Hospice Patients in Clinical Cancer Treatment Trials

Heather Paprstein, RN, BSN, OCN®

A great deal has been written about the ethical dilemma of decision making between hospice and clinical trial participation for patients with cancer (Daugherty & Steensma, 2003; Lynn, 2001). Without available curative treatments, practitioners and patients struggle with the decision of forgoing further clinical trial treatments for hospice care (McGorty & Bornstein, 2003). What if patients did not need to choose between hospice and clinical trial participation and could reap the potential benefits of both?

Definition of Hospice

The Hospice Foundation of America (2005) defined hospice as comfort and supportive care given to patients and their loved ones when illness does not respond to treatments that have curative intent. Hospice care is provided through a team approach, coordinating care among physicians, nurses, home health aides, physical therapists, social workers, other healthcare professionals, volunteers, friends, and family. Hospice provides physical care to patients and emotional, social, and spiritual care to patients and families during patients’ final days. The goal is to offer patients death that includes dignity and comfort (Hospice Foundation of America; National Hospice and Palliative Care Organization, n.d.b).

Hospice Eligibility and Reimbursement

In 1982, Congress passed legislation mandating that Medicare reimburse hospice costs for eligible patients. Other forms of third-party payers, such as Medicaid, private insurance plans, and health maintenance organizations, also may provide hospice benefits and generally follow the Medicare guidelines for reimbursement (National Hospice and Palliative Care Organization, n.d.a). However, some private plans do not offer the benefit. The eligibility requirement is based on a life expectancy of six months or less from an incurable disease as documented by two physicians; patients are to receive comfort care rather than expensive, curative therapies (Ferrera-Reid, 2004; Meghani, 2004).

In 2002, an estimated 885,000 patients in the United States received hospice care, accounting for approximately 37 of every 100 deaths (Ferrera-Reid, 2004). The National Hospice and Palliative Care Organization (n.d.a) estimated that approximately 950,000 patients in the United States were enrolled in hospice in 2003, an increase of almost 7.5% in one year.

More significantly, studies have demonstrated that as many as 12% of eligible patients are in hospice (Weggel, 1999). A small study interviewing 97 physicians found that when the physicians offered hospice to eligible patients, 63% accepted the care (Weggel). The statistics raise several key questions. When do physicians begin hospice discussions? If nearly two of every three patients accept hospice, why are so few eligible patients receiving the care? What factors lead patients to decline hospice?

When reviewing specific age populations or specific diseases, most of the more readily attained data are based on older adults and use Medicare facts and figures. A study looking at older adults receiving Medicare in 1996 found that approximately 43 of 100 cancer deaths occurred while the patients were in hospice (Virmig, McBean, Kind, & Dholakia, 2002). Other researchers have quoted ranges as wide as 20%–51% of eligible patients with cancer enrolling in hospice (Daugherty & Steensma, 2003; Tang, 2003). In 2002, approximately 60% of all cancer deaths in the United Kingdom occurred in hospice, whereas about 42% in the United States occurred in hospice (McGorty & Bornstein, 2003). Differences in reimbursement methods and healthcare models may account for the disparity, but it should be examined further. Hospice involvement in 100% of cancer deaths is impossible, but a goal should be set higher than 42% involvement to promote benefits for more patients with cancer.

Submitted November 2004. Accepted for publication May 21, 2005.

Digital Object Identifier: 10.1188/05.CJON.729-732
Length of Hospice Enrollment

Potentially increasing the enrollment of eligible patients is not the only issue. Limited lengths of stay in hospice are well documented. Median survival for all hospice patients is reported to be about 30 days, with an astounding 19% not surviving past seven days (Christakis & Iwashyna, 2000). For patients with cancer, the median survival shortens to 14–23 days (Daugherty & Steensma, 2003; Virnig et al., 2002). The transition to hospice care, including getting to know and trust who will be caring for patients, takes some time, and patients with very short stays cannot reap all of the advantages of appropriate hospice care (Lynn, 2001). Referrals to hospice should be made as early as appropriate in the course of illness (Kenny, 2003).

Practitioner Barriers to Hospice Enrollment

Many studies have been published about the hospice decision-making process and barriers that practitioners encounter when making referrals to hospice (Christakis & Iwashyna, 2000; McGorty & Bornstein, 2003; Virnig et al., 2002). Some of the main influences when determining whether to enroll patients in hospice are patients’ preferences for end-of-life care, patients’ amount of social support, and practitioners’ recommendations (Virnig et al.). Some advanced practice nurses have raised concerns that practitioners no longer have contact with patients after they are transferred to hospice (Volker, Kahn, & Penticuff, 2004a). Practitioners are concerned with their ability to determine how much time patients have to live. In addition, predictions of death are difficult to make (Christakis & Iwashyna). A study comparing generalists and oncologists found that generalists were more pessimistic but more accurate (Rose et al., 2000). However, all practitioners tend to overestimate life expectancy (McGorty & Bornstein). The landmark Study to Understand Prognoses and Preferences for Outcomes and Risks for Treatment (SUPPORT) found that the choices of dying patients were ignored or unknown (Ferrera-Reid, 2004). The SUPPORT study did not report the influences of nurse and patient communications on the decision to accept hospice; however, nurses with higher levels of education were less likely to promote hospice (Cramer, McCorkle, Cherlin, Johnson-Hurzeler, & Bradley, 2003).

Although practitioners may admit to attitudinal barriers to hospice referrals, other concerning factors also exist. Practitioners are concerned that patients and/or families have not accepted the diagnosis, the amount of social support is lacking, and patients want to continue life-prolonging treatment, which all stop physicians from making hospice referrals (Weggel, 1999). Physicians also worry that hospice referral will diminish patients’ remaining hope (Daugherty & Steensma, 2003).

Benefits of Hospice

When barriers can be overcome, the benefits to enrolling patients in hospice are numerous. Steinhauser et al. (2000) interviewed patients, families, and their practitioners and found that the agreed-upon components of a good death are pain control, making sound decisions, getting ready for death, completion, contributing to others, and affirming the patient as a whole. Patients and their support teams reported that they were afraid of the dying process more than death itself. When enrolled in hospice, patients and families report high levels of satisfaction with the care received in their last days (Weggel, 1999). Of note, families have that patients admitted to hospice longer than 30 days are more likely to report higher satisfaction with hospice care (McCorty & Bornstein, 2003). One study demonstrated that widowed spouses who were involved with their dying partners’ care actually used less healthcare resources and had fewer health concerns when they received the services of hospice (Ferrera-Reid, 2004).

Not only do patients and their families receive benefits, but the government does as well. Hospice is reimbursed on a per-diem benefit, usually around $100–$125 per day (Daugherty & Steensma, 2003; McGorty & Bornstein, 2003). The cost of hospice care for patients with cancer compared to the care for those without hospice is 13%–20% lower. When patients die earlier than expected, which most patients do, hospices cannot make a profit or recover the initial cost of enrolling and providing care (McCorty & Bornstein). One study looked at the feasibility of an inpatient palliative care unit after it admitted more than 300 patients. The mean daily charge for a patient on that unit was 38% lower than the mean daily hospital charge for all other patients (Elsayem et al., 2004). The financial benefit for Medicare is a main reason for not permitting patients to be treated on clinical trials or to receive infinite amounts of other, expensive, life-prolonging treatments, such as chemotherapy, blood products, growth factors, and large doses of palliative therapy. Many hospices will not admit patients until palliative radiation is nearly complete, even though the care is palliative only, because of the low per-diem rate they receive from Medicare. Therefore, the question is raised whether palliative treatments or clinical trials are not also appropriate for patients who are eligible for hospice.

Phases of Clinical Treatment Trials

Clinical treatment trials consist of four phases. However, laboratory research, including animal testing, takes place before an investigational agent enters the phases of a clinical trial. The first three phases are conducted prior to U.S. Food and Drug Administration approval or rejection of an investigational agent. Phase I trials test an investigational agent for the first time in humans, usually in a population of fewer than 100 people. The phase tests the safety of the agent, helps to determine a maximum tolerated dose, and captures information about side effects (Byock & Miles, 2003; National Library of Medicine, 2005). Phase II trials begin to look at efficacy of the agent while continuing to collect safety data in a larger group of people, usually several hundred. Once the investigational agent shows promise and potential efficacy, phase III trials begin. The studies are performed on a few thousand patients to prove effectiveness, usually against the current standard of care, and continue to track safety information. If the agent is approved, sometimes phase IV trials are conducted to review additional information about the benefits or use of the drug (National Library of Medicine).

Clinical Treatment Trials in Hospice-Eligible Patients

Some researchers have reported that patients should have the opportunity to pursue research trials and palliative care (Byock & Miles, 2003; Meyers & Linder, 2003). Because Medicare denies hospice coverage to patients participating in clinical trials and because private insurers nearly always follow Medicare’s lead, patients find enrolling in both difficult. Although Avery (2004) argued that patients enroll in phase I trials to give themselves hope, the true endpoints of phase I trials are not cure or disease response but rather assessment of toxicities and discovery of the maximum tolerated dose (Byock & Miles, 2003). Patients may think phase I trials are effective treatments.
that are not compatible with hospice care (Byock & Miles, 2004). Patients who enroll in phase I trials often are told that although the treatment will not benefit them, it may benefit future generations. Averry noted that helping future generations is not a reason to offer potentially harmful medications to dying patients. However, Steinhauser et al. (2000) found that patients and families want to contribute to others and affirm the person as a whole.

According to the definition of a phase I trial, potential patients must have an otherwise incurable cancer. A study of 349 phase I patients found a median survival of 6.5 months (Byock & Miles, 2003). Most, if not all, of the participants likely would have been eligible for hospice. Attempting to argue that no effective chemotherapies exist for patients with cancer in hospice is self-defeating (Avery, 2004). If no one ever received any benefit from phase I chemotherapy, the drug would never make it to market. Therefore, some phase I treatments do provide benefit, even if only for an extremely short time for palliation of symptoms.

**Hospice and Hematologic Malignancy Conflicts**

Hematologic malignancies can be problematic for patients enrolling into hospice when eligible. Despite all of the differences in survival from one type of cancer to the next, only hematologic malignancies are negatively related to hospice use (Tang, 2003). Patients diagnosed with leukemia have a one-year relative survival rate of 64% (American Cancer Society, 2003). Therefore, some patients are eligible for hospice care when the diagnosis is made and can have one recertification. Recertification occurs when patients live longer than six months after enrolling in hospice. If a patient’s prognosis at this new time point is now less than six months, the patient can be recertified to remain in hospice care for an additional six months (Centers for Medicare and Medicaid Services, n.d.). Practitioners should not be afraid that recertification signals that they were wrong about a prognosis. No penalties are incurred if a patient’s prognosis remains poor (Daugherty & Steensma, 2003).

Patients with hematologic malignancies require enormous amounts of supportive care, including chemotherapy to keep blood counts under control, growth factors and blood transfusions to elevate blood counts, and radiation to shrink the spleen and lymph nodes. None of the treatments can be administered in hospice, thus depriving patients of hospice’s benefits.

---

### Role of Advanced Practice Nursing

What is the role of nursing in this debate? Few studies have examined nursing in this context (Cramer et al., 2003; McGorty & Bornstein, 2003; Volker et al., 2004b). Physicians admit that nurses are the providers who first suggest hospice even if only to physicians; McGorty and Bornstein suggested that this should be examined further. Research needs to determine whether advanced practice nurses face some of the same barriers that physicians do when making referrals. Nursing needs to reexamine the concept of palliative care for select populations, such as those with hematologic malignancies. Every decision for treatment is intensely personal and also dependent on a patient’s condition. Decision making may be more difficult when too many choices are available, yet people may prefer having too many options as opposed to too few. Some have reported that hospice patients should not be excluded from clinical cancer treatment trials (Byock & Miles, 2003). Advanced practice nurses need to be knowledgeable about what choices their patients can make.

**Author Contact:** Heather Paprstein, RN, BSN, OCN®, can be reached at heather_litwiller@ameritech.net, with copy to editor at CJONEditor@ons.org.

### References


Steinhauser, K.E., Clipp, E.C., McNeilley, M., Christakis, N.A., McIntyre, L.M., & Tulskey, J.A. (2000). In search of a good death: Observations of patients, families, and providers. *Annals of Internal Medicine, 132*, 825–832.


Rapid Recap

Hospice Patients in Clinical Cancer Treatment Trials

- The median length of hospice enrollment for patients with cancer ranges from 14–23 days.
- Families that have a patient admitted for more than 30 days report higher satisfaction with hospice.
- One study found a median survival of 6.5 months among patients in phase I trials.
- Patients are forced to choose between clinical treatment trials and hospice care because of Medicare and insurance coverage guidelines.