How to develop cost-conscious guidelines

M Eccles
J Mason

1 Centre for Health Services Research, University of Newcastle, Newcastle upon Tyne, UK
2 Centre for Health Economics, University of York, UK

* Corresponding author
Background

Clinical guidelines, defined as ‘systematically developed statements to assist both practitioner and patient decisions in specific circumstances’, have become an increasingly familiar part of clinical care. Guidelines are viewed as useful tools for making care more consistent and efficient and for closing the gap between what clinicians do and what scientific evidence supports. Interest in clinical guidelines is international and has its origin in issues faced by most healthcare systems: rising healthcare costs; variations in service delivery with the presumption that at least some of this variation stems from inappropriate care; the intrinsic desire of healthcare professionals to offer, and patients to receive, the best care possible. Within the UK, there is ongoing interest in the development of guidelines and a fast-developing clinical-effectiveness agenda within which guidelines figure prominently. Over the last decade, the methods of developing guidelines have steadily improved, moving from solely consensus methods to methods that take explicit account of relevant evidence. However, UK guidelines have tended to focus on issues of effectiveness and have not explicitly considered broader issues, particularly cost. This report describes the methods developed to handle benefit, harm and cost concepts in clinical guidelines. It reports a series of case studies, each describing the development of a clinical guideline; each case study illustrates different issues in incorporating these different types of evidence.

Health economics and clinical guidelines

There has been no widely accepted successful way of incorporating economic considerations into guidelines. Unlike other areas of guideline development, there is little practical or theoretical experience to direct the incorporation of cost issues within clinical guidelines. However, the reasons for considering costs are clearly stated: “health interventions are not free, people are not infinitely rich, and the budgets of [health care] programmes are limited. For every dollar’s worth of health care that is consumed, a dollar will be paid. While these payments can be laundered, disguised or hidden, they will not go away”. Such opportunity costs are a universal phenomenon. In the USA it has been recommended that every set of clinical guidelines should include information on the cost implications of the alternative preventive, diagnostic, and management strategies for each clinical situation. The stated rationale was that this information would help potential users to evaluate better the potential consequences of different practices. However, it was acknowledged that "the reality is that this recommendation poses major methodological and practical challenges".

Methods of developing clinical guidelines

A guideline development process summarises the technical information about the value of treatments in a manner that makes them accessible and ready for use in clinical practice, alongside information on contextual issues. The requirement is that the presentation of costs and benefits of treatments is methodologically sound, robust and accessible. This report includes a summary of the current best practice in evidence-based guideline development, including recent methodological advances. The manner in which cost and cost-effectiveness concepts have been successfully incorporated into the guideline process is introduced.

Guideline development case studies

The ‘cost-effectiveness’ sections of 11 guidelines are reported to illustrate both the range of methods used and the nature of the recommendations.
reached by the guideline development groups when considering the profile of consequences of treatments including costs. These guidelines are broadly grouped as: (1) those using qualitative evidence summary methods; (2) those using quantitative evidence summary methods and addressing relatively narrow clinical questions; (3) those using quantitative evidence summary methods and addressing a broad clinical area; (4) a guideline based upon a decision analysis model.

Conclusions

The focus of this project was to explore the methods of incorporating cost issues within clinical guidelines. However, the process of reviewing evidence in guideline development groups is becoming increasingly sophisticated, not only in considerations of cost but also in review techniques and group process. At the outset of the project it was unclear how narrowly or broadly the concept of ‘cost’ could be considered. It is now clear that, alongside the effectiveness data and data describing quality of life, cost issues can successfully be represented as part of a profile of treatment attributes. It is also clear that, when used appropriately, modelling processes can provide valuable input into guideline development processes.

Implications of this project

This report describes methods that, in our opinion, are currently optimum for developing clinical guidelines that include consideration of multiple dimensions of evidence (effectiveness, tolerability, harm, quality of life, health-service delivery issues, costs) and it will be relevant to those who commission, develop or use clinical guidelines. The described ‘attribute profile’ approach to judging whether the costs and consequences of treatments make reasonable sense appears to be the most robust and socially defensible method at this time. The main implication from this work is that these methods should form the current minimum expected of guideline developers. It is important that the methods described are attempted and developed by other guideline methodologists and health economists and the debate about the valuation of healthcare is expanded.

Recommendations for further research

While working on the case studies a range of unanswered questions were identified, some of which are directly related to the consideration of costs within guidelines and some of which relate to clinical guideline development more generally. Further research should be carried out to answer the following questions.

- What is the relationship between the incorporation of costs into a guideline and the cost impact of a guideline? What are the optimum methods of using cost data in guideline development and of assessing the cost impact of a guideline? Should these processes be unified or separate?
- What are the implications for level of evidence and strength of recommendation taxonomies of considering a range of treatment attributes beyond effectiveness and tolerability?
- What is the role of decision analysis in the development of clinical guidelines?
- In what circumstances is it necessary to use formal consensus methods within a guideline development process?

The research questions above could be usefully informed by the use of more robust designs.

Publication

The NHS R&D Health Technology Assessment (HTA) Programme was set up in 1993 to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS.

Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

Although the National Coordinating Centre for Health Technology Assessment (NCCHTA) commissions research on behalf of the Methodology Programme, it is the Methodology Group that now considers and advises the Methodology Programme Director on the best research projects to pursue.

The research reported in this monograph was funded as project number 94/08/28.

The views expressed in this publication are those of the authors and not necessarily those of the Methodology Programme, HTA Programme or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for any recommendations made by the authors.

Criteria for inclusion in the HTA monograph series
Reports are published in the HTA monograph series if (1) they have resulted from work commissioned for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in Health Technology Assessment are termed ‘systematic’ when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

Methodology Programme Director: Professor Richard Lilford
HTA Programme Director: Professor Kent Woods
Series Editors: Professor Andrew Stevens, Dr Ken Stein, Professor John Gabbay and Dr Ruairidh Milne
Monograph Editorial Manager: Melanie Corris

The editors and publisher have tried to ensure the accuracy of this report but do not accept liability for damages or losses arising from material published in this report. They would like to thank the referees for their constructive comments on the draft document.