4.5 concerns, $p < .05$).

Conclusions: Medical practices' concerns about the HPV vaccine may be barriers to stocking it and, thus, to providing it to adolescents. Even providers who stock the vaccine reported concerns. Research is needed to address ways to ameliorate these medical practices' concerns and also to understand other potential barriers to vaccine coverage. © 2008 Society for Adolescent Medicine. All rights reserved.

Keywords:

HPV; Cervical cancer; Vaccination; Sexually transmitted infections; Adolescent health

New prophylactic vaccines against human papillomavirus (HPV) are highly effective in preventing persistent infection with HPV 16 and 18 [1,2], virus types responsible for 70% of invasive cervical cancers [3,4]. An HPV vaccine that also provides protection against genital warts was recently approved for females aged 9 to 26 years, and was recommended for routine immunization of 11- to 12-year-old girls [5]. These HPV vaccines have great promise for

reducing morbidity and mortality from cervical cancer. However, initial uptake in the United States may be uneven, with significant gaps in vaccine provision. This paper reviews potential barriers to widespread HPV vaccine uptake, and describes data on reported concerns about HPV vaccine provision from a study of medical practices in an area of North Carolina with high rates of invasive cervical cancer.

Potential Barriers to HPV Vaccination

One potential barrier to the receipt of HPV vaccination is lack of availability because healthcare facilities do not stock the vaccine. U.S. healthcare providers can purchase the HPV vaccine privately to make it available for patients able to pay on their own or whose health insurance covers it.

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*Address correspondence to: Noel T. Brewer, Ph.D., Department of Health Behavior and Health Education, School of Public Health, University of North Carolina, 364 Rosenau Hall CB 7440, Chapel Hill, NC 27516.

E-mail address: ntba@unc.edu

Providers can also stock vaccine supplied by the state for adolescents covered by the Vaccines for Children (VFC) program, a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. Providers can choose both, one, or none of these supply sources. Potential reasons for providers not stocking new vaccines, and the subsequent potential slowing of vaccine adoption and delivery, include cost-related concerns, such as up-front costs of ordering and stocking vaccines [6], inadequate reimbursement, [6–8], low or uneven insurance coverage [7], and manufacturing shortages. Clinicians may also have concerns related to safety [7,9], vaccine overloading [7], parental concerns about vaccine safety [10], parental reluctance to immunize children against a sexually transmitted infection [10], and lack of public awareness of the vaccine [7]. Concerns about adolescent immunizations may specifically include having too few adolescent patients, low confidence in addressing adolescent issues, and lack of time [6]. Low availability may be especially problematic where other healthcare services are already limited, as may be common in rural areas.

A second potential barrier is the cost to parents [11,12], who may have to pay the full cost of the vaccine. How patients afford the vaccine largely depends on whether they have health insurance that covers the HPV vaccine or are eligible to receive it through the VFC program. Categories of adolescents who qualify for VFC coverage for HPV vaccination include uninsured and underinsured, those who qualify for Medicaid, American Indians, and Alaskan natives. The HPV vaccine is more expensive than most other vaccines [12]. It costs about \$360 for three doses of the currently available vaccine, not including possible additional vaccine administration fees. Smaller but still meaningful potential barriers are fees not covered by insurance, including copayments and deductibles.

A third potential barrier is a mismatch between an adolescent's health insurance coverage and what is accepted by accessible medical facilities. If patients have to seek the vaccine at facilities outside of their regular provider for insurance reasons, this disruption to care might discourage vaccination [12]. A fourth potential barrier to HPV vaccine provision is parents who are unaware of the HPV vaccine or their daughters' eligibility for the VFC or other healthcare service programs. For example, some parents of VFC-eligible adolescents may be unaware that they can receive low-cost and free vaccines [12].

A fifth potential barrier is parents' lack of motivation to have their adolescents vaccinated against HPV. The above discussion assumes that parents, once they know how and where to get the vaccine for their daughters and how it will be paid for, will then want the vaccine for their daughters. Vaccine acceptability among parents depends on their beliefs that HPV infection is likely and dangerous, and that the vaccine is effective and safe [13]. Although a small minority of parents believe that HPV vaccination might cause girls to

become more sexually active, this belief does not appear to play a large role in vaccine acceptability [13–15].

A sixth potential barrier is federal, state, and local policies concerning vaccine provision. Because the vaccine has received federal approval, VFC will provide coverage for many uninsured female adolescents. However, the onus is still on parents to find a provider, determine coverage, and take their daughters in for three discrete doses over a 6-month period. Mandatory vaccine provision in schools has been a strategy used in the past for other vaccines that could potentially mitigate other barriers.

Our study examined the first potential barrier identified above: lack of HPV vaccine availability. We surveyed medical practices in areas of rural North Carolina with high rates of cervical cancer to characterize the practices' concerns about stocking and providing HPV vaccine. We also examined whether these concerns differed by whether the practices were providing or not providing HPV vaccines.

Methods

Medical practices

Study respondents were staff at medical practices in four counties in southeastern North Carolina: Duplin, Harnett, Sampson, and Wayne. These counties were selected from 11 North Carolina counties that met study inclusion criteria of having high rates of invasive cervical cancer (i.e., incidence >10 cases/100,000 women annually, 1993–2003; and mortality >4 cases/100,000 women annually, 1994–2004) and 20% or more African American residents. County cervical cancer incidence rates, which ranged from 10.8 to 13.9 cases/100,000 women annually, were higher than the corresponding national rate of 8.7 [16,17]. Cervical cancer mortality rates, which ranged from 4.2 to 6.5 deaths/100,000 women annually, were almost double the national mortality rate of 2.6 [16,17]. Because all but three of the 11 eligible counties clustered geographically in southeastern North Carolina, we chose among the eight counties in the same region. After matching the counties on population size, proportion of African American residents and rates of cervical cancer, we randomly selected the four study counties.

We attempted to contact all medical practices in the study counties who currently, or might in the future, provide HPV vaccines. Research staff identified medical practices through three sources: medical facilities registered with the North Carolina Immunization Board, medical service providers identified by the county health departments, and providers with active medical licenses registered with the North Carolina Medical Board. Eligibility criteria for inclusion of medical practices were serving female patients within the age range of 9 to 26 years and providing services in at least one of the following categories: pediatrics, family

Table 1
Characteristics of study practices (N = 71)

	%	Median (range)
Type of facility		
Private practice	66	
Federally qualified health center	21	
Public health department operated clinic	7	
Other (hospital-based clinics and military clinics)	6	
Type of clinicians at practice ^a		
Family/general practitioners	65	
Pediatricians	22	
Obstetricians/gynecologists	26	
Internists	30	
Size of practice		
Number of physicians		
0	6	
1	59	
2–3	17	
4+	18	
Number of physician's assistants		
0	63	
1	20	
2+	17	
Number of nurse practitioners		
0	58	
1	31	
2+	11	
Primary care practice ^b	75	
UCVDP provider	59	
Stocked VFC-provided HPV vaccine	44	
Used North Carolina Immunization Registry	45	
Number of patients seen in a week		150 (40–1125)
Patients' characteristics (as reported by practice) ^c		
Age 9 to 18 years	20%	(0%–100%)
Black	40%	(4%–98%)
Hispanic/Latino	10%	(1%–90%)
Privately insured	37%	(3%–100%)
Medicaid or North Carolina Health Choice	50%	(0%–90%)
Uninsured	15%	(0%–85%)

UCVDP = Universal Children's Vaccine Distribution Program and includes Vaccines for Children (VFC) program.

^a Sums to more than 100% because many practices had more than one type of clinician.

^b Other specialties include subspecialty care, family planning or women's health, sexually transmitted infection prevention and treatment, and vaccination services.

^c Practices reported the percentage of their patients in the categories shown. The median and range shown reflect the reported percentages for all practices.

or general medicine, general internal medicine, obstetrics, gynecology, vaccination, or treatment or prevention of sexually transmitted infections. We interviewed staff members who knew about vaccine availability and logistical issues around its provision. The North Carolina VFC program covered the HPV vaccine at the time of the study.

Procedures

Between July and November 2007, two trained interviewers called practices, determined eligibility, and asked to

speak with a staff member who could answer questions about HPV vaccine provision. Some interviews required the participation of multiple staff members because of the nature of the questions. Each interview required about 15 to 20 minutes to complete. The institutional review board of the University of North Carolina, Chapel Hill, approved the interview protocol.

Survey

A series of questions assessed concerns about HPV vaccine provision. The initial question read, "How much have the following issues been concerns to your practice?" and was followed by ten potential concerns: (1) too few patients want the HPV vaccine, (2) too few patients are in the recommended gender and age group for the HPV vaccine, (3) too high a cost to patients, (4) the practice or clinic usually provides few or no vaccines, (5) up-front costs of ordering and stocking the HPV vaccine, (6) inadequate reimbursement, (7) late reimbursement, (8) burden of determining insurance coverage, (9) vaccine expiring before use, and (10) inadequate refrigerator space. The response options were "no concern," "small concern," and "large concern." At the end of the 10-item list, issues identified as large concerns were followed up with the open-ended question, "Tell me more about why X is a concern?" The questionnaire also measured characteristics of medical practices and characteristics of the practices' patient populations. We pretested the questionnaire with five medical practices in rural North Carolina counties geographically removed from the study counties and revised it based on pretest results.

Data analysis

Because this paper is primarily descriptive, the main analyses are the tabulations of the frequency of the 10 concerns. We also compared the mean number of concerns between vaccine providers and vaccine nonproviders using a *t* test and examined crosstabulations for each concern between the HPV vaccine providers and nonproviders using

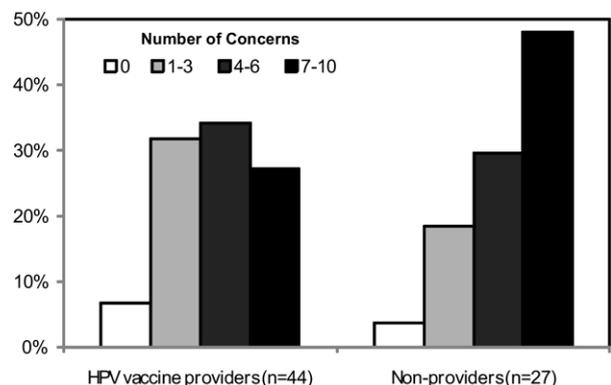


Figure 1. Distribution of concerns about HPV vaccine provision.

Table 2
Percent of practices reporting concerns about HPV vaccine provision

	All practices (N = 71)	HPV vaccine providers (n = 44)	HPV vaccine nonproviders (n = 27)	χ^2
Inadequate reimbursement	68	61	78	2.06
High cost to patients	66	66	67	.00
Burden of determining insurance coverage	66	57	82	4.55*
High up-front costs of ordering and stocking	61	55	70	1.75
Few patients want vaccine	58	55	63	.49
Vaccine expiring before use	56	43	78	8.14*
Few patients in recommended gender or age group	45	43	48	.17
Late reimbursement	44	34	59	4.31*
Practice provides few or no vaccines	25	18	37	3.14
Inadequate refrigerator space	18	14	26	1.69

* $p \leq .05$.

chi-square analyses. The statistical tests were two tailed, employed a critical alpha of .05, and were conducted using SPSS (Chicago, IL). To provide further insight into respondent concerns, their responses to the open-ended probe of “large” concerns appear after the quantitative data.

Results

Staff from 71 of the 96 practices contacted completed the survey (response rate = 74%). Twenty-one of 71 interviews required speaking with more than one staff person. Twenty-seven practices did not provide the HPV vaccine. Of 44 practices that provided the vaccine, 31 provided the HPV vaccine through North Carolina’s VFC program. Practices labeled as providers include four practices that had not yet provided doses but had it in stock. Respondents were primarily nurses (51%) or office managers (18%). Most interviews were with private practices (66%) or federally qualified health centers (21%), the majority of which provided primary care services (75%) (Table 1). Most practices included family practitioners (65%), but fewer had pediatricians, gynecologists/obstetricians, or internists. More than half were medical practices enrolled in the VFC program (59%). On average, practices characterized 41% of their patient populations as black and 19% as Hispanic. Practices characterized a smaller percentage of their patients as being uninsured (17%). Table 1 shows additional characteristics of participating medical practices and their patients.

HPV vaccine nonproviders had more concerns than did HPV vaccine providers on average (6.0 vs. 4.5, $t = 2.45$, $p < .05$). A smaller proportion of HPV vaccine providers than nonproviders endorsed 7-10 concerns (Figure 1). Practices’ specific concerns are described in greater detail below.

Inadequate reimbursement

Overall, inadequate reimbursement was the most commonly cited concern regarding the HPV vaccine (68%) (Table 2), frequently mentioned by both HPV vaccine providers and nonproviders. In the open-ended comments, some respondents reported that insurance companies may cover only slightly more than the cost of the vaccine. One vaccine provider said, “We pay one price, and insurance companies only want to give some money for the vaccine. We go in a hole not counting the cost of supplies.” A nonprovider noted that referring patients to other clinics to get vaccinated was cheaper than carrying the vaccine. Concerns about inadequate reimbursement were related to a level of uncertainty regarding potential insurance coverage and uptake of the HPV vaccine. One respondent from a vaccine-providing practice said, “It costs so much at the beginning and not knowing what insurance companies would reimburse is a concern.”

High cost to patients

The high cost of the HPV vaccine to patients was another commonly reported concern among practices (66%) among both HPV vaccine providers and vaccine nonproviders. One nonprovider stated, “Half of [our] patients are on Medicaid, and many have no insurance. The HPV vaccine is a large financial burden,” while a provider expressed, “The main concern is charge; people don’t get it if insurance doesn’t cover it.”

Burden of determining insurance coverage

Sixty-six percent of practices were concerned about the burden of determining insurance coverage for the HPV vaccine. Although this concern was high among both provision groups, statistically significantly more vaccine nonproviders (82%) than vaccine providers (57%) mentioned it ($p = .03$). Respondents explained that insurance coverage varies by insurance company and insurance plan, and that

determining insurance coverage is a time-consuming task that takes up substantial staff time. One respondent from a nonproviding practice said, “[Determining coverage is] already time consuming. You have to spend a lot of time on the phone to get all that information,” whereas another from a providing practice stated “[We] don’t have time to call. Drug reps tell offices to tell the patients to contact their own insurance, but adolescents won’t really do that.”

High up-front cost of ordering and stocking

Many respondents (61%) stated that the high up-front cost of ordering and stocking the HPV vaccine was a concern to their practice. More HPV vaccine nonproviders (70%) than vaccine providers (55%) were concerned with up-front costs, but the difference was not statistically significant. The costliness of ordering and stocking the HPV vaccine was perceived as a financial risk related to uncertainty about rates of vaccine uptake and insurance coverage. Some respondents said that the up-front costs and concerns about losing money prevented their practice from providing the HPV vaccine. One nonprovider explained, “This is a business concern. Inventory is a huge issue, an investment. Vaccine ties up money. Cash flow is tight because it is primary care... The HPV vaccine... ties up money.”

Few patients wanting the vaccine

Practices were somewhat less concerned about too few patients wanting the HPV vaccine, but it was still a common concern (58%). Even among practices that did not report too few patients in the recommended groups, 44% were concerned that too few patients want the vaccine. One provider stated that the HPV vaccine “is just starting to catch on. People are just starting to inquire about the HPV vaccine.” Another provider noted that there is “some hesitancy of getting HPV vaccine because of the fact it is a new vaccine. Possible regret. It hasn’t been on the market long.”

Expiring before use

Many more vaccine nonproviders (78%) than vaccine providers (43%) were concerned about the HPV vaccine expiring before use ($p = .004$). This concern was largely related to concerns related to potential low uptake and loss of money. One provider stated, “We spend the money to order the HPV vaccine and if people don’t want it then we are not reimbursed for it.” Similar comments were made by another provider, “HPV vaccine is very expensive. You can’t just buy one or two [doses]. If you purchase it, you have to buy many and, if patients don’t get the vaccine, you eat the cost yourself.”

Few patients in recommended sex or age group

Just under half of the practices (45%) were concerned with having too few patients in the recommended sex or age group for the HPV vaccine. Some indicated that a lack of eligible patients prevented their practices from ordering the HPV vaccine. As one respondent stated, “We don’t order it because we don’t have many patients in that age range to receive the vaccine.”

Late reimbursement

Slightly less than half of the practices had concerns about late reimbursement for the HPV vaccine. More vaccine nonproviders (59%) than vaccine providers (34%) expressed worry about late reimbursement ($p < .04$). Some respondents noted that late reimbursement for the HPV vaccine was a financial hardship that prevented their practice from being able to order and maintain a stock of the HPV vaccine. One nonprovider explained, “You normally have to purchase up front and get reimbursed 45 to 60 days later. It is an issue. We looked at the HPV vaccine months ago. It is expensive. It is hard to maintain, and we are not ready to stock yet.” This was particularly true for practices with fewer financial resources, as one nonprovider explains, “Investment is just out there until we get paid—tied up money. Two hundred dollars is a lot of money for a small practice.”

Other concerns

About a quarter of the practices reported that not usually providing vaccines was a concern. Even though many more HPV vaccine nonproviders than HPV vaccine providers were concerned with this, the difference was not significant. Inadequate refrigerator space was the least frequently mentioned concern.

Conclusions

To our knowledge, this is the first study to examine concerns about the HPV vaccine among medical practices. We studied medical practices in rural, medically underserved areas with high rates of invasive cervical cancer. Although medical practices’ concerns have the potential to hinder the availability of the HPV vaccine, it is particularly important to understand how they affect vaccine coverage in already underserved areas.

Reported concerns about the HPV vaccine were generally high among the study practices. Overall, surveyed practices were most concerned with inadequate reimbursement, the high cost of the vaccine to patients, and the burden of determining insurance coverage. Practices not providing the HPV vaccine consistently had more concerns than did HPV vaccine providers. Concerns reported more often by practices not providing the vaccine were the HPV vaccine expiring before use, the burden of determining insurance coverage, and late reimbursement. However, vaccine providers and nonproviders voiced many of the concerns equally often.

Concerns about HPV vaccine provision may prevent some medical practices from offering the vaccine to patients, thereby inhibiting patient access in areas where healthcare access is already limited. Further research is needed on how concerns about HPV vaccine affect provision and to determine how best to address these concerns. This may be important for decreasing gaps in coverage and ensuring more universal HPV immunization, especially among populations most in need.

Our study has several strengths and limitations. We focused on high-risk and high-need areas, attempting to interview all potential vaccine providers in the region. Although our sample size was limited, we made comprehensive efforts to contact all relevant providers in selected counties, and thus the data are likely to be generalizable to medical practices in the rural South and perhaps other low-resource areas of the United States. Additional research is needed to establish how generalizable the findings are to urban and high resource settings. We attempted to interview the practice staff members who were most likely to know about HPV vaccine availability and logistical issues around its provision; however, we may not have always interviewed the persons making the decision of whether or not to stock the HPV vaccine at their practice. Because we interviewed as many staff members as necessary to obtain complete answers to all survey questions, we believe the interviews were likely to capture most concerns related to stocking and providing vaccine. Although few respondents were physicians, understanding how their beliefs might affect their decisions to provide the vaccine to individual patients was not the purpose of the study; instead, we evaluated the structural and logistical issues faced by practices in deciding to stock and provide the HPV vaccine. Although the one military clinic we interviewed likely does not have input into decisions related to stocking vaccines, the concerns that were indicated by the clinic staff might be instructive in understanding why other practices choose not to stock it. The cross-sectional design of the study did not allow us to rule out several alternative explanations for the association between concerns and vaccine provision, but we feel this is a reasonable limitation for an early descriptive study.

Because this study was conducted relatively early in vaccine roll-out, practices' concerns may have changed as the issues surrounding vaccine provision have changed or become more salient. Nonetheless, many of the issues identified in this study appear to be important concerns of the clinics. Last, although concerns expressed by medical practices may be common problems for any vaccine, they reflect potential barriers to HPV vaccine provision in a high-risk area where the HPV vaccine is particularly important.

The present study found a substantial number of concerns about HPV vaccine provision among medical practices that may potentially impact HPV vaccine availability. In addition to focusing on how to best overcome these practices' concerns, future research should also address other potential barriers to

HPV vaccine provision: difficulty in finding a provider that accepts adolescents' insurance and affording costs not covered by insurance, limited awareness of available services, lack of motivation to get vaccinated, and policy constraints.

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