A Nurse's Primer on Recruiting Participants for Clinical Trials

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Purpose/Objectives: To identify common barriers to the recruitment of participants for oncology clinical trials, identify strategies that would be useful in increasing enrollment of participants in oncology clinical trials, and describe the role of the clinical trial nurse in the recruitment process.

Data Sources: Published articles and abstracts, empirical studies, conference proceedings, references from bibliographies of pertinent articles and books, and computerized databases from 1994–2001.

Data Synthesis: The barriers to participant recruitment in clinical trials may be categorized as being related to either the patient, healthcare provider, or protocol.

Conclusions: Several achievable strategies for improving recruitment to oncology clinical trials exist. Nurses need to understand the complex and diverse factors that influence participant accrual to oncology clinical trials. Strategies to increase enrollment should focus on increased communications and education for patients and healthcare providers. Dedicated clinical trials nurses can play an integral part in the recruitment and accrual of patients to oncology clinical trials.

Implications for Nursing: Clinical trial nurses play many important roles in the conduct of oncology clinical trials. To better plan and manage these investigations, nurses need to develop strategies to mitigate the complex and diverse factors that may influence accrual patterns.

Clinical trials of new cancer therapies are a necessary step in the process of translating scientific discovery and technical advancement into procedures and products that offer the prospect of a better life (Koski, 2000). In a recent survey conducted by Harris Interactive (2001), members of the public reported a strong willingness to participate in clinical trials if they ever were diagnosed with cancer. Yet, in the United States today, only 2%–4% of all adult patients newly diagnosed with cancer participate in National Cancer Institute (NCI) clinical trials annually (Lara et al., 2001). This shortage in the number of patients for clinical trials often results in a prolonged trial duration, early closure because of lack of participants, compromised generalizability of the trial's findings, increased cost of studies, and delays in the development and adoption of new treatments.

Key Points . . .

- Barriers to participant recruitment in clinical trials may be categorized as being related to either the patient, healthcare providor, or protocol.
- Strategies to increase enrollment focus on increased communication and education for patients and healthcare providers.
- A dedicated clinical trial nurse can be of paramount importance to successful recruiting for clinical trials.

Goal for CE Enrollees:

To enhance nurses' knowledge about recruiting patients for clinical trials.

Objectives for CE Enrollees:

On completion of this CE, the participant will be able to

1. Identify common barriers to the recruitment of participants for oncology clinical trials.
2. Identify strategies that would be useful in increasing enrollment of participants in oncology clinical trials.
3. Describe the role of the clinical trial nurse in the recruitment process.

Significance to Oncology Nursing

Oncology research nurses have many roles in the conduct of cancer clinical trials (Aiken, 2000; Joshi & Ehrenberger, 2001; Ocker & Plank, 2000; Sadler, Lantz, Fullerton, & Dault, 1999). One of the most important roles is assisting with the process of recruitment and accrual of participants. To better plan and manage clinical trials, nurses must gain a better

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understanding of the factors that may influence accrual patterns and identify strategies to deal with them. Common barriers to enrollment in clinical trials and possible strategies to mitigate them may be categorized as being related to either the patient, healthcare provider, or protocol (Ho, 1994; Lara et al., 2001).

Patient-Related Category

Barriers to Enrollment

The Harris Interactive (2001) survey reported that misconceptions and lack of awareness about clinical trials among patients with cancer greatly reduce enrollment in clinical trials (see Table 1). The survey results indicated that about 85% of patients with cancer polled either were unaware or unsure that participation in clinical trials was an option. Of these patients, 75% said that they would have been willing to enroll had they known it was possible. The survey also reported that, of the patients who were aware of the clinical trial option, three out of four turned it down citing the following reasons: They thought that the medical treatment they would receive in a clinical trial would be less effective than standard care, they might get placebos, they might be treated like "guinea pigs," or the insurance company would not cover the costs. The survey also reported similar misconceptions and concerns held among the general public.

Certain patient characteristics may influence participation in clinical trials. Women, minorities, socioeconomically disadvantaged groups, and elderly people are underrepresented in clinical trials (Kelly & Cordell, 1996; Underwood, 2000). Language and cultural barriers also contribute to the overrepresentation and underrepresentation of particular groups in clinical trials (Morse, Simon, Besch, & Walker, 1995; Richardson, Post-White, Singletary, & Justice, 1998; Skeel, Taylor, Harrington, Klar, & Ng, 1998; Swanson & Ward, 1995). The setting in which potential participants are screened and their disease characteristics also may influence clinical trial enrollment. Klabunde, Springer, Butler, White, and Atkins (1999) examined factors that influenced enrollment in NCI-sponsored trials at 15 medical centers in the southeastern United States. Their results suggested that neither race, gender, nor stage of the trial for which patients were eligible was a predictor of enrollment. Multivariate modeling indicated that among clinically eligible patients, those evaluated by an academic medical center were 2.5 times more likely to be enrolled in a clinical trial. Patients with later-stage disease or whose primary cancer was not breast, prostate, or colorectal also were more likely to participate in a clinical trial. Newly diagnosed patients were not more likely to be enrolled than were previously diagnosed patients whose cancer had progressed to a new stage.

Table 1. Patient-Related Barriers and Strategies to Clinical Trial Participation

Barriers	Strategies
Lack of awareness about clinical trials	Educational programs to increase community awareness and understanding about clinical trials Use of the media (e.g., radio, TV, print, Web sites) for recruitment
Quality-of-life concerns (e.g., fear loss of autonomy, side effects, and loss of functional capacity)	Pre-enrollment education and decisional support The informed consent process conducted by a clinical trial nurse
Practical considerations (e.g., burden on caregivers, inconvenience and expense of additional visits and testing, lack of adequate insurance coverage, childcare and transportation constraints)	Local grants and charitable funds for day-to-day expenses Referrals to support services within the community Flexible scheduling for visits and testing

Scott, Cooper, and Larson (2000) suggested that lack of financial coverage of patient care in clinical trials is a fundamental barrier to the recruitment and enrollment process. Most health insurance covers the cost of standard cancer care, but almost all health plans refuse to pay for experimental treatments, including high quality, peer-reviewed studies. Only 1.5% of Medicare patients participate in clinical trials (Lawrence, 2000). Medicare covers the routine costs (i.e., all items and services that generally are available to Medicare beneficiaries) of qualifying clinical trials and any reasonable and necessary services used to diagnose and treat complications arising from clinical trial participation (Health Care Financing Administration, 2001). Patients are reluctant to enroll in experimental investigations if additional, noncovered testing and procedures are involved. Lack of resources to cover the expenses associated with trial participation and fear of increasing the financial burden on their families may influence patients' decisions. Misconceptions concerning the costs of participation in a clinical trial also negatively affect the ability to recruit adequate numbers of participants. Two recent studies have revealed that the patient-care costs for participating in clinical research are similar to the costs incurred by patients receiving standard therapy (Fehrenbacher, Fireman, Gruskin, & Ray, 1999; Wagner et al., 1999). Practical considerations, such as concerns about the additional burden on caregivers; the inconvenience and expense associated with additional tests, procedures, and visits; and time, childcare, and travel constraints, also impede enrollment in clinical trials (Fleming, 1994; Joseph, 1994; Lara et al., 2001; Meadows & Fioravanti, 2000; Richardson et al., 1998; Schain, 1994).

Some patients choose not to enroll in clinical trials because they feel that once they are in a trial, their personal needs may no longer be physicians' primary concerns. Patients also are concerned about quality-of-life issues such as fear of potential side effects and loss of functional ability, perceptions about the severity of the disease and the effectiveness of the available treatments, the need for personal autonomy in choosing a treatment, difficulty accepting the uncertainty of randomization, and negative attitudes about the research process (Albrecht, Blanchard, Ruckdeschel, Coovert, & Strongbow, 1999; Cockburn & Krickler, 1998; Joseph, 1994; Lara et al., 2001; Morrow, Hickock, & Burish, 1994; Schain, 1994).

Patient enrollment in experimental investigations of new therapies is affected by the limits of the informed consent process. The timing of an invitation to participate in a clinical trial may be problematic. Most patients are told about the clinical trial option after a new diagnosis or failure of other treatments, a particularly vulnerable time to make such an important decision (Cockburn & Krickler, 1998; Mason, Crocombe,

Phillips, & Stubbs, 2000). Patient understanding of the information presented is another area of concern (Cockburn & Krickler; Schutta & Burnett, 2000; Yoder, O'Rourke, Etnyre, Spears, & Brown, 1997). The extent to which patients accurately understand the complex and difficult information in the consent form may influence their ability to make a truly informed choice. Discrepancies between what patients think they understand and what they actually do understand about the information covered in the consent process may lead to unrealistic expectations concerning outcomes of the treatment.

Strategies to Increase Enrollment

Several reasons exist as to why patients agree to enroll in clinical trials, including trust in their healthcare providers and the providers' recommendations of the study, resolved questions and issues, encouragement by family and friends, positive perceptions of the study as the "best" treatment option available, side effects viewed as manageable, a sense of altruism (i.e., future patients will benefit from the knowledge gained), a willingness to participate so that they may receive care at a particular institution, hope for therapeutic benefit, and the desire to live (Albrecht et al., 1999; Schutta & Burnett, 2000). These reasons can provide a framework for the development of strategies to increase enrollment in clinical trials and meet the needs of potential participants.

The process of obtaining a true informed consent is a critical factor in improving patient accrual to clinical trials. The informed consent process is an opportunity to provide accurate and nonjudgmental information regarding trial procedures and potential risks and benefits, correct any misconceptions and allay any unfounded fears, and provide sufficient time and resources to facilitate the thoughtful consideration necessary for patients to make the best possible personal decisions.

Huizinga, Sleijfer, van de Wiel, and van der Graaf (1998) examined the decision-making process that patients encountered before entering a phase III clinical trial. Their results suggested that the decision to enter a trial was made instantaneously after receiving information about the trial from medical oncologists, oncology nurses, or both. Patients made this decision quickly despite a minimum of one week granted for reflection between receiving information and giving consent. The investigators proposed that predecisional support provided by oncology nurses may influence the soundness of patients' decisions to enter a study. The primary goal of this decisional support would be to maintain or imitate the rational decision-making process as much as possible.

Nursing interventions that would assist patients in making well-considered decisions include helping patients gather additional relevant sources of information, describing patients' roles and rights in the studies, encouraging patients to define their own reasons for participating in clinical trials, and supporting patients in making decisions that correspond with their personal values (Sadler et al., 1999). Several critical elements should be included in the informed consent process. Cockburn and Krickler (1998) suggested that several key pieces of information are necessary to provide a true informed consent. An informed consent document should include the nature and purpose of the trial as well as explanations concerning possible risks and benefits, questionnaires and personal information, access to medical records, invasive procedures, patients' rights not to participate and to withdraw from the study at any time, and ethics committee approval. Albrecht et al. (1999) examined how physicians' behaviors influenced clinical trial accrual. Their results suggested that patients were more likely to enroll in a cancer clinical trial when their physicians verbally presented items normally included in the informed consent document and when the communication was reflective, patient-centered, supportive, and responsive. A discussion of the benefits of the protocol, the potential side effects, and resources to manage patients' concerns was associated with patients' decisions to join a trial as a treatment option.

Interventions aimed at increasing community awareness and understanding of the clinical trial process may enhance enrollment. Public awareness programs should include the positive experiences reported by patients who have participated in clinical trials (Harris Interactive, 2001; Joseph, 1994). In the Harris Interactive survey, patients who previously had participated in a clinical trial reported that they had very positive experiences. They reported that they were treated with dignity and respect (97%), rated the quality of the care they received as "excellent" or "good" (97%), described the overall experience as positive (93%), did not feel as though they were treated like "guinea pigs" (82%), did not believe that they were subjected to more tests and procedures than were necessary (81%), and would recommend participation in a clinical trial to someone else with cancer (76%). The formation of clinical trials support groups is another strategy that may provide necessary education and social support for patients considering trial enrollment. Firsthand information and support from those with similar experiences can have positive effects on participant accrual.

Simple practices such as follow-up phone calls, e-mails, or postcards while patients are considering trial enrollment can have a positive effect on patients' decisions. Li et al. (2000) evaluated the impact of recruitment strategies used in a project that studied surgical treatment outcomes for dysfunctional uterine bleeding. The results of this investigation suggested that the number of patients screened and enrolled increased after beginning weekly phone contacts with the clinical centers. A multistep, invitation to enroll procedure, such as a letter of introduction followed by informed consent education and a follow-up phone call or meeting for additional questions, also may be effective for increasing prospective participants' understanding and comfort concerning clinical trial enrollment (Cockburn & Krickler, 1998; Richardson et al., 1998).

Full information regarding the anticipated costs of participation in a clinical trial always should be made available to potential participants. Whenever necessary, measures should be taken to assist participants with the costs of day-to-day involvement in the trial, such as travel expenses and child care. Patients may receive assistance and support services through small, locally available community grants and charitable foundations.

Historically, healthcare payors and providers have been reluctant to provide clinical trial coverage, citing uncertainty of the cost, lack of known benefit, poor quality of clinical trials, potential liability for complications, and, simply, that clinical trials are not included in the contract language (Scott et al., 2000). Cross-subsidization is one way community research programs have made participation in clinical trials financially viable. A variety of cross-subsidization opportunities may be used, including donations from pharmaceutical companies, private and public organizations, local fund-raising activities, and hospital foundations. Perhaps the most sig-

nificant contribution to ensure continued access to clinical trials is to advocate the inclusion of mandated coverage for patients enrolled in National Institutes of Health-sponsored cancer clinical trials in Patients' Bill of Rights legislation at the federal level.

The use of the media in promoting and conducting clinical trials is another strategy for increasing trial enrollment. Newspaper, television, and radio advertisements have been used to increase the public's awareness about the availability of clinical trials as a treatment option. The evolution of the Internet has dramatically changed the public's ability to access information about clinical trials (Ehrenberger, 2000). Patients can access user-friendly databases like the CancerNet and NCI Web sites for information about trial participation. Increased speed of identification of clinical trials by diagnosis, class of drug, phase of trial, and geographic location makes it easier to match potential participants with appropriate clinical trials. Web-based registration and the ability to compile and analyze clinical trial data from distant locations facilitates clinical trial enrollment.

Healthcare Provider-Related Category

Barriers to Enrollment

"Physician bottleneck" (NCI, 2001) is a major barrier to the enrollment of patients in clinical trials (see Table 2). Physicians report that the ability to enroll patients in clinical trials is limited by their lack of time, limited staff resources, the burden of extra paperwork, and the costs of data management (Cockburn & Krickler, 1998; Joseph, 1994; Lara et al., 2001; Lutz & Henkind, 2000; Mansour, 1994; Morrow et al., 1994; Siminoff, Zhang, Colabianchi, Saunders-Strum, & Shen, 2000; Tripathy et al., 1998).

Physician costs may influence accrual rates significantly. The results of a survey sponsored by the American Society of Clinical Oncology (1999) revealed a high level of oncologist participation in clinical trials despite severe underfunding and lack of resources. Oncologists responding to the survey (n = 3,550) indicated that they were subsidizing the costs of trials substantially. The cost to physicians for data management and other research expenses associated with enrolling patients in a phase III government or industry clinical trial was estimated to be about $2,000 per patient. Inadequate financial resources to hire research nurses and data managers (the survey suggested that the conduct of a trial requires 1,800 nurse hours and 1,500 data-manager hours) also may impede clinical trial enrollments.

Other healthcare provider-related barriers to accrual of patients into clinical trials include lack of awareness and willingness to refer patients to clinical trials, concern about interference with provider-patient relationships, and difficulty with the informed consent process and the ethics of randomization (Cockburn & Krickler, 1998; Joseph, 1994; Klabunde et al., 1999; Lara et al., 2001; Mansour, 1994; Morrow et al., 1998; Richardson et al., 1998; Skeel et al., 1998).

Table 2. Healthcare Provider-Related Barriers and Strategies to Clinical Trial Participation

Barriers	Strategies
"Physician bottleneck" (e.g., lack of time, limited staff resources, burden of study coordination and data management)	Deployment of a dedicated clinical trial nurse to initiate recruitment, determine eligibility, obtain signed informed consent, and register patients
Lack of awareness about available protocols	Ongoing communication and education (e.g., e-mails, newsletters, staff information sessions, checklists for new charts, protocol fact sheets, posters, protocol pocket cards, inclusion of trials in care plans)

Strategies to Increase Enrollment

A dedicated clinical trial nurse (CTN) can be paramount to increasing patient enrollment in clinical trials (Trabert, 1999). CTNs can proactively identify candidates for studies, notify physicians of trial availability and required pre-enrollment testing, conduct protocol-related education and the informed consent process, and initiate patient enrollment, thus freeing physicians to devote time to other responsibilities and ensuring that patient eligibility is evaluated by individuals most familiar with the study protocol.

Ongoing communication and education for healthcare providers regarding the availability, accessibility, and benefits of participation in clinical trials is necessary for CTNs to suggest clinical trials as a treatment option for their patients. A system of sharing information regarding the status of ongoing trials and availability of new ones should be developed in institutions and oncology services. The use of regular e-mails, newsletters, or information sheets may be an effective strategy to keep healthcare providers' knowledge of available protocols current and up-to-date. Checklists on new charts with pertinent eligibility criteria, brightly colored posters listing open protocols, and the use of protocol pocket cards can help to keep healthcare providers aware of available protocols (Moore, 1999). Inclusion of the clinical trials in integrated-care pathways holds significant potential to increase physician participation in research by framing clinical trials as a viable treatment option for all eligible patients (Trabert, 1999). Recognition of healthcare providers who participate in the recruitment of patients to clinical trials also may increase institutional and community awareness concerning clinical trials and result in increased enrollments (Ford, 2000).

Protocol-Related Category

Barriers to Enrollment

Lack of available and appropriate protocols is a major barrier to the enrollment of patients in clinical trials (Klabunde at al., 1999; Skeel et al., 1998; Tripathy et al. 1998) (see Table 3). Lara et al. (2001) reported that in a survey of oncologists regarding patient characteristics and physician decision-making about protocol eligibility, 62% of new patients were considered for clinical trials; however, only 53% of the patients had protocols appropriate for their site and stage of disease available at the time.

Other protocol-related barriers include difficulty in choosing between competing protocols (Joseph, 1994; Skeel et al., 1998), rigid inclusion or exclusion criteria (Joseph; Lara et al., 2001; Morrow et al., 1994), and the complex structure of

Table 3. Protocol-Related Barriers and Strategies to Clinical Trial Participation

Barriers	Strategies
Lack of available and appropriate protocols	Membership in cooperative research groups Affiliations with research consortiums Use Web-based resources such as National Cancer Institute clinical trials Web site to identify open trials.
Multiple, competing protocols	Education and communication between patient and healthcare providers will match patients with the most appropriate clinical trials.
Rigid inclusion or exclusion criteria	Clinical trial nurses (CTNs) screen patients for trial eligibility. CTNs contribute to protocol development process.
Complex structure of some protocols	CTNs coordinate the enrollment process and protocol implementation. CTNs contribute to protocol development.

some protocols (Joseph; Kelly & Cordell, 1996; Mansour, 1994; Richardson et al., 1998; Siminoff et al., 2000).

Strategies to Increase Enrollment

Affiliations of community hospitals with cancer centers, academic institutions, and research consortiums may increase the number and variety of available protocols. Investigators should reevaluate eligibility criteria with a critical eye toward increased participation. Healthcare providers also should be encouraged to consider all patients for clinical trial enrollment (Lara et al., 2001). CTNs can increase recruitment and enrollment to clinical trials by participating in the development of new research protocols. Their unique understanding of how clinical trials are carried out at the local or community level and their experience as oncology nurses can help make new protocols more "user friendly" and ensure that protocol logistics are as feasible as possible (Ehrenberger & Aiken, 2001).

Nursing Implications

Nurses are in an ideal position to promote patient awareness of the role played by clinical trials in the advancement of the health sciences and the subsequent improvements in patient care. Ocker and Plank (2000) identified three roles for nurses in the oncology research setting: educator, patient advocate, and study coordinator. As patient educators, nurses can greatly affect prospective participants' perceptions of the research experience. CTNs are participants' clinical interpreters (Sadler et al., 1999) in that they can explain the often complex and highly technical protocols in terms that patients and their families can understand. Nurses also help mediate the flow of information between physicians and patients (Yoder et al., 1997). They educate patients and their families about how the trial will progress, what participants may expect at each stage, how to manage side effects, and the importance of reporting changes in health status. CTNs also educate physicians and other healthcare providers about trial availability and eligibility criteria.

As patient advocates, CTNs play a pivotal role at the critical gateway to clinical trial enrollment—the informed consent process. Nurses bring a holistic, patient-centered approach to the process. This perspective can greatly enhance the process by ensuring that patients are treated with dignity, respect, and as individuals. Nurses can help patients clarify their reasons for participation and their expectations about the clinical trial experience (Ocker & Plank, 2000).

The "Oncology Nursing Society [ONS] Position on Cancer Research and Cancer Clinical Trials" states that the "coordination of clinical trials is best accomplished by registered nurses who have been educated and certified in oncology nursing" (ONS, 1998, p. 973). Because they are conversant in all facets of the protocol, CTNs are in an ideal position to coordinate the identification of potential participants, ensure that eligibility criteria are met, and direct the details of recruitment and enrollment in an efficient manner.

Conclusion

To effectively recruit participants for oncology clinical trials, nurses need to understand the complex and diverse factors that influence participant accrual. Strategies aimed at mitigating these factors focus on increased communication and education for patients and healthcare providers alike. CTNs' most valuable contributions to the recruitment process, however, involve providing patients with sufficient information and support to make the best possible personal decision about participation.

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For more information . . .

- ➤ Cancer Trials
  www.cancertrials.gov
- ➤ Clinical Trials
  www.clinicaltrials.gov
- ➤ Trial Check
  www.trialcheck.org

These Web sites are provided for information only. The hosts are responsible for their own content and availability. Links can be found using ONS Online at www.ons.org.

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