

Ajouter de la «valeur» aux guides de pratique clinique

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RÉSUMÉ

OBJECTIF Déterminer dans quelle mesure les guides de pratique clinique canadiens (GPC) sur les problèmes chroniques communs (p. ex., diabète, dyslipidémie, hypertension et ostéoporose) traitent de l'importance des valeurs et des préférences des patients dans la prise de décisions thérapeutiques, et fournissent des renseignements quantitatifs permettant une prise de décisions détaillée, éclairée et partagée.

CONCEPTION Étude rétrospective par observation.

PRINCIPALES MESURES DES RÉSULTATS La présence ou l'absence de mentions précises de l'importance de tenir compte des valeurs et des préférences des patients dans la prise de décisions thérapeutiques; le nombre (relatif ou absolu) et le genre de descriptions quantitatives des avantages et des inconvénients; le nombre des interventions pour lesquelles on peut déterminer de manière quantitative la probabilité qu'un patient donné obtiendra un résultat avec ou sans l'intervention thérapeutique; et le nombre de descriptions de coûts spécifiques ou comparatifs du traitement.

RÉSULTATS Trois des 5 GPC mentionnaient que les valeurs et les préférences des patients devraient influencer les décisions de traitements. Aucun des GPC ne recommandait que les avantages et les inconvénients des thérapies soient discutés avec les patients. Parmi les 63 mentions quantitatives des effets thérapeutiques des interventions, 81% étaient présentées en termes relatifs et 19% répondaient à nos critères d'applicabilité à la prise de décisions par les patients à titre individuel. Deux des 5 GPC n'indiquaient aucun inconvénient et 3 des 5 GPC ne mentionnaient pas le coût.

CONCLUSION Cinq GPC canadiens renommés accordaient peu d'attention à la question des valeurs et des préférences des patients dans la prise de décisions thérapeutiques, même si ces facteurs revêtent une importance fondamentale dans la pratique fondée sur des données scientifiques. Ces 5 GPC offraient des renseignements quantitatifs limités sur les avantages et les inconvénients, et ne devraient donc pas être utilisés par les cliniciens pour faire participer véritablement les patients à une prise de décisions éclairée.

POINTS DE REPÈRE DU RÉDACTEUR

- La médecine fondée sur des données scientifiques n'est pas seulement un synopsis des données de recherche; elle devrait intégrer les données probantes aux valeurs du patient et à l'expérience clinique des cliniciens.
- Pour que les guides de pratique clinique permettent une véritable participation des patients aux décisions thérapeutiques, ils devraient présenter des renseignements et des outils dont peuvent se servir les cliniciens pour conseiller leurs patients sur les risques et les avantages des options thérapeutiques à leur disposition.
- Dans cette étude, on a observé que 5 guides de pratique clinique canadiens renommés ne donnaient pas assez de renseignements pour une prise de décisions complète et partagée, mais les auteurs ont présenté une série de recommandations qui peuvent servir dans l'élaboration de futurs guides de pratique clinique.

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Adding "value" to clinical practice guidelines

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ABSTRACT

OBJECTIVE To determine the degree to which current Canadian clinical practice guidelines (CPGs) for common chronic conditions (ie, diabetes, dyslipidemias, hypertension, and osteoporosis) discuss the importance of patients' values and preferences in therapeutic decision making, and provide quantitative information that would allow for comprehensive shared informed decision making.

DESIGN Retrospective, observational review.

MAIN OUTCOME MEASURES The presence or absence of specific mentions of the importance of incorporating patients' values and preferences into therapeutic decision making; the number and type (relative or absolute) of quantitative descriptions of benefit or harm; the number of interventions for which a means of quantitatively determining the probability that an individual patient will experience an end point without and with implementation of the therapeutic intervention; and the number of descriptions of specific or comparative costs of treatment.

RESULTS Three of 5 CPGs mentioned that patients' values or preferences should influence treatment decisions. None of the CPGs recommended that benefits and harms of therapies be discussed with patients. Of the 63 quantitative mentions of therapeutic effects of interventions, 81% were presented using relative terms and 19% met our criteria for applicability to decision making for individual patients. Two of the 5 CPGs did not enumerate any harms. Three of the 5 CPGs made no mention of cost.

CONCLUSION Five prominent Canadian CPGs paid little attention to the issue of patients' values and preferences in therapeutic decision making, even though these issues are fundamental tenets of evidence-based practice. These 5 CPGs provided limited quantitative information on benefits and harms and therefore could not be used by clinicians to truly involve patients in informed decision making.

EDITOR'S KEY POINTS

- Evidence-based medicine is not just a synopsis of research evidence; it should integrate the evidence with patients' values and clinicians' clinical expertise.
- For clinical practice guidelines to permit meaningful involvement of patients in therapeutic decision making, the guidelines should include information and tools that allow clinicians to counsel their patients about risks and benefits of available therapeutic options.
- While this study found that 5 prominent Canadian guidelines did not provide enough information for comprehensive, shared decision making, the authors have provided a series of recommendations for use in developing future guidelines.

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Clinical practice guidelines (CPGs) are intended to assist clinicians in making decisions about individual patient management.¹ Clinicians often rely on CPGs for therapeutic decision making, and numerous professional societies and patient advocacy groups actively disseminate CPGs.^{2,3} Many contemporary CPGs include a process by which evidence from the primary literature is incorporated into their recommendations and, as such, even if not explicitly stated, are portrayed as evidence-based.⁴

Evidence-based medicine is not just a synopsis of research evidence. Evidence-based medicine has been defined as "the integration of best research evidence with clinical expertise and patients' values."⁵ The third component of this definition, patients' values, has been further defined as "the unique preferences, concerns and expectations each patient brings to a clinical encounter and which must be integrated into clinical decisions if they are to serve the patient."⁶ Guidelines created to aid in the development of CPGs suggest CPGs "should discuss the role of patient preferences for different courses of health care for those conditions or technologies in which patients' values and preferences may be important decision-making factors"⁷ and they should "...describe the role of patient preferences when a recommendation involves a substantial element of personal choice or values."⁴

Incorporating patients' preferences is particularly important when deciding on long-term treatment of asymptomatic (at least often initially) conditions, such as diabetes, dyslipidemia, hypertension, and osteoporosis. This is illustrated by the cognitive dissonance that appears to occur between CPGs and patients' and clinicians' preferences. For instance, less than one third of patients with or without a history of heart disease expressed the willingness to take a "safe" drug if the absolute chance of reducing a heart attack over 5 years was $\leq 5\%$.⁸ However, using statins even in post-myocardial infarction patients produces less than a 5% absolute reduction in the chance of a heart attack over 5 years.⁸ Another study involving interviews with health professionals and lay people found preferences for drug therapy to prevent heart attacks were incongruent with recommendations in "evidence-based" guidelines.⁹

To enable clinicians to incorporate patients' preferences into the decision-making process for such conditions as

diabetes, dyslipidemia, hypertension, and osteoporosis, CPGs need to provide a means to estimate an individual's baseline risk of an event of interest (eg, risk of myocardial infarction over 10 years). In addition, CPGs should provide a synopsis of the evidence for therapeutic options with detail, in quantitative terms, of the magnitude of therapeutic and harmful effects for each option and some idea of the costs. Finally, approaches for using the evidence to quantitatively determine the probability that the patient will experience an end point without and with therapy, and for quantifying the harms associated with that therapy should be provided. Clinical practice guidelines, particularly those that profess or aspire to be "evidence-based," are an ideal mechanism for communicating these essential data so clinicians can integrate this information with their own clinical expertise when incorporating their patients' values and preferences into evidence-based decision making.

We analyzed the current Canadian CPG documents for diabetes, dyslipidemias, hypertension, and osteoporosis to determine the degree to which they mentioned the importance of patients' values and preferences in therapeutic decisions. In addition, we assessed whether the CPGs acknowledged the importance of discussing risks and benefits with patients, and the degree to which they presented clinicians with the tools and data that would enable them to engage patients in informed discussions about the benefits and harms of available therapeutic options.

METHODS

For the CPG selection, diabetes, dyslipidemias, hypertension, and osteoporosis were chosen as the conditions of interest. This choice was based on the high prevalence of these conditions in the Canadian population, their frequent asymptomatic nature, and the availability of numerous pharmacologic and nonpharmacologic interventions aimed at decreasing the chance of clinical sequelae of the conditions.

Several CPG documents were analyzed concerning diabetes, dyslipidemias, dyslipidemia in diabetes, hypertension, and osteoporosis.

- Diabetes: the Canadian Diabetes Association developed the 2003 CPGs for prevention and management of diabetes in Canada.¹⁰
- Dyslipidemias: the Canadian Cardiovascular Society developed the 2006 CPGs for diagnosis and treatment of dyslipidemia and prevention of cardiovascular disease.¹¹
- Dyslipidemia in diabetes: the Canadian Diabetes Association developed the 2006 CPGs for dyslipidemia in adults with diabetes.¹²
- Hypertension: the Canadian Hypertension Education Program developed the 2006 recommendations for management of hypertension.¹³⁻¹⁶

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- Osteoporosis: the Scientific Advisory Council of the Osteoporosis Society of Canada developed the 2002 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada.¹⁷

Data collection

Both authors searched the complete contents of the CPGs, including the appendices, for any mention of patients' values, preferences, or participation in informed decision making. All quantitative reports of benefits and harm mentioned and any discussions of costs were collated. Next the authors compared their individual results and resolved any discordance through discussion and reference to the source documents until they reached consensus.

All mentions of or recommendations surrounding the issues of patient values, preferences, or participation in informed decision making were captured.

The CPGs were reviewed to see if a patient-specific technique or tool for estimating baseline risk was provided, and what specific clinical end points the tools calculated. In addition, mentions of the potential limitations of these tools were also collected.

Analysis

Potential benefit. Each instance of the magnitude of benefit described in the context of a therapeutic intervention was captured and the type of measure was tabulated: use of relative measures (relative risk reduction [RRR], relative risk [RR], odds ratio [OR], hazard ratio [HR]) or absolute measures (absolute risk reduction [ARR], number needed to treat or harm [NNT or NNH], events prevented or caused per 1000 patients treated). Only magnitudes for the clinical consequences of the conditions studied were considered relevant end points for this study. Effects of interventions on surrogate end points, such as lipid levels, bone mineral density, hemoglobin A_{1c}, or blood pressure readings, were not included in the analysis. These were deemed less relevant to patients' values than clinical outcomes because the sole reason for treatment based on these surrogate markers is to decrease the incidence of specific negative clinical outcomes (Table 1).

Potential harm. All measures of harms associated with therapy were documented. Because cost of therapy is potentially important in decision making, all mentions of the costs or comparative costs of specific therapies were documented.

End points. The end points of primary interest for each CPG were as follows:

1. the presence or absence of specific mentions of the importance of incorporating patients' values and preferences into therapeutic decision making;

Table 1. Outcomes relevant in the analysis

Diabetes
Overall mortality
Cardiovascular disease mortality
Coronary artery disease events
Major adverse cardiac events
Stroke
Revascularization
Peripheral vascular disease
Heart failure
Overall serious adverse events
Avoidance of diabetes, graft survival, ophthalmopathy (retinopathy, blindness, visual acuity)
Microvascular complications
Renal failure, hospitalization, amputation
Dyslipidemias and hypertension
Overall mortality
Cardiovascular disease mortality
Coronary artery disease events
Major adverse cardiac events
Stroke
Revascularization
Peripheral vascular disease
Heart failure
Overall serious adverse events
Osteoporosis
Overall mortality
Fractures (all types)
Pain
Overall serious adverse events

2. the number and type (relative or absolute) of quantification of benefit or harm;
3. the number of interventions for which a means of quantifying the probability that an individual patient will experience an end point with or without the therapeutic intervention; and
4. the number of descriptions of specific or comparative costs of treatment.

To be considered for the third end point, 1 of 2 conditions was required:

- a risk-estimation tool must have been provided along with presentation in relative terms (RR, RRR, OR, HR) of the effect of a therapeutic intervention corresponding to the specific end point(s) estimated by the risk-estimation tool*; or
- the absolute incidence of a relevant end point in patients not receiving and receiving a therapeutic intervention accompanied by a description of the patient population in the study sufficient for a clinician to determine the degree of similarity to a patient to be treated.

Presentation solely of absolute risk reduction (ARR) was deemed insufficient, as were RR, RRR, HR, or OR in the absence of a risk-estimation tool or baseline risk-level data.

RESULTS

The 5 guidelines made up 90600 words and 197 pages in total (Table 2¹⁸).

Importance of incorporating patients' values and preferences into therapeutic decision making. All the relevant text discussing patients' values and preferences found in the CPGs is listed in Table 2.¹⁸ Three of the 5 CPGs mentioned that patients' values or preferences should influence treatment decisions (Table 2). None of the CPGs recommended that benefits and harms of therapies be discussed with patients; however in 2 CPGs, there was some mention of discussing risk levels with patients (Table 2). A total of 99 words were found to be relevant to the issues of patients' values and preferences—approximately 0.1% of the total words in the guidelines.

Measures of benefits or harms. There were a total of 63 quantifications of therapeutic effects of interventions; 81% (51/63) were presented using relative terms (Table 3). Of the 63, 47 were quantitative descriptions of drug benefits, 94% (44/47) in relative terms. The other 16 quantitative descriptions were for nondrug therapies, 44% (7/16) in relative terms. Thirty-six specific therapeutic interventions (27 drug, 9 nondrug) had at least one quantitative mention of benefit in the CPGs.

With respect to harms of therapy, 2 of the CPGs (hypertension, dyslipidemia in diabetes) provided no quantification of any harms (Table 4). In the 3 CPGs that did report harm (diabetes, osteoporosis, dyslipidemia), there were a total of 35 quantifications of harms. In contrast to the 81% of benefits presented in relative terms, 17% (6/30) of harms were presented in relative terms. Particularly notable was the absence of discussion or presentation of risks associated with widely used therapies. For example, the diabetes CPGs did not mention lactic acidosis associated with metformin. The hypertension CPGs—other than for thiazides (hypokalemia), and mentions of hypotension, hyperkalemia, and worsening renal function for angiotensin-converting enzyme inhibitors and angiotensin receptor blockers—made no mention of any side effects.

*For example, if one could estimate the 10-year baseline risk of stroke as being 4% for a specific patient, and one knew that a therapy reduced the risk of stroke by 25%, these 2 pieces of information could be used to provide the patient with a quantifiable likelihood of stroke risk reduction by implementing that therapy. Conversely, if the tool estimated the risk of overall cardiovascular disease only, data about the stroke-preventing efficacy of that therapy would not be useful in predicting an individual's risk of either stroke or cardiovascular disease.

Information we need

We offer the following recommendations to creators of therapeutic clinical practice guidelines (CPGs) for chronic conditions to maximize their utility.

1. Remind clinicians of the importance of incorporating patients' values and preferences into therapeutic decisions and provide examples of how this could be done.
2. Remind clinicians of the importance of involving patients in decisions should patients wish this.
3. Provide clinicians with a simple and practical tool to estimate patients' risk of experiencing a clinically relevant event over relevant time frames. In addition, CPGs should discuss in detail the potential limitations of such tools and, if there is evidence available, how closely the estimates relate to the population for which the guidelines are intended.
4. When describing the evidence for efficacy of interventions, include a description of the patient population studied so its applicability to the patient at hand can be judged.
5. When describing the evidence for efficacy of interventions, include clear estimates of the effects in relative terms (where an individualized risk-estimation tool is available) or describe the absolute magnitude of the effect, including the time frame over which it occurred (when no individualized risk-estimation tool is available).
6. Provide a table of results for all therapies (with all relevant clinical end points), in both relative and absolute terms, and indicate when there is no information or when the data do not apply to specific patient subsets.
7. When describing the evidence for efficacy of interventions, ensure that the end points discussed are directly relevant to the risk-estimation tool promoted in the CPG.
8. When describing the harms of interventions, include quantitative estimates of harms (preferably in absolute terms) for common adverse effects (even if minor) and serious adverse effects (even if rare), and, if possible, include a comparison with placebo so that clinicians can put the information into context for patients.
9. Explicitly state the values and preferences that underlie recommendations in which there are important inherent tradeoffs of efficacy, safety, cost, or convenience.
10. Provide clinicians with estimates of the potential costs of therapies or with comparisons between therapies.
11. Recommend that clinicians discuss the risks and benefits of the available therapies with patients before prescribing decisions are made, and provide examples of how this could be done.
12. Focus CPGs more on individualized risk assessment, clinically important effects of interventions, and shared decision making and less on specific breakpoints for surrogate outcomes (cholesterol, blood pressure, glucose, bone density).

Individualizing the magnitude of the benefit. Four of the 5 CPGs recommended the use of a specific risk-estimation tool (Table 2¹⁸), although none provided explicit instructions on how to use the tool or how to communicate this information to patients. The clinical end points for which the tools calculated a 10-year risk are listed in Table 2.

Of the relative mentions of benefit, 24% (12/51) were for end points that could be calculated using the recommended risk-estimation tool. None of the absolute mentions of benefit had associated with it a description of the studied population sufficient to allow extrapolation to a specific patient. Hence, of the 63 quantifications of benefit of interventions, 12 (19%) met our criteria for making individualized patient decisions.

Costs of treatments. In 3 of the 5 guidelines, there was no mention of costs (Table 2¹⁸). Overall, there were 3 mentions of the cost of therapy, only one of which involved a specific intervention in relation to other therapeutic options (Table 2).

INTERPRETATION

This analysis revealed that little attention was paid to the issue of patients' values and preferences for therapeutic decision making in 5 nationally prominent CPGs. In addition, the limited quantitative information provided typically could not be used to inform patients about the benefits and harms of treatments.

Among the CPGs for common chronic conditions analyzed, only 3 explicitly acknowledged the importance of incorporating patients' values and preferences into therapeutic decision making. Although 4 of the 5 CPGs promoted a scheme for estimating an individual's risk of clinical events, these tools could be used with only 24% of the interventions that were quantified.¹²

The relevance of the deficiencies identified can be illustrated by way of example. Using the dyslipidemia in diabetes CPGs,¹² clinicians could employ the United Kingdom Prospective Diabetes Study (UKPDS) risk engine to estimate patients' 10-year risk of stroke. With this information and the Heart Protection Study data presented in the CPG, clinicians can explain to patients that they have a 5% risk of stroke within 10 years without statin therapy and a 3.75% risk if they take simvastatin for those 10 years (based on a 25% RRR in stroke). Hence, patients have an estimated (though how to make the estimation is not discussed in the CPG) 1 in 80 chance of avoiding a stroke (based on the calculated ARR of 1.25%) if they take simvastatin for the next 10 years. However, no information concerning the patient's baseline risk of cardiovascular disease (CVD) or overall mortality (including CVD mortality), or the effects of statin therapy on these end points could be

delivered based on the CPG. No relevant benefit or risk information about diet, exercise, or many of the other drug options is contained in this CPG. Therefore, far less information is contained in the dyslipidemia in diabetes CPG than is required for clinicians to describe the benefits and risks of statin therapy and alternatives appropriately so that clinicians and patients can make a truly informed decision.

Similar examples involving thiazides, β -blockers, or angiotensin-receptor blockers for hypertension, involving diet, acetylsalicylic acid, or glucose-lowering agents for type II diabetes, involving diet or atorvastatin for dyslipidemia could be cited based on this analysis.

With some exceptions (myopathy and increased liver enzymes with statins, hypoglycemia with insulins and insulin secretagogues, increased low-density lipoprotein with gemfibrozil, venous thromboembolism with raloxifene, a number of adverse effects with calcitonin and hormone replacement therapy), little quantitative information related to the harms of drugs was provided.

There are 79 drugs available in Canada for use in the 4 conditions studied (hypertension, 40; dyslipidemia, 13; diabetes, 14; osteoporosis, 8; antiplatelet agents, 4).¹⁹ For only atorvastatin, simvastatin, statins (as a group), alendronate, and hormone replacement could one use the information presented in the guidelines to estimate a potential benefit. A potential harm could be quantified only for insulin, insulin secretagogues (as a group), gemfibrozil, calcitonin, hormone replacement, raloxifene, and statins (as a group).

Missing points

An important deficiency identified in most of the CPGs recommending a risk-estimation tool was little discussion of the limitations of the tools themselves. An exception was the hypertension guidelines and to a small degree the dyslipidemia guidelines. Relevant points that were generally missing from the CPGs included patients to whom the tools should not be applied, precision of the estimates, and the differences between periods over which risk is predicted and the duration of clinical trials that form the basis for risk-modification estimates. For example, numerous limitations of the Framingham risk calculator have been described.²⁰ It is important for clinicians to know about these limitations so they do not use the tool for patients to whom it does not apply or where the absolute risk estimates might not be appropriate for a specific population (eg, using Framingham data for a diabetic patient or one who already has coronary artery disease [CAD]).

Although some might argue that it is impossible or impractical to discuss values and preferences in CPGs, the explicit description of the values and preferences underlying many of the recommendations in The Seventh American College of Chest Physicians Conference on Antithrombotic and Thrombolytic Therapy suggests

Table 2. General characteristics of the clinical practice guideline documents

CHARACTERISTICS OF GUIDELINES *	DIABETES BY THE CANADIAN DIABETES ASSOCIATION	DYSLIPEMIA BY THE CANADIAN CARDIOVASCULAR SOCIETY	DYSLIPEMIA IN DIABETES BY THE CANADIAN DIABETES ASSOCIATION	HYPERTENSION EDUCATION PROGRAM	OSTEOPOROSIS BY THE SCIENTIFIC ADVISORY COUNCIL OF THE OSTEOPOROSIS SOCIETY OF CANADA
Published pages/ [†] Approximate word count (rounded to the nearest 100 and not including references)	118/40 100	10/7800	8/5400	27/18 000	34/19 300
Recommendations that patients' specific risk level be discussed with them	None	None	None	"Consider informing patients of their global risk to improve the effectiveness of risk factor modification"	"When a patient is identified as having a high risk for fracture, a discussion regarding treatment is recommended"
Explicit mentions of incorporating individual patients' values and preferences into therapeutic decision making	"Healthcare professionals must consider the needs, values and preferences of individual patients, use clinical judgement, and work with available human and healthcare service resources in their settings."	None	None	"[H]ealth care workers must ... use their own clinical judgement and consider patient preferences when applying these recommendations"	"Clinical judgment and the patient's preference, as well as evidence-based clinical trial data, will determine if, when and what treatment is initiated"
Name of risk-estimation tool recommended by document	UKPDS risk engine, CLEM at http://www.chiprehab.com/CVD/	Framingham, CLEM	UKPDS risk engine, CLEM	CLEM, UKPDS, Framingham, SCORE, though no particular tool was recommended "Global cardiovascular risk should be assessed, ... but in the absence of Canadian data, ... avoid using absolute levels of risk to support treatment decisions at specific risk thresholds"	Kanis et al ¹⁸
End point(s) predicted by risk-estimation tool—all tools predict 10-year risk	UKPDS: • Non-fatal and fatal CAD • Fatal CAD • Non-fatal and fatal stroke CLEM: • CV age • Risk of "heart attacks and fatal coronary events"	Framingham • Myocardial infarction + coronary death CLEM • CV age • Risk of "heart attacks and fatal coronary events"	UKPDS • Non-fatal and fatal CAD • Fatal CAD • Non-fatal and fatal stroke CLEM • CV age • Risk of "heart attacks and fatal coronary events"	Not applicable, as no particular tool is recommended for use	All fractures (wrist, hip, proximal humerus, or vertebral)
Mention of costs	"[L]ower cost of diuretics"	"A major consideration in terms of pharmacological therapy ... is cost"	None	None	None

CAD—coronary artery disease, CLEM—Cardiovascular Life Expectancy Model, CV—cardiovascular, LDL-C—low-density lipoprotein cholesterol, UKPDS—United Kingdom Prospective Diabetes Study.

*None had recommendations or acknowledged that benefits and harms of interventions should be discussed with patients.

[†]Not including references, appendices, indices, or separator pages

Table 3. Quantification of benefit

TYPE OF INTERVENTIONS	DIABETES BY THE CANADIAN DIABETES ASSOCIATION	DYSLIPIDEMIA BY THE CANADIAN CARDIOVASCULAR SOCIETY	DYSLIPIDEMIA IN DIABETICS BY THE CANADIAN DIABETES ASSOCIATION	HYPERTENSION BY THE CANADIAN HYPERTENSION EDUCATION PROGRAM	OSTEOPOROSIS BY THE SCIENTIFIC ADVISORY COUNCIL OF THE OSTEOPOROSIS SOCIETY OF CANADA	TOTAL
Mentions of quantitative benefit of interventions (n)	25	5	8	7	18	63
Type of quantification (n):	15	5	7	7	17	51
• Relative terms*	10	0	1	0	1	12
• Absolute terms†						
Interventions for which effects were quantified in relative terms* (number of mentions if >1)	<ul style="list-style-type: none"> • Metformin • Exercise (2—type II and type I) • Acarbose • Diet • UKPDS* (2) • Insulin (3—type I) + insulin post-MI • Antiplatelets • Laser treatment (2) • Influenza vaccination 	<ul style="list-style-type: none"> • Statins: no specific regimen mentioned (4) • Physical activity 	<ul style="list-style-type: none"> • Simvastatin (2) • Atorvastatin (3) • Statins • Simvastatin + niacin 	<ul style="list-style-type: none"> • "Antihypertensive therapy" (2) • "Beta-blockers" • Amlodipine or perindopril • Trandolapril • Valsartan • Felodipine 	<ul style="list-style-type: none"> • Alendronate (2) • Risedronate (5) • Calcitonin • HRT • Raloxifene (3) • Fluoride • Teriparatide (3) • Physical activity 	Not applicable
Specific interventions mentioned in relative terms	6 drugs 3 nondrugs	1 drug 1 nondrug	4 drugs 0 nondrug	6 drugs 0 nondrug	7 drugs 1 nondrug	24 drugs 5 nondrugs
Interventions for which effects were quantified in absolute terms* (number of mentions if >1)	<ul style="list-style-type: none"> • Islet cell transplantation • Pancreatic transplantation (4) • Kidney + pancreatic transplantation (2) • Insulin post-MI • Cataract extraction (2) 	None	Simvastatin + niacin	None	Fluoride	Not applicable
Specific interventions mentioned in absolute terms	1 drug 4 nondrugs	0 drug 0 nondrug	1 drug 0 nondrugs	0 drugs 0 nondrugs	1 drug 0 nondrugs	3 drugs 4 nondrugs
Interventions applicable to the risk-estimation scheme promoted (clinical end point)	<ul style="list-style-type: none"> • UKPDS* (MIs) • Exercise for type II diabetes (CV mortality) 	<ul style="list-style-type: none"> • Statins ("major coronary events," "CAD events") • Exercise (CAD) 	<ul style="list-style-type: none"> • Simvastatin (CV events, stroke[§]) • Atorvastatin (CV events, stroke[§]) • Statins (CV disease events[§]) 	<ul style="list-style-type: none"> • None, as no particular tool was recommended for use 	<ul style="list-style-type: none"> • Alendronate (vertebral, hip, and wrist fractures) • HRT (fractures) 	12

CAD—coronary artery disease, CV—cardiovascular, HRT—hormone replacement therapy, MI—myocardial infarction, UKPDS—United Kingdom Prospective Diabetes Study.

*Including relative risk, relative risk reduction, odds ratio, hazard ratio.

†Including absolute risk reduction, number needed to treat or number needed to harm, events caused or avoided per X patients treated, absolute risk levels.

‡The United Kingdom Prospective Diabetes Study refers to the intervention as "intensive therapy" with sulfonylurea, insulin, and metformin.

§The Cardiovascular Life Expectancy Model apparently predicts risk of death due to coronary artery disease, stroke, and "other causes" (*Arch Intern Med* 1998;158(6):655-62), but the referenced site, www.chiprehab.com/CVD/, by the McGill University Comprehensive Health Improvement Program, yields only "heart attacks and fatal coronary events" risks and "cardiovascular age."

Table 4. Quantification of harm: *Two studies (the Canadian Diabetes Association study of dyslipidemia in diabetes and the Canadian Hypertension Education Program study of hypertension) did not quantify harms.*

TYPES OF INTERVENTIONS	DIABETES BY THE CANADIAN DIABETES ASSOCIATION	DYSLIPIDEMIA BY THE CANADIAN CARDIOVASCULAR SOCIETY	OSTEOPOROSIS BY THE SCIENTIFIC ADVISORY COUNCIL OF THE OSTEOPOROSIS SOCIETY OF CANADA	TOTAL
Mentions of quantitative harm of interventions (n)	11	6	18	35
Type of quantification (n):	0	0	6	6
• Relative terms*	11	6	12	29
• Absolute terms [†]				
Interventions for which adverse effects were quantified in <i>relative terms</i> * (number of mentions if >1)	None	None	• HRT (5) • Raloxifene	Not applicable
Interventions for which adverse effects were quantified in <i>absolute terms</i> [†] (number of mentions if >1)	• Insulin (6) • Insulin secretagogues (2) • Islet transplantation (2) • Gemfibrozil	Statins (6)	• Calcitonin (9) • HRT (2) • Raloxifene	Not applicable

HRT—hormone replacement therapy.
 *Including relative risk, relative risk reduction, odds ratio, hazard ratio.
[†]Including absolute risk reduction, number needed to treat or number needed to harm, events caused or avoided per X patients treated, absolute risk levels.

otherwise.^{21,22} Others might contend that clinicians consider patients' values routinely and do not need to be told to do so by CPGs. While this might be partially true, our analysis revealed that, even if clinicians wanted to individualize the benefits and risks of commonly prescribed therapies (ie, by estimating the patient's risk of an event without the therapy, and the patient's chance of benefit and harm while using the therapy) so as to involve patients in a truly informed decision, the CPGs generally do not even recommend individualization, let alone provide the required data or guidance on how to do so. We are unaware of a routinely used alternative source of this type of information.

Not all patients wish to be involved in discussing the benefits and harms of therapies available to them^{23,24}; however, inclusion of the elements discussed in our analysis could improve clinicians' understanding of the magnitude of the benefit and harm and would aid clinicians making decisions on behalf of their patients.

Our analysis has some limitations. Quantitative effects of interventions on several clinically relevant end points were included in some of the CPGs but were not credited in our analyses (eg, following solid organ transplant for diabetes, post-myocardial infarction insulin in diabetes) because we deemed the patient population to be unsuitable for the risk-estimation tool promoted in the CPG. This would lead to a slight underestimate of the absolute number of interventions for which quantitative effects were described. We also excluded several mentions of CVD from our estimate of interventions applicable to the risk-estimation tools promoted because the tools were designed to estimate

the more limited end point of CAD. Cardiovascular disease includes stroke or transient ischemic attack, while CAD does not. For the hypertension guidelines, we analyzed only the currently published version of the guidelines, in which there were many references to supporting evidence published in previous versions of the guidelines. It could be argued that our strategy ignored efforts to provide clinicians with quantitative data applicable to individual treatment decisions in these older documents or that we held the guideline writers to an impossible standard of annually reiterating all previous results. We believe, however, that clinicians treating patients expect a guideline document to be relatively self-contained and expect all summary information required to make evidence-based treatment decisions be readily at hand. Clinicians faced with a need or opportunity to make an individualized treatment decision are unlikely to seek multiple older versions of the guidelines. This issue could be remedied by providing tables in the current versions of the CPGs summarizing quantitative risk reduction and harm information for the various treatments discussed.

Conclusion

Five prominent Canadian CPGs paid little attention to the issue of patients' values and preferences in therapeutic decision making despite the issue's importance as a fundamental tenet of evidence-based practice. These 5 CPGs provided limited quantitative information on benefits and harms; therefore, they cannot effectively be used by clinicians to involve patients in informed decision making.

Contributors

Both authors made substantial contributions to concept and design of the study, interpretation of data, and critical revision of the article for intellectual content, and gave final approval to the version to be published.

Competing interests

None declared

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