

CLINICAL PRACTICE EVALUATION PROGRAMME (CPEP)

EVIDENCE BASED ASPECTS OF CARE AND REVIEW CRITERIA FOR THE PRIMARY CARE MANAGEMENT OF

ADULTS WITH DEPRESSION

Practical tools for quality improvement in primary care

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Royal College of General Practitioners



ScHARR
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RELATED RESEARCH

University of Sheffield



MSD

Merck Sharp & Dohme Limited
Hertford Road, Hertfordshire EN11 8BU

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Introduction

The RCGP Clinical Practice Evaluation Programme (CPEP) has developed a set of evidence based aspects of care for the primary care management of adults with depression. These are drawn from recommendations in guidelines that cover the management of major depressive disorder. We have used the term “depression” throughout this document as an abbreviation for major depressive disorder.

The aspects of care can be found on the final page of this booklet, and details of the evidence base are on page 4.

CPEP evidence based aspects of care are derived from recommendations and statements about particular areas of care, drawn from the best available evidence based clinical guidelines.

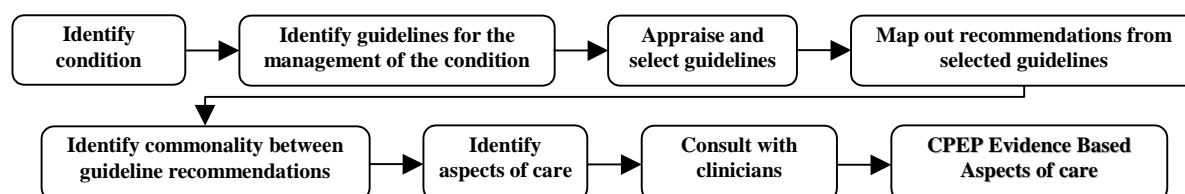
Development of aspects of care for Depression

During 1999-2000 CPEP developed and disseminated *evidence based review criteria* for the care of patients with coronary heart disease, asthma and diabetes foot care. We have adopted a rather different approach for depression for two main reasons.

First, there is a paucity of explicitly evidence-based guidelines. It was necessary therefore to use one main guideline, the North of England 1998 Guideline on the Choice of Antidepressants for Depression in Primary Care, and two other guidelines that partially meet the CPEP appraisal criteria.

Secondly, many of the guideline recommendations cover issues that, while taken into account in clinical decision-making, are frequently not recorded in the medical notes. As it is inappropriate to provide review criteria for these recommendations we have presented them simply as *aspects of care*, with a few examples of possible review criteria.

The process of development is summarised in the diagram below and more details can be found on our website (address on page 8).



This document takes into account the comments of those who very helpfully responded during the consultation phase of the depression work, and we are most grateful for their views. In particular they helped to identify aspects of care that could be audited.

Using these aspects of care

The aspects of care reflect practice recommendations but the document should not be seen as a clinical guideline. They may provide useful prompts for clinicians in managing patients with depression. Practices and Primary Care Groups/Trusts (PCG/Ts) may like to use the aspects of care within the context of the National Service Framework for Mental Health - as a starting point for local educational activities and to set local standards of care. The sample review criteria can be used for clinical audit, following local agreement on the details.

Aspects of care and any review criteria that are developed from them should be used in the context of the individual clinical situation, in which clinical judgement and patient preference play an important role in determining treatment options. Although the aspects of care remain current until December 2002, their use should also take into account any major new research findings or clinical advances in the management of depression during this period.

Approaches to managing depression

There is a range of views amongst health care professionals about the most appropriate management of patients with depression. Some favour antidepressant medication, others psychological therapies. It will be for clinicians to make the choice of treatment based on the evidence, severity of condition, preference of patient and doctor and local availability of psychological therapies.

The CPEP aspects of care focus on the use of antidepressant medication, rather than psychological treatment, reflecting the recommendations in the guidelines that meet the appraisal criteria. This focus on medication is admittedly limited. Future versions of aspects of care and review criteria should have the benefit of being based on evidence drawn from a much broader approach to the management of depression.

Diagnostic criteria

Most of the guidelines used by CPEP defined depression according to the DSM diagnostic criteria, which are similar to those specified by ICD-10. Once a diagnosis is made, the severity of the illness can be classified as mild, moderate or severe, although precise definitions may be difficult in practice.

The DSM-IV criteria (below) state that for a diagnosis of depression to be made the symptoms should not be due to physical factors or bereavement. However, the CPEP aspects of care may be of use for the care of individuals diagnosed with depression irrespective of the cause.

Adapted DSM-IV criteria for depression¹

Criteria

- A Over the last two weeks, five of the following features have been present most of the day, or nearly every day (must include 1. or 2. from the list):
1. Depressed mood.
 2. Loss of interest or pleasure in almost all activities.
 3. Significant weight loss or gain (e.g. more than 5% change in 1 month) or an increase or decrease in appetite nearly every day.
 4. Insomnia or hypersomnia.
 5. Psychomotor agitation or retardation (observable by others).
 6. Fatigue or loss of energy.
 7. Feelings of worthlessness or excessive or inappropriate guilt (not merely self-reproach about being sick).
 8. Diminished ability to think or concentrate, or indecisiveness (either by subjective account or observation of others).
 9. Recurrent thoughts of death (not just fear of dying), or suicidal ideation, or a suicide attempt, or a specific plan for committing suicide.
- B The symptoms cause clinically significant distress or impairment in functioning (social, occupational or other areas).
- C The symptoms are not due to a physical/organic factor or illness.
- D The symptoms are not better explained by bereavement (although this can be complicated by depression).

Severity of depression²

Mild to moderate depression ranges from:

- ◆ a threshold number (five) of symptoms with minimal functional impairment; through to marked symptoms and impairment of function.

Severe depression:

- ◆ all, or nearly all, DSM-IV depressive symptoms and marked functional impairment in all areas of life.

¹American Psychiatric Association (1994) *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.). American Psychiatric Association: Washington DC.

²based on British Association for Psychopharmacology (2000) guideline (see full reference on page 7)

Aspects of care for adults with depression

The table below indicates which guidelines made recommendations used for the CPEP aspects of care. The level of evidence and location of the supporting recommendation in the guideline are given. Full guideline references can be found on page 7.

indicates evidence grading applied to larger body of text from which the recommendation was taken.

Aspects of care	NofE	AHCPR	BAP
<p>Information for patients</p> <ul style="list-style-type: none"> Patients should be offered information about their condition, the benefits of treatment and potential side-effects. 		A (p.28)	Ib (p.11)
<p>Options for treatment</p> <ul style="list-style-type: none"> Patients with mild to moderate depression should be treated with psychological treatments as first line therapy. Patients with moderate to severe depression should be treated with antidepressants as first line therapy, unless contraindicated. Patients with severe depression or other risk factors should be considered for combined pharmacological and depression specific psychological treatment, unless contraindicated. 		B (p.72) A# (p.39) B-C (p.87-8)	Ia-Ib (p.8) Ia-Ib (p.7) Ia (p.8)
<p>Use of antidepressants – Initiation</p> <p>When choosing an antidepressant (tricyclic (TCA) or selective serotonin re-uptake inhibitor (SSRI)), the following should be considered:</p> <ul style="list-style-type: none"> Likely side-effect profiles. Lofepramine is a more cost effective choice than an SSRI if there is concern about the toxic effects of older TCAs. The patient's previous response to a particular drug. Patient preference. Concurrent drug therapy. Co-morbid psychiatric or medical conditions. 	IV# (p.34) III, (p34) IV# (p.34) IV# (p.34) IV# (p.34) IV# (p.34)	A# (p.39) A# (p.39) C (p.55) A# (p.39) A (p.55)	IV (p.10) IV (p.10) IV (p.10) IV (p.10) IV (p.10)
<p>Use of antidepressants – Dosage of tricyclic antidepressants</p> <ul style="list-style-type: none"> The dose of TCAs should be titrated up to the doses used in clinical trials (usually 125 mg or above for most older TCAs). Lower doses of TCAs should be used initially in older patients. If patient adherence to treatment is a concern, TCAs can be given in a once daily dosage. 	IV (p.29) IV (p.29) IV (p.29)	A# (p.39)	Ia-IIa (p.11)
<p>Use of antidepressants – Continuation/maintenance treatment</p> <ul style="list-style-type: none"> Antidepressant treatment should be continued at full dose for 4 to 9 months after symptom remission. Patients who have had 3 or more episodes of depression should be given long-term maintenance treatment of the same type and dosage found effective in acute phase treatment. 		A (p.109) A# (p.110-1)	Ib (p.14) Ia-IIb (p.15)
<p>Use of antidepressant – Non-response</p> <p>If the patient does not respond to first line drug therapy by 4 to 6 weeks:</p> <ul style="list-style-type: none"> Check adherence to drug therapy. Consider the potential contribution of social factors. Evaluate the adequacy of medication dosage. Review the diagnosis. Consider switching to another antidepressant class. Consider increasing the medication dosage if inadequate. 	IV# (p.38) IV# (p.38) IV# (p.38) IV# (p.38)	A# (p.64) A# (p.64) A# (p.66) A# (p.66)	IV (p.13) IV (p.13) IV# (p.13) IV (p.13) I-III (p.13) Ib (p.13)
<p>Use of antidepressants - Discontinuation</p> <ul style="list-style-type: none"> When TCAs are to be stopped after treatment at therapeutic dosage for 3 months or more, the dose should be tapered off over a minimum of 4 weeks. 		A (p.117)	IV (p.15)
<p>Referral</p> <ul style="list-style-type: none"> Urgent consultation with, or referral to, a psychiatrist or specialist in the treatment of affective disorders is appropriate if the patient is at risk of suicide. Consultation with, or referral to, a psychiatrist or specialist in the treatment of affective disorders is appropriate if two or more attempts at acute phase medication have failed or resulted in only partial response. 		None given (p.98) C# (p.70)	IV (p.6) IV (p.6)

Strength of evidence

The aspects of care table opposite shows the level and source of evidence for each recommendation made in the selected guidelines. The grading system used to describe the evidence base varies between guidelines, for example AHCPR grades recommendations not the evidence level behind them. Therefore it is not possible to determine the overall level of evidence for each aspect of care from clinical guidelines. Details of the evidence grading systems employed in guidelines that CPEP has used are given below.

North of England and BAP guidelines

level I	Evidence from meta-analysis of randomised controlled trials or from at least one randomised controlled trial
level II	Evidence from at least one controlled study without randomisation or at least one other type of quasi-experimental study
level III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies or case-control studies
level IV	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Levels of evidence adapted from Agency for Health Care Policy and Research. *Acute Pain Management: Operative or Medical Procedures and Trauma*. Agency for Health Care Policy and Research/US Department of Health and Human Services, Public Health Service, Rockville, MD. 1992.

AHCPR Depression guideline

A	Good research-based evidence, with some panel opinion, to support the guideline statement
B	Fair research-based evidence, with substantial panel opinion, to support the guideline statement
C	Guideline statement based primarily on panel opinion, with minimal research-based evidence, but significant clinical experience

While practices or Primary Care Groups/Trusts may wish to adapt some aspects of care to suit individual patients or local circumstances, any adaptations should remain consistent with the evidence base and maintain the integrity of each statement.

Guideline references

The following describe the guidelines from which the aspects of care were drawn. Details of where to obtain the full guidelines can be found on the CPEP website (address overleaf).

- AHCPR** Agency for Health Care Policy and Research. Clinical Practice Guideline Number 5: *Depression in Primary Care: Detection, Diagnosis, and Treatment*. U.S. Department of Health and Human Services. April 1993.
- BAP** Anderson, I. M., Nutt, D. J. and Deakin, J. F. W., on behalf of the Consensus Meeting and endorsed by the British Association for Psychopharmacology. Evidence-based guidelines for treating depressive disorders with antidepressants: a revision of the 1993 British Association for Psychopharmacology guidelines. *Journal of Psychopharmacology*, 2000; **14**(1): 3-20.
- NoFE** Eccles, M., Freemantle, N. and Mason, J. North of England Evidence Based Guideline Development Group. Evidence Based Clinical Practice Guideline: *The Choice of Antidepressants for Depression in Primary Care*. Centre for Health Services Research, Newcastle-upon-Tyne. Report No. 91. 1998.

Background to CPEP

The RCGP Clinical Practice Evaluation Programme (CPEP) aims to support the improvement of quality of care by establishing a national programme to assist general practice teams in evaluating the effectiveness of their care for patients. CPEP is a professionally led project, advised by members of a multi-disciplinary group. It is located at the RCGP Effective Clinical Practice Unit, University of Sheffield and led by Professor Allen Hutchinson. CPEP is one of ten NHS National Sentinel Audit programmes and is open to all general practice teams.

The CPEP team has also released review criteria for coronary heart disease, asthma in adults, and Type 2 diabetes foot care.

Contacting CPEP

The CPEP project has a website providing more detailed information about the method for developing the depression aspects of care and review criteria for other conditions. It will also include the aspects of care and evidence based review criteria that can be downloaded directly.

Our website address is www.shef.ac.uk/~scharr/public/cpep

The CPEP team welcomes feedback about the structure and use of the depression aspects of care and can be contacted via e-mail.

Unfortunately, we are unable to offer direct support to practices or PCG/Ts in using the aspects of care.

Our e-mail address is CPEP@sheffield.ac.uk

Clinical Practice Evaluation Programme

Section of Public Health
School of Health and Related Research
University of Sheffield
Regent Court, 30 Regent Street
SHEFFIELD.
S1 4DA.

This booklet may be freely photocopied or downloaded directly from the CPEP website. Multiple printed copies can be obtained from the RCGP Clinical and Specific Projects Network on Tel: 020 7344 3115 or Fax: 020 7589 1428.

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The views expressed in this publication are those of the authors and not necessarily those of the Institute.

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EVIDENCE BASED ASPECTS OF CARE FOR DEPRESSION

These aspects of care are derived from the best available evidence based clinical guidelines. While they may provide useful prompts for clinical practice, they reflect the clinical practice recommendations in the guidelines used by CPEP, this document should not be considered a clinical guideline. A few of the aspects of care can easily be converted into review criteria, and some examples are given below.

INFORMATION FOR PATIENTS

- Patients should be offered information about their condition, the benefits of treatment and potential side-effects.

OPTIONS FOR TREATMENT

- Patients with mild to moderate depression should be treated with psychological treatments as first line therapy.
- Patients with moderate to severe depression should be treated with antidepressants as first line therapy, unless contraindicated.
- Patients with severe depression or other risk factors should be considered for combined pharmacological and depression specific psychological treatment, unless contraindicated.

USE OF ANTIDEPRESSANTS

Initiation

When choosing an antidepressant (tricyclic (TCA) or selective serotonin re-uptake inhibitor (SSRI)), the following should be considered:

- Likely side-effect profiles.
- Lofepamine is a more cost effective choice than an SSRI if there is concern about the toxic effects of older TCAs.
- The patient's previous response to a particular drug.
- Patient preference.
- Concurrent drug therapy.
- Co-morbid psychiatric or medical conditions.

Dosage of Tricyclic Antidepressants

- The dose of tricyclic antidepressants should be titrated up to the doses used in clinical trials (usually 125 mg or above for most older TCAs).
- Lower doses of TCAs should be used initially in older patients.
- If patient adherence to treatment is a concern, TCAs can be given in a once daily dosage.

Continuation/maintenance treatment

- Antidepressant treatment should be continued at full dose for 4 to 9 months after symptom remission.
- Patients who have had 3 or more episodes of depression should be given long-term maintenance treatment of the same type and dosage found to be effective in acute phase treatment.

Non-response

If the patient does not respond to first line drug therapy by 4 to 6 weeks:

- Check compliance with drug therapy.
- Consider the potential contribution of social factors.
- Evaluate the adequacy of medication dosage.
- Review the diagnosis.
- Consider switching to another antidepressant class.
- Consider increasing the medication dosage if required.

Discontinuation

- When TCAs are to be stopped after treatment at therapeutic dosage for 3 months or more, the dose should be tapered off over a minimum of 4 weeks.

REFERRAL

- Urgent consultation with, or referral to, a psychiatrist or specialist in the treatment of affective disorders is appropriate if the patient is at risk of suicide.
- Consultation with, or referral to, a psychiatrist or specialist in the treatment of affective disorders is appropriate if two or more attempts to treat the patient's depressive disorder have failed or resulted in only partial response.

SUGGESTED REVIEW CRITERIA

- *The % of patients with moderate to severe depression who have been treated with antidepressants as first line therapy, unless contraindicated.*
- *The % of patients taking TCAs who have been prescribed doses used in clinical trials (usually 125 mg or above for most older TCAs).*
- *The % of patients prescribed medication who have been treated with full dose antidepressants for 4 to 9 months after symptom remission.*
- *The % of patients with a history of 3 or more episodes of major depression, who have been given full dose long-term maintenance treatment.*
- *The % of patients previously treated with antidepressants who have had their medication tapered off over a minimum of 4 weeks.*
- *The % of patients at risk of suicide who have been referred urgently to a psychiatrist or specialist in the treatment of affective disorders.*