The development of evidence-based European guidelines on the management of depression in palliative cancer care

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ABSTRACT

Depression is common in cancer patients, particularly those with advanced disease. It is associated with adverse outcomes such as increased pain, disability and poorer prognosis. Our aim was to produce a European evidence-based clinical guideline on the management of depression in patients receiving palliative care to inform practice, establish policy, promote European consensus and ultimately improve patient outcomes. Recommendations were devised using the best available evidence. Where evidence was absent or equivocal, Delphi consensus methods were implemented to elicit and refine expert opinion. Evidence was graded according to the process proposed by GRADE. The resulting guideline has three main sections: (1) prevention; (2) detection, diagnosis and assessment; and (3) treatment. The prevention section outlines strategies such as optimal palliative care and support, effective communication and information-giving. The detection section provides recommendations on symptoms, screening, diagnosis and severity assessment. The treatment section gives guidance on treatment decisions including choice of psychological therapy and antidepressant medication. This is the first comprehensive, evidence-based guideline on managing depression in palliative care. It has the potential to improve patient outcomes by enabling clinicians to access and implement evidence-based knowledge quickly and easily.

1. Introduction

Depression is common among patients with cancer and particularly those receiving palliative care. A systematic review by Hotopf et al. in 2002 found a median prevalence of 15% for major depression in advanced disease. Depression compounds the physical consequences of advanced disease. It is associated with disability, pain and fatigue, and there is evidence that depressed patients have poorer prognosis and higher mortality in a range of physical illnesses. Detecting depression in palliative care is difficult as somatic symptoms (e.g. poor appetite, sleep disturbance and fatigue) may be due to depression, advanced disease or medical treatment. Also, depression is difficult to distinguish from normal fear and distress, which often accompany terminal illness. In patients with advanced disease, the coexistence of multiple symptoms makes drug interactions more likely and treatment more complicated. Though antidepressants have been shown to ease depression in physically healthy people, there is doubt about whether they are appropriate for terminally ill patients. Psychological therapy is the other recommended treatment for depression, but questions surround its feasibility, acceptability and availability in palliative care.

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Two groups were constituted:

(1) A guideline development group of seven professionals from the EPCRC consortium was appointed to coordinate the project.

(2) An expert group was constituted to help identify clinical priorities, provide expert opinion and critically discuss and develop the guideline recommendations. It comprised two patient representatives and 29 professionals with knowledge and experience of depression in palliative care. Expert nominations were sought via the European Association of Palliative Care (EAPC) board, the EAPC website and other palliative care associations in Europe. To capture social, cultural and disciplinary differences in practice and opinion, experts were recruited from a range of disciplines and countries.

2.3. Preliminary literature scoping

Preliminary scoping of EMBASE, MEDLINE and PSYCHINFO was undertaken to gain an overview of the literature and identify key issues to be addressed in the guideline. In palliative care, somatic, social and psychological factors interact to precipitate, perpetuate or protect against depression. In appreciation of these complexities and the holistic principles of palliative care, we adopted an inclusive approach and sought to provide guidance on all aspects of the management of depression in palliative care. We identified three overarching themes: (1) prevention, (2) detection, diagnosis and assessment, and (3) treatment.

2.4. Evidence review

Systematic review of the literature relevant to each theme was impractical due to funding and time constraints. The guideline development and expert groups agreed that treatment should be prioritised, and a Cochrane review was undertaken to examine the efficacy of antidepressants in people with physical illness and those needing palliative care. For other aspects of the management of depression in palliative care, only the best existing evidence was identified: thus if strong evidence (e.g. from an RCT or meta-analysis) was available to answer a specific question, weaker evidence (e.g. cross-sectional surveys, case series) was not sought and appraised.

2.5. Delphi study

The Delphi method was used to elicit and evaluate expert opinion on contentious issues where evidence was equivocal or absent. Delphi is a consensus technique used for problem-solving and decision-making. It is a feasible and effective method for assessing expert agreement on clinical questions and it is increasingly used in research. We used the Delphi method to ascertain and refine expert opinion on the following contentious clinical questions:

(1) Which symptoms are most useful in diagnosing depression in palliative care?

(2) Which screening tool is most effective in detecting depression in palliative care?

(3) Which psychological therapy is most appropriate for treating depression in palliative care?

(4) Which antidepressant is most appropriate for treating depression in palliative care?
ments. The anonymised comments and median and range of ratings were reported to the experts, with a request for them to rate the items again in light of the results of the first round. The final summary scores were used to inform recommendations for the guideline.

2.6. Consultation

Best practice recommendations were drafted on the basis of existing evidence, and the Delphi studies and Cochrane review conducted by the guideline development group. The guideline was circulated among the expert group for comment and criticism and then published on the EPCRC website for wider consultation. National and international professional associations were contacted and requested to comment on the recommendations and forward to their members for further feedback. During the 6-month consultation period a total of 70 comments were received from 18 health professionals. Respondents were from a range of countries (United Kingdom (UK), Norway, Spain, the Netherlands, New Zealand, Canada and India) and a range of disciplines (palliative medicine, nursing, psychology, psychiatry, oncology, general practice, chaplaincy and clinical governance). Comments received during the 6-month consultation period were collated and considered by the guideline development group, who then revised and refined the recommendations in light of the feedback received.

2.7. Grading evidence

For each section of the guideline, the Guideline Development Group drafted evidence summaries for key recommendations. The quality of the evidence and the strength of recommendations were graded according to the process proposed by GRADE.19

3. Guideline content

The following section briefly summarises the guideline’s key recommendations.

3.1. Prevention

Good palliative care is of itself a key strategy for preventing and alleviating depression at the end of life. A recent RCT published in the New England Journal of Medicine showed that metastatic lung cancer patients who received early palliative care had improved mood and quality of life, as compared with those receiving standard oncological care.23 Palliative care integrates physical, psychological, social and spiritual care to control symptoms and distress and optimise quality of life.24,25 All health professionals caring for patients with advanced disease can apply these holistic principles. However, patients with complex or multiple needs should be referred to a specialist palliative care service that can offer additional support and expertise. Table 1 summarises recommendations on prevention.

3.1.1. Listening and communication

There is evidence that open, effective communication promotes coping and psychological adjustment to advanced disease. Skills such as active listening, patient-centred consulting, open-ended questioning and appropriate response to cues have been found to increase the ability of palliative care professionals to elicit emotional concerns and detect distress before depression develops.26-29

3.1.2. Information

There is wide variation in the type and amount of information individuals wish to receive. It is important to determine patients’ desired level of information and involvement in decisions and regularly review their preferences to capture changes that may occur at each phase of care.30,31 Providing patients with appropriate information on the nature, course and treatment of their illness promotes satisfaction with care and improves psychosocial outcomes.32-35 Health professionals should also advise patients about the range of support services available to them (e.g. counselling, complementary therapies and peer support and community groups).11,30,33,36

3.1.3. Optimal palliative care and support

There is a strong association between depression and other symptoms common in advanced disease, such as pain and fatigue.37,38 Effective assessment and treatment of patients’ physical symptoms is integral to palliative care and a prerequisite for preventing and treating depression.33,39 Psychosocial support is also intrinsic to palliative care. Clinicians should assess patients’ ability to cope and help them to retain a sense of purpose and control – for example, by engaging in support networks (social clubs, community groups and faith groups) and staying physically active.40 Such support helps patients maintain social roles and relationships, preserving self-worth and improving mood.41,42 The experience of progressive incurable illness can increase spirituality43 and some patients experience existential distress as death approaches.44 Palliative care providers should assess patients’ spiritual needs and arrange support from an appropriate spiritual advisor if desired.44,45 Clinicians should also consider the needs and concerns of family members and caregivers, and where possible provide practical and psychological support.46,47

3.1.4. Identification of ‘at risk’ groups

It is important that clinicians are aware of risk factors for depression in palliative care, such as history of depression, absence of social support, concurrent life stresses, chronic pain, poor performance status and advanced disease at diagnosis.48,49 Early referral to specialist palliative care has been found to improve quality of life and mood23,50,51 and may be particularly valuable for individuals identified as at risk of depression.

3.2. Detection, diagnosis and assessment

The high prevalence of depression in people with advanced disease attests to the need for heightened awareness and attention to depressive symptoms.2,52,53 In palliative care time is often short, so early detection and diagnosis of depression and regular reassessment is imperative.54 Table 4 sum-
Persistent low mood, loss of interest in everyday activities, and loss of libido may be due to physical disease or treatment and are, therefore, less useful in making a diagnosis of depression in palliative care. Clinicians should be aware of non-verbal cues indicative of depression, such as slumped posture, lack of movement, flat affect and reduced emotional reactivity. Somatic symptoms commonly associated with depression (e.g. appetite change, fatigue, sleep disturbance, psychomotor slowing and loss of libido) may be due to physical disease or treatment and are, therefore, less useful in making a diagnosis of depression in palliative care. Clinicians should be aware of possible cultural variations (ethnic, regional, age-related) in the presentation of depression. For example, patients from groups that stigmatise depression may be more likely to present with somatised distress. A diagnosis of depression may be viewed as shameful, so sensitivity and reassurance is required.

Clinicians should ask about mood as part of routine assessment. Patients may be more relaxed and open if depression is considered in the context of a general conversation about coping, in which they feel able to tell their story, feel heard and understood. Assessment of depression should be accompanied by an assessment of anxiety, as these symptoms are strongly associated.

There is mixed evidence on the ability of screening tools to improve depression outcomes. Nevertheless, it is unlikely that screening for depression causes patients harm and many palliative care services use screening tools to aid detection of depression due to the frequency of cases in this population. Commonly used depression-specific screening tools include the Hospital Anxiety and Depression Scale (HADS), the Brief Edinburgh Depression Scale (BEDS), a two item screening tool assessing low mood and loss of interest, and the single item 'Are you depressed?' (see Table 2).

Screening tools must balance validity of assessment against brevity. To avoid burdening very frail patients, clinicians should consider using a generic symptom assessment scale that includes one or more questions about depression (e.g. the Palliative care Outcome Scale (POS)).

### Table 1 – Prevention of depression in palliative care: evidence and recommendation summary.

<table>
<thead>
<tr>
<th>Prevention</th>
<th>Quality of evidence</th>
<th>Strength of recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation 1</td>
<td>Moderate Consistent evidence from non-randomised studies</td>
<td>Strong Moderate quality evidence; low risk of harm; consistent with patient preferences and clinical opinion</td>
</tr>
<tr>
<td>Recommendation 2</td>
<td>Moderate Consistent evidence from non-randomised studies</td>
<td>Strong Moderate quality evidence; low risk of harm; consistent with patient preferences and clinical opinion</td>
</tr>
<tr>
<td>Recommendation 3</td>
<td>High Evidence from well-conducted RCTs</td>
<td>Strong High quality evidence; low risk of harm; some evidence of cost-savings</td>
</tr>
</tbody>
</table>

It is crucial that clinicians consider alternative diagnoses for the presentation as misdiagnosis may prevent patients receiving appropriate treatment. Examples of differential diagnoses include delirium, dementia, Parkinson’s disease, hypothyroidism, uncontrolled pain, cerebral metastases and adverse drug reactions. It is also important to consider contributory factors, which if addressed might alleviate the patient’s depressive symptoms. Contributory factors may be biological (e.g. hypercalcaemia, uncontrolled physical symptoms, drugs causing depression – e.g. steroids), psychological (e.g. spiritual distress, anger relating to diagnostic delay) or social (e.g. family conflict, isolation, poor living conditions). Another challenge is distinguishing depressive disorder from...
normal sadness relating to declining health and fear of death. Patients who are sad usually retain some hope for the future and still derive satisfaction from relationships. Sadness tends to fluctuate, whereas depression is more constant and characterised by self-loathing and a sense of permanence (see Table 3).

Patients who do not meet criteria for major depression may still benefit from psychological support and referral to specialist palliative care. If there is uncertainty about the diagnosis, or if the patient is severely depressed or suicidal, they should be referred to a mental health specialist. Clinicians should ask patients directly about suicidal ideation and intent and be particularly vigilant during high risk periods such as initiation of antidepressant treatment.

### 3.3. Treatment

In physically healthy people with depression, psychological therapy and antidepressant drugs are the mainstay of treatment. In palliative care, evidence is scarcer, but there is little ground to suggest a radically different approach is required. Table 6 summarises recommendations on treatment.

#### 3.3.1. Mild, moderate, severe depression

The type and intensity of treatment provided to palliative care patients with depression depends on the duration and severity of symptoms (see Table 5).

#### 3.3.2. Short prognosis

Given the high prevalence of delirium in patients near the end of life, clinicians should first consider whether there is an organic cause for agitation and distress. Agitation should be treated symptomatically and benzodiazepines or neuroleptics prescribed if indicated. Some clinicians report benefit from psychostimulants for depression in patients with short life expectancy. However, we do not recommend the use of psychostimulants due to there being strong evidence of adverse effects and inadequate evidence of efficacy. For patients with short prognosis, the threshold for treatment resistant depression should be lowered from 6 weeks to 4 weeks.

#### 3.3.3. Choice of psychological therapy

Cognitive behavioural therapy (CBT) is the most widely used and evaluated psychological therapy for depression. It focuses on identifying and restructuring dysfunctional thought patterns. Randomised controlled trials have demonstrated the effectiveness of CBT in physically ill populations, but there is still a scarcity of studies in palliative care. Another therapy increasingly used in palliative care is problem-solving therapy – a short, focused intervention that helps patients work out steps to resolve specific problems occurring in their lives. Though there is limited data on the efficacy of problem-solving therapy, its simplicity and brevity make it a popular choice in palliative care. Other therapies that may help alleviate depressive symptoms in palliative patients include interpersonal therapy, couple therapy, group therapy, guided

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### Table 2 – Commonly used depression-specific screening tools.

<table>
<thead>
<tr>
<th>Screening tool</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-item</td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘Are you depressed?’</td>
<td>0.42–0.86</td>
<td>0.74–0.92</td>
</tr>
<tr>
<td>Two-item</td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘During the last month, have you been bothered by feeling down, depressed or hopeless?’</td>
<td>0.91–1.00</td>
<td>0.57–0.86</td>
</tr>
<tr>
<td>‘During the last month, have you been bothered by having little interest or pleasure in doing things?’</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital Anxiety and Depression Scale</td>
<td>0.68–0.92</td>
<td>0.65–0.90</td>
</tr>
<tr>
<td>14 items, 7 for anxiety, 7 for depression. Excludes somatic symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Brief Edinburgh Depression Scale</td>
<td>0.72</td>
<td>0.83</td>
</tr>
<tr>
<td>6 items covering guilt, insomnia, fear, sadness, inability to cope and thoughts of self-harm</td>
<td></td>
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</table>

Note: single item and two items can be found within composite outcome scales, such as the Palliative Outcome Scale or the Edmonton Symptom Assessment Schedule.

### Table 3 – Characteristics of depression versus appropriate sadness.

<table>
<thead>
<tr>
<th>Depression</th>
<th>Sadness</th>
</tr>
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<tbody>
<tr>
<td>Feels outcast and alone</td>
<td>Able to feel intimately connected with others</td>
</tr>
<tr>
<td>Feeling of permanence</td>
<td>Feeling that some day this will end</td>
</tr>
<tr>
<td>Regretful, rumination on ‘irredeemable’ mistakes</td>
<td>Able to enjoy happy memories</td>
</tr>
<tr>
<td>Extreme self-depreciation/self loathing</td>
<td>Sense of self worth</td>
</tr>
<tr>
<td>Constant and unremitting</td>
<td>Comes in waves</td>
</tr>
<tr>
<td>No hope/interest in the future</td>
<td>Looks forward to things</td>
</tr>
<tr>
<td>Enjoys few activities</td>
<td>Retains capacity for pleasure</td>
</tr>
<tr>
<td>Suicidal thoughts/behaviour</td>
<td>Will to live</td>
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</tbody>
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E U R O P E A N  J O U R N A L  O F  C A N C E R  4 7  ( 2 0 1 1 )  7 0 2 – 7 1 2
Clinicians should discuss the different treatment options and consider the type of comorbid physical illness, the patient’s symptom profile, potential side-effects, interactions and contraindications, clinician familiarity and patient preference.

3.3.4. Choice of antidepressant
The Cochrane review we conducted showed that antidepressants are more effective than placebo in treating depressed patients with physical illness, including those with ‘life-threatening’ physical illness. Though there is no evidence that any particular antidepressant is preferable for palliative patients, a recent meta-analysis in physically well people showed that any particular antidepressant is preferable for palliative care patients. Screening tools may help clinicians detect depression, but evidence that they improve depression outcomes is lacking.

3.3.5. Before initiating treatment
Clinicians should discuss the different treatment options with the patient and take into account their preferences and the outcome of previous treatments. Patients should be informed about potential side-effects of antidepressant drugs, discontinuation symptoms, possible delay in onset of effect, and the need to take medication as prescribed, even after remission. If there is a high risk of suicide, a limited quantity of antidepressants should be prescribed, preferably ones which are relatively safe in overdose (e.g. SSRIs).

3.3.6. Reviewing treatment
Patients should be reviewed for side-effects in the 1st week of treatment. If adverse effects occur with antidepressant treatment, clinicians should consider discontinuing treatment or switching to a different drug. A comprehensive mood assessment should be repeated every 2 weeks using a validated scale sensitive to change over time. Patients at risk of suicide should be reviewed after 1 week.

4. Discussion
The translation of research findings into systematically developed guidelines has been found to improve patient outcomes by bringing evidence-based knowledge into clinical practice. The EPCRC depression guideline was developed to address the lack of guidance on managing depression in patients receiving palliative care. It draws together the most current and important evidence in the field, enabling clinicians to access and implement new knowledge quickly and easily.

This is the first comprehensive, evidence-based clinical guideline on managing depression in palliative care. The multinational nature of our expert group meant that the guideline incorporated the knowledge, expertise and experience of experts from 10 European countries. Regional variations in policy and patient care were identified within the expert group and these were debated to determine best practice. However, guideline development was led by a UK research group and as a consequence British clinicians were over-represented in the expert group. Health care organisation and models of palliative care vary considerably across Europe and there are also important differences in public and professional perceptions, terminology and treatments. It is possible that the guideline content reflects the British
<table>
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<th>Table 5 – Treatment of depression in palliative care.</th>
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<tbody>
<tr>
<td><strong>Mild depression</strong></td>
</tr>
<tr>
<td>Characterised by a small number of symptoms with limited impact on the patient’s everyday life</td>
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<tr>
<td>If symptoms persist...</td>
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<tr>
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<tr>
<td><strong>Moderate depression</strong></td>
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<tr>
<td>Characterised by a larger number of symptoms which make it difficult for the patient to function as they would normally</td>
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<td></td>
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<td>If symptoms persist...</td>
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<tr>
<td><strong>Severe depression</strong></td>
</tr>
<tr>
<td>Characterised by a large number of symptoms which make it very difficult for the patient to carry out everyday activities. There may be psychotic symptoms, food and/or fluid refusal or severe and persistent suicidal ideation</td>
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<tr>
<td>If symptoms persist...</td>
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<table>
<thead>
<tr>
<th>Table 6 – Treatment of depression in palliative care: evidence and recommendation summary.</th>
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<tbody>
<tr>
<td><strong>Treatment</strong></td>
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<tr>
<td>---------------------------------------------------------------</td>
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<tr>
<td><strong>Recommendation 7</strong></td>
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<td></td>
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<tr>
<td><strong>Recommendation 8</strong></td>
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<tr>
<td><strong>Recommendation 9</strong></td>
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</table>
bias in composition of the expert group and that some recommend-
ations may be less applicable to countries with contrasting systems of care. In the main, though, the guide-
line promotes best practice appropriate to all European

countries, irrespective of health care context and culture, and we hope it will help harmonise palliative care policy
and practice across the continent.

Tension between the depth and breadth of information

provided in the guideline was debated at the beginning of proj-

ect when the expert group rejected the option of producing
treatment guidelines in favour of a comprehensive clinical
guideline that could also assist palliative care providers in
preventing, detecting and assessing depression. This broad
scope necessitated a pragmatic approach to reviewing rele-

vant literature. Given finite time and funding and the large
number of recommendations included in the guideline, we
could not undertake a systematic literature review for each.

Rather, we appraised the strongest and most relevant evi-
dence. Thus, if strong evidence (e.g. RCT or meta-analysis)
was available to answer a specific question, weaker evidence
(e.g. cross-sectional surveys, case series) was not sought. Sim-

ilarly, if evidence from palliative care populations existed,
studies in patients with less advanced physical illness were
not appraised. In addition, we conducted a systematic review
on the efficacy of antidepressants for treating depression in
people with physical illness generally,20 and those with a
life-threatening condition.21 This Cochrane review showed
that antidepressants are effective and acceptable for both –
providing high quality, up-to-date evidence for the treatment
section of the guideline.

An issue that arose during development of the guideline
was how to formulate evidence-based recommendations
where evidence was lacking. We found a paucity of high qual-

ty evidence on improving depression outcomes in palliative
populations. Obstacles to conducting randomised controlled
trials in palliative care are well documented and include eth-

ical concerns about vulnerability and consent, and practical
difficulties such as recruitment, attrition and compliance.97,98

Where there was no evidence in palliative care on which to
base guideline recommendations, we extrapolated data from
well-conducted studies in cancer patients with less advanced
disease. Many parallels exist in the experience of depression
in patients receiving palliative and curative cancer care, and
interventions must address the same interrelated problems of
physical and emotional suffering. Moreover, there is grow-
ing advocacy for palliative care to be introduced earlier in the
disease trajectory – as an adjunct to curative care rather than
an alternative.23 Whilst many aspects of the management
of depression in palliative care can be informed by research on
patients with curable disease, some are distinct and require

research in patients who are terminally ill. A recent systemat-

ic review identified eight studies showing that palliative
care patients are interested in participating in studies and

may even benefit from doing so.99 The data suggest that the
views of terminally ill patients are similar to patients partici-
pating in trials in the oncology setting and call into question
the special scrutiny afforded to palliative care research. Fur-

ther, studies in palliative care are achieving increasingly large
sample sizes, suggesting that practical limitations can also be
overcome.23,53

Such developments hold promise for future studies that
can address the evidence gaps identified in the EPCRC depres-
sion guideline. One research priority is to determine the opti-

mal method of detecting depression in palliative care. Screen-

ing is advocated as a systematic and cost-effective way to
improve identification of depression in this population but
there is a lack of evidence supporting its efficacy.59 Ran-

domised controlled trials are needed to test the impact of
screening on depression outcomes. RCTs in palliative patients
are also required to address unresolved issues relating to
treatment of depression at the end of life. The guideline rec-

ommends that antidepressants should be considered for
treating depression in palliative care, but there were too few
trials to determine a ‘first choice’ antidepressant for patients
with advanced disease. Trials comparing the efficacy and
acceptability of specific drugs for specific diseases are needed.
Similarly, whilst there is some evidence supporting psycho-

logical therapy for treatment of depression in palliative care,
there remains a dearth of data on the comparative efficacy
and acceptability of different types of therapy.

Contributions

L.R.: coordinating guideline development – including expert
group meetings, Delphi study, Cochrane review, guideline
consultation, literature review, writing recommendations,
grading evidence. A.P.: identifying clinical priorities, conduct-
ing Cochrane review. M.H.: winning peer review funding for
project; supervision of guideline development – including
expert group meetings, Delphi study, Cochrane review,
guideline consultation, literature review, writing recommenda-
tions, grading evidence. I.J.H.: winning peer review funding
for project, supervision of guideline development – including
expert group meetings, the Delphi study, Cochrane review,
guideline consultation, literature review, writing recommenda-
tions, grading evidence. All authors contributed to writing
this paper. L.R. and I.J.H. are co-guarantors.

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Conflict of interest statement

M.H. is an independent expert witness (instructed by the claimants’ solicitor) in a group litigation on the potential for paroxetine to cause adverse events on withdrawal of treatment. L.R., A.P. and I.J.H. do not have any competing interests. No competing interests were declared by the members of the expert group.

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