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End-of-life care pathways for improving outcomes in caring for the dying (Protocol)

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[Intervention Protocol]

End-of-life care pathways for improving outcomes in caring for the dying

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

We aim to assess the effects of end-of-life care pathways, compared with usual care or with care guided by another end-of-life care pathway across all healthcare settings (hospitals, residential aged care facilities, community). In particular, we aim to assess the effects on symptom severity and quality of life of people who are dying and/or those related to the care such as families, caregivers and health professionals.

BACKGROUND

Description of the condition

Populations of developed countries are ageing (United Nations 2002). As populations age, the pattern of diseases they die from also changes (WHO 2004). With advanced ageing, there is an increased risk of death from chronic diseases such as cancer and heart failure (WHO 2001). For example, cancer was estimated to account for about 7 million deaths (12% of all deaths) worldwide in 2000 (WHO 2001). As a result, palliative care has been identified as one of the worldwide public health priorities (WHO 2004). Whilst palliative care is concerned with “the quality of life of patients and families who face life-threatening illness, by providing pain and symptom relief, spiritual and psychosocial support from diagnosis to the end of life and bereavement.” (WHO 2009), end-of-life care focuses on the last days and hours of life (Lunney 2003). The need to provide high quality end-of-life care is essential. The needs of dying people may include, but are not limited to, knowing when death is coming, understanding what can be expected, being able to maintain a sense of control with their wishes given preference, having access to information and excellent care and having access to spiritual and emotional support as required (Steinhauser 2000; Steinhauser 2001). Quality end-of-life care may vary from person to person and may be difficult to define and accurately measure. However, such care should at least consider the following domains: quality of life, physical symptoms, emotional and cognitive symptoms, advanced care planning, functional status, spirituality, grief and bereavement; satisfaction and quality of care, and the caregiver well being (Mularski 2007). Obstacles to quality end-of-life care have also been identified in the literature and may include failure to recognise treatment futility, lack of communication among decision makers, no agreement on a course for end-of-life care, and failure to implement a timely end-of-life care plan (Travis 2002). In recent years, there has been a variety of initiatives developed worldwide to target such issues by developing systemic approaches towards end-of-life care. Some examples of these initiatives are: the National End of Life Care Programme (Department of Health 2008), Gold Standards Framework in Care Homes (Badger 2007) and the Liverpool Care Pathway (LCP) (Ellershaw 1997; Ellershaw 2003).

Description of the intervention

Integrated care pathways are documents which outline the essential steps of multidisciplinary care in addressing a specific clinical problem. They can be used to introduce clinical guidelines and systematic audits of clinical practice (Hockley 2005). The LCP is an example of an integrated care pathway specifically for the dying phase of palliation.

Historically, general hospital care for dying patients tended to be poor and it was thought that much could be learned from the way

patients were cared for in the hospice movement (Mills 1994). The LCP was an example of strategies developed by the Royal Liverpool University Trust and the Marie Curie Centre in Liverpool (Ellershaw 1997; Ellershaw 2003) based on the care received by those in the hospice setting. Other objectives of the pathway were to promote cost-effective health care by appropriate prescribing, and avoiding crisis interventions and inappropriate hospital admissions. The document is patient-centred and focuses on the holistic needs of people who are dying. It incorporates the physical, psychological, social spiritual and religious aspects of care (Ellershaw 2007). The LCP defines 19 goals considered essential in the management of dying patients and for the care of their relatives/carers after death (Ellershaw 1997; Ellershaw 2003). These goals were established with the issues identified from surveys, focus groups, expert opinion and best practice consensus.

More recently, several other groups have developed care pathways for the dying based on the concept of Ellershaw and colleagues (Bookbinder 2005; Fowell 2002; Pooler 2003). Whilst the professional consensus is that end-of-life care pathways promote best possible patient outcomes, there is no systematic review substantiating this claim.

How the intervention might work

In many clinical areas, integrated care pathways are utilised as structured multidisciplinary care plans which detail essential steps in caring for patients with specific clinical problems (Campbell 1998). Care pathways for the dying have been developed as a model to improve the end-of-life care of all patients. They ensure that the most appropriate management occurs at the most appropriate time and that it is provided by the most appropriate health professional.

Why it is important to do this review

Systematic reviews report that clinical pathways enhance efficiency of care without adverse effects on outcomes amongst patients who undergo gastrointestinal surgery (Lemmens 2008) and show a significant length of stay reduction in patients who undergo invasive procedures (Rotter 2008). In contrast, the findings from a Cochrane systematic review reported that there was no significant benefit in functional outcome, and patient satisfaction and that quality of life might actually be made worse for patients following stroke care pathways (Kawn 2004). Therefore, clinical pathways seem to be beneficial for managing certain clinical problems, but not all.

Clinical pathways for end-of-life care management are used widely around the world and have been set as the main part of the End-of-Life Care Strategy by the Department of Health in the UK (Department of Health 2008; Veerbeek 2006) as well as being the Gold Standard Framework (GSF) by the National Health Service (NHS 2005). There is a significant need for clinicians to be in-

formed about the utilisation of end-of-life care pathways with level I evidence.

OBJECTIVES

We aim to assess the effects of end-of-life care pathways, compared with usual care or with care guided by another end-of-life care pathway across all healthcare settings (hospitals, residential aged care facilities, community). In particular, we aim to assess the effects on symptom severity and quality of life of people who are dying and/or those related to the care such as families, caregivers and health professionals.

METHODS

Criteria for considering studies for this review

Types of studies

The review will include clinical trials in which the effect of the end-of-life care pathway can be compared with a control group which receives usual care. We will include randomised controlled trials (RCTs), cluster RCTs and quasi-RCTs. If limited RCTs and quasi-RCTs are available, we may consider including controlled before-and-after studies. We will assess the impact this has on the strength of our recommendations. However, we will not include any non-controlled studies. The analysis for randomised and non-randomised studies will be undertaken separately because non-randomised comparisons may overestimate treatment effects (Chalmers 1983; Sacks 1982), and the size and direction of the bias can be unpredictable (Deeks 2003).

Types of participants

Participants in the included studies will be patients and families who receive care guided by an end-of-life care pathway. Participants may have different diseases such as cancer or organ failure. However, participants who receive interventions must be receiving care guided by an end-of-life care pathway for their last days and hours of life. There will be no restriction on the age of the participant, diagnosis or setting (hospital, home, or nursing home).

Types of interventions

The comparisons will be:

- intervention (receiving care which is guided by an end-of-life care pathway) versus usual care.
- intervention A (pathway A) versus intervention B (pathway B).

An end-of-life care pathway may be part of a larger intervention, these studies will only be included if the effect of the pathway can be isolated.

Types of outcome measures

Primary outcomes

- Physical symptom severity (as measured by any instrument used by the author such as Edmonton Symptom Assessment Scale (Bruera 1991), Memorial Symptom Assessment Scale (Portenoy 1994)).
- Psychological symptom severity (as measured by any instrument used by the author. For example, Hospital Anxiety and Depression Scale (Zigmond 1983)).
- Quality of life (as measured by any instrument used by the author such as the McGill Quality of Life Questionnaire (Cohen 1995)).

Secondary outcomes

- Advanced care planning (as measured by whether it has happened or not).
- Communication between the healthcare team and families (as measured by whether a recorded family meeting has happened or not).
- Caregivers well being.
- Grief and bereavement.
- Patient/staff/caregivers' satisfaction.
- Staff confidence.
- Cost of intervention.
- Cost of care.
- Medication/treatment use.

We will include any tools used by the authors of the included studies. The validity and reliability of the tools used will be discussed in the appraisal of the studies.

Search methods for identification of studies

Electronic searches

The Pain, Palliative and Supportive Care Review group will search their Specialised Register.

We will search:

- the Cochrane Central Register of Controlled Trials (CENTRAL) on the *The Cochrane Library*,
- MEDLINE (1950 to present),
- EMBASE (1980 to present),
- PsycINFO (1980 to present),
- CINAHL (1982 to present),
- Web of Science.

The search strategy will be developed to comprise searches both for keywords and medical subject headings under existing database organizational schemes. The strategy for MEDLINE (Ovid SP) is presented in [Appendix 1](#).

There will be no restriction by language. Foreign language abstracts will be initially translated for the application of the inclusion and

exclusion criteria, and where necessary the methods, results and discussion sections will be translated for inclusion in the review.

Searching other resources

We will search the reference lists of any relevant reviews or other studies, scanning paper issues of journals relevant to interventions of end-of-life care pathway and scanning abstracts from relevant conference proceedings. We will also contact experts in the field and authors of included studies for advice as to other relevant studies.

We will search Google for the World Wide Web, Caresearch (www.caresearch.com.au), the ProQuest Dissertations and Theses database for grey literature and conference abstracts. We will search databases in TrialsCentral (www.trialscentral.org), the WHO Clinical Trial Search Portal (www.who.int/trialssearch) and Current Controlled Trials (www.controlled-trials.com) to identify ongoing or recently completed studies. If applicable, we will present relevant ongoing studies in the 'Characteristics of ongoing studies' table.

Data collection and analysis

Selection of studies

Two review authors will pre-screen all search results (titles and abstracts) for possible inclusion, and those selected by either or both authors will be subject to full-text assessment. Two review authors will independently assess the selected articles for inclusion. Any discrepancies will be resolved by consensus, overseen by a third review author acting as arbiter, with approval by one review author and the arbiter being sufficient. We will list those studies excluded after full-text assessment in the 'Characteristics of Excluded Studies' table, giving reasons for exclusion.

Data extraction and management

We will develop a data extraction form based on the Cochrane Pain, Palliative and Supportive Care Review Group's template, and pilot and amend it as necessary. We will extract the following main sets of data from each included study:

- lead author; date;
- study participant inclusion criteria;
- participants (participant diagnoses/condition(s) and demographics: race/ethnicity, gender, religion/culture, socioeconomic status, age);
- study design and timetable; randomisation; allocation concealment;
- interventions (end-of-life care pathway type);
- intervention setting (hospital, home, residential aged care facilities);
- numbers of participants in each trial arm, withdrawals and dropouts;
- outcome measures; time(s) at which outcomes were assessed.

At least two review authors will independently extract data to the data extraction form. Any discrepancies will be referred to a third review author and any errors or inconsistencies resolved by discussion. The first review author will enter the data into RevMan, with another review author checking the accuracy of the data entry.

Assessment of risk of bias in included studies

We will assess and report on the risk of bias of included studies in accordance with the guidelines in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008), which recommends the explicit reporting of the following individual domains:

- sequence generation;
- allocation concealment;
- blinding of participants, personnel and outcome assessors (assessed for each main outcome or class of outcome);
- incomplete outcome data (assessed for each main outcome or class of outcome);
- selective outcome reporting;
- other sources of bias.

We will also examine and report the following:

- validation and reliability of outcome measures;
- whether the study obtained ethics committee approval and ensured informed consent for participation;
- use of standardised protocols for information delivery. We will check for consistency of the delivery of interventions where possible.

Two review authors will independently assess the risk of bias in included studies, with any disagreements resolved by discussion and consensus, and with a third review author acting as arbiter. We will present our assessment in the risk of bias tables for each included study. We will contact study authors for additional information about the study methods as necessary. We will incorporate the results of the risk of bias assessment into the review through narrative description and commentary about each of the items mentioned.

This will lead to an overall assessment of the risk of bias of the included studies.

Measures of treatment effect

For individual studies, effect measures for categorical outcomes will include relative risk (RR) with its 95% confidence intervals (CI). For statistically significant effects, number needed to treat to benefit (NNT) will be calculated. If possible for continuous outcomes, the effect measure will be mean difference (MD) or, if the scale of measurement differs across trials, standardized mean difference (SMD), each with its 95% CI. For meta-analyses (see below), for categorical outcomes, typical estimates of RR with their 95% CI will be calculated; and for continuous outcomes, the weighted mean difference (WMD) or a summary estimate for SMD, each with its 95% CI, will be calculated.

Data will be analysed using the Cochrane Collaboration's Review Manager 5 software.

Unit of analysis issues

We do not anticipate any unit of analysis issues arising. Cross over trials are not expected for this type of intervention due to the end-of-life care pathway nature. The pathway focuses on terminal care. If cluster randomised trials are identified, we will attempt to conduct analysis at the same level as the allocation, using a summary measurement from each cluster.

Dealing with missing data

If some outcome data remain missing despite our attempts to obtain complete outcome data from authors, we will perform an available-case analysis, based on the numbers of patients for whom outcome data are known. If standard deviations are missing, we will impute them from other studies, or where possible, compute them from standard errors using the formula $SD = SE \times \sqrt{N}$, where these are available (Higgins 2008). We will also report on levels of drop outs in the intervention and comparison groups as an indicator of 'acceptability' of the intervention, and the likelihood of bias.

Assessment of heterogeneity

Heterogeneity will be tested using the Chi² statistic and any heterogeneity will be further quantified with the I² statistic (which describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error). A value greater than 50% will be considered to represent substantial heterogeneity (Higgins 2008).

Assessment of reporting biases

Reporting bias will be assessed using guidelines in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008). As the review authors do not expect to find a large number of studies it is unlikely that publication or inclusion bias will be as-

sessed. However, if enough studies are available to do a meaningful assessment of publication bias, a funnel plot will be constructed.

Data synthesis

If the studies are sufficiently similar in terms of population, inclusion criteria, interventions and/or outcomes (including the time(s) at which these are assessed), we will consider pooling the data statistically using meta-analysis. We will report the results of the individual trials separately where the outcome data is unsuitable for meta analysis. We will use fixed-effect models when population measures are similar and random-effects models where population parameters vary from study to study.

Subgroup analysis and investigation of heterogeneity

Subgroup analyses will be conducted if sufficient data can support the analyses. Subgroups may include disease type and settings where care was received.

Sensitivity analysis

If there are other sources of heterogeneity, we will explore further by using sensitivity analysis to determine the effects of the end-of-life care pathways, overall methodological quality and use of ITT analysis. Studies with high attrition rates (over 50%) will be removed from the meta-analysis to determine whether the results would be significantly different without them.

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* Indicates the major publication for the study

APPENDICES

Appendix I. MEDLINE search strategy

Database: OvidMEDLINE(R)

- 1 Palliative Care/ or palliat\$.mp.
- 2 end-of-life.mp.
- 3 terminally ill.mp. or Terminally Ill/
- 4 dying.mp.
- 5 hospice.mp. or Hospices/
- 6 end-stage.mp.
- 7 or/1-6
- 8 Critical Pathways/
- 9 ((clinical or critical or care) adj path\$).mp.
- 10 (care adj (map\$ or plan\$)).mp.
- 11 exp Guidelines/
- 12 Health Planning Guidelines/
- 13 Guideline Adherence/
- 14 (compliance adj (protocol? or policy or guideline?)).mp.
- 15 (guideline? adj2 (introduc\$ or issu\$ or impact or effect? or disseminat\$ or distribut\$ or implement\$)).mp.
- 16 nursing protocol?.mp.
- 17 professional standard\$.mp.
- 18 (practice guidelin\$ or practice protocol\$ or clinical practice guidelin\$).mp.
- 19 or/9-18
- 20 Guideline.pt.
- 21 randomized controlled trial.pt.
- 22 controlled clinical trial.pt.
- 23 Intervention Studies/
- 24 experiment\$.mp.
- 25 (time adj series).mp.
- 26 (pre test or pretest or post test or posttest).mp.
- 27 Random Allocation/
- 28 impact.mp.
- 29 intervention?.mp.
- 30 Evaluation Studies/
- 31 Comparative Study.pt.
- 32 Human/
- 33 7 and 19 and 32

HISTORY

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CONTRIBUTIONS OF AUTHORS

Writing the protocol: RC, JW

Developing the search strategy: RC

Searching for trials: RC, JW

Selecting trials: RC, JW

Data entry: RC, JW

Analysis: RC, JW

Interpreting analysis: RC, JW

Drafting final review: RC, JW

Updating the review: RC

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Cancer Care Services, Royal Brisbane and Women's Hospital, Australia.
For funding the salary and facilities for RC to conduct this systematic review
- Centre for Clinical Nursing, Royal Brisbane and Women's Hospital, Australia.
For funding the salary and facilities for JW to conduct this systematic review

External sources

- No sources of support supplied