

ARTICLE

Ethics and economics: the case for mental healthcare[†]

Sarah Byford & Barbara Barrett

Sarah Byford is a reader in health economics at King's College London, UK. She specialises in the economic evaluation of mental health services for children and adolescents and for adults. **Barbara Barrett** is a lecturer in health economics at King's College London. She specialises in the economic evaluation of forensic psychiatry services.

Correspondence Sarah Byford, Centre for the Economics of Mental Health, Box 24, Institute of Psychiatry, De Crespigny Park, London SE5 8AF. Email: s.byford@iop.kcl.ac.uk

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SUMMARY

In making treatment decisions, psychiatrists, like other medical professionals, must adhere to rules of ethical medical conduct. They may also need to negotiate the legalities associated with detention and treatment against a patient's wishes. The growth in guidance produced by organisations such as the National Institute for Health and Clinical Excellence has added further complexity. Practitioners are increasingly required to consider cost-effectiveness in their treatment decisions and this can appear to conflict with the principles of medical ethics. With particular reference to mental healthcare, this article attempts to answer two questions: Is economic evaluation unethical? And are the methods of economic evaluation unsound for the purpose of achieving an ethical distribution of resources?

DECLARATION OF INTEREST

None.

When making treatment decisions, psychiatrists must ensure that they make the care of patients their first concern, provide a good standard of practice and care, treat patients as individuals, respect their dignity and autonomy and work in partnership with them (General Medical Council 2006). Treatment decisions may need to be taken alongside consideration of the legal framework for detention and treatment against a patient's wishes, which requires psychiatrists to walk the fine line between care and coercion (Welsh 2002). To add to this already complex field, medical practitioners are increasingly required to take on the role of decision-maker in the allocation of resources and this can appear to be in conflict with the basic principles of medical ethics.

Resource allocation and cost-effectiveness

Resource allocation decisions based on evidence of the relative cost-effectiveness of treatments are difficult to avoid in the National Health Service (NHS) in England and Wales, in common with other health systems around the world, in particular Australia (Duckett 2008), Canada (McMahon 2006) and New Zealand (Braae 1999).

In England and Wales, the National Institute for Health and Clinical Excellence (NICE) is charged with providing national guidance on the promotion of good health and the prevention and treatment of ill health (National Institute for Clinical Excellence 2003). In making its recommendations, NICE is required to consider evidence of both clinical effectiveness and cost-effectiveness. It does not make recommendations solely on the grounds of cost-effectiveness (Rawlins 2004) but frequently the relative cost-(in)effectiveness of an intervention is the focus of media coverage and it is not uncommon to find headlines such as 'Pain relief drug ruled too costly for the NHS' (Hawkes 2007).

The transparency with which NICE performs its functions and the realisation that an 'effective' treatment may be denied to patients on the basis of cost has kept NICE in the headlines and raised an age-old debate about the ethics of economics. This is despite evidence to suggest that NICE is perhaps 'too nice'. In a review of the first 2 years of NICE technology appraisals, Raftery (2001) noted that NICE recommended against the use of just three of the first 22 health technologies on which guidance had been issued (14%), although for some technologies use was restricted. A later review covering 1999–2005 found that NICE recommended against 22 of 86 technology appraisals (19%) and almost two-thirds of these negative results were because of insufficient evidence rather than unacceptable cost-effectiveness (Raftery 2001, 2006).

The early years of NICE

Originally named the National Institute for Clinical Excellence, NICE was set up in 1999 and although it raised concerns almost immediately within the health service, the health technology industries and the media, the ethics v. economics debate has taken a while to creep into the mental healthcare field. The first technology appraisal completed by NICE of treatments for mental disorders was published in 2000 and focused on methylphenidate for children with attention-deficit hyperactivity disorder (ADHD) (National Institute for Clinical Excellence 2000). The guidance was not particularly controversial in terms of

cost-effectiveness, recommending the use of methylphenidate in this population but restricting prescribing to specialist physicians. Various appraisals of mental health services followed, including an evaluation of atypical antipsychotics for schizophrenia (National Institute for Clinical Excellence 2002a), computerised cognitive-behavioural therapy for depression and anxiety (National Institute for Clinical Excellence 2002b), and parent training/education programmes for children with conduct disorders (National Institute for Health and Clinical Excellence 2006). On the whole, recommendations were generally favourable and uncontroversial, causing few anxieties for clinicians or patients, although some concerns for those controlling the purse strings.

The guidance on atypical antipsychotics in schizophrenia was perhaps the first area where the announcement of a NICE appraisal may have raised fears of a negative outcome among mental healthcare professionals. At up to £2000 a year, atypical antipsychotics are substantially more expensive than typical antipsychotics, which cost around £100 a year. If NICE were in the business of rationing for the sake of saving money, these drugs would be the first to go. However, these fears were unfounded. NICE recommended that clinicians consider prescribing atypical antipsychotics for people newly diagnosed with schizophrenia. For patients already taking one of the older antipsychotics, they recommended switching to atypicals if the treating clinician and the patient agreed that the side-effects of the current medication were unacceptable. So, all was well.

This situation changed in 2007 with the release of guidance on acetylcholinesterase inhibitors for the treatment of Alzheimer's disease (National Institute for Health and Clinical Excellence 2007). NICE recommended donepezil, galantamine and rivastigmine, but only for the treatment of moderate disease, denying the drugs to patients in the early stages of the disease with only mild symptoms and those with more severe Alzheimer's disease. Although the guidance on the use of these drugs was less restrictive than earlier drafts (Ballard 2007), the recommendations were badly received and were the subject of a High Court judicial review. The Court found in favour of NICE on five out of the six grounds presented and NICE was required to amend its guidance (National Institute for Clinical Excellence 2008a). However, following an appeal, the Court of Appeal found in favour of the pharmaceutical companies involved and ruled that NICE should have allowed public access to the health economic model that it used to support the guidance. In accordance with

this ruling, NICE released the fully executable version of the model to stakeholders in November 2008. NICE has since considered the comments received from stakeholders and concluded that the technical inaccuracies highlighted were insufficient to change the original conclusions of the guidance (National Institute for Health and Clinical Excellence 2009). Since the publication of the 2007 appraisal a number of commentators, in particular the Alzheimer's Society (Ballard 2007), have published responses highlighting both ethical and methodological concerns about the NICE appraisal process.

With particular reference to the allocation of mental health service resources for the treatment of mental disorders, we consider whether economic evaluation is unethical in the modern NHS and whether the methods of economic evaluation are unsound for the purpose of achieving an ethical distribution of resources.

Is economic evaluation unethical?

Health economics is a relatively young discipline, having been around for about four decades, and was subject to harsh ethical criticisms very early on in its development. Perhaps the most cited critique is that of Loewy (1980), who suggested that 'A physician who changes his or her way of practising medicine because of cost rather than purely medical considerations has indeed embarked on the slippery slope of compromised ethics and waffled priorities'. More than a decade later, Williams (1992) wrote an equally sharp response, suggesting instead that it is unethical to ignore the costs of treatment decisions. The debate became relatively quiet during the remainder of the 1990s but has seen a resurgence in the current decade.

Economic evaluation as an ethical practice

Perhaps the best place to start in a defence of economic evaluation as an ethical practice is to make the distinction between cost defined by accountancy and cost defined by economics. Accountancy is concerned with money, whereas economics is concerned with resources. To an economist, 'What will it cost?' does not mean 'How much money will we have to part with?', but rather 'What will have to be sacrificed?' (Williams 1991). Healthcare resources are inherently limited. At any one time there are a maximum number of psychiatrists, psychologists and other mental health professionals working in the healthcare system, there are only a limited number of inpatient beds available on a limited number of psychiatric wards and there is a limited budget for psychotropic medications and other therapeutic

services. The need to consider what is to be sacrificed when considering costs is what economists call 'opportunity cost' – the benefit of the alternative foregone (Rutherford 1995). Thus, the opportunity cost of a session of psychotherapy delivered by a clinical psychologist is the benefit foregone of the psychologist doing something else with their time, for example running a group treatment, providing training for primary care practitioners or treating another individual. Every decision to fund a service or treat a patient in a resource-constrained health system is associated with a loss elsewhere and it is this loss, or opportunity cost, that is the focus of economics.

Economic evaluation is the systematic attempt to identify, measure and compare the costs and outcomes of alternative resource allocation decisions (Drummond 2005). The methods are built on the theory of welfare economics – the study of the relationship between resource allocation decisions and the well-being of individuals in society – and the viewpoint taken is societal. In other words, economics is concerned with the effect of an action on the well-being of the whole of society, not just on the individuals directly involved (Arrow 1963). The provision of community-based residential services for people who misuse drugs, for example, will not only have an impact on service users and providers, but will also affect families and friends, health and Social Services, the criminal justice sector and the general public. These effects may be negative (costs) or positive (benefits) and the aim is to ensure that total benefits to society outweigh total costs, resulting in an overall improvement in society's total well-being. The overarching aim is to maximise the benefits to society by directing resources towards those services that generate the greatest outcomes for the resources available.

Given the notion of loss and opportunities foregone, treating patients with no regard for costs also means treating them with no regard for justice, because by doing so one is ignoring the possible adverse consequences of one's actions on other people (i.e. the impact on those who could have been treated if the resources were spent elsewhere in the health system). Berghmans & colleagues (2004), in a critique of cost-effectiveness analysis and guidelines incorporating economic evidence, correctly point out that this utilitarian approach makes individually focused approaches to the operation of health services subordinate to collective considerations. We would argue that this is difficult to avoid in a nationally provided health system, funded by collective taxation, and this is equally true of clinical evaluations and guidelines based purely on evidence of efficacy or effectiveness. Clinical trials are, after all, an attempt to find the

'average' outcome for a sample, in order to make recommendations for the wider population.

Ethical conflicts

There is no doubt that the ethical principle of justice comes into conflict with other ethical considerations in medicine, particularly beneficence and autonomy, which focus on the individual. Some commentators have argued that this conflict is greater in mental healthcare than in other areas of healthcare. Berghmans and colleagues (2004) stress the highly patient-oriented approach in mental healthcare and the importance of taking the values and preferences of the individual into account in treatment decisions. Graber (2006) acknowledged the validity of this assertion, but also suggested that too much emphasis on patient autonomy, in particular the provision of branded medications in response to patient requests, may not only conflict with justice but may also result in increased patient harm. Furthermore, it is important to highlight the severity of funding pressures facing mental health services (Sainsbury Centre for Mental Health 2006; Rose 2010) and thus the heightened need for resource allocation decisions to be made with reference to notions of justice. Although economists will always strive to support resource allocation decisions that increase overall societal well-being, the desire to do so would not be so great in a system of unlimited resources. The greater the resource constraints, the greater the impetus to ensure that the available resources are used to maximum effect, which requires consideration of not only who gains (the patient), but also who loses (primarily, other patients who could benefit from the resources in question).

Few economists would apologise for giving preference to issues of justice. However, in practice, most economists agree that economic evaluation is a tool to support decision-making that should be considered alongside other evidence, including issues of equity, generalisability, study quality and policy or public preference. This can be seen in the NICE appraisal process (Box 1).

Are the methods of economic evaluation unsound?

Believing that the theory of economic evaluation is ethically sound does not place the practice of economic evaluation (or indeed clinical evaluation) beyond reproach. Nor does the transparency with which NICE undertakes its appraisals guarantee an accurate or fair appraisal. Limitations in methods and data availability leave the results of economic evaluations, clinical evaluations and evidence appraisals open to error. The production of a

perfect appraisal is further hindered by conflicting evidence, conflicting preferences, complex and bureaucratic procedures, and imbalances in the knowledge and lobbying skills of different interest groups. Theoretically, to assess the overall societal impact of a resource allocation decision, economic evaluation requires the identification and measurement of all relevant costs and outcomes of that intervention, in comparison to the next best alternative use for those resources (Drummond 2005). In practice, economic evaluations often fall short of this objective.

In particular, economic evaluations often fail to include all relevant costs and outcomes. In terms of costs, narrow perspectives are common and may lead to an inefficient allocation of resources because the exclusion of all relevant costs may alter the conclusion of a study (Johannesson 1995). Drug company evaluations are driven by the need to convince regulatory bodies and purchasers of the benefits of their products, which generally results in a narrow focus on direct health service costs. Submissions to NICE are encouraged to take a slightly broader perspective, including all health and personal Social Services costs. This perspective is still narrow, however, ignoring costs that fall on a range of other statutory sectors, such as education and housing, costs incurred by patients and their families, and costs to the economy in the form of productivity losses. Independent economic evaluations can be just as bad, taking narrow perspectives often because of time or resource constraints. The provision of mental health services is often multi-agency and a narrow focus on the cost of healthcare and Social Services ignores the costs to the housing, employment, education and training, and criminal justice sectors, as well as those falling on the patients and their families. Knapp (2003) called these the 'hidden costs of mental illness'. Seven years on, we would suggest they are no longer hidden, just ignored.

Evaluating outcomes

In terms of outcomes, evaluations often focus on narrow measures of disease, such as symptoms. This is particularly true for drug trials. By contrast, NICE appraisal methods require outcomes for the assessment of economic evidence to be measured in terms of quality-adjusted life-years (QALYs), irrespective of the disease involved, and preferably based on the EQ-5D measure of health-related quality of life (National Institute for Health and Clinical Excellence 2008b). The choice of a generic measure of outcome is to enable comparison across all disease areas. This is clearly broader than a disease-specific focus, but this perspective still falls short of the ideal because it focuses on

BOX 1 Economic evaluation in the NICE appraisal process

The notion of economic evaluation as one tool among many is incorporated into the NICE appraisal process through a number of routes:

- the consultation process involved in the choice of appraisal topics, the development of the scope of the appraisal and the content of the draft appraisal
- the range of organisations invited to participate in the consultation and appraisal processes (the manufacturers or sponsors of the technology, national professional organisations, national patient organisations, the Department of Health and the Welsh Assembly Government, relevant NHS organisations in England and local health boards in Wales)
- the combination of evidence that it considers (effectiveness, cost-effectiveness and submissions from consultees)
- the opportunity for all consultees to appeal against the final appraisal decision.

(National Institute for Clinical Excellence 2004)

health-related quality of life, rather than overall utility (welfare/well-being) and because it ignores any positive outcomes on interest groups other than the patient. The relevance of the EQ-5D and other utility-based measures of outcome to complicated areas such as mental healthcare has been questioned because these measures tend to focus primarily on physical, rather than psychological, functioning and may not be broad enough to capture the full impact of treatments for mental disorders (Chisholm 1997). As a result, generic measures of outcome are rarely used in mental health services research (Gilbody 2002), leaving the field at a disadvantage when considering submissions to NICE.

Narrow perspectives can therefore be problematic when undertaking treatment evaluations in complex areas of health, such as mental health. One of the major criticisms of the NICE appraisal on Alzheimer's disease was the underestimate of carer benefit and the exclusion and underestimate of certain costs, in particular the cost of concurrent medication and full-time care (Ballard 2007). Similarly, among the methodological challenges of undertaking economic evaluations for NICE in ADHD, Griffin and colleagues (2008) highlight the potential underestimation of the benefits of treatment through the exclusion of the impact on the family and the underestimation of costs through the exclusion of relevant costs relating to education, crime and productivity. Only by returning to economic theory and focusing on societal costs and benefits can these problems be addressed.

A second source of methodological concern in clinical and economic evaluation and evidence synthesis is the reliance on evidence from randomised controlled trials. Many good-quality, independent and randomised evaluations of effectiveness exist but these can often be outweighed by poorer-quality efficacy trials,

MCQ answers

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usually drug trials, with short follow-ups and highly selected patient populations not necessarily representative of the general patient population. The pursuit of excellence in the scientific quality of evaluations is to be applauded, but it is important to recognise that randomised controlled trials are not necessarily synonymous with good quality and the preponderance of drug trials can bias appraisals against non-pharmacological interventions, common in areas such as mental health (Berghmans 2004). Attention should therefore continue to be paid to the quality of randomised controlled trials, an aim that is supported by the decisions of journal editors and organisations such as the Cochrane Collaboration for the production and dissemination of systematic reviews, which require stringent assessment of study quality (Higgins 2008).

Although not a methodological limitation *per se*, a further difficulty that often arises in the process of technology appraisal is the lack of appropriate data, particularly data relevant to an economic appraisal. Of the first 22 NICE technology appraisals reviewed by Raftery (2001), half stated that cost per QALY estimates were very difficult or impossible to estimate, mainly because of the lack of data on the effect on patient quality of life. This was a major limitation in the Alzheimer's disease appraisal (Ballard 2007). More often than not, the preferred solution is to base resource allocation decisions on decision models swimming in assumptions and expert opinions. Not only does this greatly increase the margin for error, but it shrouds the appraisal in uncertainty and makes it an easy target for criticism, which is perhaps not a bad thing.

Conclusions

Although few negative NICE recommendations have been the result of unacceptable cost-effectiveness, it only takes one such recommendation to bring the ethics of economics into question. With an obvious bias in favour of the ethical principle of justice, economists would strongly contend that it is in fact unethical to ignore considerations of cost in the allocation of scarce health service resources, since this means ignoring the impact that treatment decisions have on patients elsewhere in the health system.

The study of medical ethics is far more complex than this article implies. All evaluations and philosophical frameworks upon which resource allocation decisions are based are loaded with implicit assumptions and ethical dilemmas. We present here a viewpoint that, although strongly held, is clearly open to debate and interpretation.

However, it is our contention that a number of the 'ethical' concerns raised by some commentators in relation to the economic evaluation of health technologies are: (1) as relevant to the evaluation of clinical effectiveness as cost-effectiveness; and (2) are less about ethics and more about the divergence between a theoretically sound economic evaluation and economic evaluation in practice. Put simply, we suggest that economic evaluations are ethical in theory but methodologically problematic in practice. This situation is hindered by methodological guidance from organisations such as NICE that strays from the theoretical basis upon which economic evaluation is built.

Even if economic evaluations were theoretically and methodologically perfect, problems would remain. Directing resources towards all services shown to be cost-effective is limited in two important ways. First, funds may be depleted before all cost-effective services are provided if these services are large in number, particularly expensive or needed by a large proportion of the population. Second, society may prefer to fund a less cost-effective service if it believes that the service will produce a more equitable distribution of resources. These considerations, among others, are an important reason why economic evaluation should not be considered in isolation when resource allocation decisions are made.

These conclusions are true for all areas of healthcare, but can be particularly problematic in more complex areas such as mental healthcare. The complexity of mental disorders, mental health treatments and mental health outcomes often requires more complicated clinical and economic evaluations, thus increasing the possibility of error as a result of methodological limitations and constraints. Unless these complexities are taken into consideration and a broader, more inclusive framework is applied to ensure the results of economic evaluations are not biased against particular areas of healthcare, inappropriate and cost-ineffective guidance for the treatment of mental disorders is a very real possibility.

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MCQs

Select the single best option for each question stem

1 The opportunity cost of a session with a clinical psychologist is:

- a the fee or salary paid to clinical psychologist
- b the benefits that the patient could have gained by doing something else instead
- c the benefits that the psychologist could have gained by doing something else instead
- d the benefits that other patients could have gained by being treated by the psychologist instead
- e the benefits to the economy generated by the employment of the psychologist.

2 The following variables must be considered in an economic evaluation:

- a costs
- b outcomes

- c costs and outcomes
- d costs, outcomes and budgets
- e costs, outcomes and equity.

3 NICE takes the following evidence into consideration in its technology appraisals:

- a cost-effectiveness
- b clinical and cost-effectiveness
- c clinical and cost-effectiveness and submissions from manufacturers of the technology
- d clinical and cost-effectiveness, submissions from manufacturers of the technology and submissions from national professional organisations
- e clinical and cost-effectiveness, submissions from manufacturers of the technology, submissions from national professional organisations and submissions from national patient organisations.

4 The proportion of NICE technology appraisals that received a negative response between 1999 and 2005 is:

- a 1–20%
- b 21–40%
- c 41–60%
- d 61–80%
- e 81–100%.

5 The theory of welfare economics takes the perspective of:

- a the individual
- b the government
- c the family
- d the health service
- e the society.