Complete Summary

GUIDELINE TITLE

Bipolar affective disorder. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Bipolar affective disorder. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2005 May. 41 p. (SIGN publication; no. 82). [182 references]

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Bipolar affective disorder

GUIDELINE CATEGORY

Diagnosis
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Psychiatry
Psychology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Pharmacists
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Substance Use Disorders Treatment Providers

GUIDELINE OBJECTIVE(S)

To present evidence-based recommendations for the management of bipolar affective disorder

TARGET POPULATION

Adults (aged 18 years or over) with bipolar affective disorder

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Assess signs and symptoms of mania and hypomania, depression, psychotic symptoms, and mixed affective states
2. Clinical assessment according to criteria from the International Classification of Diseases of the World Health Organisation, 10th edition (ICD-10) and the Diagnostic and Statistical Manual, 4th edition (DSM-IV)
3. Clinical Interview for DSM (SCID)
4. Present State Examination (PSE)
5. Diagnostic scales

Treatment

Acute Mania

1. Antipsychotic drugs
2. Valproic acid salts
3. Carbamazepine
4. Other anticonvulsants
5. Lithium alone or in combination with an antipsychotic
6. Benzodiazepines
7. Electroconvulsive treatment (ECT)
8. Reduction or discontinuation of antidepressant drug treatment

Acute Depression

1. Antidepressant drugs in combination with antimanic drug
2. Lamotrigine
3. Electroconvulsive treatment

Rapid Cycling and Mixed Affective States

Note: Guideline developers considered but did not specifically recommend lithium, antipsychotic drugs, anticonvulsant mood stabilizers, or valproate for rapid cycling and mixed affective states

Management

1. Pharmacologic relapse prevention
    - Lithium
    - Carbamazepine
    - Lamotrigine

    Note: Guideline developers considered but did not recommend valproic acid salts, antipsychotic medications, or antidepressant drugs for relapse prevention

2. Psychosocial interventions
3. Reproductive health issues
    - Contraception
    - Preconception counseling
    - Drugs in pregnancy

        Note: Guideline developers considered but did not recommend newer antipsychotic drugs during pregnancy. They discussed but did not offer specific recommendations regarding antidepressant drug use during pregnancy.

    - Drug treatment and lactation

4. Substance misuse
    - Manage under Care Programme Approach (CPA)
5. Suicide prevention
    - Optimize acute and maintenance lithium treatment

MAJOR OUTCOMES CONSIDERED

- Accuracy of diagnostic tools (e.g., sensitivity and specificity of diagnostic scales)
- Effectiveness of treatments on stabilizing mood and preventing relapse
- Morbidity and mortality associated with bipolar affective disorder
- Adverse effects of medication used to treat bipolar disorder

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence base for this guideline was synthesised in accordance with Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised by the SIGN Information Officer in collaboration with members of the guideline development group. Literature searches were initially conducted in Medline, Embase, Cinahl, Psychinfo, and the Cochrane Library using the year range 1990-2003. The literature search was updated with new material during the course of the guideline development process. A final update search was performed in April 2004. Key Web sites on the Internet were also used, such as the National Guidelines Clearinghouse. These searches were supplemented by reference lists of relevant papers and group members' own files. The Medline version of the main strategies can be found on the SIGN Web site. The work of the guideline groups for postnatal depression and puerperal psychosis and diagnosis and management of epilepsy in adults formed the basis of some of the recommendations in section 5 of the original guideline document.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies; high quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g., case reports, case series)

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

All selected papers were evaluated by either at least two members of the group or by systematic reviewers from the Collaborating Centre, using standard Scottish Intercollegiate Guidelines Network (SIGN) methodological checklists before conclusions were considered as evidence.

Additional details can be found in the companion document titled "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site.

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgement is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgement on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Evidence tables are compiled by SIGN executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will

present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Directness of application to the target population for the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them)
- Implementability (i.e., how practical it would be for the NHS in Scotland to implement the recommendation)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the group is asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

On occasion, guideline development groups find that there is an important practical point that they wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as Good Practice Points, and are indicated. It must be emphasised that these are not an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

Grade A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

Grade B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

Grade C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

Grade D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

COST ANALYSIS

Treatments for Acute Mania

Limited good quality economics studies were found on the relative cost effectiveness of treatments for acute mania. One cost-consequence study from the United States found that over a 12-week period, treatment with semisodium valproate or olanzapine produced similar clinical outcomes but showed no significant differences in total costs of care. A National Institute for Clinical Excellence (NICE) technology appraisal examining the use of olanzapine and semisodium valproate for acute mania concluded that no distinction could be made between the two drugs on cost effectiveness grounds. Two other studies were found relating to acute treatment but the applicability of the findings in each case was limited by poor quality methodology. No cost effectiveness studies were found relating to the treatment of acute bipolar depression in patients with a history of mania.

Pharmacological Treatments for Relapse Prevention

No cost-effectiveness studies were found relating to pharmacological treatments for relapse prevention. No full economic evaluations were found on psychosocial interventions to prevent relapse, but several clinical trials on such interventions did report information on resource use. Two studies concluded that cognitive therapy produced improvements in symptoms and functioning compared to waiting list control patients, in addition to reductions in hospital admissions. Using psychologists to train individuals to recognize early symptoms of relapse has also been shown to be effective in reducing manic relapses (but not depressive relapses) but, contrary to the findings above, this was not associated with significant reductions in inpatient stays, outpatient visits, or community contacts.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents its draft recommendations for the first time. The national open meeting for this guideline was held in November 2003 and was attended by all of the key specialties relevant to the guideline. The draft guideline was also available on the SIGN Web site for one month to allow those unable to attend the meeting to contribute to the development of the guideline.

The guideline was also reviewed in draft form by a panel of independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline.

As a final quality control check, the guideline was reviewed by an editorial group comprising the relevant specialty representatives on SIGN Council to ensure that the specialist reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

The grades of recommendations (A-D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Definitions and Diagnosis

Diagnostic Scales

D - A diagnosis of bipolar affective disorder should be made after clinical assessment according to Diagnostic and Statistical Manual (DSM) or International Classification of Diseases of the World Health Organisation (ICD) criteria

Acute Treatment

Recommendations for the Treatment of Acute Mania

A - Acute manic episodes should be treated with oral administration of an antipsychotic drug or semisodium valproate.

A - Lithium can be used if immediate control of overactive or dangerous behaviour is not needed or otherwise should be used in combination with an antipsychotic.

Recommendations for the Treatment of Acute Depression

B - An antidepressant in combination with an antimanic drug (lithium, semisodium valproate or an antipsychotic drug), or lamotrigine is recommended for the treatment of acute bipolar depression in patients with a history of mania.

Maintenance

Pharmacological Relapse Prevention

Lithium

A - Lithium is the treatment of choice for relapse prevention in bipolar affective illness.

A - Lithium should be prescribed at an appropriate dose with a daily dosing regimen.

A - The withdrawal of lithium should be gradual to minimise the risk of relapse.

Carbamazepine

A - Carbamazepine can be used as an alternative to lithium, particularly in patients with bipolar II, or when lithium is ineffective or unacceptable.

Lamotrigine

A - Lamotrigine can be used for prophylaxis in patients who have initially stabilised with lamotrigine, particularly if depressive relapse is a greater problem than manic relapse.

Recommendations on Psychosocial Interventions

B - Evidence based psychosocial interventions should be available to patients in addition to pharmacological maintenance treatment, especially if complete or continued remission cannot be achieved.

Reproductive Health Issues

Contraception

Combined Oral Contraception (COC)

D - The dose of the combined oral contraceptive should be adjusted accordingly when given with an enzyme-inducing drug

D - Women should be warned that the efficacy of the COC is reduced

D - Barrier methods of contraception should also be used for maximal contraceptive effect

Progesterone-Only Contraception

D - The progestogen-only oral contraceptive is not recommended for women taking enzyme-inducing drugs

D - Depot injections of progesterone may be used with enzyme-inducing drugs if given every 10 weeks

D - Progesterone implants are not suitable for women taking enzyme-inducing drugs

Drugs in Pregnancy

Anticonvulsant Drugs (ACDs)

C - All women on antiepileptic drugs as mood stabilisers should be prescribed a daily dose of 5 mg folic acid from preconception at least until the end of the first trimester.

D - Valproate should be avoided as a mood stabiliser in pregnancy.

Lithium

C - Women with severe bipolar disorder, who are maintained on lithium, can be continued on lithium during pregnancy if clinically indicated.

C - The serum levels of women who are maintained on lithium therapy during pregnancy should be carefully monitored. Detailed fetal ultrasound scanning should be offered.

Benzodiazepines

B - Benzodiazepines should be avoided in the first trimester of pregnancy

Drug Treatment and Lactation

Lithium

D - Mothers taking lithium should be encouraged to avoid breast feeding, particularly if the infant is not full-term and healthy. If a decision is made to proceed, close monitoring of the infant, including serum lithium levels, should be undertaken.

Other Psychotropic Medication

D - New prescriptions for benzodiazepines should be avoided in breastfeeding mothers.

Note: This recommendation does not cover drug dependence, where breast feeding may be beneficial if the infant has been exposed to benzodiazepines in utero.

Suicide Prevention

D - Acute and maintenance lithium treatment of patients with bipolar affective disorders should be optimised to make every effort to minimise the risk of suicide.

Definitions:

Levels of Evidence

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3: Non-analytic studies (e.g., case reports, case series)

4: Expert opinion

Grades of Recommendation

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C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Potential Benefits

- Long term prevention of illness is an important treatment aim.
- Interventions may help stabilize mood and prevent relapse.
- Effective diagnosis, treatment, and prevention may improve patients' well-being and productivity and may reduce morbidity and mortality associated with bipolar affective disorder.

Specific Potential Benefits

- Lithium: Three small but well conducted meta-analyses indicate that lithium is effective in reducing early and later relapse in patients with bipolar affective disorder for up to three years.
- Carbamazepine: Carbamazepine may be as effective as lithium in preventing relapse over six weeks to three years, although two studies report superiority of lithium over carbamazepine in patients with bipolar I, and one of these suggests equivalent efficacy for both drugs in patients with bipolar II disorder.

POTENTIAL HARMS

Lithium

- Sudden withdrawal of lithium may lead to a provocation of manic symptoms.
- Side effects include polyuria and polydipsia, hypothyroidism, gastrointestinal disturbance and tremor. Toxicity occurs at 150% of the upper limit of the

therapeutic dose range and may develop as a result of reduced kidney function during general physical illness, or through adverse interactions with other medications, such as diuretics and non-steroidal anti-inflammatory drugs.

- Patients may experience reversible changes in their ability to process information during lithium treatment, and this may have relevance to their driving skills.
- Long term treatment with lithium may show faster age related reduction in kidney function, although very few incidences of kidney failure requiring dialysis have been reported.
- Lithium toxicity has been described in a breastfed infant and lithium is known to impair thyroid and renal function in adults.

Antipsychotic Medications

Potential problems are the absence of antidepressant effects and the risk of tardive movement disorders.

Antidepressant Drugs

They have the potential to induce switching to hypomania or mania and long term monotherapy with (especially tricyclic) antidepressants is not advisable.

Reproductive Health Issues

The main risks associated with psychotropic drugs in later pregnancy are neonatal toxicity or withdrawal syndrome following delivery and the possibility of a long term impact on the infant's neurodevelopment. Similar concerns exist for breast feeding and most psychotropic drugs are not licensed for use during pregnancy and lactation.

Anticonvulsant Drugs (ACDs)

Major and minor fetal malformations occur more commonly in infants exposed to the ACDs carbamazepine, valproate, and lamotrigine during pregnancy. The overall risk of major fetal malformation in any pregnancy of approximately 2% is increased two to three-fold in women taking a single ACD. The relative risk is higher with valproate than carbamazepine or lamotrigine.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding

a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is, however, advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health Service (NHS) Health Board and is an essential part of clinical governance. It is acknowledged that not every guideline can be implemented immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

Key points for audit are identified in the original guideline document.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Bipolar affective disorder. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2005 May. 41 p. (SIGN publication; no. 82). [182 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 May

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declarations of interests were made by all members of the guideline development group. Further details are available from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Quick reference guide: Bipolar affective disorder. Scottish Intercollegiate Guidelines Network, 2005 May. 2 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on July 15, 2005. The information was verified by the guideline developer on July 26, 2005.

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