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.


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...