

Methodologic Issues in Collecting Data From Debilitated Patients With Cancer Near the End of Life

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Purpose/Objectives: To report the experience of a group of researchers who have had a year of experience in a clinical trial with homecare hospice patients.

Sample: 150 hospice patients with cancer and their primary caregivers who were accrued to a National Cancer Institute-funded clinical trial focusing on quality of life.

Methods: The investigative team kept careful records of the numbers of patient/caregiver dyads accrued to the study and the reasons for nonaccrual as well as reasons for attrition. Data were analyzed using descriptive statistics.

Findings: During a nine-month period, the hospice admitted 2,517 patients; 75% had cancer and 95% had caregivers, making them eligible for the study. However, after further screening, only 19% were eligible for contact and only 5% finally were accrued to the study. For the 125 patient/caregiver dyads actually accrued to the study, baseline data were obtained on only 50% and evaluable follow-up data on only 50%.

Conclusions: Accruing patients to clinical trials and retaining them when they are critically ill and near death are extraordinarily difficult tasks. The inability to recruit and retain subjects for clinical trials has implications for integrity of data, data analysis, success of the project, and the cost of conducting such projects in the future.

Research involving people with cancer at the end of life is fairly new, and very few large clinical trials have been attempted with this population. Although the healthcare industry has accepted that randomized clinical trials are needed to address the problems of people at the end of life, researchers are just learning about the complex issues involved in such studies (Barnett, 2001; Ling, Rees, & Hardy, 2000; Mazzocato, Sweeney, & Bruera, 2001a). The number of patients who are able to participate may be very small, requiring longer data collection periods; patients may be too ill and debilitated to provide self-reported data; or they may experience a decline during the course of the study, leaving large amounts of missing data. If studies do not result in adequate data of high quality, the results of these long and expensive clinical trials would be uninterpretable. Not only is this wasteful of resources, but it also poses the potential risk of losing knowledge about hospice care, where precious little is available about evidence-based interventions.

Data collection for a project designed to support the quality of life of patients and caregivers by teaching caregivers a method of coping with symptom management was begun in early 2000. The subjects were randomized to one of three arms of the study: standard care, standard care plus supportive visits, and standard care plus teaching of a method of cop-

Key Points . . .

- ▶ Randomized clinical trials are needed to generate knowledge about the most appropriate ways to deliver care to people with cancer at the end of life.
- ▶ Entering patients into clinical trials near the end of life can be difficult, slow, and costly because of the deterioration in the health of patients and because of the burden of caregiving on the families.
- ▶ Declining physical and functional abilities of patients near the end of life and increasing burden on caregivers can result in high attrition rates from studies, thereby threatening study integrity.

ing with patient symptoms (Grant number RO1 CA77307 McMillan, 1999–2003). Although one goal of hospice care is to positively affect the lives of patients with cancer, the research team was very aware that interventions could not be aimed at patients near the end of life who were incredibly debilitated. Instead, the intervention was directed at the caregivers in the hope that both patients and caregivers would benefit.

Researchers who study symptom management and quality of life in hospice patients with cancer are painfully aware of the problems that are encountered in this population (McMillan & Mahon, 1994). A number of problems exist in these studies that do not occur in healthier groups. The purpose of this article is to report the researchers' experience accruing patients after the first year of a clinical trial with homecare hospice patients and their caregivers.

Literature Review

Adequate management of physical and psychosocial distress is the main purpose of palliative care, and the need for research

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