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Diabetes Clinical Practice Guidelines: Could Changing the Message Change Care?

BY ONIL BHATTACHARYYA, MD, PhD, CCFP, AND ELIZABETH ESTEY, MA

The prevalence of diabetes is rising, which increases the burden on the healthcare system, and most of this burden is handled in primary-care settings. As a result, primary-care providers face many competing priorities, with diabetes often only one of several problems addressed in a patient visit. Since quality of care is suboptimal in most settings, guidelines have emerged as a way of synthesizing evidence and guiding practice; however, the complexity and ambiguity of guideline recommendations may limit their application in routine care. Quality improvement strategies usually target the practice environment or the provider, but modifying guidelines themselves may be a more efficient approach. This issue of *Endocrinology Rounds* reviews the setting of priorities in diabetes care and discusses possibilities for making guidelines easier to implement, ensuring that the most effective elements of care are consistently performed.

Improving quality of diabetes care

The prevalence of diabetes in Canada is rising, along with its burden on the healthcare system.¹ Since the majority of diabetic patients are treated by family doctors, they most often determine the quality of diabetes care.² Primary-care providers experience complex and competing demands in managing diabetes, not only because of the multiple steps required, but also because it is just one of many patient problems to be addressed, often in a single visit. Along with limited time, organizational constraints, and varying patient motivation, the result is that many aspects of diabetes care are not consistently implemented.³ The 2008 Report on Ontario's Health System by the Ontario Health Quality Council⁴ reported that: "Most (patients with diabetes) are not getting foot exams, eye exams, or periodic monitoring of blood glucose frequently enough... (and) only 6% of diabetes patients received all of the desired care at the same time."

Clinical practice guidelines (CPGs), linking the evidence from medical research with medical practice, have emerged as a way to help providers negotiate the growing evidence base for clinical practice and provide their patients with optimal care.⁵ The challenges faced by the CPGs are to summarize the evidence and enable its use in practice. While CPGs have been fairly successful in synthesizing the literature on clinical treatment options, less is known about the implementation of CPGs in practice. There are over 350 000 trials in the Cochrane collaboration database on treatments for different diseases,⁶ but only 2400 trials on the practice of consistently implementing effective treatments.⁷ As a result, more is known about recommended treatment from the guidelines than about the approaches needed to implement these treatments in practice.

Knowledge translation is the study of methods to bridge the gap between what is known as effective in medicine, and what is routinely done.⁸ Extrinsic or intrinsic implementation strategies are used to achieve this goal;⁹ extrinsic strategies focus on modifying the environment or clinician behaviour to improve guideline adherence. While this is the most common approach that is applied and has been tested in the literature, the costs as well as the effectiveness of these strategies are highly variable and it is not clear which ones offer the best value.¹⁰ Intrinsic implementation strategies, on the other hand, modify the guidelines to facilitate the application of the evidence and improve quality of care. Although intrinsic implementation strategies have not been extensively tested, they have



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the potential to be highly cost-effective. For example, focusing on changes to the guideline development process requires minimal additional resources, which potentially makes it the most efficient strategy to enhance the use of clinical practice guidelines. Prior to a detailed discussion of intrinsic approaches to guideline implementation, it is important to review how guidelines currently inform clinical decisions; in particular, how CPGs help primary-care providers prioritize care decisions in a context of constraint.

Prioritization in diabetes care

Guidelines are supposed to guide healthcare providers and enable them to make clinically relevant, evidence-based decisions. Some studies suggest, however, that providers follow “mindlines” rather than guidelines when making healthcare decisions; ie, they rapidly glean small bits of information from documents or colleagues to support clinical decisions instead of systematically reviewing guidelines.¹¹ Additional research suggests the extent to which prioritization is a conscious or reasoned decision is unclear; for example, in a survey of general practitioners from community health centres in the United States, respondents ranked monitoring of blood glucose and glycated hemoglobin (HbA_{1c}), eye exams, foot exams, diet, and exercise recommendations as equally important.¹² However, quality-of-care audits reveal that provider adherence to these recommendations is extremely variable.³ Clearly, there are gaps between what is known about what providers think is important, what they are told to do through clinical practice guidelines, and what they are able to do consistently in a clinical setting. A recent qualitative study in a context where the prioritization of care is particularly necessary summarizes some of these gaps.¹³

Sioux Lookout Zone in Northwestern Ontario has one of the highest rates of diabetes in the world; the population consists of remote Aboriginal communities where care is provided in nursing stations with periodic physician visits.¹³ Nurses, physicians, diabetes educators, and community-health representatives were interviewed to understand how they prioritized care in a context of significant resource constraint. These interviews revealed 3 main themes:

- Providers were overwhelmed with the volume and complexity of care required
- Providers were unsure about what elements of diabetes care to prioritize
- Providers did not consider that they were able to provide informed and balanced care.

Volume and complexity of care

Providers explained that they are often overwhelmed by the amount of work required and, as a result, are unable to implement all guideline recommendations consistently. As one participant explained, “It [diabetes care] is very labour intensive because there are so many

diabetics.” The suggestion that current practice guidelines be adapted, simplified, or amended to help providers better manage and prioritize their care was both implicitly and explicitly noted throughout the study.

Priority indecision

Given an inability to implement all aspects of the guidelines, providers explained their priorities and why. Some doctors ranked blood pressure as a high priority, while cholesterol management and glycemic control ranked second and third. Foot exams and neuropathy were given lower priority status because providers felt they lacked the time, knowledge, or resources to deal with these complications in a patient who screened positive. However, some doctors and most nurses did not identify any priorities at all. This is exemplified by the following doctor’s thoughts on prioritizing care:

I’m stumbling because I haven’t gotten to the point where I’ve assigned greater or lesser importance to one or the other, like there’s a number of them and I try to do them all, but if I had to choose one, I’m not sure what to choose, maybe an aspirin (laugh)... I don’t know what criteria I would use, right now, to prioritize them. So, certainly with the nurses, I try and encourage them to look at the package.

It is interesting that this provider cites acetylsalicylic acid, with a benefit that is unclear in many patients, as the one intervention possibly chosen.^{14,15} Specific supports and/or tools designed to help providers make decisions and prioritize care could clarify this and, potentially benefit both clinicians and patients.

Balancing priorities

The need for a comprehensive knowledge base, as well as many different skills to provide adequate chronic care was also raised, particularly in the context of balancing the medical management of diabetes with lifestyle counseling. As one participant explained:

You’ve got to know everything from a comprehensive clinical exam to managing everything from ACE inhibitors to statins, to glyburide, to biguanides, glitazones... and the major things that would really make a difference are proper weight and exercise, so we’ve medicalized a problem and we’re giving a double message: diet and exercise are the most important things, and I am going to spend the next 10 minutes on your medication...

This quote also speaks to the limited time available for healthcare providers to engage with patients on a large number of issues, as well as the confusion faced by providers and patients in trying to manage this balancing act.

This study and the literature on barriers to care suggest that reducing the complexity and focusing the attention of providers on certain aspects of care could improve the consistent use of interventions with the greatest impact in primary care.

Clinical practice guidelines (and their critiques)

CPGs are designed to enable healthcare providers to remain current in the latest medical knowledge, and provide the most effective and appropriate care to their patients.^{16,17} While CPGs are designed to help guide decision-making and facilitate the translation of research evidence into practice, they have been criticized on a number of different fronts. Some of the major criticisms are reviewed below.

The development of clinically valid practice guidelines has been widely discussed in the literature.^{18,19} Although beyond the scope of this article, it is important to note that both the manner of guideline development and the persons involved in the development can affect the validity and clinical relevance of a guideline.^{20,21} CPGs are thorough, but their presentation has been described by one expert as follows: “Although guidelines are an efficient exercise in research synthesis and summary, the full documentation can run to hundreds of pages—a volume that is beyond all but the most committed reader.”²² A recent article published in *JAMA* reviewed the evidence underlying the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines from 1984 to 2008.²³ The authors found that the number of recommendations has consistently increased over time and CPGs are longer now than ever before, but are not more evidence-based.²³ For instance, there are more class II recommendations (conflicting evidence and/or divergence of opinion about the usefulness/efficacy of a procedure or treatment) and a fairly constant number of class I recommendations (conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective). Further, the most common designation for the level of evidence is the lowest level (level C), meaning that a large portion of the recommendations are based solely on expert opinion, case studies, or standard care.²³ More information (that is not more evidence-based) is a potential hindrance to the implementation of these guidelines and a concern for the provision of high-quality care.

In response to the increased length of CPGs, guideline developers have adopted new formatting techniques to highlight key recommendations and summarize the vast quantity of research.²⁴ While this is meant to help clarify the important aspects of the guidelines, ambiguity and vagueness in CPGs may inhibit the ability of healthcare providers to make quick and easy decisions about care.²⁵ This relates to concerns that guidelines tend to offer general guidance, as opposed to specific and prescriptive action.²⁶ As Shaneyfelt and Centor²⁷ state:

Guidelines are often too narrowly focused on single diseases and are not patient focused. Patients seldom have single diseases and few if any guidelines help physicians manage complexity. Paradoxically, guidelines are often too comprehensive, covering every possible

intervention that could be possible for a patient with that single disease....If there is a main message in such guidelines, it is likely to be lost in the minutiae (emphasis added).

Given the complexity of guidelines and their focus, healthcare providers will undoubtedly continue struggling to understand what evidence should be used in practice and what processes of care should be prioritized.

A randomized, controlled trial (RCT) conducted by Shekelle et al²⁸ compared the effects of clinicians receiving no guidelines with those receiving vignettes containing specific and nonspecific language. These comparisons revealed an important link between the clarity of guidelines with their implementation. For example, the study found that physicians receiving nonspecific guideline recommendations make fewer appropriate clinical decisions than those receiving no guideline. Conversely, those receiving specific recommendations made more clinically appropriate decisions than those receiving nonspecific guidelines.²⁸

All of the critiques discussed above suggest that the current development, use, and understanding of CPGs may limit their implementation. The question is: what other characteristics of CPGs predict their implementation?

Implementability

The complexity of guidelines and the lack of clear or behaviourally specific language are often labelled as intrinsic barriers to CPG implementation.^{26,29} Synthesizing guidelines and presenting them in more readable and usable formats (eg, pocket cards, algorithms, etc.) are increasingly used to improve the implementation of CPGs; however, these tools are not always systematically developed, and the process may open the evidence to misinterpretation. “Implementability” is a term used to refer to a set of characteristics that predict the relative ease of implementation of guideline recommendations.⁹ By focusing on the implementability of a guideline and clarifying its message, it becomes easier to implement the recommendations and develop simple tools for practice without losing sight of the evidence.

The development and use of an “implementability tool” is one way to modify CPGs. The GuideLine Implementability Appraisal (GLIA) is a tool designed by a team at Yale to assist in providing information for guideline developers and users.⁹ Targeting guideline developers can ensure that implementability is considered in the development process because this is the ideal time to remedy the ambiguity, vagueness, and complexity of CPGs.²⁵ It is also important to engage guideline implementers (ie, healthcare providers – nurses, doctors, etc.) in using the tool to select (or prioritize) feasible recommendations or in devising strategies to overcome implementation barriers.

The GLIA tool consists of 9 different dimensions: decidability (under what circumstances should something be done); executability (what to do); effect on process of care (what the effect is on normal workflow); presentation and formatting (easily recognizable and distinct); measurable outcomes (with identified endpoints and tracking capability); apparent validity (reflecting the intents of the developers and the evidence); novelty/innovation (proposing new ideas or unconventional practices); flexibility (room for interpretation and execution); and computability (ease of electronic operationalization, when applicable).⁹ There are 24 questions to guide the user through these dimensions and their application on individual guidelines; 7 additional questions are dedicated to “global considerations,” focusing on the guideline as a whole.

Enhancing the implementability of diabetes guidelines

To test the GLIA tool, it was applied to recommendations from the Canadian Diabetes Association (CDA) 2008 Clinical Practice Guidelines¹⁴ in writing a summary for the *Canadian Family Physician*.³⁰ For brevity, the levels of evidence and grades were collapsed into a single letter score (Table 1). Table 2 outlines the original and GLIA-revised CDA recommendations. Revisions to the recommended targets for dyslipidemia and hypertension largely focused on reducing unnecessary text, clarifying if-then statements, and highlighting the key points. This is consistent with GLIA, which underlines the importance of clear, concise, valid, and flexible CPGs.

While the revision of these recommendations was fairly straightforward, applying GLIA to a more complex recommendation was challenging. Consider recommendation #2 under “Targets for Glycemic Control” in the 2008 CDA CPG:

A target HbA_{1C} of ≤6.5% may be considered in some patients with type 2 diabetes to further lower the risk of nephropathy [Grade A Level 1A (4)], but this must be balanced against the risk of hypoglycemia [Grade A Level 1A (4,5)] and increased mortality in patients who are at significantly elevated risk of cardiovascular disease [Grade A Level 1A (4)].

It is clear that simple word changes and/or reduction of text will not be sufficient because there are several areas of ambiguity. For example, what is meant by “some patients”? How do you compare the risks of nephropathy and hypoglycemia? What does a “significantly elevated risk of cardiovascular disease” mean? In order to answer these questions, the trade-offs between fidelity to the evidence and clarity of the message must be

Table 1: Criteria for assigning levels of evidence and grades to CPG recommendations

<p>Grade A: The best evidence is level 1 Level 1A: Systematic overview or meta-analysis of high-quality randomized controlled trials OR appropriately designed randomized controlled trial with adequate power to answer the question posed by the investigators Level 1B: Nonrandomized clinical trial or cohort study with indisputable results</p>
<p>Grade B: The best evidence is level 2 Level 2: Randomized controlled trial or systematic overview that does not meet level 1 criteria</p>
<p>Grade C: The best evidence is level 3 Level 3: Nonrandomized clinical trial or cohort study</p>
<p>Grade D: The best evidence is level 4 or consensus Level 4: Other</p>

understood. Facilitating a dialogue between experts in clinical evidence (guideline developers) and experts in contextual constraints (guideline users) could ensure that evidence is not lost during the clarification process.

A review of the GLIA tool and the concept of implementability raise a number of important questions. The first relates to the ease of the application of GLIA; 9 different dimensions per recommendation and 30 questions in total make the tool too complex and time consuming, even for an engaged user. Therefore, refining GLIA to highlight some key sections and clarify the purpose will likely improve its usability and effectiveness. Another concern with the GLIA tool is the primary focus on individual recommendations and, as a result, the overall ease for guideline implementation is not assessed. This focus on individual recommendations is a significant limitation because the purpose of a CPG is not only to implement the different recommendations, but also to provide guidance about providing optimal care.

Underlying the topic of implementability is the question of what can be addressed by modifying the environment versus modifying the guideline? It is not clear whether interventions that modify the environment to influence clinician behaviour (eg, reminders, audits and feedback, education, etc.) have a greater impact than modifying the guideline itself.²⁶ However, because the costs of extrinsic strategies are much higher and are not clearly more effective, further research on intrinsic implementation strategies appear to be warranted.

Table 2. A comparison between original CDA 2008 CPG recommendations and GLIA-revised CDA 2008 CPG recommendations		
	CDA 2008 CPG Recommendations	Revised CDA 2008 CPG Recommendation
Dyslipidemia	#3: Individuals at high risk of a vascular event should be treated with a statin to achieve an LDL-C \leq 2.0mmol/L [Grade A, Level 1 (20,22), Level 2 (24)]. Clinical judgement should be used as to whether additional LDL-C lowering is required for those with an on-treatment LDL-C of 2.0 to 2.5 mmol/L [Grade D, Consensus].	#3: Adults at high risk of a vascular event should be treated with a statin to achieve an LDL-C \leq 2.0 mmol/L [A].
Treatment of hypertension	#3: Persons with diabetes and hypertension should be treated to attain a systolic BP <130 mm Hg [Grade C, Level 3 (2, 13, 14)] and diastolic BP, 80 mm Hg [Grade B, Level 2 (11,12)]. These target BP levels are the same as BP treatment thresholds [Grade D, Consensus].	#3: Treatment should target BP <130/80 mm Hg ([C] for systolic BP; [B] for diastolic BP).

Conclusion

A recent study funded as part of Knowledge Translation Canada (KT Canada)³¹ is based on operationalizing the concept of implementability, and embedding it in the development of implementation tools (like pocket cards) and guidelines. Working with 2 partners, the CDA and the Canadian Thoracic Society (CTS), the goal is to extend the view of implementability to the guideline as a whole, and analyze the overall usability and feasibility of current CPGs within the context of primary care.

In this process of clarifying and simplifying guidelines, it is possible that “asking for less will provide more,” and will help providers to consistently perform to most important clinical steps. However, it is also possible that “asking for less will offer less;” ie, leading providers to neglect issues that could have been addressed. There is a great deal to learn about the relative costs and benefits of modifying guidelines to improve quality of care. Integrating these issues into the guideline development process will ensure that future guidelines can simplify complex care pathways, identify key interventions, and help providers balance these priorities given the constraints of routine clinical practice.

Dr. Bhattacharyya is a family physician and clinician scientist with the Li Ka Shing Knowledge Institute of St. Michael's Hospital. Ms. Estey is a research coordinator with the Li Ka Shing Knowledge Institute of St. Michael's Hospital.

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31. Study Accessible at: <http://ktclearinghouse.ca/ktcanada> and/or <http://www.kusp.ualberta.ca/KTCanada.cfm>

Abstract of Interest

Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

TRICOCI P, ALLEN JM, KRAMER JM, CALIFF RM, SMITH SC.

CONTEXT: The joint cardiovascular practice guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA) have become important documents for guiding cardiology practice and establishing benchmarks for quality of care.

OBJECTIVE: To describe the evolution of recommendations in ACC/AHA cardiovascular guidelines and the distribution of recommendations across classes of recommendations and levels of evidence.

METHODS: Data from all ACC/AHA practice guidelines issued from 1984 to September 2008 were abstracted by personnel in the ACC Science and Quality Division. Fifty-three guidelines on 22 topics, including a total of 7196 recommendations, were abstracted.

DATA EXTRACTION: The number of recommendations and the distribution of classes of recommendation (I, II, and III) and levels of evidence (A, B, and C) were determined. The subset of guidelines that were current as of September 2008 was evaluated to describe changes in recommendations between the first and current versions as well as patterns in levels of evidence used in the current versions.

RESULTS: Among guidelines with at least 1 revision or update by September 2008, the number of recommendations increased from 1330 to 1973 (+48%) from the first to the current version, with the largest increase observed in use of class II recommendations. Considering the 16 current guidelines reporting levels of evidence, only 314 recommendations of 2711 total are classified as level of evidence A (median,

11%), whereas 1246 (median, 48%) are level of evidence C. Level of evidence significantly varies across categories of guidelines (disease, intervention, or diagnostic) and across individual guidelines. Recommendations with level of evidence A are mostly concentrated in class I, but only 245 of 1305 class I recommendations have level of evidence A (median, 19%).

CONCLUSIONS: Recommendations issued in current ACC/AHA clinical practice guidelines are largely developed from lower levels of evidence or expert opinion. The proportion of recommendations for which there is no conclusive evidence is also growing. These findings highlight the need to improve the process of writing guidelines and to expand the evidence base from which clinical practice guidelines are derived.

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