Cancer Screening Intervention Among Black Women in Inner-City Atlanta—Design of a Study

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Synopsis

This experimental study attempts to determine if an in-home educational intervention conducted by lay health workers (LHWs) can increase adherence among low-income, inner-city black women to schedules for screening for breast cancer and cervical cancer, as well as increase the women's

B_{LACK} WOMEN are more likely than white women to have advanced breast and cervical cancers and to have a lower survival rate from those cancers (1-6). Freeman has suggested that at least half of the difference in survival among disadvantaged people is due to late diagnosis and inadequate secondary prevention (1). Papanicolaou (Pap) smears and clinical breast examinations are simple and effective methods of secondary prevention for cervical canknowledge and change their attitudes regarding these cancers. This paper is a description of the purposes, hypotheses, design, subject recruitment, intervention, and evaluation of the study conducted by Morehouse School of Medicine.

Subjects were recruited from a variety of sources, including patients seen in a community health center, women referred by the National Black Women's Health Project (NBWHP), residents of public and senior citizen housing projects, and persons identified in various community settings. Fewer than half of those asked to participate agreed to do so. The 321 women who were recruited were demographically diverse.

Overall, about half of these volunteer subjects self-reported at least one Papanicolaou (Pap) smear and one breast examination within a year before enrollment in the study. There was little variation by source of recruitment in compliance with screening recommendations, except that referrals from NBWHP were more likely (P < 0.0l) to have had a Pap test and breast self-examination, while residents of public housing projects were somewhat less likely to have done so. About 35 percent of participants ages 35 and older had a mammogram within an appropriate interval.

Participants were randomly assigned to intervention and control groups. Women in the intervention group were visited in their homes by LHWs on three occasions; the LHWs provided education on cancer and reproductive health. The groups were comparable in their baseline sociodemographic status and previous screening history.

cer and breast cancer, respectively (7-9). Mammography is probably a more effective method of secondary prevention of breast cancer, but it is more costly and much less available than clinical examinations (10). To increase screening for these cancers among low-income women and black women is one of the important goals listed in "Healthy People 2000" (10).

Little information has been published on effec-

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tive interventions to increase screening for cervical and breast cancers among black women. Black and white women alike are regularly exposed to healthrelated messages through the mass media and the work of public agencies and nonprofit organizations. Commonly used health education materials and approaches, however, may be inappropriate for minority populations. Brochures, for instance, may use pictures only of white women and may have a reading level too high for poorly educated persons. There may be few relevant teachers or role models. For example, the well publicized breast cancers of Happy Rockefeller and Betty Ford may have stimulated many white women to seek breast examinations and mammograms, but among blacks these events may simply have strengthened the misunderstanding that breast cancer is a disease of well-to-do white women. Culturally sensitive interventions use minority women as models and employ their vocabulary; they use women of the same background as the target group to deliver services.

This study is intended to test the effectiveness of a culturally sensitive, in-home education program conducted by lay health workers (LHWs). It has been jointly conducted by staff of Morehouse School of Medicine (MSM) and the National Black Women's Health Project (NBWHP), a communitybased advocacy and self-help organization. The intervention is intended to increase by at least 15 percent the rate of participation of black women in screening programs for breast and cervical cancers. This increase is consistent with the "Healthy People 2000" goal of increasing Pap screening by 13 percent (10). The educational program is also expected to increase the subjects' knowledge of breast and cervical cancers and of cancer screening. In addition, baseline survey data are collected to identify barriers to screening among black women. This report describes the study design, subject recruitment, study group assignment, and baseline characteristics of participants. We started subject recruitment in March 1989 and intervention activities in February 1990; we finished postintervention interviews in April 1992.

Target Population

This project was originally designed to identify and recruit black women, ages 18 and older, with no history of cancer, hysterectomy, or breast surgery. Subjects were initially drawn from the patient registry of the West End Medical Center (WEMC) clinics in Atlanta (Fulton County), GA. These clinics are located in two predominantly black inner-city neighborhoods at a convenient distance from MSM (4 miles) and the NBWHP office (1 mile).

Because of difficulties in identifying eligible subjects (with no history of hysterectomy or cancer) and in locating and recruiting these women, recruitment efforts were enlarged to include four lowincome public housing projects and two senior citizen housing projects in the West End area and women who were referred by the NBWHP. Four LHWs were responsible for recruitment. Strategies included house-to-house solicitation of women identified by public housing and senior citizens project managers and telephone contact with referrals from the NBWHP. Women were also recruited during visits to beauty salons, laundromats, stores, and offices and through telephone solicitation targeting the West End neighborhood.

The study team also decided to focus recruitment efforts on women ages 35 and older, who are less likely to have been screened (6,7) and more likely to develop cancer. Women less than 35 years old who were recruited into the study before the age criterion was revised were retained as participants. Other criteria for eligibility—no history of cancer, hysterectomy, or breast surgery—were retained.

The most effective recruitment strategy was door-to-door canvassing to locate women in public housing projects and places of business. The LHW assessed eligibility immediately and obtained informed consent. The problems of absent or disconnected phones and incorrect addresses were avoided. LHWs had to work in teams in these housing projects because of safety considerations. Recruiting was also effective in beauty salons and laundromats because women were available and willing to discuss participation. Overall, 170 subjects were recruited by these methods.

The least efficient strategy was followup of WEMC patients and persons referred from NBWHP; they required an enormous number of telephone contacts to obtain appointments for the baseline visits. However, we were able to recruit 55 WEMC patients and 96 NBWHP referrals. Altogether, we contacted approximately 875 women, of whom 321 agreed to participate in the study.

To take into account possible dropouts and to achieve even a higher power, we had initially set a target of 600 recruited women; the 321 women were substantially fewer than that. However, a sample size calculation showed that—assuming a 30 percent baseline rate of a variable of interest (that is, Pap smear) and a postintervention increase of 15 percent—a sample size of 150 subjects in the experimental and in the control group would provide at least 80 percent power to detect an impact of the intervention at a 0.05 level of significance.

Study Design

All subjects were interviewed by the LHWs to gather baseline information about their knowledge of cancer and attitudes toward cancer prevention activities; their history of Pap smears, breast examinations, and mammograms; and their demographic and socioeconomic statuses. With the consent of the subjects, we are obtaining their medical records to confirm their Pap smear and breast examination history.

After recruitment, the women were stratified by the source of recruitment and age. Within those stratified blocks, they were ranked by age and then randomly allocated into intervention (163 women) and control (158 women) groups (see chart).

The LHWs offered the educational material to the women in the intervention group during visits to their homes. The women have been followed over the remainder of the study period to determine the frequency with which they obtain cancer screening examinations. This followup was accomplished through a postintervention interview at least 6 months after completion of the intervention. The controls received a similar interview at the end of the study, but did not receive the intervention. At the end of the study period, all participants were reinterviewed to determine where they had sought medical care, and their medical records will be 'Incomes were low; 27 percent had an annual household income under \$5,000, and 48 percent had incomes under \$15,000. By comparison, 10.4 percent of U.S. families have incomes under the official poverty level— \$12,092 for a nonfarm family of four.'

reviewed to determine the frequency of cancer screening examinations. Women in the control group also received educational materials at the end of the followup. All women will be sent a reminder postcard if, by the end of the study, they have not obtained a recommended examination.

Intervention Process

The intervention was composed of two educational sessions, each about 1.5 hours in length, held 2 to 3 weeks apart at the home of the subject. A "booster" session was scheduled about 2 months after the second session (see chart) for the purpose of review and reinforcement.

Each educational session had a factual content. The first session included information about breast and cervical cancers as well as the tests for their early detection—Pap smear, breast self-examination, clinical breast examination, and mammogram. We have prepared a videotape of a Pap smear and breast examination for use in this session. The tape used black female models as both the patient and the physician.

The factual content of the second session included a brief review of the material from the first session and new material on reproductive health, including methods of contraception and high-risk sexual practices. Appropriate printed materials were provided and an offer extended to attend meetings of a self-help support group.

The content of the educational intervention follows:

• demonstration and teaching of breast selfexamination (BSE);

• print and video presentation of BSE, Pap smear, and pelvic examination, and reproductive health information;

• print and oral health education materials on risk factors for breast and cervical cancers;

	Cohort						
	Intervention (N = I63)		Control (N = 158)		Total (N = 321)		
	Number	Percent	Number	Percent	Number	Percent	P1
Age:							
Less than 35 years	22	13.5	21	13.3	43	13.4	
35-44 years	75	46.0	70	44.3	145	45.2	
45–59 years	36	22.1	39	24.7	75	23.3	
60 and older	30	18.4	28	17.7	58	18.1	0.96
Income:							
Less than \$5.000	43	26.4	45	28.5	88	27.4	
\$5.000-\$14.999	31	19.0	35	22.2	66	20.6	
\$15,000-\$24,999	27	16.6	20	12.7	47	14.6	
\$25,000 or more	28	17.2	21	13.3	49	15.3	
Refused or unknown	× 34	20.9	37	23.4	71	22.1	0.67
Married or live as married:							
Vae	55	33.7	48	30.4	103	32 1	
No	108	66.3	110	69.6	218	67.9	0.52
	100	00.0		00.0	210	07.0	U.UL
Years of school attainment:	F 4	04.0	50	00 F	404	00.4	
Less than 12 years	51	31.3	53	33.5	104	32.4	• • •
	40	28.2	44	27.9	90	28.0	
More than 12 years	00	40.5	01	30.4	127	39.0	0.90
Employment status:							
Employed	90	55.2	74	46.8	164	51.1	
Student or housewife	17	10.4	14	8.9	31	9.6	
	23	14.1	27	17.1	50	15.6	
Other not worked	33	20.3	43	27.2	76	23.7	0.12
Insurance. ves	86	52.8	77	48.7	163	50.8	0.47
Medicaid. ves	39	23.9	50	31.7	89	27.7	0.12
Medicare, yes	24	14.7	25	15.8	49	15.3	0.78
Time since last Pan test:							
Less than 1 year	82	50 3	82	51 9	164	51.0	
1 year or more	81	49.7	76	48.4	157	48.9	0.78
	01	40.7		-0.4		10.0	00
Time since last breast examination:				<i></i>	470		
Less than 1 year	90	55.2	88	55.7	178	55.5	
1 year or more	73	44.8	70	44.3	143	44.6	0.92
Mammography:							
Adequate ²	51	35.4	48	34.0	99	34.7	
Inadequate	93	64.8	93	66.0	186	65.3	0.81

¹ Chi-square test. ² Age >34 only: baseline mammogram if ages 35-39, within 3 years if ages 40-49, within 1 year if age >49, otherwise inadequate.

• print and oral materials on mammography;

• review and evaluation of materials previously presented;

• interpretation, referral, and followup of the subjects concerning any abnormal Pap smear or breast examination results;

• facilitation to promote the use of cancer screening services, transportation, and scheduling for other referral processes;

• encouragement to participate in NBWHP's selfhelp groups.

Intervention Agents

The LHWs, selected from NBWHP, were the key intervention agents. The NBWHP, a

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community-based women's health group, was established in 1980 in Atlanta. This organization actively seeks self-help resources for wellness and makes the black community more aware of selfhelp approaches to health in order to help empower black women. It addresses the health issues facing women and their families through national and local media, educational presentations, self-help chapters, networking, a national newsletter, national and regional conferences, and research.

In cooperation with the NBWHP, LHWs underwent a 10-week training course at MSM in interviewing, teaching, and human relations skills, as well as the women's health issues listed. Throughout the study, biweekly meetings were held to ensure that the LHWs were conducting their tasks in a similar manner and to address new training issues and topics. Each LHW was given a set of intervention rules which served as a guide in conducting the educational intervention.

Each LHW resides in the target community. Their backgrounds varied, but each of them had group facilitation skills and 1 year of grassroots organizing experience in women's health before joining our study. None is a health professional, but each has had a great deal of hands-on experience in working with women in the community as a self-help support group leader at NBWHP.

The LHWs were trained not only to provide information on breast and cervical cancers but to encourage women to ask questions and raise personal concerns about their health. Each LHW was trained to attend to these concerns and to motivate the subject to take positive control of her life by learning to care for her body and to understand her own health needs.

The intervention was designed to be "culturally sensitive," based on the following characteristics:

• It was delivered by women who are black, who are experienced in working with the target communities, and who speak and act like the women from those communities.

• The print, video, and "live" messages used black role models to help the recipients identify with the information.

• The reading level of the printed material was pilot tested to ensure its appropriateness for the target population.

• The video on Pap smear and breast examination was designed to be realistic but, through the use of simple and familiar language, to be reassuring.

• The one-on-one sessions with the lay health workers ensured that all information was transmitted or reinforced through a vocal and, more specifically, a conversational interaction. The information was discussed rather than simply presented and questions could be answered immediately.

Evaluation

Both process and outcome evaluations are planned. Process evaluation addressed the quality of the intervention's delivery and knowledge transfer. Outcome evaluation will compare changes in the experimental group with changes in the control group. Changes in cancer screening compliance, knowledge, attitudes, and practices will be evaluated. To measure changes in knowledge, we included 25 items in breast cancer etiology and 'If health educators in other locations attempt to affect screening practices of low-income black women, they are likely to encounter the same difficulties with clinic-based or roster-based recruitment that we encountered in Atlanta.'

control, 15 items in cervical cancer, and 9 items in general in both the baseline and postintervention questionnaires. We believed that these questions were simple and appropriate for inner-city women to answer. All questions were pilot tested. To determine if knowledge is associated with behavior change, we will compare changes in knowledge with changes in behavior.

Process evaluation. Process evaluation forms were completed by both the LHWs and respondents. The LHW conducted an evaluation immediately after completing each intervention. She reported which content areas had been discussed and which specific materials had been delivered to the subject. The subject reported if new information was learned and if the presentation was clear and worthwhile. Separate evaluations were completed for the first and second interventions.

Three process measures were of interest: (a) our ability to keep subjects involved in the study throughout the interventions and end point data collection, (b) the proportion of times the educational program was delivered completely and appropriately by the LHWs, (c) the amount of knowledge gained by the subjects immediately after each session.

The first was of interest because it was the most basic measure of whether the intervention could reach target women. It was also important to assure adequate statistical power, generalizability of results, and reduction of bias due to differential attrition. The second was of interest because the successful transfer of information was a hypothetically necessary (but not sufficient) condition for a successful intervention outcome. The third measure reflected the immediate impact of the education.

Outcome evaluation. The primary analysis will determine whether the intervention was effective in increasing the proportion of women who receive regular Pap smears and breast examinations. The analysis will compare the proportions of women in

Table 2. Percentage of women who had obtained cancer screening examinations within a given interval by type of examination and recruitment source

Type of examination						
	West End Medical Center (N = 55)	National Black Women's Health Project referrais (N = 96)	Public and senior citizens housing projects (N = 99)	Other (N = 71)	Ali (N = 321)	P1
Pap smear within previous year:						
Crude	52.7	60.4	40.4	52.1	· 51.1	0.17
Age-adjusted ²	51.9	³ 60.6	³ 39.2	48.0		
Ever did breast self-examination						
Crude	81.8	92.7	81.8	91.5	87.6	0.19
Age-adjusted ²	85.2	³ 93.2	³ 71.7	92.3		
Breast examination by physician within previous year:						
Crude	56.4	57.3	56.3	56.3	55.5	0.77
Age-adjusted ²	53.5	55.2	46.9	52.6		
Adequate mammography:4						
Crude	31.0	31.5	39.8	33.3	34.7	0.51
Age-adjusted ²	29.9	32.5	39.5	32.8		

 1 P-value for Mantel-Haenszel statistics with age strata: <35, 35-44, 45-59, and >59.

and public housing and senior citizens is significant at 0.01 level. ⁴ Adequate: baseline mammogram if ages 35-39, within 3 years if ages 40-49, within 1 year if age >49, otherwise, inadequate; women age <35 excluded.

² Adjusted to the age distribution of the total group of subjects.

³ The difference between the National Black Women's Health Project referrals

the intervention group and the control group who comply with recommendations for obtaining these tests at baseline and following completion of the intervention.

The analysis will adjust for variables that are shown to be predictive of compliance and are differentially distributed in the intervention and control groups at the baseline. It will also determine whether the effect of the intervention is restricted to or differs among subgroups of women.

Comparability of Subjects and Assignment

Of the 321 women recruited, 17.1 percent were recruited from the WEMC patient pool; 29.9 percent from NBWHP referrals; 30.8 percent from public housing and senior citizens apartments; and 22.1 percent from other miscellaneous sources including supermarkets, stores, beauty salons, laundromats, and unemployment offices. The study population is further described in table 1.

Although it is composed of volunteers, the study group was clearly representative of the population originally targeted—low-income blacks in Fulton County. Incomes were low; 27 percent had an annual household income under \$5,000, and 48 percent had incomes under \$15,000. By comparison, 10.4 percent of U.S. families have incomes under the official poverty level—\$12,092 for a nonfarm family of four (11). We also found that 32 percent of subjects had not graduated from high school. Sixteen percent were unemployed, and 28 percent were enrolled in Medicaid.

The randomization procedure produced two comparable study groups (table 1). They differed little in age (a blocking factor), income, marital status, or educational level. While there was little difference in employment status, the control women were somewhat less likely to be working. The groups were also similar with respect to cancer screening history. During the previous year, roughly 50 percent of each group had had a Pap test and 55 percent had had a clinical breast examination. Approximately 35 percent reported having received adequate mammography.

Baseline Screening Practice

The crude and age-adjusted percentages of subjects who ever practiced breast self-examination or who had received cervical or breast cancer examinations within the year before they answered the baseline questionnaire are indicated by recruitment source in table 2. The rate of timely cancer screening, after controlling for age, did not vary substantially among groups by method of recruitment. However, there was an indication of less frequent cervical cancer screening (39.2 percent) and breast self-examination (71.7 percent) among public housing residents and senior citizens, particularly compared with women referred from NBWHP (P < 0.01).

Discussion

This project initially attempted to recruit subjects identified from records at a community health clinic. This strategy was not successful for at least two reasons: information on addresses and telephone numbers recorded even 1 to 2 years before the study was incorrect or out of date for 34 percent of the women, and a large proportion of women identified through this mechanism (17 percent) refused to participate. Reasons commonly given for refusal were the lack of financial or other incentives as compensation for their time and general lack of interest in the study.

Expanding the study to recruit from public housing projects using door-to-door canvassing was more successful, in part because a consent for participation and an interview could be obtained immediately in person at the initial contact. The next most successful recruitment method was solicitation at places of business, again because assessment of eligibility was made instantly. Recruitment from NBWHP referrals was less successful than expected and may not be applicable to many communities in any event.

To recruit 321 women into this study, four LHWs, the project manager, and a clerk worked for 9 months and contacted about 900 women. The effort required to recruit women into an experimental study such as this may be greater than the effort that would be required to recruit women into a purely educational program. However, to be cost-effective, an intervention strategy would have to recruit participants more quickly than did this one. The door-to-door approach in recruitment seems to be one method for increasing recruitment effectiveness; it needs to be evaluated further.

Since the 321 subjects recruited to date were a volunteer convenience sample, they might differ somewhat from nonparticipants in the target area. This possibility raises the question of how the sampling method affects the generalizability of experimental findings. The study participants generally had low levels of income, education, and other measures of socioeconomic status, which suggests that we successfully recruited from the target population.

If health educators in other locations attempt to affect screening practices of low-income black women, they are likely to encounter the same difficulties with clinic-based or roster-based recruitment that we encountered in Atlanta. Therefore, they are likely to resort to recruitment from a variety of sources, sampling women who are ready to participate in such an intervention. The results of this study are likely to be generalizable to interventions with similar recruitment methods.

In any case, changes in subjects' eligibility do not affect the internal validity of this intervention study because subjects were stratified on the basis of age, and they were allocated at random to experimental and control groups. The groups were also similar in sociodemographic status and history of cancer screening. Effects may vary by recruitment source and other characteristics, and this issue will be evaluated during the data analysis at the end of the study.

In planning this study, we had assumed baseline screening rates of 30-40 percent. This assumption was based on a 1976 study in Buffalo, NY (7). In our survey, however, about half of the women reported having had at least one Pap smear test, and about half reported a breast examination within the past 12 months. These self-reported findings have not yet been verified by medical record review, and it may be found that the subjects inaccurately reported their screening histories. It has been reported that about 80 percent of women are able to recall their Pap smear history correctly (12). Rates of Pap tests have varied substantially, depending on the study population and the year (7-13).

In the 1988 telephone survey of the Behavioral Risk Factor Surveillance System, Centers for Disease Control, it was found that 82 percent of black women living in homes with telephones reported receiving a Pap smear in the preceding year (9). A 1986 study of 290 inner-city women reported that about 56 percent received adequate Pap testing, having received three or four Pap tests in the previous 4 years (13). The percentage of women in our baseline study receiving Pap smears was well within the range described in the existing literature.

Mammography is superior to palpation in detecting breast cancer at an early stage (14, 15). Studies have documented an apparent increase in female breast cancer in this country in recent years (16-21), and early detection and increased use of mammography are among the factors suggested as contributing to this increase (21). The cancer registry in metropolitan Atlanta (21, 22) also recorded an increased incidence in breast cancer in the last decade. The increase was greater for *in situ* disease than for advanced stages, and it was higher for white women than for black women in Atlanta (21). This was probably because black women have used mammography less than have white women. Only 35 percent of subjects recruited for this study had a history of adequate mammography.

Since about half of the women had a history of inadequate Pap tests and breast examinations and about 65 percent, inadequate frequency of mammograms, effective intervention strategies are needed for such populations. In the original plan for this study, we had established a goal of increasing by 15 percent the number of women in the study population who received Pap smears and breast examinations during the previous year. The current goal is to increase these percentages to at least 70-75 percent. With a sample size of 321, we will have 80 percent power to detect a significant difference between the two study groups at 0.05 level if (a) compliance in the intervention group increases 18.5 percent, (b) compliance in the control group increases by 5 percent, and (c) the full 321 subjects are included in the final analysis.

This paper describes an attempt to deliver to a group of relatively low-income black women an intervention designed to be culturally appropriate. It is delivered by black women-lay health workers—of roughly the same background as the target audience. The materials used show black models and actors, and the materials are designed with black cultural norms in mind. It is based on an "empowerment" philosophy, which calls for black women to help themselves and each other rather than to depend on the dominant cultural group to care for them. If this intervention has significant impact, it would demonstrate how health promotion methods could be modified in order to reach minority cultural groups and other disadvantaged populations.

Since only half of the women recruited to this study had complied with screening recommendations (35 percent for mammography), the need for such intervention is apparent. However, the difficulty we encountered in recruiting women to participate in this study suggests that greater attention must be paid to develop methods to contact and involve black women in interventions.

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