8 Incorporating health economics in guidelines and assessing resource impact

Health economics is about improving the health of the population through the efficient use of resources, so it necessarily applies at all levels, including individual clinical decisions. Clinicians already take resources and value for money into account in clinical decisions, and the incorporation of good-quality health-economic evidence into clinical guidelines can help make this less arbitrary and more consistent.

The GDG should take decisions based on the best available evidence of both clinical and cost effectiveness. This chapter describes the most appropriate role for health economists in the development of NICE clinical guidelines, and suggests possible approaches to considering economic evidence in the guideline development process.

8.1 The role of health economists in guideline development

The health economist is a core member of the GDG alongside the rest of the NCC technical team and should be involved at the earliest opportunity – from the beginning of scoping if possible. The economist should attend all GDG meetings.

The health economist may have skills that are specific to economic analysis, and the expertise of all the GDG members will be necessary to ensure that economic evidence is underpinned by the most plausible assumptions and the best available clinical evidence. Similarly, the economist may be able to input usefully into interpretation of clinical data.

The role of the health economist in guideline development is:

- to advise on economic aspects of the clinical issues or questions
- to review economic literature
- to prioritise topics for further economic analysis through discussion with the GDG, NCC and NICE
- to carry out additional cost-effectiveness analyses.

The relative weight given to each role will vary from guideline to guideline. There may be large differences between guidelines in the amount of relevant economics literature, its relevance, its quality, its timeliness, and its generalisability. In some areas there may be high-quality data that can be used in economic models, whereas in other areas there is little data.

8.1.1 Advising on economic issues

The health economist should encourage the group to consider the economic consequences of the guideline recommendations as well as the clinical implications. A formal presentation to the group of the basic underlying principles of health economics should be given at the first GDG meeting. Further presentations later in the guideline development may be useful. It is particularly important that the group understands that economic analysis is not simply a matter of estimating the consequences of a recommendation in terms of use of resources, but is concerned with the evaluation of both costs **and** health benefits. They should also understand that economic evaluation should

compare the costs and consequences of **alternative courses of action**. 'Cost of illness' or 'burden of disease' studies are not useful for decision-making in clinical guidelines.

Cost effectiveness is assessed to maximise health gain. If resources are employed in interventions that are not cost effective then less health gain is achievable (that is, there is a greater 'opportunity cost'). The GDG should be encouraged to consider recommendations that:

- are slightly less effective than current practice but that free up a substantial amount of resources that can be reinvested
- increase clinical effectiveness at an acceptable level of increased cost.

The GDG members may find it useful if the health economist discusses with them other economic concepts such as: incremental analysis, the NHS and Personal Social Services (PSS) perspective, measurement of quality of life and quality-adjusted life years (QALYs). The British Medical Journal has published a series of 'economics notes' that contains other concepts that the health economist may wish to explore with the GDG (see 'Further reading').

8.1.2 Reviewing information

Examining relevant published economic information is an important component of guideline development. Literature searching is the domain of the information scientist, but the health economist should be consulted about the economic search strategy. This should include a search of HEED and/or NEED. Addition of economic terms to searches of clinical databases such as MEDLINE is also helpful. Economic search filters have been developed by the Centre for Reviews and Dissemination and used extensively (see 'Further reading'). A health economist should review the abstracts and select the economic papers for inclusion, and appraise and summarise these as appropriate.

A thorough systematic review should be attempted. However, in some cases, it may be necessary to limit the search. For example, it may be appropriate to limit the search to UK-based studies, to a specific date range, to full economic evaluations, or to studies that base the estimate of clinical effect on a particular source (for example, an RCT or systematic review) if the amount of economic information is unmanageable. Any inclusion or exclusion criteria should be clearly defined and reported in the guideline methods.

Papers that are identified for inclusion should be critically appraised using a validated checklist (for example, see appendix G of Philips et al. 2004, or Drummond and Jefferson 1996). These economic checklists reflect the conventional criteria for economic evaluation (see Drummond et al. 2005).

The key criteria for assessing the relevance and quality of published economic evaluations are as follows.

- **Relevance to the guideline question**
  For example, did the study assess both the costs and effects, from an appropriate perspective, of all relevant alternatives, for the appropriate patient population, in a relevant setting?

- **Are there likely to be any important biases in the data used?**
  This includes an assessment of both the internal validity and appropriateness for the relevant population of estimates of:
  – epidemiology (disease incidence, prevalence and progression)
  – risk assessment or test accuracy (sensitivity and specificity)
  – treatment effects
  – quality of life (utility) weights
  – resource use
  – unit costs.
- **Are there any other important potential sources of bias?**
  – For modelling studies, this could include assumptions such as the choice of health states, the possible transitions between them, or the time horizon. It could also include omission of some costs or consequences (such as side effects).
  – For trial-based evaluations, biases may arise from assumptions about the extrapolation (or non-extrapolation) of observations.
- **Was cost effectiveness estimated using the correct methods?**
  This includes appropriate use of discounting, incremental analysis and uncertainty analysis.

In addition, a commentary on the quality of each paper should be presented.

8.1.3 Economic analysis

Only rarely will the health-economic literature be comprehensive enough and conclusive enough that no further analysis is required. Additional economic analyses may be appropriate, in which case new models should be developed selectively, unless an existing model can easily be adapted to answer the question.

Close collaboration between the GDG and the health economist is essential early in the guideline development process to ensure that:

- the most important topics are selected for economic analysis
- the overall modelling approach is appropriate
- all the important health effects and resource costs are included
- the clinical, epidemiological and resource evidence used is the best available and the model assumptions are plausible
- the results of the analysis are interpreted appropriately and the limitations acknowledged.

8.1.3.1 Prioritising topics for further economic analysis

Economic analysis is potentially useful for any question where one intervention or programme is compared with another. This includes comparisons of methods of prevention, screening, risk assessment, diagnosis, monitoring, rehabilitation and follow-up, as well as treatment. It may also include comparisons of different combinations or sequences of interventions, as well as individual components on the patient management algorithm. However, given the broad scope of many guidelines, it will not be possible to conduct original analyses for every component. Selecting topics for further economic analysis, including modelling, should be a **joint** decision between the health economist and the other GDG members. The selection should be

based on systematic consideration of the potential value of economic analysis across all guideline questions.

An economic analysis will be more useful if it is likely to influence the recommendation and if the health and financial consequences of the recommendation are high. The value of an analysis thus depends on:

- the overall 'importance' of the recommendation (which is a function of the number of patients affected and the potential impact on costs and health outcomes per patient)
- the current extent of uncertainty over cost effectiveness
- the likelihood that analysis will reduce this uncertainty.

For a particular topic, economic modelling may not be warranted if, for example, the clinical evidence is so uncertain that even a ball-park figure for cost effectiveness cannot be estimated; or alternatively, if the published evidence on cost effectiveness is so reliable that further analysis would be superfluous. Economic analysis may also not be a priority when it is obvious that the resource implications are modest in relation to the expected health gains.

The rationale for the initial prioritisation of topics should be explained in the economic plan, to be agreed early in guideline development (see section 3.2). The health economist should take the lead in preparing this document, but the contents should be agreed with the GDG, and formally 'signed off' between the NCC and NICE. It may become clear during development, as the effectiveness and cost-effectiveness evidence is appraised, that the initial selection of topics for economic analysis needs revision. If so, changes to the economic plan should be agreed between the economist, other GDG members, the NCC and NICE.

8.2 Modelling approaches

Economic evaluation will usually be conducted in the form of a cost-effectiveness analysis (CEA), with the health effects measured in some appropriate non-monetary outcome indicator. In circumstances where CEA is not appropriate, other validated methods may be used.

CEA with the units of effectiveness expressed in QALYs (cost–utility analysis) is widely recognised as a useful approach for measuring and comparing the efficiency of different health interventions. QALYs are overall measures of health outcome that weight the life expectancy of a patient with an estimate of their health-related quality-of-life score (measured on a 0–1 scale). There are well-documented methodological problems with QALYs; however, this is also true of other approaches. The NICE technology appraisal programme continues to follow the QALY approach. Where suitable data are available, this approach should also be followed in guideline development. However, where there are not sufficient data to estimate QALYs gained, an alternative measure of effectiveness might be considered for the CEA (such as the life years gained or cases averted, or some more disease-specific outcome).

A CEA could be modelled around a single well-conducted RCT or it might be modelled using decision-analytic techniques, with probability, cost and health-

outcome data coming from a variety of published sources. In clinical guidelines there is often a trade-off between the range of new analyses that the economist can conduct, and the complexity of each piece of analysis. Simple methods may be used when these can provide the GDG with sufficient information on which to base a decision. For example, if an intervention is associated with better health outcomes and fewer adverse effects, then an estimate of cost may be all that is needed. Or a simple decision tree may provide a sufficiently reliable estimate of cost effectiveness. In other situations, a more complicated approach, such as Markov modelling or discrete event simulation, may be warranted.

Specific guidance on methods can be found in NICE's 'Guide to the methods of technology appraisal' (available from www.nice.org.uk). In particular, the manual recommends that a 'reference-case' analysis is conducted using the following assumptions.

- All health effects on individuals are included.
- Costs are measured from the perspective of the NHS and personal social services.
- Equity weightings are not applied to QALYs.
- Costs and health outcomes are discounted at 3.5%.
- Health-related quality of life is valued using choice-based elicitation methods, a representative sample of the general population, and validated generic health-state instruments. (It is unlikely that there will be time to collect original quality-of-life valuations, therefore data collected by alternative methods may be used but should be suitably qualified.)
- The time horizon should be chosen so as to incorporate sufficiently all important costs and effects.

Departures from the reference case can be adopted, but these would have to be highlighted and reasons given.

8.2.1 General principles

Regardless of the approach taken, the following principles should be observed.

- The question for the economic analysis should be clearly specified and appropriate, with comparison of all relevant alternatives for specified groups of patients.
- An economic analysis should be underpinned by the best-quality clinical evidence.
- There should be the highest level of transparency in the reporting of methods.
- Uncertainty (around both internal and external validity) should be discussed fully and explored by sensitivity analysis (and, where data allow, statistical analysis).
- Limitations of the approach and methods taken should be fully discussed.
- Conventions on reporting economic evaluations should be followed (see Drummond and Jefferson, 1996).
- Analysis should be carried out in collaboration between the health economist and the rest of the GDG.

8.3 Economic evidence and guideline recommendations

For an economic analysis to be useful, it must be incorporated into the guideline recommendations. Cost effectiveness and clinical effectiveness should be discussed in parallel when formulating recommendations.

If there is strong evidence that one clinical strategy dominates the alternatives (that is, it is both more effective and less costly), clearly this strategy should be recommended for appropriate patients. However, if, as is often the case, one strategy is more effective but also more costly, then the magnitude of the incremental cost-effectiveness ratio (ICER) should be considered. For example, the cost per QALY gained is calculated as the difference in mean cost divided by the difference in mean QALYs, of one strategy compared with the next most effective alternative strategy.

Where one intervention appears to be more effective than another, the GDG will have to determine whether the increase in cost associated with the increase in effectiveness represents reasonable 'value for money'. There is no empirical basis for assigning a particular value (or values) to the cut-off between cost effectiveness and cost ineffectiveness. The consensus among NICE's economic advisers is that NICE should, generally, accept as cost effective those interventions with an incremental cost-effectiveness ratio of less than £20,000 per QALY and that there should be increasingly strong reasons for accepting as cost effective interventions with an incremental cost-effectiveness ratio of over £30,000 per QALY.

GDGs have discretion to take into account those factors they consider most appropriate when determining cost effectiveness. In doing so, they should make reference, as appropriate, to the principles outlined in NICE's report 'Social value judgements: principles for the development of NICE guidance' (available from www.nice.org.uk/svjguidance). When a question has not been prioritised for new economic analysis, the GDG should still consider the likely cost effectiveness of associated recommendations. This assessment may be based on published estimates of cost effectiveness if available, or a qualitative judgement where necessary.

8.4 Estimating the resource and cost impact of the recommendations

Before commissioners and trusts can implement a NICE guideline they need to assess the resource and cost implications that this may have in relation to their services. Therefore, there should be an estimate of the cost implications for the NHS in England and Wales of adopting the recommendations. Performing this assessment is not, however, within the remit of the NCC, and NICE undertakes a separate, but parallel, resource-impact analysis. This is done during the validation period of the guideline in consultation with the NCC and the GDG. During the course of guideline development, the GDG is asked to identify the key resource and cost issues. This will inform the assessment of resource impact once the recommendations have been agreed. There are more details on the process for developing cost-impact assessments on the NICE website (www.nice.org.uk/costreportprocess).

8.5 Further reading

Raftery J, editor (1999–2001) Economics notes series. British Medical Journal (bmj.bmjjournals.com)

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