

Clinical guidelines to improve patient care

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ABSTRACT

The aim of clinical guidelines is to improve quality of care by translating new research findings into practice. There is evidence that the following characteristics contribute to their use: inclusion of specific recommendations, sufficient supporting evidence, a clear structure and an attractive lay out. In the process of formulating recommendations, implicit norms of the target users should be taken into account. Guidelines should be developed within a structured and coordinated programme by a credible central organisation. To promote their implementation, guidelines could be used as a template for local protocols, clinical pathways and interprofessional agreements.

INTRODUCTION

In this number of the journal, Jacobs *et al.* describe the use of a local clinical guideline on haemochromatosis.¹ They found the adherence of care providers to key recommendations insufficient and even consider certain elements of care provision undesirable. Naturally they asked themselves why this guideline failed to reach its goal. The aim of clinical guidelines is to improve patient care by providing recommendations about appropriate health-care in specific clinical circumstances.² They should be based on the best evidence available, supplemented with clinical expertise and patient preferences. Guidelines are primarily developed to support care providers and patients, but may also be used by medical insurers in contracts and by governmental agencies in rationing healthcare policy.³

Guidelines are only one option for improving quality. They are especially useful in situations with uncertainty about appropriate practice, when evidence provides an answer.⁴ In other situations integrated care pathways or the redesign of care processes may be more suitable. While guidelines can improve the quality of patient care, we will discuss how, and which limitations occur.⁵

BENEFITS

Clinical guidelines may improve patient care by providing easily accessible information regarding optimal care. They summarise research findings and make clinical decisions more transparent. By showing gaps in current knowledge, research activities can be prioritised. Ideally, the potential cost implications of applying the recommendations are discussed. Thereby they can increase the efficiency of care and in case of inappropriate use, reduce costs.⁶ By summarising the benefits and limitations of procedures and interventions, they contribute to patient safety. To empower patients, lay versions should inform patients about optimal care.⁷ As clinical guideline development includes a systematic review of the recent scientific literature, an up-to-date guideline offers a sound basis for education. In contrast, textbooks contain material that is too general and often out of date.^{8,9} As many guidelines cover topics that involve different disciplines they provide a foundation for multiprofessional agreements and collaboration. Guidelines can be used as a reference for professional audit to evaluate the quality of care.

LIMITATIONS

If guidelines are applied inappropriately as in 'cookbook medicine', they may lead to misuse. As a hypothetical standard patient is usually taken as a point of reference, the unique clinical presentation could be neglected. By doing so guidelines oversimplify complex clinical practice.¹⁰ Inexperienced users could be encouraged to apply recommendations unthinkingly, even in situations in which departure from the recommendations is desirable.¹¹ Guidelines are produced on the basis of studies in selected populations in research settings. As a consequence their results often can not be reproduced in daily practice.¹² Because the development of a national guideline demands large resources,¹³ their cost-effectiveness is sometimes questioned, despite positive examples.¹⁴ In general, professionals strive for autonomy, which is threatened by the need to follow guidelines.¹⁵ Accordingly, professionals fear an increase in their medico-legal exposure.¹¹

DEVELOPMENT OF GUIDELINES

The implementation should be considered part of the development process. Selection of topics, composition of the guideline group, the work plan, search for evidence and involvement of clinical experts are all important in this. On the national level a representative and respected group of experts from relevant professional organisations reaches agreement on an area of healthcare. Consensus takes place on the basis of a systematic review and structured consensus. If there are marked differences between settings, translation to the local situation is mandatory. Following the instructive process with the focus on relevant local conditions is a major advantage for acceptance. A disadvantage is the time investment and the suboptimal results if a systematic review has not been performed.¹⁶

Topic selection

Of importance is the topic selection. The more relevant the topic for resolving the problems encountered, the more likely the guideline will be accepted. Some problems cannot be resolved by introducing guidelines,^{17,18} as for example shortage or incorrect use of resources, malpractice resulting from inefficient procedures or topics related to patient preferences. Appropriate topics can be selected by the relevance and prevalence of the problem, controversy about optimal care, existence of proven solutions, barriers expected when implementing improvements and motivation and improvement skills of the care providers involved. Besides scientific also psychosocial, ethical, legal and financial aspects play a role in implementing guidelines. A systematic analysis prior to guideline development contributes to its successful application.¹⁹

Composition of the guideline group

Developing credible clinical guidelines requires a balanced working group including clinical and methodological expertise to promote broad consensus and to prevent bias from conflicts of interests.¹⁹ It should also include representatives of patient groups.¹⁷ Adequate staff support is needed to perform literature searches and a cost-effectiveness analysis.²⁰ A neutral chairman and formal group processes should be used to achieve consensus.

Work plan

Next, a work plan is formulated that describes the aims of the guideline, healthcare problems and settings covered, desired outcomes (mortality, morbidity, complications, hospital admissions, quality of life), target group involved (care providers and patient population), time schedule and division of the tasks.

Reviewing evidence

The literature search starts by identifying and reviewing existing guidelines and a systematic literature review, searching for scientific evidence, an assessment of its relevance and quality, and the involvement of clinical experts to formulate and prioritise recommendations. Guidelines on the same topic can be identified by searching the US National Guideline Clearinghouse (www.guideline.gov) and the resources of the Guidelines International Network (www.g-i-n.net). These databases together contain more than 2000 guidelines. To assess the quality of the guideline the 'Appraisal – Instrument for Guidelines Research and Evaluation' (AGREE) instrument can be used.²¹ Its purpose is to provide a systematic framework for assessing key components of guideline quality including the process of development and reporting. The items cover the methodology as well as the clarity and applicability of the guideline.

Studies are best identified by systematic review. To identify high-quality systematic reviews the Cochrane Library with quarterly updates is an excellent source. If no existing review can be found a range of electronic databases (Medline, Cinahl, Embase, PubMed) should be searched. Further relevant individual studies are identified by asking experts and by hand-searching journals, reference lists of articles and abstract books. The relevance of the studies for the questions and patient group involved is evaluated on the basis of the abstract.²² The next step is to evaluate the scientific strength of the published research.²³ Information about the advantages, disadvantages and costs of the studied interventions is examined. The evidence is categorised using predefined grading schemes for preventive, diagnostic, and therapeutic procedures. In *table 1* such a grading system is shown, as developed by the Dutch Institute for Quality Improvement in Healthcare (CBO).

Table 1 Classification of the literature according to the strength of the evidence (CBO 2000)

For articles concerning intervention (prevention or therapy)

- A1 Systematic reviews of at least a few studies on the A2 level, of which the results of independent research studies are consistent
- A2 Randomised comparative clinical research of good quality (randomised, double-blind, controlled trial of adequate scope and consistency)
- B Randomised clinical trials of moderate quality or insufficient scope, or other comparative research (nonrandomised, cohort studies, patient-control studies)
- C Noncomparative research
- D Opinions of experts, such as the work group members

Involvement of clinical experts

Clinical experts should be involved because in almost half the clinical decisions there is no good scientific background.²⁴ When developing a clinical guideline for angina pectoris, only 21% of the recommendations could be based on randomised studies.²⁵ Even when there is consistent evidence for a given clinical practice, the optimal method of proceeding is seldom immediately clear. If evidence is found for certain care interventions, it is often necessary to determine whether the results can be extrapolated to other patient populations.

On the other hand, the use of experts causes problems. Some dominate the discussion with their individual preferences. By structuring the discussions, such problems can be avoided.²⁶

If no evidence can be found an interview of experienced care providers can be performed as in the Rand-modified Delphi Procedure to quantitate 'expert opinion'.²⁷ A panel of experts judges the appropriateness of different treatments in a number of characteristic patients. The judgement of the appropriateness is determined by considering the advantages (effectiveness, rapidity and duration of the response) and disadvantages (invasiveness, side effects, complications) which are scored.

FORMULATION OF RECOMMENDATIONS

In formulating recommendations the scientific evidence and clinical expertise are brought together. The following issues should be considered to ensure implementation:

- Nature and strength of the scientific evidence; the balance between the advantages of a given intervention and its disadvantages.
- Generalisability and applicability to the target population.
- Cost-effectiveness of the proposed intervention.
- Achievability of the intervention in terms of required

skills, instruments, time, available staff, patient's preferences and legal or financial limitations.

- Opinions, norms and values, and ethical considerations of the target users.

With a view to implementation, a work group cannot avoid the problem as to whether the healthcare system can afford the innovation. If a guideline recommends that a patient with a myocardial infarction must receive thrombolysis within 30 minutes of arrival at the hospital, then the entire care process must be directed to that aim. In the interpretation of evidence by experts, normative and cultural opinions about the desired health benefit and the acceptable risks play a role. An analysis of guidelines for breast cancer revealed that in the USA regular breast self-examination is advised, while the French point to the insecurity that this can evoke.²⁸

Levels of evidence

By including the level of evidence for each recommendation, the work group emphasises the degree to which application of the recommendations will lead to the intended results.²⁹ The addition of the results of reviews and the level of evidence creates a sense of thrust worthiness and makes the recommendations transparent, with a positive influence on the application in practice. Ideally, all recommendations are formulated using a democratic voting procedure in which all relevant information (evidence, costs, preferences, organisational impact) has been considered.

An external review by a sample of concerned individuals (experts, patients, managers, insurers) should be part of the development process.

Promoting acceptability

To promote support, the draft has to be presented at an open meeting allowing the audience to express their comments and suggestions. If no consensus is reached, a voting system can be used.

To facilitate its applicability in daily care the guideline is piloted in practice. The results of the pilot and the consultation process are incorporated. Finally, the clinical guideline can be submitted for approval to an independent scientific council and to the professional organisations responsible.³⁰

FORMAT OF THE GUIDELINE

The next step is designing an accessible and attractive format. Diagrams and algorithms may clarify the logic in the decision-making.³¹ A summary of key recommendations provides a quick insight.

Clinical guidelines should be published in professional journals and posted to every possible user.

Electronic versions of the guideline and tools for application (e.g. patient leaflets, educational material, a practice summary on a plastic-laminated card) have to be developed.³² For audit and performance review the guideline should include a set of clinical indicators.

EVALUATION OF THE GUIDELINE

The final step is the overall process of the evaluation of their application, their applicability and their effects.

Relevant elements are:

- How well is the guideline known and applied? Are the recommendations understood and remembered? Are they used in quality improvement activities? If not, which are not and why?
- To what extent are they effective? Does their application lead to the objectives envisioned (better health, lower costs, better quality of life and more satisfied patients)?

UPDATING GUIDELINES

Clinical guidelines require updating if the majority of recommendations are out-of-date due to changes in research findings and new available diagnostic or therapeutic interventions. In general, guidelines should be reassessed for validity every three years.³³ In rapidly evolving fields, for example AIDS or colonic cancer, yearly review is necessary.

GUIDELINE QUALITY

High-quality guidelines can improve healthcare, but low-quality guidelines may harm patients.^{5,8} The explosion of published guidelines may confront physicians with multiple conflicting guidelines on the same clinical subjects.³⁴ Many are of poor quality. Grilli *et al.* evaluated 431 guidelines developed by medical specialists. Only 5% met high-quality criteria and 54% did not meet any.³⁵ Recently an international appraisal instrument to assess guideline quality has been developed and validated: the AGREE instrument (see www.agree.collaboration.org for details).²¹

CONCLUSION

To successfully introduce clinical guidelines, their development should consider the implementation from the very beginning.³⁶ This includes attention to the relevance of the topic, credibility (systematic development by rigorous transparent methodology), involvement of all relevant

stakeholders and attention to the impact on resources, materials and facilities, accessibility and an attractive design and tools for application and monitoring in practice.

To integrate guidelines into normal care processes they should be incorporated in local care protocols, disease management programmes and clinical pathways.

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