

Clinical practice guidelines and *Helicobacter pylori* infection in children

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C Macarthur, L Jaakkimainen. Clinical practice guidelines and *Helicobacter pylori* infection in children. *Can J Gastroenterol* 1999;13(7):560-562. The objective of this paper is to review the principles, methods and issues behind the development of clinical practice guidelines. Practice guidelines have been defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances". The ultimate goal of guidelines is to improve patient outcomes; however, they may also be used as tools to decrease health care costs, improve medical education and enhance quality assurance. Evidence-based guidelines use explicit methods to link recommendations to the quality of the underlying research. Following development of the guideline, implementation and evaluation are key steps. The ultimate aim of guideline development is to influence physician knowledge, attitudes and behaviour.

Key Words: Children; Clinical practice guidelines; *Helicobacter pylori*

Directives de pratique clinique et infection à *H. pylori* chez les enfants

RÉSUMÉ : L'objectif de cet article est de passer en revue les principes, les méthodes et les enjeux qui sous-tendent le développement de directives de pratique clinique. Les directives de pratique ont été définies comme des « énoncés systématiques visant à faciliter les décisions du médecin et de son patient au sujet de soins de santé qui s'imposent dans des circonstances cliniques spécifiques. L'objectif ultime des directives est d'améliorer le pronostic chez les patients. Par contre, elles peuvent aussi servir d'outils pour réduire le coût des soins de santé, améliorer la qualité de l'enseignement médical et favoriser l'assurance de la qualité. Les directives fondées sur des preuves reposent sur des méthodes explicites pour établir un lien entre la recherche et les recommandations pratiques. Suite au développement des directives, leur mise en application et leur évaluation sont des étapes cruciales. Le but final des directives est de renseigner les médecins et influencer sur leurs attitudes et leurs comportements.

Recent articles have suggested that guidelines for the management of *Helicobacter pylori* infection in children are required (1-3). The need for specific guidelines for children is based on differences in the prevalence and spectrum of disease associated with *H pylori* infection in children compared with adults, limited understanding of the role of *H pylori* infection in symptom development, debate about the optimal diagnostic approach, and confusion around the indications for diagnosis and treatment, particularly in the primary care setting. Several consensus guidelines on the management of *H pylori* infection in adults – developed in North America, Asia and Europe – have recently been published (3-5). Only one of these guidelines, however, considered the issues around *H pylori* infection in children, with a

specific recommendation for guidelines to be developed for this age group (3). The objective of the present article is to review the principles, methods and issues behind the development of clinical practice guidelines.

CLINICAL PRACTICE GUIDELINES

Clinical practice guidelines have been defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (6). The ultimate goal of guidelines is to improve patient outcomes. However, they may also be used as tools to decrease health care costs, improve medical education and enhance quality assurance (7,8). Variation in physician practice and rising health care costs are important

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factors that have contributed to the exponential growth in the development and prominence of clinical practice guidelines in recent years (7). While variation in physician practice may be explained by differences in patient populations, availability of resources and patient preferences, there is also concern that variation may reflect either excessive or inadequate use of procedures and treatments. Furthermore, if practice variation is related to physician uncertainty about management, it has been argued that practice guidelines may help resolve this uncertainty and thereby reduce the frequency of inappropriate care (7). Given that guidelines explicitly describe the benefits and costs of different approaches to patient care, it has been argued that guidelines may also play an important role in optimizing resource utilization (7).

STEPS IN DEVELOPMENT

Woolf (8) described four approaches to guideline development: informal consensus, formal consensus, and evidence-based and explicit development. These approaches, however, are not mutually exclusive. The consensus approach uses expert panels to develop guidelines, with the formal approach differing only in its use of structured processes (eg, Delphi techniques) to reach a consensus. Guidelines developed in a consensus fashion have often been criticized. First, expert opinion may not be correct. In addition, unstructured group meetings are prone to influence by dominant personalities and politics. Last, such guidelines often fail to delineate the influence of scientific evidence on the final report.

More recently, the development of guidelines has shifted toward the use of explicit methods to link recommendations to the quality of the underlying evidence. Such evidence-based guidelines use empirical data, wherever possible, to quantify the benefits, adverse effects and economic costs of potential interventions. In a similar fashion, the probability of various health outcomes associated with the interventions is also estimated. One criticism of the evidence-based approach is that frequently there is limited acceptable evidence. Because of this limitation, many guideline developers use a combined approach that incorporates available evidence together with expert opinion. Such guidelines should make explicit the distinction between recommendations based on evidence and those based on expert opinion.

METHODOLOGY AND EVALUATION

A series of steps considered central to the development of guidelines have been described by Woolf (8). These steps are described below.

1. **Define the objectives or mission statement:** The topic of the practice parameter should be described as clearly as possible. This involves specifying the target condition (eg, duodenal ulcer) and the 'disease' for which the parameter is being developed (eg, *H pylori* infection).
2. **Define the patient:** Again, description of the patient for whom the practice guideline is intended should be as precise and specific as possible (eg, children with *H pylori*-associated duodenal ulcer).
3. **Define the intervention(s):** All clinical interventions to be considered in the development of the guideline – preventive measures, diagnostic tests, procedures, treatments – need to be listed. In the context of *H pylori* infection, interventions may include vaccines, serological tests, endoscopy and antibiotic therapies.
4. **Define providers:** The intended users of the practice guideline (eg, family physicians, primary care pediatricians, tertiary care specialists) need to be identified.
5. **Define the setting:** The intended setting for the practice guideline needs to be described. Explicit definition of the providers and the setting will influence guideline development. For example, consideration of urea breath testing or endoscopy in the guideline would require that the users of the guideline have access to appropriate facilities and equipment.
6. **List outcomes:** Health outcomes likely to be influenced through implementation of the guideline (eg, decreased ulcer recurrence) need to be specified. Both beneficial and adverse effects should be considered and quantified.
7. **Develop an evidence model:** An evidence model makes explicit the causal pathway(s) between intervention(s) and outcome(s). This process helps identify aspects of management where evidence is required.
8. **Review the literature:** A comprehensive search of the literature is combined with a critical appraisal of selected articles and extraction of pertinent data. This process makes explicit the source and quality of the evidence, while the data are used in the evidence model to quantify outcomes. The method by which data are summarized – such as informal review and formal meta-analysis – needs to be specified. The literature search also helps identify gaps in the evidence, with this information frequently used to guide subsequent research activities.
9. **Assess benefits and harms:** The benefits and harms associated with each intervention are made explicit, preferably based on published evidence. The probabilities of all beneficial and adverse outcomes should be estimated along with the degree of uncertainty associated with the estimates.
10. **Draft practice guideline:** The guideline should address not only benefits, harms and best patient care, but also feasibility issues, such as costs and availability of resources.
11. **Implement and evaluate:** The process of guideline development must also include strategies for the dissemination of the guideline to intended users as well as formal evaluation of its influence on practice.

In parallel with the development of formal methods for preparing clinical practice guidelines has been the development of formal methods for evaluating the quality and impact of guidelines (9-14). For example, Hayward et al (9) and Wilson et al (10) describe issues that should be addressed when reviewing a clinical practice guideline. Primary issues include whether all clinically reasonable interventions and outcomes are considered in the guideline and whether the process used to identify, select and combine the evidence is explicit and reasonable. Often, systematic reviews are used to synthesize the available evidence. Such reviews are considered valid if they meet certain criteria. For example, the review should address a focused clinical question, it should specify explicit inclusion and exclusion criteria for the evaluated studies, the search should be comprehensive, and studies should be critically appraised with regard to quality (11,12).

Both the Canadian Task Force on the Periodic Health Examination and the United States Preventive Services Task Force classify the quality of the evidence based on study design (8,15). A hierarchical grading system is used with randomized, controlled trials considered to be of the highest quality, followed by observational study designs (case-control and cohort), then descriptive studies and, last, the opinions of respected authorities. This approach, however, does not explicitly take into account threats to the internal and external validity of individual studies (10).

The process by which different outcomes are valued is also a key issue. In other words, linking interventions to outcomes may be based on science, but assigning preferences to outcomes is based on judgment. Patient preferences, economic costs and ethical considerations may play a role in this deliberation (9). Therefore, panels with broad representation including primary care physicians, tertiary care specialists and subspecialists, methodologists and lay persons are better suited to this task. Guideline developers need to be explicit about the source and the process of integration of value judgments into the final report.

Other important issues include whether the practice guideline is up to date and whether the guideline has been subjected to peer review and testing. In other words, confidence in a practice guideline is increased if external reviewers consider the conclusions to be reasonable and if clinicians have found the guideline to be applicable and useful in everyday practice (9).

The ultimate goal of clinical practice guidelines is to improve patient outcomes. Therefore, following development of guidelines, implementation and evaluation are key steps (13,14). The underlying rationale behind the development of guidelines is that they can influence physician knowledge,

attitudes and behaviour. Systematic reviews have shown that guidelines can influence the process of care and, ultimately, improve patient outcomes (12). Dissemination of guidelines, however, is often not sufficient to effect change. Strategies thought to improve the likelihood of guideline success include patient-specific reminders, audit and feedback (12,14). Regardless of these strategies, valid guidelines will not have a positive impact if the health care setting is inappropriate. For example, if issues such as access, availability and cost are important barriers, then the guidelines will not be implemented effectively.

In summary, the recommendations of a practice guideline should be supported by the underlying quality of the evidence. The primary intent of such guidelines is to influence practice through explicit recommendations. Whether the impetus for guideline development is the clarification of difficult management issues or incorporation of new evidence into practice, the overriding aim is for the guideline to reduce inappropriate care and improve patient outcomes.

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