

Improving Enrollment in Cancer Clinical Trials

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Purpose/Objectives: To identify successful strategies for clinical trial recruitment.

Design: Survey research.

Setting: New Jersey institutions actively recruiting patients for clinical trials.

Sample: 84 clinical research nurses directly involved with patient recruitment were surveyed, and 50 responded (60% response rate).

Methods: Focus group; 34-item, direct mail questionnaire; follow-up telephone interviews; and descriptive statistics.

Main Research Variables: Strategies for patient recruitment and retention.

Findings: Respondents agreed most strongly about the importance of emphasizing to patients that treatment would not be compromised and keeping physicians informed of available protocols. Respondents felt the most effective strategies for increasing public awareness of clinical trials were to highlight participants in past trials and to stress the value of clinical trials through campaigns sponsored by nonprofit organizations. Compared to other respondents, those from cancer centers were significantly less concerned about educating physicians on the value of clinical trials. Focus group and telephone interview participants reported that patient retention in cancer trials was a lesser issue because enrollees tend to be motivated to continue.

Conclusions: Successful recruitment may depend on how a patient is approached about participation, keeping physicians abreast of available trials, and the level of awareness the public or a patient has about clinical research prior to considering it as a treatment option.

Implications for Nursing: Research nurses often are the first to interact with patients considering clinical trial participation and remain involved throughout the trial experience. Depending on the research setting, they are likely to be more informed about available protocols than physicians. Research nurses are in a position to build rapport with and advocate for patients. Strategies to increase enrollment and retention should actively involve these key personnel.

The development of new cancer treatments depends on the expedient conduct of clinical trials. However, recruitment and retention of patients for clinical trials have been less than optimal (Joseph, 1994). The principal barriers to enrollment are fear, distrust, or misunderstanding of the clinical trial process or the standard of care offered therein; the perception that appropriate protocols are not available; and the perception of inconvenience (Collyar, 2000; Crosson, Slevin, & Keany, 1993; Ellis, 2000; Finn, 2000a, 2000b; Lara et al., 2001). Although enrollment barriers have been researched extensively, less information is available about strategies for successfully recruiting and retaining patients in clinical trials, particularly among traditionally underserved groups (e.g., ethnic minorities, the poor) (Roberson, 1994; Underwood & Alexander, 2000).

Key Points . . .

- ▶ Cancer clinical trial participation, from research nurses' perspective, is influenced by how they are involved in the enrollment process and by physicians' and patients' attitudes toward and familiarity with clinical research.
- ▶ Research nurses are in a unique position to understand, address, and influence the attitudes of physicians and patients toward research.
- ▶ Research nurses offer a broad set of tactics that can be applied to clinical trial recruitment policies to increase enrollment.

Nonphysician support staff members increasingly are recognized as having a pivotal role in successful recruitment (Ehrenberger & Aiken, 2003; Tattersall, 2002; Wright, Crooks, Ellis, Mings, & Whelan, 2002). Clinical research associates, research nurses, research coordinators, data managers, and administrators all are involved in some way with enrolling and following patients throughout the clinical trial process. All have a unique perspective (Barrett, 2002; Grunfeld, Zitzelsberger, Coristine, & Aspelund, 2002; Loh, Butow, Brown, & Boyle, 2002) and generally are seen as being able to relate complete, objective, and unhurried information to patients (Wright et al.). This pilot project identified successful recruitment strategies for the general population and the underserved from the perspective of the research nurse.

Methods

Following approval of the study protocol by the institutional review board of Rutgers University in New Jersey, data were collected using three vehicles: a focus group, survey

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