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# Assessment and certification of neurosurgery for mental disorder

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The views expressed are based on experiences of a second opinion appointed doctor and refer to neurosurgery for mental disorder. Here the general issues are sharpened by the necessity to certify informed consent and the likelihood of the alleviation or the prevention of deterioration. In an age of evidence-based medicine the criteria by which these issues are judged are critical and need to be generally agreed. The evidence needed in clinical reports and in certification is considered from theoretical and practical viewpoints and suggestions are made in reference to treatment at both new and established centres.

Neurosurgery for the treatment of mental disorder is controlled in England and Wales by the provision of Section 57 of the Mental Health Act 1983. Under this legislation the opinions of the three persons concerned in the clinical decision, the referring psychiatrist, the tertiary psychiatrist and the neurosurgeon, must be confirmed by three other persons. Of these, the second opinion appointed doctor (SOAD) has a statutory duty under Section 57 (2a) to confirm consent, and additionally, under Section 57 (2b), to certify that the treatment is appropriate to the patient's condition. The two lay persons are concerned solely with assessing the validity of informed consent. All three are appointed by the Mental Health Act Commission, but each is held personally responsible for the decision taken. The SOAD is an intermediate position between the tertiary psychiatrist and the referring responsible medical officer (RMO) (consultant psychiatrist) who, in his normal practice, may only prescribe neurosurgery for the treatment of mental disorder occasionally. In Scotland, Section 97 of the Mental Health (Scotland) Act 1984 provides that similar certification is given by the Mental Welfare Commission for Scotland, but, at present, and unlike England, only in the case of detained patients. An extension of the provisions to informal patients in Scotland is under consideration (CRAG Working Group on Mental Illness, 1996).

## The problem

Throughout these procedures clinical decisions will be made on (a) the individual case history, in relation to (b) the clinically accepted standards of

case selection (i.e. the evidence that the treatment works). Both have an element of subjectivity. If case selection, certification and the explanations given to the patient are to be reasonably consistent and congruent between the six clinicians involved then the individual histories and the professional evidence on which decisions are taken must be well known and accepted by all. The SOAD has to make his decision in two different settings where patients may be referred from: established centres where results are well known from published works or emergent rather than established centres where results are not initially known and evidence only slowly accumulates. In both groups the SOAD faces problems.

## Established centres

Established centres such as The Brook and The Priory/Atkinson Morely axis have published evidence for both the benefits and the risks of their procedures (Kelly *et al.*, 1972; Kelly, 1980; Bridges *et al.*, 1994). These are descriptive, rather than controlled studies, but the reported probability of improvement ( $P=0.5-0.6$ ) is held to be sufficient to recommend neurosurgery for severe chronic depression or obsessive-compulsive disorder (OCD), when combined with failure to respond to other treatments, intense distress and intractability. The decision to proceed rests heavily upon these characteristics, especially the (predicted) intractable course. Yet, in cases referred for surgery, some improvement without neurosurgery for the treatment of mental disorder is still possible (Freeman, 1997). Such improvement presents a serious, but not totally destructive criticism of the prevailing uncontrolled evaluations. To follow Popper (Magee, 1986), it takes the observation of only one black swan (a recovered "intractable case") to disprove the hypothesis that all swans are white (i.e. that no operated cases will recover without surgery).

Controlled series (matched pairs) have been reported for early, less modified, operations encompassing a wider range of diagnoses than those currently used (Robin, 1958*a,b*; Robin & Macdonald, 1975). The results are essentially negative. Reports from Scandinavia (Mindus *et*

al, 1994) describe efforts to provide controlled results. More recently there have been attempts to compare OCD patients with non-OCD anxiety disorders, but not with an unoperated control group (further details available from the author upon request). Half of both groups were reported symptom free at 12 months. Also, results from a bilateral anterior capsulotomy on 15 patients with OCD (one was much improved at six months) were compared with those from a more extensive similar operation on seven of the patients who had not improved after the first operation. Three, of seven, were much improved one year after the second operation. Although described "a double blind controlled trial", the results essentially compared the first operation with the second (further details available from the author upon request). The series is small and the results are not conclusive. Thus, even at established centres, the level of evidence falls below that normally accepted for the prescription of a new drug. It is a clinical consensus.

#### *Emergent centres*

When assessing cases for operation at emergent centres, the SOAD must take into account the additional possibility that the surgery there practised, while based on established procedures, may cause variation in both the benefit and risk from: (a) subtle differences within established operating technique, and (b) deliberate variations in technique (of both site and methods of ablation) based on anatomical and theoretical considerations.

Thus, when assessing cases for certification at new centres and

"... having regard to the likelihood of the treatment alleviating or preventing a deterioration of the patient's condition, the treatment should be given". (s57(2b), MHA, 1983)

it is necessary, in the absence of published outcomes for a specific operation at a specific centre, for the certifying doctor to *assume* that results will be similar to those achieved elsewhere.

When assessing the validity of informed consent, it is necessary for the patient to understand: "the nature, purpose and likely effects of treatment" (s57(2a), MHA, 1983). Members of the certifying team need to be no less well informed.

It follows from the above that, in emergent centres, when the SOAD (and indeed the local clinicians) assesses and certifies both 'consent' and that the operation should proceed they have, in Popperian terms, to take a 'Leap into the Dark' (i.e. to extrapolate from published data to the unpublished experiences of local clinicians with a small number (initially zero) of cases). If it is a

Table 1. Adverse events in small samples

Paper	Number of cases	Number of adverse events reported	Probability of adverse events at 95% CI
1	25	0	12/100
2	27	0	11/100
3	29	0	10/100
4	38	0	8/100
5	57	0	5/100
6	70	0	4/100
7	653	0	4/1000

small leap then, in ordinary clinical practice, it can be justified on theoretical grounds, but it is a leap nevertheless. If it is a large leap then the intervention of local research ethics committees or a standing advisory committee may well be required (CRAG, Working Group on Mental Illness, 1996, para. 68 & 151). It is not suggested that a leap into the unknown is unacceptable. Without innovation there would be no progress, but, until hard results can be cited, the decisions of both clinicians and SOADs should be recognised and accepted for what they are – an extrapolation of old data into a new field where, initially, hard data is scarce. Clinicians at these centres are helpful to SOADs but the difficulties in assessing emergent procedures should be recognised and accepted, until such time as more data are available.

The very smallness of a new series enhances the statistical difficulties of evaluation (Eyspach *et al*, 1995). Their concern is that in small series the expected probability of risk may be greater than the observed risk by a significant factor. At a 95% confidence level the risk is estimated in their formula as  $3/n$ , where  $n$  is the number of procedures performed. As an example (from seven published separate papers on laparoscopic appendectomy) they quote:

This shows that the probability of risk in a small series can be significantly greater than at first sight may appear. (Note the difference between the reported adverse reactions (0) and estimated risk of untoward events (12%) in the 25 cases cited in paper 1.)

#### **Basis of decision-making**

Evidence-based medicine (EBM) is fashionable, and certainly in the field of new drugs the required evidence is a well-conducted controlled trial. Critics of EBM in psychiatry (Schmidt *et al*, 1996) point out that for practical and ethical

reasons "many areas of clinical practice cannot and will not be adequately tested". This has certainly been said to be the case where neurosurgery for the treatment of mental disorder is concerned, but those who want hard 'evidence' (as opposed to a consensus), be they clinicians or 'purchasers' operating within a fixed budget, may consider that the case for neurosurgery for the treatment of mental disorder is weak.

The balanced use of 'hard data' as opposed to 'clinical intuition' is explored in the cognitive continuum (Hamm, 1988). This places levels of decision-making on a continuum ranging from a single person's intuition through to highly controlled bench experiments. In 'hardness' of evidence, controlled trials rank second to bench experiments, then, proceeding downwards, there are 'quasi-experiments' (e.g. epidemiological studies) system-aided judgement (the application of probability and estimates of 'value' to possible outcomes), peer-aided judgement and back to individual intuition. The higher levels are more structured and expensive in both time and money, as well as being slower, more conscious, more consistent and more accurate. Individual intuition is quick, cheap, of "low consistency and . . . moderately accurate", yet still better than random. Peer group consensus is a step upwards. Each decisional task needs to be matched consciously to an appropriate technique (Hamm, 1988).

### In practice

Assessment for neurosurgery for the treatment of mental disorder by the RMO and the SOAD involves individual clinical judgement and peer group discussion (referring consultant/tertiary specialist; referring consultant/SOAD). Taking the probability of risk and benefit from publications is using one component of system-aided judgement (the second, 'values', is rarely consciously considered). When, at new centres, there are no published results the probability basis of decision-making is more open. As to 'values', neurosurgery for mental disorders is a highly emotive topic for both clinicians and the public and an effort should be made to express these values more explicitly. When probabilities hover around  $P=0.5-0.6$ , as in the case of neurosurgery for the treatment of mental disorder, value weighting is more critical than if  $P=0.9-1.0$ .

SOADs try to achieve consensus and consistency in their s57 second opinions but it should be understood that in the context of s57 their task is to consider whether the treatment plan proposed by the RMO should proceed. For this purpose the SOAD will need to be presented with

a reasoned case. The consultation differs from a clinical second opinion where the second doctor is asked how he himself would manage the case. If SOADs (or RMOs) are ever taken to task in law (e.g. by a judicial review), the basis of their decision taking would be tested in the light of prevailing standards. The professional and public acceptance of their decision-making methods may then be critical. It is a working area where SOADs should, at all times, be confident of the explicit support of the Mental Health Act Commission.

### Possible solutions

The task of the SOAD would be easier if, initially, and updated before each consultation, the Commission would assist by asking new centres to provide written accounts, or reference to publications, on the following matters:

- (a) The precise site of the ablation, the method of ablation, the differences, if any, from previously reported interventions, and the reasons for the change.
- (b) The centre's criteria for case selection.
- (c) As time proceeds, and in addition to statutory returns under s61 MHA 1983, a case by case return of any adverse effects, in short or longer term, as they occur, or nil returns, and a note of any beneficial changes at three and 12 months after each operation. In short, much quicker feedback of both positive and negative results.
- (d) Where made, a copy of the protocol submitted to the local research ethics committee should also be submitted to the Mental Health Act Commission, and made available by them to SOADs.
- (e) The above data should be collated by the Commission for each centre and updated figures supplied to SOADs each time a s57 assessment visit is made.

When assessing patients at both established and new centres it would greatly assist initial assessment and later evaluation if the reports sent to the Mental Health Act Commission prior to the consultations were in a standardised format, known to the referring psychiatrist well in advance of the consultation. These reports should include:

- (a) The psychiatrist's opinion as to which of the criteria for surgery are met in his case (e.g. chronic depression, OCD, etc).
- (b) The clinical reasons or 'facts' supporting this opinion, each elaborated in turn under suggested headings (e.g. duration and severity of symptoms, the adequacy of previous treatments, results of cognitive

testing (CRAG Annex F Appendix 1) (CRAG, F2), (CRAG, Annex G, 1–3). There should be a statement about location and management of the immediate post-operative period and the medical and rehabilitative measures to be undertaken in the year following the operation. In the latter case the format of the care programme approach (Department of Health, 1990) and care management should be adopted. The responsibilities of named staff should be defined, including those for overall coordination, and the periodicity of regular reviews stated. This may involve collaboration between the tertiary centre and referring agencies but is important because of the influence of post-operative management on outcome.

- (c) At the time of the visit, the full case notes, including correspondence and prescription sheets (or a medication summary) should be available to the visiting SOAD. Cross referencing between the report and the clinical notes is only acceptable if both are available.
- (d) When cases are referred from overseas some of the suggestions in (b) and (c) may be a counsel of perfection, but nevertheless overseas referring doctors should be asked to provide a summary on these lines.

In short, start with a statement of agreed general criteria, proceed to opinions in relation to those criteria in the individual cases, and then seek a statement of reasons for holding the clinical views expressed. This structure could be either a broad guide or, in time, developed into a much more structured protocol. Current reports or letters of referral rarely give a systematic reasoned case for the opinions therein expressed.

System-aided judgement has its limitations but a pilot trial by SOADs when reporting their individual cases to the Mental Health Act Commission should be undertaken.

Patients in whom surgery is approved but in whom, for incidental reasons, it does not proceed, should be made known to a central body and followed up in order to provide further evidence on the intractability of selected cases.

The procedures outlined above do not substitute for controlled trials but a consistent and structured database would make for a more precise comparison of clinical states before and after the operation. In time this would make for a more accurate estimate of the 'probabilities' and 'values' involved and progressively minimise the problems of consensus assessment. Although here approached from the point of view of the

SOAD, these procedures would also promote cohesion within the larger clinical and formal group.

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