# Interpreting clinical guidelines

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## Abstract

Clinical practice guidelines have become an important vehicle for collating evidence examining the effectiveness and cost-effectiveness of practice, and for making recommendations for decision-makers. These recommendations can be used in several ways to improve practice, both at the level of individual decisions and at a population level. The principles for developing clinical guidelines are now well established, and have been applied to other fields including public health and social care. Users of guidelines should establish that the guidelines they are using are trustworthy and have been developed to high standards; they should also identify how particular guideline producers have expressed the strength of their recommendations. Applying guideline recommendations to individual patients remains challenging. In particular, many recommendations are likely to have been based on evidence drawn from people in research studies, who may be unlike many patients in practice in a number of ways. Therefore, the decision-maker has to consider how a particular situation differs from those in the guideline, commonly in terms of multimorbidity and variations in values and preferences.

**Keywords** Clinical practice guideline; cost-effectiveness; effectiveness

## Key points

- Clinical guidelines are an important source of recommendations on best practice
- Guidelines vary in quality, and it is important to appraise their quality
- Few guidelines consider cost-effectiveness, but, in the UK, those from the National Institute for Health and Care Excellence and Scottish Intercollegiate Guidelines Network do
- Strength of recommendation is a key concept that decision-makers should take time to understand
- Applying recommendations in individual circumstances requires an understanding of those particular circumstances, co-morbidity and values and preferences
- Guidelines are not mandatory but are intended to support decision-making

## What clinical guidelines are, and what they are not

Clinical (practice) guidelines have been defined in a report by the US Institute of Medicine as documents that 'include recommendations to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options'.[1]

This definition implies that the purpose of clinical guidelines is to aid decision-makers in choosing care options that are likely to result in optimal outcomes for their patients. The interest in and production of clinical guidelines has increased alongside the development of evidence-based healthcare as an attempt to save individual decision-makers having to locate and appraise evidence themselves.

There is evidence that printed educational materials, such as clinical guidelines, have beneficial effects on professional performance. The focus has therefore moved to ways of improving the implementation of, and adherence to, guidelines, as well as to setting standards for guideline development.[2]

Important challenges remain for clinical guideline development methods. Perhaps most important of these is the need for a shared understanding of the values and limits of recommendations made by clinical guidelines. Recommendations in clinical guidelines necessarily rely on evidence from certain groups of individuals (e.g. those observed in a trial); the role of the clinician is therefore to apply recommendations to individual patients, and to interpret the recommendations in the context of the individual circumstances of the decision being made.

These challenges have been clearly highlighted in the context of multimorbidity,[3] where evidence of treatment effects is typically derived from randomized controlled trials that have excluded people with significant co-morbidities. The relevance of such studies has to be considered if the clinical situation is complex. The same challenges exist for public health and social care guidelines, where high-quality evidence of effectiveness is often lacking, and concepts of value are rather different.

## Clinical guidelines for quality improvement

As a way of setting out what is currently seen as best practice, clinical guideline recommendations are useful tools to promote quality improvement at a system level, and to reduce inappropriate variations in practice. For example, they can be used:

- as the basis for clinical audit
- to define quality standards with associated measurement indicators
- to incentivize certain aspects of clinical practice.

In the UK National Health Service (NHS), for example, evidence that orthogeriatric input is beneficial during the care of people with hip fractures is reflected in a guideline recommendation that is, in turn, the basis for a financial incentive in the payment tariff for this care.

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Please cite this article in press as: Alderson P, Maconachie R, Interpreting clinical guidelines, Medicine (2018), https://doi.org/10.1016/j.mpmed.2018.04.001

## Clinical guidelines in the UK

The two major producers of clinical guidelines for the NHS in the UK are the National Institute for Health and Care Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN). These bodies produce clinical guidelines covering a variety of topics, and also consider cost-effectiveness. Other producers include professional bodies such as the royal colleges and professional specialist societies, although these rarely consider cost-effectiveness.

## Which guidelines should we trust?

As with any guidance or research, it is important to critically appraise clinical guidelines. As already mentioned, there have been efforts to set clear standards for developing clinical guidelines, and tools such as the Appraisal of Guidelines for Research and Evaluation (AGREE) tool (www.agreetrust.org) can help frame a critical appraisal. NICE has accredited the methods used by some clinical guideline producers, enabling these guidelines to display a 'quality mark' (www.nice.org.uk/about/what-we-do/accreditation).

Recent concerns have focused on conflicts of interest among guideline authors, so users of guidelines should consider the policy in terms of how such conflicts of interest have been managed. Sponsorship of guideline development by companies with a financial interest in the topic area would be an example of a potential source of bias in the guideline.

It remains important for clinicians to ensure they understand the evidence behind particular recommendations when considering whether or not to apply the recommendation in specific circumstances.

## Key concepts

Guideline methods and processes vary depending on who is producing them. The following descriptions are drawn from the methods used in NICE clinical, public health and social care guidelines.[4] Although the details may vary for other guidelines, the key concepts should all be addressed.

### Guidelines committee

A guidelines committee is appointed to examine the evidence and decide what recommendations to make. Committees are usually made up of experts covering the range of perspectives of those involved in the particular topic area. So, for example, a guideline on glaucoma might involve lay people with experience of the condition, ophthalmologists, optometrists, general practitioners, pharmacists, nurses and methodologists.

### Types of question

Over the timeline of developing the guideline, the committee attempts to answer a number of review questions relating to the guideline's scope. The scope should be defined with the input of stakeholders, be publicly consulted on and represent the most important clinical areas relating to the particular condition for which guidance might be useful. The inclusion of topic areas and associated review questions can be driven by high uncertainty, geographical variation, competing resource use or the emergence of new evidence.

In NICE guidelines, the review questions can cover any aspect of NHS, public health and social care activity relating to the specific disease area, and typically asks what the most clinically and cost-effective activities to undertake are. Examples from the NICE guidelines on asthma, physical activity and lung cancer, respectively, are:

- In people under investigation for asthma, what is the diagnostic test accuracy and cost-effectiveness of fractional exhaled nitric oxide (FeNO) measures?
- Which interventions in the built or natural environment are effective and cost-effective at increasing physical activity among the general population?
- What is the clinical and cost-effectiveness of different radiotherapy regimens with curative intent for people with non-small cell lung cancer stage T1a–2b N0 M0?

Some review questions are not formulated to determine clinical and cost-effectiveness. Instead, they are often exploratory and relate to areas of deep uncertainty or how the delivery of services should be configured. Examples from NICE guidelines on Acute medical emergencies and Older people with social care needs and multiple long-term conditions include the following:

- What is the appropriate level of bed occupancy in hospital to facilitate optimal patient flow?
- What are the views and experiences of older people with multiple long-term conditions and their carers, of the social care services they receive?

### Methods

Each guideline committee is linked with a development team that undertakes the technical and project management work. This team undertakes a systematic review for each review question, conducted in accordance with best methodological practice. The quality and applicability of evidence meeting the inclusion criteria for each review question is assessed using the GRADE framework.[5] Bivariate or network meta-analyses, in line with best practice guidance, can be conducted to synthesize evidence from multiple sources. The strengths and limitations of the results for decision-making purposes are then presented to the committee.

Committees writing guidelines for health systems with a fixed overall budget should consider the cost-effectiveness of their recommendations. Additional spending results in a withdrawal of funding from elsewhere in the system, so recommendations should represent a good use of resources compared with the system's best alternate use of them. Economic modelling is conducted:

- where resource use between competing options is thought to differ significantly
- where there are no published economic evaluations addressing the cost-effectiveness of the review question
- where it is important to synthesize multiple disparate outcomes (e.g. quality versus length of life, trade-offs between different benefits and harms).

As the construction of new decision models is bespoke, the committee should have repeated input into the process. Economic models should be the subject of rigorous sensitivity analyses where important input parameters are varied, and the results should be reported and discussed. These sensitivity analyses can reflect different subgroups of patients or 'best' and 'worst' case scenarios. When assessing published economic evaluations, the quality and applicability of the analyses should be assessed via published checklists.




Please cite this article in press as: Alderson P, Maconachie R, Interpreting clinical guidelines, Medicine (2018), https://doi.org/10.1016/j.mpmed.2018.04.001