



## opinion & debate

Psychiatric Bulletin (2002), 26, 243–245

ANGUS MACKAY

### Health technology assessment and mental health

In company with all other branches of the NHS, those concerned with mental health are currently the target of a plethora of standards, guidelines and derivatives thereof. In England and Wales, the responsibility for the production of national clinical guidelines rests with the National Institute for Clinical Excellence (NICE), and the Commission for Health Improvement (CHI) is charged with the monitoring of performance. In Scotland, the Scottish Intercollegiate Guideline Network (SIGN) and the Clinical Standards Board for Scotland (CSBS) undertake these respective responsibilities. However, NICE is also responsible for a rather different form of activity, and one that has forced it recurringly into the media limelight in the 2 years since its creation. This is the formulation of national advice on the clinical and cost-effectiveness of new and existing health technology. Health technology is a rather pedantic, if precisely defined, term that means essentially any health intervention and it includes medicines, devices, clinical procedures and even health care settings. Post-devolution and in the wake of the establishment of the Scottish Parliament, the Health Technology Board for Scotland (HTBS) was created by statute in April 2000. This organisation shares with NICE the responsibility for issuing advice on the clinical and cost-effectiveness of health technologies, in HTBS's case primarily to NHS Scotland. Therefore, two nationally-oriented organisations exist on either side of Hadrian's Wall, responsible to their respective Parliaments for providing authoritative opinions on whether or not a particular health intervention should be provided within the NHS. A crude approximation to the subject of this advice would be 'value for money'. While, for reasons that will be explained, such a term is potentially misleading, it does serve to identify the basic elements of the need to which this activity is a response.

#### Muddling through

A consideration of the position with regard to medicines, although only one form of health technology, is a useful way of identifying the main issues. In the early years of expansion of the pharmaceutical industry in the 1950s and 1960s, a new drug could be introduced to the NHS with no fuss and a minimum of scrutiny. Thalidomide

changed all that. In 1970, the Committee on the Safety of Medicines was established under Article 4 of the Medicines Act (1968), charged with advising the Secretary of State for Health not only on matters of safety but also on the quality and efficacy of all new substances or articles to which the Act applied. The definition of efficacy is important; it is the benefit observed under strictly-controlled clinical trial conditions – in contrast to effectiveness, which is the benefit observed in ordinary, everyday clinical practice.

Quality, safety and efficacy represent a crucial set of three hurdles that all new agents have to clear before being granted a product licence and marketing authorisation. However, this statutory process allows no consideration of cost-effectiveness.

Over the past 20 years, prescribers have been spoiled for choice, able to choose from a wide range of safe and efficacious agents by virtue of their marketing authorisation. Several have represented real quantum advances in therapeutics, but many more represented mere 'me too' variants on a theme. Recent years have seen the drugs bill for the NHS rise to proportions that, even in a reasonably well-funded health system, represent a possibly unacceptable opportunity cost. For example, Cameron Stark and his colleagues published startling figures for the escalating cost of antipsychotic drug prescription in primary care in Scotland; an increase of over 250% in 3½ years (Stark *et al*, 2000). The obvious question arises: is the net benefit derived from new atypical antipsychotics 2½ times greater than that from the older drugs? Almost as striking as the magnitude of this increase in costs was the variability between health boards across Scotland.

Clearly, any measure that could make even a small percentage impact on such enormous expenditure could free considerable resources for other uses. As Mr Sam Galbraith, MP, (Personal Communication, 1999) aptly put it, we have been 'elegantly muddling through' in a typically British way, trying to devise and apply non-draconian methods of guiding prescribers to achieve best value for money, but without the required evidence on either clinical effectiveness (as distinct from efficacy) or costs. Almost inevitably, certain new, high-profile and expensive treatments – interferon  $\beta$ , clozapine and other atypical antipsychotics, and the so-called antidementia drugs – were to test the system and find it wanting. Their



## opinion & debate

introduction to prescribers was confusing and the availability to patients inconsistent. There appeared to be ad hoc rationing and the catchy headline 'postcode prescribing' appeared for the first time.

One of the issues to which NICE and HTBS are a response is the perceived right of a patient to be given any drug that has a UK marketing authorisation and which his/her doctor feels he/she deserves. This is a problem because it represents an obligation on a publicly-funded NHS to provide agents that may be neither effective in everyday clinical terms nor cost-effective. Medicines have been used here as a high profile example, but the issues are common to all health interventions and, of course, these issues are not confined to the UK, they are worldwide.

### Health technology assessment

It must be emphasised that the output from NICE and HTBS will be advice on clinical- and cost-effectiveness and not on need, budgetary priority or affordability. Assessments will certainly inform the process of rational and equitable distribution of resources, but they are not about what a health care provider should afford or can afford, nor are they about assessing population needs or prioritising these against available resources. However, regardless of questions of priority and affordability, any reasonable person would surely not condone the provision of treatments that were either only equivocally beneficial or where the benefit per £ (sterling), or per hour of clinical time taken from some other activity, was less than an alternative. Advising on the degree of real benefit and value for money should, therefore, be seen as an aid to the evidence-based, equitable distribution of limited resources but should not be seen as 'stumbling into rationing' (Smith, 2000).

Health technology assessment is actually about much more than the thorough assessment of clinical value and value for money, and it is a holistic approach to such assessment that renders the subject particularly relevant to mental health interventions. The HTBS uses the following definition of health technology assessment, one that is based on an internationally recognised approach. It is a 'comprehensive, systematic evaluation of the consequences of using a health technology in a specific health service context, one which examines the social, ethical, medical and economic implications of using a health technology.' Assessments combine evidence from systematic reviews of scientific and 'grey' literature along with evidence from professional groups, patient groups, voluntary organisations and manufacturers. Moore has written about the 'uni-dimensional approach', which he perceives in guideline development (Moore, 2001), where outcomes in randomised controlled trials tend to be predominantly medical in the form of symptom severity scales, or similar, the content of which tends to be derived from diagnostic criteria. This may not provide useful insight into how the intervention affects the patient in the holistic sense, including the overall acceptability of the intervention. Health technology assessment,

on the other hand, aims to be inclusive of all relevant information, both in terms of a rounded appreciation of the benefit and disbenefits of an intervention for the patient, and the implications for the service (such as staffing, training, physical facilities). It also includes direct and indirect costs. All of this evidence is critically appraised and a considerable amount of judgement may have to be exercised in the formulation of the eventual advice. So, contrary to some popular media perceptions, the cost per quality adjusted life year (QALY) is by no means the deciding factor for advice about whether, and in what context, a health technology should be used. Health technology assessments are, therefore, painstaking and time-consuming exercises but they will progressively inform the content of clinical guidelines as well as providing advice to policy makers and clinicians on specific health interventions.

While the NICE and HTBS share many aims and basic values, the HTBS has learned much from its slightly older and bigger cousin, and several differences of methodology and process have resulted from their separate evolution. For example, the agenda for topics to be assessed by NICE is drawn up by the Department of Health for England and the National Assembly for Wales, whereas the HTBS chooses its topics through a process of wide consultation and open nomination from across Scotland. However, a fundamental criterion used by both organisations in the choice of topics is the likelihood that the assessment and advice will 'add value'; in other words, that an authoritative statement from a national body will help decision makers with potentially difficult decisions, whether they be to invest resources in new technologies or disinvest from existing ones. As part of its current agenda of full health technology assessments, HTBS is assessing interventions to reduce the risk of relapse in alcohol dependence. In the complex area of services for those with alcohol dependence, where drug treatments may be used in combination with various forms of psychosocial intervention, the questions to be addressed by the assessment will include which approach, or combination of approaches, is likely to yield the maximum benefit. They will also consider what is the most effective and efficient approach to service delivery, taking account of factors such as the different risk groups, locations and duration of treatment. Typically, this health technology assessment will take approximately 18 months to complete and will include wide and public consultation and clarification meetings with the manufacturers of relevant medication.

The HTBS and NICE have established a close working relationship, including a procedure, established in May 2001, through which the HTBS 'delivers' to Scotland every Technology Appraisal Guidance by NICE. This is accompanied by a comment on the relevance and implications of the NICE guidance for Scotland. In many cases, the comment will simply advise that the NICE guidance appears to be as valid for Scotland as for England and Wales, but where significant differences exist, such as in the epidemiology of a disorder or the structure and provision of health services in Scotland, a lengthier and more detailed comment is produced, which lays out the



contextual issues for Scotland. The first example of this cooperative process was the HTBS comment on the NICE Technology Appraisal Guidance on the use of donepezil, rivastigmine and galantamine for the treatment of Alzheimer's disease. Future topics in mental health that NICE is due to consider are:

- the use of the newer (atypical) antipsychotic drugs in the treatment of schizophrenia
- computerised cognitive behaviour therapy for depression and anxiety
- electroconvulsive therapy
- new drugs for bipolar disorder.

Information on the full work plans for NICE and HTBS, and on their processes and methodologies, is readily available at their respective websites: <http://www.nice.org.uk> and <http://www.htbs.org.uk>.

## Future developments

The functions provided by the NICE and HTBS are likely only to increase in prominence in the years ahead. Health technology assessment is an essential ingredient in any informed decision about the equitable distribution of capped resources within a publicly-funded health service. The need for reliable data on clinical- and cost-effectiveness and a range of other contextual information will force the clinical and broader NHS community to accommodate 'research' as part of everyday practice. In the case of new medicines, for example, there is a need to collect structured and reliable information on the benefits and costs observed in the 'real world'. These and many other ingredients of a full health technology assessment are missing from the licensing process and extensive modelling may be required in order to produce best-guess approximations during the conduct of an assessment. Until now, most, if not all, technology appraisal determinations by the NICE have been hampered somewhat by lack of such data and, not surprisingly, it is common for health technology assessments to identify the need for further research. Ideally, with cooperation from the research and development organisations in the UK, it would seem sensible to recruit networks of clinicians who would be responsible for data collection on a national, multi-centre, pragmatic basis. Data on clinical-effectiveness (including unwanted effects) would be recorded by clinicians actually using the technology. Outcome measures would have to be valid, simple and essentially those that clinicians would, anyway, be recording in case records, otherwise they would understandably be discouraged from enrolling. Already

there are good examples of attempts to tackle these data requirements in mental health (e.g. Mendelwicz, 2001). For many, particularly psychiatric, disorders it would seem sensible to look carefully at the use of patient-derived outcome measures, quantified on a simple global impression scale (CRAG, 1996). There is an urgent need for the development of a methodology for pragmatic national multi-centre trials, which becomes a normal feature of life in the health service. There are huge potential gains: the appreciation that evaluation (even of medicines) only really starts once it is introduced; the involvement of clinicians in the collection of data that will go to inform policy decisions; and the involvement of patients in the definition of outcome measures that are valid for them.

Mental health remains a high priority for health services throughout the UK and it is heartening to see that mental health topics appear on the assessment agendas of both the HTBS and NICE. The provision of mental health services involves decisions about every modality of health technology, but these decisions are as often as not taken on the basis of cursory appraisal or anecdote. Health technology assessment will gradually fill the appraisal void, but this will take time and will require the support and understanding of everyone involved in the deployment of mental health resources.

## Acknowledgements

Thanks to Ann Single and Andrew Dillon for helpful comments.

## Declaration of interest

None.

## References

- CRAG (1996) *Outcome Indicators in Acute Psychiatry*. London: Stationery Office.
- MENDLEWICZ, J. (2001) Optimising antidepressant use in clinical practice: towards criteria for antidepressant selection. *British Journal of Psychiatry*, **179**, (suppl. 42), S1–S3.
- MOORE, B. (2001) Guidelines or tramlines? The value of the NSF for mental health. *Progress in Neurology and Psychiatry*, **5**, 8–10.
- SMITH, R. (2000) Stumbling into rationing. *BMJ*, **319**, 936.
- STARK, C., JONES, J., AGNEW, J., et al (2000) Antipsychotic drug prescribing trends in primary care in Scotland 1994–1997. *Health Bulletin*, **58**, 96–101.
- Angus Mackay** Chairman, Health Technology Board for Scotland, Argyll & Bute Hospital, Lochgilphead, Argyll PA21 8LD