Cancer: Caring and Conquering

Linda H. Yoder

Patient Decision Making Concerning Clinical Trials

In the last several columns in this series, a basic overview of clinical trials was presented. In this column, decision-making issues that patients and their family members or significant others may encounter as they confront the clinical trials process will be addressed. A person diagnosed with cancer must make many decisions, ranging from selecting physicians to choosing treatment options. Patients may feel overwhelmed and question their ability to make sound decisions. Although timely treatment is important, patients should be encouraged to take enough time to understand all available options in order to make informed decisions.

Daugherty (2005) emphasized that it is important to recognize treatment decision making and information seeking as distinctive and separate components of the medical encounter. He correctly refers to evidence suggesting that although patients generally express *preferences* for information about their illness and treatment, they might not engage in *information-seeking* behavior. Mansell, Poses, Kazis, and Duefield (2000) examined clinical factors that patients desire in order to participate in their treatment decisions. These researchers concluded that physicians should provide opportunities for patient involvement in decisions about serious illness because patients *want* to be participants in those decisions. As the baby boomers continue to age, health care providers may see a change in information-seeking behavior as it relates to treatment decisions. More research is needed in this area.

Clearly, patients, family members, and significant others must be advocates for the patient. Understanding initial treatment options can be confusing to the patient, but this situation can be compounded when an individual learns the cancer has recurred or a new malignancy is present. It is important to spend sufficient time with patients to ensure they understand various treatment options. In most cases, patients may require an additional appointment to repeat the discussion because they may not have "heard" all the information at the time of diagnosis or during discussion of relapse. For patients with cancer, treatment decisions are not a one-time experience. When one treatment is no longer effective, new options are presented and more decisions must be made. Table 1 provides some tips that patients can use when discussing treatment options with their health care providers.

Deciding to Enroll in Clinical Trials

Often, patients assume their physicians will refer them to a clinical trial if standard therapy has been exhausted or if trial participation is appropriate for the individual's treatment plan. Interestingly, a study at the University of California (Davis) examined 276 patients and determined that physicians failed to refer approximately 38% to clinical trials without reviewing their eligibility. In many cases the physicians assumed there were no appropriate trials or that the patients were ineligible (Lara et al., 2001). This issue can be more

Linda H. Yoder, PhD, MBA, RN, AOCN®, FAAN, is Program Director, Evidence-Based Practice, Outcomes & Research, Adventist HealthCare, Rockville, MD.

Note: This column is made possible through an educational grant from C-Change, a Washington, DC, based organization comprising the nation's key cancer leaders from government, business, and nonprofit sectors. These cancer leaders share the vision of a future where cancer is prevented, detected early, and cured or is managed successfully as a chronic illness. The mission of C-Change is to leverage the combined expertise and resources of its members to eliminate cancer as a (major) public health problem at the earliest possible time. C-Change is both a forum and a catalyst for identifying issues and major challenges facing the cancer community and for initiating collaborative actions to complement the efforts of individual C-Change members. Medical-surgical nurses are invited to learn more about this important organization by visiting www.ndoc.org

Table 1.
Talking to the Doctor about Treatment Decisions

When you talk to your doctor and/or members of your treatment team:

1. Consider taking a family member or friend along for moral support and to assist you in asking questions and annotating answers.
2. Think about what you want to ask in advance — but do not hesitate to ask new questions as they arise in the discussion.
3. Write your questions down in advance to help you remember to ask them all.
4. Write down the answers to your questions so you can review them at your convenience.
5. Consider taking a tape recorder to the meeting to make a taped record of what is discussed. Even if you plan to write down the answers, the tape can often provide helpful information that was initially missed or forgotten.

problematic when patients are receiving care in community hospitals, where physicians may not be aware of clinical trials available in their referral region or at the National Institutes of Health Clinical Center.

Patients may believe that they can only be offered participation in a clinical trial if they have exhausted all conventional treatment options. This is not necessarily true because some phase II trials may be more promising than conventional therapy for certain types of cancer. However, patients should exhaust conventional therapy before opting to join a phase I trial because only animals have been tested prior to phase I trials. Patients receiving care in a research facility, such as an academic medical center with clinical trial centers, typically are approached by physicians who are site investigators on various clinical trial protocols. This is because patients treated in such centers are readily known to these physicians. Additionally, patients treated in such centers may be offered additional opportunities to receive clinical trial care if one trial fails and they meet the criteria for another.

Patients sometimes ask for help in the decision-making process, but it is important that participating in the trial meets the patient's goals rather than the goals of the patient's family, significant others, friends, or physician. The patient's value system must be considered. Some patients believe that every effort must be made to fight their disease and no adversity is too much to endure if there is a chance of conquering the cancer. For other patients, the issues of physical sacrifices, quality of life decrements, financial sacrifices, and negative effects on the family may be considered too much to bear.

Introducing the patient to other patients in the clinical trial or a similar type of trial can be helpful in the decision-making process. With the state of current technology, patients also can search for information on the Internet, but not all health care sites contain the most credible information about treatment options. When patients are deciding about whether to enroll in a clinical trial, they must be informed of the risks and benefits associated with the trial therapy. Additionally, patients should be told that they will most likely be receiving additional monitoring by the health care team because, in most cases, the nature of the trial requires extra visits for blood testing or other types of follow-up testing to see how the therapy is working. Patients should be informed that they may need additional time away from work, and that transportation requirements and, in some cases, overnight housing in a hotel should be considered. In some instances, these expenses may not be covered by an insurance provider or clinical trial funds.

Also, patients must be informed that in most cases, less than 10% of patients enrolled in phase I trials achieve a response from this therapy (Von Hoff & Turner, 1991). Patients should be told how randomization will occur in a trial where randomization is present. The patients should be informed clearly that they will not be allowed to choose whether they will receive the new treatment or the standard treatment. They should be informed clearly about their probability of being in the new treatment arm of the trial. Although placebos rarely are used in oncology trials, they may be used in other health care trials. The patient should be informed of the use of placebo in the trial and the probability of being assigned randomly to the placebo arm of the trial. McCabe (2004) provided some excellent questions that patients should ask when considering enrollment in a clinical trial (see Table 2).

Few studies have examined the expectations and experiences of patients participating in clinical trials (Daugherty et al., 1995; Yoder, O'Rourke, Etnyre, Spears, & Brown, 1997). However, (a) as many as 25% of patients who signed consent forms for clinical trials reported that they were unaware that they were participating in research (Larson & McGuire, 1990), (b) patients' primary reason for participating was their belief that they would derive a benefit from the treatment, increasing their chance of getting well (Cheng et al., 2000; Dehlinger, 1986; Yoder et al., 1997), and (c) participation in clinical trials was viewed as a means of attaining superior medical care (Cassileth, Lusk, Miller & Hurwitz, 1982; Yoder et al., 1997).

Costs

Making objective decisions about participating in a clinical trial may be extremely difficult, especially when all standard therapy has been exhausted and the trial appears to be the patient's only chance for prolonged life. Also, Mulay (2002) noted that patients may be so happy to qualify for a clinical trial that they

Table 2.
Questions to Ask When Considering Enrollment in a Clinical Trial

Questions about the Study
1. What is the purpose of the study?
2. Why do the researchers think the treatment may be effective?
3. Who is the sponsor of the clinical trial?
4. Who has reviewed and approved the study?
5. How is the safety of the participants being evaluated?
6. How are the study results being evaluated?
7. How long will I need to participate in the study?
8. What will my responsibilities be if I participate?
Possible Risks and Benefits
1. What are the possible short-term benefits?
2. What are the possible long-term benefits?
3. What are the short-term risks or side effects?
4. What are the possible long-term risks?
5. What other options are available?
6. How do the possible risks and benefits of the treatment/clinical trial compare with other options?
Participation and Care
1. What kinds of therapies, procedures, and or tests will I have during the clinical trial?
2. Will they hurt, and if so, for how long?
3. How do the tests in the study compare to those I would have received anyway for my cancer or during other standard therapy?
4. Will I be able to take my other regular medications while in the clinical trial? (include prescription as well as over-the-counter medications and alternative therapies within this question)
5. Where will I have my medical care?
6. Who will provide oversight or be in charge of my care?
7. How can being in this study affect my daily life? (work, family life, leisure activities)
8. Can I talk to other people in the study at this study site?
Cost Issues
1. Will I have to pay for any part of the trial, such as tests or the study drug? If so, what will the charges be?
2. What is my health insurance likely to cover?
3. Who can assist me regarding any questions from my insurance company or health plan?
4. Will there be any travel, hotel, or child care costs that I need to consider while I am in the trial?

Source: Adapted from McCabe, 2004

ignore the facts related to the financial and time commitments required. Before committing to participation in a clinical trial, patients must be counseled fully and asked if they understand all the aspects of the commitment they are making. Therefore, this counseling should include a discussion about the frequency of treatments and visits for testing, the cost of the treatment (and whether part of the therapy will be billed to the patient's insurance provider), and what may be paid by the clinical trial sponsor.

When a patient participates in the study of an experimental drug, the drug and the costs of administering the drug are typically paid by the study sponsor (pharmaceutical company). For example, if a patient enrolls in a study of a new intravenous chemotherapy agent, the sponsor will provide the drug and pay for its preparation, including the cost of the IV bag and tubing. The costs related to the nurse administering the drug and the facility costs also usually are paid by the drug sponsor. Cost issues can become more complex when a new drug is combined in a trial with an approved drug. In such a case, the drug sponsor will pay the costs associated with the new drug and its administration, but the approved drug costs are usually billed to the patient's insurance company. Some laboratory costs will be covered by the drug sponsor while others will not, and the same is true for various scans (for example, computerized tomography).

It is the patient's responsibility to obtain referrals and payment authorizations to participate in clinical trials. Many medical centers have managed care offices that can assist the patient in the authorization process by providing insurers with the documentation required. In some cases, clinical trial researchers write letters to insurance companies to facilitate authorizations. Without authorization, the patient is expected to pay for all expenses that would otherwise be billed to the insurance company.

Nursing Implications

Health care consumers increasingly are more sophisticated concerning their information needs. Therefore, a team approach between physicians and nurses can serve to support patients' needs for information as they grapple with difficult, anxiety-provoking decisions. Nurses are in a position to assist patients by answering questions regarding treatment visits, ongoing laboratory testing, and symptom/side effect management. Additionally, nurses can be instrumental in assuring that patients receive referrals for case management or social work to assist them with cost issues. Moreover, nurses can identify instances when the patient clearly needs to have an additional conversation with the physician or health care team to clarify issues or ask additional questions. Nurses are at the forefront of care and they can provide much needed care by listening carefully to patients' concerns, educating appropriately, and referring as needed. Nurses can act as the linchpin between the

patient and other members of the health care team to facilitate optimum care. ■

References

Cassileth, B., Lusk, E., Miller, D., & Hurwitz, S. (1982). Attitudes toward clinical trials among patients and the public. *Journal of the American Medical Association, 248*, 968-970.

Cheng, J., Hitt, J., Koczwara, B., Schulman, K., Burnett, C., Gaskin, D., et al. (2000). Impact of quality of life on patient expectations regarding phase I clinical trials. *Journal of Clinical Oncology, 18*(2), 421-428.

Daugherty, C. (2005). Societal issues in oncology. In V.T. DeVita, S. Hellman, & S.A Rosenberg (Eds.), *Cancer: Principles and practice of oncology* (7th ed.) (pp. 2747-2758). Philadelphia: Lippincott, Williams & Wilkins.

Daugherty, C., Ratain, M., Grochowski, E., Stocking, C., Kodish, E., Mick, R., et al. (1995). Perceptions of cancer patients and their physicians involved in phase I clinical trials. *Journal of Clinical Oncology, 13*(5), 1062-1072.

Dehlinger, M. (1986). *Cancer patient's health beliefs and the decision to participate in cancer research*. Unpublished doctoral dissertation, Catholic University of America, Washington, DC.

Lara, P.N, Higdon, R., Lim, N., Kwan, K., Tanaka, M., Lau, D., et al. (2001). Prospective evaluation of cancer clinical trial accrual patterns: Identifying potential barriers to enrollment. *Journal of Clinical Oncology, 19*, 1728- 1733.

Larson, E., & McGuire, D. (1990). Patient experiences with research in a tertiary care setting. *Nursing Research, 39*, 168-171.

Mansell, D., Poses, R., Kazis, L., & Duefield, C. (2000). Clinical factors that influence patients' desire for participation in decisions about illness. *Archives of Internal Medicine, 160*(19), 2991-2996.

McCabe, M.S. (2004). Principles of clinical research and development. In C.H. Yarbro, M.H. Frogge, & M. Goodman (Eds.), *Cancer nursing: Principles and practice* (6th ed.) (pp. 201-211). Boston: Jones & Bartlett.

Mulay, M. (2002). *Making the decision: A cancer patient's guide to clinical trials*. Boston: Jones & Bartlett.

Von Hoff, D., & Turner, J. (1991). Response rates, duration of response, and dose response effects in phase I studies of antineoplastics. *Investigational New Drugs, 9*, 115-122.

Yoder, L., O'Rourke, T.J., Etnyre, A., Spears, D.T., & Brown, T. (1997). Expectations and experiences of patients with cancer participating in phase I clinical trials. *Oncology Nursing Forum, 24*(5), 891-1896.