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Abstract

Objective: **To report on the effect of the Breast and Cervical Cancer Intervention Study (BACCIS), a multicomponent intervention conducted in the San Francisco Bay Area between 1992 and 1997.**
Methods: **BACCIS targeted ~25,000 multiethnic, underserved women in eight neighborhoods and the public health clinics that served them. An outreach intervention using lay health worker peers and clinic provider inreach intervention to improve breast and cervical cancer screening were evaluated in a quasi-experimental, controlled trial with pretest and posttest household surveys of 1,599 and 1,616 women, respectively. Surveys were conducted in English, Spanish, Mandarin, and Cantonese.**
Results: **Analyses of community survey results showed no significant improvement in reported screening behaviors. Reports of mammography in the intervention areas in the previous 2 years, or for Pap smear in the previous 3 years, did not differ significantly (73-71% and 84-87%, respectively, for pretest and posttest surveys).**
Conclusion: **High baseline screening rates, lack of sensitive measures of change at the population level, contamination of the control group, and an imbalance of predictive factors at baseline contributed to the difficulty of assessing the value of the intervention. Lessons learned from this inconclusive study may be of value to future community intervention studies of cancer screening and other health behaviors in multiethnic underserved urban populations.** (Cancer Epidemiol Biomarkers Prev 2008;17(8):1945–9)

Introduction

The efficacy of community interventions to improve cancer screening behavior has been recently reviewed (1) and the lessons learned were summarized (2). One of the conclusions reached is that multicomponent interventions directed simultaneously at several aspects of the screening process are generally successful in improving early detection practices (3-11). This article presents the results of a multicomponent intervention in the San Francisco Bay Area targeted to an underserved, multiethnic population that was not successful (12). The hypothesis was that the intervention would result in a greater change in the proportion of women reporting or having medical record evidence of adherence to guidelines for four screening procedures in the intervention communities and clinics compared with the control communities and clinics. We believe that, in light of the recent attention to this area of cancer intervention research by several reviews and by the Center for Disease Control and Prevention Community Guide to Prevention Services (1), it is important to report our results and to comment on why success was elusive.

Materials and Methods

General Approach. The Breast and Cervical Cancer Intervention Study (BACCIS) was a controlled investigation of three related cancer screening interventions in the diverse urban population of the San Francisco Bay Area. The conceptual model viewed the behaviors related to cancer screening as parallel interacting paths followed by individuals at risk and by their health care providers (13). BACCIS targeted ~25,000 low-income African American, Chinese, Hispanic, and White women, 40 to 75 years of age, in two counties. The interventions, implemented over a 3-year period, from 1993 to 1996, were designed to increase breast and cervical cancer screening and follow-up of abnormal results. The institutional review boards of the Northern California Cancer Center, the University of California at San Francisco, and the Contra Costa County Health Services Department, approved this project.

Details of the design and baseline survey results have been previously published (14, 15). The study used a 2 × 2 factorial design to test specific hypotheses for two interventions, alone and synergistically, intended to improve screening knowledge, attitudes, and behavior in the intervention arms for mammography, breast self-examination, clinical breast examination, and Pap smears. The outreach intervention used lay health

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workers (LHW) to facilitate access at special screening day events, whereas the inreach intervention consisted of provider education and computer reminders. A third patient navigator intervention to enhance follow-up and resolution of abnormal results (15) is not reported here.

Interventions. The outreach intervention identified underserved women in selected communities and provided them with the support and information needed to obtain initial and repeat breast and cervical cancer screening. It was based on a small group and one-on-one education by salaried LHWs who represented the targeted race/ethnic groups (15). LHWs interacted with women on an ongoing and personal basis to achieve maintenance of periodic screening through three channels: one-on-one visits at various events and locations; presentations to community-based organizations (agencies); and Women's Health Days, offering free mammograms, Pap tests, and breast self-examination instruction. LHWs were intensively trained in basic breast and cervical cancer biology, screening and treatment, and the availability of health care and screening services in the intervention neighborhoods. Methods for the inreach intervention included updates for providers on screening guidelines, the use of patient models to improve skills in breast and pelvic examination, and the institution of computer reminders (14, 15).

Selection of Sample. Eight low-income neighborhoods and the eight public health clinics serving them were selected for study (15). Before randomization, the eight neighborhoods were paired by county location and similarities in race/ethnic composition based on county records. One clinic in San Francisco was unable to accept new referrals from screening, so the neighborhood it served was therefore allocated to the control condition. In the inreach intervention, we paired the eight clinics by county, number of annual outpatient visits, and estimated race/ethnic composition of their patients. Random allocation of clinics for intervention was not feasible for the pair of Contra Costa Clinics because one clinic could not support development of the planned computer-based reminder system. Therefore, as previously described (15), assignment of neighborhoods and clinics was not completely random. Following the 2×2 factorial design, two clinics and surrounding neighborhoods were selected for both outreach and inreach interventions; two were designated as control for both interventions; two were selected for the outreach but not for the inreach intervention; and two were selected for the inreach but not for the outreach intervention.

Data Collection. As in the baseline survey, in-person interviews were conducted with women residing in the neighborhoods (census tracts) served by the eight public health clinics. One woman, 40 to 75 years old, was selected at random from each randomly chosen household. The same questionnaire and survey procedures were used as in the preintervention surveys with only minor modifications to assess exposure to the intervention (15). Questions were asked about demographics, screening practices and other selected medical practices, insurance coverage, and usual sources and frequency of clinic visits. Documentation of the implementation of BACCIS was collected by LHWs, who completed a report for every woman and agency contacted and for each follow-up visit (Table 1).

Analytic Methods. χ^2 Tests were used to evaluate changes from pretest to posttest in demographic characteristics and screening behavior in the outreach intervention and control areas. A z-test based on the normal approximation to the binomial was used to evaluate the difference between intervention and control in pretest to posttest change in screening prevalence. Logistic regression was used to model the effects on screening of outreach and inreach interventions and their combination, controlling for demographic characteristics. Because not all neighborhoods were randomly assigned, fixed-effects models were used. Main effects for time (posttest versus pretest) and residence in the outreach and inreach areas were included. The outreach and inreach intervention effects were each modeled as an interaction between residence in the respective intervention area and time; their combined effect was represented by an inreach-outreach-time interaction. Models also included terms for neighborhood and neighborhood-time interaction within study condition. We anticipated an interaction between the outreach and inreach interventions, such that communities that received both would have higher adherence to screening guidelines than to either one alone.

First time and maintenance screening behavior was described for the four screening procedures for all women ages 40 years and older. Mammography was reported as having one in the past 2 years and as three or

Table 1. BACCIS outreach summary, March 1993 to October 1995

Event/individual contact	Contra Costa county	San Francisco county	Total
Individual contact*	1,184	1,360	2,544
Individual follow-up†	1,432	1,313	2,745
Agency contact‡	225	290	515
Agency follow-up§	255	440	695
Group presentation/no. attendees surveys‖	93/322	181/497	274/819
Women's Health Day events/no. participants¶	8/783	1/24	9/807

*Women reached through one-to-one contact by outreach workers.
†Follow-up contacts with individual women.
‡Agencies contacted for outreach.
§Follow-up contacts with agencies.
‖Presentations to groups by outreach staff/no. attendees who completed a survey.
¶BACCIS-sponsored day-long events providing free mammograms, clinical breast examinations, pelvic and Pap smears/no. of women participating (in San Francisco, the Women's Cancer Network sponsored additional events in which BACCIS personnel participated).

Table 2. BACCIS community surveys: comparison of pretest and posttest self-reported screening behavior of respondents by outreach study arm: women ages 40+ years

Variable	Intervention			Control		
	Pretest	Posttest	χ^2 P	Pretest	Posttest	χ^2 P
	Total, n (%)	Total, n (%)		Total, n (%)	Total, n (%)	
Mammography						
Ever	798 (83)	812 (86)	NS	798 (68)	803 (77)	0.001
Past 2 y	798 (73)	812 (71)	NS	798 (57)	803 (62)	0.022
Three or more in past 5 y	794 (50)	812 (51)	NS	794 (35)	803 (41)	0.008
Clinical breast examination						
Ever	801 (94)	812 (95)	NS	798 (82)	803 (87)	0.006
Past year	800 (75)	809 (74)	NS	796 (56)	803 (60)	NS
Three or more in past 5 y	793 (73)	809 (73)	NS	792 (54)	800 (54)	NS
Pap smear						
Ever	801 (95)	812 (96)	NS	798 (83)	803 (87)	0.021
Past 3 y	799 (84)	811 (87)	NS	798 (69)	801 (75)	0.009
Breast self-examination						
Ever	800 (89)	810 (92)	0.031	793 (83)	802 (81)	NS
Monthly for the past year	800 (24)	808 (26)	NS	793 (18)	801 (23)	0.018

NOTE: Pretest was conducted in 1992 to 1993 (n = 1,599). Posttest was conducted in 1996 to 1997 (n = 1, 616).
Abbreviation: NS, not significant at the 0.05 level.

more in the last 5 years. Pap smears were reported for one or more in the last 3 years. We based our estimates for sample size and expected intervention effects on an assumed baseline adherence of 60% and a minimal detectable difference of 10% postintervention consistent with rates reported from the California Behavioral Risk Factor Survey from 1988–1991 (16).

Results

Characteristics of Outreach Study Population. The baseline surveys were in 1992 and 1993. The post-intervention surveys in 1996 and 1997 completed interviews in 1,616 of 2,370 respondents presumed eligible (68%), 75 (3%) were unavailable, and 679 (29%) refused. Of the 1,616 respondents, 459 were White, 433 were African American, 268 were Hispanic, 288 were Chinese, 84 were Filipina, and 84 were of other ethnicities. Most women chose to use English in the interview (1,266), but 224 preferred Cantonese and 126 preferred Spanish. Age and race/ethnic distributions remained the same as in the baseline survey with ~60% of the respondents over 50 years of age.

The number of women and agencies contacted through the outreach intervention are summarized in Table 1. During the course of the BACCIS project, the Center for Disease Control and Prevention Breast and Cervical Cancer Control Program (17) was instituted in all areas of the two counties, including BACCIS-designated control areas, providing free mammograms and Pap smears to all eligible, uninsured women.

Effect of the Intervention. Analyses comparing intervention and control communities showed no significant improvement in reported screening behavior for the intervention group for mammography, clinical breast examination, or Pap smear (Table 2), although more women reported ever having done breast self-examination (92% versus 89%). However, among the controls, significant and substantial improvements were reported for all behaviors. For example, mammography during the previous 2 years increased from 57% to 62% (P = 0.022). Only in the two Contra Costa neighborhoods was some improvement noted in having ever had a Pap smear (95-99% pretest to posttest) that was significant (P = 0.01). Models of the intervention effect that included variables for key differences in community characteristics, such as race/ethnicity, education, and English language capacity, did not show any substantive difference from the unadjusted comparisons (Table 3). Exposure to the inreach intervention clinics had no positive effect and there was no synergistic interaction between the outreach and inreach interventions. The strongest associations were for speaking English, having health insurance, having a regular source of care, having a checkup in the previous year, and reported use of hormone replacement therapy, all of which have more to do with being connected to the health care system than the BACCIS intervention per se.

Despite intensive efforts with outreach, just 7% of respondents from the outreach intervention areas and 6% of those from control areas had ever heard of BACCIS. However, the mean number of types of BACCIS-related events attended was significantly higher in the outreach intervention areas than in the control areas (0.85 versus 0.65, P = 0.004).

Discussion

BACCIS was one of the largest controlled community intervention trials of breast and cervical cancer screening conducted in the 1990s. It also included diverse ethnic and cultural subgroups, with intensive interventions and surveys in four languages. The lack of effect was, therefore, disappointing. However, there were several lessons learned that may benefit future community intervention of cancer screening and other behaviors.

Despite the fact that we attempted to target women in lower-income census tracts in San Francisco and Contra Costa counties, baseline levels of screening were

Table 3. BACCIS community surveys: logistic regression models of intervention effects on self-reported screening behavior of women ages 40+ y

	Mammography*			Pap smear*	
	Ever (n = 3,018)	Past 2 y (n = 3,018)	Three in last 5 y (n = 3,011)	Ever (n = 3,021)	Past 3 y (n = 3,017)
Time					
Posttest	**1.3 (1.1, 1.7)**	0.9 (0.8, 1.1)	1.2 (1.0, 1.4)	1.2 (0.7, 2.0)	1.0 (0.8, 1.3)
Pretest	**1.0**	1.0	1.0	1.0	1.0
Outreach × time					
Intervention area	0.7 (0.5, 1.1)	0.7 (0.5, 1.0)	0.8 (0.5, 1.1)	1.5 (0.6, 4.2)	0.9 (0.6, 1.3)
Control area	1.0	1.0	1.0	1.0	1.0
Inreach × time					
Intervention area	0.7 (0.5, 1.1)	0.7 (0.5, 1.1)	0.6 (0.4, 0.8)	0.5 (0.2, 1.5)	0.7 (0.5, 1.1)
Control area	1.0	1.0	1.0	1.0	1.0
Outreach × inreach × time					
Outreach = inreach	0.9 (0.6, 1.4)	1.1 (0.8, 1.6)	1.1 (0.8, 1.6)	0.5 (0.2, 1.3)	1.2 (0.8, 1.9)
Outreach ≠ inreach	1.0	1.0	1.0	1.0	1.0
Age (y)					
<50	0.5 (0.4, 0.7)	0.5 (0.4, 0.6)	0.3 (0.2, 0.4)	1.2 (0.8, 1.8)	1.3 (1.0, 1.7)
50-64	1.0	1.0	1.0	1.0	1.0
65+	1.1 (0.8, 1.5)	1.0 (0.7, 1.2)	1.1 (0.9, 1.4)	0.7 (0.4, 1.0)	0.6 (0.4, 0.8)
Ethnicity					
Hispanic	1.3 (0.8, 2.4)	0.7 (0.5, 1.1)	0.9 (0.6, 1.4)	2.1 (0.6, 7.7)	1.2 (0.7, 2.0)
African American	0.7 (0.5, 1.0)	0.9 (0.7, 1.2)	0.9 (0.7, 1.2)	**2.2 (1.0, 4.8)**	**1.5 (1.0, 2.1)**
Chinese	0.8 (0.4, 1.6)	1.0 (0.6, 1.8)	0.7 (0.4, 1.2)	1.3 (0.4, 4.4)	1.4 (0.7, 2.9)
Other	0.6 (0.3, 1.0)	0.6 (0.4, 1.0)	0.6 (0.4, 0.9)	1.2 (0.4, 3.7)	1.1 (0.6, 2.0)
White	1.0	1.0	1.0	1.0	1.0
Speaks English					
Yes	**3.2 (2.0, 4.9)**	**2.3 (1.6, 3.5)**	**2.5 (1.7, 3.8)**	**1.6 (1.0, 2.8)**	**1.7 (1.1, 2.5)**
No	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**
Insurance					
None	**0.4 (0.3, 0.5)**	**0.4 (0.3, 0.5)**	**0.4 (0.3, 0.6)**	**0.6 (0.4, 0.9)**	**0.5 (0.3, 0.6)**
Public	**0.6 (0.4, 0.8)**	**0.6 (0.5, 0.8)**	**0.6 (0.5, 0.8)**	**0.6 (0.4, 1.0)**	**0.7 (0.5, 0.9)**
Private	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**
Income					
<$20,000	0.8 (0.6, 1.0)	0.8 (0.6, 1.0)	0.7 (0.6, 0.9)	0.8 (0.5, 1.2)	0.7 (0.5, 1.0)
≥$20,000	1.0	1.0	1.0	1.0	1.0
Missing	0.9 (0.6, 1.2)	0.8 (0.6, 1.1)	0.8 (0.6, 1.0)	0.7 (0.5, 1.2)	0.7 (0.5, 1.0)
Education (y)					
<12	0.9 (0.7, 1.2)	0.9 (0.7, 1.1)	0.8 (0.6, 1.0)	0.6 (0.4, 0.9)	0.8 (0.7, 1.1)
≥12	1.0	1.0	1.0	1.0	1.0
Birthplace					
Latin America	1.3 (0.6, 2.5)	**2.8 (1.7, 4.7)**	**1.9 (1.1, 3.0)**	0.6 (0.2, 2.2)	1.4 (0.8, 2.6)
Asia	0.9 (0.5, 1.6)	1.0 (0.6, 1.6)	1.0 (0.6, 1.6)	0.2 (0.1, 0.7)	0.3 (0.2, 0.6)
U.S./Other	1.0	1.0	1.0	1.0	1.0
Residence in area (y)					
≤5	**0.6 (0.5, 0.8)**	**0.7 (0.6, 0.9)**	**0.7 (0.6, 0.9)**	**0.7 (0.5, 1.0)**	0.9 (0.7, 1.2)
>5	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**
Married					
Yes	1.1 (0.9, 1.4)	**1.2 (1.0, 1.5)**	1.1 (0.9, 1.3)	0.8 (0.5, 1.1)	**1.3 (1.0, 1.6)**
No	1.0	**1.0**	1.0	1.0	**1.0**
Employed					
Yes	1.2 (0.9, 1.6)	**1.3 (1.0, 1.6)**	1.0 (0.8, 1.3)	**1.5 (1.0, 2.3)**	1.1 (0.8, 1.4)
No	1.0	1.0	1.0	1.0	1.0
Current HRT use					
Yes	**2.0 (1.4, 3.1)**	**2.1 (1.5, 2.8)**	**2.3 (1.8, 2.9)**	**2.8 (1.3, 5.9)**	**2.4 (1.7, 3.6)**
No	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**
Regular place of care					
Yes	**1.6 (1.2, 2.3)**	**2.3 (1.6, 3.4)**	**2.3 (1.4, 3.8)**	1.4 (0.9, 2.2)	**1.5 (1.1, 2.2)**
No	**1.0**	**1.0**	**1.0**	1.0	**1.0**
Checkup in the past year					
Yes	**3.6 (2.9, 4.6)**	**5.2 (4.2, 6.4)**	**3.6 (2.8, 4.6)**	**2.9 (2.0, 4.1)**	**3.9 (3.1, 5.0)**
No	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**

NOTE: Effects significant at the 0.05 level are in bold. Pretest was conducted in 1992 to 1993 (n = 1,599). Posttest was conducted in 1996 to 1997 (n = 1,616).
Abbreviation: HRT, hormone replacement therapy.
*Controlling for area at pretest and posttest and all covariates listed.

unexpectedly high and close to national goals for the year 2000 (18) with, for example, 76% of all women having ever had a mammogram and 65% having had one in the previous 2 years. Such baseline rates limit the potential to evaluate the intervention, because there is less room for improvement. We based our power calculations on data from the California Behavioral Risk Factor Survey in 1987 to 1990 (16) and slightly earlier

reports from other underserved populations in the United States (19), which turned out to be underestimates of screening prevalence in our population.

However, segments of the population, primarily non-English–speaking women, were far from adherent to age-appropriate cancer screening guidelines Only 26% of non-English–speaking Chinese women and 43% of non-English–speaking Hispanics, for example, reported receiving mammograms in the last 2 years. We might have had more effect had we identified characteristics beyond race and ethnicity that differentiate subgroups at risk and chosen intervention approaches that matched more clearly to population needs (20).

This study also illustrates how a household survey in a random sample of urban community residents may be an ineffective measure of improvements in screening behavior at the individual level among women directly contacted by LHWs. Other studies have found LHWs as an effective intervention (2); however, our methods did not allow us to conclusively assess their effect at the community level.

During the course of the BACCIS project, the Center for Disease Control and Prevention Breast and Cervical Cancer Control Program (17) was instituted in all areas of both counties. Although this program was welcomed as a benefit to underserved women, we found that it was most heavily used in BACCIS control areas where there were substantial increases in reported screening behaviors. Suarez et al. (21) reported this same contamination phenomenon in Mexican American communities in Texas.

Finally, despite our best attempts to balance the pairs of neighborhoods before randomization, the intervention women were better educated, better insured, more likely to speak English, and less likely to be foreign born, all strong predictors of screening behavior (Table 3). These important variables were controlled for in logistic regression, but the potential for residual confounding remained and could have contributed to the lack of observed effect.

In summary, the BACCIS intervention, as measured by the results of the household survey and including evidence from clinic records for the inreach component (14), was inconclusive. High baseline screening rates, lack of sensitive measures of change, contamination of the control group, and an imbalance of predictive factors between the intervention and control arms of the study, all conspired to minimize any measurable effect of the outreach intervention. There were also no significant interactions with the inreach clinic intervention. Similar studies in the literature, when effective, have shown small or modest effects, and it may not be surprising that given suboptimal experimental conditions, the BACCIS intervention was unable to document the desired outcomes. Future community studies may want to take these lessons into account in their design and execution.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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