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Published version deposited in CURVE April 2010

**Original citation & hyperlink:**

Harrison, K. , Gray, K. and Barlow, J.H. (1998) Evaluation of clinical interventions: effectiveness, efficiency and equity.. British Journal of Therapy and Rehabilitation, volume 5 (8): 396-401.

<http://www.ijtr.co.uk/>

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# Evaluation of clinical interventions: effectiveness, efficiency and equity

Karen Harrison, Keith Gray, Julie Barlow

## Abstract

**All clinical or purchasing decisions require availability of information on the costs as well as the outcome benefits of interventions. Frequently, economic analyses are either not included in the research design or are couched in language that is inaccessible to the non-economist. Clinical and economic aspects of research require input from patients to ensure that any research undertaken is relevant and that any measures selected are appropriate.**

Clinicians or managers who purchase, plan or provide for the health-care needs of the patient population have to decide which services must be provided and to whom in order to most effectively and efficiently reduce the burden of acute illness, disability and premature death (Tugwell et al, 1985). Typical questions requiring economic insight are:

'What clinical procedure for the management of low back pain would most effectively and efficiently help the patients in my department?'

'What health services for the screening and treatment of asthma would most effectively and efficiently help the patients, on whose behalf I purchase health-care?'

Evidence-based patient care is clearly here to stay. The impetus for only providing treatment which has empirical evidence supporting its use is more than 20 years old. It was spear-headed into action through the work of Archie Cochrane, and is perpetuated today through the work of the Cochrane Foundation (Cochrane, 1972). It is obviously unhelpful to give a patient a treatment unless there is some evidence that the intervention is likely to improve the lot of the patient(s) to whom it is administered. The exciting challenge now is to make managerial decisions utilizing empirical evidence in order to best improve the situation for the patient. However, potential treatments are unequally beneficial and at the same time carry unequal costs of administration.

Managerial decisions concerning treatment provision have to take account of these economic factors when rationing a finite resource budget. The purchase or utilization decision is further complicated by a trade-off between efficiency and equity. Hence, there may be preferential treatment involving loss of efficiency whereby resources are moved, e.g. to favour the young over the old, or the poor over the rich. The managerial decision concerning the selection of treatment for utilization or purchase thus becomes increasingly complex, taking into account as it must, clinical, financial and ethical factors (Figure 1).

## HEALTH ECONOMICS AND CLINICAL DECISION-MAKING

Recent research in health economics has focused upon a number of recurring themes. These are principally the general feasibility of economic evaluations of health-care programmes and the technical and conceptual difficulties associated with such evaluations. The latter include:

*Identification of the 'best' overall economic evaluation framework:* Various techniques such as cost-benefit analysis, cost-utility analysis, cost-effectiveness analysis

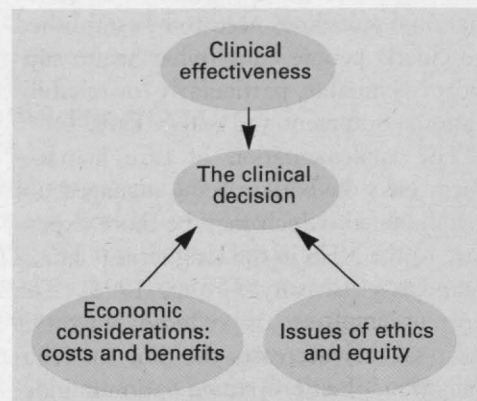


Figure 1. Components of clinical decision-making in terms of service purchase, planning or provision.

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sis and cost-ratio studies. Each have relative merits and drawbacks (Coyle and Davies, 1993; Luce and Simpson, 1995).

*Technical debate regarding the use of appropriate discount rates when costing health-related benefits and costs:* Discounting has to be applied whenever a financial cost or a financial benefit occurs at some later date (Cairns, 1992; Neuberger and Parsonage, 1992). This is because as a general principle, people value money that they have in their hand more than money which they may have in future. So future money is considered to be worth less and is discounted.

*Disagreement regarding which quality of life index should be used alongside the economic analysis:* These measures are used to indicate general practical benefit to the lifestyle of the patient or client which occurs as a result of the intervention made (Gudex, 1986; Car et al, 1996).

#### FEASIBILITY OF ECONOMIC EVALUATION

These current issues occur in addition to the continuing debate over the general feasibility of economic evaluation studies, and whether they are a worthwhile use of scarce health resources (Tolley et al, 1996). Tolley et al (1996) identified the need for future economic evaluations to satisfy at least one of the following conditions:

*Improvement of the applicability of economic evaluation studies:* There must be utilization value associated with the use of such studies.

*Reduction in misunderstanding and conflict between key players involved in resource decision-making in health care:* Such players could be Department of Health officials, members of the NHS Research and Development Board, health service purchasers and health service provider managers.

*Education to aid decision-making based upon financial evaluation studies:* Thus data should not be used blindly, but all important costs and benefits should be weighed and made accessible to non-health economists.

#### THE PATIENT PERSPECTIVE IN RESEARCH DESIGN AND ECONOMIC ANALYSIS

A key theme of the issues listed is the reality principle. How applicable are findings from the analyses? How will findings impact upon decision-making? And ultimately, what difference will this make to patient care?

The overall aim of all economic analysis in health-related research is the best use of finite resource for the maximum good of patients (Sheps and Birnbaum, 1993). This paper argues that the fundamental starting point for achievement of the conditions specified by Tolley et al (1996) is an increase in the appropriateness of specific economic evaluation methodology. This increase in appropriateness may be achieved by utilization of qualitative techniques such as interviews or focus groups to explore patient and client perceptions of treatment costs and benefits (Harrison and Barlow, 1995).

Basically, an elegant research design for a clinical trial or associated specific economic analysis is of little value if the research is not targeting issues which are important to the patient. Including the client at the stage of formulation of the initial research question and design of the economic analysis will cause that project to be appropriately focused onto tasks of relevance.

It is important to recognize the need for researchers to properly integrate both the economic and health status evaluations associated with specific health treatments (Drummond, 1994). There can be a danger that during the early stages of research design, the economic evaluation may be considered less central to the overall research programme. This is especially important given the ongoing concern among health-care professionals about the relevance and feasibility of economic evaluations (Tolley et al, 1996). The consequence can be that economic evaluations are 'bolted on' to the health evaluation, particularly if the majority of the intended economic data are to be collected outside of the controlled health trial's time-span.

A participant focus can identify the link between economic and health states, and so can help researchers to ensure that the economic analysis is fully integrated with the health analysis. The resulting research information should then contain the necessary clinical and financial information that, when

Basically, an elegant research design for a clinical trial or associated specific economic analysis is of little value if the research is not targeting issues which are important to the patient.



used together, can help managers to make optimal decisions about which treatment interventions to use or purchase.

## A PRACTICAL EXAMPLE

A randomized controlled trial is currently underway to explore the efficacy of offering arthritis self-management programmes (ASMP) to people with arthritis (Figure 2). These programmes are run by trainers who themselves have arthritis, have attended an ASMP and have been trained to deliver the ASMP by Arthritis Care, a voluntary organization working with and for people with arthritis (see *Useful addresses*). The ASMP was developed for people in North America with mild to moderate arthritis (Lorig and Gonzalez, 1992).

The ASMP comprises 6-weekly sessions of approximately 2 hours in length delivered in community settings by pairs of lay leaders, most of whom have arthritis. Topics covered include information, cognitive pain management, communication with medical professionals, problem solving and goal accom-

plishment. Randomized controlled studies have shown that, at 4-month follow-up, ASMP participants reported a reduction in pain, a reduction in depression and a decreased number of visits to physicians (Lorig and Holman, 1993).

The first evaluation of the ASMP in a UK context focused on older people with arthritis (i.e. over 55 years of age) using a pre-post test design. Results showed that after 4 months, participants demonstrated significant increases in their sense of control over arthritis, positive affect, cognitive symptom management, communication with doctors, and level of expertise in relaxation. In addition, significant decreases were found in terms of pain, depression and GP visits (Barlow et al, 1997).

Running alongside, and integral to the research design of the randomized controlled trial of the ASMP described above, is an economic analysis. Broadly, the analysis considers the costs associated with delivery of the ASMP for all parties, against the benefits (expressed wherever possible in financial terms) which result from having attended the programme.

Two different types of economic analysis are being utilized in order to assess the effectiveness of this programme provision. First, a cost-effectiveness analysis compares the cost of health against the desired change in health outcomes, expressed in measurable units. In health research such units might include number of re-admissions, change in joint range of movement and alteration in desirable health-related behaviour (e.g. weight loss or gain, exercise increase or decrease, change of blood pressure). A cost-effectiveness analysis is the most common form of economic analysis found in the literature (Sheps and Birnbaum, 1993).

It may be helpful to distinguish between the techniques of cost-effectiveness analysis and cost-benefit analysis, as the latter term is frequently heard (Figure 3). In cost-benefit analysis, both costs and benefits are described in terms of monetary value, allowing entirely different interventions for different health conditions to be compared and ranked in terms of relative net benefits. While health service workers generally feel reasonably comfortable in ascribing monetary values to the cost of treatment delivery, they often feel much less comfortable in trying to ascribe monetary values to the benefits of treatment



Figure 2. Focus group held with participants with arthritic conditions to discuss the financial impact of living with arthritis after following an arthritis self-management programme.

### Cost-effectiveness analysis

This involves a comparative description of all of the costs of the project, expressed in monetary terms, against all of the changes in health-care status which occur, expressed in relevant natural measureable units.

### Cost-benefit analysis

This involves a comparative description of all of the costs of a project with all of the benefits of a project, each expressed in monetary terms such as pounds or dollars.

### Cost-utility analysis

This relates the costs of a project expressed in monetary terms, to a measure of usefulness of outcome (or utility). One such measure is the QALY, which is a broad index which describes in combination both quantity and quality of life.

Figure 3. A summary of economic analyses.

(Simko and Conklin, 1989; Harrison, 1991).

An interesting example of this attitude is to be found in a paper evaluating cost-effectiveness of administering a screening and treatment programme for *Helicobacter pylori* in the prevention of gastric cancer (Parsonnet et al, 1996). Under the methodology section, a subsection discusses the economic impact of premature death upon costs thus:

'Since dying of gastric cancer prevents routine medical expenditures that would have accrued later in life, we estimated the financial consequences of premature death with medical expenditure data'.

In this analysis, untimely death represents a financial saving to the health service, and illustrates the dilemmas which may be associated with the process of ascribing monetary values to clinical outcomes.

The second type of economic analysis used was a cost-utility analysis. This is a form of economic evaluation which measures costs in terms of monetary values (i.e. pounds) and measures the outcome in terms of value to the recipient of the program or intervention. Utility is the perceived value of usefulness of something to somebody, and is generally measured by a broad quality measure such as quality-adjusted life years or healthy year equivalent.

Hence both techniques involve the description of costs of the intervention, but do not demand a description of benefits, in monetary terms. Where a benefit would reasonably translate into a monetary value it can be expressed, for example, as a reduction in cost of drugs following a reduction in symptoms such as pain or joint inflammation activity. This benefit may be easily costed and hence an estimate of the financial impact of the intervention made.

#### RESEARCHER IMPERTINENCE

In the initial stages of research design, members of the research team sought to identify suitable measures with which to judge this intervention in economic terms. Some costs appeared relatively straightforward to identify: payment for trainers, room hire costs, travel costs of course participants, to name a few. Benefits were much more difficult. The Euroquol quality of life measure is being utilized, but this is a very general measure which does not reflect the detailed benefits associated with attendance of the ASMP.

The research team finally concluded that they did not know precisely the costs and costed benefits of attending the ASMP, because not all of them have arthritis and none had attended the programme as a participant.

This simple story illustrates an important point; it is possible to very carefully, very rigorously and very scientifically conduct a trial or economic analysis which may miss the point. A disability perspective is imperative when conducting research in a disability field (Oliver, 1996; French and Swain, 1997). Consequently, the technique of focused group discussion was utilized to ascertain from participants the nature of the costs and benefits associated with the attendance of the training programme (Maynard, 1990).

#### Focus group technique

Focus group technique was first described by Merton et al (1956). The authors used the technique to investigate the social effects of films and television programmes upon the public audience. Essentially the technique involves a group of research participants meeting to discuss an area of interest or awareness which they all hold in common. The focus of the discussion is maintained by a researcher moderator, who acts in a facilitative, non-directive manner to both encourage the flow of discussion and hold the group of discussants on task.

Kitzinger (1995) defines the focus group as 'a form of group interview that capitalises on communications between research participants in order to generate data'. Since opinions and attitudes are both socially formed and socially articulated the focus group discussion provides the dynamic for developing, challenging and refining ideas. Analysis of the qualitative data produced involves standard corroborative thematic analysis techniques, usual for research of this type.

#### PATIENT PERSPECTIVE IN ECONOMIC EVALUATION AND RESEARCH DESIGN

In seeking to base clinical decisions on a sound evidence base, it is necessary to be able to access research information relevant to the specific area of decision-making.

Likewise, where a research project includes an economic evaluation, it is important that the changes in health status measures are those which are perceived to be important by the patient themselves.

*In seeking to base clinical decisions on a sound evidence base, it is necessary to be able to access research information relevant to the specific area of decision-making.*



However, it is relatively rare for patients to be interviewed in the process whereby a research question is formulated and refined. Likewise, it is virtually unknown for patients to be consulted in the process of defining and measuring the costs and benefits associated with achievement or maintenance of good health.

There have been repeated and increasing challenges to the medical model of health (Jones, 1994), and a growing swell of opinion supporting the right of the patient to have a voice in decisions relevant to their future (Swain et al, 1993).

This voice is increasingly being sought by decision makers in health care, and a succession of government publications beginning with the *Working for Patients* 1988 white paper have supported this approach. An example is to be found in the white paper *The NHS: A Service with Ambitions* which states:

'Our ambition is for a high quality, integrated health service which is organised and run around the health needs of individual patients, rather than the convenience of the system or institution' (Department of Health, 1996).

It could be proposed that there is a place for hearing the voice of the patient not only at the point of making a clinical decision about health care, but also, to move back a step in the decision-making process, in order to define areas of importance for

research to generate the evidence upon which clinical decisions are to be made. Additionally, where such research projects carry on economic evaluation, the benefits or impact of intervention should be defined in partnership with the patients who are the subject of that research.

'Greater lay involvement in setting the research agenda would almost certainly lead to greater open-mindedness about which questions are worth addressing, which forms of health care merit assessment and which treatment outcomes matter' (Chalmers, 1995).

In this way the 'evidence' that forms the base of decision-making in practice will be truly relevant to those who will be the focus of the clinical decisions of the future.

## CONCLUSIONS

Economic analysis in health care is fundamentally a set of principles for assessing resource use in comparison with outcomes in order to determine the best course of action when having to make choices between two or more alternative courses of action. In this context, the allocation of all health-care resources requires an economic 'bottom-line' (Muller, 1991). In simple terms, one would generally not make a purchase (or select an option) without knowing both the usefulness or value of the object and its cost.

However, economic analyses have not been widely used in the field of health research. Downie (1995) undertook a study commissioned by the Department of Health to collect information on current health services research and related work in the UK. Downie recorded 6185 projects that were either in progress or completed between January 1990 and August 1992, of which 33% were concerned with health technologies. Of the 2060 health technology projects, less than 10% appeared to have a costing element. As a result of this demonstrable deficiency, a report on health technologies prepared for the Central Research and Development Committee has laid emphasis on the need for rigorous assessment of the effectiveness and safety of new and existing technologies, their cost effectiveness, and their social, ethical and organizational impacts (Downie, 1995).

## KEY POINTS

- The current context of health-care practice requires therapists and managers to take decisions where choices are made between different courses of action.
- All purchase decisions require that not only the value, but also the cost of the product (or service) is known.
- Currently, economic analysis is under-used and frequently inaccessible to the non-economist reader.
- Research activity must combine at the stage of inception a consideration of both clinical effectiveness and cost-efficacy.
- Research design must show relevance to issues considered to be important by the patient.
- Managerial judgment may choose to over-ride factors of efficacy or efficiency, in order to offer equity to patients with poor access to health-care provision.

It is important that the information contained within the economic analysis should be comprehensible to health service clinicians and managers. If information is not accessible it cannot be used in the decision-making process within the operational health-care field. If relevant research evidence cannot be understood it will not impact upon clinical practice, and thus have little practical value. Clinicians need a greater awareness of the importance of the production and documentation of measurable outcomes in their day-to-day operation (Simko and Conklin, 1989). Decision makers are more likely to use the products of research if they themselves have been involved in the production of the results, or similar epistemological development activity (Gibbons et al, 1994; Pettigrew, 1996).

Finally, patients or clients need to be involved in all aspects of research design from formulation of the research question to the identification of specific factors for later collection and detailed empirical analysis. Such involvement can be achieved using qualitative research techniques, such as interviews or focused group discussion. Thus the new 'perfect' research design will be patient focused, include both clinical and economic data collection and analyses, and feature both quantitative and qualitative methodologies. Only then will research evidence be provided which is sufficiently relevant and accessible to guide the process of clinical and purchasing decision-making in the health-care field. **BJTR**

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**USEFUL ADDRESS**

Arthritis Care  
18 Stephenson Way  
London  
NW1 2HD

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