

Guidance on the use of electroconvulsive therapy

Technology Appraisal Guidance 59

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This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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1 Guidance

- 1.1 It is recommended that electroconvulsive therapy (ECT) is used only to achieve rapid and short-term improvement of severe symptoms after an adequate trial of other treatment options has proven ineffective and/or when the condition is considered to be potentially life-threatening, in individuals with:
- severe depressive illness
 - catatonia
 - a prolonged or severe manic episode.
- 1.2 The decision as to whether ECT is clinically indicated should be based on a documented assessment of the risks and potential benefits to the individual, including: the risks associated with the anaesthetic; current co-morbidities; anticipated adverse events, particularly cognitive impairment; and the risks of not having treatment.
- 1.3 The risks associated with ECT may be enhanced during pregnancy, in older people, and in children and young people, and therefore clinicians should exercise particular caution when considering ECT treatment in these groups.
- 1.4 Valid consent should be obtained in all cases where the individual has the ability to grant or refuse consent. The decision to use ECT should be made jointly by the individual and the clinician(s) responsible for treatment, on the basis of an informed discussion. This discussion should be enabled by the provision of full and appropriate information about the general risks associated with ECT (see Section 1.9) and about the risks and potential benefits specific to that individual. Consent should be obtained without pressure or coercion, which may occur as a result of the circumstances and clinical setting, and the individual should be reminded of their right to withdraw consent at any point. There should be strict adherence to recognised guidelines about consent and the involvement of patient advocates and/or carers to facilitate informed discussion is strongly encouraged.
- 1.5 In all situations where informed discussion and consent is not possible advance directives should be taken fully into account and the individual's advocate and/or carer should be consulted.

- 1.6 Clinical status should be assessed following each ECT session and treatment should be stopped when a response has been achieved, or sooner if there is evidence of adverse effects. Cognitive function should be monitored on an ongoing basis, and at a minimum at the end of each course of treatment.
- 1.7 It is recommended that a repeat course of ECT should be considered under the circumstances indicated in 1.1 only for individuals who have severe depressive illness, catatonia or mania and who have previously responded well to ECT. In patients who are experiencing an acute episode but have not previously responded, a repeat trial of ECT should be undertaken only after all other options have been considered and following discussion of the risks and benefits with the individual and/or where appropriate their carer/advocate.
- 1.8 As the longer-term benefits and risks of ECT have not been clearly established, it is not recommended as a maintenance therapy in depressive illness.
- 1.9 The current state of the evidence does not allow the general use of ECT in the management of schizophrenia to be recommended.
- 1.10 National information leaflets should be developed through consultation with appropriate professional and user organisations to enable individuals and their carers/advocates to make an informed decision regarding the appropriateness of ECT for their circumstances. The leaflets should be evidence based, include information about the risks of ECT and availability of alternative treatments, and be produced in formats and languages that make them accessible to a wide range of service users.

2 Clinical need and practice

- 2.1 This appraisal considers electroconvulsive therapy (ECT) in the treatment of: depressive illness, schizophrenia, catatonia and mania.
- 2.2 Depressive illness is associated with discrete episodes that are characterised by feelings of sadness, despair, loss of interest in daily life and discouragement. The severity of depressive illness is determined by the number, intensity and frequency or persistence of depressive symptoms and the presence of specific symptoms such as delusions, hallucinations and suicidal ideation. Severe depressive illness can deteriorate into a 'depressive stupor' where a person is conscious but is non-responsive to any stimulation. This extreme manifestation of depressive illness has become less frequent because of the advent of modern treatments.
- 2.3 Schizophrenia is characterised by a broad range of cognitive, emotional and behavioural problems, which are in general classified into positive and negative symptoms. Individuals with delusions or hallucinations are described as psychotic.
- 2.4 Catatonia is a syndrome that is associated with both schizophrenia and affective (mood) disorders. It is characterised by marked changes in muscle tone or activity that may alternate between the extremes of a deficit of movement (catatonic stupor) and excessive movement (catatonic excitement).
- 2.5 Mania is characterised by elated, euphoric or irritable mood and increased energy. The term may refer to a mental disorder or to a mood state or symptom, and mania is associated with bipolar disorders. In severe manic episodes, individuals are psychotic and require continual supervision to prevent physical harm to themselves or others.
- 2.6 In 2000, the Psychiatric Morbidity Survey conducted by the Office of National Statistics (ONS) found the prevalence of a depressive episode per thousand population to be 25 in England and 37 in Wales. The prevalence of schizophrenia is estimated at between 2 and 10 per 1000 in the general population, and the incidence of first-onset schizophrenia is approximately 1 per 10,000 population per year. Recent estimates have suggested that bipolar affective disorder has a point prevalence of up to 50 per 1000 of the general population, of whom 1% are admitted to hospital for mania each year. There are no recent epidemiological studies on the incidence of catatonia.

- 2.7 Depressive illness, schizophrenia and mania are frequently chronic, relapsing conditions and are associated with considerable suicide risk. Diagnosable depressive disorders are implicated in between 40% and 60% of suicide attempts. The 2000 ONS Psychiatric Morbidity Survey found that in individuals with a current depressive episode, 5% reported a suicide attempt within the past year. Common estimates are that 10% of people with schizophrenia will eventually have a completed suicide, and that attempts are made at two to five times that rate.
- 2.8 Severe mental health disorders are associated with considerable personal suffering, occupational and social disadvantage and impairment in interpersonal and family relationships in the long term. They also have a high economic impact, with the indirect costs far exceeding the direct costs.
- 2.9 Depressive illness is managed with antidepressants, psychotherapy and counselling, either alone or in combination. Although the management of schizophrenia frequently centres on antipsychotic medication, individuals also require substantial clinical, emotional and social support. Catatonia is usually treated with benzodiazepines; the introduction of effective psychotropic agents has led to a marked reduction in its prevalence. Acute manic episodes are treated with antipsychotics, lithium or anticonvulsants. Many individuals with mental health disorders benefit from self-help techniques including support groups.
- 2.10 ECT is used in current UK clinical practice as a treatment option for individuals with depressive illness, catatonia and mania. It is also occasionally used to treat schizophrenia. Guidelines for the use of ECT were developed by the Royal College of Psychiatrists in 1995 and are currently undergoing revision. Guidance for nurses has also been produced by the Royal College of Nursing.

3 The technology

- 3.1 During ECT, an electric current is passed briefly through the brain, via electrodes applied to the scalp, to induce generalised seizure activity. The individual receiving treatment is placed under general anaesthetic and muscle relaxants are given to prevent body spasms. The ECT electrodes can be placed on both sides of the head (bilateral placement) or on one side of the head (unilateral placement). Unilateral placement is usually to the non-dominant side of the brain, with the aim of reducing cognitive side effects. The amount of current required to induce a seizure (the seizure threshold) can vary up to 40 fold between individuals.
- 3.2 Although ECT has been used since the 1930s, there is still no generally accepted theory that explains its mechanism of action. The most prevalent hypothesis is that it causes an alteration in the post-synaptic response to central nervous system neurotransmitters.
- 3.3 In recent years, there have been moves to improve standards in the administration of ECT, with the introduction of practice guidelines published by the Royal College of Psychiatrists and the Royal College of Nursing, and the monitoring of the implementation of these guidelines through ongoing audit. However, there is still variation in the use and practice of ECT within England and Wales.
- 3.4 ECT administration affects the central nervous system and causes changes in cardiovascular dynamics, which dictates the need for special caution in those individuals who are at increased risk of a cardiovascular event. There are also other immediate potential complications, such as status epilepticus, laryngospasm and peripheral nerve palsy, which overall have an estimated incidence of 1 per 1300 to 1400 treatments. The mortality associated with ECT is reported not to be in excess of that associated with the administration of a general anaesthetic for minor surgery.
- 3.5 ECT may cause short- or long-term memory impairment for past events (retrograde amnesia) and current events (anterograde amnesia). As this type of cognitive impairment is a feature of many mental health problems it may sometimes be difficult to differentiate the effects of ECT from those associated with the condition itself. In addition there are differences between individuals in the extent of memory loss secondary to ECT and their perception of the

loss. However, this should not detract from the fact that a number of individuals find their memory loss extremely damaging and for them this negates any benefit from ECT.

- 3.6 Advance directives are statements made by an individual that express decisions about the healthcare they wish to receive, in anticipation of a time when they may not be competent to make or communicate such decisions. Clinicians are legally obliged to take informed and unambiguous advance refusals of treatment made by a competent individual into account unless: (1) it does not apply to the circumstances that have arisen; (2) the Mental Health Act is used to override the individual's intentions about treatment; (3) it requires the clinician to do something illegal; or (4) it requires treatment that the clinician considers not to be in the individual's best interests. Advance consents are not legally binding because specific medical treatment cannot be demanded, but clinicians should generally take such wishes into account.
- 3.7 The number of sessions undertaken during a course of ECT usually ranges from 6 to 12, although a substantial minority of patients respond to fewer than 6 sessions. ECT is usually given twice a week; less commonly it is given once a fortnight or once a month as continuation or maintenance therapy to prevent the relapse of symptoms. It can be given on either an inpatient or day patient basis. In England between January and March 1999, there were 16,482 administrations of ECT to 2835 individuals, 41% of whom were aged 65 years or over. Seventy-five per cent of the individuals were not formally detained under the Mental Health Act 1983, and of the 709 individuals formally detained, 59% did not or were not able to consent to treatment.
- 3.8 Six treatment sessions of ECT have been estimated to cost £2475. This does not include inpatient costs, estimated as £171 per day.

4 Evidence and interpretation

The Appraisal Committee considered evidence from a number of sources (see Appendix B).

4.1 Clinical effectiveness

- 4.1.1 The evidence presented in the Assessment Report was primarily drawn from a recent Cochrane Review of ECT in schizophrenia and a systematic review commissioned by the Department of Health on the use of ECT in schizophrenia, depressive illness and mania. Both reviews are of high quality and consider a total of 119 randomised controlled trials (RCTs) and a number of observational studies. Evidence submitted by patient and professional groups was also considered.
- 4.1.2 There were problems with the design of many of the RCTs. A large proportion were conducted before the introduction of modern techniques of administering ECT, and therefore do not reflect current practice. There were large variations in the parameters of the ECT administered that included the machine used, the number of sessions, the dosage and wave form, electrode placement, and the type and dosage of concomitant therapy. A number of studies used fixed dosage rather than individual thresholds. There was little evidence to support the routine prescription of a set number of treatment sessions per course of ECT or of the value of continuation (maintenance) ECT. The validity of many of the measurement scales used in the studies to measure outcome has not been clearly established and no study adequately captured either users' views or quality of life.
- 4.1.3 The Assessment Report reviews data from 90 RCTs in individuals with depressive illness, of different grades of clinical severity, who were referred for ECT. Overall, these RCTs provide evidence that real ECT (that is, where an electric current was applied) is more effective than sham ECT (where no electric current was applied) in the short term. The data provide evidence that the stimulus parameters have an important influence on efficacy; at the end of a course of treatment, bilateral ECT was reported to be more effective than unilateral ECT. Raising the electrical stimulus above the individual's seizure threshold was found to increase the efficacy of unilateral ECT at the expense of increased cognitive impairment. In trials comparing ECT with pharmacotherapy, ECT had greater benefit than the use of certain antidepressants but the trials were of variable quality

and inadequate doses and durations of drug therapy were frequently used. The combination of ECT with pharmacotherapy was not shown to be superior to ECT alone, although the duration of the RCTs was insufficient to show whether pharmacotherapy was beneficial. Compared with placebo, continuation pharmacotherapy with tricyclic antidepressants and/or lithium reduced the rate of relapses in people who had responded to ECT. Preliminary studies indicate that ECT is more effective than repetitive transcranial magnetic stimulation.

- 4.1.4 Evidence from 25 RCTs suggests that ECT may be effective in acute episodes of certain types of schizophrenia and reduce the occurrence of relapses, although the results are not conclusive and the design of many of the studies did not reflect current practice. The data on differing efficacy related to electrode placement and stimulus parameters are equivocal and firm conclusions could not be drawn. No RCT investigated the use of ECT in comparison with atypical antipsychotics, and the studies that included individuals with treatment-resistant schizophrenia did not consider the use of clozapine. The combined weight of evidence suggests that ECT is not more effective, and may be less effective, than antipsychotic medication. The combination of ECT and pharmacotherapy may be more effective than pharmacotherapy alone, but the evidence is not conclusive.
- 4.1.5 The four RCTs reviewed in the Assessment Report suggest that ECT may be of benefit in the rapid control of mania and catatonia and this suggestion is supported by evidence from a number of observational studies and testimony from clinical experts. However, the evidence on which to base any general conclusions about the effectiveness of ECT or to determine the most appropriate therapeutic strategy is weak.
- 4.1.6 There is clear evidence that cognitive impairment occurs both immediately after administration of ECT and following a course of therapy, and this may cause considerable distress to those affected. The impairment is greater in individuals who have had electrodes applied bilaterally than in those who have had them placed unilaterally, and unilateral placement to the dominant hemisphere causes more impairment than placement to the non-dominant hemisphere. A reduction in the risk of cognitive impairment is, however, mirrored by a reduction in efficacy. There is some limited evidence from RCTs to suggest that the effects on cognitive function may not last beyond 6 months, but this has been inadequately researched. There is also evidence to suggest that the impairment of cognitive function associated with ECT differs

between individuals and that it is linked to the dose administered, although the relationship with the seizure threshold has not been adequately defined. There is no evidence to suggest that the effect of ECT on cognitive function differs between diagnoses.

- 4.1.7 In addition to testimony from user groups, a systematic review of evidence from non-randomised studies relating to patients' accounts and experiences of ECT was also considered. This provided important evidence on the experiences of individuals receiving ECT, particularly cognitive impairment and its impact, and the validity of neuropsychological instruments used in clinical trials. There was evidence that the measurement scales used in RCTs do not adequately capture the nature and extent of cognitive impairment, and qualitative studies have indicated that the impairment may be prolonged or permanent. Additionally, there was testimony that individuals are not provided with sufficient information on which to base a decision regarding consent. Also, some individuals are unaware of their rights to refuse treatment, or may feel unable to do so because of the perceived threat of detainment under the Mental Health Act.
- 4.1.8 There was no evidence to suggest that the mortality associated with ECT is greater than that associated with minor procedures involving general anaesthetics, and there were limited data on mortality extending beyond the trial periods. The six reviewed studies that used brain-scanning techniques did not provide any evidence that ECT causes brain damage. While there is no evidence to suggest that benefits and safety are age-dependent, there are no studies on the impact of ECT on the developing brain. Furthermore, it is likely that co-morbidities could increase the risk of harm. The use of ECT during pregnancy is known to cause complications, but the risks associated with ECT need to be balanced against the risks of using alternative (drug) treatments.

4.2 Cost effectiveness

- 4.2.1 There are no published economic studies relating to ECT, and none of the submissions from consultees contained any economic analyses. The Assessment Group therefore constructed economic models of ECT for depressive illness and schizophrenia based on a review of published evidence. They were not able to construct robust models for mania and catatonia because of the low volume of data in these areas.

- 4.2.2 The depressive illness model had a 1-year time horizon and compared the cost effectiveness of inpatient ECT with other inpatient treatments for adults with severe depressive illness. The key comparators were different classes of antidepressants, with lithium given in addition for third-line therapy. After three drug treatment strategies, non-responders were assumed to receive 8 weeks of psychotherapy and to make a moderate improvement.
- 4.2.3 The results of the depressive illness model showed that, for eight different scenarios, total costs range from £10,592 to £15,354, and total quality-adjusted life years (QALYs) range from 0.424 to 0.539. Given the small differences in total costs and QALYs between the strategies that included ECT and the one that did not, and the uncertainty in the data available, ECT and pharmacotherapy are likely to be equally cost effective.
- 4.2.4 The schizophrenia model also had a 1-year time horizon and compared the cost effectiveness of ECT in combination with a typical antipsychotic with that of (a) clozapine, and (b) chlorpromazine or haloperidol for adults hospitalised with treatment-resistant schizophrenia of moderate symptomatology.
- 4.2.5 The results of the schizophrenia model suggest that ECT is dominated by clozapine – that is, ECT is associated with fewer QALYs (0.842 vs 0.863) at a higher cost (£55,267 vs £34,787). For individuals who do not respond to clozapine, ECT dominates chlorpromazine/haloperidol, resulting in more QALYs (0.842 vs 0.820) at a lower cost (£55,267 vs £58,265). However, these results do not take into account the degree of uncertainty in the estimates of both cost and effectiveness.
- 4.2.6 To summarise, there is no published evidence regarding the cost effectiveness of ECT. The modelling exercises undertaken by the Assessment Group, while fairly crude and based on a number of uncertain assumptions, suggest that – for those with severe depressive illness and treatment-resistant schizophrenia – ECT and pharmacological treatment may be equally cost effective, with no consistent differences in costs or outcomes.

4.3 Consideration of the evidence

- 4.3.1 The Committee reviewed the evidence on both the clinical effectiveness and the cost effectiveness of ECT. It considered written and verbal evidence on the nature of the conditions and the experience of people who have received or may be eligible for ECT, those who represent them, and clinical experts. It was also mindful of the need to ensure that its advice took account of the efficient use of NHS resources.
- 4.3.2 The evidence submitted to the Committee, both written and verbal, demonstrated that, on balance, current opinion is that ECT is an effective treatment for certain subgroups of individuals with mental disorders. However, opinion varies from those who consider that its adverse effects are tolerable to those who consider that it is associated with unacceptable side effects including brain damage, severe confusion and considerable cognitive impairment in both the short and longer terms. While some individuals considered ECT to be a beneficial and lifesaving treatment, others reported feelings of terror, shame and distress, and found it positively harmful and an abusive invasion of personal autonomy, especially when it was administered without their consent.
- 4.3.3 In consideration of these extremes of opinion, the Committee concluded that the wishes of the patient must be of paramount importance and that it is essential that all attempts should be made to obtain valid and informed consent, following recognised guidelines. The Committee felt strongly that consent should never be obtained by coercion – either explicit or implicit – through threat of compulsory treatment under the Mental Health Act, and mechanisms to monitor and prevent this from occurring should be developed and implemented, in consultation with appropriate professional and user organisations.
- 4.3.4 Testimony was heard that the information currently given to individuals does not always adequately inform consent, and the Committee discussed the need for nationally agreed evidence-based patient information leaflets. These should be accessible to a wide range of service users (see Section 7) and should emphasise the right of the individual to withhold consent or to withdraw it at any point.
- 4.3.5 While the limitations of advance directives were appreciated (see Section 3.7), the Committee believed that, whenever possible, they should be developed and documented in individuals' care programmes and be taken into account when considering ECT.

- 4.3.6 The Committee considered that, on the evidence put before it, the short-term effectiveness of ECT in individuals with severe depressive illness has been demonstrated. There is less robust RCT evidence to suggest that it is effective in the acute treatment of catatonia and mania. However, the Committee considered that the data appraised, taken in conjunction with the strength of clinical opinion and the experiences of users, provided a sufficient basis on which to recommend the use of ECT in restricted circumstances when the alternative treatment options have proven ineffective. The evidence for the effectiveness of ECT in schizophrenia in general was not conclusive and therefore ECT is not recommended in this population. Further research is required to establish clearly the benefits in subgroups of individuals with schizophrenia, for example those with severe symptoms of depressive illness or catatonia.
- 4.3.7 The Committee considered that there was no conclusive evidence to support the effectiveness of ECT beyond the short term or that it is more beneficial as a maintenance therapy in depressive illness than currently available pharmacological alternatives. It was particularly concerned that the value of ECT maintenance therapy remained unproven in the context of the lack of information on whether the adverse effects of ECT (for example, on cognitive function) may be cumulative with repeated administration.
- 4.3.8 In appreciation of the special circumstances in which ECT is administered and the recognition that RCTs cannot adequately capture the long-term effects of ECT, the Committee took special note of the evidence from observations of users' experiences relating to the adverse effects of ECT. In particular, the incidence, extent and timescale of cognitive impairment following ECT was discussed in detail. It was apparent that the nature of cognitive impairment experienced by users was variable and often long lasting to such a degree that it outweighed their perception of any benefit from ECT treatment. The Committee considered that further research, both qualitative and quantitative, was needed to define the effect of ECT on cognitive impairment, especially whether the effects are cumulative with repeated administrations. It was also concerned that the potential for cognitive impairment following ECT may not be highlighted during the consent process. These factors featured significantly in the Committee's deliberations, and specifically in its decision to restrict the use of ECT to situations in which all other alternatives had been exhausted or where the nature of the mental illness was considered to be 'life-threatening'.

- 4.3.9 The Committee noted that the efficacy and adverse effects of ECT are clearly linked to the method of delivery, although the optimum technique and stimulus parameters have not been adequately researched; for example, gains in efficacy as a result of modifications to electrode placement and stimulus parameters are achieved at the expense of an increased risk of cognitive side effects. The Committee therefore considered that the evidence was not sufficient to allow conclusions to be drawn.
- 4.3.10 The RCT evidence considered by the Committee also leaves unanswered a number of important questions, and these require further research (see Section 5). Consideration was given to the fact that the majority of the RCTs are not applicable to modern practice because of advances in pharmacological management and ECT administration techniques. The outcomes considered in the RCTs also did not adequately capture the experience of service users, and the validity of many of the scales used to measure outcome had not been clearly established. There was insufficient information to allow appropriate risk–benefit assessment for certain groups of individuals, for example during pregnancy, in older individuals, and in children and young people. Of particular concern were the lack of research into the number of treatment sessions that should be given, and the lack of long-term evidence regarding adverse effects on cognitive function and mortality. The Committee could not establish, in the context of the use of appropriate pharmacological treatment, the value of ‘maintenance’ ECT therapy following its use to achieve rapid and short-term improvement of severe symptoms. The Committee was persuaded on the balance of the evidence received from patients and carers that the practice of ‘continuation’ of ECT therapy for short periods following the initial control of severe symptoms was only acceptable in the context of Sections 1.6 and 1.7 of the guidance.
- 4.3.11 The ongoing deficiencies in current practice were highlighted to the Committee, and the Committee strongly believed that action is required to ensure that appropriate standards of care are enforced whenever ECT is undertaken and that outcomes are continuously monitored. The Committee considered that ECT should be administered only in a suitably equipped unit by professionals who have been trained in its delivery and in the anaesthetic techniques required for the administration of ECT. These professionals should maintain an appropriate level of skill, both through the regular clinical practice of ECT and through undertaking appropriate continuing professional development. Urgent consideration should be given to the establishment of units

dedicated to ECT, and of audit networks, which have been shown to be successful in Scotland.

- 4.3.12 Despite the uncertainty in the estimates of clinical effectiveness and the small differences in costs and outcomes generated in the economic models, the Committee considered that ECT is likely to be cost effective in appropriate patient groups.
- 4.3.13 In summary, the Committee considered that the evidence appraised supported the effectiveness of ECT in certain groups of individuals. However, the Committee recognised there remained a number of uncertainties, including a lack of information on longer-term outcomes. The Committee was aware of the negative experiences of some individuals who have undergone ECT. Therefore the Committee considered that that ECT should be used with caution and only in the restricted circumstances recommended in the guidance in Section 1. It is anticipated that NICE guidelines currently under development (see Section 8) will further define the place of ECT in the care pathways for individuals with depressive illness.

5 Recommendations for further research

- 5.1 There are a number of ongoing research projects that include studies of clinical and cost effectiveness in specific groups and an examination of the effects of seizure parameters.
- 5.2 Further research is urgently required to examine the long-term efficacy and safety of ECT, including its use as a maintenance therapy and its use in particular subgroups who may be at increased risk, for example older people, children and young people, and during pregnancy. This research should reflect modern techniques and the use of ECT in comparison with and in conjunction with the antipsychotic and antidepressant drugs used in current practice. In addition to the use of appropriately validated psychometric scales, outcome measures should include user perspectives on the impact of ECT, the incidence and impact of important side effects such as cognitive functioning, and mortality.
- 5.3 Further research into the mechanism of action of ECT is encouraged, because it may provide important information on aetiology and future treatment strategies.

- 5.4 It is clear that the stimulus parameters impact on the safety and efficacy of the technique and recent research needs to be augmented. Further evaluation is needed of whether it is necessary to induce a full seizure for therapeutic effect, and how the efficacy and cognitive effects are influenced by the amount by which the applied electrical dose exceeds the seizure threshold.
- 5.5 More research is also needed to determine the cost effectiveness of ECT. In particular, better quality-of-life information is needed for people considered for, or who have received, ECT.

6 Implications for the NHS

- 6.1 As this guidance recommends the use of ECT only in certain restricted circumstances, it is not anticipated that the guidance will increase the use of ECT in England and Wales above current levels. As ECT appears to be of similar cost to alternative treatments, it is unlikely that a change in the use of ECT will result in an increase or decrease in NHS expenditure. However, there will undoubtedly be costs associated with addressing the continuing deficiencies in the standards of care that have been highlighted (see Section 3.3).

7 Implementation and audit

- 7.1 NHS Trusts should ensure that ECT is carried out in accordance with the recommendations in Section 1 and only by clinical staff trained in its application. Such staff should maintain an appropriate level of skill through routine practice and continuing professional development.
- 7.2 NHS Trusts currently offering ECT, and all clinicians involved in the care of individuals receiving ECT, should review policies and practices regarding its use to take account of the guidance set out in Section 1.
- 7.3 Local guidelines or care pathways involving ECT should incorporate the guidance in Section 1.
- 7.4 To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix D.

- 7.4.1 ECT is used only for an individual with any of the following:
- severe depressive illness
 - catatonia
 - a prolonged or severe manic episode.
- 7.4.2 ECT is used only to achieve rapid and short-term improvement of an individual's severe symptoms after an adequate trial of other treatment options has proven ineffective and/or when the condition is considered to be potentially life threatening.
- 7.4.3 An assessment of the risks and potential benefits to the individual undergoing ECT is documented. If the individual is pregnant, an older person, or a child or young person, the clinician(s) involved should exercise particular caution and the individual or their advocate or carer should be made aware that the risks associated with ECT may be enhanced in these circumstances.
- 7.4.4 The individual undergoing ECT provides valid consent if he or she has the ability to grant or refuse consent. In situations where joint decision making, informed discussion and consent are not possible, advance directives are fully taken into account and the individual's advocate and/or carer is consulted.
- 7.4.5 The consent process provides that the clinician(s) responsible for treatment:
- involves the individual's advocate and/or carer where possible
 - provides full and appropriate information in a suitable format and language to enable an informed discussion
 - explains and discusses the general risks of ECT, risks specific to the individual and potential benefits to the individual
 - does not pressure or coerce the individual into consent to the treatment
 - reminds the individual that he or she has the right to withdraw consent at any point.

- 7.4.6 The individual's clinical status is assessed following each ECT session and the individual's cognitive function is monitored on an ongoing basis and at a minimum at the end of each course of treatment.
- 7.4.7 ECT treatment is stopped once a response is achieved, if there is evidence of adverse effects, or if the individual withdraws consent.
- 7.4.8 A repeat course of ECT is considered only for an individual:
- under the circumstances described in 7.4.1 and 7.4.2 above who has previously responded well to ECT
 - who has not responded previously but is experiencing an acute episode and all other options have been considered, and following discussion with the individual and/or where appropriate the carer/advocate of the risks and benefits of such a course of action.
- 7.4.9 ECT is not used as a maintenance therapy in depressive illness.
- 7.4.10 ECT is not used in the general management of schizophrenia.
- 7.5 Local clinical audits should include input from service users on at least criteria 7.4.4–7.4.9 and reference to standards in the current handbook on ECT published by the Royal College of Psychiatrists and the Royal College of Nursing, and the suggested indicators for audit of anaesthesia for ECT published by the Royal College of Anaesthetists.

8 Related guidance

- 8.1 The Institute has issued guidance on the use of newer (atypical) antipsychotic drugs for the treatment of schizophrenia.
- National Institute for Clinical Excellence (2002). Guidance on the use of newer (atypical) antipsychotic drugs for the treatment of schizophrenia. *NICE Technology Appraisal Guidance No. 43*. London: National Institute for Clinical Excellence. Available from: www.nice.org.uk
- 8.2 The Institute has issued guidance on the use of computerised cognitive behavioural therapy for depressive illness and anxiety,

- National Institute for Clinical Excellence (2002). Guidance on the use of computerised cognitive behavioural therapy for anxiety and depression. *NICE Technology Appraisal Guidance No. 51*. London: National Institute for Clinical Excellence. Available from: www.nice.org.uk
- 8.3 The Institute is preparing guidance on the use of atypical antipsychotics and anticonvulsants for the treatment of acute mania in bipolar affective disorder (anticipated publication date July 2003).
- 8.4 The Institute has issued guidelines for schizophrenia: core interventions in the treatment and management of schizophrenia in primary and secondary care. *NICE Clinical Guideline 1*. London: National Institute for Clinical Excellence. Available from: www.nice.org.uk. The Institute is preparing guidelines for depression (anticipated publication date September 2003) and depression in children (publication date to be confirmed).

9 Date for review of guidance

- 9.1 The guidance on this technology will be reviewed in November 2005.

Andrew Dillon
Chief Executive
April 2003

Appendix A

Appraisal Committee members

NOTE The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets twice a month other than in December, when there are no meetings. The Committee membership is split into two branches, with the chair, vice-chair and a number of other members attending meetings of both branches. Each branch considers its own list of technologies and topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declaration of interests, are posted on the NICE website.

Professor R L Akehurst
Dean, School of Health Related
Research, Sheffield University

Professor David Barnett (Chair)
Professor of Clinical
Pharmacology, University of
Leicester

Professor Sir Colin Berry
Retired Professor of Morbid
Anatomy & Histopathology, The
Royal London Hospital

Dr Sheila Bird
MRC Biostatistics Unit,
Cambridge

Professor Rosamund Bryar
Professor of Community &
Primary Care Nursing, St
Bartholomew's School of
Nursing & Midwifery, London

Professor Martin Buxton
Director of Health Economics
Research Group, Brunel
University, Uxbridge

Dr Karl Claxton
Health Economist, University of
York

Professor Sarah Cowley
Professor of Community Practice
Development, Kings College,
London

Mr Chris Evennett
(resigned June 2002)
Chief Executive, Mid-Hampshire
Primary Care Trust, Winchester

Professor Terry Feest
Clinical Director & Consultant
Nephrologist, Richard Bright
Renal Unit, & Chair of UK Renal
Registry, Bristol

Professor Gary A Ford

Professor of Pharmacology of
Old Age/Consultant Physician,
Newcastle upon Tyne Hospitals
NHS Trust

Mrs Sue Gallagher

Former Chief Executive, Merton,
Sutton & Wandsworth Health
Authority, London

Dr Trevor Gibbs

Head, Global Clinical Safety &
Pharmacovigilance,
GlaxoSmithKline, Greenford

Mr John Goulston

Director of Finance, St
Bartholomew's Hospital & the
London NHS Trust

Professor Philip Home

Professor of Diabetes Medicine,
University of Newcastle upon
Tyne

Dr Terry John

General Practitioner, The Firs,
London

Dr Diane Ketley

(term of office ended August
2002)

Research into Practice
Programme Leader, NHS
Modernisation Agency, Leicester

Dr Mayur Lakhani

(term of office ended August
2002)

General Practitioner, Highgate
Surgery, Leicester, & Lecturer,
University of Leicester

Mr Muntzer Mughal

Consultant Surgeon, Lancashire
Teaching Hospitals NHS Trust,
Chorley

Mr James Partridge

Lay Representative, Chief
Executive, Changing Faces,
London

Professor Philip Routledge

Professor of Clinical
Pharmacology, College of
Medicine, University of Wales,
Cardiff

**Professor Andrew Stevens
(Vice-Chair)**

Professor of Public Health,
University of Birmingham

Dr Cathryn Thomas

General Practitioner, & Senior
Lecturer, Department of Primary
Care & General Practice,
University of Birmingham

Dr David Winfield

Consultant Haematologist, Royal
Hallamshire Hospital, Sheffield

Appendix B

Sources of evidence considered by the Committee

The following documentation and opinions were made available to the Committee:

- A** **Assessment Report** prepared by The School of Health and Related Research, University of Sheffield and Nuffield Institute for Health, University of Leeds
Electroconvulsive Therapy (ECT) for Depressive Illness, Schizophrenia, Catatonia and Mania, May 2002
- B** **Professional/specialist group submissions** from:
- British Psychological Society
 - Department of Health and Welsh Assembly Government
 - Health Technology Board for Scotland
 - Hertfordshire Health Authority (now Welwyn Hatfield Primary Care Trust)
 - Mental Health Act Commission
 - Nursing and Midwifery Council
 - Portsmouth City PCT
 - Royal College of Anaesthetists
 - Royal College of Psychiatrists ECT Sub-committee
- C** **Patient/carers group submissions** from:
- Depression Alliance
 - ECT Anonymous
 - Long Term Medical Conditions Alliance
 - Manic Depression Fellowship
 - MIND
 - Rethink (formally the National Schizophrenia Fellowship)
 - Sane
 - UK Advocacy Network
- D** **Expert perspectives** from:
- Dr Ian Anderson, Senior Lecturer, Adult Psychiatry, Neuroscience and Psychiatry Unit, University of Manchester
 - Andy Brogan, Clinical Executive, Bolton, Salford and Trafford Mental Health Partnership
 - Dr C John Bowley, Consultant Anaesthetist, Nottingham City Hospital
 - Alison Faulkner, Freelance User/Consultant, Service User Research Enterprise (on behalf of MIND)
 - Pete Fleischmann, Researcher and User Involvement Consultant, Service User Research Enterprise (on behalf of MIND)

- Dr Chris Freeman, Chair, Royal College of Psychiatrists ECT sub-Committee
- Louise Puddephatt, Co-chair and ECT Representative, UK Advocacy Network
- Peter Relton, Co-chair, Bradford and District Mental Health Forum (member organisation of UK Advocacy Network)

E. National Collaborating Centre for Mental Health perspective from:

- Mr Stephen Pilling, Co-Director, National Collaborating Centre for Mental Health

Appendix C

The use of electroconvulsive therapy

Understanding NICE guidance – information for service users, their advocates and carers, and the public

The information in this appendix has been designed to support the production of your own information leaflets. You can download it from our website at www.nice.org.uk where it is available in English and Welsh. If you would like printed copies of the leaflets please ring the NHS Response Line on 0870 1555 455 and quote reference number N0207 for the English version and N0208 for the version in English and Welsh.

What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance for both the NHS and patients on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures and under what circumstances they should be used.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance. Each appraisal takes about 12 months to complete.

NICE was asked to look at the available evidence on electroconvulsive therapy and to provide guidance that will help the NHS in England and Wales decide when it should be used.

What are depressive illness, mania, schizophrenia and catatonia?

Depressive illness, mania and schizophrenia are all mental health disorders.

Depressive illness is associated with a change in mood that may not have an obvious cause. It involves feelings of sadness, despair, hopelessness and helplessness, lack of interest in life and difficulty concentrating. These feelings deepen over time. People with severe depressive illness may be unable to eat or sleep or to take part in social activities, and may become completely withdrawn. They may think about harming or killing themselves.

'Mania' is when someone has an extreme elevation of mood, which isn't accounted for by what is happening in his or her life, over-activity and sometimes irritability. People with mania often develop beliefs that they are very powerful, strong or important in ways they wouldn't normally think. When it's very severe, people experiencing a manic episode may do socially unacceptable things they would never normally do, or may try to harm themselves. Sometimes mania occurs on its own but more often it is part of another disorder, bipolar disorder (or manic-depressive illness), when someone experiences periods of mania and depression.

Schizophrenia is a major mental illness that involves a range of symptoms that affect understanding, emotion and behaviour. When people are ill with schizophrenia they usually hear voices (hallucinations) and develop strange ideas and beliefs that others don't agree with (delusions), although exactly what type of symptoms a person has is very individual. Typically in schizophrenia, there's a pattern of repeated breakdowns (or 'acute episodes') but some people are never ill again after the first episode and a small number of people remain ill for much of the time.

Catatonia is characterised by abnormalities of movement or posture. It is sometimes associated with schizophrenia or with mood disorders. Someone with catatonia may remain rigid and unmoving and may stop eating and drinking, or they may become very excited for no apparent reason and move around excessively.

Treatments for depressive illness include medicines, counselling and psychotherapy, which can be given alone or in combination. Treatment for schizophrenia often centres on antipsychotic medicines, but can also include psychological treatments such as family therapy and cognitive behavioural therapy. Catatonia and episodes of mania are usually treated with medicines.

What is electroconvulsive therapy?

Electroconvulsive therapy (or ECT for short) is a treatment that has been used in the treatment of depressive illness, mania, catatonia and, occasionally, schizophrenia. Although ECT has been used since the 1930s, how it works is still not fully understood.

During ECT, electrodes are put onto the head and an electric current is passed briefly through the electrodes to the brain, which causes a seizure (a 'fit'). ECT is given under a general anaesthetic and a muscle relaxant is also given to prevent body spasms.

Usually ECT is given twice a week for 3 to 6 weeks (that is, a course of 6 to 12 sessions of ECT in all). Sometimes, it is given once every 2 weeks or once a month to prevent the symptoms returning.

The heart and blood pressure can be affected by ECT, but the most common problem people report after ECT is short-term or long-term memory loss, which can be very distressing.

There are laws concerning people's consent to have ECT; at the time that this guidance was issued, the draft Mental Health Bill (June 2002), which deals with some of the specific issues that are applicable to ECT, was under consultation.

People can make 'advance directives' about their treatment. An advance directive is a written statement made by someone who is mentally capable of deciding about the treatment they want or do not want to receive if the need arises in the future and they are mentally incapable of giving consent. Advance directives guide health professionals in the event that someone becomes unable to make decisions for him or herself.

What has NICE recommended?

NICE has looked carefully at the evidence and has recommended that ECT should only be used for the treatment of severe depressive illness, a prolonged or severe episode of mania, or catatonia if the conditions described in the following paragraphs are applied.

ECT should be used to gain fast and short-term improvement of severe symptoms after all other treatment options have failed, or when the situation is thought to be life-threatening.

A risk–benefit assessment for the individual should be made and documented. It should include the risks associated with the anaesthetic, whether the person has other illnesses, the possible adverse effects of ECT (particularly problems with memory), and the risks of not having treatment.

Doctors should be particularly cautious when considering ECT treatment for women who are pregnant and for older or younger people, because they may be at higher risk of complications with ECT.

Someone who is mentally capable of making a decision about their treatment should decide, after discussion with the doctor, whether or not they want to give their consent to have ECT. To help in the discussion, full and appropriate information about ECT should be given, including information about its potential risks and benefits, both general and specific to the individual. NICE recommends that information leaflets to help people to make an informed decision about their treatment should be developed nationally and should be available in formats and languages that will make them accessible to a wide range of service users.

The doctor should keep strictly to recognised guidelines about consent, should not put any pressure on the person to give their consent and should remind the person that they have the right to change their mind either for or against treatment at any time. NICE considers that doctors should encourage the involvement of an independent person who speaks on behalf of the service user (an ‘advocate’) or the person’s carer(s).

If discussion and informed consent are not possible at the time treatment is needed, any advance directive should be fully taken into account and someone who speaks on behalf of the person who is ill, or their carer(s), should be consulted.

The person should be re-assessed after every session of ECT. There should be ongoing checks for any signs of memory loss, and as a minimum, a check at the end of each course of treatment.

The treatment should be stopped as soon as the person has responded, if there are any adverse effects, or if they withdraw their consent.

It is recommended that more than one course of ECT should be considered only for people who have severe depressive illness, catatonia or mania and who have previously responded well to ECT. As for the first course of treatment, it should be used only to gain fast and short-term improvement of severe symptoms after all other treatment options have failed or when the situation is thought to be life-threatening. For someone who is experiencing an episode of severe depressive illness, catatonia or mania and who has not responded to a

previous course of ECT, the doctor should consider a repeat course of ECT only if all other treatment options have been considered and after discussion of the risks and benefits with the service user and where appropriate their advocate or carer.

NICE recommends that ECT should not to be used as a long-term treatment to prevent recurrence of depressive illness, and that it should not be used in the general management of schizophrenia.

What should I do?

If you or someone you care for might be recommended for ECT, you should discuss this guidance with your hospital doctor at your next appointment.

Will NICE review its guidance?

Yes. The guidance will be reviewed in November 2005.

Further information?

The NICE website (www.nice.org.uk) has further information on NICE and the full guidance on ECT that has been issued to the NHS. The guidance can also be requested from the NHS Response Line by phoning 0870 1555 455 and quoting reference N0205 .

If you have access to the Internet, you can find more information about depressive illness, manic–depressive illness, and schizophrenia on the NHS Direct website (www.nhsdirect.nhs.uk). You can also phone NHS Direct on 08 45 46 47.

Appendix D

Detail on criteria for audit of the use of electroconvulsive therapy

Objectives for an audit

An audit on electroconvulsive therapy (ECT) could be carried out to ensure that ECT is used appropriately.

Patients to be included in the audit

All individuals who have received ECT in a suitable time period for audit, for example, 6 months or 1 year. Alternatively, the audit could be undertaken concurrently with the provision of ECT treatments.

Measures that can be used as a basis for audit

The measures that can be used in an audit on ECT are as follows.

Criterion	Standard	Exception	Definition of Terms
1. The individual receiving ECT has one of the following: a. severe depressive illness b. catatonia c. a prolonged or severe manic episode	100% of individuals receiving ECT	None	Local clinicians will have to agree on how and where the indications for ECT are documented for audit purposes.
2. ECT is used to achieve rapid and short-term improvement of severe symptoms when an adequate trial of other treatment options has proven ineffective, and/or the individual has a potentially life-threatening condition	100% of individuals receiving ECT	None	Local clinicians will have to agree on how severe symptoms and response to other treatment options and potentially life-threatening conditions are documented for audit purposes.
3. An assessment of the risks and potential benefits of ECT for the individual is documented	100% of individuals receiving ECT	None	The documented assessment before treatment should note: risks associated with the anaesthetic; current co-morbidities; anticipated adverse events, including cognitive impairment; and the risks of no treatment.
4. The individual provides consent for each course of ECT treatment	100% of individuals receiving ECT	<p>A. The individual does not have the ability to grant or refuse consent, in which case advance directives are fully taken into account and the individual's advocate and/or carer are consulted.</p> <p>B. The individual is detained under the Mental Health Act</p>	<p>Local clinicians should agree on how consent to ECT is documented for audit purposes.</p> <p>A course of ECT is usually 6 to 12 sessions, usually given at the rate of two a week. The individual who has had/is having ECT should be asked for his/her views as to whether or not this criterion is being met.</p>

Criterion	Standard	Exception	Definition of Terms
5. The consent process provides that the clinician(s) responsible for treatment carries out all of the following: a. involves the individual's advocate and/or carer where possible b. provides full and appropriate information in a suitable format and language to enable an informed discussion c. explains and discusses the general risks of ECT, risks specific to the individual, enhanced risks for individuals in specific groups and potential benefits to the individual d. does not pressure or coerce the individual into consent to the ECT treatment e. reminds the individual that he/she has the right to withdraw consent at any point	100% of individuals receiving ECT	A. The individual is detained under the Mental Health Act B. The individual does not have the ability to grant or refuse consent but is compliant with treatment and 5a-e is carried out with an advocate and/or carer	Local clinicians should agree on how the format and language used to communicate the information provided and the involvement of advocates or carers prior to consent to ECT are documented for audit purposes. See 3 above for a list of general risks to be discussed. Groups of people for whom there may be enhanced risks to be discussed include individuals who are pregnant, older or a child or young person. The individual who has had/is having ECT should be asked for his/her views as to whether or not this criterion is being met.
6. The individual's clinical status is assessed after each ECT session	100% of individuals receiving ECT	None	Local clinicians should agree on what constitutes an assessment of clinical status following an ECT session.
7. The individual's cognitive function is monitored: a. on an ongoing basis and b. at a minimum at the end of each course of treatment	100% of individuals receiving ECT	None	Local clinicians should agree on what constitutes monitoring of cognitive function and how monitoring is documented for audit purposes. The individual who has had/is having ECT should be asked for his/her views as to whether or not this criterion is being met.

Criterion	Standard	Exception	Definition of Terms
8. ECT is stopped if one of the following occurs: a. a response is achieved b. there is evidence of adverse effects c. the individual withdraws consent	100% of individuals receiving ECT	None	Local clinicians will have to agree on what constitutes a desired response and evidence of adverse effects for audit purposes. The individuals who has had/is having ECT should be asked for his/her views as to whether or not this criterion is being met.
9. A repeat course of ECT is provided only for an individual in either one of the following circumstances: a. the individual meets criteria 1 and 2 above and has previously responded well to ECT or b. the individual has not responded previously but is experiencing an acute episode and all other options have been considered and following discussion with the individual and/or where appropriate the carer or advocate of the risks and benefits of such a course of action	100% of individuals receiving a repeat course of ECT	None	Local clinicians will have to agree on what constitutes a good response to ECT for audit purposes. See 4 above for definition of course of treatment. See 3 and 5 above for reference to risks.

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