Canadian Medical Association

Handbook on Clinical Practice Guidelines

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Dave Davis, MD
Joanne Goldman, MSc
Valerie A. Palda, MD, MSc

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888 855-2555 or 613 731-8610 x2307
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Using this handbook

The objective of this handbook is to provide up-to-date, evidence-based, experience-driven guidance on how to use clinical practice guidelines (CPGs) most effectively to improve the care of patients.

It was written for individuals and groups interested in the development, adaptation, implementation and evaluation of CPGs, including

- health care practitioners — physicians, nurses, allied health and alternative medicine practitioners
- health care administrators
- groups, organizations and societies involved in CPG development, adaptation or implementation
- health care policy-makers who make decisions about the development, adaptation and implementation of CPGs.

Background

The field of CPGs has experienced significant changes during the decade since the Canadian Medical Association (CMA) created its original publications on the subject: *Guidelines for Canadian Clinical Practice Guidelines* in 1994 and *Implementing Clinical Practice Guidelines*: *A Handbook for Practitioners* in 1997. In that time, debate, research and practice have illustrated the benefits and challenges of CPGs, with sizable emphasis on improving the quality and relevance of CPGs and their impact on practice.

The decision to include both development and implementation in one document reflects our belief that the processes involved in adapting, developing, implementing and evaluating CPGs are heavily interdependent. We cannot imagine a situation in which a CPG is developed without thinking and planning for its adoption by clinicians, the public, patients or health policy-makers. For example, CPG developers need to understand factors that promote the usability of CPGs to optimize their impact. Similarly, we cannot imagine translating CPGs into practice without being fully aware of the process used to produce them; implementers need to be able to locate and assess the quality of CPGs. Both groups may be involved in adapting CPGs to local contexts.

The handbook: a guide to its use

The structure of this handbook reflects the major stages in the CPG process. Chapter 1 provides an overview of CPGs and their position within a broader health care quality framework. Chapter 2 focuses on the adaptation and development of CPGs and chapter 3 provides insight into the process of translating CPGs into practice. In chapter 4, we discuss methods to evaluate CPGs. Finally, we review key messages and offer some insights into future directions for the field of CPGs. The content of the various chapters is highlighted at the beginning of each.

For each part of the CPG process, we

- review the key parts of the process with reference to the published evidence
- suggest practical approaches to complete that part of the cycle
- provide illustrative examples
- offer lists of resources and links for interested readers.

This handbook is based on comprehensive reviews of relevant research studies, systematic reviews, theoretical perspectives, reports from expert meetings and collaborations and Internet sites. We have included case studies as examples of the steps in the CPG process where we think they are helpful.

We have attempted to provide the most up-to-date evidence and resources available and links to many useful Internet sites and organizations, and we have incorporated a Canadian perspective when possible.

Writing the handbook

The CMA partnered with the Ontario Guidelines

Advisory Committee (GAC) — a body of the Ontario Ministry of Health and Long Term Care and the Ontario Medical Association — to develop this handbook. Its principal authors are

- **Dave Davis**, MD, CCFP, FCFP, FRCPC (Hon)
  During the writing of this book, Dr. Davis was chair of the GAC. He is now vice-president for Continuing Health Care Education and Improvement, American Association of Medical Colleges, Washington, DC
- **Joanne Goldman**, MSc
  Continuing Education and Professional Development, Faculty of Medicine, University of Toronto
- **Valerie A. Palda**, MD, MSc, FRCPC
  Assistant professor, Departments of Medicine and Health Policy Management and Evaluation, University of Toronto; medical advisor, GAC

Dr. Davis acknowledges the assistance of several colleague organizations that helped in the writing and intellectual content of this workbook: the National Institute for Clinical Studies, Melbourne, Australia, and the Association of American Medical Colleges, Washington, DC. No conflicts of interest were recorded or noted by the principal authors.

Under the guidance of the CMA, the GAC took the lead in writing and organizing the contents and structure of the handbook. An international expert advisory group, representing the target audiences for the handbook, was involved in preliminary discussions concerning the goals of the handbook and contributed to the document according to their areas of expertise by reviewing, editing and providing content. Conflict of interest statements were not recorded for this group.

Expert advisory group members

Melissa Brouwers, PhD
Associate professor (PT), Department of Clinical Epidemiology and Biostatistics, McMaster University; Director, Program in Evidence-based Care, Cancer Care Ontario

John Patrick Browne, PhD, CPsychol
Senior lecturer, Health Services Research Unit, London School of Hygiene and Tropical Medicine
National Collaborating Centre for Acute Care
Clinical Effectiveness Unit, Royal College of Surgeons of England, United Kingdom

Heather Buchan, MB, ChB, MSc, FAFPHM
Executive director, National Institute of Clinical Studies, National Health and Medical Research Council, Australia

Norm Campbell, MD, FRCPC
Professor, Departments of Medicine, Pharmacology and Therapeutics and Community Health Sciences, Libin Cardiovascular Institute of Alberta, University of Calgary

Atul Kapur, MD, MSc, FRCPC, FACEP
Assistant professor, Department of Emergency Medicine, University of Ottawa, Emergency Physician, The Ottawa Hospital Medical Advisor, Ontario GAC

Jessica Meleskie, BSc (Hon), MBA
Coordinator, Evidence-Based Care Program
Grey Bruce Health Network

Guido Van Rosendaal, BSc, MSc, MD
Professor, Departments of Community Health Sciences and Medicine, University of Calgary

Ryan Sommers, BSc, MD
Family medicine resident, Dalhousie University Northumberland Family Medicine Teaching Unit

1. Introduction to clinical practice guidelines

This chapter

- introduces the field of quality of health care and discusses the significance of the process by which knowledge, more specifically evidence-based research, is incorporated into routine practice
- discusses the key role of CPGs within this broader framework of quality of health care.

Quality of health care

Quality of health care is a major concern in Canada and internationally. As described by Health Canada, "Quality health care is about delivering the best possible care and achieving the best possible outcomes for people every time they deal with the health care system or use its services. Essentially, it means doing the best possible job with the resources available."[1] Box 1.1 outlines the characteristics considered by the World Health Organization as appropriate descriptors of "quality health care."[2]

This focus on quality comes in the wake of accumulating reports demonstrating disparities in health care at a number of levels in the health care system.[3,4] These reports reveal a range of types of disparities, as well as underlying factors. One type of disparity is the "clinical care gap" — a discrepancy between evidence-based knowledge and day-to-day clinical practice. There are numerous examples in Canada and elsewhere of clinical care gaps (Box 1.2).

Box 1.1: World Health Organization dimensions of health care quality[2]

- effective
- efficient
- accessible
- acceptable/patient-centred
- equitable
- safe

To minimize such gaps and to improve the quality of health care, the Canadian Health Services Research Foundation has indicated a need for a system-wide, multilevel integrated strategy involving all decision-makers. In this case, decision-makers include all those involved in health care — practitioners, program and health system managers, policy-makers and patients. The goals of such a strategy are to identify the current state of quality of care; develop and test our knowledge of effective strategies to enhance quality; and disseminate proven management interventions.[9]

One strategy to enhance quality of health care is to improve the process by which knowledge — more specifically, clinical research findings and evidence-based prac-

Box 1.2: Examples of clinical care gaps in Canada

- *Suboptimal management of dyslipidemia*: There is widespread underutilization of effective lipid-modifying therapy; almost half of high-risk patients do not attain guideline-recommended lipid targets.[5]
- *Suboptimal management of rheumatoid arthritis*: A review of administrative billing data on rheumatoid arthritis cases in British Columbia between 1996 and 2000 found that care was not consistent with CPGs that recommend early, aggressive and persistent use of disease-modifying antirheumatic drugs to prevent joint damage in all people with active inflammation, as well as evaluation by a rheumatologist, when possible.[6]
- *Inadequate control of diabetes*: In a 1-year study of people with diabetes, 42% never received HbA1c testing, and less than half of those tested had ideal or optimal blood glucose levels.[7]
- *Overuse of benzodiazepines*: The use of benzodiazepines is inconsistent with the recommendations of educational groups, regulators and manufacturers, especially and most seriously among the elderly.[8]

tices — are incorporated into routine practice by health care practitioners and consumers. A variety of terms have been used to describe this evidence-to-practice process, such as knowledge translation (commonly used in Canada) and implementation research (widely used in Europe). The terms system or provider improvement and quality improvement (QI), are used in the United States.

Although the terms differ, they possess a common objective: to optimize the exchange of high-quality information among key stakeholders and ensure that clinical knowledge is used to provide the highest quality and most effective health care.

The "knowledge-to-action" process

Graham and colleagues[10] have developed a framework called the knowledge-to-action process to support improvements in quality of health care (Fig. 1.1). This framework illustrates and integrates 2 major concepts: knowledge creation and action. It addresses the objectives of identifying high-quality information and putting this knowledge into practice.

The first stage, *knowledge creation*, is represented as a funnel through which available evidence is filtered and refined, becoming more useful, valid and relevant for stakeholders in the process. Knowledge creation comprises *knowledge inquiry* (the primary studies or information, frequently of variable quality); *knowledge synthesis* (systematic appraisal of the information, such as reviews); and *knowledge tools/products* (clear, concise and usable messages in accessible formats for relevant stakeholders, intended to influence their behaviours).

The *action* component of the framework comprises stages and strategies for the dissemination and implementation of the knowledge contained in the tools or products. These include identifying a problem that needs addressing; reviewing and selecting the knowledge or research results relevant to the problem; adapting the identified knowledge or research to the local context; assessing barriers and enablers to using the knowledge; selecting, tailoring and implementing interventions to promote the use of the knowledge; monitoring knowledge use; evaluating the outcomes of using the knowledge; and sustaining ongoing knowledge use.

As Graham and colleagues note, although these stages are portrayed as discrete elements, in reality, the process is complex, dynamic and iterative.

Clinical practice guidelines: a tool for improving quality of health care

As the knowledge-to-action framework demonstrates, a key element of quality-improvement initiatives is the development of high-quality knowledge tools that are relevant and accessible to the key stakeholders, or the adaptation of such tools, and devising an effective implementation strategy that will result in improvements in health care and outcomes. Clinical practice guidelines (CPGs) are one type of "knowledge tool" that play an important role in this broader quality-improvement process.

CPGs are defined as "systematically developed statements to assist practitioner and patient decisions about

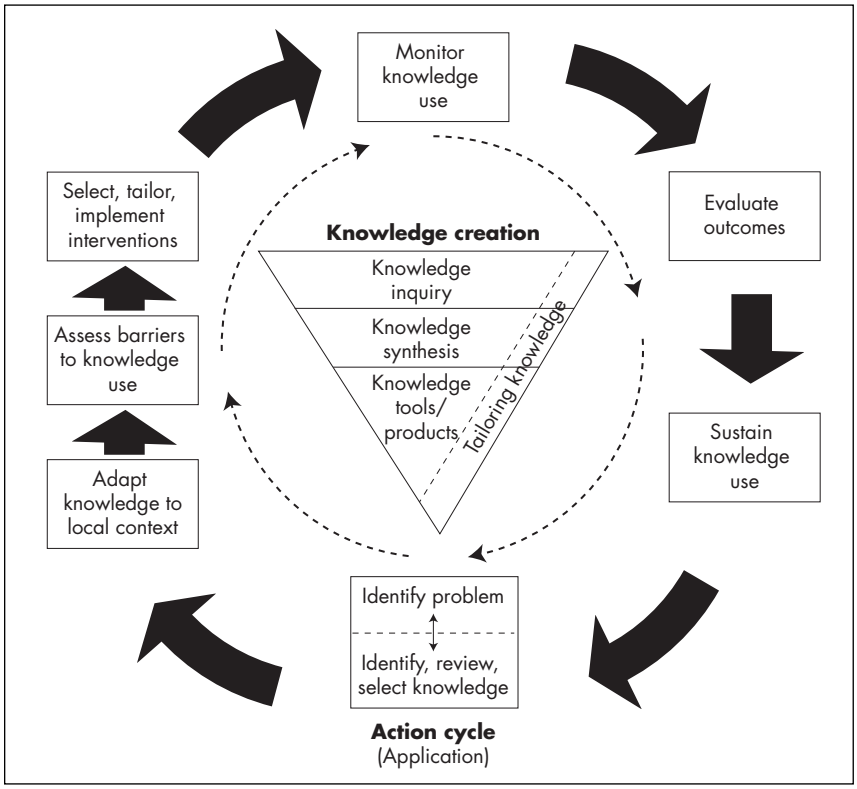

Figure 1.1: Knowledge-to-action process. Reproduced from Graham et al, *Journal of Continuing Education in the Health Professions*,[10] with permission from John Wiley & Sons Inc. Copyright 2006.

appropriate healthcare for specific clinical circumstances."[11] The systematic process of developing CPGs is meant to ensure that they are based on the *best available evidence*, supplemented by *clinical expertise* and *patient preferences*.[12] CPGs have their origins in the evidence-based medicine movement of the 1980s, a product of concerns about the quality, consistency and cost of health care.[13] They also emerged in response to the phenomenon of information overload, reflecting the huge knowledge explosion that every practitioner faces.

What are the purposes of CPGs? According to Woolf and colleagues[14] and Wollersheim and co-workers,[12] they are intended to

- improve the quality of patient care and health care outcomes
- summarize research findings and make clinical decisions more transparent
- reduce inappropriate variation in practice
- promote efficient use of resources
- identify gaps in knowledge and prioritize research activities
- provide guidance for consumers and inform and empower patients
- inform public policy
- support quality control, including audits of clinicians' or hospitals' practices.

It is important to note that CPGs are not intended to

- provide a "menu-driven" or "cookbook" approach to medicine where the clinician has no discretion
- provide guidance in all circumstances and for all patients
- provide in-depth background clinical knowledge, such as information related to etiology, epidemiology and prognosis, which is usually covered in medical textbooks
- be a legal resource in malpractice cases; their more general nature renders them insensitive to the particular circumstances of individual cases.

Box 1.3: Challenges of CPGs[12,14]

- Definitions of "quality of care" may vary for different stakeholders (e.g., clinicians, patients, policymakers).
- The complexity of clinical practice may be difficult to capture in CPGs.
- Study results may not easily translate into daily practice.
- The existence of conflicting CPGs can be confusing.
- CPGs may not be easily implementable.
- Disease-specific CPGs may provide conflicting advice for patients with co-existing diseases.
- The implementation of CPGs depends on a range of factors, often beyond the control of the individual clinician.
- Keeping CPGs up to date requires ongoing work and resources.
- Recommendations of the CPG may be inappropriately biased by the composition of the group preparing them.
- The development and implementation of CPGs can be expensive.

CPGs have the potential to be a key component of initiatives to improve the quality of care across health care settings. Ongoing scholarly work is addressing previously identified challenges of CPGs (Box 1.3), and increasing our knowledge about how to optimize their value within the context of a broader knowledge-to-action process.

Extensive research and policy efforts occurring nationally and internationally are addressing these challenges and other salient issues through the development of common, evidence-based processes for the adaptation, development and implementation of CPGs. These initiatives provide guidance in dealing with issues, such as conflicting CPGs, making CPGs relevant to stakeholders and minimizing bias, among other goals. These efforts are detailed in the following chapters on CPG adaptation, development, implementation and evaluation.

Resources and links

Canadian Health Services Research Foundation
www.chsrf.ca
CHSRF promotes and funds management and policy research in health services and nursing to increase the quality, relevance and usefulness of this research for health system policy-makers and managers.

Canadian Health Services Research Foundation/Canadian Institutes of Health Research Chair on Knowledge Transfer and Innovation
kuuc.chair.ulaval.ca/english/index.php

KU-UC database with documents on knowledge transfer, innovation and health service policies and management.

Canadian Institutes of Health Research: Knowledge Translation Strategy 2004–2009, www.cihr-irsc.gc.ca/e/26574.html
CIHR is the Government of Canada's health research funding agency.

Davis D. Continuing education, guideline implementation, and the emerging transdisciplinary field of knowledge translation. *J Contin Educ Health Prof* 2006;26:5-12.

Grol R, Wensing M. What drives change? Barriers to and incentives for achieving evidence-based practice. *Med J Aust* 2004;180:S57-60.

Guidelines International Network, www.g-i-n.net
G-I-N is an international not-for-profit association of organizations and individuals involved in the development and use of CPGs. G-I-N seeks to improve the quality of health care by promoting systematic development of CPGs and their application in practice by supporting international collaboration.

Health Canada: Resources on Quality Health Care
www.hc-sc.gc.ca/hcs-sss/qual/res/index_e.html

Health Research Policy and Systems
www.health-policy-systems.com
An open access, peer-reviewed, online journal that aims to publish research on the role of evidence-based health policy and health research systems in ensuring the efficient use and application of knowledge to improve health and health equity, especially in developing countries.

Implementation Science, www.implementationscience.com
An open access, peer-reviewed online journal that aims to publish research relevant to the scientific study of methods to promote the uptake of research findings into routine health care in both clinical and policy contexts.

Journal of Continuing Education in the Health Professions
www.jcehp.com
JCEHP publishes articles relevant to the theory and practice of continuing education in the health sciences.

Quality & Safety in Health Care, qshc.bmj.com
An international peer-reviewed journal in the area of quality and safety improvement. It provides essential information for those wanting to reduce harm and improve patient safety and the quality of care.

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2. Adaptation and development of CPGs

This chapter

- asks the question, "Do you need a CPG?" to clarify the role of CPGs
- presents common salient elements in the adaptation and development of CPGs
- outlines a process for adapting CPGs for local or regional use
- highlights key elements of CPG development
- offers resources to assist with these initiatives.

The adaptation and development of CPGs are rigorous processes requiring extensive expertise and resources to ensure a high-quality outcome. Consequently, these initiatives should only be undertaken following a thorough assessment of their appropriateness and assurances that the required resources are available.

The processes of developing or adapting a new CPG are not new. Many groups, organizations and collaborations have produced documents detailing steps for modifying CPGs for local purposes and for their de novo development. For example, the ADAPTE group,[1] an international collaboration of researchers, guideline developers and guideline implementers, has worked together to develop and validate a generic adaptation process to foster valid and high-quality adapted guidelines. The United Kingdom's National Institute for Health and Clinical Excellence[2] and the Scottish Intercollegiate Guidelines Network[3] have also produced extensive manuals, with accompanying tools or guides, to explain how they develop CPGs. Such resources are critical for the production of methodologically sound CPGs, providing strategies to promote a consistent, evidence-based, transparent process. This chapter draws on these resources and others.

In this chapter, we present elements that are common to the adaptation and creation of CPGs as well as stages unique to each process (Fig. 2.1). As we noted in chapter 1, the purpose of this handbook is to highlight key stages and issues; for more detailed information, we direct readers to the resources identified throughout and at the end of the chapter.

Is a CPG needed?

The first issue to address is whether a CPG is needed, that is, whether a CPG can play a role in improving an identified care gap. A health care gap can become apparent in various ways. For example, clinicians may become aware of differences of opinion through conversations with colleagues or may be frustrated by a frequent diagnosis that requires a more systematic approach. Health care managers may identify inconsistencies in the treatment of common patient complaints. Assessments of provincial or national databases (e.g., those of the Canadian Institute for Health Information or other provincial health data sources) may demonstrate inconsistencies in health care practices or outcomes. New evidence, regulations, technology or procedures can introduce questions about optimal health care. Generally, a CPG has the potential to play an important role when[3,4]

- there is uncertainty or a difference of opinion about what care should be provided, as evidenced by wide variation in practice or outcome
- there is proven treatment for a condition and mortality or morbidity can be reduced
- there is a need to bring together scientific knowledge and expertise on a subject
- there are iatrogenic diseases or interventions carrying significant risks or costs.

Some topics do not lend themselves to CPGs. For example, if there are scant or no published reports on a given topic, it is difficult to generate recommendations. Some decisions may be driven entirely by patient preference, so that no guidance other than "this situation requires discussion with the patient" may be given.

If a CPG is appropriate for a given topic, the topic itself must be focused. For example, looking for and applying guidance for "diabetes" is a much more challenging task than identifying and implementing recommendations for "diabetic foot care." What "key questions" do you want to answer? The questions listed in Table 2.1, can help focus the process and improve the usefulness and applicability of the CPG adaptation/development process. A discussion of these questions also allows for appropriate representation in the CPG working group. Resource requirements needed to carry out the CPG initiative cannot be ignored; they should be considered as an investment in the quality of the final product.

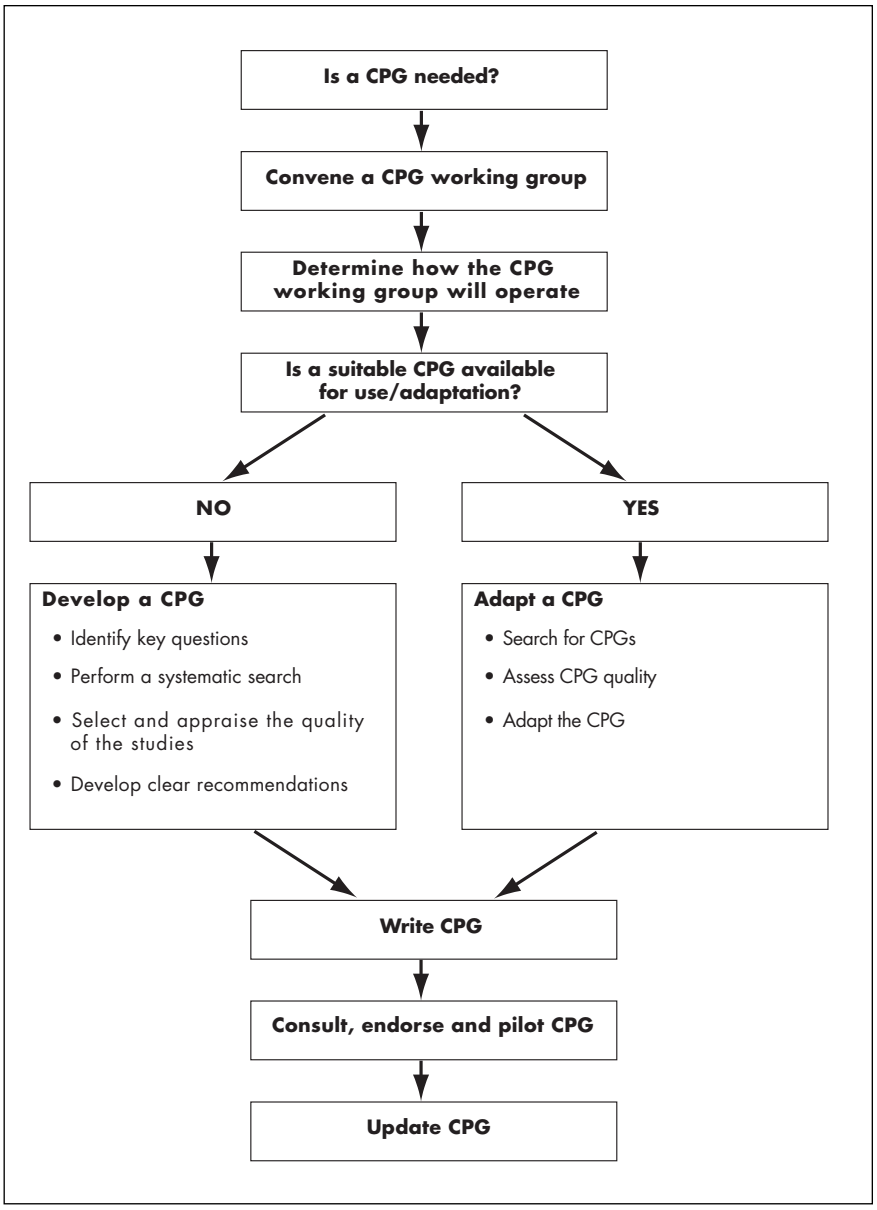

Figure 2.1: Major steps involved in adapting or creating a CPG

Financial and other biases in CPGs

As noted, resources are needed for CPG initiatives. In many cases, the funding of CPG development or adaptation has come from industry, in particular pharmaceutical companies that have links with members of the CPG working group. For example, Choudhry and colleagues[5] surveyed authors of CPGs published between 1991 and 1999 and endorsed by North American and European societies and found that 87% of authors surveyed had some form of interaction with the pharmaceutical industry; 58% had received financial support to perform research; and 38% had been an employee of or a consultant for a pharmaceutical company. These connections are of concern as CPGs are based on both evidence and the subjective judgement of the members of the CPG working group. Although subjective judgements are valuable in supporting experience-based relevant recommendations, they also create the potential for error and bias.[6,7,8]

The existence and impact of such biases on CPG recommendations has been investigated.[9,10,11] In the study by Choudhry and colleagues,[5] although only 7% of authors reported that their own relations with the pharmaceutical industry influenced their recommendations, 19% thought that their coauthors' recommendations were influenced. Financial bias has been the type of bias most widely discussed, yet other potential sources of bias also exist, such as long-term service to government committees or private insurers, participants' previously established "stake" in an issue, the way that one makes one's living and personal experiences.[7]

In addition to industry, other groups that commonly provide funds for CPG initiatives are local and regional patient advocacy organizations, medical specialty societies, hospital administrations and organizations that require formal submissions (e.g.,

ministries of health, Canadian Institutes of Health Research, Agency for Healthcare Research and Quality). Users of this handbook will need to balance the need for support with the potential bias inherent in interested funders by using strategies that address the potential impact of CPG panels members' biases on CPG recommendations. One strategy that is being increasingly endorsed is complete disclosure of financial, personal and professional relations with industry.[8,9] A recent review of the literature on conflicts of interest in guideline development by Boyd and Bero[12] concluded that

- The use of specific, detailed, structured forms that request as much information as possible about the nature and extent of the competing interests can be developed and disseminated to the CPG group members to complete. While minimal or open-ended formats are likely to be less informative, there is little empirical evidence to guide the development of such disclosure forms.
- The use of explicit conflict-of-interest criteria should be considered. While there is no empirical evidence that explicit criteria are preferable to ad hoc committee decisions when deciding if a conflict of interest exists, explicit criteria may make decision-making about conflicts easier.
- According to descriptive studies, management of conflict of interest is best conducted on a case-by-case basis.

It has also been suggested that CPG organizers should try to find a balance between CPG members with expertise, who are more likely to be subject to these various forms of bias, and nonexperts who may have less knowledge but also fewer factors that contribute to bias.[7] Some note that CPGs should not be funded by industry or others with an interest in the outcome, although even government sponsorship does not guarantee that committee members do not have commercial interests.[8,9] Independent organizations with financial security have been proposed as an optimal strategy.[8]

The stages outlined in this handbook on CPG adaptation and development draw on resources promoting a consistent, evidence-based, transparent process, but clearly biases operate at various levels, and strategies must be in place to delineate how they will be identified and managed.

Who should be in the CPG working group?

A CPG initiative requires the formation of "a CPG working group" that is responsible for the adaptation or development process. Such a group should be large enough to include representatives with expertise and experience, but small enough to ensure effective group processes. For the initial phases of CPG development, the working group may be a handful of lead members. After the decision to proceed with a CPG has been made, broader representation will improve eventual uptake of the CPG.

Table 2.1: Practical considerations for focusing the CPG topic

Which patients or practice settings do you want to look at?	• What inclusion or exclusion criteria might you apply to this question?
Which diagnostic tests or interventions will be covered by the CPG?	• What is the focus of this CPG—therapeutic agents, diagnostic/screening techniques, surgical procedures, others? What evidence exists about the effect and application of these interventions?
What outcomes do you want to change?	• Patient outcomes (e.g., mortality, morbidity, complications, quality of life)? • Organizational outcomes (e.g., rate of hospital readmissions)? • Public health outcomes?
Who are the target users of the CPG?	• Which health care professionals and other employees will be affected by the CPG? • Will patients be targeted as CPG users?
What resources are available for the CPG initiative?	• What resources exist to support the development and implementation of the CPG? (Issues to consider: administrative costs, meeting costs, honorariums to participants, implementation budget, etc.) • Do you have the commitment of major agencies for dissemination and uptake?

Among those to consider including in the working group are

- *Group facilitator*: This person should be neutral and have expertise in leading small groups. This may be the same person as the methodological expert, as this person often does not have a specific clinical agenda.
- *Representation from professional groups significantly affected by the CPG*: Professionals affected in a relatively minor way can be invited to comment on specific sections or attend particular meetings, as involvement of "all stakeholders" could result in too large of a working group.
- *Methodological experts*: Experts may be chosen from disciplines such as epidemiology, biostatistics, health care research, bioethics and information sciences. We recommend that someone with experience and possibly expertise in CPG development be included in the process.
- *Patient/civic representation*: It is increasingly common (and desirable) to gain input from non-health professionals and groups who are affected by the CPG (e.g., patients, providers of patient care such as family members, non-profit organizations). The most appropriate strategy to gain such input will need to take into account such issues as the use of scientific language and the technical nature of the CPG process that pose challenges to their involvement.
- *Policymaker or influential manager*: This person may be a valuable member of a working group, for example, if organizational or public health outcomes are being sought.
- *Administrative support*: Support staff may coordinate meetings, facilitate exchange of information and be responsible for other matters.

How will the CPG working group operate?

Who is chosen to be a member and how they interact can affect the final recommendations of the CPG working group.[13,14] To achieve the optimal functioning of the group and minimize bias, we suggest agreement on the mode of operation before the process begins. Although each CPG working group will need to make its own decisions, literature reviews have found that formal consensus development methods generally work as well or better than informal methods. Formal consensus development methods "involve the generation of group judgements based on explicit aggregation of individual participants' judgements and allow participants to revise their judgements in private following structured interaction and formal feedback of group views".[15,16] The most commonly used consensus development methods are

- the nominal group technique
- the Delphi survey and
- the RAND/UCLA appropriateness method.

Providing for both group discussion and private consideration allows for creativity and validation of ideas, but does not inhibit less-verbal people in the group who may have significant expertise to contribute. It also minimizes possible tensions, such as conflicts of interest or interprofessional "turf" issues.[13] Convened groups may be more effective than those that rely on mail only, as face-to-face meetings may produce more interaction and engagement, possibly generating more trust and thus a better outcome.[14,16] The literature does not indicate which formal method is best. Resources for consensus development methods can be found in the systematic review by Murphy and others.[15]

As in any project, such as planning a continuing education event, the initial objectives of the CPG working group should be to set timelines, clearly outline responsibilities, define the scope of the work and agree on other issues, such as the manner in which conflict of interest will be dealt with or publication plans.

Can we adapt a CPG for our purposes? Or do we need to develop our own CPG?

CPG working groups face a choice between adopting or adapting an existing CPG or creating a new one. CPG adaptation — defined as "the systematic approach for considering the use and/or modifying guideline(s) produced in one cultural and organizational setting for application in a different context"[1] — takes advantage of existing high-quality CPGs while enabling modification to meet the needs, priorities, legislation, policies and resources of a targeted setting.[1,17] Given the work involved in creating CPGs and the expertise required, we recommend adapting an existing CPG when feasible.

In the next sections, we review the elements of CPG adaptation, then discuss new CPG development. The

remaining sections focus on stages common to both processes.

CPG adaptation

Although it might seem that adapting an already-developed CPG would produce a valid and scientifically sound document, local CPG programs might introduce bias by choosing only some recommendations in the CPG without using a systematic approach. To address such problems, the ADAPTE collaboration[1] was established to develop and validate a generic adaptation process to foster high-quality CPGs. The ADAPTE process is organized in stages: set up, adaptation and final phases. Although we have used this process ourselves for this handbook and highlight certain elements, the ADAPTE manual and Web site (www.adapte.org) provide extensive details and guidance.

The set-up phase involves many of the issues addressed above, such as forming a CPG panel or working group, identifying the topic and establishing a protocol.

The adaptation phase consists of the following steps:

1. Determine the health question(s) to be addressed.
2. Search for guidelines and other relevant documents.
3. Screen retrieved guidelines.
4. Select guidelines for review from the larger number retrieved by title or abstract search.
5. Assess guideline quality, currency, content, consistency.
6. Assess acceptability and applicability of the recommendations.
7. Review and balance assessments.
8. Select from the guidelines and recommendations to create an adapted guideline.
9. Prepare a draft adapted guideline.
10. Test the adapted guideline locally to get feedback on its use and endorsement of the final product.

Searching for CPGs

CPGs can be found on Web sites of Canadian and international organizations developing or promoting CPGs and in databases for scientific studies and reviews; an extensive listing is provided in the "Resources and links" section at the end of this chapter. It can also be useful to search the Web sites of relevant specialty societies and associations. For example, if you're searching for information on acute myocardial infarction, the Web sites of the Canadian Cardiovascular Society, the Heart and Stroke Foundation of Canada, the American Heart Association, the British Heart Association and the National Heart Foundation of Australia could be useful resources.

Assessing guideline quality

The ADAPTE group recommends the use of the Appraisal of Guidelines Research & Evaluation (AGREE) instrument to assess quality of CPGs.[1] The AGREE instrument is a validated systematic framework for assessing expert-identified key components of guideline quality including the process of development and reporting.[18] Many groups use the AGREE instrument, with or without modification, as the major screening source for selection of CPGs.

The final version of the instrument contains 23 items grouped into 6 quality domains with a 4-point Likert scale to score each item.[18] The domains are:

- scope and purpose
- stakeholder involvement
- rigour of development
- clarity and presentation
- applicability
- editorial independence.

The AGREE Web site (www.agreecollaboration.org) provides access to the detailed AGREE instrument, as well as to further information about the collaboration, and appraisal of guidelines. This tool can be used by CPG users searching for a CPG and deciding between conflicting CPGs; alternatively, CPG users may wish to choose a CPG endorsed by an organization that uses the AGREE instrument to assess and recommend particular CPGs. The Guidelines Advisory Committee (GAC; Ontario Ministry of Health and Long-term Care and the Ontario Medical Association, www.gacguidelines.ca) is one such organization.

The AGREE instrument does not assess the quality of the evidence supporting the recommendations, nor whether the recommendations accurately reflect the evidence that supports them.[18–20] For this reason, some groups, such as the GAC, favour CPGs that identify the level of evidence supporting the recommendation.

Adapting the guideline

If more than one CPG is found, several options exist. The GAC selects 1 CPG, based in part on its AGREE score and how applicable it is to the relevant practice setting. An alternative is to choose the most appropriate recommendations and tools from several guidelines. The ADAPTE approach[1] outlines the following 5 options for CPG adaptation.

1. Reject the entire guideline.
2. Accept the entire guideline and all of its recommendations.
3. Accept the evidence summary of the guideline.
4. Accept specific recommendations.
5. Modify specific recommendations.

The final phase of the ADAPTE process involves external review, scheduled review and update, and the creation of the final product,[1] steps discussed later in this chapter.

CPG development

As previously noted, CPG development should only be undertaken if an existing CPG cannot be identified and if sufficient resources and expertise are available.

Creating a new CPG can take place at the national or local level; there are benefits and disadvantages to both approaches. A national approach will mean greater availability of expertise and resources to enable the creation of high-quality, valid CPGs with a broad perspective. However, it may be difficult to apply a national-level CPG to a local setting due to regional differences, varying resource availability and the lack of involvement (and thus potential buy-in) of local end-users. Although local initiatives to develop a new CPG increase ownership and commitment, the process is extensive.

Several resources exist to guide the reader in developing CPGs (see "Resources and links" at end of this chapter). The AGREE and Shaynefelt instruments have both been validated[21] and illustrate what a good quality CPG should include. Like a scorecard, they guide not only the rating of CPGs, but also their development.

Core aspects of the CPG development process involve:

- identifying key questions
- performing a systematic search
- selecting and appraising the quality of the studies found
- developing clear recommendations.

Identifying key questions

This step may already be done, as outlined in the first section of this chapter. Group consensus on exactly which questions need to be answered will drive the evidence search, the quality appraisal and the recommendation development, hence the term "key" questions. It might be helpful to circulate a set of questions to the CPG development group for their review and discussion.

Performing a systematic search

We strongly urge the CPG working group to employ the expertise of an information specialist to perform a systematic search of the literature on the selected topic, using key words agreed on by the working group. The more specific the key questions, the easier it will be for the information specialist to find relevant literature.

The main sources of evidence are individual studies and systematic reviews found in a range of databases, which are listed in the "Resources and links" section at the end of this chapter. The search for evidence should also involve input from experts in the field, manual searching of journals and reviews of the reference lists in articles and books.

Selecting and appraising the quality of the studies found

The CPG development group must establish and apply criteria for including and rating studies to ensure a systematic and transparent approach. Various quality rating systems also address how to incorporate the evidence into recommendations, which is the next stage. We recommend an up-front commitment to a particular approach that guides decisions on grading the evidence and developing recommendations. All those involved in developing the CPG should have some training in the system chosen.

A recent effort by the Canadian Optimal Medication Prescribing and Utilization Service[22] to identify and evaluate these systems identified the Grading of Recommendations, Assessment, Development and Evaluation

(GRADE) and Scottish Intercollegiate Guidelines Network (SIGN) methods as the highest scoring instruments. The United States Preventive Services Task Force[23] also has a recognized system for grading the internal validity of studies. The type and quality of the study design (also called "level of evidence") is generally considered the most important, although not the only, factor affecting quality, and randomized controlled trials are favoured. Any other relevant issues should also be noted during this appraisal process. It is preferable that all studies be assessed by 2 abstractors. CPG developers then need to consider whether the findings are consistent across studies, address outcomes of interest and apply to the particular practice setting and patient population.

Developing clear recommendations

Once decisions about the quality of the studies are made, the group must develop recommendations that reflect the evidence, consider values and are clearly worded. Seemingly an easy final step, writing recommendations may be the trickiest part of the CPG development process, as many factors other than the evidence come into play at this stage.

The GRADE, SIGN and SORT approaches (Boxes 2.1, 2.2 and 2.3) strive to achieve transparency for those internal and external to the process. This involves a clearly recorded description of the factors considered, the analyses performed and how decisions were made for each recommendation. This process allows the reader to decide whether he or she shares the same values and would come to the same conclusion.

The provision of both the level of evidence to support a recommendation and a grade that reflects the strength of the recommendation may be confusing. However, applying 2 taxonomies to each recommendation allows for cases where a strong recommendation may not be supported by strong evidence. This reflects the fact that more than just the evidence affects the strength of a recommendation. For example, see Box 2.4, which contains a United States Preventive Services Task Force recommendation for screening for visual impairment in children younger than 5 years.

In our experience, some working groups may not be able to articulate with precision why they recommend a certain course of action. For this reason, if they have not already done so, we strongly recommend that they use an impartial formal facilitator at this stage to allow them to

Box 2.1: The Grading of Recommendations, Assessment, Development and Evaluation system

The GRADE working group began in 2000 as a collaboration interested in developing a common grading system that would address the limitations and draw on the strengths of existing systems.[25,27,28] The GRADE system provides a sequential assessment of the quality of evidence, the balance between risks and benefits and a judgement about the strength of recommendations.[29]

GRADE describes recommendations as "strong" or "weak":

Strong recommendations are made when the group is "confident that adherence to the recommendation will do more good than harm or that the net benefits are worth the costs."[29] A recommendation can be made for or against a particular intervention. The language of strong recommendations, "we recommend" or "should," reflects the clinical message that the recommendation applies to most patients under most circumstances.

Weak recommendations are made when the group is "uncertain that adherence to the recommendation will do more good than harm or that the net benefits are worth the costs."[29] The language of weak recommendations, "we suggest" or "might," reflects the clinical message that there is a need to consider more carefully than usual individual patients' circumstances, preferences and values. The uncertainty associated with weak recommendations follows either from poor-quality evidence or from closely balanced benefits and downsides. Although the basic study design is the main determinant of the quality of evidence, there are factors that may decrease or increase the quality.

The GRADE system Web site (www.gradeworkinggroup.org) contains a list of frequently asked questions and information about software applications. The group is developing software and a detailed manual to simplify its use in response to concerns that the GRADE system is too complex. An article by Schünermann and colleagues[29] provides a useful overview of the GRADE system and tables addressing such issues as what factors panels should consider in deciding on a strong or weak recommendation; determinants of the quality of evidence and factors that may increase or decrease the quality; and a checklist for developing and grading recommendations.

state explicitly the "other," non-evidence factors that influence the strength of a recommendation.

The GRADE working group discusses some of the subtle values that influence phrasing of recommendations.[25] Recommendations should be clearly identified as such and be written in the active tense. The Guideline Implementability Appraisal instrument (ycmi.med.yale.edu/GLIA), developed to identify obstacles to CPG implementation, can also help in the clarification of recommendations in the final draft of a CPG.[26]

Organizations may wish to commit to a particular grading system for all their CPG development activities; an expert in the field could be helpful in selecting a system.

The following sections on formatting, consulting, endorsing, piloting and updating CPGs are relevant to both CPG adaptation and development.

Write the CPG

The Conference on Guideline Standardization (COGS) has developed a checklist to establish a standard for guideline reporting (gem.med.yale.edu/cogs/).[31] It is valuable for CPG developers, journal editors and other disseminators, and for CPG implementers. The purpose of the checklist is to promote the systematic reporting of details that are necessary to understand the development, recommendations and potential issues in the CPG's application. The checklist alone cannot be used to assess the quality of a guideline.[31]

A study assessing quality scores for 32 oncology guidelines from 13 countries found the strongest predictor of quality to be the "availability of background information" (rated as no information, some information or only references or detailed and structured documentation). It is important to include clear, detailed information about the objectives and context of the CPG development, including methods used and people and organizations involved.[32] A recording of the level of evidence for each recommendation makes recommendations transparent.[20] Electronic formats with hyperlinks can be useful in providing sufficient information while

Box 2.2: The Scottish Intercollegiate Guidelines Network method

SIGN was formed in 1993 to improve the quality of health care for patients in Scotland by reducing variation in practice and outcomes, through the development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence. The *SIGN Guideline Development Handbook: SIGN 50* provides a detailed description of SIGN's methods as well as examples of checklists, evidence tables and considered judgement forms.[3]

The SIGN approach assigns levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) depending on the type and quality of the study design. A grade of recommendation (A, B, C or D) is then given according to the assigned level of evidence. The SIGN approach uses "considered judgement" forms to help CPG development in situations where decisions need to be made according to experience as well as knowledge of the evidence and the underlying methods. These forms include the quantity, quality and consistency of evidence, generalizability of study findings, directness and clinical impact.[3]

Box 2.3: The Strength of Recommendation Taxonomy

SORT was developed by United States family medicine and primary care journals and the Family Practice Inquiries Network to address the need for 1 consistently applied taxonomy of evidence. SORT emphasizes the use of patient-oriented outcomes, defined as "outcomes that matter to patients and help them live longer or better lives, including reduced morbidity, mortality or symptoms, improved quality of life or lower cost."[30]

The SORT taxonomy rates quality of individual studies: 1, good-quality, patient-oriented evidence; 2, limited-quality, patient-oriented evidence; or 3, other evidence. The strength of recommendations is graded using an A, B, or C designation. An A recommendation is based on consistent and good-quality patient-oriented evidence. A B recommendation is based on inconsistent or limited-quality patient-oriented evidence. A C recommendation is based on consensus, usual practice, opinion, disease-oriented evidence or case series for studies of diagnosis, treatment, prevention or screening.[30]

keeping the CPG from becoming overly lengthy.[20]

In the case of adapted CPGs, all documents used to create the CPG should be referenced, and permission to use any CPG or CPG recommendation should be obtained.[1]

CPG developers need to consider the needs of the end user. The following factors enhance the use of a CPG[33]:

- clear statements
- decision aids, patient educational materials and practice tools
- identification of specific evidence-based indicators and criteria for clinical performance.

The Guideline Implementability Appraisal instrument, which was developed to identify obstacles to CPG implementation, can also be used by CPG developers to improve their CPGs.[26]

Consult, endorse and test the CPGs

Given that there is a limit to the number of people who can be involved in CPG adaptation or development, it is valuable to consult and pilot test a CPG to gain further input into its relevance and usability and to encourage broad uptake and buy-in.

Consultation involves seeking input on the CPG from target groups, stakeholders and experts. For adapted CPGs, the ADAPTE process suggests that the draft guideline be sent to the developers whose recommendations were used in the adapted CPG, especially in cases where changes have been made to the original recommendations.[1]

Lorenz and colleagues[34] have demonstrated that practitioners prefer tested, convenient and respected evidence sources and rely on the familiarity and reputation of an evidence source. Thus, widely respected professional organizations and locally respected leaders play an important role in appraising and endorsing a CPG. A CPG can be pilot tested by a few departments, practices or health care teams before a wider launch. This step can provide an invaluable opportunity for detecting any problems in formatting, acceptance of recommendations and other issues.

Box 2.4: United States Preventive Services Task Force summary of recommendation[24]
The USPSTF recommends screening to detect amblyopia, strabismus, and defects in visual acuity in children younger than age 5 years.
Rating: B Recommendation

***Rationale*:** The USPSTF found no direct evidence that screening for visual impairment in children leads to improved visual acuity. However, the USPSTF found fair evidence that screening tests have reasonable accuracy in identifying strabismus, amblyopia, and refractive error in children with these conditions; that more intensive screening compared with usual screening leads to improved visual acuity; and that treatment of strabismus and amblyopia can improve visual acuity and reduce long-term amblyopia. The USPSTF found no evidence of harms for screening, judged the potential for harms to be small, and concluded that the benefits of screening are likely to outweigh any potential harms.

Update the CPG: the "living guideline"

CPGs must be kept up to date. Based on an assessment of the validity of 17 practice guidelines published by the Agency for Healthcare Research and Quality, Shekelle and co-workers[35] recommend that guidelines be reassessed for validity every 3 years — yearly in rapidly evolving fields. The GAC recommends adding a "stale date" to its CPG summaries. CPGs may require updating because of changes in[20,35]

- evidence on existing benefits and harms of interventions
- outcomes considered important
- available interventions
- resources available for health care.

The following practices may help ensure that necessary updates are conducted in a timely manner, leading to the creation of a "living guideline." First, people familiar with the topic, such as a Cochrane review group, may conduct limited searches on a routine basis to check for new developments. Second, the CPG working group can identify research where results might require revision of the CPG; proactive searches can focus on relevant research

areas. Third, a CPG working group may elect to have its CPG reviewed by experts who are not involved in developing CPGs. Finally, the group may wish to establish an ongoing CPG panel with members serving fixed periods, perhaps with rotating membership.[19]

Conclusion

In this chapter, we provided background, methods and resources for adapting or developing CPGs, demonstrating the need for these processes to be rigorous, comprehensive and transparent. Those involved in CPG initiatives should have adequate training or leadership to ensure that a high-quality product is developed.

In the next chapter, we address CPG implementation, where the goal is to ensure that the CPG leads to changes in health care practices and, ultimately, patient outcomes.

Resources and links

Searching for CPGs

Canadian sites

British Columbia's Guidelines and Protocols Advisory Committee
www.hlth.gov.bc.ca/msp/protoguides/index.html

Canadian Agency for Drugs and Technologies in Health
www.cadth.ca

Canadian Medical Association Infobase
mdm.ca/cpgsnew/cpgs/index.asp

Canadian Task Force on Preventive Health Care
www.ctfphc.org

Guidelines Advisory Committee, www.gacguidelines.ca

Institute for Clinical Evaluative Sciences, www.ices.on.ca

Public Health Agency of Canada guidelines
www.phac-aspc.gc.ca/dpg_e.html

Registered Nurses Association of Ontario's Best Practice Guidelines, www.rnao.org/bestpractices

Toward Optimized Practice, www.topalbertadoctors.org/top

International sites

Agency for Healthcare Research and Quality, www.ahrq.gov

American College of Physicians Clinical Practice Guidelines
www.acponline.org/sci-policy/guidelines

Australian Government National Health and Medical Research Council, www.nhmrc.gov.au

Clinical Knowledge Summaries (CKS) Prodigy Guidance
cks.library.nhs.uk

eGuidelines, www.eguidelines.co.uk

Geneva Foundation for Medical Education and Research
www.gfmer.ch/000_Homepage_En.htm

Guidelines International Network, www.g-i-n.net

Institute for Clinical Systems Improvement, www.icsi.org

Medical Journal of Australia Clinical Practice Guidelines
www.mja.com.au/public/guides/guides.html

National Guideline Clearinghouse, www.guideline.gov

National Institute for Health and Clinical Excellence
www.nice.org.uk

National Library of Health: Guidelines Finder Specialist Library
www.library.nhs.uk/guidelinesFinder/Default.aspx?pagename=HOME

New Zealand Guidelines Group, www.nzgg.org.nz

NHS Health Technology Assessment Program
www.hta.nhsweb.nhs.uk/index.htm

Primary Care Clinical Practice Guidelines (University of California at San Francisco), medicine.ucsf.edu/resources/guidelines

Scottish Intercollegiate Guidelines Network
www.sign.ac.uk

Trip Database, www.tripdatabase.com/index.html

United States Preventive Services Task Force
www.ahrq.gov/clinic/uspstfix.htm

University of Michigan Medical School, Continuing Medical Education, cme.med.umich.edu/iCME/default.asp

Databases for finding studies, systematic reviews and CPGs

Cochrane Collaboration, www.cochrane.org
A worldwide, not-for-profit organization that produces regularly updated systematic reviews, published quarterly, using common methods within a standardized format.

PubMed (MEDLINE), www.pubmed.gov
The National Library of Medicine's bibliographic database covering the fields of medicine, nursing, dentistry, veterinary medicine, the health care system and the preclinical sciences.

CINAHL, www.cinahl.com
The Cumulative Index to Nursing & Allied Health database provides coverage of the literature related to nursing and allied health.

EMBASE, www.embase.com
The Excerpta Medica database, produced by Elsevier Science, is a major biomedical and pharmaceutical database.

CPG adaptation and development

ADAPTE, www.adapte.org
The ADAPTE Collaboration's *Manual for Guideline Adaptation* (2007) and *Resource Toolkit for Guideline Adaptation* (2007). contact@adapte.org

Appraisal of Guidelines Research & Evaluation (AGREE)
www.agreecollaboration.org
Instrument to assess quality of CPGs.

Canadian Task Force on Preventive Health Care
www.ctfphc.org
History and methods section.

Current methods of the US Preventive Services Task Force. A review of the process. *Am J Prev Med* 2001;20(3S):21-35.

Harris RP, Helfand M, Woolf SH, et al. for the Methods Work Group, Third U.S. Preventive Services Task Force.

Health Research Policy and Systems
www.health-policy-systems.com
In 2005, the World Health Organization (WHO) asked its Advisory Committee on Health Research (ACHR) for advice on ways in which WHO could improve the use of research evidence in the development of recommendations, including guidelines and policies. The ACHR established the Subcommittee on the Use of Research Evidence (SURE) to collect background documentation and consult widely among WHO staff, international experts and end users of WHO recommendations to inform its advice to WHO. The reviews have been published in *Health Research Policy and Systems*.

National Institute for Health and Clinical Excellence, United Kingdom, *The guidelines manual 2007*
www.nice.org.uk/page.aspx?o=guidelinesmanual
A guide for patients and carers: contributing to a NICE clinical guideline www.nice.org.uk/page.aspx?o=guidelinecontribute

Scottish Intercollegiate Guidelines Network
www.sign.ac.uk/guidelines/fulltext/50/index.html
SIGN 50: A Guideline Developers' Handbook

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3. Implementation of CPGs to change practice and outcomes

This chapter

- outlines the nature and challenges of "knowledge translation," the process by which best-evidence CPGs are adopted by clinicians, patients and policy-makers
- describes the stages in planning a CPG implementation strategy: analyzing the context, reviewing the relevant literature and designing a strategy based on this information.

The recognition that simply publishing CPGs has not resulted in the expected changes in practice has led to research, in Canada and internationally, on how to translate evidence into practice.[1] This field of CPG implementation research falls within a larger field often referred to as knowledge translation.[2]

Evidence concerning CPG implementation, while rapidly increasing, is difficult to interpret because of wide variations in the clinical conditions being addressed, the implementation methods used and the settings in which they occur.[3] In a recent review[4,5] of evaluations of the effectiveness of CPG implementation strategies, the authors reported that "the majority of interventions observed modest to moderate improvements in care" but there was "considerable variation in the observed effects both within and across interventions,"[5] indicating that some strategies or combination of strategies can achieve significant increases in adherence to a particular treatment. Other research supports this view.[6] It is also important to realize that even a modest improvement in adherence to an effective practice can have a significant impact on public health[7] and that some CPGs are relatively easy to adopt (perhaps indicating subtle changes in practice) while others are more complex.

Box 3.1: Ineffective CPG implementation

FitzGerald and colleagues[9] conducted telephone interviews with adults with asthma and surveyed physicians by telephone and mail between April and August 2004. They found that 97% of 893 patients believed that they had controlled asthma, yet only 47% had their disease under control according to symptom-based guideline criteria. Although physicians were highly aware of the Canadian asthma guidelines, only 39% of the 463 physicians surveyed based their treatment recommendations on these guidelines most or all of the time. Only 11% of patients had written action plans and half of them did not use them regularly. Almost three-quarters of patients expressed concerns about taking inhaled corticosteroids. The authors concluded that guideline implementation had not resulted in significant changes in asthma-related morbidity since the last major national survey in 1999.

Planners of CPG implementation programs should focus on individual recommendations, rather than on the CPG as a whole, and identify measures that demonstrate adherence to the recommendation. This approach makes the implementation initiative manageable, focuses efforts on the most important and relevant aspects of the CPG and enables measurement and evaluation of the effects of implementation. To determine which strategy, or combination of strategies, is likely to be effective for particular CPG recommendations and circumstances, implementers should

- analyze the health care context
- review the relevant literature and resources
- develop a targeted plan.

The team that adapted or developed the CPG must consider forming a CPG implementation working group. As in the case of the development group, the implementation group should include those who will be affected by the CPG to optimize the relevance of the intervention and buy-in. It is also wise, if possible, to include people with expertise in knowledge translation and evaluation

research. If it is impractical to form a working group, a leader of the implementation process can consult with these stakeholders.

Analyze the health care context

In planning a targeted intervention, the CPG implementation working group must examine the multitude of factors — both barriers and facilitators — that may affect the adoption of the CPG recommendations. The knowledge and decisions of individual health care practitioners are not the only factors that determine whether a CPG recommendation is translated into everyday practice.[8] In Box 3.1, we describe a situation in which physicians were aware of asthma CPGs, but more effective implementation efforts were needed to decrease asthma-related morbidity.

Table 3.1 outlines the various levels and examples of specific questions that might need to be explored in analyzing the context. Although these questions and issues are categorized here, many are interrelated; for example, cost implications are important in the political context and practitioners' perceived barriers to change can be related to organizational or system factors.

A variety of methods can be used to gather this type of information, such as surveys, focus groups, interviews, informal discussions, observations and case studies. The National Institute of Clinical Studies document, *Identifying Barriers to Evidence Uptake*[10] describes these methods in greater detail than space permits here. Box 3.2 describes 2 studies that used health care professional interviews to examine barriers to the use of CPGs.

Minimal evidence exists about the most effective methods for identifying barriers to changing practice. Fretheim and colleagues[13] evaluated the use of different methods for identifying and addressing barriers to change in their study on improving prescribing of antihyperten-

Table 3.1: Assessing the context for facilitators and determining barriers to change

Context	Questions and issues in the implementation process
Health care practitioners	• Are practitioners aware of practice gaps and the need for change? • Are practitioners knowledgeable about the CPG recommendations? • What are practitioners' attitudes toward the CPG recommendations? • Are practitioners motivated to change? • What are practitioners' perceived barriers to change? • Do needs differ among the various health care practitioners?
Patients/public	• Are patients and the public aware of and do they understand the evidence for best practice? • What are their attitudes toward the recommendations? • Do they have the resources to adopt the recommendations? • What resources or services would support their adoption of the recommendations? • What are their perceived barriers to adopting the recommendations?
Organization	• What characteristics of the health care team might facilitate or challenge adoption of recommendations? • What features of the work processes might facilitate or challenge adoption of recommendations? • What education mechanisms are available in the organization? • What technological resources are available? • Is the organizational culture supportive of the change? • Is there clinical and organizational leadership for change? • Who are the key organizational stakeholders who should be consulted? • Are necessary organizational resources, services and equipment available?
Economics	• What resources are required to implement the changes and sustain them in the long term? • Will the CPG intervention contribute to increased or decreased costs? • Will the changes have cost implications for other services?
Policy	• Are there regulations or legislation that affects CPG implementation? • Is there a political will to change practice?

sive and cholesterol-lowering drugs. Their initial methods consisted of structured reflection, searching for other relevant trials, a survey of general practitioners and discussion with physicians during pilot testing of the intervention to improve prescribing. Structured reflection occurred among the 3 authors based on their own experience as physicians and the use of a worksheet that listed factors acting as possible barriers in the practice environment, the professional environment and those that related to knowledge, skills and attitudes. The survey, sent to 265 physicians, sought information on the following questions:

1. Do physicians assess cardiovascular risk before prescribing antihypertensive or cholesterol-lowering drugs?
2. If not, would physicians be more likely to do so if they received a fee for this?
3. Do physicians comply with current regulations limiting the reimbursement of cholesterol-lowering drugs?

Feedback from physicians about barriers was obtained during pilot testing of the intervention. The researchers then conducted focus groups with international researchers in the field of quality improvement in health care and telephone interviews with physicians in the intervention group.

The structured reflection process resulted in the identification of a wide range of barriers and suggestions for several interventions, and the survey led to some adjustments. Studying other trials, pilot testing, post hoc focus groups and the post hoc survey did not reveal important issues, barriers or interventions that had not been considered. The authors concluded that "a simple approach to identifying barriers to change appears to have been adequate and efficient."

In the end, it falls to the CPG implementation leader or working group to decide on a method for examining barriers to and enablers of change. The choice will be affected by the resources available, the clinical practice being examined and feasibility issues, such as access to people with relevant expertise (e.g., social or behavioural scientists, health researchers, statisticians and other professional groups). Multiple methods or participant groups might be needed as certain individuals or groups might only provide particular perspectives concerning existing barriers and enablers. The information obtained must be used in the design of the implementation of the intervention. Before testing the intervention, the plan should be reviewed to determine whether the identified barriers and enablers have been adequately addressed.

Review the relevant literature and resources

A significant and growing body of research, resources and Web sites provide information about a variety of CPG implementation strategies and evidence of their effective-

Box 3.2: Interviewing health care professional to assess barriers to CPG use

Tan and others[11] interviewed anesthesiologists, surgeons and perioperative administrators to find out what obstacles they perceived to the use of CPGs for the timely administration of prophylactic antibiotics to prevent infections at surgical sites. They found that participants were knowledgeable about the guidelines, but perceived consistent failure in the proper timing of antibiotic administration. The authors attributed this failure to the low priority and inconvenience of administering the antibiotics, workflow, organizational communication and role perception. The authors concluded that individual values and professional and organizational conflicts would need to be addressed to improve evidence-based practice.

Sinuff and co-workers[12] interviewed physicians, residents, nurses and respiratory therapists who used noninvasive ventilation (NIV) to treat acute respiratory failure in patients with chronic obstructive pulmonary disease or congestive heart failure. They conducted interviews before and after NIV guideline implementation to determine knowledge about and attitudes toward the guideline and potential barriers to its use. The NIV guideline was perceived as defining individual clinical responsibilities, improving clinician comfort with the use of technology, increasing patient safety and reducing practice variability. Barriers to guideline use were lack of awareness of the guideline, unclear format and presentation of the guideline and reluctance to change practice. The authors concluded that use could be improved through education to improve guideline awareness and increase comfort with the recommended practices.

Table 3.2: CPG implementation strategies

Focus of strategy	Strategies	Examples of studies
Practitioners	• Educational meetings: Conferences, lectures, workshops or traineeships, grand rounds, seminars, and symposia.	• Schneeweiss and Ratnapalan[14]
	• Educational materials: Printed or electronic information.	• Kucher et al.[15] • Dormuth et al.[16]
	• Web-based education: Computer-based educational activities.	• Fordis et al.[17]
	• Educational outreach/academic detailing: A trained person meets with providers in their practice setting to provide information with the intention of changing the provider's practice. The information may include feedback on the performance of the provider(s).[18]	• Young and Ward[19]
	• Audit and feedback: Any summary of clinical provision of health care over a specified period; may include recommendations for clinical action. The information is obtained from medical records, databases or observations of patients.[18] Summary may be targeted at the individual practitioner or the organization.	• Herbert et al.[20]
	• Reminders: The provision of information verbally, on paper or on a computer screen to prompt a health professional to recall information or to perform or avoid a particular action related to patient care.[18]	• Sequist et al.[21]
	• Local opinion leaders: Providers nominated by their colleagues as "educationally influential."[18] In general, such individuals are identified by their peer colleagues, are trained as change agents and operate within their communities to teach and enable change.	• Majumdar et al.[22]
	• Patient-mediated interventions: Interventions directed at patients (e.g., mass media campaigns, reminders, education materials) to optimize professional–patient interactions.	• Buchbinder and Jolley[23]
	• Practice tools: Tools designed to facilitate behavioural/practice changes, e.g., flow charts.	• Müller et al.[24] • Dubey et al.[25]
Patients	• Patient education materials: Printed/electronic information aimed at the patient, consumer, family, caregivers, etc.	• Michie and Lester[26]
	• Mass media campaigns	• Buchbinder et al.[27]
	• Reminders: The provision of information verbally, on paper or electronically to remind a patient/consumer to perform a particular health-related behaviour.	• Lafata et al.[28]
	• Decision-support tools: Aids designed to facilitate shared decisions by patients and their physicians.	• McAlister et al.[29]
Organizations and regulatory bodies	• Changes to health care teams: Changing tasks or responsibilities of health professionals or compositions of health professional groups.	• Wensing et al.[30]
	• Information and communication technology: Electronic decision support, order sets, care maps, electronic health records, office-based personal digital assistants, etc.	• Garg et al.[31]
	• Audit and feedback: Any summary of clinical provision of health care over a specified period; may include recommendations for clinical action. The information is obtained from medical records, databases or observations by patients.[18] Summary may be targeted at the individual practitioner or the organization.	• Bours et al.[32]
	• Administrative procedures/policies	• Calderon-Margalit et al.[33]
	• Formularies: Drug safety programs, electronic medication administration records.	• Nutescu et al.[34]
	• Financial incentives or penalties: The use of remuneration for the performance of certain functions or actions, e.g., screening procedures in primary care.	• Rosenthal et al.[35]
	• Mandated practices	• Goldstein et al.[36]

ness. A useful resource in this regard is the Research and Development Resource Base (www.cme.utoronto.ca /search).

The various strategies that have been used to implement CPGs differ in their mechanism and target. For example, educational meetings are designed to improve knowledge gaps among health care professionals, whereas local opinion leaders may convince health care professionals who are knowledgeable but skeptical about the evidence of its importance and the need to change practice. The introduction of electronic prescription writing is an organizational strategy that aims to change the process of care. Table 3.2 lists various types of CPG implementation strategies.

Systematic reviews and individual studies provide evidence of the effectiveness of the strategies. Reviews compare the results of studies of a particular intervention, including those that adhere to specific methodological criteria, to assess their consistency and generalizability. Reviews provide a valuable summary of existing research and can be found in databases of scientific studies (see Box 3.3) and the Cochrane Collaboration Library.

The Cochrane Effective Practice and Organisation of Care Group (EPOC) is a collaborative review group of the Cochrane Collaboration, an international organization that prepares, maintains and ensures the accessibility of systematic reviews of the effects of health care interventions. EPOC produces systematic reviews of educational, behavioural, financial, regulatory and organizational interventions designed to improve health professional practice and the organization of health care services in any clinical area. The EPOC Web site[37] provides a listing of all EPOC published reviews and protocols.

Researchers have conducted systematic reviews of CPG implementation strategies (e.g., educational outreach visits) and their effectiveness for various clinical conditions (e.g., interventions to improve the management of asthma in primary care settings). These studies highlight what has been effective in which clinical contexts and what we still do not know. In Table 3.3, we provide a few examples of these systematic reviews to illustrate the nature of the topics and findings. It is important to note that, although the reported changes may seem small, they may be clinically meaningful and economically effective.

Although systematic reviews can provide a sense of "overall findings" on a particular intervention or interventions, given the uniqueness of health care conditions and settings and of CPGs, it can also be useful to review individual studies that have characteristics in common with your own CPG implementation initiative and setting. Further, systematic reviews include studies with certain methodological criteria; however, important insights can be gained from studies using other methods, such as qualitative measures. Individual studies, which can be found in the databases listed in Box 3.3, can provide information about barriers to

Box 3.3: Databases of scientific studies and reviews of CPG implementation strategies

PubMed (MEDLINE)

www.pubmed.gov

The National Library of Medicine's bibliographic database covering the fields of medicine, nursing, dentistry, veterinary medicine, the health care system and the preclinical sciences.

CINAHL

www.cinahl.com

The Cumulative Index to Nursing & Allied Health database, provides coverage of the literature related to nursing and allied health.

EMBASE

www.embase.com

The Excerpta Medica database, produced by Elsevier Science, is a major biomedical and pharmaceutical database.

RDRB

www.cme.utoronto.ca/search

The Research and Development Resource Base, is a database of literature focusing specifically on continuing education, continuing professional development and knowledge translation in the health disciplines.

The Cochrane Library

www.cochrane.org/index.htm

Contains high-quality, independent evidence to inform health care decision-making. It includes reliable evidence from Cochrane and other systematic reviews, clinical trials and more. Cochrane reviews bring you the combined results of the world's best medical research studies and are recognized as the gold standard in evidence-based health care.

and enablers of change, interventions that have been used in particular contexts and their effectiveness and possible reasons for the results obtained.

Box 3.4 provides 3 examples of such studies. The first identifies factors that enhance effectiveness of audit and feedback, the second provides evidence that the effectiveness of opinion leaders may be disease specific and the third demonstrates the significance (and maybe limitations) of uniprofessional groups in attempting to introduce an innovation in health care.

The studies discussed above represent only a few examples of the large, and expanding, evidence on CPG implementation. Valuable resources can also be found on Web sites of organizations committed to knowledge translation. Some of these organizations are listed in the "Resources and links" section at the end of this chapter. One resource is a publication by the Institute of Health Services and Policy Research of the Canadian Institutes of Health Research called, *Evidence in Action, Acting on Evidence: A Casebook of Health Services and Policy Research Knowledge Translation Stories*.[45] This document highlights original submissions from across Canada that focus on lessons learned from both successful and less than successful knowledge translation activities.

Develop a targeted plan

After assessing barriers and enablers and reviewing the literature to become familiar with various CPG implementa-

Table 3.3: Examples of systematic reviews of CPG implementation strategies

Study question	Conclusions
What is the effectiveness of local opinion leaders on professional practice and health care outcomes? Doumit et al.[38]	For the 12 studies that met the inclusion criteria, an overall decrease of 10% in non-compliance occurred in the intervention group. Most of the studies were in hospitals. More information is needed about what opinion leaders do and how they do it.
What is the effectiveness of audit and feedback on professional practice and health care outcomes? Jamtvedt et al.[39]	According to this review of 118 studies, audit and feedback can improve practice, but the effects are generally small to moderate, and variable. The effectiveness of audit and feedback is likely to be greater when there is low baseline adherence to the recommended practice and the feedback is delivered more intensively.
What strategies are effective for implementing obstetric CPGs? Chaillet et al.[40]	To change behaviours in the field of obstetric care, a multifaceted strategy using audit and feedback and local opinion leaders is recommended.
What is the effectiveness of interventions in improving antibiotic prescribing practices in ambulatory care? Arnold and Straus[41]	Among the 39 studies that met the inclusion criteria, use of printed educational materials or audit and feedback alone resulted in no or only small changes in prescribing (with 1 exception). Interactive education was more effective than didactic lectures. Educational outreach visits and physician reminders produced mixed results. Patient-based interventions (e.g., delayed prescriptions) effectively reduced antibiotic use by patients and did not result in excess morbidity. Multifaceted interventions combining physician, patient and public education in a variety of venues and formats were the most successful in reducing antibiotic prescribing for inappropriate indications. The effectiveness of an intervention on antibiotic prescribing depends to a large degree on the particular prescribing behaviour and the barriers to change in the community.
What is the effectiveness of strategies aimed at the diffusion and dissemination of cancer control interventions? Ellis et al.[42]	31 studies were identified that evaluated dissemination strategies in the 5 topic areas: smoking cessation, healthy diet, mammography, cervical cancer screening, and control of cancer pain. No strong evidence currently exists to recommend any 1 dissemination strategy as effective in promoting the uptake of cancer control interventions.

tion strategies and issues related to their effectiveness, the CPG implementation group is now in a position to address the following 2 questions to help them develop an implementation strategy:

1. Which implementation strategies could address the identified barriers to and enablers of change?
2. What resources are available and how would they be best used to put these strategies in place?

Identify implementation strategies

At this point, it is not possible to provide specific guidance on how to translate identified barriers into tailor-made implementation interventions. Bosch and colleagues[46] analyzed 20 quality improvement studies reporting barrier analyses to increase our understanding of methods to tailor educational and organizational interventions. They found that information gained from barrier analysis was more commonly used to inform the content of the intervention rather than the type of intervention selected. Further research will need to provide more details about the factors affecting the selection of a particular intervention, which will enable further development of methods for designing quality improvement interventions.

As noted previously, CPG implementation strategies have different targets and mechanisms for change and varying levels of effectiveness for particular clinical conditions and settings. The following 2 examples (Boxes 3.5 and 3.6) demonstrate the development of interventions to address identified barriers.

These 2 examples illuminate the process of choosing interventions in response to the identified barriers and research evidence. The CPG implementation group will have to decide whether to use 1 strategy or a combination of strategies aimed at different levels of the health care system. Box 3.7 describes a Canadian initiative that uses an extensive array of knowledge translation methods.

During the decision-making process, the group should also consider the scheduling of strategies so that each intervention can be optimally executed and plan to address the question of sustainability. Will the intervention be temporary or long-term? Will the changes be sustained over time or will further interventions be needed to support long-term change?

Box 3.4: Studies illuminating the effect of CPG implementation strategies

Hysong and colleagues[43] conducted semi-structured interviews with employees of medical centres with high and low adherence to 6 CPGs to assess differences in the use of audit and feedback. They found that timeliness, individualization, non-punitiveness and customizability characterized the audit and feedback of higher performing facilities.

Majumdar and co-workers[22] conducted a community-based randomized controlled trial to examine the impact of patient-specific 1-page evidence summaries generated and endorsed by local opinion leaders on the prescribing of angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) in heart failure and that of statins in ischemic heart disease (IHD). Overall, the intervention contributed to a small and statistically nonsignficiant 6% absolute improvement in prescribing compared with the control group; however, it is possible that the intervention was condition specific. The intervention contributed to an 18% absolute improvement in the use of ACE inhibitors or ARBs among patients with heart failure, but was not associated with improvements in the use of statins among patients with IHD. The authors discuss potential reasons for their findings and future areas of exploration.

Ferlie and others[44] performed a qualitative study of 8 comparative "innovation" case studies, which were selected for the degree of scientific evidence and the innovation complexity (the number of organizations and occupational groups involved in implementation); 4 were based in acute care settings and 4 within primary care settings. Based on extensive interviews and observations, they found that innovation was nonlinear and complex and that professionals construct and act within uniprofessional communities of practice. Each professional group has its own knowledge base and research culture, and the group's social and cognitive boundaries impede the spread of innovations. Future research should examine conditions and strategies that would bridge these barriers within large, multiprofessional organizations.

Consider resource issues

The following issues relate to the cost of the interventions and the economic implications of implementing a CPG:

- What is the available budget for the implementation strategy?
- What are the costs of the intervention(s) involved in this strategy?
- What are the benefits and costs in relation to the intervention and anticipated outcomes? For example, educational outreach requires tremendous resources whereas printed educational materials are a relatively inexpensive intervention.
- What are the economic consequences of the intervention on other aspects of health care? For example, Rahme and co-workers[51] found that prescribing practices adhering to CPGs on prophylactic use of gastroprotective agents with nonselective nonsteroidal anti-inflammatory drugs for patients at risk of gastrointestinal complications would increase drug acquisition costs to the health care payer, compared with actual prescribing patterns.

It could be beneficial to identify any groups, agencies or organizations that are active or have an interest in the CPG recommendation and could be valuable partners in the sharing of resources.

Theories and models of change

Researchers have looked at theories and models of behavioural and organizational change to improve our understanding of change in health care practices and why certain CPG implementation strategies work better than others in particular circumstances. Grol and Wensing[52] categorize these theories and models as "characteristics of the innova-

Box 3.5: Development of a strategic CPG intervention to address identified barriers

In 2002, the Ontario GAC and the Institute for Clinical Evaluative Sciences collaborated to reduce the excessive use of preoperative testing, in particular chest radiography and electrocardiograms for low-risk surgery, in Ontario hospitals.[47] Evidence demonstrated that there was marked variation in preoperative testing between different low-risk procedures and between different providers working in the same hospital. Dissemination of CPGs failed to improve outcomes. To address this problem, a multifaceted approach was implemented. The following strategies were used.

Identified barrier	CPG implementation strategy
Lack of knowledge	Educational meetings and materials: Information on routine preoperative testing was disseminated through journal articles; workshops were provided.
Lack of practice tools to implement guidelines	Preoperative testing checklist provided to hospitals.
Knolwedge of CPGs, but did not change practice	Opinion leaders were identified, consulted about barriers to adoption of evidence and trained to facilitate change.
Hospitals and clinicians unaware of performance	Audit and feedback: Hospital-specific feedback on preoperative testing rates was provided to all Ontario hospitals.

Despite limitations (e.g., SARS outbreak), an evaluation demonstrated a modest but statistically significant decrease in the use of chest radiography in the period following the intervention (2.6% absolute reduction; 13% median relative reduction). Larger changes were observed for some individual procedures, and institutions with high rates of chest radiography use in the initial period had marked decreases following the intervention (e.g., from over 40% tested to less than 15% tested). No overall change was seen in the use of preoperative electrocardiograms, reflecting their non-invasive nature and the more equivocal nature of the recommendation regarding ECGs compared with radiography.

tion," "models relating to individual professionals" and "models relating to interpersonal factors and system characteristics." We use this typology to outline relevant theories below. Although current research efforts are ongoing (e.g., an investigation into the use of psychological theories to explore factors associated with adherence to evidence-based health care[1]), the evidence base for the use of these theories in health care is lacking and further research is needed to demonstrate whether and how such theories can provide a basis for selecting interventions to translate CPGs into practice.

Box 3.6: Development of a strategic CPG intervention to address identified barriers

Baker and colleagues[48] interviewed general practitioners with high and low rates of referral for lumbar spine radiography (LSX) for the management of low-back pain (LBP) to understand observed variations in referral rates. Both groups of practitioners were aware of, and did not challenge, current CPGs, which suggested limiting the use of LSX for patients with LBP. Both groups disclosed that social factors, such as patient expectations and pressure on family physicians to "do something," influenced their referral decisions and that they experienced difficulties with waiting lists for referral to secondary care or more advanced technological imaging and, thus, the ideal treatment pathway was not always possible. The high-use group had stronger beliefs that LSX provides reassurance to patients that can outweigh the risks, pessimism about the management options for LBP and a belief that denying LSX would adversely affect their relationship with the patient. Physicians in the low-referral group expressed more concerns about exposure to radiation, whereas those in the high-referral group minimized the risks. High-referral physicians also perceived their own use of LSX to be relatively low.

The authors discussed possible interventions to address the identified barriers. They noted that feedback about physicians' use of LSX compared with others may be an option, as they perceive their own use to be relatively low, but studies have shown that this strategy is ineffective in changing referral rates for LSX. Thus, for future investigation, they suggest interventions that educate physicans about the radiation risks associated with LSX and a reassessment of the costs and benefits of these examinations.[48]

Characteristics of the innovation

According to Rogers' diffusion of innovation model, the following 5 elements affect the adoption or diffusion of a new activity, in this case new or substitute clinical behaviour as represented by a CPG[53]:

- *relative advantage*: the degree to which an innovation is perceived as better than the idea it supersedes
- *compatibility*: a measure of the degree to which an innovation is perceived to be compatible with existing values, past experiences and the needs of potential adopters
- *complexity*: a measure of the degree to which an innovation is perceived as difficult to understand and use (a clinical procedure is more likely to be adopted if it is simple and well defined)
- *trialability*: the degree to which the innovation may be tested and modified
- *observability*: the degree to which the results of the innovation are visible to others.

Box 3.7: The Canadian Hypertension Education Program[49,50]

The Canadian Hypertension Education Program (CHEP) has improved the management of hypertension in Canada through its knowledge translation efforts. The CHEP task force annually develops updated evidence-based management recommendations, implements the recommendations and examines the impact of CHEP on hypertension management and hypertensive complications. The program includes all primary care disciplines and the public. The implementation strategy includes the following components:

- Educational materials: scientific manuscripts, a variety of short clinical and scientific summaries tailored to the audience, brief handouts, PowerPoint education kits, slide sets, text books
- Reminders: posters, advertisements
- Practice tools: pocket cards
- Educational meetings: workshops
- Teaching opinion leaders to provide workshops

Models relating to individual professionals

Some models attribute characteristics of individuals, such as lack of awareness and motivation, as important barriers to adopting CPGs and others employ models of "stages of change."[52] For example, Pathman and colleagues[54] tested the awareness-to-adherence model of the steps to CPG compliance. This study of pediatric vaccine recommendations, confirmed that physicians generally proceeded through sequential steps of guideline awareness, agreement, adoption and adherence and that different strategies are needed to support practitioners' progression through these stages. They suggest that, in cases where physicians adopt a CPG without agreement, other factors, such as peer pressure, patient demand and practice organization policies, are likely playing a role.

Grol and Wensing[52] have developed and are currently testing a 10-step model for changing professional behaviour based on a mix of stages of change theories. We have adapted it for use here, emphasizing that the impetus rests with the CPG implementer or implementation body to:

1. Promote awareness of the desired CPG recommendations
2. Stimulate interest and involvement in the adoption process
3. Create an overall understanding of the CPG and the nature of the specific changes recommended
4. Develop insights into practice routines
5. Develop positive attitudes to change
6. Create positive intentions or a decision to change
7. Try out change in practice
8. Confirm the value of change
9. Integrate new practice into routines at the individual or team level
10. Embed new practice in the organization

Models relating to interpersonal factors and system characteristics

There are models that consider the role of social and organizational factors related to CPG implementation. For example, the PRECEDE–PROCEED model developed in health education outlines 3 elements of change: predisposing factors, enabling factors and reinforcing factors. Predisposing factors are those characteristics of a person or population that motivate behaviour before the occurrence of the behaviour (e.g., knowledge, beliefs, values, attitudes). Enabling factors are characteristics of the environment that facilitate action and skills or the resources required to perform the behaviour (accessibility, availability, skills, regulations). Reinforcing factors are rewards or penalties following the behaviour.[52,55] In designing educational interventions, Davis and colleagues[56] suggest that predisposing elements might include lectures or print materials and that enabling factors (such as flow charts, patient-mediated strategies) and reinforcing elements (among which are reminders at the point of care, audit and feedback) would improve the effect of interventions.

Examples of organizational models that have been proposed include a contingency model of innovation adoption in long-term care facilities with a particular focus on CPGs[57] and the Promoting Action on Research Implementation in Health Services (PARIHS) model, which focuses on the nature of the evidence, the quality of

Table 3.4: Using predisposing, enabling and reinforcing strategies to ensure adherence to guidelines[60]

Strategy type	Steps to CPG compliance			
	AWARENESS	AGREEMENT	ADOPTION	ADHERENCE
PREDISPOSING	Printed materials (newsletters), simple-message handouts, didactic lectures and conferences	Endorsement by a reputable or recognizable organization		
ENABLING		Peer-group discussion	Patient education materials, workshops	Patient-meditated strategies
REINFORCING				Reminders, feedback

the context and the type of facilitation in the successful implementation of evidence.[58]

Although there is as yet little evidence to support the use of these models and theories for CPG implementation, they may be helpful in planning the best design of an intervention. For an overview of change implementation theories, see Grol and colleagues.[59]

Table 3.4 provides a broad framework for the design of a CPG implementation strategy, drawing on the models of change described above. On one axis, the Pathman model takes the clinician from awareness through agreement, adoption and finally adherence. On the other axis, we list strategies categorized as predisposing, enabling and reinforcing.[54,55] In this context, the CPG implementation group may decide whether its major recommendations are a matter of awareness (new medications, or a new standard of care) or they represent issues of agreement, adoption or adherence. Once these decisions are made, strategies to promote uptake can be planned — increasing agreement by local practice group education or opinion leader training, enhancing adoption by patient education methods or flowcharts, improving adherence by reminders at the point of care, audit and feedback, perhaps financial incentives. Although this table focuses on clinician education, it can also be adapted for use at the public or policy level.

Conclusion

As we noted in the beginning of this chapter, although most CPG interventions result in modest to moderate improvements in care, there is considerable variation in the observed effects both within and across interventions.[5] The approach presented in this chapter — to assess the context, review the relevant literature and develop a systematic intervention, possibly with the help of theories of behavioural and organizational change — is an approach that is currently recommended. It has led to both successful and non-successful CPG implementation projects. Each CPG implementation project has unique factors and an individualized approach is needed in planning. Initial testing of an intervention on a small scale to identify any problems that might need to be addressed before going on to large-scale implementation can be valuable. Rigorous evaluation, the topic of the next chapter, is a key component of a CPG implementation initiative to identify whether the desired outcomes were achieved. The knowledge gained can also contribute to the broader field of CPG implementation research.

Resources and links

Canadian Institutes of Health Research, Institute of Health Services and Policy Research
www.cihr-irsc.gc.ca/e/30660.html
Evidence in action, acting on evidence: a casebook of health services and policy research knowledge translation stories.

Canadian Health Services Research Foundation/Canadian Institutes of Health Research Chair on Knowledge Transfer and Innovation
kuuc.chair.ulaval.ca/english/index.php
KU-UC database with documents on knowledge transfer, innovation and health service policies and management.

Canadian Institutes of Health Research
www.cihr-irsc.gc.ca/e/7517.html
Useful links on knowledge translation.

College of Family Physicians of Canada
www.toolkit.cfpc.ca
Primary Care Toolkit for Family Physicians Web site

Effective Practice and Organisation of Care Group (Cochrane Collaboration), www.epoc.uottawa.ca

Estabrooks CA, Thompson DS, Lovely JE, et al. A guide to knowledge translation theory. *J Contin Educ Health Prof* 2006;26:25-36.

Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q* 2004;82:581-629.

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Institute for Work and Health
www.iwh.on.ca/assets/pdf/IWH_kte_workbook.pdf
From research to practice: a knowledge transfer planning guide

Knowledge Translation Program at the Li Ka Shing Knowledge Institute, St. Michael's Hospital and the University of Toronto, www.ktp.utoronto.ca

Moulding NT, Silagy CA, Weller DP. A framework for effective management of change in clinical practice: dissemination and implementation of clinical practice guidelines. *Qual Health Care* 1999;8:177-83.

National Institute of Clinical Studies
www.nhmrc.gov.au/nics
Australia's national agency for closing the gaps between evidence and practice in health care

Registered Nurses Association of Ontario
www.rnao.org/bestpractices/PDF/BPG_Toolkit.pdf
Toolkit: implementaion of clinical practice guidelines

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4. Evaluation of CPGs

This chapter

- provides a brief overview of methods for the evaluation of clinical practice guidelines.

Evaluation is necessary for stakeholders to know whether a CPG initiative has been successful. At this stage, the CPG group identifies what should be evaluated, the data collection strategy that will provide information about these outcomes and the study design. It is wise to consult CPG evaluation experts at all stages of the evaluation (e.g., planning, data collection, data analysis, report writing); they might be available within one's organization (e.g., quality improvement programs), through collaborations (e.g., researchers at universities) or as external consultants.

What should be evaluated?

CPG implementation can affect both the process and outcome of care. When designing an evaluation, the CPG group should decide which of these components they wish to measure. Hakkennes and Green[1] conducted a review of published research on the effectiveness of CPG interventions to identify the types of outcomes and methods that have been used to measure change in these studies. The outcomes were grouped into 5 categories: 2 at the patient level, 2 at the health practitioner level and 1 at the organization or process level (Box 4.1).

Further research into CPG outcomes will enhance our understanding of which outcomes should be used in particular circumstances. For example, although the ultimate goal of CPG interventions is to improve patient-level outcomes, when a CPG intervention addresses a clinical behaviour for which there is strong evidence of benefit, it may be sufficient to measure whether the change in practitioner behaviour occurred. Standardized core sets of outcome measures are being developed in certain areas of health care.[1]

Box 4.1: Categorization of CPG evaluation outcomes[1]

Patient level

- Measurements of change in health status of the patient, e.g., pain, depression, quality of life, HbA1C
- Surrogate measures of change in health status of the patient, e.g., patient attitudes, lengths of stay

Health practitioner level

- Measurements of change in practice, e.g., compliance with CPGs, changes in prescribing rates
- Surrogate measures of change in practice, e.g., health practitioner knowledge and attitudes

Organization or process level

- Measurements of change in the health system (e.g., waiting lists), change in policy, costs and usability or extent of the intervention

What data should be collected?

Because CPGs are part of the larger framework of improving quality of care, measurement of CPG implementation should reflect one or more of the domains of quality outlined in the Institute of Medicine's report: *Crossing the Quality Chasm*.[2] This report states that health care should be safe, effective, patient-centred, timely, efficient and equitable. Quality indicators are data elements that allow measurement of these domains. A quality indicator is "a measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality, and hence change in the quality of care provided."[3] The choice of quality indicator should be informed by published resources. The National Quality Measures Clearinghouse sponsored by the Agency for Healthcare Research

and Quality is a useful resource (www.qualitymeasures.ahrq.gov).

Which data collection techniques could be used?

There are a variety of techniques for collecting data on CPG outcomes. The following methods have been used in CPG research to date[1]:

- medical record audit, by chart review or using electronic records
- health practitioner survey/questionnaire/interview
- patient survey/questionnaire/interview
- database (e.g., medical billing information)
- log books/department record/register (e.g., register of presentations to the emergency department)
- encounter chart/request slips/diary (e.g., laboratory tests, diary kept for the study data collection)
- other (e.g., results of blood tests, clinical examination).

Jennett and colleagues[4] provide a useful description of some of these methods. Other resources are listed at the end of this chapter in "Resources and links." When choosing a data collection technique, always consider whether the measures will provide the desired information.

Box 4.2: Example of a randomized controlled CPG trial

Varonen and colleagues[10] conducted a multicentre randomized controlled trial in 30 health centres to evaluate the impact of a CPG implementation program on the management of acute maxillary sinusitis in primary care. The health centres were randomly chosen to implement the CPG either according to a problem-based learning method or an academic detailing method facilitated by local family physicians; there were also external controls. The results showed that CPG implementation contributed to minor changes toward the recommended practices, and there were no significant differences between the 2 implementation methods. Fewer than half of the participating health centres were able to accomplish the project as outlined, decreasing the internal validity of the study. The authors suggested that more focused approaches that addressed the problems and practices of each health centre might have improved the outcomes.

What study design can be used?

Various study designs can be used in CPG evaluations. Some provide more detailed information and less-biased

Box 4.3: Example of an observational CPG evaluation

Müller and others[11] conducted a prospective before-and-after study to determine the effectiveness of a 1-page flow chart in reducing the use of blood transfusion in patients undergoing hip and knee replacement surgery. The flow chart, developed by hospital physicians and nurses and endorsed by local chief physicians, was widely distributed, presented to nurses and physicians during small-group teaching sessions that emphasized local "ownership" and responsibility and enclosed in patients' charts. Following this intervention, the proportion of patients receiving blood after total joint replacement dropped by more than 40%, with a concomitant reduction in costs. The authors attribute the effectiveness of the flow chart to simplicity, wide distribution, no requirement for major changes, endorsement by local opinion leaders and sense of ownership.

Box 4.4: Example of CPG process evaluation

Flottorp and colleagues[13] conducted a process evaluation to determine why their tailored intervention to support the implementation of a CPG for the management of urinary tract infections and sore throat had little effect on the main outcomes. They used observations, semistructured telephone interviews, a postal survey and data from electronic medical records to evaluate how the interventions were received and to understand why practices did or did not change. They found that 63% of the general practices agreed with the CPG, only 35% reported having regular meetings and 33% discussed the project before its start, although 75% reported agreement about participating within the practice. Only 33% reported meeting to discuss the CPGs. Use of the various components of the interventions ranged from 11% to 48%. The authors concluded that no single factor explained the observed variation in the extent of change across practices and that inadequate time, resources and support were the most salient factors that might explain the lack of change.

results, but are more resource intensive. The CPG evaluating group should decide not only what is feasible, but also how much detail is required. For example, an evaluation could be conducted to learn about a particular project in a specific setting or to inform scientific knowledge.[5] The latter approach will require a more rigorous study design.

A randomized controlled trial is the most rigorous type of study design.[6,7] Box 4.2 contains a description of a randomized controlled CPG trial. This type of study requires extensive expertise and resources.[6,8] CPG implementation falls within the umbrella of complex interventions, which present particular methodological difficulties because they are multifaceted and highly dependent on the social context.[8,9] These types of research studies are most frequently undertaken by investigators with research funding.

Observational study designs, including interrupted time series analyses, controlled before-after studies and uncontrolled before-after studies have the risk of greater bias, but are a viable option if randomized trials are not feasible[5] Box 4.3 provides an example of an observational CPG evaluation.

Evaluations aimed at examining process or organizational outcomes will likely require different study designs. In small-scale projects, a process evaluation can be used to make changes to an ongoing CPG intervention, whereas in an experimental study, the process data, in combination with the outcome data, can be used to interpret the results. The data for the process evaluation can be quantitative or qualitative.[8,12] Box 4.4 provides an example of process evaluations.

Conclusion

Rigorous research studies are needed to advance the field of CPGs and have informed much of this handbook. Local evaluation efforts are important in determining the next stages in a CPG implementation effort and creating an iterative, cyclical process. In such an evaluation, it is also necessary to consider whether the outcomes will be maintained over the long term. This relates to Graham and colleagues'[14] final stage — "sustaining ongoing knowledge use" — and points to the need to create an organizational culture that encourages CPG adherence.[15]

Resources and links

Bonetti D, Eccles M, Johnston M, et al. Guiding the design and selection of interventions to influence the implementation of evidence-based practice: an experimental simulation of a complex intervention trial. *Soc Sci Med* 2005;60:2135–47.

Boynton P, Greenhalgh T. Selecting, designing, and developing your questionnaire. *BMJ* 2004;328:1312–5.

British Medical Journal, Topics: non-clinical: statistics and research methods, www.bmj.com/cgi/collection#non-clinical

Britten N. Qualitative research: qualitative interviews in medical research. *BMJ* 1995;311:251–3.

Canadian Health Services Research Foundation/Canadian Institutes of Health Research Chair on Knowledge Transfer and Innovation
kuuc.chair.ulaval.ca/english/index.php
Knowledge transfer resources and an e-watch bulletin

Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321:694–6.

Effective Practice and Organisation of Care Group (Cochrane Collaboration), www.epoc.uottawa.ca

Grimshaw J, Eccles M, Thomas R, et al. Toward evidence-based quality improvement. Evidence (and its limitations) of the effectiveness of guideline dissemination and implementation strategies 1966–1998. *J Gen Intern Med* 2006;21:S14–20.

Grol R, Wensing M, Eccles M (editors). Part VI: Evaluation. In *Improving patient care: the implementation of change in clinical practice*. Edinburgh: Elsevier; 2005.

Health Research Policy and Systems, www.health-policy-systems.com
An open access, peer-reviewed, online journal that aims to publish research on the role of evidence-based health policy and health research systems in ensuring the efficient use and application of knowledge to improve health and health equity, especially in developing countries.

Implementation Science, www.implementationscience.com
An open access, peer-reviewed online journal that aims to publish research relevant to the scientific study of methods to promote the uptake of research findings into routine health care in both clinical and policy contexts.

Jones D, Story D, Clavisi O, et al. An introductory guide to survey research in anaesthesia. *Anaesth Intensive Care*. 2006 34:245–53.

Kelley K, Clark B, Brown V, et al. Good practice in the conduct and reporting of survey research. *Int J Qual Health Care* 2003;15:261–6.

Journal of Continuing Education in the Health Professions
www.jcehp.com

National Quality Measures Clearinghouse
www.qualitymeasures.ahrq.gov

Powell AE, Davies HTO, Thomson RG. Using routine comparative data to assess the quality of health care: understanding and avoiding common pitfalls. *Qual Saf Health Care* 2003;12:122–8.

Registered Nurses Association of Ontario
Toolkit: implementaion of clinical practice guidelines
www.rnao.org/bestpractices/PDF/BPG_Toolkit.pdf

Rowlands G, Sims J, Kerry S. A lesson learnt: the importance of modeling in randomized controlled trials for complex interventions in primary care. *Fam Pract* 2005;22:132–9.

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5. Conclusion

In this handbook, we have provided guidance through the complex processes of CPG adaptation, development, implementation and evaluation. We discussed the role of CPGs within a quality of health care context, emphasizing that CPGs are one important tool, among many others, that can be a part of a broader strategy to improve the processes and outcomes of health care. In particular situations, CPGs can play an important role, and their development and adaptation should be rigorous, transparent processes; the expert resources identified in this handbook provide direction. The adoption or adaptation of an existing CPG should be a first choice, and only if a relevant CPG is not available should development of a new CPG be considered. The ultimate goal of a CPG is to contribute to improved health care practices and outcomes; thus the evidence of CPG implementation provides direction for how to translate CPG recommendations into practice. Evaluation should always be an integral part of a CPG initiative and be built into the initiative as early as possible.

The field of CPGs is continually evolving with the production and dissemination of new evidence and approaches to CPG adaptation, development, implementation and evaluation. Newly published studies and documents were incorporated into this document during the course of its development and, thus, it is current at the time of production. But, just like CPGs, it will need updating in the future. CPGs play a key role in the quality of health care, and resources are required to continue to support CPG-related research and initiatives. Some examples of current developments in the field of CPGs that will contine in the future include interdisciplinary collaboration across the CPG spectrum and the notion of "fused CPGs," which recognizes, especially in primary care and general medicine, that most patients may have more than one clinical condition for which a CPG may be useful. For example, the care of an elderly person with depression, diabetes and hypertension may require the use of several CPGs, some of which may have conflicting recommendations. Technological developments are also providing opportunities; for example, electronic formats of CPGs in the clinical practice setting or linkages through electronic medical records could enhance their uptake.

We hope that this handbook has provided useful direction in the current field of CPG adaptation, development, implementation and evaluation and has given the reader resources to continue to engage in this evolving field.