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# Recruitment Strategies for Cervical Cancer Prevention Study<sup>1</sup>

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**Objective.** The aim of this study was to describe recruitment strategies for a single-visit cervical cancer prevention study.

**Methods.** From January through December 1999, low-income, predominantly Latino women were recruited to participate in a single-visit cervical cancer prevention study. For the first 6 months, all women who had ever visited one of two community-based study clinics were invited to participate (clinic registry recruitment). For the remainder of the year, recruitment was modified to be primarily inclusive of advertisements in English- and Spanish-language community newspapers and fliers left in local businesses and organizations (media campaign recruitment). Eligible volunteers were randomized to one of two study arms, usual-care program or single-visit program. All study subjects completed demographic and medical questionnaires delivered by bilingual staff. Women who declined to participate in this study were asked to provide reasons for this preference. Statistical analyses included the use of chi-square, logistic regression, and Student's *t* test.

**Results.** The proportion of women who agreed to participate was higher in the media recruitment group than in the clinic registry group [51% (535/1041) compared to 26% (405/1542), *P* < 0.001]. The no-show rate among participants solicited from the media strategy was significantly less than that from the clinic registry. There were no significant differences in the median age, number of months since the last Papanicolaou smear, incidence of abnormal Papanicolaou smear, education, or income of the subjects based on the recruitment strategy.

**Conclusion.** A media-based recruitment strategy was effective for this single-visit cervical prevention study. This approach may be effective for recruitment of other low-income groups to clinical trials. © 2002 Elsevier Science (USA)

**Key Words:** recruitment strategies; cervical cancer screening.

## INTRODUCTION

The barriers to cervix cancer screening and management have been well described. They include poverty, lack of health insurance, limited transportation, language difficulties, lack of childcare, lack of telephone access, and certain cultural-based attitudes and health behaviors [1–5]. Low-income and minority women shoulder a disproportionate share of the cervical cancer burden in this country [6].

We believe that the usual approach to cervical cancer screening, diagnosis, and management accentuates some of these barriers because it is cumbersome, ordinarily involving multiple clinic or hospital visits and requiring a period of months to complete. Therefore it is important to evaluate new approaches that take advantage of the available screening methods to more effectively control this preventable cancer. The goal of our project was to implement and evaluate an innovative cancer control program. In order to demonstrate the effectiveness of this program, it was necessary to recruit a large number of Latino and non-Latino White women into the study. The objective of this article is to review the recruitment strategies associated with recruiting Latinas into prevention trials such as this one.

## METHODS

### Study Protocol

Before discussing the recruitment strategies and results, it is important to put the findings into perspective by describing the protocol for the study. In brief, the larger study aimed to determine if a single-visit cervical cancer prevention program could decrease the lost-to-follow-up rate for women with abnormal Papanicolaou smears and whether the program would be acceptable to the women. The study is ongoing; however, results of a pilot study with similar methods appear elsewhere [7]. The objective of this article is to describe the recruitment strategies for a single-visit cervical cancer prevention program.

Eligible patients were scheduled for a visit at one of two UCI community-based Family Health Centers in Anaheim or Santa Ana, California. In these clinics 90% of the patients have

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family incomes below the 100% federal poverty level. Sixty-six percent of the patients in these clinics are Latino. Both of these clinics are easily accessible by bus. After the study consent was signed, the participants were randomized in blocks of four to one of two study arms, usual-care program (UCP) or single-visit program (SVP). After informed consent, eligible patients underwent inspection of the cervix, Papanicolaou smear, and pelvic examination by a nurse practitioner. Patients with grossly suspicious lesions of the cervix were biopsied and referred for definitive treatment. All subjects completed questionnaires eliciting information related to demographics, risk factors for cervical cancer, prior Papanicolaou smears, attitudes about cervical cancer screening and prevention, and barriers to health care.

Women randomized to the UCP arm of the study were discharged home immediately after the pelvic examination, Papanicolaou smear collection, and interview. Subjects were notified of their Papanicolaou smear results by mail within 2–4 weeks. If the Papanicolaou smear was abnormal, the subject was also contacted by telephone and advised to seek additional evaluation for this cervical abnormality. If the subject had no identifiable primary care practitioner or gynecologist, a referral was made to the UCI gynecologic abnormal cytology clinic.

Every woman randomized to the SVP arm of the study remained at the clinic until the result of her Papanicolaou smear was available. The Papanicolaou smears of the women randomized to SVP were delivered to the UCI pathology department by courier where they were immediately processed and interpreted. Cytologic evaluation was conducted according to the revised Bethesda system. Results were verbally communicated to the study nurse practitioner; however, for Papanicolaou smears indicative of a high-grade intraepithelial lesion, abnormal glandular cells of undetermined significance, or carcinoma, a report was faxed to the clinic and communicated directly from the pathologist to the study investigator. Diathermy loop excision was offered and performed on SVP subjects with these abnormal Papanicolaou findings. These subjects received the appropriate discharge instructions and returned 2 weeks later and 3 months later for follow-up. SVP subjects with diagnoses of atypical squamous cells of unclear significance or low-grade squamous intraepithelial lesion were referred to either their primary-care practitioner or the UCI gynecologic abnormal cytology clinic for additional evaluation and treatment.

### *Recruitment Strategies*

From January 11, 1999, to December 31, 1999, women were recruited to participate in a single-visit cervical cancer prevention study. For the first 6 months of the study (clinic registry recruitment), all women who had ever visited either of the clinics in Anaheim or Santa Ana as either a patient or a guardian were identified from the clinic registries. The information provided by the clinic registries was limited to the

names, addresses, and home telephone numbers of women who had not visited either clinic within the previous 12 months.

Bilingual (English/Spanish) letters of introduction to the study were mailed. Postcards were enclosed with the letter, which allowed women to decline/accept participation and to indicate the best time to contact them by telephone. Three weeks later, three attempts were made by telephone to screen women who either had agreed to participate in the study or did not return their postcards. These follow-up telephone calls were placed by bilingual research personnel who explained all aspects of being a participant in the study including the randomization procedure, Papanicolaou smear collection, and the possibility of having a cervical diathermy loop excision. The study protocol was explained in the language of their preference.

For the latter 6 months (media recruitment), the recruitment strategy was modified to be primarily inclusive of women outside the UCI clinic system. The study was advertised weekly in community and regional newspapers, in either English or Spanish language, within the underserved communities surrounding the two clinics. Study fliers were placed in local community businesses, such as supermarkets, employment agencies, and community organizations such as YWCA, churches, mental health and free clinics, and a Spanish-language television station. Women who telephoned in response to these announcements were screened for eligibility and scheduled for examination at the UCI clinic of their choice.

### *Study Population*

Women were considered eligible to participate in this program if they were older than 18 years, had no history of invasive cervical cancer, and were not pregnant. Exclusion criteria included the absence of a cervix, abnormal vaginal bleeding, cervical cancer screening within the previous 12 months, reluctance to be randomized, unwillingness to wait for Papanicolaou smear results, or unwillingness to undergo diathermy loop excision of the cervix. All reasons for ineligibility or refusal to participate were documented. Women were excluded if there was a gross cervical lesion suspicious for malignancy at the time of examination.

All study subjects completed demographic, medical history, and satisfaction questionnaires delivered by a bilingual researcher. SVP subjects also completed a knowledge and beliefs questionnaire while awaiting the results of their Papanicolaou smears. Each subject completed a self-addressed reminder postcard, which was mailed 12 months later to remind the patient to follow-up for a repeat Papanicolaou smear.

### *Statistical Analysis*

With the exception of age at examination, interval since last Papanicolaou smear, parity, and age at first sexual intercourse, the variables used for this analysis were categorical. Statistical analyses were completed using SAS. Student's *t* test was used

**TABLE 1**  
**Comparison of Demographic Characteristics of Subjects**  
**from the Two Recruitment Strategies**

	Clinic registry N = 405	Media campaign N = 535	P value
Age (mean years)	43.6	42.0	0.03
Ethnicity (%)			
Latino	73.4	83.0	<0.01
Non-Latino White	26.6	17.0	
Time since last Papanicolaou (months)	41.5	44.2	0.52
Income (%)			
≤\$10,000/year	41.1	37.6	0.46
>\$10,000/year	58.9	62.4	
Education (%)			
<High school graduate	54.7	48.5	0.19
≥High school	45.3	51.5	
Marital status (%)			
Married/ living as married	58.1	63.5	0.47
Never married	15.4	12.2	
Divorced/ separated	18.8	17.5	
Widowed	7.7	6.8	
Smoking history (%)			
Ever	26.6	25.7	0.79
Never	73.4	74.3	
Employment status (%)			
Employed	38.2	36.7	0.65
Unemployed	61.8	63.3	
Insurance status (%)			
None	77.7	84.7	<0.01
Private or federal	22.3	15.3	
Papanicolaou result (%)			
Normal	94.6	95.9	0.36
Abnormal	5.4	4.1	
Previous abnormal Papanicolaou (%)			
No	89.8	89.9	0.94
Yes	10.2	10.1	
Parity (mean)	3.6	3.3	0.11
Number of lifetime sexual partners (mean)	4.4	3.6	0.36
Age at first intercourse (mean years)	18.9	19.0	0.95

to compare continuous variables. Chi-square test was used for comparisons of categorical variables. Odds ratios (OR) were calculated using logistic regression with the clinic registry cohort as the reference group. Only two-tailed *P* values < 0.05 were considered statistically significant.

## RESULTS

Nine hundred seventy-one women presented to the clinic for randomization; 31 patients were excluded prior to randomization. The reasons for exclusion of the patients were the following: Pap smear within the past year, 8; prior total hysterectomy, 11; current pregnancy, 8; nonuterine bleeding, 3; unable to wait in the clinic for results, 1.

The two recruitment strategies resulted in the enrollment of women who were similar with respect to many important variables such as income, education, employment status, interval since the previous Papanicolaou, previous history of an abnormal Papanicolaou smear, number of lifetime sexual partners, and age at first sexual intercourse. The median age of the subjects was 42 years (range 17–78 years). The median number of months since the prior Papanicolaou smear was 24 months (range 12–599 months). The median SVP clinic visit was 2.4 h (range 2.0–3.2 hours). The median time for courier delivery, processing, and interpretation of the single-visit pap smears was 67 min (range 58–69 min). The media recruitment strategy yielded more Latino subjects than the clinic registry recruitment method (83% compared with 73%, *P* < 0.01) and more uninsured subjects (85% compared with 78%, *P* < 0.01). (See Table 1.)

The results of the two strategies are presented in Table 2. Of the more than 5000 letters of invitation that were mailed during the first 6 months of the study, 1542 women were successfully contacted and screened by telephone. When the media recruitment strategy was compared with the clinic registry method, a larger proportion of the women screened were eligible (81 and 75%, respectively, *P* < 0.001), and more eligible women gave telephone consent to participate (83% compared with 65%, *P* < 0.001). Women recruited by the media campaign strategy were three times more likely to present to the clinic than the volunteers recruited via the clinic registry [OR 3.00; 95% confidence interval (CI) 2.38–3.78]. Of the women screened by telephone, recruitment was almost three times more successful among the cohort ascertained via the media campaign in comparison to those from the clinic registry (OR 2.97; 95% CI 2.52–3.51)

For both recruitment strategies the primary reason for non-participation was the reluctance to participate in a “study.” Other commonly offered reasons were work conflicts and childcare problems. A large proportion of subjects recruited by the clinic registry strategy declined to participate because they already had a provider for gynecologic care; however, this proportion was lower for the women recruited through media campaign. Transportation difficulties were less frequently re-

**TABLE 2**  
**Outcome of the Two Recruitment Strategies**

	Clinic registry	Media campaign
Women screened	1542	1041
Eligible*	1159/1542 (75%)	846/1041 (81%)
Telephone consent*	756/1159 (65%)	704/846 (83%)
Presented to clinic*	416/756 (55%)	555/704 (79%)
Eligible for randomization	405/416 (97%)	535/555 (96%)
Proportion evaluated/women screened*	405/1542 (26%)	535/1041 (51%)

\* *P* < 0.01.

**TABLE 3**  
**Reason for Declining to Participate**

	Clinic registry declines <i>N</i> = 403	Media campaign declines <i>N</i> = 142
Did not wish to participate in a "study"	75 (19%)	41 (28.9%)
Childcare problems	22 (6%)	6 (4.2%)
Work conflict	54 (13%)	23 (16.2%)
No time	14 (4%)	6 (4.2%)
Modesty or embarrassment	3 (1%)	1 (0.7%)
Uncomfortable with Papanicolaou	13 (3%)	3 (2.1%)
Transportation problems	26 (7%)	3 (2.1%)
Other insurance/physician/clinic	160 (40%)	34 (23.9%)
No reason/refused to answer/other	36 (8.5%)	25 (17.6%)

ported as a reason for nonparticipation among the women recruited by the media strategy than the clinic registry (Table 3).

## DISCUSSION

Recruiting and retaining participants for longitudinal prevention trials, such as the Single-Visit Cervical Cancer Prevention Study, are extremely challenging tasks. Even in treatment trials, where participants may easily perceive a benefit from the investigational drug or other therapy, participation rates are low (3–20%) [8]. In prevention trials, where the benefits may not be as evident, the motivation to participate may be even less [8, 9]. When one considers the time and expense involved for the participant, it is not difficult to understand why a small proportion of society chooses to enroll in these studies and why an even smaller number of economically disadvantaged minority group members enter them [8–12].

The Single-Visit Cervical Cancer Prevention Study provided the opportunity to compare two recruitment methods that targeted low-income women, predominantly Latinas. Although an estimate of the number of women aware of this study can be made for the clinic registry strategy, a similar estimate cannot be determined for the media campaign. However, comparison of these two recruitment strategies suggests an advantage of the media campaign approach. There was a significantly greater no-show rate in the group of women recruited through the clinic registry when compared to the media campaign strategy (45 and 21%, respectively) and a statistically significant greater participation among the women recruited by the media strategy [51% (535/1041)] in comparison to the clinic registry [26% (405/1542)]. This difference can be attributed to a bias in the form of greater motivation among the women who volunteered themselves for the study after learning of the prevention program from various media sources. Although patients recruited from the media campaign population might have been more eager to participate, they were similar to the patients derived from the clinic registry with respect to many important factors

such as the interval since the last Papanicolaou smear, previous abnormal pathology, number of sexual partners, parity, and age at first sexual intercourse. Noteworthy is the fact that the media strategy yielded a significantly larger number of Latina and uninsured women into the study.

Latinos have been underrepresented in previous prevention and screening trials for many reasons [13]. First, Latinas are often poor. For people who lead a day-to-day existence with regard to food and shelter, health care is generally important only in the presence of symptoms. Therefore, preventive measures may receive low priority and participating in a study on prevention may receive an even a lower priority. Second, Latinos often lack health insurance, with resulting limited access to medical care and limited information about cancer prevention services. This lack of access may make them feel devalued by the health care system and reluctant to participate in prevention studies. Third, minorities in our society may have fear and distrust of federally funded projects. This fear may be based on their knowledge of unethical studies conducted with minority groups in the past. Fourth, Latinos have cultural beliefs and myths about cancer that may dissuade them from obtaining screening services. For example, some Latinas believe that they do not need Papanicolaou smears because they do not engage in activities that are associated with cervical cancer, such as having multiple sexual partners [13]. Fifth, transportation to and from the study sites creates problems for many Latinos. Particularly older Latinas may not have access to cars and may have to depend upon buses for transportation. Sixth, language may also be a barrier to recruitment. Poorly translated materials and forms that require a high level of education to read deter participation. Finally, study design issues may be barriers to recruitment efforts. Complex self-report forms, even when appropriately translated, may be difficult for Latinas to complete.

The ability of a single-visit screening and intervention program to be effective in reducing cervical cancer incidence and mortality on a large scale will depend on the feasibility of public health centers to recruit individuals at risk, and specifically to tailor mass-media campaigns to specific communities and to coordinate the use of indigenous staff with existing community resources.

## REFERENCES

1. Pérez-Stable EJ, Otero-Sabogal R, Otero-Sabogal F, McPhee SJ, Hiatt RA. Self-reported use of cancer screening tests among Latinos and Anglos in a prepaid health plan. *Arch Intern Med* 1994;154:1073–81.
2. Roberts RE, Lee ES. Medical care use by Mexican-Americans. *Public Med Care* 1980;18:267–81.
3. Samet JM, Hunt WC, Lerchen ML, Goodwin JS. Delay in seeking care for cancer symptoms. A population-based study of elderly New Mexicans. *J Natl Cancer Inst* 1988;80:432–8.
4. Hubbell FA, Waitzkin H, Mishra SI, Dombrink J, Chavez LR. Access to medical care for documented and undocumented Latinos in a Southern California county. *West J Med* 1991;154:414–7.

5. Hubbell FA, Chavez LR, Mishra SI, Valdez RB. Beliefs about sexual behavior and other predictors of Papanicolaou smear screening among Latinas and Anglo women. *Arch Intern Med* 1996;156:2353-8.
6. Henson RM, Wyatt SW, Lee NC. The National Breast and Cervical Cancer Early Detection Program. A comprehensive public health response to two major health issues for women. *J Public Health Manage Pract* 1996;2:36-47.
7. Burger RA, Monk BJ, Van Nostrand KM, Greep N, Anton-Culver H, Manetta A. Single-visit program for cervical cancer prevention in a high-risk population. *Obstet Gynecol* 1995;86:491-8.
8. Swanson GM, Ward AJ. Recruiting minorities into clinical trials. Toward a participant-friendly system. *J Natl Cancer Inst* 1995;87:1747-59.
9. Hunninghake DB, Darby CA, Probstfield JL. Recruitment experience in clinical trials: literature summary and annotated bibliography. *Control Clin Trials* 1987;8(Suppl 4):6S-30S.
10. el-Sadr W, Capps L. The challenge of minority recruitment in clinical trials for AIDS. *JAMA* 1992;267:954-7.
11. Blumenthal DS, Sung J, Coates R, Williams J, Liff J. Recruitment and retention of subjects for a longitudinal cancer prevention study in an inner-city black community. *Health Serv Res* 1995;30:197-205.
12. McCabe MS, Varricchio CG, Padberg RM. Efforts to recruit the economically disadvantaged to national clinical trials. *Semin Oncol Nurs* 1994;10:123-9.
13. Marin G, Marin BV. *Research with Hispanic populations*. Newbury Park, CA: Sage, 1991.