A Literature Review of Randomized Controlled Trials of the Organization of Care at the End of Life

Roger E. Thomas
Faculty of Medicine, University of Calgary

Donna Wilson
Faculty of Nursing, University of Alberta

Sam Sheps
Faculty of Medicine, University of British Columbia

RÉSUMÉ

Nous avons entrepris des recherches en neuf bases de données électroniques pour des essais randomisés au sujet des derniers mois de vie, et nous en avons trouvé 23. Nous avons examiné leur qualité avec les critères de la Collaboration Cochrane. Les essais randomisés ont étudié trois thèmes: (a) l'effet de la provision des soins palliatifs par des équipes spécialisés sur la qualité de vie, l'amélioration des symptômes, la satisfaction avec les soins, la durée des soins, et le lieu de la mort; (b) les effets des interventions de soins palliatifs spécifiques ; planification avancée des soins pour les derniers mois de vie, des dossiers tenus par les patients, la provision d'information aux patients et aux médecins, l'éducation pour améliorer le chagrin des proches, l'éducation sur les soins palliatifs pour les infirmières, et les soins palliatifs pour les patients avec la démence ; et (c) les coûts des soins palliatifs en comparaison aux soins conventionnels. Nous avons identifié des difficultés de recherche sur les soins palliatifs et des solutions, et des thèmes de recherche possibles pour l'avenir.

ABSTRACT

We searched nine electronic databases for randomized controlled trials (RCTs) about care at the end of life and found 23 RCTs. We assessed their quality using the criteria of the Cochrane Collaboration. The RCTs researched three themes: (a) the effect of providing palliative care through dedicated community teams on quality of life, on the management of symptoms, on satisfaction with care, on the duration of the palliative period, and on place of death; (b) the effects of specific palliative care interventions—advanced planning of care for the end of life, patient-held records, providing quality-of-life data to patients and physicians, grief education for relatives, palliative care education for nurses, and palliative care for patients with dementia; and (c) the costs of palliative compared to conventional care. We identify difficulties in conducting research on palliative care and solutions and discuss future possible research themes.

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Roger E. Thomas, MD, PhD, CCFP, MRCGP
Professor, Department of Family Medicine, Faculty of Medicine
University of Calgary,
Calgary, AB T2N 1M7
(rthomas@ucalgary.ca)

Introduction

To promote the maximum comfort of dying patients and to meet their other care needs during the dying process, the quality, the availability, and the patient-centredness of end-of-life (EOL) care are critical. Some practitioners of palliative care argue that randomized controlled trials (RCTs) (Grande & Todd, 2000; Hudson, Aranda, & McMurray, 2001; Mazzocato, Sweeney, & Bruera, 2001) and integrative reviews of the literature provide one important evidence base for the practice of palliative health care (Daniels & Exley, 2001; Evans, Stone, & Elwyn, 2003). For those aspects of EOL care where randomized controlled trials and systematic literature reviews can provide guidance, we inquire whether compassionate care can be improved by an analysis of the methodological quality and results of these investigations.

There have been several systematic literature reviews of palliative care (Hearn & Higginson, 1998; Kaasa & Loge, 2002; Piggott & McGee, 2004; Rinck et al. 1997; Salisbury et al. 1999; Smeenk, van Haastregt, de Witte, & Crebolder, 1998), but only Smeenk et al. (1998) applied formal methodological criteria, and only Piggott and McGee (2004) assessed the extent to which RCTs of palliative care have been reported using the CONSORT statement (Moher, Schulz, & Altman, 2001) for describing the methodological quality of RCTs. No systematic review has used Cochrane Collaboration criteria to assess the literature; this review uses those criteria (Cochrane Collaboration, 2005) to assess the methodological quality of RCTs of palliative care.

Hearn and Higginson (1998) identified five RCTs and eight prospective studies of specialist palliative care teams and concluded that patients cared for by a specialist palliative care team spend more time at home and fewer days in hospital, have better symptom control, and have lower costs, and patients and caregivers are more satisfied. Smeenk et al. (1998) identified eight RCTs assessing palliative home care and found that two out of five studies found an increase in patient satisfaction, three out of seven an improvement in the physical aspects of quality of life, one out of six an improvement in the psychological dimensions of quality of life, and two out of five studies a decrease in readmission rates. Salisbury et al. (1999) identified seven RCTs of different models of specialist palliative care and concluded that there is limited evidence from methodologically weak studies that pain control is better in hospital. Kaasa and Loge (2002) reviewed measures of quality of life in palliative care and concluded that measurement tools had improved but that a common standard for scoring would improve their usefulness. Wilkinson et al. (1999) systematically reviewed patient and caregiver preferences for specialist models of palliative care and concluded that, in the United Kingdom, consumers were satisfied with all types of palliative care and appreciated the psychosocial climate in hospices, but they noted the dearth of high-quality comprehensive research on consumer preferences, opinions, and satisfaction with hospices, home care, and other forms of palliative care in the community.

This systematic literature review was conducted to identify and analyse all published RCTs that focus on the organization of EOL care provided to persons who are terminally ill, near death, or dying.

Literature Search and Method of Analysis

Searches of nine health research literature databases (EMBASE; MEDLINE; CINAHL; AHMED; Psychinfo; ERIC; HealthStar; Sociological Abstracts; and the Cochrane Library, including the Cochrane Controlled Trials Register and Library of Systematic Reviews) were undertaken using the key words ''terminal care *or* end-of-life care *or* death *or* dying *or* hospice care *or* palliative care'' *or* ''research'' *or* ''policy'' *and* ''randomized controlled trial'' *or* ''clinical trial'' *or* ''random''. We excluded studies of medications because a recent Cochrane article on palliative chemotherapy (Best et al., 2005) has reviewed this area; studies of medical or surgical interventions; studies where the outcomes for palliative patients could not be separated from those for other patients; and studies of relatives which did not include the palliative patients.

Two reviewers (RT and DW) independently assessed each RCT for potential sources of bias and continued discussion until differences were resolved. The Cochrane Collaboration criteria in the *Cochrane Handbook for Systematic Reviews (2006)* were used to assess the methodological quality of RCTs. These four sources of bias, summarized from chapter 6 of the *Handbook*, were assessed:

1. *Selection bias*. Bias may arise during the selection and/or allocation of subjects to comparison (i.e., treatment or control) groups. Details of efforts used to prevent selective assigning of subjects, such as blinding and concealment of the randomization sequence from the researchers, should be reported to evidence awareness of this threat, and efforts to reduce or eliminate it.
2. *Performance bias*. Although controlled trials aim to compare treatment and control groups fairly, subjects within groups may be treated differently. As such, the placebo effect or an unintended difference may occur. It is necessary to report details of efforts to prevent or

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address performance bias. [We ascertained whether there was a process analysis that observed if the intervention was fully delivered to all participants in the manner planned in the protocol].

3. *Attrition bias*. When subjects drop out of an RCT, systematic differences may occur or be accentuated between the treatment and control groups and test results may be affected. Details of efforts to proactively and/or reactively manage attrition are thus needed to ensure it does not bias the integrity of the RCT. [We recorded an attrition analysis as performed only if the authors reported an analysis assessing if the intervention and control arms were differentially affected by attrition. We recorded it as not present if the authors only stated the numbers of participants who began and completed the study and did not analyse differential attrition].
4. *Detection bias*. Since determining the outcomes of one or more interventions is often the focus of RCTs, the assessment of outcomes must not be biased. One method of preventing detection bias is to blind the assessors, a method that is particularly important when the outcome measurement is subjective in nature (e.g., stress level measurement). It is thus important to report details about efforts to prevent detection bias.

We assessed three additional potential sources of bias. These were

1. whether a power computation was used to determine the required sample size to avoid Type II errors (a Type II error occurs when, despite the fact that the sample size is too small to detect an effect, an intervention is found to have had no effect).
2. whether the authors of a study stated they had planned and undertaken an intention-to-treat analysis; some studies with very small samples retained all the participants until the end of the trial and thus completed the equivalent of an intention-to-treat analysis without having planned it—these we did not report as having an intention-to-treat analysis.
3. whether the data were analysed using appropriate statistical tests.

Results

Fifty-eight potential RCTs were assessed. When the full text was reviewed, 35 were excluded because they either were not RCTs or were not directly about the care of palliative patients, leaving 23 RCTs of palliative care for assessment (see Figure 1).

The 23 RCTs retained in the systematic review were further assessed for 11 aspects of methodological quality (see Table 1).

Most of the reviewed publications did not meet these methodological criteria and there was, therefore, a high risk of bias in most of the currently available RCTs. A few RCTs met more of the criteria and thus had a lower risk of bias. Of the 23 RCT publications, 10 included a power computation, 5 described their method of randomization, 5 concealed the randomization sequence from the primary researchers, none blinded the participants or care providers, 2 undertook a process analysis of whether the intervention was delivered according to the protocol, 3 provided an analysis of the effects of sample attrition, 3 assessed patients blindly, and 6 used an intention-to-treat analysis.

The 23 RCTs were systematically reviewed for the country where the research was conducted, the models of end-of-life or the interventions that were compared, the data collection measures, the subjects, the numbers at baseline and at the end of the project, and the results (see Table 2).

A content analysis revealed three overall themes:

1. the effect of providing palliative care through dedicated community teams on:
   a. ratings of quality of life and management of symptoms
   b. satisfaction with care
   c. the duration of the palliative period and the place of death
2. the effects of specific palliative care interventions:
   a. advanced planning of EOL care
   b. making data available—patient-held records
   c. making data available—providing quality-of-life data to patients and physicians
   d. grief education for relatives
   e. palliative-care education for nurses
   f. care for a specific group of patients—patients with dementia
3. the costs of palliative compared to those of conventional care

The Effect of Providing Palliative Care through Dedicated Community Teams

On Ratings of Quality of Life and Management of Symptoms

Six studies found some improvement in ratings of the quality of life and perceived management of symptoms of patients through the provision of care by palliative care teams. Hughes et al. (2000) found that, for the patients cared for by the Veterans Affairs palliative care team, terminal patients improved significantly on six of the eight HR-QoL subscales (MOS SF 36) (Ware & Sherbourne,

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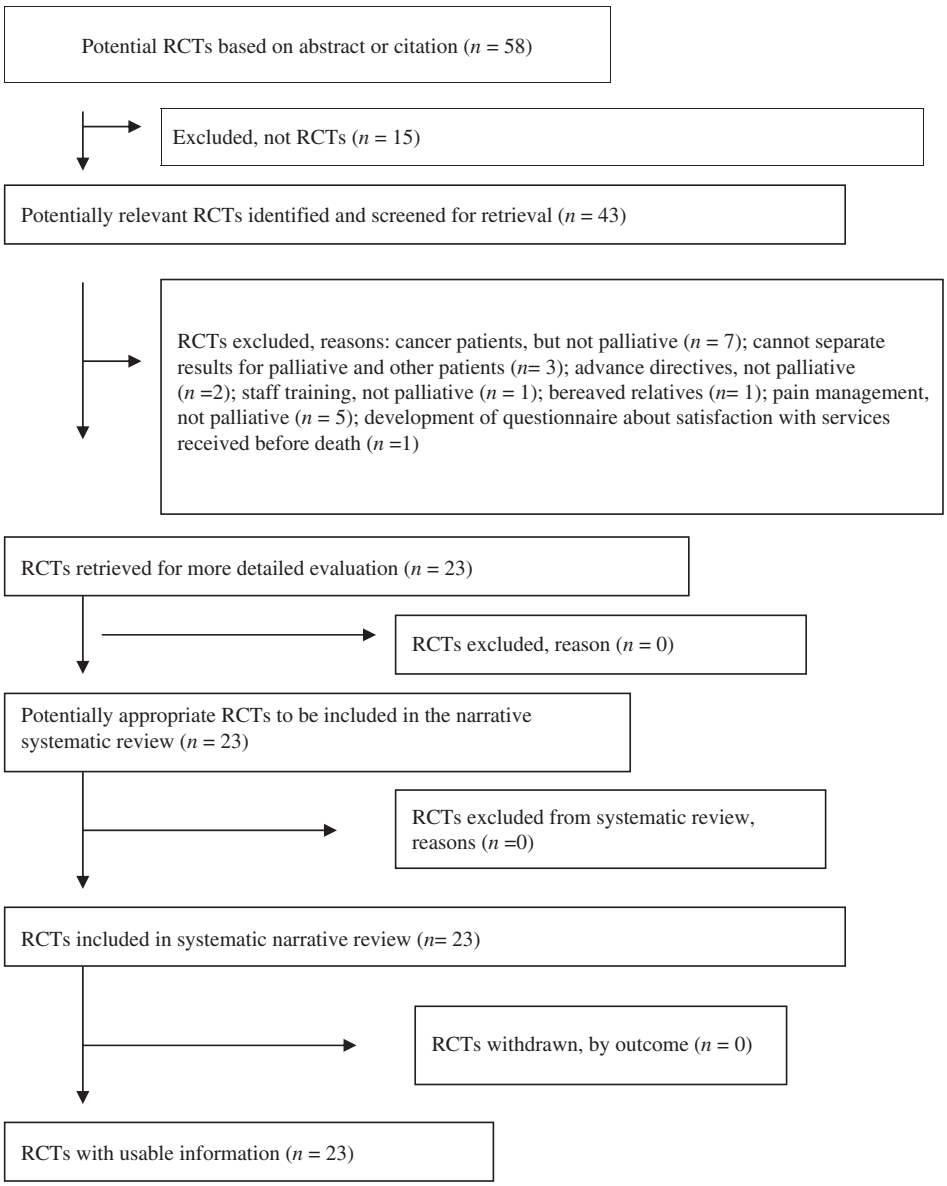

Figure 1: Trial flow for RCTs of interventions in palliative care

1992): *role function—emotional* ($p < 0.001$), *social function* ($p = 0.03$), *bodily pain* ($p = 0.02$), *mental health* ($p = 0.008$), *vitality* ($p = 0.05$), and *general health* ($p = 0.03$), whereas the non-terminal group improved only in bodily pain ($p < 0.006$).

Grande, Todd, Barclay, and Farquhar (2000) found that the provision of 24-hour practical nursing care in the patient's home improved quality of life by alleviating perceived pain, anxiety, and depression: Carers assessed control subjects as having more pain ($p = 0.049$), nurses reported control subjects needed more help with night nursing ($p = 0.0001$) and more caregiver help ($p = 0.005$), and GPs rated the patients in the control group as having higher anxiety and depression and needing more psychological support ($p = 0.037$).

Addington-Hall et al. (1992) randomized patients with advanced cancer in one inner London health district to either care coordination by district nurses or routine care. They found few differences in either patient or family outcomes between the groups, but the patients who received coordinated care were less likely to report vomiting and itchy skin, they were more likely to report effective treatment for vomiting, and caregivers were less likely to feel angry about the patient's death. The authors argued that, because the care coordination project did not have a budget, it could not affect EOL care provision, and they

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queried whether the professional skills of the district nurses conflicted with their coordinating role. Raftery et al. (1996) for the same study found that the coordinated care group had fewer home visits ($p < 0.01$) and fewer hospice and hospital days ($p < 0.01$).

Hanks et al. (2002) found that patients who received support from a palliative care team had significant improvements in the severity of their most bothersome symptom ($p < 0.0001$), in quality of life ($p < 0.0001$), in not being bothered by emotional problems ($p < 0.0001$), and in mood ($p < 0.0001$), as measured by the HR-QoL (Aaronson et al., 1993). The group that received support from the palliative care group only by telephone had improvement only in the severity of their most bothersome symptom ($p < 0.001$) and in HR-QoL ($p < 0.044$).

McCorkle et al. (1989) studied patients with progressive lung cancer in King County, Washington, and compared specialized oncology palliative home nursing care, standard home care, and office care and found no statistically significant differences on the McGill-Melzack Pain Questionnaire (Melzack, 1975) or the Profile of Mood States (McNair, Lorr, & Droppleman, 1992) scales, or in length of hospital stay. The home care group experienced a significant increase in symptom distress scores, but this occurred 6 weeks later than for the office care group ($p = 0.02$).

McCorkle, Hughes, & Levinson (1998) studied a sub-set of 37 patients who received surgery for solid tumours and found that patients who had been randomized to receive usual post-surgical care plus a *home care intervention* (a comprehensive clinical assessment; care by advanced-practice nurses; coordination of care with family; care by a primary care physician, community resources, and a home health agency; and three home visits and five telephone calls over a 30-day period). Those who had more symptom distress on the Symptom Distress Scale of McCorkle and Quint-Benoliel (1983) received more nursing interventions for reassurance and emotional support ($p < 0.05$).

Three RCTs found no improvement in symptoms. Ahronheim, Morrison, Morris, Baskin, and Meier (2000) randomized palliative care patients in Mount Sinai Hospital, New York, to receive either in-hospital palliative care team recommendations or standard care (i.e., no recommendations). There were no significant differences in admissions, procedures, interventions, decisions to forgo treatments, or having a palliative care plan. The authors concluded that the small sample, selection bias, difficulty in making plans with surrogates, and lack of physician continuity might account for these findings.

Kane, Bernstein, Wales, and Rothenberg (1985); Kane, Klein, Bernstein, and Rothenberg (1985, 1986); Kane, Wales, Bernstein, Leibowitz, and Kaplan (1984); and Wales, Kane, Robbins, Bernstein, and Krasnow (1983) found no significant differences between patients receiving hospice and home care and those receiving in-hospital care in survival patterns, symptoms, pain, ADLs, or depression, although hospice patients were more satisfied with care ($p < 0.01$). Jordhøy, Fayers, Loge, Ahlner-Elmqvist, and Kaasa (2001) found no differences in pain or other physical symptoms between a coordinated palliative program care and conventional non-coordinated EOL care.

On Satisfaction with Care

One study by Kane et al. (1984) found higher patient satisfaction among the patients receiving home/hospice care than among those receiving standard hospital-based EOL care. Another study by Hanks et al. (2002) found equal increases in satisfaction for patients who were randomized to a hospital palliative care team or just telephone support from the team.

Two studies found no increase in patient satisfaction. Latimer, Crabb, Roberts, Ewen, and Roberts (1998) found, for patients who used a portable patient care record, no significant differences in satisfaction with health care, additional use of health services, mood states, or pain relief, but patients did have less uncertainty about their situation ($p = 0.09$ 2-tail, $p = 0.045$ 1-tail). Hughes et al. (2000) studied terminally ill patients who received coordinated multidisciplinary care and home-based care and found that there were no significant changes in satisfaction with care, whereas the non-terminal group were significantly more satisfied with five of six aspects of care.

Three studies found increased caregiver satisfaction. Zimmer, Groth-Juncker, and McCusker (1985) studied patients cared for by the palliative care team and found that there were no differences in patient satisfaction, although caretaker satisfaction was higher at both 3 months ($p < 0.0001$) and 8 months ($p < 0.001$). Hughes et al. (1992) studied patients randomized to be cared for by the Veterans Affairs palliative care team and found, at one month, that patients in the treatment group showed a significant improvement in their Barthel scores (Sherwood, Morris, Mor, & Gutkin, 1977) ($p < 0.0001$), cognitive status ($p < 0.0001$), morale ($p < 0.0001$), and satisfaction with care ($p < 0.0007$). Caregivers improved with respect to morale ($p < 0.0001$) and satisfaction with care ($p < 0.0001$). The numbers of patients declined from 96 at one month to 28 at six months, and the authors questioned whether the non-significant findings at six months were reliable.

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Table 1: The methodological quality of RCTs of palliative care

Study	Selection Bias		Performance Bias				Detection Bias				
	Method of Randomization	Randomization Concealed	Blinding of Participants	Blinding of Care Providers	Co-interventions	Process Analysis	Attrition Analysis	Assessment Blinded	Intention-to-Treat	Power Computation	Appropriate Analysis
Addington-Hall et al. (1992)	No	No	No	No	No	No	No	Yes	No	Yes	*
Raftery et al. (1996) [reporting same study as Addington-Hall et al. (1992)]	No	No	No	No	No	No	No	Yes	No	Yes	*
Ahronheim et al. (2000)	No	No	No	No	No	No	No	Yes	No	No	Yes
Aikman et al. (1999)	No	No	No	No	No	No	No	No	No	No	Qualitative summary
Connor (1992)	No	No	No	No	No	No	No	No	No	No	Yes
Cornbleet et al. (2002)	No	No	No	No	No	No	No	No	Yes	Yes	Yes
Detmar et al. (2002)	No	No	No	No	No	Yes	No	No	Yes	Yes	Yes
Ditto et al. (2001); Coppola et al. (2001)	No	No	No	No	No	No	No	No	No	Yes	Yes
Grande et al. (1999)	Yes	Yes	No	No	Yes	No	No	No	Yes	Yes	Yes
Grande et al. (2000)	Yes	Yes	No	No	Yes	No	No	No	Yes	Yes	Yes
Hainsworth (1996)	No	No	No	No	No	No	No ‡	No	No‡	No	Yes
Hanks et al. (2002)	Yes	Yes	No	No	No	No	No	No	Yes	Yes	Yes
Hughes et al. (1992)	No	No	No	No	No	No	No	No	No	No	Yes
Hughes et al. (2000)	Yes	Yes	No	No	No	Yes	Yes	No	Yes§	No	Yes ‖
Jordhøy et al. (2000)	No	No	No	No	No	No	Yes	No	No	Yes	Yes ++
Jordhøy et al. (2001)	No	No	No	No	No	No	Yes	**	No	Yes	Yes ++
Ringdal et al. (2002) (reporting same study as Jordhøy et al. [2000] and Jordhøy et al. [2001])	No	No	No	No	No	No	No	No	No	No †	Yes ++

Kissane Jordhøy et al. (2003); Chan et al. (2004)	Yes, by an RCT Institute	No	No	No	No	No	No	No	No	No	Yes
Latimer Jordhøy et al. (1998)	No	No	No	No	No	No	No	No	No	No	Yes
McCorkle et al. (1989)	No	No	No	No	No	No	No	No	No	No	Yes
McCorkle et al. (1998)	No	No	No	No	No	Yes	No	No	No	No	Yes
Schwartz et al. (2002)	No	Yes	No	No	No	No	No	No	Yes	No	Yes
van Boxel et al. (2003)	No	No	No	No	No	No	No	No	No	No	No
Wales et al. (1983); Kane et al. (1984)	No	No	No	No	No	No	No	No	No	No	Yes
Kane et al. (1986); Kane, Bernstein et al. (1985); Kane, Klein et al. (1985)											
Zimmer et al. (1985)	No	No	No	No	No	No	No	No	No	No	Yes

* 13 of the 79 control practices were transferred to the existing coordination group of 89 practices during the trial. Allocation was by practices, and an adjustment was not made for clustering by computing intra-class correlations or multiple-level modelling. However, the authors state that, since there were so few patients from each practice, allocation by practices was ignored in the analysis.
‡ The potential pool of RNs was 288; only 28 participants were recruited and 28 completed the study.
§ Intention-to-treat analysis was used only for the cost data.
|| During the study, several hospitals closed their step-down units, and several staff moved to other positions or institutions.
++ Appropriate analysis for clustering (allocation was by community health care districts).
** Patients replied by mailed questionnaires.
† For original study only.

Table 2: Summary of the comparisons, outcomes, subjects, and results of the RCTs

Study Country	EOL Care or Model Comparisons	Measures or Focus of Data Collection	Subjects and Data Collection at Baseline (b) and at End of Study (e)	Results
Addington-Hall et al. (1992) England	Randomization to care coordination by district (to community or public health nurses) or to routine care	Presence and severity of physical symptoms; psychiatric morbidity; use of and satisfaction with services; informal caregiver problems (hospital anxiety and depression scale [Zigmond & Snaith, 1983]; family Apgar score [Smilkstein et al., 1982]; and Spitzer quality-of-life index [Spitzer et al., 1980])	Advanced cancer patients in one Inner London Health District, who were not expected to live more than one year, $N = 554$, of whom 281 had a baseline interview and 203 had at least one follow-up interview (b) $n = 318$ coordinated care and $n = 236$ control (e) $n = 104$ coordinated group and $n = 99$ control	Few differences between groups in either patient or family outcomes. Coordination group patients were less likely to report vomiting, more likely to report effective treatment for vomiting, and less likely to report an itchy skin. Caregivers were less likely to feel angry about the patient's death. The authors argue that, because the care coordination project did not have a budget, it could not affect EOL care provision, and they queried whether the professional skills of the district nurses conflicted with their coordinating role.
Raftery et al. (1996) England (reported on the cost data for Addington-Hall et al. [1992])	Same as Addington-Hall et al. (1992)	Costs associated with in-patient hospital days and nurse home visits; direct and indirect costs to patients and their families	(b) Analysis restricted to 167 for whom complete service data was available; $n = 81$ (control), $n = 86$ (treatment) (e) $n = 81$ (control), $n = 86$ (treatment)	The coordinated care group had fewer home visits ($p < 0.01$), fewer hospice and hospital days ($p < 0.01$), and lower costs per patient (£4,773) compared to the control group (£8,034), with an expenditure of £70,000 for the coordinating service and savings of £280,000, for a ratio of savings to costs of 4:1 for the patients who died.
Ahronheim et al. (2000) USA	Randomization to either in-hospital palliative care team recommendations or standard care (no recommendations)	Hospitalizations; length of stay; use of non-palliative procedures; diagnostic tests; invasive tests; Do Not Resuscitate (DNR) orders, use of Cardio-Pulmonary Resuscitation (CPR); anti-biotics; decisions to forgo treatment; a terminal care plan; mortality	Hospital in-patients in Mount Sinai Hospital, New York, in stages 6d–7f on the Functional Assessment Staging Tool (FAST) (Reisberg, 1988) $N = 99$. (b) $n = 51$ (treatment) $n = 48$ (control) (e) same	No significant differences in admissions, procedures, interventions, decisions to forgo treatments, or having a palliative care plan. The authors concluded that the small sample, selection bias, difficulty in making plans with surrogates, and lack of physician continuity might account for these findings.
Aikman et al. (1999) Canada	Randomization to use either the generic or the HIV-specific forms of the University of Toronto Centre for Bioethics Living Will	Decisions about proxies; preferences about healthcare decisions; and decisions about personal care	318 eligible patients, of whom 41 were satisfied with a previously completed *advance directives* form, 40 did not reply, 9 lived outside the study area, 6 declined, 4 were too ill, 5 booked interviews and did not attend; 3 other reasons (b) 210 (106 from the University of Toronto Immunodeficiency clinic plus 104 from the AIDS Committee of Toronto) (e) 124 who completed forms (94 completed HIV-specific will, 5 the generic will, and 5 their own form)	No comparison of answers to the three different forms. Most participants did not want their life prolonged if they were ill; 50% were concerned about adequate pain control; and nearly all wished to remain at home as long as possible.

Cornbleet et al. (2002) UK	Randomization of patients to using the Newcastle patient-held record (Lecouturier et al., 1999) with notification of physician, or to control.	Interview; 5-point Likert scales of satisfaction and being informed	244 patients with advanced cancer attending oncology day centres or receiving hospice home care or day care in Scotland; 13 not randomized; (b) 117 experimental, 114 control; in the experimental group, 6 declined to participate/were not contactable, and 28 died; in the control group, 4 declined, 3 were uncontactable, and 10 died (e) experimental = 80, control = 97	No improvement in provision of information to patients, or family involvement, or patients' satisfaction with information provided by health professionals
Detmar et al. (2002) Netherlands	Randomization of physicians (with at least 10 patients per physician) for patients to receive either the European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire—Core 30 (QLQ-C30), with printed graphic record provided to patient and physician before each consultation, or be assigned to a control group. After a buffer period of 2 months, the physicians were crossed over and at least 10 new patients per physician were recruited.	All medical consultations were taped, transcribed, and content-analysed by three raters, blinded as to group assignment, to determine whether the QLQ-C30 topics were discussed at the consultation; physicians completed the Dartmouth Primary Care Cooperative Information Functional Health Assessment form (COOP) (Nelson et al. 1987) and the WHO Project of National Colleges and Academics (WONCA) charts (Nelson et al. 1987); medical records and audiotapes were assessed and a composite management score for actions taken about the items mentioned on the QLQ-C30 was derived; Patient Satisfaction Questionnaire C; Medical Outcomes Study 36-Item Short-Form Health Survey (SF36)	Patients receiving palliative chemotherapy at the Antoni van Leeuwenhoek Hospital, a specialist cancer treatment hospital in Amsterdam, were eligible; 12 eligible physicians and 382 eligible patients; 273 agreed (50 declined because of poor physical or emotional condition; 43 indicated insufficient interest or time; 16 objected to the audiotaping; 2 of the 12 eligible physicians declined). Before cross-over: (b) experimental $n = 67$ patients; control $n = 79$; (e) experimental $n = 51$, control = 67 After cross-over: (b) experimental (formerly control) $n = 66$, control (formerly experimental) $n = 61$; (e) experimental $n = 47$, control = 49	HRQL issues were discussed significantly more frequently in the intervention than control group (mean communication scores 4.5 vs. 3.7 ($p = 0.01$); no statistically significant differences on SF-36 scores; no significant differences in duration of visits or management decisions
Ditto et al. (2001); Coppola et al. (2001) USA	Randomization of surrogate decision makers to reviewing either scenario-based or value-based directives written by patients and discussing or not discussing the directives with the patients to assess if these interventions increased the accuracy of surrogate decisions, or to control	Accuracy of surrogate predictions about patient preferences and perceived benefits of advance directives.	2,544 out-patients affiliated with six primary care practices in Akron, of whom 408 were randomized (b) treatment 1 (*health care directive*) $n = 163$; treatment 2 (*valued life activities directive*) $n = 163$; control $n = 82$ (e) treatment 1 (health care directive) $n = 160$; treatment 2 (valued life activities directive) $n = 161$; control $n = 80$	No intervention produced statistically significant improvements in the accuracy of surrogate decision makers. However, discussions improved perceived surrogate understanding and comfort for those patient and surrogate pairs where the patient had not completed an advanced directive.

continued

Table 2: Continued

Study Country	EOL Care or Model Comparisons	Measures or Focus of Data Collection	Subjects and Data Collection at Baseline (b) and at End of Study (e)	Results
Grande et al. (1999) England	Randomization of patients to hospital-at-home (24-hour home care from nurses for final 2 weeks) or to standard care to evaluate whether type of care affects place of death	Location of death	262 eligible patients in Cambridge Health District who were consecutive referrals to hospital-at-home over a 15 month period (b) randomized to hospital-at-home $n = 186$; control $n = 43$ (e) of those randomized to the hospital-at-home option, 113 were admitted and 73 were not admitted; and 12 patients were alive when the study was concluded	In an intention-to-treat analysis there were no significant differences in patient characteristics between those allocated to hospital-at-home who died at home and the control group; patients in the hospital-at-home group who were admitted to the service survived 16 days and those who were not admitted survived 8 days ($p = 0.0003$).
Grande et al. (2000) England	Randomization to a hospital-at-home program (24-hour practical nursing care for 2 weeks) or usual EOL care	Remaining at home or hospitalizations during the last 2 weeks of life; control of symptoms, anxiety, and depression; number of after-hours physician visits; adequacy of night care; and perceived support for the home caregiver	Persons referred to the Cambridge palliative care program with a prognosis that they had 2 weeks or less to live; $N = 262$ (b) randomized to hospital-at-home $n = 186$; control n = 43 (e) of those randomized to the hospital-at-home option 113 were admitted and 73 were not admitted; and 12 patients were alive when the study was concluded	No difference in use of hospitals over the last 2 weeks of life; fewer GP evening ($p = 0.022$) and night ($p = 0.0003$) visits. Carers assessed control subjects as having more pain ($p = 0.049$). Nurses reported control subjects needed more help with night nursing ($p = 0.0001$) and more caregiver help ($p = 0.005$). Physicians rated the control subjects as having higher anxiety and depression and needing more psychological support ($p = 0.037$)
Hainsworth (1996) USA	Nurses on adult medical–surgical units in an urban teaching hospital volunteered to be randomized to receive three 2-hour sessions on personal awareness of death, or no intervention	Waltman's Attitudes, Subjective Norms, and Behavioural Intentions of Nurses toward Care of Dying Persons and Their Families Scale (Waltman 1990)	The potential pool of RNs working in a large hospital in Syracuse, NY ($N = 288$) (b) only 28 volunteered (e) $n = 14$ intervention; $n = 14$ control	The death education intervention was not associated with any effect on the attitudes or behavioural intentions of RNs, but there was an effect on subjective norms ($p = 0.01$)
Hanks et al. (2002) England	Randomization to hospital palliative care team care or to telephone support from team	Symptom control was measured by the EORTC QLQ-C30; the severity of most bothersome symptoms by visual analogue scales (VAS); mood by the Memorial Pain Assessment Card (MPAC; Fishman et al., 1987); emotional problems by the WONCA scale (Scholten & van Weel, 1992); length of stay; rates of readmission; patient satisfaction with hospital care were assessed by the caregiver by four items from MacAdman's Assessment of Suffering Questionnaire (MacAdman & Smith, 1987), the FAMCARE scale (Kristjanson, 1993), the Hospital Anxiety and Depression Scale (HADS); and a critical incident interview	At the United Bristol Healthcare Trust hospital palliative care team the pool of available patients was 684, but only 261 were available for randomization (b) treatment $n = 175$, control $n = 86$ (e) Treatment: alive after 1 week $n = 129$, after 2 weeks $n = 95$, after 3 weeks $n = 79$, after 4 weeks $n = 76$; Control: alive after 1 week $n = 62$, after 2 weeks $n = 44$, after 3 weeks $n = 38$, after 4 weeks $n = 33$	There were significant improvements in the severity of the patients' most bothersome symptom for the full PCT group ($p < 0.0001$) and the telephone control group ($p < 0.001$); in HRQoL quality of life ($p < 0.0001$; $p < 0.044$); and in not being bothered by emotional problems ($p < 0.0001$, $p < 0.008$); and in mood only for the full PCT group ($p < 0.0001$). There were no significant differences between the groups at 1 and 4 weeks; and both groups were satisfied with care.

Hughes et al. (1992) USA	Comparison of the costs of home-based palliative care delivered by a home care team based in a Veterans Hospital (HBHC) and usual care	Barthel Self-Care Index; Short Portable Mental Status Questionnaire (SPMSQ); 10 items from the OARS Multidimensional Functional Assessment Questionnaire (OMFAQ; Duke University, 1978); the Philadelphia Geriatric Center Morale Scale for patients and caregivers (Lawton et al. 1982; Lawton, 1975a, 1975b); utilization of health care resources; and a health diary	944 patients admitted to the Edward Hines Jr. VA hospital were screened; 331 met the criteria for the terminally ill group; and 175 participated (b) 87 hospital-based home care team; 88 customary care (e) hospital-based home care team $n = 85$; customary care $n = 86$	HBHC patients received 19 home visits, controls 14 ($p < 0.05$); stayed longer on home care (68 days) compared to controls 46 days ($p < 0.05$); and there were significant differences in patient Barthel Self-Care Index scores, Cognitive Status, Morale, and Satisfaction with Care scales at 1 month, and in caregiver satisfaction and morale; HBHC patients had 10 in-patient VA hospital days compared to controls (16 days, $p = 0.002$); 0.73 clinic visits compared to 2.59 ($p = 0.01$); HBHC total costs were higher (US$4,249) than controls ($3,479) (*ns*) but the HBHC had lower hospital costs ($p = 0.04$) and out-patient costs ($p = 0.01$)
Hughes et al. (2000) USA	Randomization to Veterans Affairs team-managed home-based primary care (TM/HBPC) or to customary Veterans Affairs post-discharge care	Functional status by the Barthel Index; patient and caregiver HR-QoLs by MOS SF-36; the Ware Satisfaction with Care Scales (Ware et al., 1983); Short Portable Mental Status Questionnaire (Duke University, 1978); the Smith Co-morbidity Index (Weinberger et al., 1988); cost information from national data files and local hospital computer systems	Hospitalized in-patients with a terminal illness prognosis or two or more ADL impairments at 16 USA Veterans Affairs medical centres, and living within a 25–35 mile radius of the hospital; 1,966 patients and 1,883 caregivers were randomized (b) $n = 981$ treatment and $n = 985$ control, some terminally ill, some not (e) n = 331 treatment, n = 336 control	Significant improvements for terminally ill treatment subjects in emotional role function, social function, pain, mental health, vitality, and general health. Significantly better caregiver quality of life and reduced caregiver burden. Although hospital admissions decreased, health care costs for the TM/HBPC group at months 1–12 were higher at US$31,401 ($n = 981$) and $28,008 for the control group ($n = 885$, $p < 0.005$); the terminal group ($n = 188$) improved significantly on six of the eight HR-QoL (MOS SF 36) subscales for role function—emotional ($I < 0.001$); social function ($p = 0.03$); bodily pain ($p = 0.02$); mental health ($p = 0.008$); vitality ($p = 0.05$); and general health ($p = 0.03$); whereas the non-terminal group improved only in bodily pain ($p < 0.\ 006$). There were no significant changes in satisfaction with care in the terminal group, whereas the non-terminal group were significantly more satisfied with five of six aspects of care; caregivers for terminal patients ($n = 289$) improved significantly on 6 of 10 aspects of HR-QoL and caregivers for non-terminal patients ($n = 1,317$) improved significantly on 8 of 10 aspects; the satisfaction of caregivers looking after terminal patients with burden of care improved significantly on five of six aspects, and for caregivers of non-terminal patients on all six aspects. There were no significant changes in re-hospitalization rates.

continued

Table 2: Continued

Study Country	EOL Care or Model Comparisons	Measures or Focus of Data Collection	Subjects and Data Collection at Baseline (b) and at End of Study (e)	Results
Jordhøy et al. (2000) Norway	Randomization to team palliative care intervention or to conventional care	Home vs. hospital as place of death; days as an in-patient in the last month of life; and health-related quality of life	Six districts of Trondheim and two rural communities with 707 eligible patients (b) $n = 235$ treatment and $n = 199$ control, clustered by site into group (e) $n = 219$ intervention and $n = 176$ control	Median survival was 99 days in the experimental and 125 in the control group (*ns*); in the experimental group, 25% of deaths were at home and 15% in the control group ($p = 0.02$); fewer of the deaths in the experimental group (9%) occurred in nursing homes compared to the control group (21%; $p < 0$ 0.01); there were no differences in hospital use
Jordhøy et al. (2001) Norway	Same as Jordhøy (2000)	Health-related quality of life by the EORTC QLQ-30, the Impact of Event Scale (IES) (Horowitz et al. [1979]; Kaasa et al. [1993]); five social support items; three items of general well-being; and place of death	Same as Jordhøy et al. (2000)	No statistically significant differences between groups in symptoms or quality of life
Ringdal et al. (2002) Norway (reporting same study as Jordhøy et al. [2000] and Jordhøy et al. [2001])	Same as Jordhøy et al. (2000) and Jordhøy et al. (2001)	Family satisfaction with patient care	434 eligible patients and 312 close family members (b) intervention $n = 230$, control $n = 196$ (e) One month after the patient's death, 183 close family members completed the FAMCARE questionnaire (intervention $n = 113$; control $n = 70$)	The intervention group were significantly more satisfied as measured by total scores ($p < 0.01$) and more satisfied on 11 of 18 individual items of patient care ($p < 0.05$)
Kane et al. (1984); Kane et al. (1986); Kane, Bernstein et al. (1985); Kane, Klein et al. Rothenberg (1985); Wales (1983) USA	Randomization to home and in-patient hospice care or to conventional hospital-based care	The symptom scale was adapted from the California Pain Assessment Profile (Oleson & Bresler, 1979); the depression scale was adapted from the NIMH Center for Epidemiologic Studies depression scale (Radloff, 1977); anxiety measures were adapted from the general well-being measure used in the Rand Health Insurance Study (Ware et al., 1987); satisfaction with care measures were adapted from the Ware scale; satisfaction with the physical environment was adapted from the McCaffree and Harkins scale (McCaffree & Harkins, 1976); involvement-in-care questions from the National Cancer Institute's Hospice Study (Baker, 1981); and functional status by the Katz ADL scale (Katz et al., 1963)	Terminally ill cancer patients at a Veterans Administration hospital assessed by their physician as having between 2 weeks and 6 months to live; 263 eligible patients (17 declined, 10 withdrew) (b) treatment $n = 137$, control $n = 110$ (e) all patients followed until the time of their death	No significant differences in survival patterns, symptoms, pain, ADLs, depression, or costs of care; hospice patients were more satisfied with care ($p < 0.01$)

Kissane et al. (2003); Chan et al. (2004); Kissane et al. (2004) Australia	Randomization of patients with their relatives to Family Focused Grief Therapy (FFGT) or to control	Family Assessment Device (FAD) (Epstein et al., 1983); cognitive items on the Beck Depression Inventory (BDI) (Scogin et al. 1988); Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983); and the modified Social Adjustment Scale (SAS) (Cooper et al. 1982)	Patients at six palliative care units in Melbourne with at risk family functioning, designated as a score of 9 or less on the Family Relationships Index (FRI) and a score of less than 4 for cohesiveness, (classified by the poorest score of any family member on the FRI); 483 families were eligible; 176 families refused consent, 26 were inaccessible, 24 avoided calls; 257 families (701 individuals) were screened and 183 families (71%) were at some risk of morbid outcome; 81 families (a total of 363 individuals) gave consent	The only results published to date are for a subset of 28 randomly selected families who were analysed for the fidelity of the treatment they received: 86% of therapists adhered to the core model; 94% of therapists had a strong therapeutic alliance; family strengths were affirmed in 90%; and there was a focus on the themes the patients and therapists had agreed to discuss in 76% of sessions.
Latimer et al. (1998) Canada	Randomized either to use a portable health record or to standard care (no portable health record)	A pain severity scale developed by the Hamilton Civic Hospitals Pain Study Group; the Mishel Uncertainty of Illness Scale (MUIS) (Mishel, 1984); the Profile of Mood States (POMS); a four-item general satisfaction with life scale; and utilization of health care services was measured by Browne's inventory (Browne et al. 1990)	298 eligible patients enrolled in a palliative care program in Southern Ontario, of whom 61 were deemed to be eligible by diagnosis or emotional status (b) travelling record group $n = 22$ control group $n = 24$ (c) at 1–2 month follow-up travelling record group $n = 12$; control group $n = 9$	Patients using the health record had reduced uncertainty ($p = 0.09$ 2-tail, $p = 0.045$ 1-tail); no significant differences in additional use of health services, mood states, pain relief, or satisfaction with health care
McCorkle et al. (1989) USA	Randomization to either specialized oncology/ palliative home nursing care or to standard home care or to office care	The Symptom Distress Scale; the McGill-Melzack Pain Questionnaire; the Inventory of Current Concerns; the Profile of Mood States (POMS); Depression by the CES-D; the Enforced Social Dependency Scale; the General Health Rating Scale (Ware, 1976); and use of health services	Patients with progressive lung cancer in King County, Washington (b) $n = 166$; it was not stated how many were randomized to treatment 1, 2, or control groups (e) oncology home care $n = 24$; standard home care $n = 27$; usual care $n = 26$	No statistically significant differences on the Pain or POMS scales or length of hospital stay; the office care group had significantly increased symptom distress scores 6 weeks earlier than the home care groups ($p = 0.02$)
McCorkle et al. (1998) USA	Randomized to either: (1) Home care intervention (comprehensive clinical assessment; advanced-practice nurses; coordination of care with family, primary care physician, community resources and home health agency; three home visits and five telephone calls over 30 day period) or to (2) usual post-surgical care	The Symptom Distress Scale (SDS) (McCorkle & Quint-Benoliel, 1983); the Enforced Social Dependency Scale (ESDS) (Benoliel et al. 1980); the Center for Epidemiologic Studies-Depression Scale (CES-D); nursing interventions were classified using Grobe's Nursing Intervention and Taxonomy (Grobe, 1995)	The 375 eligible patients were those who received surgery for solid tumours; the report concerns the subset $n = 37$ in McCorkle (1989) who died after receiving the complete home nursing intervention (b) treatment $n = 37$ (e) all patients followed until death	Patients with more symptom distress received more nursing interventions for reassurance and emotional support ($p < 0.05$)

continued

Table 2: Continued

Study Country	EOL Care or Model Comparisons	Measures or Focus of Data Collection	Subjects and Data Collection at Baseline (b) and at End of Study (e)	Results
Schwartz et al. (2002) USA	Randomization of patients either to receive two pamphlets and discuss an advance care plan with a health care agent and a nurse facilitator or to receive the Massachusetts Health Care Proxy form	*Patient Knowledge* questionnaire of advance care directives; treatment preferences were assessed using a modified version of the Emmanuel and Emmanuel Medical Directive (Emmanuel & Emmanuel, 1989); the Beliefs and Values Questionnaire (Pearlman et al. 1999); pain, anxiety, and alertness were measured by visual analogue scales (Sprangers et al. 1999). Health agents received the same knowledge questionnaire as the patients; an adaptation of the Medical Directive questionnaire given to the patients; and the *Agent Comfort* questionnaire designed by the researchers (unpublished)	337 eligible patients in the practices of two geriatricians and an independent living facility in Massachusetts; of these, 66 agreed to participate and 61 completed baseline interviews (b) *Respecting Choices* interview $n = 31$; non-directive interview $n = 30$ (e) *Respecting Choices* interview $n = 31$; non-directive interview $n = 30$	[The authors only report effect sizes and do not report probabilities or odds ratios] 76% of patients and health care agents in the intervention group were in complete agreement about EOL care preferences and 55% in the control group (effect size = -0.43); intervention group patients had a greater increase in knowledge (ES = 0.22); were less willing to undergo life-sustaining interventions for serious medical problems (ES = -0.25), were more willing to undergo such treatments for an incurable progressive disease (ES = 0.24), and were less willing to tolerate poor health states (ES = -0.78) compared to the control group
van Boxel et al. (2003) UK	Nurses were asked to choose six worksheets on physical symptoms and six on psychological issues, then were randomized to receive palliative care workshops by a palliative care consultant either by videoconference or face-to-face; then groups were crossed over	Analysis of the tutor's teaching style and presentation in the two modes of presentation; analysis of the physical characteristics of the two modes of presentation and ability to convey verbal and non-verbal teaching instructions; amount and type of classroom interaction by participants; learners' opinion about the learning effectiveness of the two modes of presentation; and their preference for mode of teaching	Community nurses in Newcastle, UK (b) videoconference $n = 10$; face-to-face $n = 10$; (e) attendance for sessions on (a) pain workshops: videoconference group, $n = 9$ nurses, face-to-face group, $n = 5$; (b) constipation/nausea and vomiting/breathlessness workshops: videoconference $n = 8$, face-to-face $n = 6$; (c) helping the anxious/withdrawn/angry person: videoconference $n = 9$, face-to-face $n = 5$; (d) loss workshops: videoconference $n = 4$, face-to-face $n = 3$	Nurses were satisfied with the instruction presentation in both formats and preferred face-to-face workshops. There were no significant differences in learning outcome scores for the workshops between groups.
Zimmer et al. (1985) USA	Randomization either to home health care team (internist, nurse practitioner, medical social worker), available 24/365, or to usual care	*Health Service Utilization Diary* designed for this study; Sickness Impact Profile (SIP) (Bergner et al. 1981); Philadelphia Geriatric Center (PGC) Morale Scale (Lawton 1975, 1975b); Patient and Caretaker Satisfaction Questionnaires (McCusker, 1984); date and place of death	243 patients were referred to the team in Rochester, NY, during the 27-month intake period; 210 were eligible, of whom 167 entered the study and 158 completed the initial interview (b) team $n = 85$, control $n = 82$ (e) alive at 3 months: team $n = 59$, control $n = 53$; alive and under follow-up at 6 months team $n = 51$, control $n = 47$	In-home day costs were higher for the team at US$10.74/day for the first 6 months; there was no statistical difference in mortality; there were no differences in patient satisfaction, but caretaker satisfaction was higher at 3 months ($p < 0.0001$) and 8 months ($p < 0.001$) compared to the usual care group

Ringdal, Jordhøy, and Kaasa (2002) examined data from the Jordhøy studies (Jordhøy et al., 2001; Jordhøy, Fayers, Ahlner-Elmqvist, & Kaasa, 2002) and found that the caregivers in the intervention group were significantly ($p < 0.05$) more satisfied on 11 of 18 items of patient care and on total scores ($p < 0.01$) than were those in the control group.

On the Duration of the Palliative Period and on Place of Death

Grande, Todd, Barclay, and Farquhar (1999) enquired whether providing a *hospital-at-home* palliative care service would increase the likelihood of dying at home and found that it did not. Jordhøy et al. (2000) sought to determine whether providing care through a palliative care team would lengthen survival and found that patients cared for by a palliative care team had a median survival of 99 days compared to 125 for the control group (*ns*); 25 per cent of deaths were at home compared to 15 per cent for the control group ($p = 0.02$); and fewer of the deaths (9%) occurred in nursing homes compared to the control group (21%, $p < 0.01$), but there were no differences in hospital use. Whether the shorter (and non-significant) median survival of those looked after by a palliative care team reflects less suffering for the patients was not ascertained.

The Effects of Specific Palliative Care Interventions

Advanced Planning of EOL Care

Schwartz et al. (2002) found that a facilitated discussion on advanced EOL care planning with terminally ill patients and their health care agents defined and documented EOL care preferences: 76 per cent of patients and health care agents in the intervention group and 55 per cent in the control group were in complete agreement about EOL care preferences. Patients in the intervention arm were less likely to undergo life-sustaining treatment for a new serious health problem.

Two RCTs assessed responses to different forms of *advanced care directives*. Aikman, Thiel, Martin, and Singer (1999) randomized AIDS patients in Toronto to use either the generic or the HIV-specific forms of the University of Toronto Centre for Bioethics Living Will but did not compare the answers on the three different forms. Most participants did not want their life prolonged if they were ill; 50 per cent were concerned about adequate pain control; and nearly all wished to remain at home as long as possible.

Coppola, Ditto, Danks, and Smucker (2001) and Ditto et al. (2001) randomized 401 patients, 65 and older, and their surrogate decision makers (62% spouses, 29% children) to four experimental conditions (the patient completed a *health care directive* and either did or did not discuss it with the surrogate; or the patient completed a *valued life activities directive* and either did or did not discuss it with the surrogate) or to a control group with no directives and no discussion. Then, surrogates predicted the patients' preferences for four life-sustaining treatments in nine scenarios. None of the interventions produced any statistically significant improvements in the accuracy in predicting of the surrogate decision makers.

Making Data Available: Patient-Held Records

Patient care records completed by a physician or nurse and reviewed with the patient have been used with the intention of increasing patient input. Cornbleet, Campbell, Murray, Stevenson, and Bond (2002) randomized 244 patients with advanced cancer attending oncology day centres or receiving hospice home care or day care in Scotland to use of a patient-held record. However, there was no improvement in provision of information to patients, or in family involvement, or in patients' satisfaction with the information provided by health professionals.

Latimer et al. (1998) studied 21 patients in a palliative care program in southern Ontario and found that those who used a portable record over a two-year period had more certainty about exchange of information with health professionals on subjects such as their current status, past and present treatment and medications, and treatment decisions and goals of care ($p = 0.09$ 2-tail, $p = 0.045$ 1-tail) but there were no differences in pain control, in satisfaction with care, or in mood compared to standard care.

Making Data Available: Providing Quality-of-Life Data to Patients and Physicians

Detmar, Muller, Schornagel, Wever, and Aaronson (2002) randomized patients receiving palliative chemotherapy at the Antoni van Leeuwenhoek Hospital in Amsterdam to receive the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire—Core 30 (QLQ-C30) (Aaronson et al., 1993) and provided printed graphic records to the patients and their physician before each consultation. The results showed that Health Related Quality of Life (HRQL) issues were discussed significantly more frequently in the intervention than in the control group (mean communication scores 4.5 vs. 3.7, $p = 0.01$), but there were no statistically significant differences in SF-36 (36-item short-form health survey) (Ware & Sherbourne, 1992) scores, duration of visits, or management decisions.

Grief Education for Relatives

Kissane et al. (2003, 2004) and Chan, O'Neill, McKenzie, Love, & Kissane (2004) defined patients and their relatives at six palliative care units in

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Melbourne as having *at risk* levels of family functioning if they scored a total of 9 or less on the Family Relationships Index (FRI) (Moos & Moos, 1981) or 4 or less on the cohesiveness items. They were randomized to either Family Focused Grief Therapy (FFGT) (Kissane & Bloch, 1992) or to a control group. For a subset of 28 randomly selected families who were analysed for the fidelity of the treatment they received from the therapists, 86 per cent of therapists adhered to the core model and 94 per cent of therapists formed a strong therapeutic alliance. Family strengths were affirmed in 90 per cent of the families, and there was a focus on the themes agreed between the family members and the therapist in 76 per cent of sessions.

Palliative-Care Education for Nurses

Hainsworth (1996) assessed the impact of education about death on the intentions of hospital nurses to provide EOL care. There was no effect on the attitudes of the nurses towards EOL care or on their intentions to provide care at the end of life, but their perceptions of how others might perceive their provision of EOL care were improved.

Van Boxel, Anderson, and Regnard (2003) randomized 20 community nurses in Newcastle, UK, to receive palliative care workshops by a palliative care consultant either by video conference or face-to-face. Those nurses who attended were satisfied with the presentation in both formats but preferred the face-to-face workshops. There were no significant differences in learning for the two modes of presentation.

Palliative Care for a Specific Group of Patients: Patients with Dementia

Ahronheim et al. (2000) randomized patients with advanced dementia to either an in-hospital palliative care consultation or standard hospital care and found that there was little difference in the care provided to hospitalized persons with advanced dementia, whether they received a palliative care consultation or not, and concluded that it is difficult for a palliative care team to influence hospital care.

The Costs of Palliative Compared to Conventional Care

Three studies showed that an increase in costs results from using palliative care. Hughes et al. (2000) found that health care costs for patients cared for by the Veterans Affairs home-based EOL care palliative care team, despite a reduction in hospital admissions, were 6.8 per cent higher after 6 months and 12.2 per cent higher after 12 months (US$31,401) compared to the costs for those receiving conventional hospital care or care from other care providers ($28,008; $p < 0.005$).

Hughes et al. (1992) studied home care services based in a Veterans Affairs (VA) hospital and found that home-based care patients had fewer in-patient VA hospital days (10) compared to controls (16, $p = 0.002$), lower hospital costs ($p = 0.04$), fewer clinic visits (0.73) compared to controls (2.59, $p = 0.01$), and lower outpatient costs ($p = 0.01$) but received more home visits (19) compared to controls (14, $p < 0.05$) and stayed longer on home care (68 days) compared to controls (46 days, $p < 0.05$), and the cost of their care was (US$4,249) compared to that of the controls ($3,479). Zimmer et al. (1985) found day-care costs for those cared for by the palliative care team were US$10.74 higher than for usual care.

Two studies found no differences in costs. Kane et al. (1984) found that hospice/home care was as expensive as conventional care because the hospice/home care group did not have a reduction in in-patient hospital admissions, care days, or procedures performed. Grande et al. (2000) found that, when terminally ill persons received 24-hour home-based practical nursing care, there were fewer after-hours visits to general practitioners, but there was no reduction in hospitalizations.

Two studies found lower costs for palliative care. Raftery et al. (1996) found that the group that received coordinated palliative care by nurses had lower costs per patient (£4,773) compared to the control group (£8,034) ($p = 0.006$). The total expenditure for the palliative care coordinating service was £70,000, and for the 86 patients, applying the ratio of the costs above (£4,773 for each patient in the palliative care service and £8,034 for each patient in the control group), the savings were £280,000 (a ratio of savings to costs of 4:1 for the patients who died). Jordhøy et al. (2001) found there was an increase in home deaths among the treatment group receiving community-based palliative care, with a reduction in hospital admissions and health care costs.

Discussion

Methodological Problems

Only 23 RCTs of EOL care for terminally ill or dying persons were identified, mostly published in the late 1990s or early 2000s and mostly single-site studies with small sample sizes. This scarcity of RCTs may be due to several factors, in all likelihood including the following: undervaluing of EOL care in comparison to cure-oriented health care, the difficulties of recruitment and retention when conducting investigations that involve terminally ill or dying persons (who often suffer from fatigue and mental anguish and tend to have only a few weeks of life left), the labour-intensive nature of RCTs with this group of patients, and the relative recency

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of modern palliative care and hospice palliative care programs.

This review also identified considerable methodological problems with the various RCTs. The RCTs included few methodological details about avoidance of bias, which may indicate a lack of awareness on the part of researchers about the prevention of bias or insufficient space allocated by journals for full reporting of methods. Piggott and McGee (2004) have also noted that the quality of reporting in RCTs in palliative care is poor, and, even in the most recent trials, a description of the randomization process, allocation concealment, an intention-to-treat analysis, and a power computation were reported by less than 30 per cent of published reports. Rinck et al. (1997), in an earlier review of 11 comprehensive palliative care RCTs, identified a wide range of methodological problems and commented that these problems illustrated the difficulties in conducting EOL research, particularly about treatment or care outcomes. Jordhøy et al. (2002) noted that randomization of treatment by community may be the most feasible option in palliative care trials, but that such cluster randomization makes it very difficult to achieve concealment, which may introduce systematic bias.

Achieving the sample size required for a power computation may be difficult and need particular attention. McWhinney, Bass, and Donner (1994) illustrated the problems of conducting an RCT of community palliative care that did not achieve the desired sample size of 220 patients. The power computation assumed a reduction of 33 per cent in the main outcomes of pain and nausea and attrition of 20 per cent, with $\alpha = 0.05$, $\beta = 0.20$, but of the 307 patients referred to the trial, 141 were ineligible, 20 declined to participate, 146 were randomized, 36 died within 1 month, 14 failed to complete the questionnaires, and only 74 caregivers completed the questionnaires.

Another problem is choosing measurement instruments with appropriate sensitivity. Stephens, Hopwood, Girling, and Machin (1997) found only 78 per cent agreement between ratings of patient symptoms by physicians and patients, with physicians consistently underrating the more severe symptoms. Kaasa and Loge's (2002) review of quality-of-life assessment in palliative care indicated similar methodological and reporting problems.

Whether community or home-based care is more cost effective or not remains unclear. It is possible that RCTs to date have not adequately measured the total costs of health care and so underestimate the cost savings associated with home care and home deaths. Robinson and Pham (1996) noted that hospice care is a different form of EOL care from hospital care and that comparisons between hospices and hospitals often do not fully cost out services or cost savings and concluded that there are savings from use of hospice care mostly in the last month of life.

It is difficult to synthesize an accurate overview of the state of science of EOL because the RCTs were conducted in different countries and health systems, with varying terminal illnesses and circumstances of dying, and across approximately 20 years of time. Nevertheless, a key finding of this review is that community or home-based EOL care compares favourably with more traditional or conventional hospital-based and episodic medical care in improving symptoms and in the opinions of patients and caregivers.

Difficulties of Undertaking Research in Palliative Care and Future Research Possibilities

The National Institutes of Health (2005) State-of-the-Science Conference on Improving End-of-Life Care identified five key questions and provisional answers (we state their questions verbatim and précis and copy parts of their answers):

1. What defines the transition to end-of-life? They stated that it is uncommon to be able to clearly identify the end of life for an individual, it is difficult to predict accurately an individual's time of death, and there are several transitions that may involve co-morbidities and frailty.
2. What outcome variables are important indicators of the quality of the end-of life experience for the dying person and for the surviving lived ones? Measuring the association between end-of-life care and the quality of life could be strengthened by clear definitions and consistent measurements of quality of life.
3. What patient, family, and health care system factors are associated with improved or worsened outcomes? Research is based on small samples and narrowly defined populations, with assessment and management of symptoms most thoroughly studied in patients with cancer.
4. What processes and interventions are associated with improved or worsened outcomes? A detailed list of areas of research and a critique of problems in research designs is presented.
5. What are the future research directions for improving end-of life care?

They concluded that the following are needed:

- operational definitions of end-of-life and palliative care
- the development of an infrastructure of investigators and well-defined cohorts of patients

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- the development of a consensus on the minimum set of measures for end-of-life domains
- the categorization of measures by sources of information, level of information, and cognitive requirements
- testing of measurement tools across disease, ethnic, age, gender, and cultural groups
- improvement of information from proxies
- development of instruments that minimize the burden of response for patients and families
- attention to ethical issues, such as the concept of a good death
- enlisting patients at the beginning of a serious illness to obtain their comments on their health care throughout the period of illness
- clarification of the manner in which individual, family, and health care system factors affect outcomes
- identification of patient preferences
- multi-centre studies with appropriate power computations
- identification of the needs of surviving loved ones

Morrison (2005) in a review of palliative care outcomes research similarly emphasized the need for appropriate comparison groups, adjustment for potential confounding variables, and consistent composition of palliative care teams in terms of education and experience in palliative care. Morrison also emphasized the need for clear descriptions of the interventions in order to make the studies replicable in other environments as well as for assessment of the cost-effectiveness of palliative care.

Much research in palliative care has focused on cancer. The U.S. National Cancer Policy Board has made several recommendations to improve research in this area. Specifically, it recommended that the U.S. National Cancer Institute should designate specific cancer centres as centres of excellence in symptom control and palliative care control for children and adults and that the U.S. Health Care Financing Administration should reimburse projects that integrate palliative care and life-prolonging therapies throughout the course of the illness. Finally, it was recommended that organizations that distribute patient-oriented material should provide comprehensive information about palliative care (National Institutes of Health, 2005).

There is a need for research about patients with palliative care needs who do not have cancer. Goldstein and Morrison (2005) note that there is need for research on elderly patients with multiple chronic medical conditions and co-morbidities, such as advanced heart failure, diabetes, chronic obstructive lung disease (COPD), cognitive impairment, and osteoarthritis, and that patients over 75 are underrepresented in palliative care research. For example, the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (Murphy et al., 2000; SUPPORT Principal Investigators, 1995) led to the conclusion that 20 per cent of patients with several chronic illnesses had severe dyspnea in the six months preceding death. Another special population not often discussed is prisoners, particularly those with a terminal HIV infection (Dubler, 1998).

There is also a need to implement the sensitivities required to work with palliative care patients. Addington-Hall (2002) noted that their condition may change rapidly, they may have no prior knowledge of being terminally ill to draw upon when making decisions, their priorities may change (they may wish to spend all their time with their families), and a questionnaire that they could answer one day may be daunting the next. Patients need to be identified early so that they have an opportunity to comment on the care they received during the entire continuum of care before they became palliative. The effects of gate keeping by family members or health professionals to protect patients from the burdens of participating in research also need to be assessed. Several researchers have emphasized that cognitive impairment is common in patients with serious illnesses, and it is necessary to assess the capabilities of seriously ill patients to make decisions, with attention to the dimensions of appreciation, reasoning, and expression of consistent choices (Casarett, 2003).

There is also a need to focus on key symptom areas to make further progress. Tassinari et al. (2005) identify patient quality of life as the main outcome for palliative care research. Pain has also been identified as a key aspect of quality of life and a symptom to be measured in palliative care research. The European Association of Palliative Care (Caraceni et al., 2002) assessed pain-measuring tools and recommended the McGill Pain Questionnaire (Melzack, 1975) and Brief Pain Inventory (Derogatis & Melisaratos, 1983) as instruments that have been validated in several language versions. Kaasa and De Conno (2001) note that patients can respond to the EORTC QLQ-C30 (Aaronson et al., 1993) until the last one to two weeks of life, but there is a need to validate qualitative measures of quality of life for imminently dying patients. The U.S. National Cancer Institute has established the Office of Cancer Complementary and Alternative Medicine to support scientific studies of alternative therapies (Smith, 2004). The French Fédération Nationale des Centres de Lutte Contre le

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Cancer set up a multidisciplinary working group to assess the literature on standards for palliative nutrition and found little level-A evidence about nutrition (A = a high-standard meta-analysis or several high-quality RCTs that give consistent results) (Bachmann et al. 2003).

A theme that occurs frequently is the need to organize multi-centre multidisciplinary studies and influence policy makers to obtain adequate funding. Hughes and Addington-Hall (2005) conducted a pilot study of how to present palliative care research findings to policy makers and found that a good way to cope with the time pressures on policy makers was to present findings in layers, beginning with a short executive summary, and that the policy makers wanted clear, logical, fair presentations of results, with numbers of patients clearly identified, not just percentages.

The way forward is for researchers to include patients before the palliative stage, to use validated and reliable scales, to work sympathetically with patients and caregivers in order to motivate them to continue with studies as their health status changes (in the same way that the researchers in the Hutchinson RCT of smoking-prevention in schools worked with school principals to explain the benefits of research to society and the importance of continued participation in an RCT over 12 years [Mann, Peterson, Jr., Marek, & Kealey, 2000; Peterson, Kealey, Mann, Marek, & Sarason, 2000]), to include an appropriate representation of different cultural groups, to work in multi-institution groups to achieve the required sample sizes, and to include trialists and statisticians in their research groups if these are not already participating.

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