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Community-Based Screening for Cervical Cancer: A Feasibility Study of Rural Appalachian Women

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Abstract

Objectives—To describe women's comfort levels and perceptions about their experience self-collecting cervico-vaginal swabs for HPV testing; to determine whether nurse-guided patient navigation increases the odds of women receiving a traditional Pap test after HPV screening; and to test the hypothesis that women testing positive for oncogenic HPV would be more likely to have a subsequent Pap test than those testing negative.

Methods—400 women were recruited from eight rural Appalachian counties, in 2013 and 2014. After completing a survey, women were provided instructions for self-collecting a cervico-vaginal swab. Specimens were tested for 13 oncogenic HPV types. Simultaneously, women were notified of their test results and offered initial navigation for Pap testing. Chart-verified Pap testing within the next six months served as the endpoint.

Results—Comfort levels with self-collection were high: 89.2% indicated they would be more likely to self-collect a specimen for testing, on a regular basis, compared to Pap testing. Thirty women (7.5%) had a follow-up Pap test. Women receiving added nurse-guided navigation efforts were significantly less likely to have a subsequent test (P = .01). Women testing positive for oncogenic HPV were no more likely than those testing negative to have a subsequent Pap test (P = .27). Data were analyzed in 2014.

Conclusions—Rural Appalachian women are comfortable self-collecting cervico-vaginal swabs for HPV testing. Further, efforts to re-contact women who have received an oncogenic HPV test result and an initial navigation contact may not be useful. Finally, testing positive for oncogenic HPV may not be a motivational factor for subsequent Pap testing.

Keywords

Cervical cancer screening; HPV testing; self-collection; Appalachia; rural

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Contributors

R. Crosby conducted the analysis and led the writing of the article. T. Collins and N. Jones guided data collection. R.C. Vanderpool, M. E. Hagensee, N. Nelson, A. Parrish, T. Collins, and N. Jones assisted with analysis, interpretation, and writing. All authors approved the final article as submitted.

Human Subjects Protection

This study was approved by the institutional review board of the University of Kentucky.

Introduction

Cervical cancer mortality is preventable if women and their health care providers remain vigilant about following Pap-testing guidelines: cytology every 3 years from ages 21 through 65.[1] Although traditional, clinic-based Pap testing remains valuable,[2,3] the Food and Drug Administration recently (April 2014) approved the cobas® Human Papillomavirus (HPV) Test (to detect HPV types 16 and 18) as an initial screening method.[4] This approval creates an important opportunity, in that cervico-vaginal swabs can be self-collected allowing screening to occur in non-clinical settings. Ample evidence exists suggesting that self-collected swabs for HPV testing are comparably effective to clinician-collected samples.[5–16] Studies of women who have self-collected cervico-vaginal swabs for HPV testing have concluded that self-collection is easy to perform, provides privacy, and is less embarrassing and more comfortable to women than physician collected samples.[7–9,12,13,16,17–21] Evidence also supports the idea that use of self-collected swabs for HPV testing can become a valuable strategy for reaching underserved populations.[5–9,12,14,16,18–21]

Two behavioral research questions emerge from the new opportunities to reach women who may not be adherent to Pap screening guidelines. First, the question of whether patient navigation (assisting women, as needed, to complete all recommended steps in the medical care process) can be applied to women testing positive for oncogenic HPV via non-clinical testing (self-collected cervico-vaginal swabs) is vital. Given the present ability to have women self-collect cervico-vaginal swabs, making refinements in patient navigation for those tested in the community is now an important endeavor. Patient navigation programs are especially effective for increasing screening rates for breast and colorectal cancers.[22–23] Related to cervical cancer screening, recent interventions reveal that patients who receive navigation services self-report completing Pap testing at significantly higher levels than do control groups.[24–25] However, self-reporting of Pap tests does not prove the validity of using self-testing for HPV DNA detection.[26] Further, to our knowledge, only one study has been published regarding the use of self-collected cervico-vaginal swabs as a component of a navigation intervention.[21] An obligation of testing women in non-clinical settings is the corresponding effort needed to bring those testing positive for oncogenic HPV to a clinic for Pap testing, colposcopy with directed biopsy, and possible treatment. Key issues to receiving screening and care related to cervical cancer among Appalachian women could include economic and environmental barriers that prevent regular Pap testing.[21,28–29]

The second behavioral question involves whether testing positive for an oncogenic HPV type may motivate women to seek clinical prevention services has not yet been addressed empirically. The purpose of this study was threefold: 1) to describe women's comfort levels and perceptions about their experience of self-collecting cervico-vaginal swabs for HPV testing, 2) to determine whether nurse-guided patient navigation efforts increase the odds of women receiving a Pap test after being screened for HPV via self-collected swabs not collected in a clinical setting, and 3) to test the hypothesis that women testing positive for oncogenic strains of HPV would be more likely to have a subsequent Pap test than those testing negative.

Methods

Study Sample

A total of 441 women were invited to participate in the study. Of these, 41 refused yielding a participation rate of 90.7% and a sample size of 400. Recruitment occurred in eight economically distressed counties (as designated by the Appalachian Regional Commission)[27] of rural Appalachian Kentucky from late 2013 through mid-year of 2014. Economic barriers include lack of health insurance or lack of the ability to cover co-payments; whereas environmental barriers include issues such as transportation and childcare. Also, the selected area experiences one of the nation's highest death rates from cervical cancer.[30] Eligibility criteria were: 1) being between 30–65 years of age, 2) reporting not having a Pap test in the past three years, and 3) reporting not currently being pregnant, 4) reporting never testing positive for HPV, 5) reporting sexual activity in the past 12 months. Women under 30 years of age were not included because HPV testing is not recommended as a screening strategy.[1] Recruitment flyers were posted in all seven of the regionalized local health departments comprising the district. Women were also recruited personally at community outreach events and non-traditional healthcare settings (e.g., mental health and substance use treatment clinics). Recruitment occurred from September of 2013 through April of 2014.

Procedures

All study procedures were approved by the Office of Research Integrity at the University of Kentucky. Only female research assistants were employed. Women completed a paper-and-pencil survey instrument prior to receiving instructions for specimen collection. Survey questions collected demographic and health information, as well as attitudes toward sexual health and HPV in particular. Next, a research assistant read aloud a specimen collection instruction sheet, before providing a hard copy to each woman. Women took the instructions into a public or private restroom (depending upon recruitment venue). After self-collecting, women then swirled the collection brush 40 times in a specimen vial containing Preservecyt®, a fixing solution. They then sealed the specimen vial, placed it in a pre-labeled bag, and returned the sealed bag to a research assistant. Upon returning the specimens, women completed a post-survey regarding their self-collection experience. Women received $20 to compensate their time. Samples were stored in a temperature-controlled environment (30°F or −1°C) until they were shipped on dry ice to a third-party laboratory (Louisiana State University Health Science Center).

Research nurses native to the catchment area provided results to women via their indicated method of choice (i.e. phone or face-to-face) within 1–2 weeks of receiving the results from the laboratory. Regardless of the HPV test results, all women were offered navigation to traditional Pap testing services. Navigation included offering assistance with scheduling examinations, transportation and childcare services, and attending appointments with women. Women testing positive for oncogenic HPV were provided with detailed information on HPV and its link to cervical cancer; informed that their risk of developing or having cervical cancer was elevated; and that follow-up Pap testing was an important means

of detecting any cervical abnormalities. Navigation efforts also included assistance in obtaining colposcopy when indicated by a provider.

All women were re-contacted 1-month after the initial navigation attempt. Women who self-reported receiving Pap tests answered questions regarding the date and location of services, as well as results if they were known. Verification of results occurred via chart review. Women who reported not having completed Pap testing 1-month after receiving HPV results were again offered navigation. This process was repeated a final time for women who remained unscreened three months after receiving their results. Navigation assistance was offered to all women receiving results. Most women had received medical services through the local county health departments. Women lacking insurance or having no income they were informed of the Women's Cancer Screening program available through their county health department (a program providing services free or on a sliding scale). It was emphasized to women with positive test results that if they qualified the Women's Cancer Screening Program that they would be eligible for further treatment following an abnormal Pap, if needed.

Self-Reported Measures

Several likely covariates were measured relative to the analysis of the nurse-guided patient navigation efforts and whether women testing HPV-positive were more likely to have Pap tests. First, a 6-item scale (developed by the authors) assessed women's perceptions of fatalism regarding cervical cancer. Items were: 1) "Getting cervical cancer is beyond my control," 2) "If I am supposed to get cervical cancer, there is nothing I can do to prevent it," 3) "The odds are that women in the [8-county catchment area] will get cervical cancer," 4) "Getting cervical cancer is a matter of bad luck," 5) "If I get cervical cancer I cannot control my odds of survival," and 6) "The odds are low that a women in the [8-county catchment area] will survive cervical cancer." The scale produced a marginally acceptable inter-item reliability coefficient (Cronbach's alpha = .692). Higher scores represented a greater degree of fatalism. Second, a question asked: "Have you ever had a Pap test? (note, a Pap test is done to detect early signs of cervical cancer)." In addition, the following covariates were assessed: intent to have a Pap test if testing positive for HPV, whether women did test positive for oncogenic HPV, age, marital status, and whether women reported a monthly household income of less than $1,000.

Laboratory Analysis

HPV was detected by Polymerase Chain Reaction (PCR) analysis. Cellular DNA was extracted from the self-collected swabs using a Qiagen DNA extraction kit. The DNA was extracted from BSC cells as an extraction control with every 20 samples.[31] HPV DNA was amplified and genotyped using the Roche reverse line blot system.[31,32] This assay utilized the extended-spectrum and biotin-labeled L1 consensus (PGMY09/11, amplicon 450 bp) and biotin-labeled β-globin primers (PC04, GH20, amplicon 250 bp). Specimen samples demonstrating the 450 bp L1 amplicon were genotyped using the 37 types contained on the reverse line blot: the 13 high-risk HPV types were defined as 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68. Any bands that were more intense than the low β-globin band intensity were scored as positive.

Data Analysis

To test the nurse-guided patient navigation efforts and whether women testing HPV-positive were more likely to have Pap tests, chi-squared analyses were used, followed by the construction of two multivariable logistic regression models. In both models, the outcome variable was whether women had a Pap test subsequent to HPV testing. The first model regressed the variable capturing second navigation contacts on the assessed covariates as well as whether women tested positive for oncogenic HPV. The second model regressed whether women tested positive for oncogenic HPV on the covariates. Data were analyzed in 2014, using SPSS (version 20.0). Significance was defined by an alpha-level of .05

Results

Average age of the sample was 40.2 years (standard deviation=9.3 years). The majority reported their race was White (93.8%), with 2.8% identifying as Black and the remainder identifying as other races. The majority (59.3%) reported a monthly household income of less than $1,000. Only 5.3% reported a monthly household income exceeding $5,000. The mean number of children living with women was 1.09 (standard deviation=1.19), with 41.5% indicating that no children currently lived in their household. Other descriptive characteristics are shown in Table 1.

Women's Experience in Self-Collecting Swabs

Because the consent process included the point that women would be asked to self-collect a cervico-vaginal swab, the study was not designed to describe or quantify the refusal to self-collect. The majority (97.5%) of the 400 women who enrolled in the study reported that they understood the directions they were given for self-collection of the cervico-vaginal specimen. When asked "how comfortable were you with collecting the specimen," 41.9% selected the option of "comfortable," 17.8% selected "somewhat comfortable," 16.8% selected "slightly comfortable," 17.3% selected "neither comfortable nor uncomfortable," and 5.5% selected "uncomfortable." About 18% (18.5) reported experiencing some pain during the collection process, and 10.5% reported bleeding during the collection process. A majority (89.2%) reported they would you be more likely to do this test on a regular basis compared to having Pap tests. Finally, in responding to a question asking for level of agreement regarding whether women would have a Pap test or colposcopy "if my HPV test is positive", 55.9% selected the response option of "strongly agree", with 26.6% selecting "agree," 8.5% selecting "slightly agree," and the remainder selecting a level of disagreement. For subsequent analyses, this measure was dichotomized to compare those indicating "strongly agree" (an optimal measure of intent) to the remaining 44.1% of the women.

Nurse-Guided Navigation Success

Of the 400 enrolled women, all were successfully contacted to receive their results and immediately offered navigation assistance. Of these 400, 264 (66.0%) were successfully contacted for a second navigation attempt (beyond the initial attempt that occurred when women were informed of their test result). Also, 30 (7.5%) received a chart-verified Pap test within six months of study enrollment. None of the women received colposcopy. In a cross-

tabulation of these two variables, 12.5% of the women who did not receive the second navigation contact had a subsequent Pap test, compared with 4.9% for those who did receive this second contact (P = .006). Bivariate contrasts between having a chart-verified Pap test within six months of HPV testing and the selected covariates are shown in Table 1. As shown in this Table, none of the covariates obtained significance and the effect of testing positive for oncogenic HPV was not significant. Additionally, mean differences in age (not shown in Table 1) did not differ significantly between women having a Pap test (40.2 years) and those not (41.4 years) having a Pap test (t=.73, df=398, P=.46).

In a multivariable logistic regression model controlling for the influence of age, marital status, a household income of less than $1,000 per month, intent to have a Pap test, testing positive for oncogenic HPV, and the 6-item measure of cervical cancer fatalism, the adjusted odds ratio for the navigation variable was .36 (95% CI=.16–.80), indicating significantly lower odds of having a Pap test for women receiving a second navigation effort. None of the covariates were significant in this model (Table 2).

Effect of Testing HPV-Positive

Overall, 31.3% of the women tested positive for oncogenic HPV. More specifically, 15.8% tested positive of one HPV type and 15.5% tested positive for two or more types. Chi-squared analysis indicated no differences in subsequent Pap testing between women testing negative (n=275, 68.7%), those testing positive for one type (n=63, 15.7%), and those testing positive for two or more types (n=62, 15.5%). Thus, the two groups of women testing positive were collapsed into one (this was done because women were only told whether they tested positive or negative thus a behavioral effect of testing positive for two or more strains could not have occurred).

As shown in Table 1, a significant association between testing positive for HPV and having a subsequent Pap test was not found (P=.33). Of the 125 women testing positive for one or more strains of HPV, 5.6% had a chart-verified Pap test in the next six months. In contrast, of the 275 women testing negative, 8.4% had a chart-verified Pap test. Although this 50% difference favored women testing negative, it was not statistically significant.

To test whether the selected covariates would influence this non-significant bivariate association, the second multivariable logistic regression model was constructed (this model excluded the variable representing the second navigation contact). As shown in Table 3, the effect of testing positive was not significantly associated with subsequent Pap testing after removing the variable representing the second navigation contact and after controlling for the assessed covariates.

Finally, whether testing positive for oncogenic HPV moderated the significant association between a second navigation contact and subsequent Pap testing was investigated by a layered chi-squared test. A moderating effect did occur, with the association between navigation and Pap testing being significant only for women testing negative for HPV. Among women testing negative and not receiving a second navigation contact, 13.7% had a chart-verified Pap test compared to 5.2% of those testing negative and receiving a second contact (P=.014). Conversely, among women testing positive and not receiving a second

navigation contact, 8.8% had a chart-verified Pap test compared to 4.4% of those testing positive and receiving a second contact (*P*=.34).

Discussion

With some exceptions, women were physically comfortable with the process **for** self-collecting cervico-vaginal swabs for HPV testing and 89% preferred this method of screening over traditional, clinic-based Pap testing. Although this finding suggests the utility of non-clinical screening for medically underserved women, the findings pertaining to the second and third study purposes did not support the study hypotheses. Rather than being predictive of having a subsequent Pap test, those receiving a second navigation contact were significantly less likely to have a chart-verified Pap test within six months. This finding suggests that multiple navigation attempts may not increase the chances of having a Pap test. The counter-intuitive finding may simply be a consequence of the idea that second attempts were made for women who already rejected the initial navigation, meaning that these women had already decided against a Pap test. More specifically, women who are motivated by receiving an HPV test result and an initial navigation contact promoting a Pap test will do so without having to be re-contacted and those who are re-contacted will be unlikely to have a Pap test. This effect, however, was significantly magnified for women testing negative for oncogenic HPV thereby suggesting a need for further investigations designed to determine women's psychosocial responses to an HPV-negative test result. Regardless of why HPV status moderates the relationship, it is vital to emphasize that women testing positive were not significantly more likely than those testing negative to have a follow-up Pap exam. This latter finding strongly suggests that simply notifying women of HPV-positive test results may not be enough; instead navigation efforts should emphasize Pap testing to women testing positive for oncogenic HPV. This emphasis may need to take the form of a brief, intensive, tailored education session that can be delivered efficiently by phone.

That only 7.5% of the women received a Pap test within six months of having the HPV test suggests that a simple linkage between non-clinical HPV testing and the receipt of clinical services may not exist for rural Appalachian women. Data from these women suggest that clinical services may not be reaching some women, especially given that 87 of the 400 women had never had a Pap test (mean age=40.5 years, standard deviation=9.8 years). Of the 313 women who reported ever having a Pap test, the estimated mean number of year-intervals between tests was 3.6 years (standard deviation=5.3), well over the recommended intervals. Thus, constructing "bridges" that lead under-served women into clinical care is an important priority for rural Appalachian women.[23,24]

The fact that none of the assessed covariates achieved significance with the outcome of having a chart-verified Pap test was surprising. Thus, the apparent lack of access and/or complacency about a follow-up Pap test may occur for rural Appalachian women regardless of marital status, low-income status, whether they have ever had a Pap test, and their age. Further, although fatalism about cervical cancer was common in this sample, women were equally unlikely to have a follow-up Pap test regardless of whether this fatalism was high. This suggests that a "life-saving" type of behavioral intervention program may be ineffective. Finally, it is intriguing to note that women's expressed intent to have a follow-

up Pap test, if they tested positive for oncogenic HPV, had no meaningful bearing on whether this actually occurred. In a post-hoc analysis of just the women testing positive for oncogenic HPV, we observed that 7.7% of those stating this intent had a chart-verified Pap test compared to 2.1% of those not stating this intent (P=.19). Although not statistically significant, this post-hoc analysis of only 125 women was clearly underpowered given that only seven received a Pap test. Further investigation is warranted.

Limitations

Findings are limited by the use of a convenience sample. Also, the study design could not determine whether motivational issues or access issues operated to preclude Pap testing. For instance, women may have been motivated to have a Pap test as a consequence of being tested for HPV, but they may have perceived a lack of access to these services (despite our navigation attempts). In addition, our selection of covariates was limited; clearly unmeasured confounding may have occurred. For instance, we did not assess women's health insurance status or their past use of healthcare services. Also, it must be noted that women were selected for this sample based on lack of Pap testing in the past three years, thereby precluding generalization to all rural Appalachian women. Finally, the very low numbers of women having a chart-verified Pap test created an unanticipated lack of statistical power for the study.

Conclusions

Findings suggest that optimizing community-based screening for cervical cancer among rural Appalachian women will require substantial linkages to clinical care. A key challenge will be navigating oncogenic HPV-positive women who do not seek Pap testing once this test result is provided to them. Health communication interventions should be created that educates and persuades women testing oncogenic HPV-positive to seek Pap testing.

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Table 1

Bivariate Associations with Having a Pap Test After Being Screened for HPV via Self-Collection of a Cervico-Vaginal Swab (N = 400)

Correlate		% Having Pap Test	*P*
Second navigation occurred			
No	(n = 136)	12.5	
Yes	(n = 264)	4.9	.006
Tested positive for oncogenic HPV			
No	(n = 275)	8.4	
Yes	(n = 125)	5.6	.33
Covariates			
Scored high[a] on fatalism for cervical cancer			
No	(n = 222)	8.6	
Yes	(n = 171)	5.8	.31
Ever had a Pap test			
No	(n = 82)	7.3	
Yes	(n = 313)	7.7	.91
Married			
No	(n = 216)	6.0	
Yes	(n = 180)	9.4	.37
Household income > $1,000 per month			
No	(n = 237)	5.9	
Yes	(n = 163)	9.8	.14
Intend to have Pap test if HPV test is positive			
No	(n = 177)	6.2	
Yes	(n = 223)	8.5	.38

[a]The distribution for this construct was dichotomized by a median split

Table 2

Association of Second Navigation, and Assessed Covariates, with Having a Pap Test After Being Screened for HPV via Self-Collection of a Cervico-Vaginal Swab (N = 400)

Outcomes	**AOR**[a]	**95% CI**[b]	***P***
Second navigation occurred	.36	.16–.80	.01
Age	1.01	.97–1.05	.69
Married	1.00	.97–1.03	.79
Household income > $1,000 per month	1.53	.70–3.36	.28
Intend to have Pap test if HPV test is positive	1.55	.67–3.59	.31
Tested positive for oncogenic HPV	1.65	.63–4.35	.31
Scored high[c] on fatalism for cervical cancer	1.50	.66–3.42	.34
Ever had a Pap test	.87	.33–2.30	.78

[a] Adjusted Odds Ratio

[b] Confidence Interval

[c] The distribution for this construct was dichotomized by a median split

Table 3

Association of Testing Positive for Oncogenic HPV, and Assessed Covariates, with Having a Pap Test After Being Screened for HPV via Self-Collection of a Cervico-Vaginal Swab (N = 400)

Outcomes	AOR[a]	95% CI[b]	*P*
Tested positive for oncogenic HPV	1.71	.66–4.44	.27
Age	1.01	.97–1.06	.52
Married	1.00	.97–1.03	.80
Household income > $1,000 per month	1.78	.81–3.91	.15
Intend to have Pap test if HPV test is positive	1.69	.73–3.88	.22
Scored high[c] on fatalism for cervical cancer	1.46	.65–3.31	.36
Ever had a Pap test	.83	.31–2.18	.70

[a] Adjusted Odds Ratio

[b] Confidence Interval

[c] The distribution for this construct was dichotomized by a median split