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Original Article

Acceptability and Feasibility of Human Papilloma Virus Self-Sampling for Cervical Cancer Screening

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Abstract

Objectives: Women in safety-net institutions are less likely to receive cervical cancer screening. Human papilloma virus (HPV) self-sampling is an alternative method of cervical cancer screening. We examine the acceptability and feasibility of HPV self-sampling among patients and clinic staff in two safety-net clinics in Miami.
Materials and Methods: Haitian and Latina women aged 30–65 years with no Pap smear in the past 3 years were recruited. Women were offered HPV self-sampling or traditional Pap smear screening. The acceptability of HPV self-sampling among patients and clinic staff was assessed. If traditional screening was preferred the medical record was reviewed.
Results: A total of 180 women were recruited (134 Latinas and 46 Haitian). HPV self-sampling was selected by 67% women. Among those selecting traditional screening, 22% were not screened 5 months postrecruitment. Over 80% of women agreed HPV self-sampling was faster, more private, easy to use, and would prefer to use again. Among clinic staff, 80% agreed they would be willing to incorporate HPV self-sampling into practice.
Conclusions: HPV self-sampling was both acceptable and feasible to participants and clinic staff and may help overcome barriers to screening.

Introduction

Fifty years ago, cervical cancer was the leading cause of cancer deaths among women in the United States. Since then, largely as a result of widespread screening with Pap smears, the incidence and mortality of cervical cancer has declined substantially. Despite these dramatic improvements, cervical cancer disproportionately affects ethnic minority women.[1] African American and Latina women have higher rates of cervical cancer incidence than non-Hispanic whites (NHWs) (9.6 and 10.9 vs. 7.9 per 100,000, respectively).[2] They also have higher mortality rates (4.2 and 2.9 vs. 2.2 per 100,000).[2] Similarly, in Miami-Dade County, the cervical cancer mortality among African American women is 5 per 100,000 versus 2.3 among NHWs.[3,4] Minority immigrant women in Miami are particularly at risk with Haitian women having an incidence of cervical cancer of 38 per 100,000 and 11 per 100,000 among Latina women.[5]

Disparities in cervical cancer screening contribute to this difference. For example, in 2010, 78.7% of Latina women had a Pap smear in the last 3 years compared to 84% of NHWs.[6] Immigrants are particularly vulnerable to not being screened with only 67% of those living in the United States for less than 10 years reporting a Pap smear and 78% for those living in the United States for over 10 years, versus 85% of U.S. born women.[7] Among Haitians in Miami, fewer than half have been adequately screened.[8]

Among such populations access to care, lack of insurance, no usual source of care, and lack of financial resources are repeatedly identified as major barriers to adequate Pap smear screening.[7,8a,9–11] For such immigrant and other low income populations the safety-net system, which includes public hospitals and Federally Qualified Health Centers (FQHCs), plays a critical role in providing healthcare services.[12] However, often times, there remain numerous barriers to Pap smear screening in such settings.[10,13,14] Resource constraints, staff, space, and cultural factors such as modesty and fatalism make provision of Pap smears at such sites challenging.[8a,9,13,–15] In addition, many patients have competing issues such as poorly controlled chronic conditions and psychosocial challenges, which providers may prioritize for more immediate attention than preventive servcies.[9] As a result, in 2012 only 57% of

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age eligible women in FQHCs were up to date with cervical cancer screening.[16]

One recent innovation that may help address some of these barriers is screening for cervical cancer through human papilloma virus (HPV) testing instead of the traditional Pap smear. HPV is the virus that causes nearly all cases of cervical cancer. In the United States, HPV testing for cervical cancer screening is only recommended in combination with traditional Pap smear but in 2014, the FDA-approved HPV testing for primary cervical cancer screening.[17,18] Globally, the World Health Organization has already recommended a shift in cervical cancer screening from Pap smear screening to HPV testing, particularly in resource limited settings.[19] A major strength of HPV screening is that it can be performed through self-sampling. In this approach, the woman inserts a sampling device into her vagina then places the sample into appropriate media. HPV self-sampling has been shown to be as sensitive as physician collected samples.[20–26] Having women perform the test themselves may also address some cultural barriers. An added benefit is that since the woman can do the test herself without a physician, the resources, staff time, and costs are substantially lower using this approach.[27,28]

In other countries, HPV self-sampling has already been shown to be successful. For example, in Sweden, incorporation of HPV self-sampling into their organized cervical cancer screening program by mailing self-samplers to nonscreened women was demonstrated to increase rates of screening.[29] In other countries that lack such comprehensive screening programs, opportunistic approaches using HPV self-sampling have also led to increased rates of screening among hard-to-reach populations.[30,31]

In the United States, our team is currently finalizing a randomized study testing HPV self-sampling among minority women lacking adequate screening from community-based nonclinical settings.[32] However, given our experience in using this approach in community-based samples and proven success in other clinical settings in other countries, we hypothesized that HPV self-sampling may be a viable strategy for cervical cancer screening in clinical settings. In this study we assess the feasibility and acceptability of HPV self-sampling among patients and clinic staff in two such settings.

Materials and Methods

Setting

The study was conducted at two safety-net clinics. One was a hospital-based teaching outpatient clinic, which is part of Miami-Dade County's public hospital system (Jackson Health System's ambulatory care center [ACC]). Over 80% of the patients in the ACC are uninsured and most receive care based on a sliding fee scale. The other was a community-based clinic in Miami's Little Haiti neighborhood. This clinic, the Center for Haitian Studies (CHS), is a nonprofit facility supported by various federal, state, and foundation sources. The clinic primarily caters to Haitians. Nearly all of the patients at this site are uninsured.

Participants

Female patients were eligible if they were aged 30–65 years, had not had a Pap smear in the prior 3 years, were not pregnant, were not actively menstruating, and had not had their uterus removed.

Recruitment

In this feasibility and acceptability pilot study, our goal was to obtain data on a minimum of 100 women who may choose HPV self-sampling. Based on our experience, we estimated that about 50% of women would choose HPV self-sampling. Thus, to recruit at least 100 women who preferred HPV self-sampling, our target was to identify 200 study eligible women. Participants were recruited by convenience sampling from the waiting room of the above two clinics. Recruitment took place between May 2013 and February 2014. Two community health workers (CHWs) recruited participants. The CHW assigned to the ACC was Hispanic and the other at CHS was Haitian. At ACC our CHW was instructed to only recruit Latina patients and at CHS only Haitian patients. At both sites the CHW approached women waiting to be seen by their healthcare provider. The CHW introduced herself and gave a brief description of the study. For potentially interested participants CHWs administered a five question screening survey to assess eligibility. If eligibility criteria were met and women were interested in participating, informed consent was obtained.

Study procedures

After informed consent, a brief demographic survey was administered. Participants then received a short information session on cervical cancer screening using a flipchart. The flipchart described normal female anatomy, provided information about cervical cancer progression and risk factors. Women then received information about the traditional Pap smear as a means to screen for cervical cancer and an explanation of HPV self-sampling as an alternative means of screening. Patients were given a description of the procedure for performing HPV self-sampling, and the follow-up and navigation that would be provided for women in whom HPV is detected. The participants were then given one of two options. They could choose HPV self-sampling, which would be done on site before the provider visit. Participants could also discuss HPV self-sampling with their provider and have the procedure done after they discussed the two options with their provider. The other option for women who opted not to have HPV sampling was to discuss with their provider about their need for cervical cancer screening through the traditional Pap smear.

If HPV self-sampling was selected a sampler was provided to the participant. We used the Preventive Oncology International/National Institute of Health (POI/NIH) self-sampler manufactured by Puritan Medical Products.[33] The patient performed the test in the clinic bathroom with the CHW waiting outside to answer any questions. The vial having the sample was then given to the CHW who submitted it for processing through Quest diagnostics. Initially, the test used was the Cervista™ HPV HR Invader Assay but later changed by the laboratory to the Aptima® HPV Assay.[34] These are both signal-based assays that are widely used as screening tests. However, both have slightly lower sensitivity than polymerase chain reaction-based tests.[23]

Guidelines for the follow-up of women with high risk HPV detected on self-collected cervical samples continue to

evolve.[35] Current guidelines support that if genotypic testing is performed, women having HPV 16 or 18 detected should be directed to colposcopy.[36] Otherwise, repeat co-testing at 1 year is recommended. Since genotyping was not performed and after obtaining input from various clinicians at each practice, we decided that all women in this study who were found to have high risk HPV would be navigated to providers at each clinic to have a Pap smear with additional testing to be done at the discretion of each clinician.

Participants selecting HPV self-sampling were also administered a 12-item survey assessing attitudes toward and acceptability of HPV self-sampling and the Pap smear. Items were based on a prior survey of HPV self-sampler acceptability, which was translated and back translated into Spanish and Haitian Creole (Supplementary Table S1).[37] Detailed contact information was also collected so that participants could be notified of the test result. If HPV was detected, the participant was offered navigation to Pap smear by the CHW. Notes concerning the test and its result were also noted on the patient's medical record by a study team clinician.

If HPV self-sampling was not chosen, the participant was encouraged to discuss the need for cervical cancer screening with her provider during the visit. Detailed contact information was also obtained from these women. Five months after the visits, the medical records were examined to determine whether they had a Pap smear performed at their clinical site.

All participants (180) received a $20 grocery gift card for their time in participating in this study.

Provider survey. At start of the study, clinic staff and providers were informed of the study through one-to-one sessions, group meetings, and/or emails. Questions regarding the study and HPV self-sampling were also answered. Clinic staff were also informed that at study conclusion, we would be contacting them to respond to a nine-item anonymous survey. The survey included questions on demographics, acceptability of HPV self-sampling, and willingness to incorporate HPV self-sampling into clinical practice (Supplementary Table S2). Items were obtained from a prior provider survey of screening test acceptability.[38] Emails were sent twice to all providers at each site inviting them to participate in the survey. We also visited each clinic site and gave the providers paper copies of the anonymous survey, which they could return to us.

Data collection. Study data were collected and managed using REDCap electronic data capture tools.[39]

Analysis

Frequencies and percentages for the entire sample and by groups (ACC, CHS) were calculated to describe the participants' and providers' characteristics and their responses to acceptability items. Differences in proportions were tested by chi-square (or Fisher's exact test, if applicable). A p-value of <0.05 was considered statistically significant. SAS v9.3 (SAS Institute, Inc., Cary, NC) was used for all statistical analysis.

The study protocol was approved by the University of Miami Institutional Review Board and the Jackson Health System Clinical Research Review Committee.

Results

We assessed 1,964 women for study eligibility (1,545 at ACC and 416 at CHS). Of these, 301 (15%) were not eligible due to age. Among the remaining 1,663 women, 24% (406) had not had a Pap in the last 3 years and thus potentially study eligible [18% (282/1,545) at ACC and 30% (124/416) at CHS]. Of these, 407 were excluded because they either had a hysterectomy (286), were pregnant (107), or menstruating (14). Of the 200 study eligible women, 10% (20) declined to participate in the study. Thus, our final sample included 180 study eligible women. Of these, 134 were Latinas recruited from the ACC, 43% (58) were Cuban, 12% (16) Nicaraguan, 11% (15) Honduran, and 10% (13) Colombian with the rest coming from 10 distinct Latin American ethnicities. At CHS, we recruited 46 Haitian women. The mean age of all the women in the sample was 52 (SD 8), 96% (173/180) lacked health insurance, and only 12% (22/180) reported annual household incomes of over $15,000. Among Haitians only 11% (5/46) were U.S. citizens and 26% (12/46) had completed 12 years of schooling versus 33% (44/134) and 67% (90/134) of Latinas ($p<0.01$ for each comparison).

Of the 180 participants who were offered HPV self-sampling, 67% (121) accepted this method of testing and all women choosing HPV self-sampling had it done (Table 1). Complete data measuring acceptability was available for 99% (120/121) of participants selecting HPV self-sampling (one participant terminated the survey early when called to see her provider). Acceptance of HPV self-sampling was associated with age, with 73% (93/127) of participants above the age of 50 years selecting HPV self-sampling ($p=0.03$). Compared to Latinas, Haitian women were more likely to choose HPV self-sampling [87% (40/46) vs. 60% (81/134), $p<0.01$; Table 1]. At both sites, over 90% of respondents

Table 1. Screening Test Results

	All	*Site*	
	N = *180* *(100%)*	*ACC* N = *134* *(74%)*	*CHS* N = *46* *(26%)*
Testing type selected			
HPV self-sampler	121 (67)	81 (60)	40 (87)
Traditional screening	59 (33)	53 (40)	6 (13)
Test performed			
HPV self-sampler	121 (67)	81 (60)	40 (87)
Pap smear	46 (26)	43 (32)	3 (6.5)
No Pap smear 5-months post-recruitment	13 (7)	10 (8)	3 (6.5)
HPV self-sampler results			
Detected	12 (10)	3 (4)	9 (22.5)
Not detected	106 (88)	75 (92)	31 (77.5)
Indeterminate	3 (2)	3 (4)	
Pap smear results			
Normal	36 (78)	35 (81)	1 (33)
ASCUS	7 (15)	6 (14)	1 (33)
LGSIL	1 (2)	1 (2)	0
Missing results	2 (4)	1 (2)	1 (33)

Due to rounding some percentages do not add up to 100%.

ACC, ambulatory care center; ASCUS, atypical cells of undetermined significance; CHS, Center for Haitian Studies; HPV, human papilloma virus; LGSIL, low-grade squamous intraepithelial neoplasia.

Table 2. Participant Acceptability Survey Results

	All	*Site*	
	N = *121* *(100%)*	*ACC* N = *81* *(67%)*	*CHS* N = *40* *(33%)*
I chose the HPV self-sampler because it allows more privacy than the Pap smear			
Agree	113 (93)	77 (95)	36 (90)
Neutral	6 (5)	4 (5)	2 (5)
Disagree	2 (2)	0	2 (5)
I chose the HPV self-sampler because it is easier to perform than the Pap smear			
Agree	107 (88)	75 (93)	32 (80)
Neutral	14 (12)	6 (7)	8 (20)
I chose the HPV self-sampler because I have had discomfort with the Pap smear			
Agree	67 (55)	55 (68)	12 (30)
Neutral	26 (22)	10 (12)	16 (40)
Disagree	28 (23)	16 (20)	12 (30)
I chose the HPV self-sampler because it is faster than the Pap smear			
Agree	106 (88)	77 (95)	29 (73)
Neutral	13 (10)	3 (4)	10 (25)
Disagree	2 (2)	1 (1)	1 (2)
I chose the HPV self-sampler because my provider did not offer cervical cancer screening			
Agree	28 (23)	14 (17)	14 (35)
Neutral	21 (17)	17 (21)	4 (10)
Disagree	72 (60)	50 (62)	22 (55)
I found the self-sampler easy to use			
Agree	118 (97)	80 (99)	38 (95)
Neutral	1 (1)	1 (1)	
Disagree	1 (1)	0	1 (2.5)
Missing	1 (1)	0	1 (2.5)
I feel I performed the self-sampler test correctly			
Agree	116 (96)	78 (96)	38 (95)
Neutral	4 (3)	3 (4)	1 (2.5)
Missing	1 (1)	0	1 (2.5)
I would use the self-sampler again			
Agree	118 (97)	80 (99)	38 (95)
Neutral	2 (2)	1 (1)	1 (2.5)
Missing	1 (1)	0	1 (2.5)
I would recommend using the self-sampler to my female family members and friends			
Agree	117 (97)	79 (98)	38 (95)
Neutral	3 (2)	2 (2)	1 (2.5)
Missing	1 (1)		1 (2.5)
I felt comfortable using the test in the clinic			
Agree	111 (92)	80 (99)	31 (77.5)
Neutral	1 (1)	1 (1)	
Disagree	8 (6)	0	8 (20)
Missing	1 (1)		1 (2.5)
I experienced pain and/or discomfort using the self-sampler			
Agree	16 (13)	13 (16)	3 (7.5)
Neutral	8 (7)	6 (7)	2 (5)
Disagree	96 (79)	62 (77)	34 (85)
Missing	1 (1)	0	1 (2.5)
I prefer the self-sampler method over the Pap smear			
Agree	93 (77)	72 (89)	21 (53)
Neutral	25 (20)	8 (10)	17 (42)
Disagree	2 (2)	1 (1)	1 (2.5)
Missing	1 (1)	0	1 (2.5)

Possible responses to each question were ''agree, neutral, disagree.'' If there were no responses to any of one category in each item that particular category was not listed.

choosing HPV self-sampling agreed that the test was easy to perform and felt they did it correctly (Table 2). In addition, at both sites, over 95% of women noted they would use the HPV sampler again and would recommend it to family and friends (Table 2). Less than 20% (96/121) reported any pain or discomfort when obtaining the sample (Table 2). Among Latinas, 68% (55/81) stated they chose HPV self-sampling due to prior discomfort during the Pap smear and 89% (72) stated they would choose HPV self-sampling over the Pap smear (Table 2). Among Haitians almost half of women responded neutral when asked preferences for HPV self-sampling versus Pap smear or about pain during prior Pap smear (Table 2). However, the CHW conducting the survey noted the reason being that most of these respondents had never had a Pap smear and thus could not compare Pap versus self-sampling (data on this variable were not collected).

Of the 121 women who chose HPV self-sampling, 98% (118) had an adequate sample for processing (the three others were referred and completed Pap smear tests). Among those having adequate sampling, high risk strains were detected in 10% (12/121) of women, with Haitian women being more likely than Latinas to have high risk HPV detected [22.5% (9/40) vs. 4% (3/81), $p < 0.01$]. At the ACC, the CHW was able to navigate all three women who had high risk HPV detected at a subsequent Pap smear (one also had a colposcopy). At CHS, the CHW was able to contact all nine participants to inform them of their result and stress to them, the need for a Pap smear, and close follow-up with a clinician. She was then able to navigate six of these to a subsequent Pap smear, but two missed multiple appointments for a Pap smear and one was unreachable for additional follow-up.

There were 59 participants (33%) who did not choose the HPV self-sampling option (Table 1). Our CHWs encouraged all of these women to discuss having a Pap smear with the provider. We reviewed the medical records of these women 5 months after study enrollment (follow-up visit data were available for 57 of the 59 women). Of these, 22% (13/59) had not had a Pap smear (Table 1). Of the 46 women having a Pap smear, 17% (8) needed follow-up including 7 women with atypical cells of undetermined significance and one with low grade squamous intraepithelial neoplasia (Table 1).

Provider survey

A total of 178 clinic staff including medical assistants, nurses, nurse practitioners, and physicians were sent surveys.

Table 3. Clinic Staff Survey Results

	N = *39 (100%)*
Position	
Medical assistant	10 (26)
Nurse/nurse practitioner	3 (8)
Physician	26 (66)
I think cervical cancer screening is an important part of healthcare	
Agree	39 (100)
I am concerned patients are not adequately screened for cervical cancer	
Agree	27 (69)
Neutral	8 (21)
Disagree	4 (10)
It is difficult to perform a Pap smear because of time constraints	
Agree	26 (66)
Neutral	5 (13)
Disagree	8 (21)
It is difficult to perform a Pap smear due to lack of adequate staff	
Agree	13 (33)
Neutral	9 (23)
Disagree	17 (44)
I am aware of HPV self-sampling as a means to screen for cervical cancer	
Agree	21 (54)
Neutral	4 (10)
Disagree	14 (36)
I am comfortable discussing HPV self-sampling with patients	
Agree	18 (46)
Neutral	6 (15)
Disagree	15 (39)
I would be willing to incorporate HPV self-sampling into my clinical practice	
Agree	31 (79)
Neutral	5 (13)
Disagree	3 (8)

Possible responses to each question were ''agree, neutral, disagree.'' If there were no responses to any of one category in each item that particular category was not listed.

Of the 39 who responded (22% response rate), 20 (51%) were physicians and all responders completed the survey fully. Of the respondents, 66% noted it was difficult to perform a Pap smear because of time constraints and 80% agreed they would be willing to incorporate HPV self-sampling into their clinical practice (Table 3).

Discussion

We found that among Haitian and Latina women at two safety-net clinics, HPV self-sampling was a feasible approach to cervical cancer screening, having high acceptability among patients and providers. When offered a choice of HPV self-sampling or traditional screening with a Pap smear, two-thirds of participants selected HPV self-sampling. Our findings on patient acceptability of HPV self-sampling are consistent with data among other vulnerable groups and similar to our prior findings among a community-based sample of Haitian women.[37,40–44] We also found that Haitian women at CHS were more likely to choose HPV self-sampling than Latinas at ACC. Our prior work has shown that Haitian women have much less familiarity and experience with Pap smear than Latinas.[42–44] However, financial considerations may have also played a role in why more Haitian women chose HPV; at CHS women have to pay separately for a Pap smear (based on a sliding fee scale) while at ACC the service is included when done as part of the visit. We also found that HPV prevalence among the participants varied by ethnicity with Haitian participants demonstrating a higher prevalence than Latinas, whose prevalence was notably lower than previously measured in a national sample.[45] The higher prevalence of HPV among Haitians is consistent with our prior work, but the reasons for this difference remain unclear.[44,46]

Although screening for cervical cancer using HPV testing is gaining increased acceptance, the United States Preventive Services Task Force has still not endorsed it as a primary screening test for cervical cancer. Given a lack of specific guidelines and limited prior provider awareness and knowledge about HPV self-sampling as an alternative approach to cervical cancer screening, we had expected provider attitudes to be more heterogeneous. Instead, among clinic staff we found that the majority agreed (79%) that they would be willing to incorporate HPV self-sampling into their clinical practice. This finding was similar among physicians and nonphysicians. Difficulties in providing Pap smears due to time constraints may have contributed to the high level of support. In these safety-net primary care clinics, many patients have several chronic medical conditions as well as psychosocial challenges. Since doing a Pap smear often warrants additional time in having the patient put on a gown, finding a chaperone (often a nurse or medical assistant), equipment set-up, and doing the test, it may be difficult to incorporate a Pap smear into a standard 15–30 minutes visit that must also address several other active issues. Thus, it was not surprising that an alternative method of screening that did not involve time from providers or specialized clinic staff was deemed as acceptable to providers at these two sites.

One important characteristic of our intervention was the use of CHWs dedicated to this project. These are lay health workers sharing similar cultural and linguistic backgrounds as their patients.[47–49] Both had over 2 years of experience as CHWs in research studies at these sites and one was already familiar with HPV self-sampling from a prior study. The other was a diabetes-trained CHW whom we retrained in cervical cancer and HPV sampling. Cultural sensitivity, patient communication, and motivational interviewing techniques are all important features of our CHW training programs and likely contributed to the high uptake. CHWs took the time to explain the two alternatives in detail using culturally tailored educational materials we had previously developed and answered all questions before the intervention. Excluding the survey interview, CHWs estimate that on average it took them 10–15 minutes to have these discussions with patients and an additional 5 minutes for patients to do the HPV-self sampling. We doubt we could have achieved a similar level of high uptake had the intervention been delivered by clinic staff lacking dedicated time, training, and cultural sensitivity of the CHWs we used. However, CHWs are increasingly being used by safety-net

facilities and this could be a viable mechanism to deliver such interventions in these settings.

Limitations

Several caveats need to be considered. In the design of the study, clinic staff made it clear the intervention should not impede patient flow. Our patient surveys were brief and designed to collect only the most salient information to answer our research question. Thus, we did not assess other variables such as acculturation, health literacy, and *a priori* knowledge and familiarity with cervical cancer screening. Second, despite our attempts to mitigate nonresponse by sending two waves of the web-based survey and visiting each clinic site with paper copies, our response rate among providers was low, which is not atypical of provider surveys.[50,51] In addition, the providers at these sites were salaried and most of the women were uninsured. In other settings where women are insured and where providers are financially remunerated based on volume of services they deliver, provider acceptability may be lower. Lastly, we did not examine acceptability among women having a Pap smear and thus there is no control group to directly compare acceptability of HPV self-sampling versus Pap smear. However, we found that the majority of women choose HPV self-sampling over Pap smear and among those choosing HPV self-sampling, nearly all would prefer it versus a Pap smear.

Conclusions

In these two safety-net sites, HPV self-sampling was feasible and had high acceptability among patients and staff. In other countries HPV self-sampling has already been shown to be successful.[52] Our findings add increasing impetus for this approach to cervical cancer screening in the United States, particularly in resource limited settings. As our healthcare delivery system moves to one that prioritizes cost-effective approaches that maximize quality and outcomes and not volume, the leaders of healthcare organizations, particularly those in safety-net settings, may find HPV self-sampling as an attractive alternative to traditional Pap smear screening. Additional work should explore whether strategies such as providing self-sampling devices through the mail, as has been shown in other countries, can also improve participation in cervical cancer screening in the United States.[22]

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Author Disclosure Statement

No competing financial interests exist.

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