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This study examines the impact of a multiple outcall intervention designed to increase adherence to mammography guidelines by low income and minority women, age 50+. While original plans involved using a geodemographic database to identify low income neighborhoods throughout the State of Colorado and conduct recruitment by telephone, this plan has been revised to involve face-to-face recruitment at grocery stores. Once recruited, women are counseled over the phone regarding screening mammography. Women not in compliance with guidelines receive up to a total of five counseling calls. The counseling is based on the stages of change model. Success of the intervention in promoting screening mammography is evaluated by means of telephone interviews conducted six months after the initial telephone call. The results of counseling in this group will be compared to results from a recently completed intervention study involving single outcalls. To date, pilot studies have been completed and 225 women (20% of the target) have been enrolled in the main study. Validation of self-reported mammography adherence will utilize records of the Colorado Mammography Advocacy Program. Cost-effectiveness will compare costs of this study condition with two conditions recently completed.

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Lori A. Crane 10-26-95

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INTRODUCTION

The proposed study addresses the issue of delivering effective and cost-effective health care to women for the early detection of breast cancer. To date, early diagnosis holds the greatest promise for women with breast cancer. When breast cancers are found early, they are most likely to be effectively treated. At present, routine screening mammography is the best known method for early identification of breast cancer in women over the age 50. Still, recent research indicates that only 41% of American women are receiving routine mammograms.¹ Low income and minority populations are generally less likely to have obtained cancer screening tests² and are more likely to be diagnosed with cancer at a later stage,^{3,4,5,6} with income being the critical factor. With regard to mammography screening, studies have consistently shown higher screening rates among white women compared to black women, Hispanic women, and women from other ethnic minorities,^{7,8,9,10,11,12,13} and higher screening rates as income increases.^{9,13,14,15} Stein et al⁹ found that stratification by income reduced differences in mammography rates between whites and blacks to only 1-2 percentage points in the low SES category, and 1-5 percentage points in the high SES category. However, while high SES Hispanics reported screening rates approximately equivalent to whites and blacks, rates of ever receiving mammography among low SES Hispanics were about half that of low SES whites and blacks, suggesting an interaction between ethnicity and income.⁹ Survival data for breast cancer also suggest inadequate screening and consequently later diagnosis among low income and minority women. One study found that black women were two times more likely to present with Stage IV breast cancer and one and one-half times more likely to present with Stage III breast cancer than white women.³ Other findings indicate that only 63% of black women are alive five years after diagnosis of breast cancer, compared to 75% of white women.^{16,17} In addition, Hispanic women are more likely than non-Hispanic white women to present with larger tumors and with regional or distant metastases.^{18,19,20} However, multivariate analyses indicate that income may be the primary explanatory factor for racial/ethnic differences in stage at diagnosis and survival, with racial/ethnic differences diminishing after adjustment for SES.^{4,5,6}

Research into barriers to screening mammography has generally pointed to one major factor: failure to receive a physician's referral for mammography.^{14,15,21,22,23,24,25,26,27,28,29,30} Low income women are particularly vulnerable, as they are less likely to have visited a physician during any particular time period, are less likely to have a regular source of care, and are less likely to receive regular preventive check-ups.^{2,31} Sporadic use of health care and use of multiple facilities tend to decrease the chance of receiving a doctor's recommendation for a mammogram.^{14,21,32,33,34,35,36,37,38,39} In addition, patients presenting with a specific complaint are less likely to receive recommendations for prevention (including mammography) than patients attending a general check-up or physical exam.⁴⁰ Physicians also report concern about cost to the patient as a primary reason for failing to refer for mammography^{36,41,42,43,44} -- this is more likely to suppress referrals for mammography to low income patients than to middle or upper income patients.^{44,45} In sum, low income women are unlikely to receive a mammography referral for a number of reasons, suggesting that other avenues of increasing screening among this population must be explored.

Recent research has identified many barriers, in addition to lack of a physician's referral, which impede the receipt of screening mammography by low income and minority women, including: lack of perceived risk; lack of perceived seriousness of the disease; cost; fear of radiation; fear of pain; fear of losing a breast; lack of knowledge; transportation; and lack of health insurance.^{1,2,7,9,14,24,26,31,32,35,46,47,48,49,50,51,39,52,53} Some barriers appear to be particularly important to subgroups. For example, embarrassment, respect, politeness, family involvement and anxiety over results are major concerns among Latinos.^{48,49,54,55,56,57} For African American women, research has found that lack of knowledge, cost, lack of perceived susceptibility, fear of pain, and fatalism toward cancer are particularly important.^{58,59,60,61} In addition, barriers specific to older women include lack of knowledge of the procedure and need for it, and lack of symptoms.^{26,32,62,63,64}

A telephone outreach strategy has potential for reaching low income women who may be missed in clinic or community-based programs. According to the Federal Communications Commission, 72% of U.S. households in the lowest income category (lowest fifth percentile) have telephones.⁶⁵ Telephone interventions that aim to overcome specific barriers have proven successful at promoting mammography in some populations. This approach capitalizes on the use of the telephone as an interactive tool, allowing the intervention to be uniquely tailored and personalized to the needs of the individual, as opposed to other community avenues (e.g., mass media, direct mail). Two recent studies have employed telephone counseling to promote screening mammography. In a study by Marcus and colleagues,⁶⁶ female callers to the Cancer Information Service (CIS) were randomly assigned to standard care or interactive barriers counseling which asked callers to identify issues which might keep them from getting a mammogram. For each listed barrier, a scripted response provided a counter-argument promoting mammography. A referral to a mammography facility in the caller's area was also offered. Results indicated that this protocol was effective in increasing use of mammography.

A similar study conducted by Rimer and colleagues was designed to increase the utilization of mammography and clinical breast exams among 50,000 women, ages 50-74, who were members of an IPA model HMO in Philadelphia.⁶⁷ Interventions were directed at women, primary care physicians, and radiologists. The intervention for women included a stepped care approach in which more intensive interventions were used for women who did not respond to less intensive ones. All women were sent yearly health education packets that included mammogram referrals. Women who did not respond within 45 days were sent reminder notices. At 95 days, women who still had not responded were randomly assigned to one of the three intervention conditions: a second reminder notice; a letter from her primary care physician's office; or **outcall counseling**. The counseling strategy was based on the decision counseling methods developed by Janis and was designed to elicit and overcome women's personal barriers to mammography, using principles from the Health Belief Model⁶⁸ and the Transtheoretical Model.⁶⁹ Counselors identified the woman's behavioral stage, and then, if appropriate, sought to heighten perceived susceptibility, identify barriers and ways of overcoming them, increase self-efficacy, and heighten perceptions about the benefits of screening.

From 1988 to 1990, 9,405 outcalls were attempted. In 4,095 of the 5,342 completed calls, mammography was discussed using the barriers protocol; 2,037 women identified barriers and received the counseling. Only 2% of the women refused to talk with the counselor. Outcome evaluation in 1990 indicated that 35% of the women in the telephone counseling group had obtained mammograms, compared to 12.6% in the reminder group and 10.5% in the physician letter group ($p < .001$).⁷⁰

In the Marcus and Rimer studies, telephone promotion was conducted by organizations familiar to the call recipients (e.g., the CIS and the recipient's HMO). In the Pawtucket Heart Health Program, two outreach campaigns in 1984 utilized a telephone strategy to reach individuals not connected to the organization.⁷¹ The campaigns were conducted by volunteers from an organization of active and retired telephone company employees, who received brief training and were coached throughout the campaign. Approximately 4,000 calls were made to households, resulting in registering almost 400 individuals for risk factor reduction groups or self-help behavior change kits. A promotional letter mailed to addresses during the campaign appeared to increase the response to the telemarketing strategy.

The successes using telephone promotion described above and statistics confirming telephone access to low income populations provided the rationale for Dr. Crane's study "CIS Initiated Outcalls to Increase Screening Mammography Among Low Income Women."⁷² In this study, households in low income and minority neighborhoods throughout the State of Colorado have been randomly assigned to receive: (1) a single outcall, using an interactive barriers counseling protocol, to promote screening mammography to any female household resident age 50+; (2) an advance letter plus outcall as described in (1); or (3) no intervention. The effectiveness of this approach in promoting screening mammography is being evaluated by means of a telephone interview conducted 6 months after the outcall.

Telephone strategies employing multiple contacts to recipients also show promise for promoting health behaviors. Mamon et al⁷³ utilized this strategy to promote cervical cancer screening. Unscreened women were identified through a telephone survey and then called back by trained lay peer

educators in order to encourage screening. In the first telephone contact, the educator identified concerns related to the Pap test, attempted to resolve barriers, and encouraged the making of an appointment for a Pap smear. About one week later, a second contact was made to confirm whether an appointment had been made. A third call was made a few days before the Pap appointment, and a final call was made after the scheduled appointment. Additional calls were made as needed at each of these stages. This intervention was successful in convincing 43% of these previously underscreened women to make an appointment.

A similar strategy was used in the American Cancer Society program: Tell a Friend.⁷⁴ ACS volunteers were asked to name 10 friends or relatives that they would be willing to contact to encourage screening mammography. The ten contacts were randomized into two groups -- an intervention group that received up to 3 calls over a 6 month period or a control group that received no calls. Evaluation results indicated that this strategy of telephone contacts between acquainted women was successful: 49% of the women receiving calls received a mammogram compared to 34% of control women ($p < .001$). The strategy was effective for white and black women of all ages, but results indicated that it was **particularly effective among women with household incomes less than \$40,000.**

There are theoretical reasons for expecting a multiple contact strategy to be superior to a single call strategy. Models of health behavior change, in particular the Stages of Change or Transtheoretical Model,^{69,75,76} suggest that change occurs in a step-wise fashion, over a period of time. Thus, a multiple outcall protocol may yield significantly more behavioral change than a "one-shot" intervention. In fact, African American women attending a November, 1993, focus group on the topic of implementing an outcall mammography intervention recommended that a multiple call strategy would be better than a single call strategy. Although a multiple outcall approach is more costly than a single call approach, if behavior change is greater, it may also prove to be more **cost-effective**. That is, the "per unit cost" of achieving behavior change may actually be lower if more women are moved to obtain a mammogram. This is because a significant proportion of the intervention costs are incurred just in the process of *identifying* an eligible woman. Our estimates for the single outcall study described above indicate that over 6000 households must be called in order to identify 1000 women eligible and willing to participate. Once an eligible woman is identified, making additional calls to this woman represents a relatively minor cost.

The current study *adds* a fourth study arm to Dr. Crane's single outcall study⁷² described above. There are several advantages to testing the multiple contact approach within the structure of the existing study. First, it provides a relatively low cost mechanism for determining effectiveness within a randomized controlled research design; the costs of intervention development and three comparison groups (see above) will be incurred by the existing study. Another advantage of conducting this test as an add-on to the existing study is that results can be achieved in a much shorter time frame than if a separate study were constructed and carried out.

This research fills several voids in the literature on telephone health interventions. First, of the previously reported studies, only Mamon et al⁷³ targeted low income or minority populations, and this was for cervical cancer screening. Second, except for Mamon et al⁷³ and Schwertfeger et al,⁷¹ all telephone strategies have been conducted by an organization with which the call recipient was familiar. Third, none of these studies have compared the effectiveness of a single call approach to a multiple contact approach within the same population in a randomized trial. Fourth, none of the previous studies have examined the cost-effectiveness of the approaches utilized.

In addition to the above, none of the above telephone campaigns have linked health recommendations to access to health care services for low income clients. This study is in the unique position of doing this. The State of Colorado is a recipient of funds under the Breast and Cervical Cancer Mortality Prevention Act of 1990, which aims to provide screening services to low income women. Of the appropriations, 60% must be used by state health departments for the direct provision of breast and cervical cancer screening and diagnostic services. This study is working closely with the Colorado Cancer Program, which is implementing the Breast and Cervical Cancer Mortality Prevention Act in the State of Colorado. As part of the outcall protocol, eligible women are given referrals to

facilities offering low and no-cost screening as part of the Act. This will serve to demonstrate a partnership model which ultimately could be implemented on a broader scale. By making low income women aware of the new benefits available to them, and then by carefully working to remove other barriers, this project could exert a significant positive influence on the proportion of women receiving breast cancer screening on a regular basis.

HYPOTHESES

The hypotheses to be tested in this study are:

- H₁: The proportion of women **receiving a screening mammogram** during a six month period will be higher among the multiple outcall group than in all other groups.
- H₂: The average "**stage of change**" for **mammography behavior** will be higher among women in the multiple outcall group than in all other groups.
- H₃: Delivery of multiple outcalls will be more **cost-effective** than either the single outcall or advance letter plus single outcall approach.

TECHNICAL OBJECTIVES

The objectives to be accomplished in this 30 month study include:

1. Modify existing "interactive barriers counseling" protocols for use in multiple calls. (Current version is for a single call.)
2. Pilot test counseling protocols on 10 subjects.
3. Implement multiple outcalls protocol in 941 eligible women.
4. Measure the costs associated with delivering the multiple outcall intervention.
5. Conduct six-month follow-up interviews to determine mammography behavior and progress through stages of change.
6. Validate self-reports of screening mammography through the State of Colorado Mammography Advocacy Program (CMAP).
7. Prepare a final report to the DOD that summarizes the effectiveness and cost-effectiveness of multiple outcalls in promoting screening mammography, compared to: no intervention; single outcall; and advance letter plus single outcall.

METHODS AND RESULTS

Sampling

In the original workplan for this study, low income households were to be identified and randomly selected using a commercially available system known as INFORUM. Residents of households randomly assigned to the multiple outcall group would then be screened for eligibility and the intervention implemented. However, when the original plan was written, it was not known that written

informed consent would be required of all participants in this educational program. Under Department of Health and Human Services regulations, research of this nature which does not involve risk to subjects, and involves only standard education and survey procedures that would not require consent outside a research setting, does not require written informed consent. These are the guidelines under which the three other arms of this larger research study have been conducted. Upon funding in late September, 1994, the research team sought to appeal the Department of Defense's requirement of written informed consent for this study. Several months later, the appeal was denied.

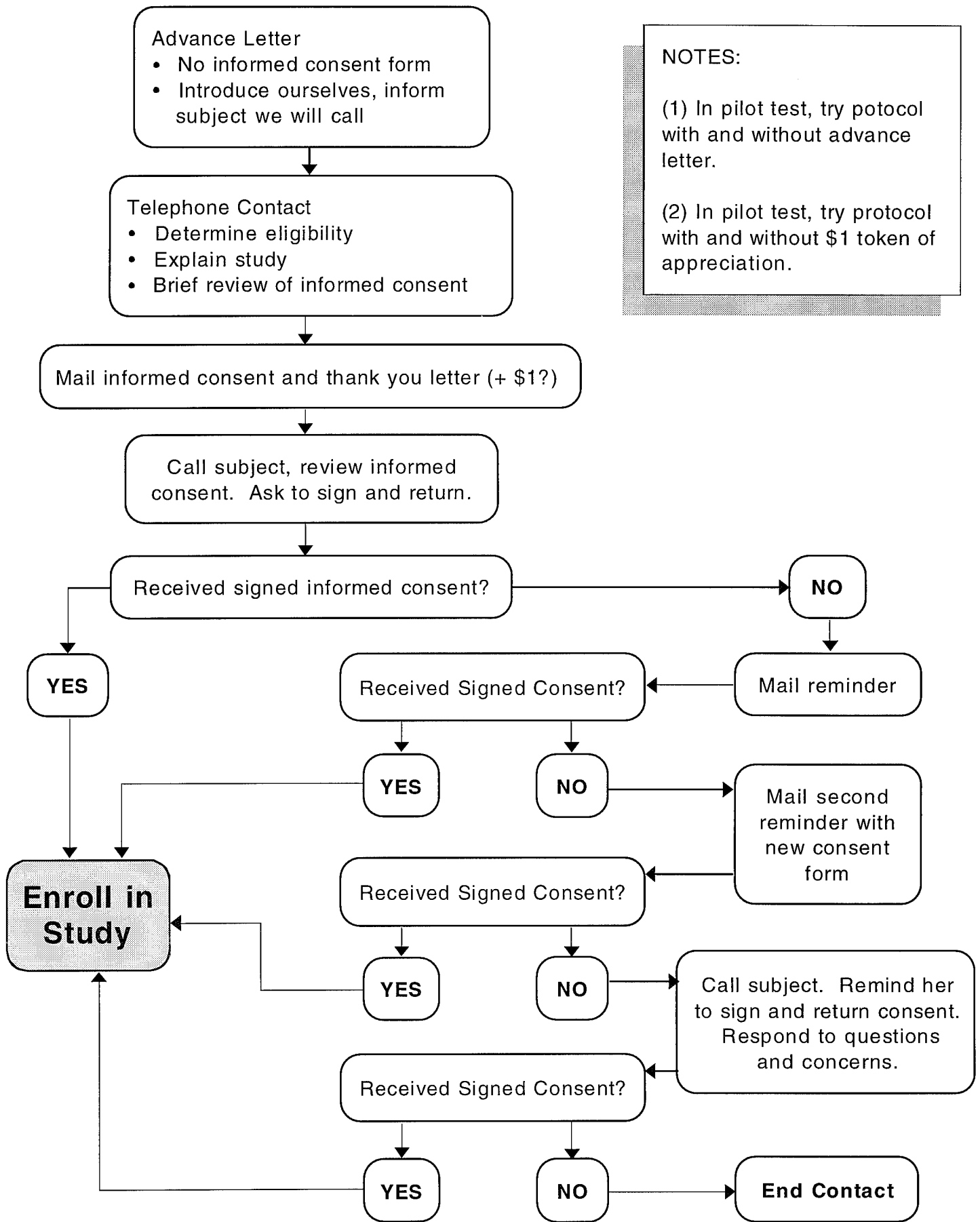
In June, 1995, the research team undertook a pilot study of an informed consent procedure that involved multiple attempts by phone and mail to screen and obtain written consent from participants. The protocol followed for this purpose is diagrammed in Figure 1 (on the following page). As shown, it involved an advance letter, a phone call to determine eligibility, a mailing of the consent form, a follow-up phone call to review the consent form, and numerous telephone and mail contacts to those not returning the consent forms. This pilot study incorporated two tests: 1) to determine whether the advance letter improved participation rates; and 2) to determine whether a one dollar incentive included with the consent form mailing improved participation rates. The results of this pilot study are presented in Table 1. As shown, while the existing study to which this study arm was appended achieved approximately a 16% completion rate per household, in the pilot study of the written informed consent procedure, completion rates of 2-5% were obtained after completion of the extensive consent protocol. The advance letter appeared to have somewhat of an effect on recruitment, while the one dollar incentive did not appear to improve recruitment. However, given the extremely labor intensive protocol and the extremely poor success rate, it was concluded that the recruitment quota required for the study design (941 women) could not be achieved under the funding received. Consequently, other approaches for recruitment were explored. The 14 women recruited by this method received the counseling intervention; these women constitute the pilot test of the intervention.

Table 1: Results of Pilot Test				
Condition	# Households	# Agreed to Receive Consent	# Returned Consent	Success Rate
Advance Letter + \$1	102	13	4	3.9%
Advance Letter Only	102	15	5	4.9%
\$1	94	12	2	2.1%
None	102	13	3	2.9%
Single Outcall*	6613			16.1%

* Results from initial study - no informed consent was required.

In August, 1995, project staff devised an in-person recruitment plan. This plan involved setting up a recruitment table at grocery stores and approaching women to describe the project and request signing of the informed consent statement at that time. In less than two days of piloting this alternative recruiting procedure, 52 women completed the written informed consent and enrolled in the study. This is in stark contrast to the 14 women recruited in four weeks using the telephone/mail recruitment. Additional pilot testing of the initial counseling calls was successfully completed for 46 of the 52 women recruited in person.

Figure 1: Informed Consent Protocol for Pilot Study



NOTES:

(1) In pilot test, try potocol with and without advance letter.

(2) In pilot test, try protocol with and without \$1 token of appreciation.

Given the written informed consent requirement and the incredible success of this approach, we revised the recruitment strategy for this project. A plan was developed to conduct in-person recruitments in grocery stores and "mart"-type stores in various locations throughout the State of Colorado. Because the project targets low-income and minority women, stores located in appropriate neighborhoods have been selected. Table 2 provides the revised recruitment schedule for the study.

Table 2: Recruitment Schedule	
Time Frame	Location of Recruiting Trip
September, 1995	Durango, Cortez
November, 1995	LaJunta, Lamar
January, 1996	Pueblo, Trinidad
February, 1996	Colorado Springs, Security-Widefield
March, 1996	Denver metro area
April, 1996	Denver metro area
May, 1996	Loveland, Greeley

A recruitment trip to Durango/Cortez Colorado was completed in early September, 1995. A total of 225 age-eligible women were recruited, and initial outcalls to 80% of these women were completed by October 24, 1995. Additional calls to these women are underway. Table 3 presents the current status of this sample.

Table 3: Disposition of Subjects Recruited in September, 1996	
Disposition	N
Completed Call	180
Could not reach	5
Ineligible	8
Pending Completion	5
Refused	5
Still Attempting	22
TOTAL	225

Approximately 30% of the counseled women were eligible for additional counseling calls due to their mammography adherence status. Six-month follow-up interviews, to determine impact of the intervention, will begin in March, 1996. The primary variable of interest is receipt of a screening mammogram. Characteristics of women recruited using the in-person recruitment (pilot and main) are presented in Table 4. Since the Durango/Cortez area is predominantly white, this early portion of the study sample reflects that. Future trips will emphasize African American and Hispanic neighborhoods.

Table 4: Characteristics of Subjects (n=208)		
CHARACTERISTIC	N	PERCENT
<u>Age</u>		
50-59	74	35.7
60-69	61	29.5
70-79	54	26.1
80+	18	8.7
<u>Race/Ethnicity</u>		
White	169	82.0
Black	14	6.8
Asian	0	0
Hispanic	15	7.3
Native American	2	1.0
Other	6	2.9
<u>Education</u>		
0-8 years	18	8.7
9-11 years	23	11.2
12 years	70	34.0
13-15 years	51	24.8
16 years	20	9.7
17+ years	24	11.7
<u>Income</u>		
<\$15,000	49	29.9
\$15,000-\$24,999	44	26.8
\$25,000-\$39,999	40	24.4
\$40,000+	31	18.9
<u>Mammography Status</u>		
No mammogram ever	28	13.5
Last mammogram more than two years ago	30	14.4
Had mammogram in last two years	150	72.1

Theoretical Basis and Description of Outcall Intervention

The outcall intervention is based on the Stages of Change Model, developed by Prochaska and DiClemente,^{69,75,76} as well as the concepts embodied in motivational interviewing,⁷⁷ which is consistent with the Stages of Change Model. The model suggests that adoption of a health-related behavior can be described by a series of stages through which a person progresses, including **precontemplation, contemplation, decision, action, and maintenance**. The model assumes movement in either direction along the continuum; thus from any point a person may move onto the next stage or cycle back to an earlier stage. The model further specifies that individuals utilize **ten processes of change** in order to move from one stage to the next, including: consciousness-raising, self-liberation, social liberation, self-reevaluation, environmental reevaluation, counterconditioning, stimulus control, reinforcement management, dramatic relief, and helping relationships. Some processes are more useful in earlier stages (e.g., consciousness-raising in precontemplation and contemplation stages) and others are more useful in later stages (e.g., helping relationships and social reinforcement in action stage).⁷⁵

In addition to stages and processes of change, the model also includes the construct of decisional balance. Central to this is evidence from Prochaska and DiClemente's work that as people move toward behavioral change, the perceived "pros" or the benefits associated with the behavior increase and the perceived "cons" or negatives associated with the behavior decrease. Thus, as an individual moves along the continuum, the "pros" begin to outweigh the "cons." Rakowski et al⁷⁸ have applied the model to screening mammography, and identified "pro" and "con" factors which distinguish between four stages of adoption: precontemplation (no prior mammogram and no plan for one in the coming 6 months); contemplation (no prior mammogram but planning one); action (one prior mammogram and planning one in the next 1 to 2 years); maintenance (more than one prior mammogram and planning one for the next 1 to 2 years); and relapse (at least one prior mammogram, but more than 2 years ago, or a mammogram within 2 years but not planning another mammogram).

The model is directly relevant to the planning of health behavior interventions, as it suggests that interventions will be more effective if they are matched to the stage of change of the individual.⁷⁶ For example, there is little sense in providing locations of mammography facilities to a woman who believes that mammography is only necessary if symptoms are present (precontemplation stage). Instead, this woman needs information on the use and benefits of mammography.

The outcall intervention for this study begins with an assessment of each woman's personal stage of change according to the model. Assessment is followed by a scripted interactive barriers intervention directed specifically at moving each woman closer to adoption of routine screening using mammography. For women in the precontemplation stage, the focus is on providing information on the need for and benefits of mammography. For contemplation women, specific perceived barriers to mammography are determined and directly addressed. The goal is to increase the "pros" and decrease the "cons". Decision/action stage women are provided with "how to" information, including referrals to convenient, low-cost facilities. Those who have reached the maintenance stage are given reinforcement to continue receiving annual mammograms. Because the sampling plan for this study aims to over-sample low income and minority women, special attention is paid in the intervention to addressing issues relevant to these groups.

In addition, because mammography use rates have been shown to decline with age,^{11,22,26,62,79} special attention is paid to addressing the following issues with older women: age is the most important risk factor for breast cancer; women past menopause need mammograms; mammography is important in the absence of symptoms; and the efficacy of mammography as an early diagnosis tool. All of these topics are included in intervention scripts, to be used according to the needs of each individual woman.

The State of Colorado is a recipient of funds for breast cancer screening under the Breast and Cervical Cancer Mortality Prevention Act of 1990. Therefore, an additional emphasis of this intervention for low income women is to provide referrals to facilities offering low or no-cost mammography under the Act.

At the conclusion of the outcall intervention, the counselor again assesses the stage of change of the individual, in order to determine the immediate impact of the intervention, and if appropriate, deliver intervention components relevant to the current stage.

At the end of the first outcall, all women who are not currently adherent with NCI screening guidelines and/or not planning to maintain adherence are asked for permission to be contacted again, in approximately two weeks, so that the caller can answer any additional questions that may arise subsequent to the call. Women who agree are called again, up to a total of five calls, as necessary to achieve adherence to guidelines. Thus, these calls will continue until either: (1) the woman reports that she has **had** a mammogram; or (2) a total of five calls has been completed. Each call follows the basic format of the first call: assess stage of change; elicit barriers; counsel according to existing barriers; and reassess stage of change. If the call concludes with a commitment by the woman to make an appointment for a mammogram, the following call focuses on whether the appointment has been made and any barriers to keeping the appointment. At the point that a woman reports that she has had a mammogram, the call focuses on promoting maintenance of routine screening according to guidelines.

The second call is made approximately two weeks after the initial call. Subsequent calls are made according to the status of the subject. Until the point at which a woman reports that she has made an appointment, calls continue about every 2 weeks. If an appointment for a mammogram has been made, the next call will be made two-three days prior to the scheduled appointment, in order to remind and promote appointment keeping. At any time, the woman may refuse to receive any additional calls.

A computer assisted telephone interviewing (CATI) system is used to computerize the protocols for ease in administering the outcalls. There are several advantages to this. First, it greatly assists those delivering the outcalls, as advancement to different branches of the protocol is automated, saving the caller from flipping through pages of a paper protocol. Second, this virtually eliminates errors in administration of the outcall and provides for the highest level of standardization between callers. Third, it allows for immediate feedback regarding those branches most likely to be used -- information which can be used to train outcallers regarding what to expect when they reach an eligible woman. In addition, this feedback can be used to trigger the development of further referral resources in order to address barriers. For example, if transportation is repeatedly mentioned by recipients of the outcalls, a decision may be made by project staff to provide specific information to callers regarding bus lines which access particular mammography facilities.

Program Implementation

It was initially planned that outcalls for this study arm would be implemented by telephone information specialists of the Rocky Mountain Cancer Information Service. The Cancer Information Service (CIS) is a national "hotline" for cancer information funded by the National Cancer Institute's Office of Cancer Communications, in existence since 1976. The United States is divided into 19 regions, each serviced by a regional CIS office, accessed by the common 1-800-4-CANCER telephone number. Nationwide, the CIS responds to approximately 500,000 calls a year. The Rocky Mountain CIS (RMCIS) is located in Colorado Springs, Colorado, and responds to calls from region 16 of the CIS (Colorado, New Mexico, Utah, Arizona, Wyoming and southern Idaho). CIS information specialists implemented the three study arms of the main study. However, when it was learned that written informed consent would be required of subjects in this study arm, the decision was made to conduct this work at AMC Cancer Research Center, using AMC staff members. This decision was made because the CIS is primarily a service-delivery organization, not a research organization, and implementing an intensive recruitment process is outside their main area of expertise. The recruitment process could be more carefully monitored and implemented at AMC. The implementation staff at AMC includes one full-time health educator (formerly an information specialist at the CIS), and one project director/health educator at 60% time.

Follow-Up Assessment

In order to determine the efficacy of the proposed outcall intervention in increasing adherence to mammography guidelines, an interview will be conducted with each subject six months after receipt of the first outcall. This interview represents the main source of data for the **outcome evaluation**. This interview will include questions which determine the stage of change for mammography according to the Prochaska and DiClemente model. In addition, knowledge of mammography and screening guidelines, attitudes towards mammography, perceived barriers to and supports for mammography, and current adherence to NCI guidelines will be assessed. All respondents will be asked whether anyone suggested that they have a mammogram within the last year; those who refer to the outcall intervention will be asked a series of **process evaluation questions** related to the intervention, including how they felt about the multiple outcall procedure (intrusive, etc.), and whether they feel that it changed their attitudes or behavior related to mammography. This interview is expected to take approximately 20-25 minutes to conduct, and will be administered by the Survey Research Laboratory of the University of Illinois, under the direction of Dr. Warnecke (Co-Investigator). Follow-up interviews are scheduled to begin in March, 1996.

Validation of Adherence to Mammography Guidelines

King, Rimer, Trock et al⁸⁰ have reported a high level of agreement between self-report of mammography and medical records in an HMO population. Mandelblatt et al⁸¹ subsequently found high agreement (92%) in a primarily African American public health clinic population. The implementation of this project in the State of Colorado provides an opportunity to validate reports of receipt of mammography in this study of mixed-ethnicity low income women.

In 1988, the Colorado Department of Health Cancer Control Program established a cooperative agreement with the Centers for Disease Control to support the development of a computerized tracking and follow-up system to monitor mammography screening patterns and results in Colorado. This system is known as the Colorado Mammography Advocacy Program (CMAP). The primary objectives of CMAP are the promotion of compliance with routine breast screening and the conduct of follow-up for women with abnormal screening results in order to assure that timely, state-of-the-art medical evaluation and treatment is provided. Women are offered participation in CMAP when they attend one of the designated mammography centers. Currently, 37 facilities are actively participating in CMAP and more are slated to join over the next several months. This represents one third of all mammography facilities in the State of Colorado, and 100% of the facilities in the State of Colorado offering low and no-cost mammography under the Breast and Cervical Cancer Mortality Prevention Act. Virtually all of the women attending a CMAP facility agree to participate in this program and are entered into the CMAP registry. The current size of the CMAP database includes about 130,000 women.

Using the CMAP database, it will be possible to validate reports of receipt of screening mammography during the study period, to the extent that women involved in this study attend mammography facilities that participate in CMAP. The likelihood of attendance at a CMAP facility within the target population is great, since all facilities offering low-cost or no-cost mammography as part of the Breast and Cervical Cancer Mortality Prevention Act in Colorado are participants of CMAP, and it is anticipated that many of the referrals made as a part of the intervention will be to women who are eligible for the Breast and Cervical Cancer Mortality Prevention Act monies.

After collection of baseline and follow-up interview data, CMAP records will be reviewed for those respondents who report receiving a mammogram at a CMAP facility. Rates of agreement between self-report and CMAP records will be computed, and this information will be used in the determination of eligibility for a mammogram and in the creation of dependent variables for the outcome evaluation.

ACCOMPLISHMENT OF TECHNICAL OBJECTIVES

The accomplishment of the technical objectives listed on page 8 is well underway. Objective 1 (revision of protocols) has been completed. Objective 2 involves pilot testing the protocols. As described above, this has been completed for approximately 60 subjects, more than initially expected. Objective 3 involves the recruitment of eligible women. While the recruitment plan has changed considerably, we have successfully recruited approximately 20% of our overall goal. Objective 4 involves the measuring of costs associated with this intervention strategy. Measurement of costs of program development, recruitment, and counseling are underway. The remaining objectives will be accomplished beginning in March, 1996.

Although the start-up of this project was delayed due to the requirement for written informed consent, the success of the new recruitment strategy has made it possible to compress the originally planned 13 month recruitment into 10 months. The current timeline is presented in Table 5. We expect to complete data collection for the study in December, 1996. This will allow approximately three months for data analysis and report-writing, and completion of the study as originally scheduled.

Table 5: Timeline	
ACTIVITY	TIME PERIOD
In-person recruitment of subjects	Sept. 1995 - June 1996
Counseling of recruited subjects	Sept. 1995 - Oct. 1996
Six-month follow-up interviews	March 1996 - December 1996
Data analysis and Report writing	January 1997 - March 1997

CONCLUSIONS

The research to-date supports the following conclusions:

- 1) The imposition of written informed consent in a study which recruits by telephone decreases participation by approximately 75%. This leads to a highly biased sample of women.
- 2) In-person recruitment at grocery stores is extremely efficient, leading to high numbers of women enrolled in a short period of time. How representative these women are of low income women remains to be seen.
- 3) Nonadherent women appear to be agreeable to receiving multiple outcalls regarding mammography. The impact of these outcalls on screening behavior has yet to be determined.

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