

GUEST EDITORIAL

Health economics: basic principles and application in mental health

Introduction

Technological developments in medicine have conspired to increase costs, not only because they often require more expensive procedures, but also because they increase the size of the patient population who, at least potentially, could benefit from treatment. Health care has been considered a right of citizenship to which every person must have guaranteed equal and unlimited access. However, because of relentless pressure on public health care budgets, health care is now being treated in much the same way as food or housing or pensions – the government simply establishes a guaranteed base level of protection. Economics is about getting better value from the deployment of scarce resources when a choice has to be made. An important purpose of economic evaluation is that it should serve as a tool for decision-making regarding the allocation of scarce resources (Drummond *et al.*, 1997). Cost effectiveness means cutting costs, but not at the expense of less effective outcomes (Mooney and Drummond, 1982). There appear to be lots of mental health issues with health economic implications.

This guest editorial aims to provide an overview of recent issues, basic principles and essential procedures in the conduct of an economic evaluation of mental health care. It also aims to provide a basic knowledge of health economics for those mental health professionals who wish to incorporate an economic perspective in their research activities.

An 'effective, but not cost-effective' issue in the drug treatment of dementia

Dementia is placing substantial medical, social, psychological, and financial burdens on patients, their families, and their communities. Community-based care for patients with dementia is an explicit policy preference today. Current economic pressures on available resources – and especially concerns about future resource pressures – have attracted growing attention to the costs and cost-effectiveness of community care from national and local policy-makers, service providers and funding bodies (Knapp and Wigglesworth, 1998). Cholinesterase inhibitors (ChEIs) such as donepezil, rivastigmine, and galantamine have been widely used for people with mild to moderate Alzheimer's disease (AD). An earlier review of ChEI studies, which specifically assessed the short-term benefits, concurred with the manufacturers' conclusions that there was evidence to suggest a benefit to patients. Initially, the UK National Institute for Health

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and Clinical Excellence (NICE) accepted the review. However, in March 2005, it published a draft report stating that the ChEIs were of little long-term benefit, and further recommended that they should not be used for the treatment of Alzheimer's disease. The NICE report concluded that the longer-term use of ChEIs only delayed the need for a patient to go into full-time care by about one month when measured over a five-year period. Given the side-effect burden to the patient and the cost of the treatment regime, they concluded that the use of ChEIs could not be justified. The recommendation not to fund ChEIs provoked protests from patient groups and strong rebuttals from the companies involved. It has been argued that the drugs do show beneficial effects in individual patients which will always be lost when effects are averaged out, and that the benefits to individual patients in terms of quality of life were not adequately addressed in the report (O'Neill, 2005). In January 2006 NICE published preliminary revised recommendations on the use of ChEI drugs in AD, which were confirmed in late 2006: three ChEIs (donepezil, galantamine, and rivastigmine) were recommended only for people with AD of moderate severity (with MMSE scores between 10 and 20 points), while memantine was not recommended for people with AD (Mental Health Economics Task Force of the International Psychogeriatric Association, 2006).

The new recommendations mean that ChEIs in the United Kingdom will not be prescribed for those at an earlier stage of decline (MMSE > 20 points). As a result, no-one in the UK will now benefit from an early diagnosis of dementia in terms of drug therapy. Similar issues have not been raised for other chronic common diseases such as hypertension and diabetes mellitus, which, like the range of MMSE scores in AD, are also diagnosed according to a certain range of blood pressure or level of serum glucose. Hypertension and diabetes mellitus are treated routinely with little expectation of immediate clinical improvement, but rather to reduce or delay the risk of debilitating complications of these diseases. People with AD should have the same right of access to medical treatments as those with other common chronic illnesses.

An 'effective, but potentially risky' issue in the drug treatment of dementia

There is another issue relating to the use of atypical antipsychotics for the treatment of behavioral and psychological symptoms of dementia (BPSD) that has the potential to inflict much heavier economic costs on society. Great concerns about drug safety were raised in 2003 and 2004 based on the emerging evidence of a possible raised risk of cerebrovascular adverse events (CVAEs) in some people with dementia who had taken risperidone and olanzapine in placebo-controlled trials (Zaraa, 2003; Ames, 2005). In March 2004, the UK Committee on Safety of Medicines (CSM) informed clinicians that risperidone and olanzapine should not be used to treat BPSD because of an increased risk of strokes with both drugs and an increased risk of mortality with olanzapine (Committee on Safety of Medicines, 2004). In response, the US Food and Drug Administration (FDA) put a black-box warning on the off-label use of atypical antipsychotics (aripiprazole, ziprasidone, risperidone, olanzapine) used in the control of psychotic symptoms in AD patients.

If the burden of BPSD is small and if there are adequate alternative treatment options that are equally effective, recommendations to eliminate certain treatments from the physician's toolbox may seem reasonable. However, the burden of BPSD is high and treatment difficult, so any outright ban of specific treatments (like the pharmacological treatment of BPSD) may not be the most prudent approach (Shah and Suh, 2005). Putting severe restrictions upon the use of antipsychotics for people with dementia is likely to have a discriminatory effect, not only on those deemed so severely disturbed as to require them, but also on the prescribers and associated carers who are seen to be condoning an extreme practice, and further likely to place an economic burden on society (McKeith, 2005).

Economics and mental health

Economics can be defined as a social science that seeks to analyze and describe the production, distribution, and consumption of goods and services. It studies how individuals, coalitions, and societies seek to satisfy wants and needs when available resources are insufficient to satisfy them all. Concepts of mental health include subjective well-being, perceived self-efficacy, autonomy, competence, intergenerational dependence, and self-actualization of one's potential. It is generally agreed that mental health is broader than a lack of mental disorders. Mental disorders are common, affecting more than 25% of all people in all countries and societies and individuals of all ages. Mental disorders have an economic impact on society and on the quality of life of individuals and their families. Individuals who suffer the distressing symptoms of mental disorders may be unable to participate in work and leisure activities, while their families are required to provide physical and emotional support. In addition to the direct burden and lost opportunities, families often have to set aside a major part of their time to look after a mentally ill relative, and suffer economic and social deprivation because he or she is not fully productive.

The economic impact of mental disorders on society is large and manifold. Mental disorders are more likely to result in disability than in premature death. Disability causes loss of productivity and higher costs in providing care and support. The global recognition of mental disorder as a significant public health problem has led to additional demands being made on health care resources that are already stretched. It is therefore increasingly important to be able to prove that an investment of health care resources into mental health care and prevention is needed and is worthwhile. This translates into generating evidence on affordable and cost-effective mental health care strategies.

Principles of economic evaluation

Scarcity of resources lies behind all the barriers to improved mental health. Thus, a series of choices has to be made to maximize the health gain from any given budget. Allocation of resources may be done by prioritizing competing needs. Economic evaluation is a technique that was developed to assist decision-makers in choosing between different courses of action or investment. It entails drawing up a balance sheet of the advantages (benefits) and disadvantages

(costs) associated with each option so that choices can be made. Rising costs, often associated with new technologies or novel drugs, and spending limits, have prompted a search for greater efficiency. Therefore, economic evaluation has increasingly become part of modern health care. Making a choice implies in turn the sacrifice or foregoing of an alternative action or investment. The economic approach attempts to value the worth of a particular resource, decision or strategy, with reference to its “opportunity cost,” namely the value attached to the next best alternative.

In an economic evaluation, the scope or perspective should be decided at the planning stage – i.e. whether to take a societal perspective or a specific payer's point of view. This refers to the viewpoint from which the analysis is being taken, which, in ascending order of comprehensiveness, might be that of a particular agency or government department (e.g. ministry of health), the statutory/formal sector as a whole (for example, social services), or a societal perspective which assesses the impact of the intervention on all agencies, including patients themselves, as well as their carers or households. The choice of viewpoint will influence what costs and outcomes are to be measured. A viewpoint should be determined according to whether the intervention under study is expected to exert a differential impact on these various agencies/sectors. Limiting the economic analysis only to the health care sector or the public sector therefore excludes substantial costs from the analysis. For example, there are many components involved in the delivery and financing of dementia care. The main costs of dementia are costs for living and caring, whereas the costs for therapies are rather low. In most countries, the burden of dementia care is shouldered by the community and/or an informal caregiver. Therefore, limiting the economic analysis only to the health care sector or the public sector excludes substantial costs. An important principle of economic evaluation is that it takes a broad, societal perspective, where all costs are included, regardless of where they occur and regardless of who pays. For example, allowance should be made for inputs of unpaid volunteers/family carers as well as formal care inputs.

Designing economic studies

In undertaking an appropriate economic evaluation of an intervention, program or strategy for mental health, a number of study designs need to be considered. Since economic evaluations often take place alongside clinical evaluations or trials, the design of the study typically will need to be agreed in conjunction with other evaluators. The most desirable design requirements for the economic evaluation of a mental health care intervention revolve around the presence of a control group (against which to draw comparisons with the intervention group), and the prospective follow-up of these two groups over time. The control group is essential, such as a placebo group (or a “do-nothing” alternative), or a comparison between two interventions (Drummond *et al.*, 1997). “Do nothing” does not actually mean to do nothing, it just implies that the intervention of interest is added to some kind of standard or established therapy. This “experimental” study design is the “gold standard” of clinical and economic evaluation since it is able to demonstrate most clearly that

changes in selected measures are attributable to the intervention, as opposed to other possible explanatory factors ("confounding" variables). Where it is not possible or practicable to carry out an experimental study, an observational study design can be used. This may have better external validity – preserving the context in which care is provided – but shifts the focus of the analysis toward identifying associations between the intervention and changes in costs or outcomes (as opposed to attributing a causal relationship). A further desirable aim is recruitment of a sufficient sample of patients and/or centers to show statistically significant changes between groups (at least 100–200 subjects per group if possible); the sample size necessary to show a economically significant difference may be much greater than that necessary to show a clinically significant difference between study groups.

Mode of economic evaluation

As well as deciding on the most appropriate study design, consideration must also be given to the mode of economic evaluation (that is, the manner in which costs and outcomes data are to be combined). The simplest of cost evaluations is commonly referred to as *cost-minimization analysis* (CMA), but this is only appropriate if it is known that outcomes are identical (very unlikely). A CMA merely focuses on finding the least costly method of achieving these outcomes. A much more common mode of economic evaluation in the field of mental health care is *cost-effectiveness analysis* (CEA), which assesses not only the costs but also the outcome of an intervention, expressed as a non-monetary quantified unit such as the cost per reduction in symptom level, the cost per nursing home admission averted, symptom free days gained, and cure rate. Where there is more than a single measure of outcome under investigation, it is more correct to label this type of study a *cost-consequences analysis* (CCA). However, results may be difficult to interpret and the selection of outcome is a critical issue. A further mode of evaluation is *cost-utility analysis* (CUA). The CUA has considerable appeal for decision-makers since it generates equivalent and therefore comparable study data upon which priorities can be based. The effect is expressed in terms of utilities, a combined index of the mortality and quality of life or disability effects of an intervention. In CUA, the concepts of quality-adjusted life years (QALYs) are frequently used. The final option is *cost-benefit analysis* (CBA), which refers to a form of evaluation in which all costs and outcomes are valued in monetary units, thereby allowing assessment of whether a particular course of action is worthwhile, based on a simple decision rule that benefits must exceed costs. This approach is difficult to undertake because of the requirement to quantify outcomes in monetary terms, and consequently is found very rarely in mental health care evaluation.

Cost measurement

Most costs should be calculated in two stages. First, resource utilization is expressed in terms of physical units (such as number of days of an inpatient admission, number of visits to an outpatient clinic, days in a nursing home,

hours of home support). Secondly, the unit cost or price in money terms for each resource used should be investigated to calculate the actual cost (= amount of used resource \times unit cost). The data collected on each individual's resource utilization can provide detailed information on the wide range of resources consumed. Resource utilization should include health care services (inpatient, outpatient, day hospital, emergency room, community mental health center, general practitioner, community practice nurse, medication), social care services (social worker, day care center, meals on wheels, home care or support), accommodation, out-of-pocket purchase for self-support (private hire of a paid caregiver or a paid home helper, health food and supplements, etc.), caregiver time and missed work of caregiver. Most economic evaluations consider *direct costs*. These are the changes in resource utilization. Meanwhile, in some cases, significant resource inputs are made by the patient or family in terms of travel time, home adaptations and informal care. Some time commitments may result in lost work opportunities or lost productivity. These are known as *indirect costs*.

At the initial stage in the collection of resource utilization data, we should identify relevant units of potential resource utilization, such as contacts with doctors, other health other professionals, community-based private or voluntary sector providers and hospital inpatient and outpatient care. According to differing scope (perspective), objectives and settings of the study, as well as particular health care needs of the target population, we should collect different kinds of data on resource utilization. For example, users with more severe or enduring mental disorders, such as people with AD, often need a wider range of service supports than people with common mental disorders such as depression and anxiety (e.g. day care services and residential care). For economic analyses carried out alongside clinical evaluations, the most convenient means of data collection is often via the use of an interviewer-administered service receipt schedule, which can record resource utilization over defined retrospective periods at the various assessment points of the study. It is also important to ensure that data are collected on the socio-demographic and socio-economic characteristics of the studied individuals, including lost opportunities to work. The cost and effectiveness are also determined (to a significant extent) by the accessibility, availability, and quality of mental health services. It is therefore vital to gain an understanding of the characteristics of the local health and social care system. Data are needed at a local level in two domains: *socio-demography* (including the age, sex, education, and employment profiles of the population), and *health care services* (including the structure, organization, and financing of both general medical and mental health services, plus the availability of these services by the population under study).

Outcome measurement

In health economic evaluations, the outcome used must be relevant and appropriate. Surrogate or intermediate end points are inappropriate for CEA (Johannesson *et al.*, 1996). An important distinction must be made between indicators of intermediate outcomes and final outcomes. The former, which can also be referred to as process indicators, should not be the focus of the analysis,

since improvement in detection rates may not result in improved patient welfare or mental health. For example, the MMSE, a measure of cognitive ability, is often used in dementia intervention studies. However, it is questionable if these measures are relevant outcomes for health economic evaluation, since they should be regarded as surrogate end points. It is not the cognitive decline itself that causes most problems in dementia care (Wimo *et al.*, 2000). A delay in nursing home placement has been suggested and used as a clinically relevant outcome measure in dementia intervention studies, since there is a basic belief that a prolonged period at home (that is outside an institution) improves the quality of life for the patient. However, a prolonged period at home may also produce more stress for the informal caregiver and, as a consequence, a higher cost of informal care (Max, 1996). Therefore, it may not be regarded as a relevant outcome. Thus, while process indicators are undoubtedly an important source of differentiation between study samples, their use as indicators of improved patient welfare needs to be treated with caution. Final outcomes, on the other hand, are concerned with detecting changes in the physical, psychological or social well-being of individuals, and commonly revolve around the measurement of symptoms, functioning and disability, quality of life and service satisfaction. Quality of life of both patients and caregivers is considered as a relevant outcome. Instruments to measure quality of life should be preference-based to be appropriately applied to CUA (Feeny *et al.*, 1996; Gold *et al.*, 1996). Quality-adjusted life years (QALYs) frequently are used as an outcome measure in health economic research, since they reflect both quantity and quality of life (Torrance, 1996). The use of QALYs also gives opportunities to make comparisons with other diseases. QALYs are expressed as figures between 0 (death) and 1 (perfect health) and are widely used in CUA. The main problem with QALYs is determining how the preference score for a specific health state should be measured. There are other approaches that can be used in CUA such as DALYs (disability-adjusted life years) (Allotey *et al.*, 2003), and HYEs (healthy years equivalents) (Dolan, 2000). DALYs focus on productivity rather than quality of life, and HYEs require the analysis of a great number of health scenarios.

Analysis and assessment of costs and outcomes

Economic evaluation provides a means of comparing the costs and outcomes in an explicit framework. This enables decision-makers to assess the extent to which the intervention or strategy can offer a good use of scarce resources. An analysis of costs alone, or indeed of outcomes alone, does not provide such information. It is important to stress the fact that it is the incremental result that is of interest, which can be explained in terms of the incremental cost-effectiveness ratio (ICER):

$$\text{ICER} = \Delta C / \Delta E = (C_N - C_O) / (E_N - E_O) \text{ where } C = \text{costs}, E = \text{effects}, N = \text{new treatment or intervention}, O = \text{old treatment or intervention.}$$

There are a number of scenarios that can be considered when assessing whether an intervention or treatment represents a worthwhile use of resources (see Figure 1).

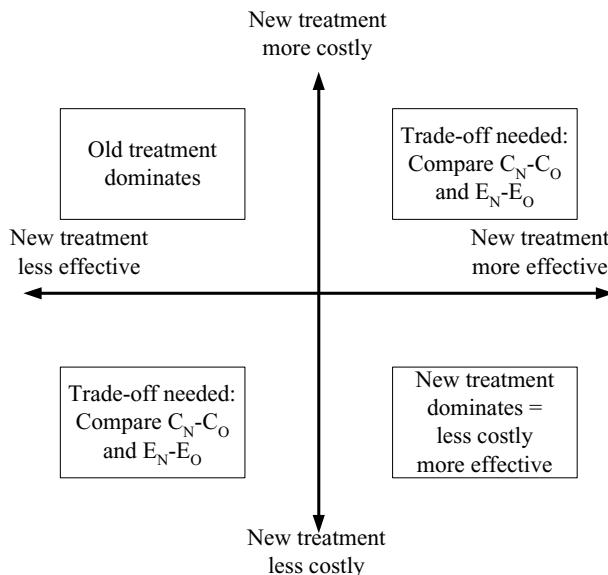


Figure 1. The cost-effectiveness plane and domination

Scenario 1

If statistical analyses of cost and outcome data show that the new intervention is both significantly less costly and more beneficial than the control group (usual care or “do-nothing”), one can immediately conclude that the new intervention is preferable. Likewise, usual care or “do-nothing” is the preferred choice when it is cheaper and more effective.

Scenario 2

If the costs and outcomes are found to be equivalent, then either is acceptable. If only cost is equivalent, then the more effective intervention is preferable, and if only outcome is equivalent, then the cheaper intervention is preferable.

Scenario 3

When the evidence shows that one of the two (or more) interventions is both more costly and more effective, it is necessary to assess whether the additional costs are worth the greater effectiveness. This can be established by calculating an ICER. The ICER is positive when one of the groups costs more and produces a superior outcome. The ICER is negative when the new intervention costs less but has superior outcomes (i.e. cost saving), or when the innovation costs more but produces worse outcomes (i.e. a bad investment).

In any of these circumstances, the usefulness of these estimates depends on the validity and credibility of the evidence about the sampled populations of the study, and this is never perfect. In other words, it is impossible to exclude uncertainty completely. A key strategy to combat these uncertainties in an economic

evaluation is to carry out a *sensitivity analysis*, which involves the introduction of alternative values to important study parameters, including both costs and outcomes, with a view to assessing whether overall conclusions are robust in relation to these plausible changes or whether results are very sensitive to them.

Summary

The list below summarizes the stages of a typical economic evaluation. All stages need to be considered and carried out in order to obtain a valid and reliable set of findings.

- (1) Perspective or scope: identification of the essential category of the costs and outcomes that must be included.
- (2) Design: definition of the alternative interventions to be evaluated (experimental or observational), and duration of the intervention (16-week clinical trial or 1-year longitudinal study).
- (3) Mode of evaluation: CMA, CEA, CCA, CUA, or CBA.
- (4) Data collection: costs (direct provision of health and social care, social opportunity costs, lost productivity, carer costs, other public sector costs) and outcomes (long-term clinical effectiveness such as morbidity and mortality with patient self-assessed health state or interviewer-assessed health state).
- (5) Valuation: quantification of these identified costs and outcomes and further consideration of social weight.
- (6) Analysis: comparison of costs and outcomes (i.e. ICER).
- (7) Qualification: revision of findings in the light of risk, uncertainty and sensitivity.

Methodological debates on various aspects of economic evaluation, such as the alternative techniques available for measuring health state preferences, are still continuing. In this context it is worth noting that economic evaluation is no panacea for making the 'right' decision when having to allocate scarce resources; rather, it is an additional tool that can facilitate explicit, evidence-based decision-making.

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