

Evaluating the cost-effectiveness of interventions designed to increase the utilization of evidence-based guidelines

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Evidence-based medicine has highlighted examples of where clinicians' treatment decisions do not accord with 'best practice' defined by high-quality research. This has resulted in the development of implementation interventions which attempt to change professional practice, such as educational programmes and audit with feedback. As these behavioural interventions themselves require a share of the health service's finite resources, it is important to evaluate their cost-effectiveness in terms of their effect on health care and hence on health outcomes. This paper considers the economic characteristics of implementation interventions and introduces methods by which their cost-effectiveness can be estimated in advance of significant investment. The paper emphasizes that implementation interventions cannot be good value for money unless the 'good practice' for which increased utilization is considered important is itself cost-effective. Furthermore, the likelihood that an implementation strategy will be cost-effective will depend on a number of factors including its cost, its effectiveness in terms of increasing utilization of 'good practice' and the costs and benefits of 'good practice' relative to an appropriate comparator.

Introduction

In recent years, there has been developing interest in the use of interventions to change clinical practice. Their use has been a response to the widespread observation that treatment decisions taken by clinicians frequently do not reflect the findings of research evidence. For example, the least effective drug for the management of menorrhagia, on the basis of a meta-analysis of randomized trials, was found to be the drug prescribed most frequently for the condition in a sample of general practices.¹ A range of implementation techniques has been employed, including educational programmes, sessions from opinion leaders and audit with feedback,² and their general objective has been to increase the utilization by practitioners of health care that has been defined as 'good practice' within published evidence-based guidelines.

Given the increasing use of interventions to change professional practice, it has been recognized that research is needed to evaluate their effectiveness and cost-effectiveness,³ and a number of evaluations are now in progress.² This programme of research has raised a

variety of methodological issues regarding appropriate research design for evaluations of implementation interventions. Most of this interest has been directed towards the methods for evaluating effectiveness (i.e. the extent to which the strategies increase the utilization of good practice^{4,5}). However, given the importance of assessing the value for money of interventions to change clinical practice, there are also some important methodological issues associated with evaluating their cost-effectiveness. This paper considers some of these issues.

Defining cost-effectiveness

As a starting point, it is important to be clear about the meaning of the term 'cost-effective'. This has been defined elsewhere,^{6,7} but can usefully be illustrated using Figure 1. This shows the economic comparison of two health care interventions, A and B. For example, these might be two drugs for menorrhagia. The interventions can be compared in terms of their costs and of their health consequences. (By costs, we mean the full health service cost implications, not just the acquisition cost of the drug; so the costs of any subsequent diagnostic tests and surgical treatment should be included.) Figure 1

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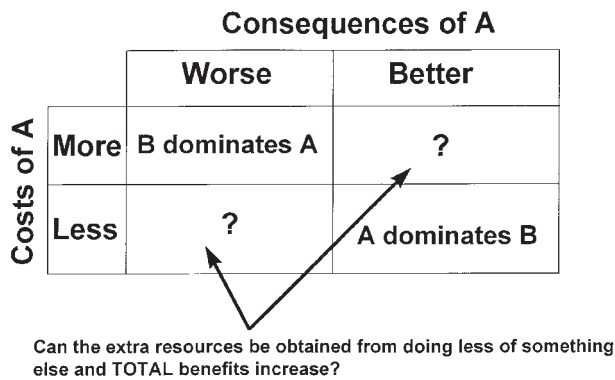


FIGURE 1 Classification of the costs and consequences of two hypothetical treatments, A and B, for the same condition.

shows that A can cost less or more than B and can generate better or worse health consequences. Hence, four cells can be defined, as shown in Figure 1, relating the differential cost and consequences of the two interventions. In the bottom right cell, A is more effective (better health consequences) and less costly than B. Assuming that the objective of the health care system is to maximize health, the situation in this cell can be termed economic dominance and, in these circumstances, A would be considered unequivocally more cost-effective than B. Conversely, in the top left cell, B would dominate A as it generates better health consequences and costs less. (This is a simplified analysis. In reality, costs and effects are stochastic rather than deterministic and it is necessary to refer to the probability of an intervention being in one of the four cells.)

Although examples of dominance exist in the literature,^{8,9} most economic evaluations locate interventions in the other cells, where one intervention is both more effective and more costly than its comparator. It would be wrong to believe that such an intervention cannot be considered cost-effective. As shown in the figure, if treatment A is more effective and more costly than B (top right cell), it could be defined as cost-effective if it is possible to do less of something else in the health service, transferring the resources saved into A, and end up with a net gain in health. For example, if tranexamic acid and norethisterone were being compared for the treatment of menorrhagia, the former would probably be considered more effective and more costly than the latter.^{1,10} If resources were saved by doing less of something else (e.g. funding fewer hernia operations per year), the savings could be devoted to funding tranexamic acid. The key test of whether tranexamic acid is cost-effective is whether its incremental cost per unit of health gain is less than the health service considers good value for money on the basis of other interventions it has funded in the past. Hence, it is possible to define a cost per unit of health gain threshold below which interventions would be termed cost-effective although they are more costly than their comparator(s).

Implementation strategies and cost-effective practice

The rationale for implementation interventions is to increase the utilization of 'good practice' as defined by evidence-based guidelines. However, 'good practice' can be defined in several ways. One way relates to the effectiveness of a health care intervention, i.e. the extent to which it improves health relative to other interventions, and this has conventionally been the focus of evidence-based medicine and clinical guidelines.¹¹ However, a health care intervention can be defined as effective without it being cost-effective. With reference to Figure 1, an intervention could be more effective than its comparator, but more costly. If its incremental cost per extra unit of health gain is higher than the threshold referred to earlier, it would not be deemed cost-effective.

If a health care intervention that is considered 'good practice' on effectiveness grounds is not considered cost-effective, then it follows that strategies, such as educational programmes or computer prompts, that might be used to increase the utilization of that intervention, can never be cost-effective. Hence, if interventions to change professional practice are themselves to be cost-effective, it is a pre-requisite that the practice for which increased utilization is required should itself be cost-effective.⁴

When are interventions to change professional practice likely to be most cost-effective?

This principle can be extended. If the cost, the effectiveness and the cost-effectiveness of the health care intervention under consideration are known, it is possible to provide an indication of the potential cost-effectiveness of strategies designed to increase the utilization of that form of health care by professionals. This can facilitate estimates of the level of resources which it is economically justified to devote to the implementation strategies and to research into the effectiveness and cost-effectiveness of implementation strategies.

This point can be illustrated with the following hypothetical example. Table 1 shows the costs and effectiveness of two notional health care interventions: treatment A, which is a new intervention, and treatment B, which is standard care. It can be seen that treatment A dominates

TABLE 1 The costs and effects of the notional health care intervention evaluated in Figure 2

Treatment	Costs	Health benefits
A (New therapy)	100	10
B (Standard care)	200	5

treatment B because it is less costly per patient but also more effective in terms of health benefits. On the basis of these results, health care professionals would be expected to switch away from treatment B and to utilize treatment A, and guidelines may have been published to emphasize this. However, assume that 2 years after the research which generated the results in Table 1, a majority of practitioners were still administering treatment B. It may be sensible to consider the use of interventions to change clinical practice such as an educational programme or computer prompts. Before investing in these behavioural interventions, however, it would make sense to use a simple model to explore the likely cost-effectiveness of these interventions in terms of their impact on health care and hence on health outcomes.

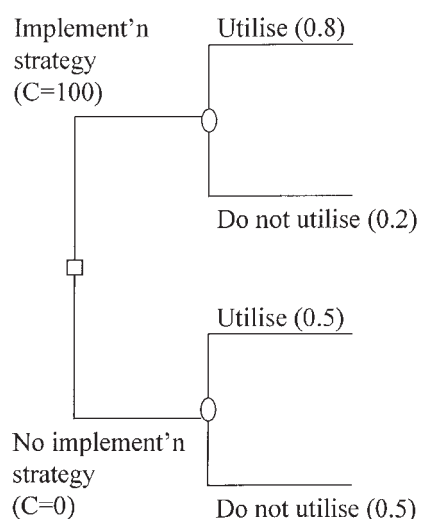
An example of such a model is shown in Figure 2. The decision tree shows that currently, without an implementation strategy, utilization of treatment A is 50%, with the other 50% of patients receiving treatment B, despite it being more costly and less effective. Assume the implementation strategy were to cost £100 per patient. (Although the implementation interventions are focused on the doctor or practice, it is possible to express their costs at the level of the patients for whom they are responsible.) If, based on previous experience with these sorts of behavioural interventions, the utilization of treatment A could be expected to increase from 50 to 80%, it is possible to calculate the cost-effectiveness of the strategy. This is also shown in Figure 2. With the intervention to change practice, the costs faced by the health service (per patient) would be £220: £100 (cost of the intervention) + $(0.8 \times £100 \text{ cost of treatment A}) + (0.2 \times £200 \text{ cost of treatment B})$; under the strategy, the benefits will be 9: $(0.8 \times 10) + (0.2 \times 5)$. Without the implementation strategy, with only 50% of patients

receiving treatment A, the overall cost would be £150: $(0.5 \times £100) + (0.5 \times £200)$; the overall benefit would be 7.5: $(0.5 \times 10) + (0.5 \times 5)$.

Therefore, the use of the intervention to change practice would add to health service costs, although it would also generate additional health benefits compared with no such implementation strategy. Based on the principles of cost-effectiveness analysis described above and in Figure 1, the key result is the incremental cost per additional unit of health benefit. In this case, it would be £46.67 $(£220 - £150) / (9 - 7.5)$, and whether an implementation strategy with these results would be considered cost-effective depends on whether that ratio falls above or below the maximum threshold that the health service is willing to pay.

Clearly, the numbers used in the model would be subject to uncertainty, as this sort of exercise would be undertaken prior to the use of implementation strategies to explore their likely cost-effectiveness. There would, therefore, be a need to use various tools that have been developed to explore the robustness of the conclusions of modelling exercises to changes in parameter values, in particular sensitivity analysis¹² and stochastic modelling.¹³ However, some broad conclusions are possible from this sort of analysis which may be useful in considering the value for money of implementation strategies.

Firstly, although the health care intervention, the use of which is recommended in an evidence-based guideline, may be cost-effective, it does not follow that implementation strategies designed to increase utilization will themselves be cost-effective. An illustration of this is provided in Table 1 and Figure 2: although treatment A is highly cost-effective as it dominates treatment B, the implementation strategy designed to increase the utilization of treatment A is not dominant as it increases health care costs.



Implementation	Costs	Benefits
Yes	220	9
No	150	7.5

Incremental cost per extra unit of benefit = 46.67

FIGURE 2 Hypothetical example of the cost, effectiveness and cost-effectiveness of an implementation intervention for treatment A in Table 1.

Secondly, based on the model in Figure 2, it is possible to show that the cost-effectiveness of the implementation strategies is a function of some key variables:

- *The cost-effectiveness of the health care intervention of interest.* Other things being equal, if the treatment dominates its comparator or generates an incremental cost per unit of health gain markedly less than the maximum threshold, then strategies designed to increase its utilization stand a better chance of being cost-effective than if the treatment's incremental cost per unit of health gain is just below the maximum. In other words, it is possible to determine the scope for implementation strategies to be cost-effective based on the costs and benefits of the treatment of interest.
- *Utilization rates without treatment.* Clearly, the utilization of the health care intervention deemed to represent good practice cannot be more than 100%. Hence, the nearer the utilization rate is to 100% without the implementation strategy, the less the scope for such a strategy to be cost-effective.
- *The cost of the implementation strategy.* The higher the cost of the educational programme, the audit with feedback or the computer prompt, the less likely the implementation strategy is to be cost-effective.
- *The effectiveness of the implementation strategy.* Clearly, the extent to which a strategy can be defined as 'good value for money' depends partly on its effectiveness in increasing the utilization of 'good practice'. An important dimension of effectiveness in this context is the duration of any effect on utilization: if practitioners change their practice towards the more cost-effective treatment, but only do so for a month, after which they return to their previous clinical practice, the implementation strategy will not be as cost-effective as if the change in practice is permanent.

The process of working through the economic characteristics of health care interventions and of implementation strategies that might be designed to increase their utilization will, therefore, provide insight into the likelihood that implementation interventions will represent a cost-effective use of resources. This should be undertaken prior to any substantive investment in implementation strategies.

Implications for implementation research

A number of evaluative research studies are now underway looking at the effectiveness and cost-effectiveness of implementation strategies.² The approach outlined

above can provide some insights into the appropriate design of this form of research from the viewpoint of its cost-effectiveness.

The first point to note is that such research needs to focus on the key parameters associated with implementation outlined above, i.e. effectiveness in terms of changing utilization rates, including the duration of that change, and the cost of the implementation strategy. Several papers have considered the methodological issues associated with their design from the point of view of measuring effectiveness.^{4,5} On the cost side, the measurement issues, in large part, will reflect the characteristics of the implementation intervention. However, the general principles of costing in economic evaluation should be followed,^{7,14,15} with a consideration of the cost of labour inputs, consumables, capital equipment, building space and overheads.

A corollary of this point is that it is not necessary, within an evaluation of implementation strategies, to evaluate changes in health outcomes or resource costs generated by the health care intervention itself. Given the argument above, it is inappropriate to embark on the use of implementation interventions without knowledge of the costs, benefits and cost-effectiveness of the health care intervention for which increased utilization is considered important. It is not, therefore, necessary to collect these data again in any implementation evaluation.

Conclusions

One of the implications of the arguments presented in this paper is that there needs to be clarity regarding the type of guideline that is being considered. It is important to distinguish between clinical guidelines which focus on the effectiveness of treatments, and system or policy guidelines which are concerned with establishing what the health service can afford, i.e. the identification of cost-effective treatment options.¹⁶

There have, however, been relatively few examples of system guidelines in the UK, and this remains an important area of research activity, possibly under the co-ordination of the National Institute for Clinical Excellence. Indeed, before guidelines exist to indicate which treatments represent the most efficient use of health service resources, it is surely premature to devote significant resources to implementation interventions.

Discussion

The general discussion covered two main topics: researching the implementation of cost-effective guidelines, and the service impact of nationally recommended guidelines. Techniques for developing guidelines to promote cost-effective practice were not discussed.

Evaluating the costs of achieving behavioural change

A view was expressed at the outset that, since the primary purpose of implementation research is to achieve behavioural change, trials based on clinically effective guidelines are still justifiable. (The guidelines could also be cost-effective, although this attribute may not have been established.) Even where guidelines based on strong evidence of cost-effectiveness are implemented, for instance on drug prescribing, patterns of clinical practice may not remain static as the roles of the health professionals (doctors and nurses) evolve, with substitution occurring. This may affect the costing assumptions. There is also the technical problem of a lack of statistical power within a trial to measure cost consequences and their sustainability. In these circumstances, modelling can be employed, although confidence intervals in the data may pose difficulties. Cost-effectiveness, unlike clinical effectiveness, does not, however, have to have a 95% confidence limit (refer to Briggs and Gray¹⁷ for a discussion of appropriate confidence limits when dealing with ratio information). There are, additionally, various ways for formulating decisions under uncertainty, which are not specific to the field of economic evaluation. A suggestion was put forward that sequential measurements of outcome variables could be made throughout the intervention period of a trial. These measurements would enable trends in professional behaviour to be observed, such as the shape of any learning curve and the durability of the intervention to be assessed. The data also would be valuable for carrying out sensitivity analysis.

Designing studies to measure the cost-effectiveness of implementing guidelines is not a straightforward business, even when financial benefits of a treatment or management strategy are widely recognized. Thrombolytic therapy for acute myocardial infarction was cited as an intervention with too many independent variables for systematic examination within a single cost-effectiveness study.¹⁸

In common with other health technology evaluations, economic evaluations of guideline implementation strategies differ in their purpose and complexity, ranging from basic cost consequence analyses through cost-effectiveness analyses to cost-benefit analyses. When cost-effectiveness is selected as the evaluative technique, researchers need to consider whether they should take the extra step and formulate a cost-effectiveness ratio using QALY (quality adjusted life year) measurements. A particular advantage of cost-benefit analysis, using perhaps a balance sheet approach, is that wider implications of altering current patterns of staffing, such as levels of skill mix or service provision, can be observed.

Service impact of guidelines

Now that the National Institute for Clinical Excellence for England and Wales has been established, even more attention than previously is going to be directed towards

the identification of optimal strategies for disseminating guidance on best practice. Experience has shown that internationally recommended practice may not, at a national level, be taken up in the same way because of differences in the organization of countries' health services. Within the UK, with its National Health Service (NHS), this factor should not apply. Primary care groups responsible for commissioning primary care services are, however, newly created bodies within the NHS and they will take the lead locally for disseminating national guidelines. The production of guidelines recommending cost-effective practice is even more of a priority now that this infrastructure exists.

National guidelines focusing on the professional practice of individuals may need to be accompanied by 'impact' statements. These statements would advise health service commissioners and providers of the likely implications of the guidelines on, firstly, the configuration of local services in the primary or community, secondary or tertiary care sectors, and, secondly, manpower resources, especially with respect to recruitment and training requirements. The importance of the relationship between authoritative guidelines for improving clinical performance and the provision of appropriate professional training in the short and longer term, needs to be fully recognized.

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