
GUIDELINES WORKSHOP

ATELIER SUR LES LIGNES DIRECTRICES

Workshop on Clinical Practice Guidelines: summary of proceedings

Department of Health Care and Promotion, Canadian Medical Association

The CMA Quality of Care Program in collaboration with the National Partnership for Quality in Health (NAPAQH) sponsored a workshop on clinical practice guidelines, held Nov. 15 to 17, 1992. There were more than 90 participants representing interested organizations. The workshop was designed to propose guiding principles for the development and implementation of clinical practice guidelines in Canada. In their deliberations the participants used a series of background papers, which have now been published in *CMAJ*.¹⁻⁷ This summary of the workshop discussions, which includes the guidelines and action items developed by the participants, is the last in the series of articles. It combines related guidelines and therefore differs from the full workshop proceedings.

Philosophy, ethics and the law

The participants strongly endorsed the goal of practice guidelines to improve the quality of health care in Canada. They identified effective care, the efficient use of resources and the determination of the appropriate level of health care as important elements of quality.

Guideline: Clinical practice guidelines should be developed to improve the quality of health care. The efficient use of resources is usually inherent in high-quality care.

There was considerable debate on whether the elements of efficiency and effectiveness should be stated explicitly in the guideline. This debate highlighted the need to develop a definition of quality for use in guidelines development.

Action item: A definition of quality that reflects both the process and the outcome of care should be produced for the purposes of clinical practice guidelines development.

Clinical practice guidelines should improve the quality of decision making by physicians and patients. The participants strongly supported the view that such guidelines should not be seen as a substitute for individual judgement but, rather, should facilitate informed decision making by physician and patient, enhance the physician's judgement and empower the patient.

The participants recognized that physicians and patients make decisions in complex and highly individualized situations. They agreed that clinical practice guidelines should not only provide technical information but also explore issues in the management of patients.

Guideline: Clinical practice guidelines developed to meet the goal of improved quality of care will be most effective if they allow for physician and patient judgement and facilitate the decision-making process between physician and patient.

There was strong support for the full exploration of ethical issues during all phases of guidelines development and implementation. Issues of cost-effectiveness and resource allocation must also be part of the ethical debate. When appropriate, discussions of ethical considerations should involve the public, particularly with regard to decisions about resource allocation.

Guideline: The consideration of ethical issues should be a part of all phases of the clinical practice guidelines process.

A complete workshop report, including proceedings, background papers, glossary and participant list, is available from the CMA Membership Services Department, (800) 267-9703, ext. 2307.

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Clinical practice guidelines are a means of improving clinical practice. They should encourage the best practice by minimizing practice variations not justified by the evidence. They should also focus exclusively on promoting good medical practice and not be formulated on the basis of concerns that they would become legal standards.

Participants agreed that a sound ethical and legal approach to practice guidelines will reduce the likelihood of medical malpractice litigation. The developers of guidelines have a legal responsibility to carry out their task with reasonable care. They must also ensure that clinical practice guidelines in the public domain are revised to reflect current knowledge and practice.

Guideline: Developers of clinical practice guidelines should focus primarily on promoting good medical practice rather than be guided by a desire to influence the standard of care for malpractice litigation.

The participants strongly endorsed the concept that the physician's responsibility is primarily to the patient and then to society to ensure the wise use of finite health care resources. They had different perspectives on whether this dual commitment would be a potential source of conflict. Different principles apply on the individual and the societal levels, and physicians cannot operate on both levels at the same time. It was suggested that clinical practice guidelines developed by different organizations might emphasize different perspectives; the inconsistency between these perspectives could cause ethical conflicts for practitioners.

Guideline: Clinical practice guidelines should emphasize that the physician's responsibility is primarily to the individual patient and secondarily to society.

Methodology

There was a consensus that methods for developing clinical practice guidelines are not well established. This recognition led to the suggestion that a national resource group be formed to provide expert advice to guidelines development groups. Furthermore, this resource group should develop, through a national workshop, a manual of practical methods and should more fully define the issues involved in clinical practice guidelines development in Canada.

Action item: A national workshop should be held to develop a manual that outlines practical methods for the development of clinical practice guidelines and to define further the methodologic issues related to guidelines development in Canada.

The participants agreed that setting priorities was essential to guidelines development; however, they clearly recognized that the conflicting interests of different parties may complicate this process. Some suggested that the selection of topics for development is iterative: it involves the insights and goals of many different people and organizations. A similar process takes place in the evaluation of guidelines. The group concluded that better methods are needed to rank priorities for clinical practice guidelines and to evaluate them.

Guideline: Developers of clinical practice guidelines should articulate clear goals for guidelines development programs and should use and document explicit, open, iterative processes for setting priorities and assigning resources for new and revised guidelines.

The participants recognized that clinical practice guidelines will often address issues on the front line of scientific knowledge. They noted that it is unrealistic to expect definitive statements in areas of evolving knowledge. However, developers should explain their methods as best they can. Regular feedback from user groups was considered an important means of ensuring that the guidelines reflect the reality of clinical practice.

Some of the participants felt that scientific uncertainty should not be regarded as an impediment to the development of clinical practice guidelines. Others recommended that areas with little scientific evidence should receive low priority. With regard to the methodologic approach, it should be made explicit that these guidelines for guidelines are based on expert opinion rather than on well-accepted scientific evidence.

Guideline: In collaboration with interested parties, those involved in the development of clinical practice guidelines should state as explicitly as possible their objectives, methods and audience before the actual development of the guidelines.

The participants agreed that quantifying the strength of the supporting evidence for a recommendation can be imprecise, especially in areas of scientific controversy. Ways were discussed to strengthen the evidence-based approach to developing guidelines. It was suggested that each recommendation have an individual citation.

Guideline: Each clinical practice guideline should cite the specific positive and negative evidence that most directly supports the recommendation. Ideally, guideline reports should indicate the strength of the evidence and the date of the most recent evidence considered.

It was agreed that physicians must take the greatest responsibility for developing clinical practice guidelines and should collaborate with other interested groups and those with specialized knowledge. There was a strong consensus that expert and user groups be involved. Only in this way can guidelines be practical and timely and reflect the best clinical judgement.

The concept of a field trial or feasibility study before publication received general support. Such review processes should include intended users and related specialists when appropriate. Wide distribution for review would complement the expertise of representatives on the guidelines development committee.

The participants acknowledged that development of clinical practice guidelines is demanding and that the addition of a field trial would prolong an already lengthy process. It was suggested, however, that external review before publication can minimize unexpected serious problems with guideline recommendations. The participants expressed the need for explicit mechanisms to revise guidelines on the basis of new evidence and evidence of effectiveness and the impact on health.

Guideline: Before publication, clinical practice guidelines should be fully reviewed by expert and user groups as appropriate and, if possible, tested through such mechanisms as field trials.

There was some agreement that the development of new guidelines must build on past efforts. Useful guidelines should not be discarded simply because they are presented in different formats.

The participants agreed that a simple standardized summary of the key elements of a guideline would increase its utility to practising physicians and facilitate the flow of information between physician and patient. Some of the participants suggested that standardized summaries should be an integral feature of every clinical practice guideline; others expressed the view that such summaries should be prepared only when it is reasonable to do so. It was noted that, in general, a practice guideline should contain a summary, a list of recommendations and a detailed background report of the documentation and methods.

The content of a guideline must vary to suit the needs of the target audience, and the intended users of the guideline should be consulted to ensure that the format encourages both acceptance and use.

Guideline: When appropriate, the developers of a clinical practice guideline should use a standardized summary to report fully on the development process and key recommendations.

Implementation

There was general agreement that implementation is both the most crucial and the most difficult part of the whole process. Ineffective implementation strategies waste scarce resources, alienate physicians and diminish the capacity of guidelines to effect positive changes in quality of clinical care. There was consensus that adequate resources should be allocated for implementation.

The participants noted that implementation involves the dissemination or marketing of information on both a micro and a macro educational level. However, the publication of guidelines will not by itself bring about a desired change in clinical practice; various approaches must be used. There was considerable consensus that implementation strategies, as with all other aspects of guidelines development, must be based on the concept of continuous quality improvement and must allow for the direct involvement of practitioners, patients and other stakeholders, such as administrators and governments. Strategies should be tailored to the purpose and users of specific clinical practice guidelines.

Divergent views were expressed about the need to determine an implementation strategy before a clinical practice guideline is developed. A requirement for multiple or specific strategies could be perceived as an insurmountable technical and financial barrier to guidelines development.

The participants agreed that the adoption of clinical practice guidelines must be voluntary. Compulsory compliance, through recertification, resource allocation, regulation or other means, fails to recognize the individualized nature of the physician-patient interaction.

Consensus was reached on the need for successful educational strategies to modify professional behaviour to be positive, personalized and peer-related. Clinical practice guidelines should explain why and how to implement recommendations. Feedback was identified as an important element in sustained behaviour change.

It was noted that the greater the physician participation in guidelines development the greater the opportunity for a sustained change in clinical practice. In this regard, it was suggested that the duplication of effort in guidelines development could be viewed as a positive rather than a negative indicator of success, since it provides more avenues for more physicians to be a part of the development process.

Guideline: There should be effective and coordinated implementation strategies for voluntary adoption of clinical practice guidelines. Physician involvement should be emphasized.

The participants agreed that research into implementation strategies is essential and should build on the expertise of other disciplines, such as educational psychology. It was proposed that new areas for research should include development of means to identify appropriate target(s) for clinical practice guidelines, development of appropriate implementation strategies for different audiences (e.g., physicians, consumers, planners and people from diverse ethnic or cultural communities), evaluation of existing strategies for implementation and exploration of the role of legislative action.

The participants also discussed research methods. It was suggested that research into implementation strategies should take the form of process evaluation — that is, an assessment of their effectiveness.

Guideline: Program evaluation is needed to assess the effectiveness of the implementation process. Research into new strategies for implementing clinical practice guidelines is essential.

Coordination

It was agreed that the development and quality control of clinical practice guidelines should involve specialty societies and provincial and local agencies. Local control and involvement heightens the individual practitioner's sense of commitment, whereas too much national action may be perceived as interference by those who are distant from the realities of the physician-patient relationship. However, some form of national collective action will be necessary to obtain funding, keep people in touch with each other and ensure that practitioners continue to influence the clinical practice guidelines process in Canada.

There was support for collective action to standardize methods of developing clinical practice guidelines and to establish links between experts in methods and the organizations involved in development. Such links could overcome regional variations in expertise and strengthen guidelines efforts across Canada.

Different views were expressed about the appropriate structure for collective action to be undertaken nationally. The term "network" seemed most acceptable. The participants agreed that this network should support local efforts to develop, implement and evaluate clinical practice guidelines through the provision of services when requested. It was recommended that an existing organization, such as the NAPAQH or the CMA, be asked to establish a network.

The funding of clinical practice guidelines was also discussed. Reliance on government funding

could result in a loss of control of the process by practitioners. Funds should be generated from non-government sources to ensure an independent perspective.

The participants expressed diverse views on whether the network should become involved in the allocation of resources for guidelines development. It was proposed that the network could solicit requests for proposals based on a standardized format for development and implementation, grant development awards on a competitive basis, and solicit and coordinate funding. Other participants suggested that the network play no role in this area.

Action item: A network of guidelines developers should be established by NAPAQH and other stakeholders. Goals and objectives would be defined by the network and could include the establishment of formal links, standardized methods and service provision to support the clinical practice guidelines process.

There was strong support for the creation of a database or registry for clinical practice guidelines. The participants did not agree, however, on the administrative structure for the database.

Action item: A continually updated database of clinical practice guidelines should be developed, maintained and made readily available to clinicians, patients and others.

Future steps

The four proposed action items will be the basis for further collective efforts in the development of guidelines for guidelines. This work will be undertaken by the network of developers to be established by NAPAQH and other stakeholders.

The workshop proceedings report will be used as the foundation for a consensus report on guidelines for clinical practice guidelines to be distributed for further discussion in the fall of 1993. The final report is expected to be published in January 1994.

References

1. Carter A: Background to the "Guidelines for Guidelines" series. *Can Med Assoc J* 1993; 148: 383
2. Battista RN: Clinical practice guidelines: between science and art. *Ibid*: 385-389
3. Hayward RSA, Laupacis A: Initiating, conducting and maintaining guidelines development programs. *Ibid*: 507-512
4. Anderson G: Implementing practice guidelines. *Ibid*: 753-755
5. Jutras D: Clinical practice guidelines as legal norms. *Ibid*: 905-908
6. Somerville MA: Ethics and clinical practice guidelines. *Ibid*: 1133-1137
7. Oxman AD: Coordination of guidelines development. *Ibid*: 1285-1288