

Recruiting Patients With Breast Cancer and Their Families to Behavioral Research in the Post-HIPAA Period

Deborah J. Bowen, PhD, Jesse R. Fann, MD, MPH, M. Robyn Andersen, PhD, Isaac C. Rhew, MPH, Julie R. Gralow, MD, Frances M. Lewis, PhD, RN, Julie R. Hunt, PhD, Melanie Palomares, MD, MS, Carol M. Moinpour, PhD, and Donna P. Ankerst, PhD

Purpose/Objectives: To describe a process for, response rates of, and indicated interest in recruiting patients with breast cancer and their spouses and family members from a clinical setting into behavioral and psychiatric research studies since the Health Insurance Portability and Accountability Act (HIPAA) regulations have taken effect.

Data Sources: Published articles, books and book chapters, MEDLINE®, government agency information and HIPAA regulatory Web sites, and survey data.

Data Synthesis: Response rates among the three target groups—patients, spouses and partners, and female first-degree relatives—were 77%, 95%, and 88%, respectively. Interest was high in the three target groups, with 77%, 87%, and 65% of responding patients, spouses and partners, and female first-degree relatives, respectively.

Conclusions: Taken together, these data indicate that high participation rates can be expected from patients with breast cancer and their families in clinical settings.

Implications for Nursing: Regulations pose barriers to patient and family recruitment, but thoughtful systems actually can improve rates of recruitment.

Key Points . . .

- Recruiting patients with cancer and their family members into research, specifically randomized trials, requires multiple steps.
- Most patients and families will provide background information to determine study eligibility.
- Many patients and families are interested in behavioral research.

1997; Newcomb, Love, Phillips, & Buckmaster, 1990; Taylor, Margolese, & Soskoline, 1984).

Furthermore, clinical data now are more difficult to incorporate into research activities. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 described how clinical entities can use or disclose protected health information, including for research purposes. The regulations affect how

Recruiting patients from clinical settings into cancer clinical trials is a difficult but essential element of the success of the National Cancer Institute's efforts to reduce cancer mortality. Overall, less than 50% of patients with cancer participate in treatment trials nationwide (Beskow, Sandler, & Weinberger, 2006; Elting et al., 2006; Gotay, 1991; Heiney et al., 2006). Even institutions with appropriate trials available that are dedicated to recruiting patients for clinical and behavioral trials often reported that recruitment rates are modest, varying from 19%–53% (of clinically eligible patients older than age 35) (Hunter et al., 1987; Lee, Marks, & Simpson, 1980; Spiro, Gower, Evans, Facchini, & Rudd, 2000). Low recruitment yields into clinical trials commonly are reported among patients with cancer (Ashing-Giwa, 2005; Ashing-Giwa, Padilla, Tejero, & Kim, 2004; Hunter et al.; Hutchins, Unger, Crowley, Coltmant, & Albain, 1999; Sears et al., 2003). Recruitment yields in those studies have ranged from 16%–36%. Modest rates of recruitment occur for several reasons. Key barriers to patient participation in clinical trials often are provider-related, including the time commitment involved, obtainment of informed consent, and intrusion of the study on the physician-patient relationship (Benson et al., 1991; Lovato, Hill, Hertert, Hunninghake, & Probstfield,

Deborah J. Bowen, PhD, is a joint member at the Fred Hutchinson Cancer Research Center in Seattle, WA; Jesse R. Fann, MD, MPH, is an associate professor in the School of Medicine at the University of Washington (UW) in Seattle; M. Robyn Andersen, PhD, is an assistant member of the division of Public Health Sciences at the Fred Hutchinson Cancer Research Center; Isaac C. Rhew, MPH, is a predoctorate research associate in the Department of Epidemiology at UW in Seattle; Julie R. Gralow, MD, is an associate professor in the School of Medicine at UW in Seattle; Frances M. Lewis, PhD, RN, is a professor in the School of Nursing at UW in Seattle; Julie R. Hunt, PhD, is a senior staff scientist in the Division of Public Health Sciences at the Fred Hutchinson Cancer Research Center; Melanie Palomares, MD, MS, is an assistant professor in medical oncology in the Division of Population Sciences, a staff physician for the Cancer Screening and Prevention Program, and a member of the Comprehensive Cancer Center at the City of Hope in Duarte, CA; Carol M. Moinpour, PhD, is an associate member of the Fred Hutchinson Cancer Research Center; and Donna P. Ankerst, PhD, is an associate research professor in the Health Science Center at the University of Texas in San Antonio and a research scientist at the University of Munich in Germany. This research was supported by a grant (CA82894) from the National Cancer Institute and by Fred Hutchinson Cancer Research Center developmental research funds. (Submitted March 2007. Accepted for publication April 3, 2007.)

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researchers interact with participants and hospitals, physicians, and other organizations that provide access to participants and their data. Covered entities can disclose protected health information to researchers only if the study has obtained direct consent from patients, signed HIPAA authorization forms from patients, or a waiver of authorization from an institutional review board (IRB). Study recruitment materials and consent forms also must provide clear information to participants about who will have access to their medical information and how it will be used (HIPAA Advisory, 2003; Sands, 2003; U.S. Department of Health and Human Services, 2003). In November 1999, the U.S. Department of Health and Human Services published proposed regulations to guarantee patients new rights and protections against the misuse or disclosure of their health records. After extensive comments from thousands of individuals and organizations, the revised rules took effect on April 14, 2001.

The new rules resulted in confusion and concern at most academic research facilities. Ambiguities in interpretation and appropriate implementation left researchers unable to use standard procedures and forms for informed consent. Similarly, clinical facilities had to interpret the new laws and adjust approved procedures for providing researchers access to patients for research purposes.

Behavioral intervention research for patients with cancer and their family members includes psychosocial interventions to improve coping (Andersen, 1992; Baum & Andersen, 2001; Sears et al., 2003) and dietary and exercise changes as methods of preventing recurrence or improving physical functioning and quality of life (Chlebowski et al., 1993; McTiernan et al., 1998; Pierce et al., 1997). Behavioral research with patients and families also involves interventions to improve the health and coping of caregivers of patients with cancer (Donnelly et al., 2000). Obtaining high response rates is important in such studies because psychological and behavioral differences between responders and nonresponders limit generalizability.

Concerns were raised that complications of the HIPAA regulations would result in low response rates (Wolf & Bennett, 2006) or costly recruitment procedures (Friedman, 2006). Other investigators proposed that implementing HIPAA-based procedures would make recruitment of patients and families more confusing to potential study participants (Shalowitz & Wendler, 2006). As a result, a plan was created for approaching patients with breast cancer and their family members for research using rules based on implementation of the HIPAA regulations; the plan was implemented to determine eligibility and interest for future intervention research. The aim of this article is to assess the potential recruitment yields for patients and family members into behavioral research using a planned approach. Specifically, the article reports on the eligibility of patients with breast cancer and their family members to enter a set of behavioral intervention trials, their interest in participating in the trials, and the willingness of patients to provide contact information of spouses or partners and female first-degree relatives for entry into separate research projects.

Recruitment Process

Participants in the present study were recruited from the Seattle Cancer Care Alliance in Washington, a multi-institution National Cancer Institute–designated comprehensive cancer center that includes the Fred Hutchinson Cancer Research Center, the University of Washington Medical Center, and the

Children's Hospital and Regional Medical Center of Seattle. The Seattle Cancer Care Alliance's Breast Center offers various clinical, diagnostic, and treatment services to patients in a multidisciplinary setting. Patients, their spouses or partners, and their female first-degree relatives were to be recruited for separate randomized trials to reduce risk of recurrence (patient) or first primary cancer (others). The research received human subjects review approval from the Fred Hutchinson Cancer Research Center IRB.

The Seattle Cancer Care Alliance maintains a computerized database that tracks patient information, including age, gender, name, address, phone number, cancer diagnosis, and dates of clinic visits. Using the database, the Seattle Cancer Care Alliance Breast Center staff generated a list of the 100 patients with breast cancer most recently seen for treatment by a practicing oncologist in the year prior to initial study contact. After removal of duplicate or invalid contact information, 91 patients were available for contact. All participating patients were recruited from the contact list with a passive consent letter for initial contact. Eligible patients were at least 18 years old, diagnosed only with primary breast cancer, and (for one study) reporting high levels of depressive symptoms.

Recruiting male spouses or partners and female first-degree relatives to participate in studies of health behavior change and risk reduction also was attempted. Eligible spouse or partner participants were male and living with previously recruited patients. Eligible female first-degree relative participants were at least 18 years old and never diagnosed with breast cancer. Payment was not offered to participants as an incentive for completing the study survey or for agreeing to participate in future research.

Recruiting Procedures in a Specific Clinical Setting

One of the major barriers to recruitment is moving contact information from a clinical setting to a research setting in a legal and ethical way. Figure 1 presents the flow chart for study recruitment. HIPAA regulations focus on protecting participant privacy at several points of contact but do not specify the means of protection. The present study was performed shortly after the regulations were in effect, so procedures had to be defined to ensure the protection of participant privacy. Specifically, research teams could no longer access patient information and obtain initial consent from patients to be contacted about a potential research project. Therefore, a clinical contact step was included to allow patients to opt out of the recruitment process. Once patients had a chance to refuse participation, contact information could flow to the research team, who directly contacted nonrefusing patients to describe the study, collect eligibility and initial interest data, and invite participants for more intensive consent and data collection activities. Participants could refuse to participate further at each step of the process.

The research team worked closely with clinical staff to implement the new recruitment procedures. Clinical staff sent the initial approach passive consent letter that described the survey and was signed by the principal investigator of the study and patients' treating oncologist to the 91 patients identified as potential study participants. The letter requested patients' permission to contact them via the telephone and provided a toll-free study telephone number to call if they did not wish to be contacted. During the subsequent survey, the interviewers asked each patient if she had a male spouse or

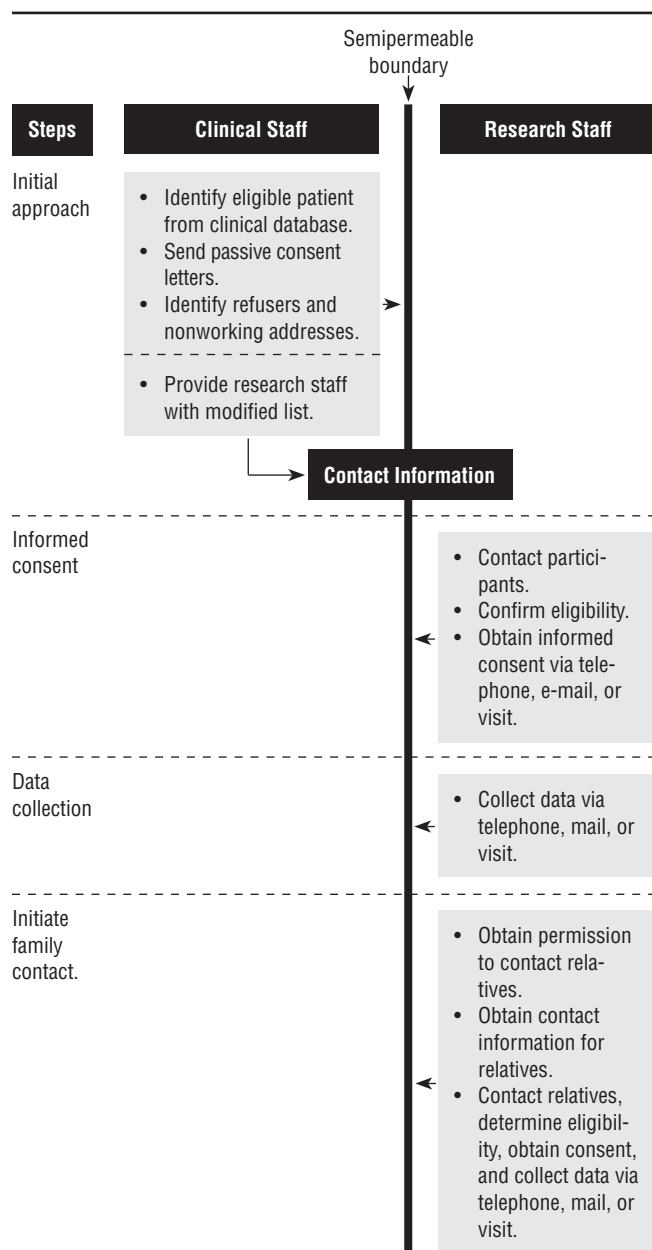


Figure 1. Recruitment Process for Participants and Relatives

partner or living female first-degree relative(s). If the patient reported a male spouse or partner or living female first-degree relative(s), the interviewer asked whether the patient would be willing to allow the researcher to contact her spouse or partner or female relative(s) to participate in a survey about possible future research studies. Patients were not asked to call the relatives to obtain separate consent.

Seven days after initial consent, research interviewers called the nonrefusing patients and asked them to complete a 30-minute telephone survey covering questions about their health history, depression, sensitive psychosocial history, height and weight history, age, relatives' cancer history, and interest in potential research studies. If patients provided their consent to contact relatives, they were asked to supply the contact information for those family members.

Spouses or partners and female first-degree relative(s) for whom patients provided contact information were approached first by a letter stating that permission had been obtained from the patient to get in touch with them about the study and that they would be called to provide more information and were under no obligation to participate in the study. A telephone number was provided in the letter that family members could call if they did not wish to be contacted via telephone.

Six months later, data were collected on the spouses or partners and female first-degree relatives of the patients. The wait period was six months to minimize interaction between research staff and families during their loved ones' acute therapeutic period. Research interviewers contacted nonrefusing family members to explain the study further, obtain verbal consent, and complete the survey if they chose to participate.

Table 1 shows the recruitment yields for patients, spouses or partners, and female first-degree relatives in the present study. Seventy-seven percent of patients, 95% of spouses or partners, and 88% of female first-degree relatives provided survey data. The proportion of participants lost because of the researchers' inability to locate them was low; 10% of patients and no spouses or partners or female first-degree relatives were unable to be contacted, and fewer had non-working phone numbers. Only 7% of patients, 2% of spouses or partners, and 2% of female first-degree relatives personally refused the survey offer.

Patient Consent to Contact Relatives

At first contact, patients were asked about their willingness to allow researchers to contact their spouses or partners and female first-degree relatives regarding future research studies. At recontact, patients gave consent by confirming their initial willingness to allow the interviewer to contact a spouse or partner or female first-degree relative(s). Consenting patients also provided the contact information.

Most of the patients were willing to allow the interviewer to contact spouses or partners and female first-degree relatives and to provide the necessary contact information. At first contact, 55 and 68 patients reported the existence of a living spouse or partner and a living and eligible female first-degree relative, respectively. A total of 52 (95%) of the patients with spouses or partners stated that they would allow the interviewer to contact their spouses or partners, and 61 (87%) allowed the interviewer to contact female first-degree relatives. At recontact, 49 of the patients initially allowing spouse or partner contact were contacted. Forty-three (88%) of those patients provided consent and contact information for their spouses or partners. Fifty-eight patients who initially allowed at least one female first-degree relative to be contacted were reached; 48 (83%) provided consent and contact information for at least one female first-degree relative.

Eligibility for Future Studies

Age and self-reported height and weight were obtained from patients and first-degree female relatives. In addition, because one of the planned future studies required the recruitment of depressed patients with breast cancer, the nine-item depression scale found in the Patient Health Questionnaire (PHQ) was administered (Kroenke, Spitzer, & Williams, 2001; Spitzer, Kroenke, & Williams, 1999). Items include questions about the presence of different symptoms of depression.

Table 1. Survey Approach Results for Patients and Relatives

Survey Approach	Patients	Yield (%)	Spouses and Partners	Yield (%)	First-Degree Female Relatives	Yield (%)
Approach letters mailed	91	—	41	—	85	—
Letters remailed	1	1	2	5	2	2
Incorrect address	—	—	—	—	—	—
Call records fielded	91	100	41	100	85	100
Unable to contact	9	10	—	—	—	—
Nonworking phone number	4	4	—	—	—	—
Refused personally	6	7	1	2	2	2
Refused via family member	2	2	—	—	3	4
Deceased	—	—	—	—	—	—
Unable to speak with	—	—	1	2	5	6
Total completed surveys	70	77	39	95	75	88

Relatives' Assistance Needs

Spouses, partners, and female first-degree relatives were asked about their need for information about nine specific breast cancer topics (risk factors, risk in relatives, screening, treatment, healthful foods and exercise behaviors for prevention, coping with feelings, hearing others' experiences, and ways to talk with healthcare providers). For each topic, spouses and partners were asked about how much assistance in receiving information on that topic they would like in dealing with their wives' or partners' breast cancer. Female relatives were asked about how much assistance in receiving information on that topic that they would like for themselves. Answer choices were "not at all," "a little bit," "some," and "very much." Participants who responded "very much" were considered as reporting a high need for information. Table 2 presents data on the specific needs reported by spouses and partners and female relatives. The most frequently self-reported needs in both groups were learning about cancer treatments, healthful foods, exercise, and breast cancer risk factors. No apparent differences existed in frequency of responding between the two groups.

Interest in Participating in Future Studies

Patients were asked about their interest in participating in (a) a research project on the possible benefits of exercise for patients in recovery from initial cancer treatment, (b) a research project involving possible benefits of social support, relaxation, and other psychosocial coping skills during recovery from initial treatment, and (c) a clinical trial of the antidepressant sertraline as a treatment for depression in patients with breast cancer. Spouses and partners were asked whether they would be interested in hearing more about a study in which they would learn ways to help their wives or partners with breast cancer. They also were asked whether they would be interested in participating in such a study. Spouses and partners were asked whether specific appointment schedules for the research would be manageable. To assess female first-degree relatives' interest in research, researchers asked them whether they would like to participate in a study designed to help female family members of patients with breast cancer understand their own breast cancer risk and learn ways to cope with their risk.

Interest in the research studies was high among all three groups. A total of 57 of 69 responding patients (83%) reported

interest in participating in an exercise intervention study. Even if participation meant being assigned to a group not receiving an exercise intervention, 49 patients (70%) still reported that they would be interested in such a study. Of 69 responding patients, 53 (76%) reported interest in participating in a coping skills training study. If participation included the possibility of being assigned to a group without special coping skills training, 56 patients (81%) agreed to participate. Patient interest in a trial to test the efficacy of an antidepressant medication also was high, with 47 of 66 (71%) respondents reporting interest in participation. Fourteen patient participants (20%) had a probable presence of moderate depression based on the data from the PHQ depression screening, indicating eligibility for a behavioral study to treat depression in patients with cancer. Those participants reported particularly high rates of interest in the relevant research studies compared to nondepressed participants. Eleven of the 14 (79%) participants with moderate depression reported interest in the antidepressant clinical trial. In comparison, 36 participants (69%) who were not likely depressed reported interest.

Among the spouse and partner participants, 37 (95%) reported interest in hearing more about a study to help their wives or partners with breast cancer, and 34 (87%) reported interest in actually participating. In addition, 30 (77%) spouses or partners reported that a six-month, biweekly research clinic appointment schedule was manageable and 32 (82%) spouses or partners reported that a three-appointment and two-telephone session schedule was manageable. Among female relatives, 64 (85%) reported willingness to be contacted about a study to help family members understand their risk for breast cancer, and 49 (65%) reported actual interest in participating.

Discussion

The data indicate that procedures to contact, recruit, and obtain consent from patients and family members for behavioral research activities complementary to their primary cancer treatment can be implemented successfully in the era of new stringent privacy regulations, even during the acute diagnosis and treatment period. Research staff working together with clinical staff to plan and conduct the initial consent resulted in very few refusals at the initial contact point. Several strategies were identified for making the relationship functional; the strategies have received support from similar studies (Albert

Table 2. Assistance Needs of Relatives of Patients With Breast Cancer

Assistance Need	High Need (%)	
	Spouses and Partners	Female First-Degree Relatives
Breast cancer risk factor information	46	37
Information on risk in relatives	33	47
Information on screening	36	53
Learning about cancer treatments	67	48
Learning about healthful foods	64	63
Learning about exercise	64	52
Coping with feelings about cancer	33	39
Hearing others' experiences	18	27
Help with talking to providers	41	36

& Levine, 2005; Wolf & Bennett, 2006). In the present study, strategies that reduced cost while improving yield included discussions between clinical staff and research staff, financial support of clinical staff by the research team, and the addition of the clinical director to the key personnel of research grants. This IRB-approved process will serve as a model for the recruitment of participants for future studies.

Researchers screened 100% of eligible participants via telephone, making calculating the overall yield on a population basis easier. The screening results differ from the percentage of eligible participants identified in previous research (Sears et al., 2003). The initial positive response to the approach via telephone likely would be replaced by lower yields when participants are faced with actually attending a visit to determine eligibility and obtain consent, although increasing the burden on participants by scheduling a visit would be a good strategy to establish which participants actually would adhere to the study protocol.

The interest rates of spouses or partners and female first-degree relatives approximately were equal, and a relatively large proportion of patients provided contact information for both. Getting a high yield of intact families, then, is possible, providing that the initial interest leads to actual participation. In another study of family recruitment (Helmes, Bowen, Bowden, & Bengel, 2000), initial interest clearly was related to participation in study activities; therefore, contacting potential participants to glean interest most likely will assist with overall recruitment yield.

In addition to assessing interest over the telephone, researchers were able to estimate eligibility for certain characteristics (e.g., body mass index) in the survey. The approach may not be the most accurate way to assess eligibility criteria but cer-

tainly provided a prevalence estimate for important variables. Confirming eligibility during an in-person data collection session would be necessary to obtain the accuracy required for an intensive intervention study. Using a computerized database to identify potential patients and to perform much of the initial screening for eligibility can reduce the amount of time physicians need to spend on research study activities to allow their patients to participate (Newcomb et al., 1990). Similarly, having research staff instead of clinical personnel handle informed consent for studies in which such procedures would be appropriate also reduces the amount of time physicians need to spend on study enrollment. This allows patients to participate in research while continuing their usual medical care with their physicians uninterrupted, thus minimizing interference with the physician-patient relationship.

Little has been published about the health promotion or physical needs of family members of patients with cancer. The reported needs of potential family participants in the present study were diverse, but most wanted to learn about cancer and cancer treatments, dietary change, and exercise behavior change. The interest in prevention activities was exciting because of the new options for testing prevention and survivorship interventions. Participants interested in prevention would be eligible for many behavioral studies designed to change cancer risk. Risk reduction strategies often require hundreds of thousands of participants to achieve adequate power to identify differences in endpoints. Strategies developed in the present study would be helpful in recruiting the large samples needed for risk reduction studies.

Complaints about obtaining proxy consents or family contact information to the IRB or to clinical or research staff were not received from patients, their relatives, or their healthcare providers during this study. Modifying procedures to meet the current regulations was a straightforward process. The exercise improved clinical and research staff relationships because the roles of each were clearly delineated. Collaboration between overburdened clinical staff and eager research team members to modify and pilot procedures worked well in the present study. Procedures were designed by clinical investigators and staff, and the clinic procedures already in practice were considered in how best to organize the large amount of material for contact, mailing, and consent. When possible, the research staff shouldered any burden; otherwise, procedures were developed as a team that were easy to follow and did not deviate considerably from regular clinic procedures. Implementing a joint strategy to meet current guidelines and new ones as they come into play will be necessary.

Author Contact: Deborah J. Bowen, PhD, can be reached at dbowen@bu.org, with copy to editor at ONFEditor@ons.org.

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Call for Institutes and Open Sessions: 2008 ONS Institutes of Learning

The Institutes of Learning (IOL) Team invites ONS members to submit ideas for institutes or open sessions to be offered at the 2008 IOL. The conference will be held November 14–16, 2008, in Seattle, WA. The IOL Team will make decisions regarding institutes, content, and speakers at its January 2008 meeting. An institute provides three or six hours of intense training on a cutting-edge topic of interest, and the 90-minute open sessions focus on a variety of clinical and current healthcare issues. Selection of topics, content, and speakers is the sole responsibility of the IOL Team. Decisions of the IOL Team regarding content are based on identified ONS member learning needs.

Requirements: The IOL Submission Form requests the following: name of institute or open session, rationale, brief content outline, and identification of potential speakers.

To submit an idea for an institute or open session online, visit www.ons.org/cecentral in December for further instructions.