The Oncology Nurse's Role in the Informed Consent Process

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Cancer clinical trials are a necessary component of the effort to improve cancer prevention, diagnosis, and treatment. Essential to this process is the informed consent of the individuals who participate in these research studies. The purpose of this article is to describe patient, provider, and informed consent process issues with presentations of data reported in the current literature. The role of nursing in the facilitation of informed consent is discussed.

Clinical trials are a fundamental link between discoveries in the laboratory and improved cancer treatment and prevention strategies. Conducted in a variety of settings, clinical trials examine the safety and efficacy of new agents, drug combinations, surgical and radiology procedures, and screening and therapeutic devices. Cancer clinical trials rely on patient participation; however, data indicate that only 1% to 3% of eligible adult cancer patients participate in trials. Reasons for this low participation rate are complex; this article will focus on ethical issues and the role of oncology nurses in the informed consent process.

The initial informed consent process is also an appropriate time to address any misconceptions and allay unfounded fears of potential trial participants. This is important since patients who...
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participate in clinical trials have often exhausted other treatment options, they often have advanced
disease, and they may be vulnerable to unfounded fears as well as to unrealistic hopes for cure of
their disease. The informed consent process is not a one-time interaction that ends when the
informed consent document is signed, but rather it is an ongoing process designed to provide
patients with continuing dialogue and ready access to information.

As part of the oncology team, nurses are in a position to assist cancer patients in making
well-informed decisions about whether to enroll in clinical trials.[1] Such nursing interactions include
helping patients gather additional relevant sources of information, describing patients' roles and
rights in 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 and wishes,
including not participating in a clinical trial.[2]

Elements of Informed Consent
The consent process is intended to give trial subjects an informed opportunity to choose whether or
not to participate. To this end, the informed consent process should contain several key elements:

- Adequate disclosure of information (diagnosis, nature and purpose of treatment, risks involved,
and alternative treatments);
- Freedom of choice (free of any coercion or promises of benefits which may not be fulfilled);
- Comprehension of the information (an understanding of what has been said);
- Capacity for decision-making; and
- Consent.[3-6]

In providing consent, the patient authorizes the physician to enroll him in research.[4,7]

Understanding the Patient's Expectations
Oncology nurses play a vital role in helping patients understand their opportunities for participating
in clinical trials. Some patients choose to be altruistic and enroll in clinical trials in order to benefit
others and advance medical knowledge.[8,9] However, we know that self-interest is a primary
motivation to participate in clinical trials—the hope of receiving better care or a novel treatment
available only in a clinical trial.

Cox et al.[10] conducted a qualitative study to identify the psychosocial impact of participating in
clinical trials as experienced by the patients themselves. The study sought to interpret patients'
ways of coping with their individual situations, and also to identify the various consequences of trial
involvement. Of the 55 patients involved in the study, the offer to participate in a cancer clinical trial
was seen as a turning point.

Thirty patients (54%) described the offer of participation as being "the light at the end of a tunnel"
because they perceived that hope was offered, and 54% felt special, privileged, pleased, lucky, and
honored to have been offered participation. On the other hand, 58% of subjects described how the
trial offer generated uncertainty. The majority of patients interpreted the offer of trial participation
as being the right plan of action because their physicians presented them with the opportunity.

Reasons for patients to accept trial participation include the desire to be in expert hands (54%) and
to help others (52%).[10]

Among patients who do enroll in trials, several studies suggest that shortcomings persist in
comprehension of treatment procedures involved during the course of clinical trials. Joffe and
colleagues[11] found that although patients were satisfied with the informed consent process, many
did not fully understand at least one of the following: 1) awareness of standard treatment, 2)
potential for incremental risk or discomfort, 3) the unproven nature of treatment, and 4) the
uncertainty of benefits to self.

Similarly, Daugherty and colleagues[12] found that 93% of participants in phase I clinical trials
reported understanding most or all of the information provided, but only 31% of those questioned
were able to explain accurately the purpose of phase I studies, which primarily determine the
pharmacologic actions of drugs in humans and the side effects associated with increasing doses.

Provider Perspectives
Collaborative communication between provider and patient is critical to the success of informed
consent. Although critical information such as treatment procedures, risks versus benefits, and
possible out-of-pocket costs is usually standard in the informed consent documents, a patient’s
signature alone does not constitute an informed consent. The manner and context in which the
information is conveyed are almost as important as the information itself; that is, effective
communication needs to occur.[6]

Brown and colleagues[13] evaluated ethical communication strategies to guide oncologists in
discussing clinical trials with patients. Three key areas were considered essential to seeking
informed consent in an ethical manner:
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Physician attitudes toward cancer clinical trials also play a crucial role in the informed consent process. Studies have shown that physicians sometimes perceive clinical trials as conflicting with clinical judgment skills.[8] Many physicians have difficulty acknowledging uncertainty regarding treatment benefits or discussing treatment choices with patients, which oftentimes would include enrolling in a clinical trial.[8] Other physician-related barriers include concerns regarding patient-physician relationship, belief that doctors should make the decisions, and the feeling of tacitly coercing patients to participate.[14]

The Nurse's Role

Nurses play multiple roles in disseminating information related to informed consent and clinical trials.[15] As patient and family educators, nurses provide explanations of highly complex and intricate protocols using patient-friendly language instead of difficult medical jargon.[16] Nurses frequently outline the specific protocol process, expectations at each stage, possible side effects, and the importance of the patient communicating any changes in his or her health status to practitioners.

Outside resources can improve nurses' familiarity with the informed consent process and offer tools to help them better communicate with patients. The National Cancer Institute (NCI) provides extensive resources for providers and patients in understanding the informed consent process (http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide). The American Cancer Society also provides useful resources on clinical trials (www.cancer.org). After a physician initiates discussion of clinical trial enrollment, the oncology nurse involvement with the patient and family offers a seamless transition and an opportunity for nurses to gauge the patient's initial level of understanding as well as provide a contact liaison for the patient and family. When discussing informed consent documents, nurses should encourage patients to clarify their reasons (eg, physical, psychological, social, spiritual) behind decisions to participate. In assessing a patient's knowledge of clinical trials, nurses should direct questions based on the physician's previous explanation of the trial. Most importantly, nurses also should encourage dialogue around the patient's specific expectations from participating in the trial. The role of the nurse is not to "sell" the study, but rather to inform and support patients in their decisions. Table 1 provides questions that nurses can use to determine a patient's level of comprehension about the clinical trial.

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<th>Table 1: Five Important Questions to Determine Patients' Understanding of Clinical Trials</th>
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<tr>
<td>1. Can you tell me what the doctor has told you about this trial?</td>
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<td>2. Did you have any questions about the information the doctor has shared about the trial?</td>
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<tr>
<td>3. What do you understand to be the possible benefits and risks to you in participating in the trial?</td>
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<td>4. Have you decided on what treatment you’d like to pursue? Can you tell me how you came upon this choice?</td>
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<td>5. Is the possibility of benefiting others in the future a factor in your choosing to participate?</td>
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Nurses should also be ready to provide clear and thorough answers to patient’s questions regarding clinical trials. Patients generally want comprehensive information about the study drug, treatment schedule, and possible side effects. Most importantly, the nurse must discuss in detail the treatment schedule required for the clinical trial. It is not uncommon for trial participants to have numerous blood draws as well as other baseline laboratory tests, scans, and biopsies while on study. This potentially burdensome aspect of trial participation should be discussed in advance in order to allow patients and family time to plan for transportation needs and schedules. Table 2 provides a list of common questions from patients regarding their participation in clinical trials.

Table 2: Common Questions From Patients About Clinical Trials

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<th>Question</th>
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<td>1. Can I get this study drug if I am not enrolled in the trial?</td>
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<td>2. How does this drug compare to the treatments I had before?</td>
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<tr>
<td>3. How often do I need to come back to be treated for the trial?</td>
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<tr>
<td>4. Are any other tests required for this trial?</td>
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<tr>
<td>5. What types of side effects will I have from the drug?</td>
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<td>6. Whom should I call if something happens while I’m being treated on the trial?</td>
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Initial discussions with the patient about a clinical trial include an oncologist as well as an oncology nurse and may also include others such as a social worker, patient representative, and/or staff psychologist. The information should be given logically and at a comfortable pace, with plenty of time allowed for the potential participant to consider it and ask questions. At the end of this encounter, the nurse should be available by phone or other modes of communication if participating patients need continuing dialogue regarding the clinical trial. This support system should continue until the completion of the entire informed consent process.

Strategies such as follow-up phone calls or emails while patients are considering clinical trial participation can have a positive effect on their decision-making process.[16] Aaronson et al[2] conducted a study to test the efficacy of telephone-based nursing intervention on improving the effectiveness of the informed consent process in cancer clinical trials. This randomized study compared the effectiveness of telephone-based intervention in patients who were randomized to standard informed consent procedures based on verbal explanation and written information or the standard informed consent process plus the supplementary telephone intervention. The results demonstrated that the intervention group was significantly better informed about the following: 1) the risks and side effects of treatment, 2) the clinical trial context of the treatment, 3) the objectives of the clinical trial, 4) where relevant, the use of randomization in allocating treatment, 5) the availability of alternative treatments, 6) the voluntary nature of the participation, and 7) the right to withdrawal from the clinical trial. The intervention did not have any significant effect on patients' anxiety levels nor on the rates of clinical trial accrual.[2]

Summary
Over the years, the role of oncology nursing in clinical trials has expanded. Nurses are now integral members of most research teams and are ideally positioned to provide patients with important information regarding informed consent. Nurses involved in clinical trials must enhance patient understanding through effective communication about the goals of clinical research and the treatment procedures, and they must assess patients’ understanding of the informed consent information.[17,18] This contribution will result in ethical conduct of research and, in turn, benefit the overall quality of cancer care.
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