Published in final edited form as:

Vaccine. 2009 May 21; 27(24): 3195–3200. doi:10.1016/j.vaccine.2009.03.042.

Human Papillomavirus (HPV) Vaccine Availability, Recommendations, Cost, and Policies Among Health Departments in Seven Appalachian States

Mira L. Katz¹, Paul L. Reiter¹, Brenda C. Kluhsman², Stephenie Kennedy³, Sharon Dwyer⁴,
Nancy Schoenberg⁵, Andy Johnson⁷, Gretchen Ely⁶, Karen A. Roberto⁴, Eugene J.
Lengerich², Pamela Brown³, Electra D. Paskett¹, and Mark Dignan⁷

¹ College of Public Health and the Comprehensive Cancer Center, The Ohio State University

² College of Medicine, Pennsylvania State University

³ Mary Babb Randolph Cancer Center, West Virginia University

⁴ Department of Human Development, Virginia Polytechnic Institute and State University

⁵ Department of Behavioral Science, University of Kentucky

⁶ College of Social Work, University of Kentucky

⁷ Department of Internal Medicine, University of Kentucky

Abstract

Telephone interviews of health department personnel in six states and review of an immunization database from one state were conducted to assess human papillomavirus (HPV) vaccine availability, recommendations, cost, policies, and educational materials in health departments in seven Appalachian states. Most (99.1%) health departments (n=234) reported receiving patient requests for the HPV vaccine, and only two (1%) health departments reported that they did not provide the vaccine for patients. HPV vaccine supply was reported to not meet demand in 10.5% (24/228) of health departments due to high costs. Level (state, region, county) at which policy about the HPV vaccine was determined, vaccine recommendations, costs, and available educational materials varied among states. This study documented variation in vaccine availability, recommendations, cost, policies, and educational materials in Appalachian health departments that could significantly affect vaccine distribution. Findings highlight the need for more comprehensive and consistent policies that maximize accessibility of the HPV vaccine to women, especially those in underserved areas.

Keywords

HPV Vaccines; Health Care Disparities; Appalachian Region; Health Policy

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Correspondence Mira L. Katz, PhD, Associate Professor, College of Public Health, The Ohio State University, A352 Starling Loving Hall, 320 West 10th Avenue, Columbus, Ohio 43210, (614) 293-6603, FAX (614) 293-5611, E-mail: mira.katz@osumc.edu.

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1. INTRODUCTION

Cervical cancer incidence and mortality rates have steadily decreased over the past several decades in the United States (U.S.) due to the introduction of the Papanicolaou (Pap) smear, yet it is estimated that 11,070 new cases of invasive cervical cancer will occur and 3,870 women will die from this disease in the U.S. during 2008 [1]. Approximately 70% of cervical cancers are caused by high-risk human papillomavirus (HPV) types 16 and 18 [2,3] and low-risk HPV types 6 and 11 cause genital warts and low-grade cervical lesions, but do not lead to cervical cancer [4]. HPV infection is a common sexually transmitted infection in the U.S., with an estimated 20 million individuals infected with HPV; another 6.2 million become newly infected each year; and approximately half of all sexually active men and women will become infected during their lifetime [5,6].

Elevated cervical cancer incidence and mortality rates persist among certain segments of the U.S. population, because women have biologic variations, different behavioral risk factors, and have not benefited equally from cervical cancer screening, follow-up of abnormal Pap smears, and treatment [7]. One example of a population group still experiencing increased cervical cancer rates is women living in the Appalachian region of the U.S. [8–11]. Many social factors contribute to the cervical cancer disparities among women living in this geographic region, including values, beliefs, and attitudes about cervical cancer, the social environment (limited healthcare access and public transportation, low socioeconomic status), pathophysiological changes (prevalence of HPV), provider-patient communication issues (including lack of recommendation for screening), psychosocial factors (fear of cancer, stress), as well as behavioral factors (tobacco use, sexual activity) [12–16].

In June 2006, the U.S. Food and Drug Administration (FDA) approved a quadrivalent vaccine (Gardasil®), given in three doses, for females 9–26 years of age to protect against infection with HPV types 6, 11, 16, and 18 [17]. The Advisory Committee on Immunization Practices recommends HPV vaccination for females age 11–12 years, but the vaccine may be administered as early as age 9, with catch-up vaccinations for females ages 13–26 [18]. In September 2008, the FDA extended the vaccine for the prevention of vaginal and vulvar cancer caused by HPV types 16 and 18 [19].

Acceptance of the HPV vaccine among women has varied and most studies evaluating HPV vaccine acceptance were conducted prior to FDA approval of the vaccine [20]. Additionally, among medical practices, the potential barriers for providing the HPV vaccine have been described and include the financial issues associated with stocking and providing the vaccine [21]. Specifically in Appalachia, a few studies have documented general acceptance of the HPV vaccine among women for themselves or for their daughters [22–24].

Women living in Appalachia have a great potential to benefit from widespread diffusion and uptake of the HPV vaccine because of the persistence of high cervical cancer incidence and mortality rates in this region [8,11,25]. The HPV vaccine is available through the federally funded Vaccines For Children (VFC) Program, however, little is known about vaccine availability and the cost of the vaccine within public health departments serving women who live in the Appalachian region.

To gain insight into HPV vaccine availability, recommendations, costs, policies, and educational materials being used in public health departments in Appalachia, we collected data from health departments serving Appalachian counties in seven states. The findings from this study provide information that can be used to evaluate existing policies, formulate new policies, and to develop community-based interventions to improve HPV vaccine rates among women living in Appalachia.

2. METHODS

This study was conducted in collaboration with the five institutions that compose the Appalachian Community Cancer Network (ACCN), one of the 25 participants of the National Cancer Institute (NCI)-funded Community Networks Program. The goal of the ACCN is to support community-based participatory education, training, and research in Appalachia. ACCN includes investigators at the University of Kentucky (UK), The Ohio State University (OSU), The Pennsylvania State University (PSU), Virginia Polytechnic Institute and State University (VT), and West Virginia University (WVU). ACCN-affiliated institutions also serve residents living in the Appalachian counties of New York and Maryland. ACCN investigators partner with community members and organizations to focus on prevention and early detection of cervical, lung, and colorectal cancers, all of which have high incidence and mortality rates in this seven-state Appalachian region.

2.1 Development of the Questionnaire

A semi-structured questionnaire was developed and pilot tested with personnel working in public health departments by the Ohio ACCN team of investigators and staff. The questionnaire was then reviewed and revised by investigators and staff from the five ACCN institutions, before being used in this study. The questionnaire consisted of a mix of open and closed ended questions that focused on HPV-related health policy issues, vaccine availability, provider recommendations for vaccination, cost and financial assistance for the vaccine, and HPV vaccine educational materials available to patients at the health departments. The questionnaire is available by request. The Institutional Review Board at each institution (UK, OSU, PSU, VT, WVU) approved this study.

2.2 Telephone Interviews

In six states, telephone interviews were conducted between April and July 2008 with a representative from each health department. At each institution, interviews were conducted by a staff member or graduate student who had received training on administration of the survey by an ACCN investigator or staff member. Each health department serving the Appalachian counties in the six states was contacted, and the interviewer asked to speak to the person most knowledgeable about HPV vaccine provision in his/her health department.

After a brief introduction explaining the purpose of the study, individuals verbally agreed to be interviewed, their names and positions were documented, and the interviews were conducted by following the questions in the interview guide. The interviews took approximately 20 minutes to complete, allowing time for discussion. Responses to the questions were recorded on an electronic Teleform survey.

2.3 Immunization Database Review

In Pennsylvania, there is not a local health department structure comparable to the other states, therefore, data were obtained from a statewide immunization database provided by the Director of Immunizations and staff at the Pennsylvania Department of Health. These data were obtained by an ACCN staff member at Pennsylvania State University. Information was recorded on an electronic Teleform survey.

2.4 Data Analysis

All completed surveys were sent to the Behavioral Measurement Shared Resource of the OSU Comprehensive Cancer Center, and were entered into a database by scanning and verifying the electronic documents. SAS version 9.1 (Cary, NC) statistical software was used to calculate summary statistics (means, standard deviations, percentages).

3. RESULTS

A total of 234 health departments were identified as eligible to participate in this survey study. At 181 (77.3%) departments, a representative was contacted and completed the survey with information from the remaining 53 (22.7%) obtained from the Pennsylvania immunization database. Although job titles varied among the key personnel, the majority of interviews were conducted with department nurses, nursing supervisors, senior immunization nurses, and directors of immunization programs. The number of counties (n=227) located in Appalachia in each of the seven states is listed in Table 1, and ranges from 13% of the counties in Maryland to 100% of West Virginia. Depending on the state, health departments were organized at the city, county, district/region, or state level. In addition, the level at which health policy, and specifically policy about the HPV vaccine was determined, varied among states. Although HPV vaccine policy was determined at multiple levels in some states, it included the state level in five states (excluding Kentucky and Maryland).

A significant portion of the data collected during the interviews focused on HPV vaccine requests, availability, recommendations, and costs (Table 2). Most (230/232; 99.1%) of the health departments reported receiving patient requests for the HPV vaccine. On average, monthly requests for the vaccine in health departments per state ranged from 10.3 to 21.5 requests.

Although most (99.1%) health departments across the states reported that they had the HPV vaccine available for patients, two departments reported not supplying the vaccine. One county health department in Ohio reported that the HPV vaccine was not needed for the women in their county, and one health department in New York was being re-organized and was planning to have the HPV vaccine available in the near future. Health departments also reported differences in their supply of the HPV vaccine. Supply met demand for the vaccine in 100% of the health departments in Pennsylvania, whereas supply met demand in only 48% of the health departments in Virginia (Table 3). Reasons provided for the lack of available HPV vaccine were the high costs associated with stocking the vaccine and the high demand for the vaccine by patients at some health departments.

Among health departments providing the HPV vaccine, the estimated average monthly number of HPV vaccine doses provided to patients ranged from 6.4 to 22.5 doses. An estimation of the average percent of health department female patients aged 9 to 26 years who had received the vaccine also varied from a mean of 15.0% to 45.4% of the patients. The health department personnel also estimated that the percent of female patients who began the vaccine regimen and received all three doses of the HPV vaccine varied from a mean of 37.9% to 90.3%.

The HPV vaccine was available through the Vaccines For Children (VFC) program in all states, and some health departments in six of the seven states limited the HPV vaccine only for patients in the VFC program (Table 4). This limited availability of the vaccine was reported by none of the health departments in Maryland to all of the health departments in Pennsylvania.

In health departments that provide the HPV vaccine, 99.1% (229/231) reported that their healthcare providers recommend the vaccine to patients. Health department personnel reported that the age range for HPV vaccine recommendation varied from an average from 9.0 to 10.7 years of age to an average age of 18.0 to 26.0 years. In three states, personnel in four health departments reported that the HPV vaccine was recommended for females above the age of 26 and in five states (KY, NY, OH, VA, WV) half of the health departments reported providing the HPV vaccine to females younger than 18 years of age without parental permission (among those who did not qualify for the VFC program).

The cost of the HPV vaccine per dose for women who did not qualify for the VFC program varied within and among states. The average cost per dose among states ranged from no cost in Virginia to \$146.00 in Maryland. The largest cost difference within one state was in Kentucky where the vaccine ranged from no cost to the patient in some departments to \$160 per dose in other health departments. In health departments that provide the HPV vaccine for patients who do not qualify for the VFC program, financial assistance varied within and among states and ranged from being available in 17% to 100% of the health departments.

Information about available educational brochures and the source of the brochures also varied within and among states (Table 5). Most (231/233; 91.1%) health departments reported having HPV educational materials available for their patients. Among health departments who provided HPV vaccine educational materials, most reported using HPV vaccine brochures/fact sheets provided by the Center for Disease Control and Prevention (CDC) (191/230; 83.0%) or Merck & Co, Inc. (153/231; 66.2%). Although Pennsylvania reported using educational brochures developed specifically for their health departments, only a small percent of the health departments in three other states (KY, OH, WV) reported having developed educational materials specifically for their health department.

4. DISCUSSION

A disproportionate cervical cancer burden persists for women living in Appalachia. The reason for this continuing public health problem is multifaceted and includes many of the social determinants of health that have been described by Marmot and Wilkinson [26]. The development and distribution of the HPV vaccine is important to women living in Appalachia because it protects against infection with high-risk HPV types 16 and 18, which cause more than 70% of cervical cancers [5,6]. Since HPV is a sexually transmitted infection (STI), various concerns about the HPV vaccine have emerged including sexual politics (young women's bodies and behaviors), parental rights, costs, efficacy and safety, and cultural attitudes [27–29]. These concerns have been raised and brought to the general public's attention by advocates who have suggested mandating HPV vaccination in the U.S. [27,28,30,31].

To our knowledge, this is the first study to provide information regarding the HPV vaccine availability in public health departments across multiple Appalachian states where the cervical cancer burden is disproportionately high. This is important because health departments provide medical care to many of the residents living in Appalachia [32]. Overall, there was variation within and among state health departments for most of the information documented in this study. Differences occurred relative to the level at which HPV vaccine policy decisions were made (state, district/region, county, city), vaccine availability, providers' recommendations for the vaccine, patient costs, the availability of financial assistance, and the educational materials used by the different public health departments. Although some variation among states was expected, the variation within states was not predicted, especially the HPV cost differences among health departments within one state for females who do not qualify for the VFC program.

Results of this study also raise policy issues regarding provision of the HPV vaccine by public health departments. For example, in Pennsylvania, females who do not qualify for the VFC program because of age are referred to other providers and the cost of the vaccine is covered by public assistance or on a sliding scale. In other states, some public health departments limit the HPV vaccine solely to patients who are eligible for the VFC program. The vaccine cost ranged from being free of charge to \$160 per dose at public health departments within one state (if the patient does not qualify for the VFC program). Some health departments provided financial assistance for the vaccine while others provided no assistance. These data suggest that health departments located in Appalachia do not provide the vaccine to all women who

are eligible to receive it. Thus, access to the HPV vaccine is limited to many women who would benefit most from being vaccinated.

Other interesting findings in this study are that some health departments reported that they provided the vaccine to women under the age of 18 years without parental permission and other departments reported providing the vaccine to women over the age of 26 years. Both practices are contrary to the current FDA approved guidelines for the HPV vaccine [17]. Although these practices are probably occurring elsewhere, there are no reports to document this in the scientific literature. In one survey study, pediatricians were more likely to support vaccination without parental permission than the general public (77% vs. 47%; $p < 0.001$), but this study did not report actual practice patterns of the pediatricians [33]. The clinical benefit of vaccinating women older than 26 years of age is less clear based on cost-effectiveness data [34]. Although women may receive the vaccine “off label,” it is important to note that insurance companies are unlikely to cover the cost of the vaccine among women in this age group [35, 36].

The findings of this study highlight the potential complexity of developing policies about the HPV vaccine in a geographic region where the cervical cancer burden is high. Currently, there is legislative activity in many states focused on many issues including but not limited to mandating the HPV vaccine for school enrollment (with parental right to opt out provision), mandating insurance coverage, state funding to support vaccination and to develop public awareness campaigns and educational programs. If the HPV vaccine is required by law, it is predicted that the vaccination rates would probably increase substantially similar to the increased vaccination rate for the hepatitis B vaccine after requiring it by law [37,38]. Failure of previous legislative attempts to require the HPV vaccine have been influenced by lack of knowledge about the vaccine, lack of long-term results, negative feelings toward the pharmaceutical industry including the cost of the vaccine, and cultural and value differences [28].

This study has several limitations including that the method of obtaining the information in one state (Pennsylvania statewide database and interview with the Director of the state’s Immunization Program) was different than how the information was obtained from the other six states (telephone interviews with health department personnel). Although the method in one state was different, the information obtained from this state was complete and there were no outliers. Another limitation was that the person identified as the most knowledgeable about the HPV vaccine at each health department provided estimations of the numbers of HPV vaccine requests, provider recommendation patterns, monthly doses provided, the number of females who have received the vaccine and all three doses of the HPV vaccine. While the numbers are estimations, and are higher than a recent nationwide report of HPV vaccination among adolescents [39], the key personnel who participated in this study were chosen as respondents because they knew what was happening in their department. In addition, the nationwide report only included adolescents age 13 to 17 for the year 2007 [39]. Another limitation was the cross-sectional study design which did not allow us to capture changing HPV vaccine policy or availability, although we believe that this would be limited because the study was completed in a relatively short time frame. Some variation among states may be due to differences in the organization of the public health departments in those states and may not be specific to the HPV vaccine. Thus, the findings may not be generalizable to public health departments located in non-Appalachian states, the non-Appalachian regions of the states included in this study, or other Appalachian states.

The strength of this study included the use of a questionnaire designed to obtain HPV vaccine data from the public health departments providing health services to women living in the Appalachian counties of seven states. This allowed us to document important variations about

the provision of the HPV vaccine within and among states, which is important because of the significant burden from cervical cancer among women living in this region of the United States.

Findings from this study suggest that there is variation within and among public health departments located within Appalachian states regarding HPV vaccine policy, availability, recommendations, costs, financial assistance, and educational materials. This study highlights the many challenges to deliver new scientific advancements in the prevention of cancer in a user-friendly format to underserved populations, especially rural populations. The differences within and among states found in this study also highlight the need for more consistent policies that maximize accessibility of the HPV vaccine to women, especially those living in underserved areas.

Acknowledgments

This study was supported by National Cancer Institute Grants #CA113932 (Appalachia Community Cancer Network), CA107079 (MLK), and the Behavioral Measurement Shared Resource at The Ohio State University Comprehensive Cancer Center, P30 CA016058.

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Number Of Counties In Appalachia, Health Departments Serving Appalachian Counties, and Level Of Health Policy In Seven States

Table 1

	KY	MD	NY	OH	PA	VA	WV
Number of counties in Appalachia	51/120 (42.5%)	3/24 (12.5%)	14/62 (22.6%)	29/88 (33.0%)	52/67 (77.6%)	23/95 (24.2%)	55/55 (100%)
Number of health departments (city, county, region, state) in Appalachia	51	3	14	37	53	27	49
Number of health department districts/regions in state	15	n/a	4	4	6	35	8
Health Department districts/regions associated with counties located in Appalachia	6	n/a	3	3	6	6	8
Level health-related policy issues are determined	S,R,C	S,C	S,C	S,R,C	S	S	S,R,C
Level HPV vaccine policy is determined	R,C	C	S	S,R,C	S	S	S,C

KY= Kentucky; MD=Maryland; NY=New York; OH=Ohio; PA=Pennsylvania; VA=Virginia; WV=West Virginia

HPV= Human Papillomavirus;

n/a=not applicable, no health department districts/regions

S= State; R= Region/District; C=County

* On October 8, 2008, President Bush signed into law the Appalachian Regional Development Act Amendments of 2008 which added new counties to the Appalachian Region (3 in Ohio, 3 in Kentucky, and 2 in Virginia). These new Appalachian counties were not included in this study.

* OH: includes 8 city health departments; PA: 1 county has 2 departments; VA=23 counties and 7 city departments report to 27 departments; WV: 2 counties report to 1 department and 6 counties report to 1 department

Table 2
HPV Vaccine Requests And Recommendations In Health Departments In Seven States

	KY (n=51)	MD (n=3)	NY (n=14)	OH (n=37)	PA (n=53)	VA (n=27)	WV (n=49)
Requests							
Patients request the HPV vaccine in health department	50/50 (100%)*	3/3 (100%)	13/14 (93%)	37/37 (100%)	53/53 (100%)	26/27 (96%)	48/48 (100%)*
Estimated number of HPV vaccine requests per month [Mean (SD)]	16.6 (30.9)*	21.5 (26.2)*	10.3 (11.2)*	13.2 (12.9)*	n/a	15.1 (15.4)*	11.8 (8.6)*
Recommendations							
If vaccine available, providers recommend the HPV vaccine	50/51 (98%)	3/3 (100%)	13/13 (100%)	35/36 (97%)	53/53 (100%)	27/27 (100%)	48/48 (100%)*
If recommended: youngest age [Mean (SD)]	10.4 (1.7)	9.0 (0)	10.6 (1.4)	10.4 (1.1)	9.0 (0)*	10.5 (1.7)	10.7 (1.5)
If recommended: oldest age [Mean (SD)]	24.2 (3.6)	26.0 (0)	23.2 (3.9)	23.9 (3.6)	18.0 (0)*	19.5 (3.3)	21.6 (4.1)

* Missing data; n/a= data not available HPV=Human Papillomavirus; VFC=Vaccine For Children

KY= Kentucky; MD=Maryland; NY=New York; OH=Ohio; PA=Pennsylvania; VA=Virginia; WV=West Virginia

Table 3
HPV Vaccine Availability In Health Departments In Seven States

	KY (n=51)	MD (n=3)	NY (n=14)	OH (n=37)	PA (n=53)	VA (n=27)	WV (n=49)
HPV vaccine available in health department	51/51 (100%)	3/3 (100%)	13/14 (93%)	36/37 (97%)	53/53 (100%)	27/27 (100%)	48/48 (100%) *
Estimated number of HPV vaccine doses provided per month at health department [Mean (SD)]	22.5 (38.3) *	14.0 (13.9)	15.3 (16.9) *	11.4 (10.2) *	6.4 (9.5)	11.8 (12.8) *	14.8 (10.8) *
Estimation of the percent of females (9–26 years old) who have received HPV vaccine [Mean (SD)]	25.7 (24.5) *	15.0 (0) *	45.4 (34.4) *	24.1 (27.6) *	n/a	15.9 (18.8) *	33.9 (27.3) *
Estimation of the percent of females who received initial vaccine dose completed all 3 doses of HPV vaccine [Mean (SD)]	43.5 (36.0) *	60.0 (28.3) *	58.0 (34.7) *	90.3 (10.4) *	37.9 (19.6)	47.5 (41.9) *	88.1 (16.2) *
Current HPV vaccine supply meets demand	48/51 (94%)	2/3 (67%)	10/13 (77%)	33/35 (94%) *	53/53 (100%)	13/27 (48%)	45/46 (98%) *

KY= Kentucky; MD=Maryland; NY=New York; OH=Ohio; PA=Pennsylvania; VA=Virginia; WV=West Virginia

* missing data

HPV Vaccine Provided Via The VFC Program And Cost In Health Departments In Seven States

Table 4

	KY (n=51)	MD (n=3)	NY (n=14)	OH (n=37)	PA (n=53)	VA (n=27)	WV (n=49)
HPV vaccine available only through VFC Program	16/51 (31%)	0	5/13 (39%)	18/36 (50%)	53/53 (100%)	17/27 (63%)	33/48 (69%) *
HPV vaccine available if patient does not qualify for VFC Program	35/51 (69%)	3/3 (100%)	8/13 (62%)	18/36 (50%)	0	10/27 (37%)	15/48 (31%) *
Females (< 18 years) who do not qualify for VFC Program may receive vaccine without parental permission	3/35 (9%)	0	1/6 (17%) *	9/18 (50%)	0	5/10 (50%)	10/15 (67%)
Females who do not qualify for VFC Program: cost (dollars) per dose of HPV vaccine [Mean \$ (SD)]	\$120 (28)	\$146 (15) *	\$98 (61)	\$132 (26)	n/a	0	\$89 (66) *
Females who do not qualify for VFC Program: financial assistance available for HPV vaccine	6/35 (17%)	3/3 (100%)	5/7 (71%) *	5/18 (28%)	n/a	1/1 (100%) *	10/14 (71%) *

* Missing data; n/a=data not available SD=standard deviation

HPV=Human Papillomavirus; VFC=Vaccine For Children

KY= Kentucky; MD=Maryland; NY=New York; OH=Ohio; PA=Pennsylvania; VA=Virginia; WV=West Virginia

Table 5
Human Papillomavirus (HPV) Vaccine Educational Brochures and Brochure Source in Health Departments

	KY (n=51) n (%)	MD (n=3) n (%)	NY (n=14) n (%)	OH (n=37) n (%)	PA (n=53) n (%)	VA (n=27) n (%)	WV (n=49) n (%)
HPV vaccine educational brochures available in health departments	51/51 (100)	3/3 (100)	13/14 (92.9)	36/37 (97.3)	53/53 (100)	27/27 (100)	48/48 (100)*
Source of HPV vaccine brochures							
Health Department developed brochure	10/51 (19.6)	0	0	1/35 (2.9)*	53/53 (100)	0	4/48 (8.3)*
Merck & Co., Inc.	37/51 (72.6)	3/3 (100)	13/13 (100)	29/36 (80.6)	0	27/27 (100)	44/48 (91.7)*
Center for Disease Control and Prevention (CDC)	42/50 (84.0)*	3/3 (100)	11/13 (84.6)	21/36 (58.3)	53/53 (100)	21/27 (77.8)	40/48 (83.3)*
Other**	18/50 (36.0)*	1/3 (33.3)	7/13 (53.9)	14/29 (48.3)*	0	4/26 (15.4)*	21/46 (45.7)*

KY= Kentucky; MD=Maryland; NY=New York; OH=Ohio; PA=Pennsylvania; VA=Virginia; WV=West Virginia

* missing data

** Additional sources of HPV vaccine educational materials available in health departments: American Cancer Society, American Social Health Association, Ohio Department of Health, West Virginia Vaccines For Children, West Virginia DHHR