Initiating, conducting and maintaining guidelines development programs

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Clinical practice guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[1] Valid and influential guidelines could facilitate more consistent, effective and efficient medical care and ultimately lead to improved outcomes for patients. Unfortunately, the quality and intent of guidelines vary widely,[2] and relatively few of the more than 1200 existing guidelines merit attention or application by typical clinicians.[3] If practice guidelines are to facilitate high-quality care they must be developed and described carefully.

Practice guidelines can be produced by organizations of different sizes. Large national bodies, such as the Canadian Task Force on the Periodic Health Examination,[4] may be engaged to develop a series of guidelines; a small organization of physicians in group practice may develop guidelines only occasionally, in response to unique local needs. All organizations should be explicit in their planning, development and evaluation of individual guidelines projects. Organizations that develop more than one set of guidelines should also consider planning, managing and monitoring a guidelines development program (Table 1).

Guides for guidelines programs

Developing good guidelines is time-consuming and expensive. Unnecessary or poor guidelines frustrate practitioners, confuse patients and erode the credibility of guidelines in general. Before initiating a guidelines project, developers should define goals for their program, establish a priority-setting process for selection of the guidelines to be developed, match the scope of the guidelines project to the available resources and monitor the impact of the program so that goals, priorities and resource allocations can be reassessed in the light of experience.

Defining goals

A good starting place is the mission of the sponsoring health care organization: what it wants to accomplish and for whom. Improving the quality of health care is a laudable but generic objective; organizations are more likely to differ in the secondary interests of their members. An association of practitioners, for example, may devote considerable energy to maintaining its members' skills, autonomy, credibility and income. A government funding agency may devote equal energy to constraining practitioner reimbursement in a politically expedient way. The extent to which considerations of quality of care are tempered by other considerations — the special interests of patients, clinicians, institutions or so-

Table 1: Guides for guidelines

Guidelines programs	Guidelines projects
• Define goals	• Plan
• Set priorities	• Develop
• Allocate resources	• Validate
• Monitor impact	• Report
	• Disseminate
	• Implement
	• Maintain

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ciety — determines the context in which guidelines are developed. This can explain how guidelines developed primarily by experts in lipids, for example, might differ from those developed primarily by epidemiologists.[5]

Guidelines pertain to decisions. When a prospect for influencing clinicians' choices exists, practice guidelines may serve a number of purposes. They may help to codify current knowledge, clarify or resolve clinical controversies or promote more effective, efficient or consistent medical practices at lower cost or at less risk to patients. Guidelines may be used to assist clinicians with patient care (e.g., by means of clinical algorithms and reminders), to evaluate practices retrospectively (e.g., through utilization review and quality assurance) or to set limits on practitioner choices prospectively (e.g., through preapproval of surgical procedures and the granting of credentials). Pathway guidelines describe a preferred course of action, whereas boundary guidelines mark the limits of appropriate practices.[6]

Anticipating how guidelines will be used can help determine whether they should focus on health conditions or on practice interventions. For example, guidelines may be developed to assess the merits of various methods of screening for breast cancer (condition-focused guidelines) or to identify all the appropriate indications for mammography (intervention-focused guidelines). If the goal is to help practitioners sort out complex clinical decisions, then condition-focused guidelines are preferred. If an organization is interested in controlling the dissemination of new technologies or in setting criteria to support peer review, certification, reimbursement or audit activities, then intervention-focused guidelines may be more appropriate.

Taking the time to articulate program goals can be valuable in several ways. The goals will inform priority-setting processes. They will also suggest who should be involved in guidelines development: those whom the guidelines should benefit, those who must implement the guidelines and those who may have a stake in the costs associated with implementation. Collaborating organizations with compatible goals can be identified, and they may consider sharing the burden of guidelines development. Practitioners can determine whether there is a good match between the goals of the developers and the goals of the users of guidelines. Finally, specific, measurable goals can focus efforts to evaluate the success or failure of a guidelines program.

Assigning priorities

Many clinical problems merit evaluation. However, just one problem consumes many months of work, and there are few technical experts available to help practitioners generate valid recommendations about a problem. Thus, health care organizations that wish to develop guidelines need to set priorities.

Priorities for guidelines development may be implicit when fresh clinical, financial, legal or professional imperatives compel organizations to make or re-examine clinical policies. Alternatively, priorities may be derived from an explicit, reproducible, fair and open appraisal of the need for new or revised policies about various topics.[7] The Institute of Medicine in the United States has recently formulated and tested a systematic method for setting priorities for technology assessments.[8] This can be adapted for use with clinical practice guidelines (Fig. 1).

The goal of priority setting is to rank potential guidelines topics to reflect the goals of the health care organization and the values of the population it serves. This can be facilitated if specific criteria are used to judge the relative importance of various guidelines topics (Table 2). Possible objective criteria include the prevalence of the target health condition or problem, the cost of the technologies used to manage it and the degree of practice vari-

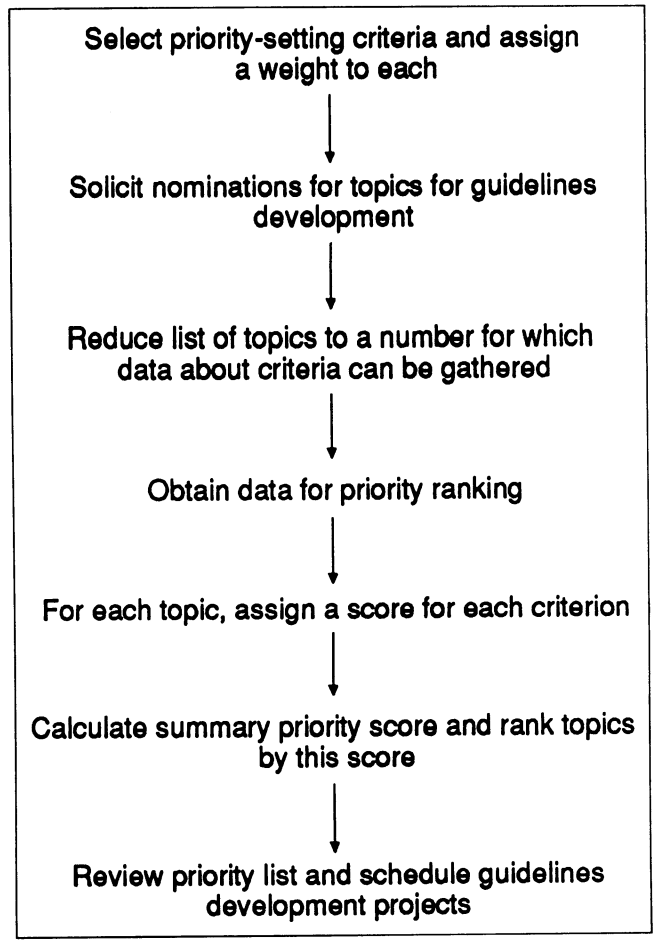

Fig. 1: A model priority-setting process (adapted from reference 8).

ation in its management. These criteria can often be quantified with data from the medical literature. Possible subjective criteria include the burden of illness imposed by the condition and the potential of guidelines to change health outcomes or costs or to otherwise affect ethical, legal or social issues. Subjective criteria are more difficult to gauge, and data are rarely published.

Each priority-setting criterion can be assigned a weight that reflects its relative value. Potential guidelines topics can then be given a score on each criterion. When the criterion scores are integrated with the preassigned criterion weights a summary score can be generated for each topic in the list of nominations.[8]

Allocating resources

The guidelines that are needed most may also prove the most difficult to develop. Health care organizations should try to anticipate what can be accomplished with the resources available for a particular project. When critical evidence is lacking (as is often the case) how far will the guidelines-development team go to redress the deficiency? Some teams may have to work to the best of their ability with what is available, whereas others may be charged with synthesizing expert opinions or even generating new evidence. Such practical considerations may motivate organizations to focus on topics for which the supporting evidence is plentiful or to seek collaborative arrangements with other organizations.

Even when the evidence concerning a health problem is strong, the end product of a guidelines project may be futile if resources are not allocated to validation, reporting, dissemination and implementation initiatives.

Monitoring impact

As guidelines are developed and disseminated much time and effort may be expended with very little change in physician practices.[9-12] Organizations that develop practice guidelines should plan to monitor the impact of their guidelines on the targeted clinicians or to determine whether the goals of the guidelines program were accomplished. Failure to meet the goals demands reappraisal of both goals and methods.

Table 2: Possible priority-setting criteria*

Objective
Prevalence of the clinical condition
Cost of the health practice(s) commonly used to manage the condition
Variation in health practices used to manage the condition
Subjective
Burden of illness
Potential to change health outcomes
Potential to change costs
Potential to affect ethical, legal or social issues

*Adapted from reference 8.

Guides for guidelines projects

We believe that valid, important and applicable guidelines are more likely to be developed if organizations adopt a systematic approach to planning, developing, validating, reporting, disseminating, implementing and maintaining individual guidelines.

Planning

Before handing a project over to a development team the sponsoring health care organization should decide who will lead the team, how much independence the team will have, with whom the team will collaborate, who will monitor the guidelines-development process and who will audit the result.

Guidelines recommendations are unlikely to influence decisions if the principal ingredients of clinical decision making are not sorted out beforehand. Also, appropriate methods for gathering and synthesizing evidence and preferences pertaining to the decision should be identified in advance.

Objectives: Guidelines developers should begin by defining precisely the health care problem they wish to clarify. For guidelines concerned primarily with the management of a health condition the stage of illness and any intent to prevent, detect, diagnose, treat or palliate the disorder should be determined. For guidelines concerned primarily with the appropriate use of a health care technology the intervention and its role in patient management should be defined.

Options and outcomes: Guidelines developers should identify all the relevant management options for the stated health care objective. For guidelines involving the management of health conditions alternative preventive, diagnostic or therapeutic strategies should be compared. For procedural or technologic guidelines a control practice should be identified (e.g., the next best practice, the usual practice or no intervention). The principal outcomes used to compare the merits of alternative practices should also be identified. Health outcomes, such as rates of illness and death and the quality of life, should be distinguished from economic and process outcomes, such as changes in what constitutes patient care and how care is administered.

Evidence to be considered: To estimate the probable effect of a health care intervention on an out-

come, appropriate data must be collected and appraised. Guidelines developers should decide ahead of time what kind of evidence they are looking for, how the evidence will be gathered, how evidence from different sources will be combined and how the assembled evidence will be analysed. Potential sources of evidence include the published or unpublished results of scientific studies, expert testimony, public or private health databases, results of surveys, input from patients or consumers and various fee schedules. Criteria for gauging the quality of information from different sources may be used (Table 3).

Scientific evidence is often missing or conflicting. This should be anticipated and a strategy prepared for dealing with uncertainty. Explicit, preferably quantitative, methods for combining results from scientific studies (e.g., meta-analysis) or opinions of experts (e.g., the Delphi technique) must be planned to secure the technical expertise needed by a guidelines-development panel.[14-16]

Values to be considered: The recommendation of a practice presumes that preferences for the health, economic and process outcomes associated with different options have been determined. These are matters of opinion and value. Consequently, the major groups whose values must be represented should be identified, and the method by which consensus will be sought should be planned. It is especially important to consider how patient preferences will be represented. Again, guidelines developers will need to plan how uncertainty (ambivalence) and variability (disagreement) will be recorded and reported. Criteria for grading the strength of a recommendation are useful.[17]

Developing

There is no perfect way to develop guidelines. Different approaches have been promoted by different organizations, each with unique strengths for meeting particular objectives.[18,19] Some groups assign considerable importance to expert opinion. The RAND corporation has developed a sophisticated process for obtaining blind ratings of the appropriateness of medical interventions in various clinical circumstances.[20] Another approach holds that the most important "experts" are the physicians who must actually implement the guidelines. Clinicians at the Harvard Community Health Plan have popularized a local process that emphasizes attaining consensus among group members after a careful review of the published evidence.[21] Other groups, such as the Canadian Task Force on the Periodic Health Examination, base recommendations more strictly on the results of randomized controlled trials.[13] However, high-quality clinical trials are often not available, and committees must make recommendations with less than optimum information.[22] A difference in the willingness to rely on expert opinion in the face of such uncertainty can result in conflicting recommendations on the same topic from different organizations.[23] Although there is nothing wrong with this, careful attention to the choice of guidelines-development methods both in project execution and in reporting can help prospective guidelines users to understand the reasons for such conflicts.

Table 3: Grades of evidence[13]

I	Evidence obtained from at least one properly randomized controlled trial
II-1	Evidence obtained from well-designed controlled trials without randomization
II-2	Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one centre or research group
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin in the 1940s)
III	Opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees

Validating

The ultimate goal of most guidelines is to improve health outcomes; however, even the strongest recommendations based on firm evidence and sound judgements and implemented by targeted providers may not produce the intended changes in health care practices or outcomes.

Guidelines developers should not release guidelines until at least some effort has been made to validate them. Although the ideal would be to conduct a randomized clinical trial to assess whether guidelines implementation results in the predicted outcomes this is rarely achievable within the time frame of most projects. An alternative but weaker form of validation might be some form of external review of the evidence and the values that underlie the recommendations.

Reporting

To be clinically useful a guidelines report should be clear, applicable and flexible.[1] Clarity is achieved through unambiguous language, precise definition of terms and logical, easy-to-follow modes of presentation. A guidelines report is applicable if targeted patients, providers and settings are specified so that readers can tell who should do what, when, where and to whom. Flexibility is reflected in the guide-

lines' consideration of patient or practice characteristics that require individualized recommendations or that justify departures from the recommendations.

To be clinically important a guidelines report should convince the reader that the benefits of following new recommendations merit the expected cost of implementation. The benefits and harms resulting from the application of recommendations to typical patients in typical settings should be reported in absolute as well as relative terms (e.g., a 50% reduction in disease incidence from 50/100 to 25/100 is more compelling than a 50% reduction from 5/10 000 to 2.5/10 000).[24] The principal undesirable outcomes associated with alternative interventions should be identified, including the consequences of misapplying the practice guidelines or of mislabelling patients. If a formal cost–benefit analysis is performed, then estimates of both costs of guidelines implementation should be given.

The use of structured abstracts for clinical practice guidelines could help readers quickly appraise their potential applicability, importance and validity for specific providers, patients and settings. A recently proposed format for guidelines abstracts emphasizes disclosure of the primary methods by which evidence was assembled and synthesized and the implicit or explicit processes used to determine preferences for alternative outcomes (Table 4).[25]

Disseminating

Guidelines developers should plan how they will get their guidelines to the intended users. More needs to be learned about how specific dissemination strategies — direct mailing to targeted providers, continuing medical education, scientific presentations, academic "detailing" and promotion by influential clinicians — can be best matched to particular types of guidelines.

Guidelines developers should also consider how intended users can have access to specific guidelines. Computerized searches of the medical literature can be made easier by the use of structured abstracts and guidelines-specific key words. More useful might be a readily accessible database of clinical practice guidelines that is regularly updated and improved.

Table 4: Format for structured abstracts of clinical practice guidelines[25]

1. Objective: the primary objective of the guidelines, including the health problem and the targeted patients, providers and settings
2. Options: the clinical practice options considered in formulating the guidelines
3. Outcomes: significant health and economic outcomes considered in comparing alternative practices
4. Evidence: how and when evidence was gathered, selected and synthesized
5. Values: disclosure of how values were assigned to potential outcomes of practice options and who participated in the process
6. Benefits, harms and costs: the type and magnitude of the expected benefits and harms to patients and the expected costs of guidelines implementation
7. Recommendation(s): summary of key recommendations
8. Validation: report of any external review, comparison with other guidelines or clinical testing of guidelines use
9. Sponsor(s): disclosure of the person(s) who developed, funded and endorsed the guidelines

Implementing

Publishing or mailing guidelines falls far short of the effort required to get physicians to heed new advice. Acceptance of the guidelines may be facilitated through their introduction to target physicians by respected opinion leaders, through the use of audit and feedback to alert physicians to deviations of their practices from the guidelines' recommendations and through the provision of financial or other incentives.[26] Various guideline-implementation strategies are discussed in the next part of this series.

Maintaining

Guidelines often concern complex health problems about which new knowledge is sought. Because of the long time required to assemble and review evidence and then achieve consensus about appropriate recommendations, guidelines developers should report at least two dates: that on which the most recent evidence was published and that on which the final recommendations were rendered. Better still would be the identification of important studies in progress, an estimation of the size of any change in evidence needed to change the guidelines and a commitment to reassess guidelines regularly. Potentially labile guidelines could be classified as "temporary" or "provisional" with specific expiration or review dates.

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