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

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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.

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, Gowera, 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, 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

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