

Low-Income Women with Abnormal Breast Findings: Results of a Randomized Trial to Increase Rates of Diagnostic Resolution

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Abstract

Background: Timely diagnostic resolution of abnormal breast findings represents a critical step in efforts to reduce breast cancer morbidity and mortality. Yet, follow-up rates among resource poor populations are not optimal. Efforts to mitigate this disparity are needed. We report results of a randomized trial assessing the effectiveness of a patient support and navigation intervention in increasing timely diagnostic resolution of abnormal breast findings among indigent women.

Methods: Women ($n = 1,708$) diagnosed with a breast abnormality at two public hospitals were randomized to an intervention or control group. The intervention, delivered through telephone, involved one call from a professional health worker and multiple calls from a lay health worker. The outcome, timely diagnostic resolution, defined as receipt of a definitive diagnosis (malignant or benign) within 6 months of the index referral, was assessed through medical chart audit.

Results: Intent-to-treat analyses revealed no significant effect of the intervention on timely diagnostic resolution. Diagnostic resolution rates were 55% and 56%, respectively, in the intervention and control arms. The significant predictors were method of abnormality identification (odds ratio = 1.50) and location of first scheduled appointment (odds ratio = 0.62).

Conclusions: The intervention was not effective in creating change within the County health system. Achieving optimum diagnostic follow-up may require more intensive interventions than the one tested. In addition, system-level rather than patient-level interventions may hold more promise.

Impact: There are no randomized trials reported in the literature testing interventions to increase diagnostic follow-up of breast abnormalities. Future research might test patient and system-level interventions that can be sustained beyond the study period. *Cancer Epidemiol Biomarkers Prev*; 19(8); 1927–36. ©2010 AACR.

Introduction

The United States, in the past two decades, has seen much progress in breast cancer screening accessibility to a broad spectrum of women. Although breast cancer screening can reduce morbidity and mortality from the disease, this potential can only be realized with prompt and appropriate diagnostic work-up of abnormal breast findings. Incomplete or delayed diagnostic resolution can result in larger tumors, locally advanced or metastatic cancer, costlier treatment options (1), higher re-

current rates (2, 3), and lower 5-year survival rates (4-7). However, little research has focused on improving timely resolution of abnormal findings (8). This is troublesome given that only about 75% of all patients in the general population and 50% to 70% of minority women who test positive on any screening test receive appropriate follow-up care (9, 10). Although a few intervention studies have reported positive findings for reminder systems (11-13), patient education (12, 14), patient navigators (15-18), and efforts to modify physicians' processes of care, there are no randomized controlled trials reported in the literature testing interventions to increase diagnostic follow-up of breast abnormalities (19). We report the results of a randomized trial to test the effectiveness of a telephone-based patient support and navigation intervention on timely diagnostic resolution of abnormal breast findings. Timely diagnostic resolution was defined as receipt of a definitive diagnosis (malignant or benign) within 6 months of the index referral. The study was based in a public health system and targeted low-income, indigent, minority women who have particularly low rates of diagnostic follow-up.

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Materials and Methods

Objective and hypothesis

This study was designed to increase timely diagnostic resolution among women with an abnormal breast finding. The hypothesis was that a greater proportion of women in the intervention group, compared with the control group, would have a definitive diagnosis (benign versus malignant) within 6 months of an index referral for diagnostic work-up.

Our study was conducted in close collaboration with the two participating county hospitals. Based on prior work in these settings (20-25) and on the judgments and preferences of county clinicians and administrators, the major aim of the study was to improve diagnostic resolution (malignant or benign) versus to increase attendance at first diagnostic appointment. This was based on the observation that despite a fairly high rate of attendance at first diagnostic appointment (e.g., 84% in this study in treatment and control groups, and both hospitals as indicated in Table 1), the rate of diagnostic resolution was unacceptably low (56% in this study, as indicated in Table 1). Therefore, the intervention was

designed to provide support and navigation during the entire phase of diagnostic work-up, leading up to final diagnostic resolution, which generally includes multiple procedures and appointments.

Allowing the 6-month window for completion of the diagnostic process (achieving diagnostic resolution) was also done in collaboration with county staff and based on the realities of delivering care in a large public health system. Given resource constraints in the system, the consensus was that time to diagnostic resolution was a lesser concern than actually achieving a definitive diagnosis within a reasonable time frame, which county staff judged to be 6 months.

Setting and study participants

The study, conducted from 1995 to 2000, targeted low-income, predominantly minority women with a breast abnormality receiving care at two public hospitals in the Los Angeles County Department of Health Services, the nation's second largest public health care system. Hospital A is a large facility (roughly 300,000 outpatient and 38,000 inpatient visits a year) located in a high-density urban area. Hospital B is a smaller facility

Table 1. Characteristics of study sample by health facility

	<i>P</i>	Health facility		Total (<i>N</i> = 1,671)
		Hospital A (<i>n</i> = 1,217)	Hospital B (<i>n</i> = 454)	
Diagnostic resolution at 6 mo	<0.001	626 (51%)	303 (67%)	929 (56%)
Study group	0.686			
Intervention		614 (50%)	224 (49%)	838 (50%)
Control		603 (50%)	230 (51%)	833 (50%)
Age (y)	<0.001			
<40		243 (20%)	202 (45%)	445 (27%)
40-49		398 (33%)	131 (29%)	529 (32%)
50+		576 (47%)	121 (27%)	697 (42%)
Ethnicity	0.001			
Hispanic/Latina		953 (78%)	321 (70%)	1,274 (76%)
Non-Hispanic/Latina		264 (22%)	133 (29%)	397 (25%)
Type of abnormality	<0.001			
Mass		806 (66%)	382 (84%)	1,188 (71%)
Other		411 (34%)	72 (16%)	483 (29%)
Method of abnormality identification	<0.001			
Patient/Self		201 (17%)	224 (49%)	425 (25%)
Clinical		98 (8%)	149 (33%)	247 (15%)
Radiographic		918 (75%)	81 (18%)	999 (60%)
Location of first appointment	0.002			
Surgery		724 (59%)	307 (68%)	1,031 (62%)
Radiology		493 (41%)	147 (32%)	640 (38%)
Status of first appointment	0.002			
Kept		1,000 (82%)	401 (88%)	1,401 (84%)
No show		217 (28%)	53 (12%)	270 (16%)

NOTE: *P* values refer to comparisons between Hospital A and B.

(~176,000 outpatient and 15,000 inpatient visits a year) located on the outskirts of Los Angeles (26), although still in a heavily populated urban area. In the past 10 years, the County has not made significant changes to its delivery of health care services (27).

All women referred to the hospitals' Surgery or Radiology Departments for immediate work-up of a breast abnormality (e.g., lump, abnormal mammogram) were enrolled in the study. These referrals were made from multiple clinics within the hospitals as well as from ambulatory comprehensive health centers that are part of the county health system. This index referral served as the point of identification and enrollment of women into the study. Only women ≤ 18 years and/or with breast pain and tenderness, a history of breast cancer, or a breast cancer diagnosis were excluded from the study. A total of 1,708 women were enrolled into the study.

Randomization and study design

A randomized posttest only control group design was used to assess intervention effectiveness (see Fig. 1). On study enrollment, women were randomized into an intervention ($n = 859$) or usual-care control ($n = 849$) group within each hospital (that is, stratified randomization). The intervention group received a telephone-based intervention, involving multiple contacts, delivered by a team of professional and lay health workers. Control group women received usual care and had no contact with study staff. Six months following the index referral, medical chart reviews were conducted on all enrolled women to obtain study outcome data. Given the importance of delivering the intervention as soon as feasible after the index referral and maintaining a naturalistic usual care control group, we made a decision not to collect baseline information before delivering the intervention.

This project was considered an administrative aspect of each hospital's quality improvement process. Informed consent was therefore obtained through the County hospitals' general consent process. This general consent process allows both hospitals to conduct and evaluate quality improvement programs without obtaining explicit patient consent each time they conduct and implement a study. Thus, under the auspices of general consent, we were able to enroll patients into our study. The protocol was first approved by the Institutional Review Board at each hospital and then by the University of California at Los Angeles Institutional Review Board. At least one physician from each hospital was closely involved in the conduct of all aspects of the study.

Conceptual framework

The intervention was based on the Health Behavior Framework (28), which represents a synthesis of constructs from some of the major theoretical formulations in the area of health behavior (29-35) and in addition considers characteristics of the provider and the health care setting (36, 37), as well as larger community and societal influences (38, 39).

The framework depicted in Fig. 2 is a generic representation of the relationships among the various constructs. The model recognizes that various mediating and moderating relationships, and multiple pathways will lead to the health behavior in question. The Health Behavior Framework assumes that individual variables, and provider and health care system factors influence behavioral intentions, which in turn influence health behavior in the short and long term (e.g., repeat screening). Intentions do not automatically translate into behavior. Rather, this connection depends on the absence of barriers and/or presence of supports, which may function at the level of the individual (e.g., cultural beliefs), the health system (e.g., practice patterns), or society (e.g., impoverished neighborhood). Supports and barriers may also bypass intentions and exert direct influence on health behaviors. It is useful to categorize model constructs as either mutable or immutable, and this designation may vary depending on the specific situation. Mutable factors represent potential targets for intervention. For example, individual-level interventions may attempt to promote health behaviors by increasing knowledge or reducing barriers. Mutable provider-level factors such as practice norms or structural barriers are another common intervention target. However, the Health Behavior Framework recognizes that it is generally not feasible for any single trial to intervene at all or multiple levels of the model due to resource constraints and research design considerations.

Our intervention was designed to influence individual-level mutable factors (e.g., knowledge, perceptions of disease susceptibility/severity, beliefs, and barriers) within the context of the county health system, which functioned as immutable in this trial. This is represented in Fig. 2 by the bold outlines around the relevant boxes. We hypothesized that the intervention program would increase knowledge of breast abnormalities, breast cancer, and diagnostic tests; positively influence health beliefs such as perceived susceptibility to breast cancer, perceived efficacy of diagnostic procedures, and treatments; provide emotional and social support by engaging women in multiple conversations and addressing fears and concerns; and reducing barriers, such as orienting women to financial and child-care services offered by the hospitals. Health workers were trained to frame and deliver messages that reflected a thorough understanding of the immutable factors that form the context within which individual behavior occurs. These immutable factors include financial burdens, family and childcare responsibilities, lack of transportation, lack of insurance, and aspects of the county system, such as long wait times and lack of in-language services. The conceptual framework was used to guide the development of the intervention and training of the professional and lay health workers. It allowed for a systematic consideration of multiple factors that might support or impede the completion of all of the procedures needed to achieve diagnostic resolution.

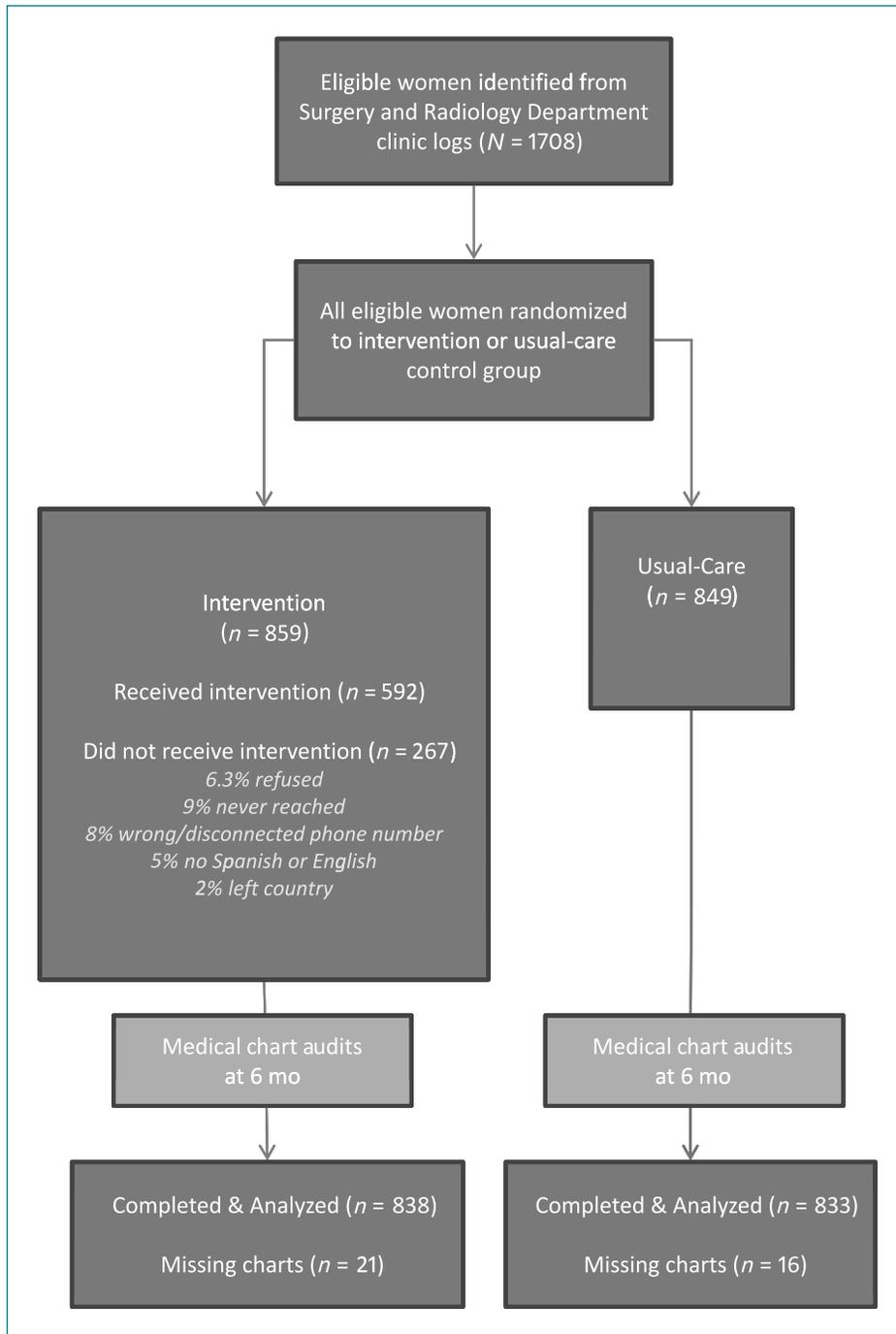


Figure 1. Study flowchart.

Intervention protocol

Usual-care control group. Referrals from within and outside the hospital for additional work-up of an identified breast abnormality are submitted to Surgery or Radiology Departments. Referrals are reviewed for appropriateness by a physician in surgery/radiology and an appointment is scheduled (referred to hereafter as “first scheduled appointment”) for each woman within

1 to 2 weeks of review. Women do not have a choice of appointment date or time. They receive notice of the scheduled appointment date, time, and location through a mailed postcard. After initial evaluation at this first visit, women are scheduled for a series of follow-up appointments, as needed, until resolution of the breast abnormality. If a woman does not show for this first scheduled appointment, hospital protocol requires that

she be rescheduled for another appointment. Thus, all women who miss their first scheduled appointment receive a second postcard with the new appointment date and time. After this point, the follow-up procedure depended on the clinic. Surgery staff at Hospital A called, and Radiology staff at Hospital B sent letters to all women who missed appointments. However, Radiology at Hospital A and Surgery at Hospital B did not have the resources to contact women who missed appointments. At Hospital A, for example, the Radiology staff only tracked women with lesions highly suspicious for breast cancer.

Intervention group. The telephone intervention consisted of one call from a professional health worker followed by multiple calls from a lay health worker.

The professional health workers held masters or doctoral degrees in sociology, psychology, or other related field. Professional health workers attempted to contact women in the intervention group within 2 to 4 days of receiving information about their first scheduled appointment. The goal was to reach them before the first scheduled appointment. However, because hospital protocol required the first appointment to be within 1 to 2 weeks of the index referral, we had an extremely limited opportunity to reach subjects before their first appointment. The call was designed to establish a relationship with the patient at the start of the diagnostic process and provide information, support, and encouragement to attend all appointments, especially the first scheduled appointment.

Each professional health worker session averaged 30 to 40 minutes and provided women with information on breast abnormalities and help with emotional and concrete barriers to attendance at follow-up appointments. These calls focused on how to navigate the complex county health system, fee schedules, waiver of payment, and appointment scheduling. The content of calls was tailored to a woman's individual needs and concerns, such as need for transportation, concerns about the follow-up process, level of knowledge, and perceived efficacy of diagnostic procedures, as well as whether she was reached before or after her first scheduled appointment, and whether she had attended that appointment. After the call, we mailed each woman two commercially available education pamphlets from *Krames Communications*, selected by the research team after careful review of many breast health education materials. *Krames* materials were selected for their simplicity, low reading level, use of clear color graphics, and availability in Spanish (materials can be accessed at <http://www.krames.com>). The Breast Lump booklet described the normal breast, different types of breast lumps, various diagnostic tests, and explained breast cancer treatment options. The Breast Surgery booklet was similar, but described the process from biopsy to reconstruction in more detail.

Lay health workers were community members recruited from senior centers and other community settings in the Los Angeles area who received \$5 for every completed phone call and reimbursement for phone charges. Thirty-one lay health workers of diverse

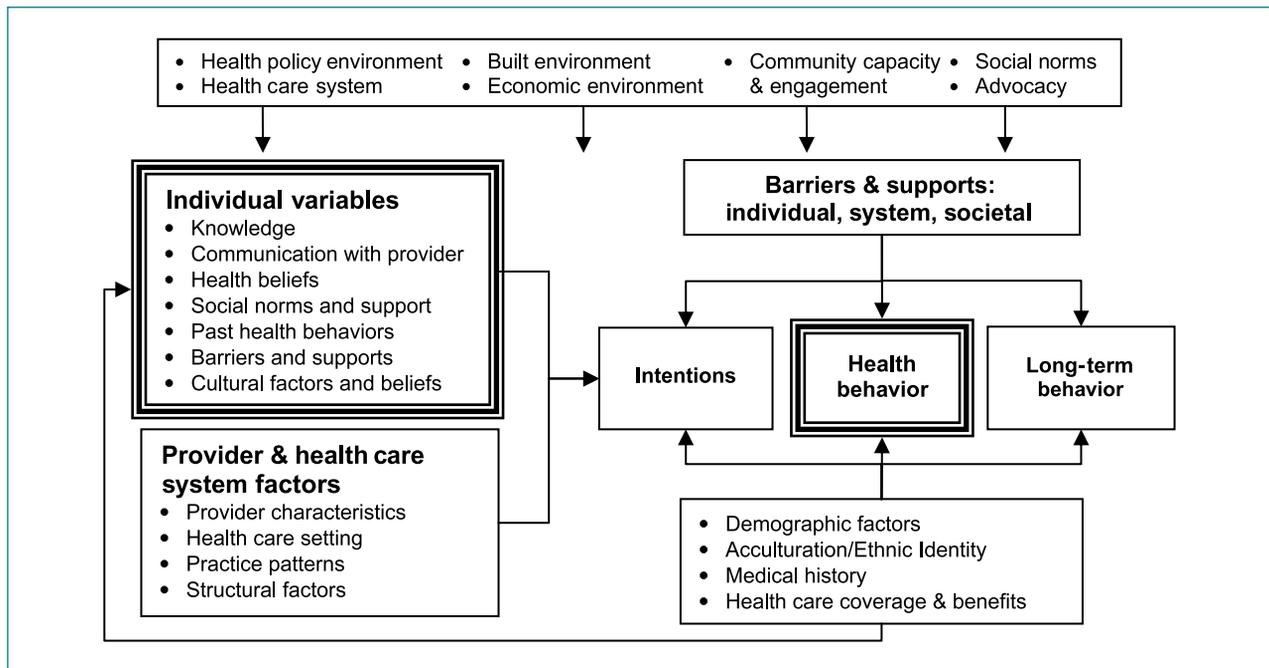


Figure 2. Health Behavior Framework.

ethnic backgrounds were recruited: 20 Latina, eight Caucasian, two African-American, and one Asian.

Through a 7-week training program provided by the Center for Healthy Aging (formerly the Senior Health and Peer Counseling Center) in Santa Monica, CA, lay health workers learned basic counseling skills (e.g., listening, paraphrasing, probing, reinforcing, and summarizing), general breast abnormality/cancer information, and hospital-specific information regarding the structure and functioning of the County health system (e.g., resources and payment options). Lay health workers received a specially prepared manual summarizing communication hints and techniques, and general medical information, and attended monthly supervision meetings to share their experiences and discuss specific cases and issues related to the telephone sessions and/or the research study.

Patients and lay health workers were paired by matching them first on language preference followed by ethnicity and age, and time availability of the lay health worker and a patient's preference for receiving phone calls. A summary of each professional health worker session was given to the lay health worker, who attempted to call women 2 to 4 days before and after each follow-up appointment. Calls were designed to provide ongoing informational, emotional and social support, encouragement to attend clinic appointments, and assistance in navigating the system. Women received an average of about six intervention phone calls, each lasting 5 to 15 minutes. Women who received a cancer diagnosis ($n = 92$) during the intervention phase continued to receive support calls until completion of treatment, even beyond the 6-month follow-up period. This was done as a service activity and was not part of the intervention trial or data collection.

Data collection

Data on new patient referrals were collected weekly from the Surgery and Radiology Departments at both hospitals. Study staff made weekly visits to Hospital A and photocopied referral forms received throughout the week, and generated computer printouts of patients with scheduled appointments and patients who had kept their appointment the previous week. At Hospital B, Surgery staff faxed copies of referral forms on a daily basis and clinic appointment lists on a weekly basis. Because few referrals came through Radiology at Hospital B, we periodically visited Radiology for copies of referral forms.

Chart audits were completed for 98% ($n = 1,671$) of study participants. Medical records (paper charts) for each study participant were reviewed retrospectively on site at each hospital 1 year after the index referral. To facilitate complete medical record data abstraction at 1 year, we collected weekly appointment lists from Surgery and Radiology Departments to track appointment dates and attendance. An appointment history for each woman helped us systematically sift through an entire medical record folder. Missing charts (2%) were re-

quested at least twice from the hospital's medical records office. Abstraction of a medical record was considered complete when we confirmed diagnostic resolution of an abnormality or we could find no additional appointment records after requesting the chart at least twice from medical records.

Chart audits were conducted by medical record abstractors who underwent detailed training in medical terminology and coding procedures. The majority of abstractors had at least a bachelor's degree. All completed abstraction forms were reviewed for thoroughness by the project director and a trained research assistant. To ensure consistency in coding among record abstractors, we assessed interrater agreement at two different time points during the chart abstraction period. The same patient records were coded by each medical record abstractor, and agreement among the abstractors was assessed by the project director and trained research assistant. Results were discussed with the abstractors as part of quality monitoring for data management.

Outcome measure

The main outcome measure, timely diagnostic resolution of the identified breast abnormality, was defined as receipt of definitive diagnosis of malignant or benign within 6 months of the index referral. This outcome is based on medical record data and coded as a binary variable (that is, definitive diagnosis versus no definitive diagnosis). County physicians, administrators, and other staff agreed that 6 months in the County health system was a clinically appropriate time frame for resolution of a breast abnormality.

Predictor variables

The main predictor variable was study group status, that is, whether patient was in the intervention or usual-care control group. Covariates obtained from medical record data were as follows: (a) system factors, that is, location of referring clinic (within, outside hospital), location of first appointment (Surgery, Radiology), method of abnormality identification (patient/self, clinical, radiographic), and hospital (A, B) and; (b) patient variables, that is, age (<40, 40-49, 50+ y) and ethnicity (Hispanic/Latina, non-Hispanic/Latina). Age and ethnicity were the only patient demographic characteristics available in medical charts. Ethnicity was constructed using data from medical records and the U.S. Census Bureau's 1990 Heavily Hispanic Surname File, which contains >12,000 names highly correlated with Hispanic ethnicity (40). When available, ethnicity from medical records was recorded. Otherwise, patient last names were matched against the surname file.

Statistical analyses

An intention-to-treat analysis, based on the original random assignment to intervention or usual-care control group, was used to determine the effect of the intervention on diagnostic resolution at 6 months. We also

conducted an as-treated analysis to determine the effect of the intervention among women in the intervention group who received the professional and lay health worker calls. For this analysis, women were dichotomized by whether they had received at least one intervention call.

To account for effects of other covariates on the outcome, we fitted multivariate logistic regression models predicting outcome at 6 months. The multivariate regression equation was specified as a function of study group status, demographic characteristics, type of abnormality, method of abnormality identification, location of referring clinic, and location of first appointment. Interaction terms, with group status, were entered to model hospital differences in predictors. To assess sensitivity of the intervention to time to diagnosis, we conducted a logistic regression predicting outcome at 3 months as well as a survival analysis censored at 6 months.

Before running any analyses, we conducted multiple imputations to account for missing data in predictor variables. Missing data frequencies were age (2.7%), type of abnormality (3.5%), method of abnormality identification (12%), location of referring clinic (3.9%), and location of first appointment (1.4%). We used the imputation by chained equations (ICE) procedure in Stata Release 9 that uses switching regression to conduct five imputations, which is sufficient when data have up to 20% missingness (41).

Results

Participant and hospital characteristics

Table 1 displays patient demographics and system characteristics by hospital. The hospitals differed significantly on all measured predictor variables and the outcome. Hospital B had a lower proportion of Hispanic/Latinas and a younger patient mix than Hospital A. Most

abnormalities at Hospital B were either self-identified (49%) or clinically detected (33%). At Hospital A, 75% of abnormalities were radiographically identified and women were more often referred to Surgery than Radiology for their first appointment. Although 56% ($n = 929$) of women overall received timely diagnostic resolution, the proportion was higher at Hospital B (67%) compared with Hospital A (51%).

The intervention and control groups were virtually identical on all variables in Table 1. There were no significant differences in demographics, hospital characteristics, or outcomes between the two groups (data not shown).

Treatment reach

Professional health workers reached 69% ($n = 592$) of women in the intervention group, with a 6.3% refusal rate. Of the 592 women who received the intervention, 515 women (87%) were reached before their first scheduled appointment. All women reached by a professional health worker received at least one call from a lay health worker. Issues most often discussed during the calls were emotional and interpersonal problems about the breast abnormality (e.g., fear or no social support), lack of medical information (e.g., unfamiliar with breast changes or tests), and navigating the health system (e.g., financial services). Calls were in Spanish (77%) and English (23%).

Treatment effectiveness

Table 2 shows the results of the intent-to-treat analysis, revealing no significant effect of study group status on percent receiving diagnostic resolution by 6 months at either hospital ($P < 0.56$). However, as-treated analyses (Table 2) revealed that, at both hospitals, women in the intervention group who received at least one call were significantly more likely to receive diagnostic resolution by 6 months (60%) compared with women in

Table 2. Intervention effect on timely diagnostic resolution: intent-to-treat and as-treated analyses

	Hospital A			Hospital B			Total		
	<i>n</i>	% TDR	<i>P</i>	<i>n</i>	% TDR	<i>P</i>	<i>n</i>	% TDR	<i>P</i>
Intent-to-treat effect									
Intervention	614	50	0.50	224	67	0.92	838	55	0.56
Control	603	52		230	67		833	56	
As-treated effect									
Intervention women who <i>received</i> the intervention vs <i>did not receive</i> the intervention	421	56	<0.0001	147	73	0.011	568	60	<0.0001
Intervention women who <i>received</i> the intervention vs <i>control</i>	421	56	0.249	147	73	0.200	568	60	0.129
Intervention women who <i>did not receive</i> the intervention vs <i>control</i>	193	38	0.0007	77	56	0.093	270	43	0.0002
	603	52		230	67		833	56	

Abbreviation: TDR, timely diagnostic resolution.

Table 3. Multivariate logistic regression predicting diagnostic resolution within 6 months

	Hospital A + B (N = 1,671)	
	n	OR (95% CI)
Study group		
Intervention	838	0.94 (0.75, 1.18)
Control	838	Reference
Age (y)		
<40	445	Reference
40-59	529	1.25 (0.95-1.65)
50+	697	1.29 (0.98-1.70)
Ethnicity		
Hispanic/Latina	1,274	Reference
Non-Hispanic/Latina	397	0.89 (0.70-1.14)
Type of abnormality		
Mass	1,188	Reference
Other	483	1.04 (0.82-1.32)
Method of abnormality identification		
Patient/Self	425	1.50* (1.09-2.08)
Clinical	247	1.02 (0.66-1.56)
Radiographic	999	Reference
Location of first appointment		
Surgery	1,031	Reference
Radiology	640	0.62* (0.49-0.79)
Status of first appointment [†]		
Kept	1,401	
No show	270	
Hospital		
A	1,217	Reference
B	454	2.05* (1.12-3.75)
Interaction terms		
Hosp B × intervention		1.12 (0.71-1.77)
Hosp B × radiology		3.47* (2.07-5.82)
Hosp B × patient/self		0.46* (0.21-0.79)
Hosp B × clinical ID		0.61 (0.28-1.29)

Abbreviation: OR, odds ratio; 95% CI, 95% confidence interval.

*Significant at $P < 0.05$.

[†]Status of first appointment not included in multivariate analysis.

the intervention group who did not receive any intervention calls (43%). Comparison of these two groups did not reveal any significant differences in patient characteristics. We also compared women who received the intervention to all women in the control group and found no significant intervention effect in either hospital. We then compared the subgroup of women in the intervention group who did not receive the calls to all women in the control group. Results suggest that at Hospital A, the control group had higher odds of receiving timely diagnostic resolution than intervention group women who did not receive the intervention. There

were no significant differences in other patient characteristics between these two groups of women at either hospital.

We also examined the effect of attendance at first scheduled appointment on the outcome, which was a near perfect predictor. Among women who attended the first scheduled appointment, 66% received timely diagnostic resolution (52% at Hospital A; 75% at Hospital B). In contrast, women who failed to attend the first scheduled appointment had a zero probability of timely diagnostic resolution at either hospital. Due to the highly skewed distribution of this variable, we did not enter it as a predictor in the logistic regression predicting outcome.

Multivariate logistic regression

After controlling for all other study variables, there was still no difference in outcome by study group status (Table 3). The only significant predictors of timely diagnostic resolution included method of abnormality identification, location of first scheduled appointment, and hospital.

Method of abnormality identification. Women with self-identified abnormalities were significantly more likely to receive diagnostic resolution at 6 months compared with women with radiographically diagnosed abnormalities. A significant interaction emerged, indicating that at Hospital B compared with Hospital A, the odds of timely diagnostic resolution were significantly lower among women with self-identified abnormalities compared with women with radiographically identified abnormalities.

Location of first scheduled appointment. Women scheduled to Radiology had significantly lower odds of timely diagnostic resolution than women scheduled to Surgery. A significant interaction emerged, indicating that at Hospital B compared with Hospital A, women with an appointment to Radiology had higher odds of timely diagnostic resolution than women scheduled to Surgery.

Hospital. Women at Hospital B were significantly more likely (odds ratio = 2.05) to receive diagnostic resolution within 6 months compared with women at Hospital A.

A logistic regression predicting the outcome at 3 months produced identical results, including no intervention effect (data not shown). Survival analysis also failed to find a significant intervention effect (data not shown).

Discussion

We implemented a telephone patient support and navigation intervention to address low follow-up of abnormal breast findings and put it to a rigorous test in a large randomized experiment. Results indicated that the intervention was not effective in increasing timely diagnostic resolution of breast abnormalities in low-income, mostly Latina women receiving care at two public hospitals in Los Angeles. In addition, there were no differential intervention effects by race/ethnicity or other characteristics (42, 43). These negative findings emerged although our intervention was theory driven and based on

interventions reported to be effective in increasing follow-up after abnormal Pap smears, including among low-income and minority populations (44, 45).

There are several possible explanations for these negative findings. First, our patient-directed intervention may not have addressed the "critical factor" underlying the low follow-up in our target population. System-level factors at both hospitals may have been the causal agents. This explanation is supported by our finding that location of first appointment and method of abnormality identification were two of the three independent predictors of timely diagnostic resolution. As previously reported (46), this is likely due to Radiology at Hospital A fast-tracking women with self-identified abnormalities and aggressive follow-up by Surgery at Hospital A and Radiology at Hospital B. Attendance at the first appointment following identification of the abnormality was also a very powerful predictor of the outcome. Among women who attended the first appointment, 66% had timely diagnostic resolution. In contrast, women who missed their first appointment had a zero probability of timely diagnostic resolution at either hospital (46). Women who keep their first appointment may benefit from associated staff communication and tracking of the follow-up process. It is also possible that women who kept their first appointment were a self-selected group more inclined to adhere to all diagnostic procedures recommended. We found no controlled trials of system-level interventions in this area, a glaring literature information gap that needs attention.

Second, although we implemented our telephone intervention as a cost-efficient alternative to on-site or in-person interactions, this medium may have inadvertently diluted the "navigation" aspects of the intervention. Our intervention was designed to provide both support and navigation. The support aspects of the intervention were based on the cervical cancer literature (44, 45) and included encouragement, empathy, and provision of informational and emotional support. Our professional and lay health workers received intensive training about the structure and processes of care at both hospitals and were expected to assist patients in navigating the system to receive appropriate and timely care. However, unlike most patient navigation programs (14, 17, 47), our health workers were not based at nor embedded into the organizations in which the women were seeking care. Health workers had only indirect contact with the two hospitals through their interactions with patients and through the monthly supervision and debriefing group sessions with study staff. This limited their ability to provide more direct case management services. This limitation is especially serious if system factors were indeed the main impediment to receipt of care in our sample.

Third, we only delivered the intervention to 69% of women assigned to the intervention group, thus attenuating potential intervention effectiveness. Although there were no significant differences among women who received versus those not receiving the intervention, unreachable women may have been fundamentally

different from participating women on unmeasured variables such as motivation, drive, interest in personal health, ability to navigate the health care system, and personal resources. Thus, we may have reached and delivered the intervention to women who would have returned for follow-up without our intervention and failed to reach the women who would have benefited from our intervention.

Although the intervention was not effective, results of the as-treated analysis reveal that women in the intervention group who actually received the intervention were more likely to receive timely diagnostic resolution than women who did not receive any calls. Results, however, are likely due to a self-selection bias because receipt of counseling was not a random event.

Limitations of the study include lack of generalizability to hospitals beyond the ones included in our research, significant differences between the two hospitals on all measured variables, and incomplete coverage of the intervention group with respect to intervention delivery. However, this is the first randomized trial reported in the literature to test the efficacy of an intervention directed at improving diagnostic follow-up of a medically identified breast abnormality. The lack of intervention effect is a disappointment, but also a learning opportunity that can provide guidance for future work. Lastly, findings must be interpreted in light of the overall changes in public awareness of breast cancer, advocacy efforts, and policy initiatives since the intervention was tested. Further research is needed, in the field, to test patient-directed interventions before abandoning them as ineffective. In-person navigation efforts, although more costly, may need to be used in resource poor health systems and populations. Rigorous research is also needed to develop effective system-level interventions that can be sustained beyond the study period. Rather than start afresh, future work to improve follow-up of abnormal breast findings could benefit from lessons learned from successful intervention efforts to increase follow-up of cervical and colorectal abnormalities.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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