National Institute for Clinical Excellence

Appraisal of ElectroConvulsive Therapy

Decision of the Appeal Panel

1. Introduction

1.1 The Appeal Panel convened a hearing on 12 February 2003 to consider an appeal against the Institute's Guidance to the NHS on ElectroConvulsive Therapy ("ECT") as set out in the Final Appraisal Determination ("FAD") of the Appraisal Committee dated November 2002.

1.2 The Appeal Panel comprised Dr Susanna Lawrence (Chair of the Appeal Panel and Non-Executive Director of the Institute), Mr Frederick George (Non-Executive Director of the Institute), Mrs Mary McClarey (Non-Executive Director of the Institute), Mrs Jean Gaffin (Patient Representative) and Dr Angus Sim (Industry Representative).

1.3 An appeal had been lodged by the Royal College of Psychiatrists ("the Appellant").

1.4 The Appellant was represented by Drs Chris Freeman, Allan Scott and Ian Anderson. A patient also attended the hearing as part of the Appellant's team in order to help address one of the specific appeal points.

1.5 The following members of the Institute's staff were also in attendance: Professor Peter Littlejohns (Executive Lead), Dr Sarah Garner (Technical Lead), Professor David Barnett (Chair of Appraisal Committee), Dr Carole Longson (Appraisal Programme Director), Ms Kathleen Dalby (Appraisal Project Manager) and Ms Alexandra Webb (Appraisal Administrator). Mr Julian Gizzi of Beachcroft Wansbroughs was present to provide legal advice to the Appeal Panel.

1.6 The three grounds upon which the Appeal Panel can hear an appeal are:

(1) The Institute has failed to act fairly and in accordance with its published procedures as set out in the Institute's Guide to the Technology Appraisal Process.

(2) The Institute has prepared guidance which is perverse in the light of the evidence submitted.

(3) The Institute has exceeded its powers.

1.7 The Appellant appealed under ground (2).

2. **Appeal Ground (2): The Institute has prepared guidance which is perverse in the light of the evidence submitted**.

2.1 Assertion a): The evidence base does not support the restriction of ECT to severe symptoms.

2.1.1 The Appeal Panel ascertained that the Assessment Report reviewed data from randomised clinical trials ("RCTs") assessing symptoms and treatment of individuals with a range of depressive illness. Both the Appraisal Committee and the Appellant agreed that the evidence base derived from these RCTs included patients with severe and moderate symptoms, and did not distinguish between them.

2.1.2 The Appeal Panel questioned Professor Barnett as to the reasoning which led the Appraisal Committee to recommend ECT for individuals with severe symptoms only. They heard that the Appraisal Committee had considered the acknowledged limitations of the evidence base, the lack of trials addressing long term effects, the evidence that described the patient experience, and in particular the concerns regarding impaired cognitive function. The Appeal Panel were told that the Appraisal Committee had concluded that, given the uncertainties regarding both the benefits and the adverse effects of treatment, the risk/benefit ratio justified the recommendation in FAD 1.1, but did not justify such a recommendation for individuals with moderate symptoms.

2.1.3 The Appeal Panel's assessment was that this was not a perverse judgment, and assertion a) was therefore dismissed.

2.1.4 However, it was agreed that the wording of the first sentence of FAD 4.1.3 was misleading in its reference to data from 90 RCTs in individuals with severe depressive illness. The Appeal Panel referred this to the Guidance Executive for rewording with the suggestion that the word "severe" should be omitted.

2.2 Assertion b): The guidance in FAD 1.1 is in conflict with that in FAD 1.2 and 1.4. If patient choice is paramount, then patients with moderate depression should be allowed to choose this type of treatment.

2.2.1 The Appeal Panel asked the Appellant to clarify this point. It became clear that the Appellant had interpreted FAD 4.3.3 to support the premise that patient choice is paramount. The Appeal Panel considered FAD 4.3.3 and decided that the statement that "the wishes of the patient must be of paramount importance" referred to issues of consent to treatment, rather than patient choice. The Appeal Panel believed that the meaning was clear when FAD 4.3.3 was read in its entirety,

and in the context of the preceding paragraphs.

2.2.2 The Appeal Panel examined FAD 1.2. and 1.4 in the light of the above, and concluded that there was no conflict between the paragraphs.

2.2.3 Assertion b) was therefore dismissed.

2.3 Assertion c): The Guidance requires sufferers of recurrent depressive illness, who have previously responded to ECT, to have to wait until their illness is either severe or life threatening before they could choose ECT.

2.3.1 The Appeal Panel established that this assertion referred to the recommendation in FAD 1.7 that a repeat course of ECT should be considered under the circumstances indicated in FAD 1.1 only for individuals who have severe depressive illness, catatonia or mania **and** who have previously responded well to ECT.

2.3.2 The Appeal Panel had already determined that the recommendation in FAD 1.1 that ECT be restricted to individuals with severe depressive illness is not perverse. This was on the basis that in the Appraisal Committee's judgement, the risk/benefit ratio supported treatment only for individuals with severe depressive illness. The Appeal Panel considered that the recommendation in FAD 1.7 was entirely consistent with FAD 1.1 and that it was not perverse to apply the same reasoning to repeat treatment. The Appeal Panel recognised, however, that a patient's previous history will be considered by a clinician reaching a judgement about an individual patient's management.

2.3.3 Assertion c) was therefore dismissed.

2.4 Assertion d): The FAD does not distinguish between continuation and maintenance therapy. FAD 1.8 states that ECT is not recommended as maintenance therapy in depressive illness. Some patients cannot stay well without maintenance treatments.

2.4.1 From questioning Professor Barnett, the Appeal Panel were satisfied that the Appraisal Committee properly appreciated the distinction between continuation and maintenance therapy, but noted that much of the evidence base did not make this distinction.

2.4.2 There was agreement that the evidence base for maintenance and continuation therapy in depressive illness was weak. The Appeal Panel considered that FAD 1.8 was a reasonable interpretation of the evidence before the Appraisal Committee and was not perverse.

2.4.3 Assertion d) was therefore dismissed.

2.4.4 The Appeal Panel judged, however, that the reference in FAD 4.3.10 to "continuation (maintenance) ECT" was unclear and referred this wording to the Guidance Executive for clarification.

2.5 Assertion e): FAD 3.6 requires clarification.

Although the Appeal Panel did not regard this observation as falling strictly within Appeal Ground (2), it was acknowledged that FAD 3.6, as drafted, did not present an accurate statement of the law. Whilst the Appeal Panel did not consider that this affected the recommendations in the FAD, they referred the matter to the Guidance Executive for clarification.

3. Outcome of Appeal

3.1 The Appeal Panel dismissed the appeal for the reasons stated in this decision.

3.2 There is no possibility of a further appeal within the Institute. However, the decision of the Appeal Panel and the Institute's decision to issue the Guidance may be challenged by an interested party through an application to the High Court for permission to apply for judicial review. Any such application must be made promptly and in any event within three months of this decision or the issue of the Guidance.

24 February 2003