

Cancer symptom control trials: how may we advance this field?

N. MacDonald CM MD

Canadian Institutes of Health: Research definition of palliative care:

Palliative care aims to improve the life of patients and families through the early identification and impeccable management of suffering associated with advanced illness and emphasis on the positive aspects of life inclusive of physical, psychosocial and spiritual sources. Palliative care is an exercise in prevention—prevention of suffering through prioritizing the diagnosis and skillful care of sources of distress throughout the course of illness and for the family into the bereavement period. It is not simply an end of life concept separate from other aspects of research and control. Palliative care research focuses on fundamental symptom mechanisms as well as the experience of the patient and the family.

—Adapted, with thanks, from the World Health Organization

The preceding palliative care definition, endorsed by the Canadian Institutes of Health Research (CIHR) Institute of Cancer Research, emphasizes early identification of sources of suffering in cancer patients and, by inference, the importance of clinical trials on symptom-control therapies introduced early in a patient's course of illness. This noble objective is fully in keeping with the reports of an influential panel which recommends that patients and families have access to the full range of care measures at disease onset ¹.

Today, few would disagree with the concept that therapy for symptom and psychosocial problems should be integrated with traditional measures of

Richard J. Ablin, PhD, Research Professor of Immunobiology, University of Arizona College of Medicine and the Arizona Cancer Center, Tucson, Arizona, U.S.A., and Phil Gold, PhD MD, Professor of Medicine, Physiology, and Oncology, McGill University, Montreal, Quebec, Canada, Section Editors. curing or controlling cancer (surgery, radiotherapy, chemotherapy). However, model programs blending these elements of care from diagnosis are still not common.

Cancer centres may be making progress in moving from rhetoric to reality, but slowly in the clinical research sphere. For example, anorexia—cachexia is often encountered early in the course of the illness, but research on the problem is modest. In 2005, 15 of 4917 abstracts published by the American Society of Clinical Oncology were concerned with cancer nutrition, including cancer cachexia. Only a few of these were clinical trials, with small patient enrolment. No progress was seen in 2006, with its 10 nutrition presentations. Research presentations on the problems of chronic symptoms—aside from those on pain (a dramatic, acute source of suffering demanding immediate attention)—continue to lag.

Because of the common presence of cancer anorexia—cachexia as a source of patient—family distress, and because of its devastating effects (loss of function, and consequent dependency and poorer prognosis), I will use that symptom as a theme to illustrate problems in conducting clinical studies that need to enlist patients early in the course of their illness.

DIFFICULTIES WITH TRIAL ENROLMENT AND DROPOUT

I recently served as the Canadian Principal Investigator (PI) for an international anorexia trial. Canadian patients represented approximately 25% of the patients enrolled in that study ², but most came from my home institution, one other academic centre, and a community cancer centre; enrolment from our largest cancer centres was poor. When the local investigators were asked about their low enrolment, they replied that they had had difficulty in keeping the trial "front and centre" with their oncology colleagues. Failure to recommend patients for the trial until cachexia was far advanced was also a problem. Another major reason expressed for the delay in trial consideration was competition with conventional cancer chemoradiotherapy trials.