Randomized Controlled Trial of Mammography Intervention in Insured Very Low–Income Women

Nasar U. Ahmed1, Gillian Haber1, Kofi A. Semenya2, and Margaret K. Hargreaves3

Abstract

Background: The expectation that insurance coverage mitigates health disparities and equalizes use of healthcare assumes that services are equally accessed; however, the insured low-income target population in this research had a mammography rate of 23.4%, well below the general population. Our objective was to determine the most effective intervention to improve mammography use in low-income women insured by a managed care organization (MCO).

Methods: The study was a randomized controlled trial. Participants were 2,357 women noncompliant with screening mammography randomly assigned to one of three groups: control (n = 786) received usual care; simple intervention (n = 785) received prompt letter from the MCO medical director; and stepwise intervention (n = 786) received the same prompt letter from the MCO; if noncompliant, a second prompt letter from their primary care physician and, if still noncompliant, counseling from lay health workers. Outcome was completion of screening mammography extracted from medical records.

Results: Screening rates were 13.4% for the control, 16.1% for the simple intervention, and 27.1% for the stepwise intervention. Compared with the control, the primary care physician letter in the stepwise intervention increased the likelihood of screening by 80% [Relative Risk (RR) = 1.80; P < 0.001], and counseling tripled the likelihood of screening (RR = 3.11; P < 0.001).

Conclusions: Compared with the control and simple intervention, a stepwise intervention to increase mammography is effective in a target population of hard-to-reach, low-income, insured women.

Impact: The research provides evidence for the impact of stepwise interventions to improve cancer screening in low-income insured populations, although the screening rates remain well below those of the general population. Cancer Epidemiol Biomarkers Prev; 19(7); 1790–8. ©2010 AACR.

Introduction

Lack of health insurance is the most commonly reported barrier to accessing and using the existing U.S. healthcare system, following lack of a regular healthcare provider (1-5). The general expectation in the current healthcare debate is that health disparities will be mitigated by the provision of insurance coverage. This expectation relies on the assumption that all healthcare services are equally available and equally accessed.

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Note: This article is dedicated to the late Robert Hardy, M.D., M.P.H., Professor of Internal Medicine, Oncology, for his leadership in the development of the intervention strategies.

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However, there is a body of evidence indicating that insured low-income people find accessing the healthcare system more difficult and do not receive preventive care at the same rates as the general population (6-12). Thus, the provision of health insurance alone might not be the universal remedy as otherwise thought, and attention must be given to strategies to increase the use of preventive services, particularly among those not accustomed to or comfortable with using the healthcare system. This research serves as an example of an intervention to increase the use of preventive services (screening mammography) in an insured very low-income population.

Physician recommendation remains the strongest predictor of screening mammography use among all women (13, 14); whereas the most common barriers to mammography in low-income and minority populations include lack of insurance (15) and lack of a regular provider (16). In this research, our very low-income target population was enrolled in a network of managed care organizations (MCO) that provided free screening mammography and an assigned primary care physician. It was expected that the removal of the insurance barrier and access to a personal physician...
would result in mammography rates similar to those of the general population; however, the mammography use rate of the women, extracted from medical records, was 23.4% substantially lower than the general population percentage.

Our previous research on mammography beliefs and knowledge in this insured population identified empowering factors and obstacles to screening (17-19). The empowering factors were items that encouraged women in this population to seek preventive care and included awareness of community resources, items related to self-efficacy, and support of family and friends; obstacles included fear, fatalism, and lack of knowledge of breast cancer (17-19). Removal of the insurance and provider barriers, combined with the results of the previous research (17-19), allowed a clear path to identify strategies to improve rates of mammography screening in these women.

Based on previous studies and our research on this target population, a theoretical framework was developed for a stepwise intervention design and delivery based on Rogers’ Innovation Diffusion Theory (20), stages of adoption predictive of mammography screening; and Bandura’s Social Learning Theory (21), peer counseling leading to self-efficacy. Rogers’ theory addresses the incremental levels of attention (intervention) needed to capture people in the process of change in behavior; from those eager to take on change (early adopters) to those that are slow or difficult adopters to behavior change; whereas Bandura’s theory addresses the need for opinion leaders and change agents (e.g., lay health workers) to prompt the desired health behavior.

Studies have shown that reminder letters, telephone calls, and lay health worker outreach programs have resulted in significantly increased rates of screening mammography (22-27); however, systematic reviews (28, 29) have shown that interventions that were effective with predominantly middle- and upper-income insured women (reminder letters), differ significantly from those that were effective with low-income, predominantly uninsured women (lay health worker counseling, vouchers). Our sample was a “hybrid” of both groups (17-19): they were insured (similar to the middle- and upper-income women) and they were low income (displaying beliefs and behavioral patterns associated with low-income populations). As such, they had system access but were behaviorally unfamiliar with or mistrustful of preventive health seeking behaviors (17-19).

The present study used a randomized controlled trial design of a stepwise approach to determine which level of intervention gives the desired result of increased compliance with mammography screening guidelines in a “hybrid” population of very low-income insured women. The approach uses the less difficult and less expensive elements first, with more expensive and operationally time-consuming efforts used for the targeted hard-to-reach subjects.

Our primary hypothesis was that a stepwise intervention would increase mammography screening rates over and above those achieved through a single method and/or usual care in an insured low-income population.

## Materials and Methods

### Participants

The study population consisted of very low-income women (mean and median annual household income $8,447 and $6,994 respectively) who were 40 years and older and enrolled in the Tennessee Coordinated Care Network, a network of MCOs serving the healthcare needs of the working poor. The participants had been insured by the MCO for ~4 to 5 years and were previously either not insured or insured through Medicaid. More than one third has not had a physical checkup in the past 3 years. Screening mammograms were covered at no cost as part of preventive care benefits for eligible members. Computerized medical claims data were accessed and reviewed by designated MCO personnel in the MCO head office in Nashville, Tennessee, to identify eligible female enrollees. Inclusion criteria were women 40 years and older without a history of breast cancer whose claims data indicated noncompliance with mammography screening in the previous 2 years (for women 50 years and older) or 3 years (for women 40-49 years old).

### Intervention

An intervention composed of reminder letters, and Community Health Outreach worker counseling was developed to test and compare the effectiveness of three strategies. The intervention was conducted from 1999 to 2001 by the outreach and health promotion personnel of Tennessee Coordinated Care Network who were trained by the Meharry Medical College intervention coordinator. The three experimental groups were characterized as follows: Group 1 (control/usual care/no intervention) received usual care only; Group 2 (simple intervention) received usual care plus a reminder letter from the MCO medical director (strategy 1) stating the need for annual mammograms; Group 3 (stepwise intervention) received usual care plus, first, the reminder letter from the MCO director (strategy 1); second, if no mammogram had taken place within 3 months, a letter from the woman’s personal primary care physician (strategy 2); and third, if still no mammogram had taken place after 3 months, Community Health Outreach worker counseling (strategy 3) by the existing outreach workers employed by the MCO.

Usual care for members of this MCO included monthly newsletters on a variety of health topics, health pamphlets, and access to Community Health Outreach workers. Breast cancer and mammography was mentioned in at least one of the newsletters, and a specific breast cancer...
and mammography pamphlet was mailed to all members during Breast Cancer Awareness Month.

The letters from both the MCO medical director and the primary care physician were generated by a computer program that individualized the salutation line. Both letters were signed through a computerized scanned signature. The letter from the MCO medical director focused on screening and breast cancer. The primary care physician letter had a more friendly and personal tone ("As your doctor, I want to help you to stay well. For most health problems, the key is to find and treat the problem early. A short time ago, you received a letter from the MCO medical director offering you a free mammogram. If you have not already taken advantage of this offer, consider this a friendly reminder...") and focused on encouraging screening participation. Women were referred to on-site mammography facilities or to a site convenient to them.

The Community Health Outreach workers, who had been previously hired from within the study population and trained by Tennessee Coordinated Care Network, were already compliant with preventive health care measures. For this research, they received additional training about breast cancer and mammography and were further taught to engage clients in an open-ended conversational setting, tailored to the specific barriers, needs, and empowering resources of each woman, without the use of fixed guiding scripts or computer prompts. The Community Health Outreach workers were trained to clarify misconceptions of the women; address issues of fear, mistrust, and fatalism; and provide information on screening and treatment. The Community Health Outreach counseling took place through face-to-face meetings at locations chosen by the participants and was measured as one completed counseling session. Although any MCO member was able to contact a Community Health Outreach worker for any health related question or concern, the women in the stepwise intervention were specifically contacted by the Community Health Outreach to discuss mammography.

Informed consent

The study was approved by the Meharry Medical College Institutional Review Board. Informed consent was taken by the MCO through its membership contract, which clearly explained that data can be used for studies to improve the services of the MCO and that outreach workers may visit the participants to help navigate the system and discuss health issues. The intervention was created by the researchers to run within the confines of existing MCO resources and consent agreements. Researchers did not contact participants nor acquire any personal identifiable information.

Variables

The outcome variable was completion of mammography screening. Information on screening completion, age, race, and county of residence were extracted by the MCO staff from an in-house medical records database.

Randomization

MCO network personnel accessed all records and selected those women who fit the inclusion criteria. As we did not draw a sample, all eligible subjects were considered. Of those records, removal of duplication resulted in 2,642 women assessed for eligibility and 2,357 women randomized to one of three groups (Fig. 1). The study was powered to detect at least 5% difference between groups using a two-tailed test, with \( \alpha \) set at 0.05. To achieve 80% power, each arm needed 435 participants; in this research, each arm had at least 785 participants, indicating that the study had 95% power to detect any significant effects of the intervention strategies.

Randomization of participants was determined by a two-step random allocation sequence procedure. First, the entire sample was sorted by geographic location, then by race/ethnicity, then by ascending age. Second, letters A, B, and C were allocated to subjects within each location-race group using the following sequencing pattern: ABC, CBA; BAC, CAB; and BCA, ACB. The initial sequence start was determined through a random draw. The process eventually created three approximately homogeneous groups of subjects corresponding to the three letters A, B, and C within each location-race category. After randomization, levels of intervention (control, simple, stepwise) were allocated to groups A, B, and C by random draw.

Statistical analysis

To test for significant differences between interventions, a \( \chi^2 \) or \( Z \) test (as appropriate) was done between the components of the intervention and between the groups. A conventional \( P \) of 0.05 for a level of significance using a two-tailed method was applied. Contingency tables with relative risk, 95% confidence interval (95% CI), and the exact \( P \) for difference were estimated to study the magnitude of the effect of the intervention components and group approaches over the reference (i.e., control) group. A multiple logistic regression model was performed to adjust for age, geographic location, and race/ethnicity to check for consistency of the results with and without adjustment. Because adjusted relative risks were similar to unadjusted actual relative risks, the actual relative risks are reported.

Results

Use of a stratified random allocation process resulted in three groups with an average size of 786 subjects. The groups showed no significant differences in age, race/ethnicity, and geographic location (0.90 < \( P < 1.00 \)), indicating that the randomization process was close to perfect (Table 1).
The cumulative number of mammograms completed by intervention group is shown in Fig. 2. By the end of the 1-year intervention period, the subjects in the stepwise intervention received 213 mammography screenings (27%) compared with 126 screenings for the simple intervention group (16%) and 105 screenings in the control group (13%).

Comparison of the intervention strategies and groups are shown in Table 2. In testing the effectiveness of the MCO Medical Director’s letter, the letter increased the likelihood of receiving screening by 33% over the control, although this difference did not achieve statistical significance [Relative Risk (RR) = 1.33; 95% CI, 0.86-2.05; P = 0.21]. At the second stage of the intervention, only those in the stepwise intervention who were still noncompliant with mammography screening received a prompt letter from their primary care physician. Those receiving the primary care physician letter were 80% more likely to obtain screening compared with the control group (RR = 1.80; 95% CI, 1.20-2.69; P = 0.004). For the final phase of the intervention, those subjects in the stepwise group who were noncompliant with screening 3 months after the primary care physician letter were counseled by the Community Health Outreach workers. Counseling was three times as likely to increase mammography screening as compared with the control group (RR = 3.11; 95% CI, 2.16-4.44; P < 0.001).

Figure 1. Mammography randomized controlled trial among low-income insured women: Consolidated Standards of Reporting Trials (CONSORT) flow diagram. CHO, Community Health Outreach.
To estimate the relative effectiveness of each intervention group, cumulative results (Table 2) indicate that stepwise participants were approximately twice as likely to receive screening as the control group (RR = 2.03; 95% CI, 1.64-2.51; *P* < 0.001) and 69% more likely to receive screening as compared with the simple intervention (MCO letter) group (RR = 1.69; 95% CI, 1.39-2.06; *P* < 0.001).

**Discussion**

The present investigation focuses on the use of screening mammography among very low-income insured women in an effort to identify interventions that increase the use of cancer screening in an insured target population not accustomed to or comfortable with accessing preventive services from the healthcare system (17-19). In contrast to other studies on this issue in which lack of insurance coverage and/or access to care are confounded with income status, this research separates low-income status from those confounders through the use of a low-income sample with insurance coverage, access to care, and personal physicians.

The overall results of the intervention show an increase in mammography rates over the course of the 1-year intervention from 0% to 13.4% in the control group, 16.1% in the simple intervention group (MCO letter only), and 27.1% in the stepwise intervention group (MCO letter, primary care physician letter, Community Health Outreach worker counseling). The intensive effort of the stepwise intervention doubled the rate seen in the control group, resulting in a net gain of 13.7 percentage points over the control group (27.1% stepwise–13.4% control).

To summarize, the study findings suggest that a stepwise intervention approach involving multiple layers of reminders and support is more effective in increasing mammography rates among low-income insured women compared to a simple intervention or control group. The results also highlight the importance of addressing both financial and non-financial barriers to screening in low-income populations.
mammography rate of 23.4%, our efforts did not attain a substantial increase over the population rate. These rates fall short of the self-reported mammography screening rate of the general U.S. population (30), which at the time of this research (as reported by the National Health Interview Survey), was 70.4%, with lower rates seen in women with low educational attainment (less than high school diploma, 57.7%), poor women (54.8%), and uninsured women (40.7%).

The results of the present study are consistent with some previous randomized community-based trials targeting low-income women in terms of the type of strategies that work. A recent systematic review of randomized controlled trial mammography educational interventions for low-income women found mixed results in the use of prompt letters from physicians (29). Although two studies showed significant results, relative risk of 1.38 in a study by Segnan et al. (32) and odds ratios ranging from 1.97 to 2.33 in a study by Fox et al. (33), comparable with the rate of 1.80 in this study, three other studies had nonsignificant results (29). Of the studies with significant results, the most significant increases were seen in letters directly from the physician as in our study. This finding is consistent with literature that states that physician recommendation is the most powerful determinant of mammography use (14, 16, 34) because physicians are well regarded as subject matter specialists and are the most trusted source for health issues (35).

Mailed messages can reach many women at low cost, but they may not be persuasive enough to increase mammography rates beyond a certain level (36) as in our study. Our findings suggest the letters helped improve screening rates up to a threshold level but that letters alone are not sufficient to assure that women, particularly low-income women with many barriers and competing priorities, obtain a mammogram (19, 29).

In comparing the results of the stepwise intervention to existing research, it is important to note that there are significant differences between the sample and study design of this study compared with other randomized community trials of multistategy approaches, specifically in terms of insurance status. However, given these differences, the results of the stepwise multicomponent intervention were consistent with at least two other studies testing multistategy approaches in low income women, albeit with lower rate increases. Compared with the 27% increase seen in our stepwise intervention group, Weber et al. (37) found a 41% increase and Champion et al. (38) found a 49% to 55% increase through the use of multicomponent interventions. Other studies have shown mixed results (39) or nonsignificant results (40).

It is clear that, in keeping with the Innovation Diffusion Theory, hard-to-reach nonadherent women required

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4 It is important to recognize the overestimation of self-reported mammography compliance found in national surveys; a recent meta-analysis on this National Health Interview Survey self-reported figure of 70.4% found an actual adjusted mammography prevalence of 56%, with significant differences attributed to race/ethnicity (31).

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Table 2. Mammography randomized controlled trial among low-income insured women; comparison of mammogram intervention strategies: relative risk, confidence intervals, and P values

<table>
<thead>
<tr>
<th>Time</th>
<th>Phase I (MCO letter)</th>
<th>Phase II (PCP letter)</th>
<th>Phase III (CHO worker counseling)</th>
<th>Cumulative results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number screened (%)</td>
<td>RR (95% CI)</td>
<td>Number screened (%)</td>
<td>RR (95% CI)</td>
</tr>
<tr>
<td>Group 1: control/usual care</td>
<td>34 (13.4)</td>
<td>Reference</td>
<td>35 (13.4)</td>
<td>Reference</td>
</tr>
<tr>
<td>(n = 786)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2: simple intervention</td>
<td>45 (16.1)</td>
<td>1.33 (0.86-2.05)</td>
<td>34 (13.4)</td>
<td>0.99 (0.62-1.57)</td>
</tr>
<tr>
<td>(n = 785; MCO letter only)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Group 3: stepwise intervention</td>
<td>45 (16.1)</td>
<td>1.32 (0.86-2.04)</td>
<td>62 (16.1)</td>
<td>1.80* (1.20-2.69)</td>
</tr>
<tr>
<td>(n = 786; MCO letter, PCP letter, CHO worker counseling)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 3: Group 2 as reference</td>
<td>1.82* (1.21-2.73)</td>
<td>2.35† (1.69-3.25)</td>
<td>1.69† (1.39-2.06)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: MCO, Managed Care Organization Medical Director; PCP, Primary Care Physician; CHO, Community Health Outreach.

*P ≤ 0.01.
†P ≤ 0.001.
a more personalized approach (21). The most effective programs for increasing screening among low-income women involve the use of peer educators (29) because these women can serve as opinion leaders, change agents, and change aides to prompt the desired health behavior (21). In our study, the Community Health Outreach workers were from the peer group, had similar life experiences, and previously held and overcame similar beliefs (distrust, fear, fatalism, lack of self-efficacy). They were able to share their stories, approaches, and strategies, helping the women they were counseling to model the desired preventive health behavior. This finding is consistent with several studies involving telephone (41-43) and in-person intervention counseling (26, 27, 44-46), both of which have been shown to increase mammography screening rates. In our population, it is important to note that the circumstances surrounding the socioeconomic status of these women made it difficult to reach them for intervention. Telephone contact proved to be not feasible (47, 48), and we were unable to counsel 3.9% of the stepwise intervention participants because of multiple contact difficulties ranging from “unwillingness to cooperate” to “worker safety concerns.”

The incrementally intensive stepwise intervention was the most feasible way to improve mammography rates among our low-income insured population. As each step of the intervention advanced, we faced the progressively difficult task of working with the remaining hard-to-reach subjects. In this process, the realized effect of each strategy is more convincing as it illustrates the need for increased attention toward increasingly harder-to-reach women. Moreover, the economic and administrative merits of this approach are that it places an emphasis on the use of less difficult and less expensive elements first, with more expensive and operationally time-consuming efforts used for the targeted hard-to-reach subjects last.

The cornerstone of these results is the understanding that low-income insured women who are not accustomed to using the healthcare system for cancer screening require a multipronged personalized approach. Although the stepwise (incremental) intervention was the most feasible and cost-efficient way to improve cancer screening practices with a reasonable increase in cost for the hard-to-reach group, results of 27% are low and suggest that perhaps we should rethink at interventions to increase preventive healthcare in low-income insured women. Because low-income women are often faced with multiple competing priorities related to day-to-day survival that make preventive healthcare a low priority (19), efforts to promote compliance on cancer screening, when the issue is not of immediate concern to the patient, require extra effort and innovation, including perhaps a search for different approaches or different combinations of approaches.

Strengths and limitations

Strengths of this study include the use of a stratified random selection process to yield homogeneity among the groups and reduce the effect of known and unknown confounders; interventions progressing in a logically sequential order, with results showing the relative effect of each intervention ordered by ascending difficulty and cost; no baseline, final surveys, or any other form of assessment because there is evidence to show that these can subconsciously or consciously drive participants to engage in the desired behavior beyond the planned intervention effect (49); maintenance of a natural setting by implementing the interventions within the community and by not offering incentives (cash or in kind) to the women for completion of mammogram screening; ascertainment of screening mammography completion by review of medical records data and not self-report, consequently removing the inherent bias of overestimation from self-reported data (31, 50); use of existing Community Health Outreach workers; and a sample size that is one of the largest in studies on this kind (24, 25, 29).

As a community trial within a natural setting, we could not control for the possibility that the decision to undergo mammography could have come from other sources, including usual care by the MCO: (a) Monthly newsletters were sent to all MCO members discussing health issues and the importance of screening; (b) A pamphlet was sent to all MCO members annually encouraging mammography screening; (c) The Community Health Outreach workers were available to all women insured by the MCO. Hence, we cannot assume that only women in the stepwise intervention received lay health worker counseling. Furthermore, efforts to promote breast cancer screening by the coalition of the American Cancer Society, Y-Me, and Neighborhood for Life were ongoing in the community at the same time as our intervention and may have had an effect on all groups. Although the results remain robust in their impact, it is important to note that, despite multiple concurrent efforts directed to increasing mammography use, the screening rates in our study population remained low.

Summary

As previous research has shown, insured low-income people find accessing the healthcare system more difficult and do not receive preventive care at the same rates as the general population. This research tested a stepwise intervention designed to increase the use of preventive health services (mammography screening) in very low-income insured women. Our results, which may only be generalized to the provision of preventive care in very low-income insured populations, indicate that, although stepwise interventions can increase use of mammography screening, the gain was modest and additional personal strategies are most likely necessary to increase the use of these services among insured persons not accustomed to or comfortable with using the healthcare system for preventive care.
Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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