NICE work?

Potential and problems for psychiatry in the new National Health Service

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What is NICE and how will it work?

The National Institute of Clinical Excellence (NICE) is heralded as one of the flagships of the 'new National Health Service (NHS)', which along with the Commission for Health Improvement (CHImp) is intended to improve "quality of care", and will "sort the wheat from the chaff" in terms of what works (Secretary of State for Health, 1998*a*; Department of Health, 1999). Its Chairman, Professor Sir Michael Rawlins, formerly chair of the Committee on Safety of Medicines, has identified three main functions: (a) the appraisal of new and existing health technologies; (b) the development of clinical guidelines; and (c) the promotion of clinical audit and confidential inquiries (Rawlins, 1999). The first of these functions, 'technology assessment', deserves cautious welcome and is discussed here. For the first time, this will mean that psychiatric interventions may be judged on the basis of their clinical and cost effectiveness and wider impact (positive and negative) if adopted in the NHS.

NICE will appraise submitted evidence of clinical and cost effectiveness, generally from drug manufacturers, and will make one of three recommendations:

> *Category A.* The technology is recommended for routine use in the NHS for all licensed indications, or for only specified subgroups.
> *Category B.* The technology should be used in the NHS only in the context of appropriate clinical trials, that is, more research needed.
> *Category C.* The technology is not recommended for use in the NHS for any group of patients (for specified reasons of lack of clinical effectiveness or cost effectiveness), that is do not use it.

The dual role of NICE in promoting clinically and cost effective treatments and demanding better quality research evidence is both clear and laudable. What is less clear, is how cost ineffective treatments will be handled. Many new treatments show marginal or no clinical superiority, but at greatly exaggerated cost, making them cost ineffective. In some health care systems, such as those in Australia and Canada, drugs that would fall into Category C are not reimbursed from the public purse (Drummond & Aristedes, 1997). Under the proposed mechanism the decision as to whether to fund clinically and cost ineffective interventions or not will ultimately be made by the Department of Health.

Why we need NICE in psychiatry

New drugs

Psychiatry has recently seen a rush of new and relatively expensive drug treatments, the uncritical adoption of which will have major cost implications. For example, it was estimated in 1993 that a shift to the routine prescription of selective serotonin reuptake inhibitors as the first line treatment of depression would add £240 million to the annual drug bill (Effective Health Care, 1993). Similarly, it has been estimated that the use of atypical antipsychotics will add £210 million to the annual UK drug budget if prescribed for all patients with schizophrenia, and £54 million if restricted to those with treatment-resistant schizophrenia (Davies, personal communication, 1998). These costs alone could consume the greatest part of the 'extra' £700 million which was recently allocated to mental health over the next three years (Secretary of State for Health, 1998*b*). Without an explicit consideration of clinical and cost effectiveness, we have no way of knowing whether this is a reasonable thing to invest in, given other competing interventions which could be funded for this money.

The fact that new drugs are costly (in terms of net purchase cost) does not mean that they should not be funded, since expensive drugs can (it is claimed) offset this cost by improving adherence, reducing service use and improving patient outcome. Such hypotheses are testable using rigorous evaluations of clinical and cost effectiveness – ideally in the form of prospective randomised studies conducted in real world clinical settings. Currently, this evidence is not demanded and has generally not been produced.

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In the absence of a national regulatory framework, regional drugs and therapeutics committees have hitherto been forced to make 'rationing' decisions (NHS Management Executive, 1994); often based on poor quality evidence and without the necessary expertise to judge clinical and cost effectiveness. The result has been either 'prescription by postcode' for some new drugs (such as antipsychotics), or the unregulated introduction of others (such as new antidepressants). For example, under this system new antidepressants have now become the routine first line treatment for depression (Donaghue *et al*, 1996), despite marginal clinical superiority and very poor quality evidence of clinical and cost effectiveness produced by the pharmaceutical industry (Hotopf *et al*, 1997). The evidence of clinical and cost effectiveness presented by manufacturers has been similarly poor for new antipsychotics (Maynard & Bloor, 1998) and antidementia drugs (Melzer, 1998). The NHS Health Technology Assessment (HTA) programme has retrospectively recognised the lack of evidence of clinical and cost effectiveness of these new drugs and has commissioned randomised evaluations, which are imminent or ongoing. In the future, such evidence would be required before a drug was adopted. This framework could ensure that patients are prescribed new drugs if these are justified and that increased expenditure is met nationally. Similarly, cost ineffective drugs can be rejected nationally. In this way genuine innovation can be rewarded and patients will benefit.

Other interventions

Although 'health technologies' is intended to include "drugs, devices, diagnostic tests, surgical procedures and other innovations" (Rawlins, 1999), the framework NICE proposes is clearly designed to evaluate drugs. Rawlins discusses the sponsors of new products as well resourced commercial organisations, and the model that is proposed for NICE (Department of Health, 1999) borrows much from the Australian system for evaluating new drugs (see Drummond & Aristides, 1997). Psychiatry is more than just drug treatment. What has NICE got to offer in this respect?

The introduction of the Care Programme Approach (CPA) is instructive, since its implementation was not preceded by an explicit consideration of its clinical and cost effectiveness or wider impact on services working under finite resources. The CPA is just one of a number of alternative models of community care which have been proposed – another is Assertive Community Treatment (ACT). A systematic review of randomised evaluations of ACT show it to be labour intensive and costly, but effective in reducing relapse and readmission for those with severe mental illness (Marshall & Lockwood, 1998). ACT is potentially cost effective, although under researched in a UK health care setting. If the CPA were adopted at all, it might have been in the context of an appropriate clinical trial against ACT, with a consideration of the measures involved (monetary cost and time) in it's national adoption (e.g. Category B evidence). Practitioners might feel that this would be preferable to the imposed bureaucratic exercise that many perceive the CPA has been (Vaughan, 1998).

Similarly, many psychosocial interventions are clinically effective, but of unknown cost effectiveness. For example, family intervention is clinically effective in schizophrenia (Mari & Streiner, 1998), but is labour intensive and underused in the NHS. Evaluations of clinical and cost effectiveness are needed to inform the adoption of this treatment by the NHS, which if positive should be used to encourage its use. Conversely, 'counselling' is now widely adopted, despite poor quality evidence of clinical and cost effectiveness (Effective Health Care, 1997). An explicit technology assessment might reveal the need for more research before services are further expanded.

The pharmaceutical focus of NICE should make us vigilant that it is not only drugs which are evaluated. Unfortunately, there is no commercial imperative to evaluate 'other interventions' in the same way as drugs, and there is a role for the NHS HTA programme in plugging this gap. Psychiatrists should also demand the same level of evidence for policy initiatives and psychosocial interventions as that proposed for new drugs. This argument has been made in wider health care, to ensure that surgical procedures and screening programmes are considered 'health technologies' and are therefore first appraised for safety and effectiveness (Sheldon & Faulkner, 1996).

What role for psychiatry in NICE appraisal?

So far the specific details of the NICE appraisal of new technologies are under discussion (Department of Health, 1999), and it will remain to be seen what specific inputs psychiatry (including the Royal College of Psychiatrists) will have into this process and how this influence will be delivered. However, psychiatry will have to work alongside other disciplines and areas of expertise in the decision making process. Individual appraisal committees will comprise a clinician (as chair) and two medical practitioners together with representatives from nursing; public health/epidemiology; health economics; health

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policy; NHS management; patient groups; clinical pharmacology and pharmacy. The emphasis is one of inclusivity and transparency of decision-making, involving a scientific appraisal of presented research evidence alongside an interpretation of this evidence in the light of clinical experience. For example, advice offered by NICE might involve:

> "Clinical guidance on the appropriate use of the intervention, covering issues such as indications for use, training, issues to raise with patients in seeking informed consent, monitoring and evaluation, and indications for stopping treatment" (Department of Health, 1999).

The Royal College of Psychiatrists has (at the time of writing) not given any (publicly available) response to NICE, and it remains to be seen how their influence will be brought to bear.

Perhaps psychiatry's greatest input into any policy decision making process is the research we produce (see Kendell, 1999). We psychiatrists have thus far not produced a body of research evidence that is particularly useful in informing decision making in the real world. Available research is dominated by underpowered short-term evaluations of drug efficacy (see Thornley & Adams, 1998), rather than the longer term studies on real world patients in routine care settings which are needed to assess clinical and cost effectiveness (Lewis, 1997). If we are to influence the NICE decision-making process in any positive way, then it is incumbent upon us to lobby for and to produce this evidence.

Rationing by the back door?

On the topic of rationing, Professor Rawlins comments:

> "NICE has been established neither to cut costs, nor to introduce rationing, but to help the NHS get value for money. Indeed, anyone who believes NICE will reduce NHS expenditure is whistling in the wind." (Rawlins, 1999)

Like many clinicians and politicians before him – the 'R' word is avoided but the 'P' word used instead – no rationing, but priorities are acknowledged. A moment's reflection will make us all realise that rationing is an inevitable and existing fact of life – given that every psychiatrist and provider of psychiatric care works under limited resources and that all demands cannot be met.

It can be argued that the current method of rationing ('implicit rationing'), whereby priorities and allocations are made in secrecy and without public and professional debate is unfair, inequitable and ensures that psychiatry ultimately loses out. Psychiatry struggles against higher profile specialities and represents the interests of a disenfranchised section of the population. As a consequence, psychiatric care has remained towards the bottom of politicians' and the public's implicit 'priority list'. NICE provides a framework within which psychiatry can potentially compete on a level playing field and in which new and existing treatments can be introduced which are to the benefit of our patients.

How many psychiatrists would welcome 'explicit rationing' if this meant less form filling as part of the CPA and the ability to concentrate on those activities which are of known clinical and cost effectiveness? Implicit rationing has many perverse effects, including the things that we cannot do because of the time and expense given to clinically and cost ineffective exercises ('opportunity cost'). If a new technology is not clinically and cost effective, then we can refuse to adopt it and be supported in this decision. Conversely, if a new technology is clinically and cost effective, then we can argue for more resources or make rational decisions about what we are going to stop doing in order to adopt a new technology.

Psychiatrists would be right to be cautious of 'rationing' since rationing has been used to mean cost cutting and the denial of treatments to needy patients. However, this is a managerial abuse of the term, when rationing is in fact an explicit consideration of cost and clinical effectiveness in decision-making. The debate about rationing should no longer be about whether rationing exists or is desirable, but about how psychiatry can face up to difficult decisions in an open and truthful manner. NICE has something to contribute to this debate.

Conclusions

The current status quo is not tenable in psychiatry and a regulatory framework is needed to ensure that new drugs, psychosocial interventions and policy initiatives benefit our patients and wider society. To this end, NICE has merit and can potentially contribute to this shift in emphasis. The main reason for psychiatry to be vigilant is the danger that only drug treatments can and will ever get the NICE 'stamp of approval', and that as a consequence 'other treatments' are either under researched, unregulated or unused.

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