Developing Quality Clinical Practice Guidelines

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Abstract

Technological advances have increased our capacity to access information and advance knowledge. In healthcare this has created the imperative to base practice on scientific evidence rather than opinion. Evidence-based guidelines can provide a link between evidence and practice by translating research findings into actionable recommendations. Therefore, the quality of guidelines is important, as they are used to inform practices that have an impact on health outcomes.

The process of developing infection control guidelines has traditionally relied on consensus among experts and literature reviews, rather than a systematic approach to locating, appraising and applying the available evidence. There is increasing expectation on the part of consumers, clinicians, governments and other stakeholders that recommended practices should be explicitly linked to the best available evidence and developed according to acceptable methodological standards. While there is room to improve the way in which infection control guidelines are developed, the skills, time and financial resources needed to undertake the development of evidence-based guidelines are substantial and often underestimated.

This article is based on the guideline development literature and on the personal experiences of the author, who has been involved in the development of consensus-based and evidence-based guidelines. It provides an overview of the purpose of clinical practice guidelines, methods of guideline development, implementation and revision strategies and areas to consider when developing infection control guidelines in the future.

Introduction

A 'guideline' is a rule or principle that can be used to guide behaviour. Clinical practice guidelines are defined as 'systematically developed evidence-based statements which assist providers, recipients and other stakeholders to make informed decisions about appropriate health interventions'[1]. The purpose of guidelines (which generally encompass a series of recommendations) is to improve health outcomes through improvements to health practices. However, for guidelines to have the desired impact on health outcomes, users need to know they exist and have easy access to them, and they must perceive them to be a valid, relevant and practical source of information. Ultimately, recommended practices are embedded into all processes as part of an integrated, system-wide strategy to provide safe, quality health services.

The quality of guidelines is important because of their potential impact on clinical practice and health outcomes. To function as a credible link between evidence and practice, they must be of high quality. Guideline development methodology plays an important role in the quality of recommendations. Standards for the development of new guidelines have been set by a number of groups [1,2,3], and there is evidence of international convergence in the approaches they recommend [4]. In addition, there is a move to have standard requirements for reporting how guidelines have been developed to help users evaluate the quality of the process [5]. Safeguarding trust in the guideline development process is critical to promoting user uptake of the content.

In Australia, the National Health and Medical Research Council (NHMRC) has been the prime mover in developing and publishing

national clinical practice guidelines and establishing methodological standards [2]. As the process has become increasingly complex and resource-intensive, government-funded agencies have moved away from direct participation in the process of developing guidelines to a monitoring and advisory role.

External groups, such as professional organisations, are now taking the lead in guideline development. However, preparing guidelines that meet strict standards requires specialised skills and funding that may not be available at a local level [6]. There is evidence that guidelines of high quality are more likely to be produced by established guideline programs and government-funded agencies than by professional organisations, probably because of differences in available resources [4,7]. National guideline clearing houses have been established in the US and UK to oversee guideline quality [5,8] and Australia may be moving towards this model.

Developing quality guidelines – overview

The development of high-quality guidelines is complex, requiring sufficient resources, appropriate skills and adherence to methodological standards [4,9]. The NHMRC has developed a series of comprehensive booklets on developing clinical practice guidelines, and has outlined the principles (Table 1) and process (Table 2). These booklets are available at www.nhmrc.gov.au [2,10,11,12,13].

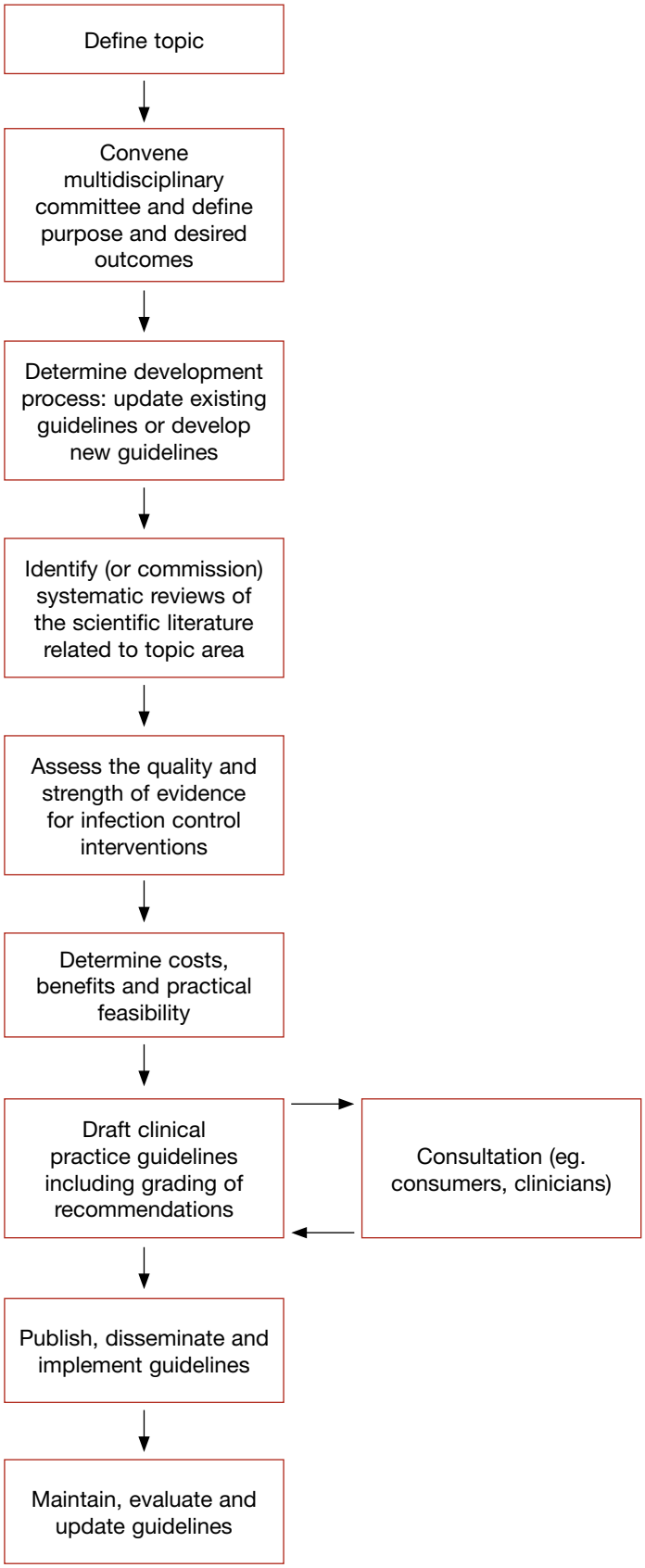
Good quality recommendations should be based on the best scientific evidence available. Systematic reviews have become the cornerstone of evidence-based practice and provide the evidence foundation for contemporary clinical practice guidelines.

Table 1: Principles of guideline development.

- Guideline development and evaluation should focus on achieving the best possible health outcomes.
- Guidelines should be based on the best available evidence and state the strength of the recommendations.
- The method used to synthesise the evidence should be the strongest applicable.
- The process should be multi-disciplinary and should include consumers.
- Guidelines should be flexible and adaptable to local conditions.
- They should be developed with resource constraints in mind.
- Should be developed, disseminated and implemented according to the needs of target audiences.
- The validity and usefulness of the guidelines should be reviewed.
- Guidelines should be regularly revised.

Source: Adapted from [2].

Table 2: Process of guideline development.



Source: Adapted from [12].

A systematic review is different from a traditional literature review, which describes previous studies but does not systematically search for them, assess their quality or synthesise their combined results to develop recommendations. When done well, systematic reviews are considered the highest level of evidence for decision-making. It is important to be aware that the quality of systematic reviews varies [14].

It is expected that guidelines (recommendations) are based on a thorough evaluation of the evidence; however, in the absence of evidence or when the evidence is conflicting or insufficient to form a recommendation, consensus-based recommendations are acceptable as a *de facto* level of 'evidence'. Being explicit about how the recommendations are derived makes the user aware of the level of evidence for a recommended practice.

Guideline development requires substantial financial and human resources. The average time to develop new guidelines is approximately two years, and many individuals and tasks are involved [8]. The average budget to develop one new guideline varies from US$10,000 to US$200,000, with dissemination budgets in the region of US$200,000 [4]. The evidence review process alone is estimated to take between 216 and 2518 hours, depending on the number of studies included [15].

Project planning and protocol development, conducting an evidence review, synthesising the evidence, collating and documenting the process of the review, engaging in regular meetings, arranging consultation, writing and editing and arranging for publishing and dissemination are some of the key responsibilities. The successful completion of these tasks requires a substantial commitment from many people, and methodological and content expertise. Despite this, panels usually comprise people with limited experience in guideline development [5].

Using existing guidelines

After convening a multi-disciplinary guideline development group, the next step is to search for existing relevant clinical practice guidelines. As the evidence base for infection control (and other practices) is global, it is useful to do a broad search for guidelines already published by peak professional and government agencies overseas, as well as in Australia. Ultimately, it will be more efficient to minimise the number of times the same body of evidence is systematically reviewed by different groups.

A number of organisations are renowned for developing quality clinical practice guidelines, including the Scottish Intercollegiate Guidelines Network (SIGN) and the National Institute of Health and Clinical Excellence (NICE). A quick internet search yielded infection control guidelines developed according to rigorous methodological standards. Guidelines for infection control in primary and community care settings have been published by NICE [16], and the recently published 'epic2' hospital infection control guidelines developed collaboratively by key stakeholder groups in the UK [17]. The quality of clinical practice guidelines can be assessed using a validated guideline appraisal tool, such as the AGREE instrument (www.agreecollaboration.org) [18].

Once a guideline has been selected, the group will need to decide if it needs updating. A preliminary search of MEDLINE, CINAHL and other major reference databases can help to determine whether this is necessary. If updating is required, the methodology used to systematically search, retrieve and appraise studies used in the original document should ideally be reproduced. Details of search terms, databases, search date(s) and other parameters can usually be obtained by writing to the original authors. Information on study selection criteria, quality appraisal techniques, levels of evidence and the grading of recommendations is also needed to make the update consistent and comprehensive. It will be necessary to cite the original work, provide a detailed description of the process used to update the work, and may be necessary to obtain permission from the original authors and publisher to use the existing document as the basis for an updated version.

Developing new guidelines

When it is not possible to update existing guidelines, new guidelines are needed. As there are no pre-existing parameters for the search and appraisal processes, it is important to plan the methodological approach. A review protocol can outline this process, and the *Cochrane Handbook for Systematic Reviews of Interventions* [19] (www.cochrane.org) provides information on developing a review protocol and conducting systematic reviews. In addition, *SIGN 50: A Guideline Developers Handbook* [20] (www.sign.ac.au) is another useful resource, providing an excellent overview of all aspects of guideline development. Methodological expertise is needed during the planning phase so that potential problems that may not become evident until they are very difficult to rectify, can be identified and prevented. Decisions that occur during planning for the process of guideline development will significantly affect the final outcome [21].

Once the protocol is established, a search of databases of systematic reviews is usually conducted. This should include the Cochrane Library of databases (www.cochrane.org) and the Joanna Briggs Institute (www.joannabriggs.edu.au). Many other organisations and individuals have published systematic reviews, and they vary in quality [14]. The team will need to choose an instrument to appraise the quality of relevant systematic reviews.

Where a new systematic review is needed, the scope of the review should be defined following preliminary database searches. Limitations to the evidence will inevitably be encountered, including a lack of relevant or high quality studies, problems with translating results from different populations and settings, and the use of different outcome measures. It may be necessary to restrict the parameters of the evidence review to make the task manageable.

However, while the quality of information increases as the scope of the review narrows [22], the usefulness of subsequent recommendations is compromised [21].

In the absence of relevant literature, it may be necessary to make recommendations based on a consensus of experience, opinion and common sense. A method for attaining consensus in the case of limited, contradictory or statistically incomparable evidence should be established at the outset. As noted earlier, the basis for recommendations, whether evidence or consensus-based, must be explicit.

Group dynamics

The involvement of a multi-professional panel is recommended regardless of whether guidelines are based on existing guidelines or developed *de novo* [2]. Recruiting people with a range of skills and expertise who represent key organisations is essential for guideline development and to improve the uptake of the finished product. However, individual personalities and political and organisational issues can cloud the 'evidence'. The involvement of a range of interests has implications for group development, function and progress, and the quality of the product [23].

Status hierarchies exist within and between professional groups, and the interplay of status and group participation has implications for the validity and reliability of guidelines [24]. Peer support can offset the pressure of social influence. Ensuring that people on the guideline development panel are present on behalf of a peak organisation is a means of providing peer support, and indirectly involves grassroots members in the guideline development process. Inviting the members of peak bodies (and other stakeholder groups) to comment on the draft version and gaining written endorsement of the finished product also fosters ownership and organisation-wide uptake of practice guidelines.

The issue of competing interests among group members needs to be considered, particularly if there is crossover in service delivery. It is critical for all members of the guideline development group to agree on the search strategy and study selection criteria prior to commencing evidence reviews to avert future conflicts over study selection and conclusions. Criteria for determining the level of evidence and grading recommendations should also be agreed at the outset. A written review protocol, endorsed by all members of the group, can outline these processes.

Dissemination and implementation

For guidelines to have an impact on the processes or outcomes of care, they must be implemented. If they are not used, a lot of valuable time and effort will have been wasted, and potential improvements in health outcomes will not be realised. Simply disseminating guidelines provides no guarantee that the target audience will be aware of them and use them. It is likely that the success of different strategies depends to a large degree on local circumstances [25].

Strategies to promote uptake of the finished guidelines should be considered early in the guideline development process, following an assessment of barriers to dissemination and implementation. Potential barriers include poor accessibility, lack of awareness, user characteristics, organisational and economic constraints to implementation and consumer-related barriers [11]. Examples of strategies include:

- Creating a credible document by adhering to accepted standards for guideline development.
- Involving representatives of peak organisations and other stakeholder groups to improve ownership.
- Developing recommendations that are relevant, and economically and practically feasible.
- Making guidelines easy to obtain and use, and creating different versions for target audiences.
- Embedding the most important principles in local operational protocols.
- Using a variety of approaches to market the guidelines (eg using existing communication networks such as profession colleges and consumer organisations, and involving opinion leaders);
- Improving credibility by gaining endorsement from peak organisations and government bodies;
- Keeping guidelines up to date.

Strategies for implementation are important, regardless of whether the guidelines are an update of existing work or newly developed. Guidelines are only worthwhile developing if they are used.

Review and revision

Keeping guidelines up to date is important to maintaining the credibility of the document, and is an implementation strategy. Many guidelines have regularly scheduled review and revision dates to maintain their currency. This method may be more resource intensive than necessary if the rate of change in a particular field is relatively slow. The following principles have been suggested to prompt review and updating of guidelines:

- When there is a substantial change to the evidence for practice.
- When new interventions become available.
- When changes in societal values occur.

- When there is evidence that current practice is optimal (and no further need for the guidelines).
- When changes occur in the availability of health resources [26].

It may be useful to contact members of the multi-disciplinary guideline development committee, who are likely to be aware of substantial changes in their respective fields, to ask whether they think the guidelines need updating. This contact could be made annually and be supplemented with a search of relevant databases for new studies. In the context of infection control, changes to the evidence for infection control practices, the emergence of new infectious diseases and the availability of new technologies and products are situations that might prompt an update of the guidelines.

Infection control guidelines – future considerations for development

Infection control guidelines, like guidelines in other healthcare fields, have traditionally relied on a non-systematic, expert opinion-based approach to development. Dedicated human and financial resources, technical skills and methodological capacity, and awareness of modern standards for guideline development may be lacking. A review of infection control guidelines developed in Australia highlights areas for improvement based on best practice guideline development strategies discussed earlier in this article:

- Consider adopting existing high quality infection control guidelines and updating where necessary.
- Be explicit in explaining how guidelines are developed, including methods used to assess the quality of the evidence and grade the recommendations.
- Involve nominated representatives of relevant peak bodies, a consumer representative and representatives of major hospital- and community-based user groups (eg professional medical, nursing and allied health associations) to promote broad uptake.
- Secure sufficient human and financial resources to develop quality guidelines and consider hiring a project manager.
- Consider upskilling the guideline development team (eg Cochrane reviewers course, electronic database search/library skills), and consider outsourcing systematic reviews.
- Assess barriers to implementation and develop an implementation strategy early in the process.
- Maintain the currency of electronic resources and develop a means for disseminating updates to maintain currency of paper-based versions (eg communiqués on urgent issues).
- Seek endorsement of guidelines by peak organisations and publicise this endorsement.
- Consider publishing a range of documents: a full description of the evidence review; summary document for clinicians and material for consumers. All should be available electronically, and if resources permit, consider distributing hard copies of the clinician summary to peak organisations involved in developing the guidelines.
- Identify gaps in the infection control literature to develop a research agenda.
- Establish a means for members of the guideline development group to recommend updating the guidelines or the need to disseminate urgently needed information.

Conclusion

The implementation of guidelines represents the interface of research and practice. To facilitate implementation, it is essential that guidelines are seen as a credible source of information. To maintain credibility, they should be developed according to accepted methodological standards. There are opportunities to improve the way in which infection control guidelines are developed in Australia. Sufficient financial resources, a range of skills and substantial time are needed to meet increasingly rigorous standards.

New methods are needed to streamline the complex task of guideline development to ensure that quality and credibility are paramount. Establishing partnerships with organisations holding expertise in particular aspects of the process, such as systematic reviews, using existing quality guidelines to reduce duplication of effort, and seeking opportunities for international collaboration in evidence collection and analysis are measures to improve the effectiveness and efficiency of guideline development.

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