Self-Sampling for Human Papillomavirus in a Community Setting: Feasibility in Hispanic Women

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Abstract

Background: The aim of the study was (*a*) to assess sensitivity and specificity of self-sampling in a community setting for identifying high-risk human papillomavirus (HPV) infection and abnormal Papanicolaou (Pap) smears and (*b*) to assess satisfaction with this collection method among Hispanic women.

Methods: Lay health workers distributed self-collection kits to Hispanic women in the community. Participants collected an unsupervised vaginal sample at home or in the place and time of their preference.

Results: A total of 1,213 Hispanics were included and provided a self-sample for HPV testing and were invited for a Pap smear; 662 (55%) of them had a Pap smear and the first 386 of these also had a physician-collected sample for HPV retesting. Using physician collection as the gold standard, unsupervised self-collection had a sensitivity of 90% and specificity of 88% for identifying high-risk HPV. Compared with physician sampling, self-sampling in a community setting had comparable sensitivity for identifying a low-grade lesions or greater in the Pap smear (50% versus 55%; *P* = 0.45) but lower specificity (94% versus 79%). Overall experience with self-sampling was reported as excellent or very good by 64% and only 2.6% reported a poor or fair experience.

Conclusions: Unsupervised self-collection of vaginal samples for HPV testing in a community setting has a high sensitivity for identifying high-risk HPV and a high satisfaction among Hispanics. This approach may benefit populations with limited access to health care or with cultural barriers to cervical cancer screening. (Cancer Epidemiol Biomarkers Prev 2008;17(8):2163−8)

Background

Despite recent increases in Papanicolaou (Pap) smear use (1), Hispanics remain disproportionately affected by cervical cancer and have the highest incidence (2) and the second highest mortality rates (3) of any ethnic/racial group in the United States.

Although the gold standard for cervical cancer screening continues to be the Pap smear, human papillomavirus (HPV) DNA testing is currently recommended as an adjunct to Pap smears in women ages ≥30 years and as part of the triage process in women with low-grade cytologic abnormalities (4, 5). Although most HPV infections clear spontaneously, persistent infection has been causally linked to cervical cancer (6, 7). In the United States, more than 20 million people are currently infected and roughly 6 million are newly diagnosed each year (6, 7).

Although physician sampling for HPV is the most common method, self-sampling may be an alternative. Previous reports indicate that self-sampling under optimal conditions in clinical or supervised settings is both accurate (8-15) and preferred by patients (16-19). In a recent systematic review, the sensitivity and specificity of self-sampling for identifying high-risk

HPV were 74% and 88% compared with physician sampling (12). In these cases, self-collection was done at a clinic and under supervision of a physician, nurse, or other clinic personnel. However, self-sampling for HPV in a nonclinical setting such as the patients' homes or other familiar place, at their convenience and with no direct supervision, may have additional advantages. In addition to privacy and confidentiality, because no clinic visit would be initially required, it may help overcome obstacles such as the lack of time, access to health care, health insurance, transportation, or child care—barriers that disproportionately affect Hispanic and other minority women (20-23). Self-sampling in a community setting may be considered in programs using HPV DNA testing alone as primary screening for cervical cancer (24, 25) or, in low resource settings, as part of ''screen and treat'' approach. Additionally, a positive HPV result may motivate women who are not up to date with Pap smears to get screened.

The feasibility of self-sampling in a community setting, unsupervised, at home or other nonclinical site and at the time of their preference, has not been fully assessed (26-28). The aim of the study was (*a*) to assess sensitivity and specificity of self-sampling in a community setting for identifying high-risk HPV infection and abnormal Pap smear and (*b*) to assess satisfaction with this collection method among Hispanic women.

Materials and Methods

The cross-sectional study took place in Orange County, California from July 2004 to July 2007. Women in the

community were recruited by lay health workers from Latino Health Access, a community-based organization located in Santa Ana, CA. Hispanic women ages ≥18 years who had no Pap smear in the past year and reported no history of hysterectomy or invasive cervical cancer were eligible for inclusion. Exclusion criteria included pregnancy and unwillingness to follow study protocol. The local Human Subjects Review Committee approved the research protocol (institutional review board 2003-2870).

Recruitment was done through several mechanisms. Indirect methods included referrals from initial subjects, flyers distributed in places frequently visited by Hispanic women, and ads in Spanish local newspapers. Direct methods included personal invitations by lay health workers to women in health fairs, public spaces, door-to-door, or cancer screening presentations. These presentations were part of the educational mission of Latino Health Access, were in Spanish, and took place at different local sites such as the community-based organization headquarters, schools, churches, or health fairs. Attendees to other ongoing programs at the community-based organization (diabetes mellitus, depression, nutrition, etc.) were also invited to participate in the study.

Volunteers who met inclusion criteria and signed informed consent were provided with a kit for self-collection of a vaginal sample for HPV testing. A brief questionnaire to confirm eligibility criteria was administered at this time. Based on lay health workers' previous experience in this community, the questionnaire did not include sociodemographic items other than age and country of origin due to fear that immigration status would negatively affect recruitment.

The women received a HPV self-sampling kit including a plastic specimen bag, a cotton tip swab, a container with transport media, and instructions in Spanish. The unsupervised self-collection for HPV could be done at the participants' homes, in a bathroom at the recruitment site or any other convenient place when none of the following circumstances were present: menstruation, sexual activity or vaginal douches within 24 h, or use of vaginal creams or medication within the last 7 days. In brief, the self-sampling kit instructed the women to sit on the toilet, to introduce the cotton tip swab in the vagina as far as possible, to rotate it 5 times in either direction, and to place the sample in the container. Lay health workers also verbally instructed the women on self-collection. Samples were returned to the lay health worker for processing as soon as collected.

Hybrid capture II HPV-DNA assay (Digene) done by AmeriPath Laboratories was used to test for high-risk HPV types. All women were notified of their HPV results within 1 week after self-collection. All HPV-positive women and all HPV-negative were invited for a Pap test at a local hospital. Based on power analysis, the first 386 participants also had a physician-collected cervical sample for HPV testing along with the Pap smear. In all cases, Pap smear and physician HPV sample collection were done within 2 weeks of notification of HPV results and 3 weeks after self-collection. At this point, participants joined a study protocol described in previous publications (29, 30).

All Pap smear samples were immediately interpreted by a single pathologist according to the 2001 Bethesda System (31). Cervical loop electrosurgical excision pro-

cedure was offered to women with Pap smears indicative of a high-grade squamous intraepithelial lesion and abnormal glandular cells of undetermined significance. Women with cancer were referred to gynecology-oncology for further management. Participants with diagnoses of atypical squamous cells of unknown significance or low-grade squamous intraepithelial lesion were referred to their primary-care practitioner for additional evaluation and treatment. A questionnaire including items on education level, employment status, and cost related to participating in the study was administered at that time the Pap smear results were provided to participants.

To compare unsupervised self-sampling and physician sampling for HPV, we assessed (*a*) sensitivity and specificity of unsupervised self-sampling to detect high-risk HPV using physician sampling as the gold standard and (*b*) sensitivity and specificity of both sampling methods for abnormal Pap smear result. Because of the small number of high-grade squamous intraepithelial lesion or carcinomas in our population, we assessed sensitivity and specificity for identifying atypical squamous cells of unknown significance or greater and low-grade squamous intraepithelial lesion or greater lesions. Positive and negative predictive values were also calculated.

To assess satisfaction with self-sampling, a four-point Likert scale was used to evaluate degree of satisfaction in each of the following categories: (*a*) overall experience, (*b*) clarity of instructions, (*c*) ease of use of self-collection kit, (*d*) understanding of what the results mean, and (*e*) convenience of unsupervised self-sampling compared with physician sampling at a clinic. In addition, a logistic regression analysis was done to determine the effect of sociodemographic factors such as age and education level on satisfaction with self-sampling. Items assessing these two factors were only asked to women who had a Pap smear; consequently, the regression analysis was limited to this group. Overall satisfaction was the dependent variable in the model (excellent or very good/good/fair) and all other factors available such as age (continuous), national origin (Mexican/Mexican American or other), employment status (employed full-time or part-time or unemployed), education level (less than high school or high school or more), number of pregnancies (≤3 or ≥4), and time since last Pap smear (≤2 years or ≥3 years/never) were included as independent variables.

For the data analysis, we first generated descriptive statistics for each study variable. To characterize factors associated with the outcomes of interest, we then conducted a bivariable analysis using χ^2 tests to compare categorical variables and *t* tests for continuous variables. Two-tailed *P* values ≤ 0.05 were considered statistically significant. All data analysis was done with SAS statistical software.

Results

Characteristics of Participants. A total of 1,213 women were included in the study and performed unsupervised self-sampling for HPV testing. The vast majority were of Mexican/Mexican American origin (89.4%; Table 1). Almost half (47.5%) were ages 35 to 49 years and close to one third (31.3%) were ages 18 to 34 years. By design,

Table 1. Characteristics of study participants

	Women who had unsupervised self-sampling for HPV ($n = 1,213$), n (%)	Women who had unsupervised self-sampling for HPV and a Pap smear ($n = 622$), n (%)
Age distribution (y)		
18-34	380 (31.3)	154 (24.8)
35-49	577 (47.5)	308 (49.5)
≥50	256 (21.1)	160 (25.7)
National origin		
Mexican/Mexican American	1,084 (89.4)	555 (89.4)
Central American	79 (6.5)	45 (7.2)
South American	42 (3.5)	18 (2.9)
Other Hispanic	7 (0.6)	3 (0.7)
Time since last Pap		
Never	34 (2.8)	17 (2.8)
1-2 y ago	951 (78.3)	490 (79.2)
≥3 y ago	228 (18.9)	115 (18.0)
Previous abnormal Pap	129 (10.6)	80 (12.9)
No. full-term pregnancies		
0	75 (6.2)	43 (6.9)
1-3	691 (57.1)	330 (53.4)
≥4	443 (36.6)	245 (39.6)
Education level		
Less than high school	— (—)	445 (71.5)
High school	— (—)	90 (14.5)
College or more	— (—)	87 (13.9)
Employment status		
Full-time	— (—)	118 (18.9)
Part-time	— (—)	125 (20.1)
Unemployed/homemaker/student	— (—)	379 (60.9)

none of the women had received a Pap smear within the past year. Most participants had a Pap test within 2 years before enrollment in the study (78.3%), 18.9% had Pap smear ≥3 years before enrollment, and 2.8% never had a Pap smear. A total of 13.6% of study participants had a positive result for HPV on self-collected samples.

Of the 1,213 who performed unsupervised self-collection of vaginal samples for HPV testing, 622 had a Pap smear and the first 386 of them had a physician-collected cervical sample for HPV retesting. The profile of this subgroup is similar to that of the whole sample (Table 1). We additionally collected information on education and current employment in this subgroup; 71.5% had less than high school education and only 39% were employed full-time or part-time. Most Pap tests were normal (95.4%), but 2.6% had abnormal squamous cells of undetermined significance, 1.0% had low-grade squamous intraepithelial lesion, and only 1.0% had high-grade squamous intraepithelial lesion or cervical cancer.

Sensitivity and Specificity. Of the 386 consecutive participants who had HPV retest using a physician-

collected sample, 87.8% had the same result. That is, 314 (81.3%) remained negative and 25 (6.5%) remained positive for HPV. However, 45 (11.6%) were positive for HPV in unsupervised self-sampling but negative on the physician sampling and 2 (0.5%) were negative for HPV on unsupervised self-collection but positive in physician sampling.

Using physician collection as the gold standard, unsupervised self-sampling had a sensitivity of 92.6% and specificity of 87.7%. Compared with physician sampling, unsupervised self-sampling had a higher sensitivity for abnormal Pap, although the difference was not statistically significant ($P = 0.45$). However, physician sampling was more specific for both the abnormal Pap categories used in the study ($P < 0.0001$). The sensitivity and specificity for a low-grade lesion or greater in Pap smear were 55% and 79% for self-sampling and 50% and 94% for physician sampling (Table 2).

Satisfaction. The majority of participants were very satisfied with the unsupervised self-sampling for HPV; 33.7% report their satisfaction with overall experience as

Table 2. Sensitivity and specificity for abnormal Pap smear of unsupervised self-sampling and physician sampling for HPV testing

	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Abnormal Pap: atypical squamous cells of unknown significance or higher lesion				
Unsupervised self-sampling	56	80	11	98
Physician sampling	44	95	26	98
Abnormal Pap: low-grade squamous intraepithelial lesion or higher lesion				
Unsupervised self-sampling	55	79	6	99
Physician sampling	50	94	15	99

Table 3. Satisfaction with self-sampling in unsupervised setting for HPV testing among Hispanic women (*n* = 1,213)

	Excellent (%)	Very good (%)	Good (%)	Fair (%)
Overall experience	33.7	30.8	32.9	2.4
Clarity of instructions for using the kit	48.6	34.1	16.5	0.7
Ease of use of kit	48.7	34.0	16.5	0.7
Understanding of what the results mean	46.8	36.9	15.8	0.4
Convenience of self-sampling compared with physician sampling at a clinic	45.3	36.5	16.4	0.2

excellent and 30.8% as very good (Table 3). Similar trends were observed in clarity of instructions for self-collection, ease of use of kit, and understanding of results. Likewise, when participants were asked about the convenience of unsupervised self-sampling compared with physician sampling at a clinic, <2% reported poor or fair convenience of self-sampling.

In the logistic regression analysis including only participants who had a Pap smear as part of the study (*n* = 622), younger age (odds ratio, 1.12; 95% confidence interval, 1.01-1.24), non-Mexican origin (odds ratio, 2.56; 95% confidence interval, 1.42-4.59), and higher education level (odds ratio, 1.18; 95% confidence interval, 1.10-1.30) were associated with excellent satisfaction with overall experience. Conversely, employment status, number of pregnancies, and having a Pap smear ≥3 years ago were not associated to excellent overall satisfaction.

Discussion

Our results indicate that unsupervised self-sampling for HPV in a nonclinical setting has a high sensitivity for identifying high-risk HPV infections and abnormal Pap smears and a high satisfaction among Hispanics. Almost 9 of 10 participants had the same results on self-collected and physician-collected samples. Most cases with differing HPV results consisted of a positive HPV on self-sampling and negative result on physician collection, possibly suggesting a slightly higher prevalence of vaginal rather than cervical HPV infection as reported in previous studies (10, 27, 32-34). The higher prevalence of high-risk HPV in self-sampling may also be explained, in part, by cross-reactivity of the hybrid capture II assay with nononcogenic HPV types more common in the vagina (35). The proportion of cases with differing HPV results between unsupervised self-sampling and physician sampling in our study is within the range in previous reports comparing self-sampling in a supervised setting and physician sampling (12, 15, 27, 33). This suggests that unsupervised self-collection may be as reliable as self-sampling in a supervised setting. Yet, because no clinic visits or supervision is required, it may be more practical and more acceptable to patients.

The sensitivity for abnormal Pap smear of unsupervised self-sampling found in our study is similar to that of physician sampling. A low false-negative rate is always a desirable characteristic of a test. In this case, it would help minimize the number of women with abnormal Pap smears that would escape detection. This is particularly relevant if the unsupervised self-sampling is used as a primary screening tool for cervical cancer. Although most of the previous studies found a lower sensitivity for abnormal Pap smear of self-sampling

compared with physician sampling (33, 34, 36, 37), not all did (15). In a study done in Brazil, Holanda et al. found that home self-sampling had a sensitivity of 66.7% for low-grade squamous intraepithelial lesions compared with 63.3% of physician-collected sample; the sensitivity for high-grade lesions was the same in both sampling methods (26). Furthermore, the very high negative predictive value of unsupervised self-sampling in our study suggests that the risk of an undetected cervical lesion is very low. On the other hand, physician sampling had a higher specificity for abnormal Pap smear; this may be explained by the fact that self-sampling identifies high-risk HPV vaginal infections that do not necessarily involve the cervix or have an effect on Pap smear results (38).

We found high satisfaction rates with unsupervised self-sampling for HPV; most patients report excellent or very good satisfaction with overall experience, with ease of use and convenience. Younger, more educated, and non-Mexican origin Hispanics were more likely to report excellent satisfaction with unsupervised self-sampling. High satisfaction with self-sampling in supervised settings has also been reported by most of the previous studies (10, 18, 33, 39). Yet, some report preference for physician collection of samples (16, 19) and, in a study done in China, rural women preferred to do self-sampling at the clinic rather than at home (28). Further study is required to identify factors affecting satisfaction with home or unsupervised self-sampling for HPV and to identify populations more likely to benefit from this sampling method.

Our study has several limitations. The possibility of selection bias exists because our sample was not randomly selected; the characteristics of women and satisfaction with unsupervised self-sampling of those who did not volunteer to participate in the study may differ from that of women included in the study. Only limited sociodemographic information was collected, which restricts the analyses that can be done on study data. Because of the unique characteristics of our sample, the results of the study cannot be generalized to other populations.

A test that can be done at home or any other place without supervision, that does not require pelvic exam, and that has high sensitivity for abnormal Pap smears and high satisfaction among users may be an acceptable primary screening method for cervical cancer in resource limited settings. In places with adequate health-care resources, unsupervised self-sampling for HPV may substitute physician sampling or self-sampling in a supervised setting and may be used as part of alternative strategy for screening. For instance, only women who test positive for HPV in unsupervised self-sampling

would be scheduled for a Pap smear or, in a different strategy, for colposcopy without a previous cytology. In this scenario, unsupervised self-sampling for HPV offers several advantages over self-sampling in a supervised setting. Because sample collection does not require a specific time or place, it may help women overcome barriers such as lack of time, transportation, or child care. By reaching more women and helping to overcome barriers to cervical cancer screening, unsupervised self-sampling may also help improve Pap smear use rates in underscreened populations. Moreover, a positive HPV result in unsupervised self-sampling may help motivate women who previously refused pelvic exam or deferred Pap smears for other reasons to get screened for cervical cancer. However, this approach may also have some limitations. For instance, a positive HPV result does not guarantee that those women will follow-up for further evaluation or treatment at a clinic. In addition, a negative HPV test in unsupervised self-sampling may prevent or delay seeking medical care for other gynecologic problems.

Unsupervised self-sampling for HPV in a nonclinical setting has a high sensitivity for identifying high-risk HPV infections and abnormal Pap smears and a high satisfaction among Hispanics. This approach may be an alternative to physician sampling and may provide an additional tool for cervical cancer control, especially in populations with limited access to health care or with cultural or sociodemographic barriers to cervical cancer screening.

Disclosure of Potential Conflicts of Interest

None disclosed.

Acknowledgments

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