## Reports

### The Development of Canadian Clinical Practice Guidelines: a literature review and synthesis of findings

Discussion paper prepared for the CCA/CFCRB Task Force on Chiropractic Clinical Practice Guidelines June 15, 2002

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#### 1. Preamble

In April 2002, the joint CCA/CFCRB Task Force overseeing the development of Clinical Practice Guidelines for Chiropractic put out a call for a paper addressing certain issues related to guidelines.

The terms of reference of the paper were to address the following:

- Review the literature as well as practices of other professions and make recommendations regarding the development and utilization of clinical practice guidelines.
- Review the literature and make recommendations regarding the level of evidence required for research to be considered in a guideline.
- Review the literature and make recommendations regarding the structure (layout) of a guideline.
- Review the literature and make recommendations regarding the subject areas to be covered in the guideline.
- Review the literature and make recommendations regarding the purpose of the guidelines (e.g. what they are and are not)
- Review the literature and make recommendations regarding what the parameters of the guidelines will be (e.g. condition based, treatment based); etc.

This paper explores these topics through a comprehensive review of the literature followed by recommendations that are drawn from the information, as it applies to the chiropractic profession.

The appendices that follow the paper contain selected references from the extensive literature that are deemed to be of greatest value, and should be read in their entirety by all individuals working on clinical practice guideline development.

#### 2. Methodology

Three primary research strategies were employed in the development of this paper.

- 1 Internet search engines, including yahoo, google, dogpile, and alta vista were searched for the terms: guidelines, clinical practice guidelines, and in conjunction with the terms development, evidence, structure, definition, purpose, organization. Dozens of links were explored, and as the research continued, it became evident which ones were most prominent. A list of approximately 20 of those deemed most appropriate was further probed. Canadian content and reputability were the criteria used to retain the best websites.
- 2 National professional associations of medicine, dentistry, optometry, psychology, massage therapy, nursing, physiotherapy, psychiatry, obstetrics were contacted via telephone or Internet. Health Canada, the Canadian Coordinating Office of Health Technology Assessment, Canadian Institute for Health Information, the CMA Guidelines Database and several other smaller agencies were also surveyed.
- **3** The most comprehensive search, after key terms and concepts were narrowed down, was a Medline search on PubMed with the MeSH headings of clinical practice guidelines and the other terms in section 1 above. The HealthSTAR database was also searched. Over 200 literature sources were identified, which were then screened and filtered down to approximately 30. These sources were then obtained and formed the bulk of the literature review, based primarily on date of publication (after 1997) as well as relevancy to the terms of reference of this report.

#### 3. Backgrounder – common themes in clinical practice guidelines

During the process of reviewing the literature and contacting organizations, certain fundamental observations were made with regards to the development of clinical practice guidelines (CPGs) in general. To better understand the literature review and recommendations that follow in this report, there are certain observations and findings in the CPG arena that should be noted.

The origins of modern clinical practice guidelines in North America began in 1978 with a National Institutes of Health Consensus Conference on Guidelines, to give guidance with regard to the adoption of new technology and optimal treatment. The impetus for this was the daunting diversity of new publications of medical advances, and an exponential proliferation in the production of clinical guidelines.<sup>1</sup>

In the United States, the Institute of Medicine (IOM), the American Medical Association (AMA) and the Agency for Healthcare Research and Quality (AHRQ) – formerly the Agency for Health Care Policy and Research – are the most respected and leading institutions in the development of clinical practice guidelines. The AHRQ and AMA sponsor a website known as the National Guideline Clearinghouse, which is a public resource for evidencebased CPGs. In Canada, clearly the most often cited and reputable organization maintaining a clearinghouse of medical clinical practice guidelines is the Canadian Medical Association (CMA). The CMA's CPG Infobase, contains guidelines that are produced or endorsed in Canada by a national, provincial/territorial or regional medical or health organization, professional society, government agency or expert panel (stores over 2000 CPGs). There is no government agency in Health Canada or elsewhere in any province that has such a role in CPG maintenance and development. To date, the CMA Infobase is the most comprehensive database of Canadian clinical practice guidelines. Health Canada disseminates its own guidelines, but is not involved in the dissemination of guidelines developed by other organizations. There are no publications for guideline development issued by Health Canada. Another very reputable organization in CPG development is the Scottish Intercollegiate Guidelines Network (SIGN) Initiative in Scotland. Any or all of these organizations are always referred to in the literature on CPG development and associated conceptual issues.

The quality of CPGs is continuously probed throughout the literature. It is striking to note the quantity of literature assessing the quality of CPGs, and its finding that most guidelines housed by authoritative institutions are lacking in quality.<sup>37,38</sup> The single most consistent finding in the literature is that CPGs need to be evaluated and improved. The methodological rigor used to develop CPGs is inconsistent and poor. For example, one study found that of 217 drug therapy guidelines developed or endorsed by Canadian organizations in the period 1994-1998 (and housed in the CMA database), only 15% met half or more of the authors' criteria for rigor in the developmental process.<sup>2</sup> There are too many organizations creating too many CPGs on too many similar health concerns, therefore the role of those bodies evaluating guidelines and deciding the ones that are acceptable is becoming more important.

Another common theme throughout the literature is that in spite of an explosion of CPGs, clinicians are not using them. The concern is that guidelines are developed and not incorporated into practice, therefore making them useless. There is an abundance of literature analysing the reasons CPGs are not implemented, and the psychology behind clinician behavior modification. This falls outside the scope of this report, however it is important to realize that the dissemination and incorporation of CPGs into practice is a critical area of study in the CPG developmental cycle. In fact, one of the weaknesses of the original CPGs developed by the Canadian Chiropractic Association was that there were few dissemination and implementation strategies. This is a very common problem that plagues all CPGs across all medical and health professional specialties.

Clinical practice guidelines are tailored to the biomedical, allopathic model of health care. Issues such as how guideline topics are chosen, to the type of evidence that is considered necessary for valid CPG development, are premised on the Western model of medicine. As such, the randomized clinical trial (RCT) is considered the gold standard for evidence. RCTs are structured to study the effect of one specific intervention on one specific outcome measured. This translates into the predominant format of guidelines; following the structure of one specific intervention for a specific disease process or condition. In reviewing the (biomedical) literature on CPGs, it is clear the greatest challenge for the chiropractic profession in developing guidelines is how to bridge the gap between the evidence and belief systems used in the two health belief systems. Non-allopathic disciplines, such as chiropractic, have fundamental differences with how they define target conditions, causes of disease, interventions, and outcome measures of effectiveness. The notions of standardization and evidence-based, inherent in guideline development, face challenging methodological problems when applied to non-allopathic medicine, which considers many different treatment practices appropriate and encourages highly individualized care.<sup>3</sup>

In reviewing the literature it is clear that there exist as many different formats for CPGs as organizations producing them. Even within the CMA database, the layout and format of guidelines produced from the various medical specialty groups are highly variable and follow protocols set within each organization producing them. Some guidelines are a only two pages long with very little supporting evidence, others are very extensive and evidence-exhaustive but tend to focus on one specific treatment intervention or one disease entity. The literature details the methodology and process that various organizations use to derive CPGs, as well as the criteria that the main CPG databases use to consider the inclusion of a guideline.

#### 4. Synthesis of findings from literature review

#### A. Purpose of clinical practice guidlines

Over the past decade there has been a surge of interest in the use of clinical practice guidelines fueled by the discovery of large, unexplained variation in physician practice, documentation of significant rates of inappropriate care, and an interest in managing health care costs. It is believed therefore that CPGs are used to improve the quality, appropriateness, and cost-effectiveness of health care, and can serve as valuable educational tools.<sup>4</sup> They are the culmination of empirical study of medical treatment efficacy, and serve to improve clinical performance and outcomes by enhancing physician knowledge and skills.<sup>5</sup>

CPGs are designed for a variety of purposes. At present, the most common guidelines are those intended to determine the appropriate application of procedures or use of medications, with some designed to guide the evaluation and treatment of acute presenting complaints. Some guidelines address management of chronic problems focusing on ongoing care, whereas still others prescribe the appropriate use of preventive interventions.<sup>6</sup>

The most widely quoted definition for CPGs is one coined by the Institute of Medicine in the Unites States which states that CPGs are "systematically developed statements to assist practitioners and patients in arriving at decisions on appropriate health care for specific clinical circumstances"<sup>7</sup> This definition clearly positions clinical practice guidelines to be used within the clinical encounter in a discussion between the patient and the clinician. It also implies that CPGs are intended to inform clinical judgements, *not replace* them.

CPGs are deployed as enabling strategies to help clinicians and patients become aware of the evidence about what works and what does not work in health care, so that better choices are made. At the level of the clinical encounter, guidelines help practitioners deal with the varying quality of health information available to them.<sup>8</sup> In medicine, they have been created as documents that serve as information resources for the systematization of clinical practice; their intended purpose is to provide physicians and other professionals with a useful reference for optimizing patient care.<sup>9</sup> They also serve to identify which treatment practices are based on good evidence and which are based on consensus opinion.

CPGs also serve a purpose for stakeholders besides practitioners and patients. Payers and policy makers view guidelines as a means of controlling costs and optimizing the value of health services. Professional provider groups sometimes pursue CPGs for self-legitimization, to document their role in the treatment of conditions or performance of procedures, or to gain reimbursement from payers. It is evident that the purpose of CPGs varies according to the different audiences that use them. For example, health providers are not generally interested in cutting costs to the system, whereas paying agencies and governments are. CPGs are for patients, not for payers.

It is important to distinguish practice standards from practice guidelines. Practice standards typically provide specific requirements for practice and are applied, with few exceptions, to all relevant clinical situations. Standards are defined by a governing body or administrative body and detail the *absolute limits* on acceptable clinical practice, whereas individual health providers practice based on their personal protocols. The purpose of clinical practice guidelines is to address the grey area in between these two.<sup>10</sup>

A recent survey of 3000 Canadian family physicians

assessed their opinions on the purpose of CPGs.<sup>11</sup> It is important to understand what the most important usersthe clinicians- believe the purpose of guidelines to be (Table 1). Attitudes and opinions of chiropractors and other primary contact health professionals are likely similar to those of physicians. It is important to note that physicians in Canada believe that CPGs are developed for the main purpose of enhancing the quality of patient care.

In summary, the literature indicates that the purpose of clinical practice guidelines is to:<sup>10,12,39</sup>

- influence health care practice in a scientific direction by providing concise guides to practice based on the consensus of experts;
- provide up-to-date summaries of evidence-based "best practices" accessible to practitioners in a format they find usable;

Table 1	
Canadian physician's opinions on the	
purpose of clinical practice guidelines	

Purpose	Percent Agree/ Strongly Agree
To be used for quality-assurance review	67
Development motivated to improve quality of care	63
To be used in physician disciplinary action	60
Development motivated by desire to cut costs	55
Convenient source of advice	53
Good education tool	51
Unbiased synthesis of expert opinion	32
Challenge to physician autonomy	23
To be used to practice 'cookbook' medicine	22

- synthesize data on the use of diagnostic tests, treatment interventions, adverse effects and costs, and propose recommendations for a clinical scenario;
- provide a basis for educating the public on the value, risks and benefits of diagnostic and therapeutic procedures;
- represent a teaching tool, a format for improving informed decision-making by physicians;
- limit variations in practice that may signal problems in the quality of service;
- eliminate unnecessary costs associated with variations in practice.

Clinical practice guidelines are not intended to:8

- serve as practice standards against which practitioners are held accountable;
- restrict legitimate healthcare choices outside the setting of the clinical encounter, and within the encounter they cannot be used as justification to withhold information from patients about available effective treatment alternatives;
- act as a final arbiter in favor of cost savings;
- replace clinical judgement in issues related to legal liability;
- be considered as the legal standard of care by courts unless they are widely accepted as reasonable and expected care by a substantial portion of the health care community – even then, guidelines are not decisive, but one opinion<sup>13</sup>.

#### B. Development of clinical practice guidelines

Practice guidelines are "professionally derived recommendations for practices and patterns of prevention, diagnosis, treatment, and in some cases, disability management. They can be developed in a variety of ways, for several purposes, and with varying levels of usefulness and quality."<sup>6</sup>

The clinical practice guideline development cycle incorporates a formal process of problem definition, evidence review, consensus development, guideline formulation, and eventual adoption and implementation of clinical recommendations.<sup>14,40</sup> A study in The Lancet found that only a quarter of CPGs reviewed were developed by multidisciplinary panels, an approach that has been repeatedly suggested as a way to avoid a biased view in the formulation of recommendations. In addition, the study found it troubling that there was a paucity of guidelines developed involving patients and consumer representatives, which raises the concern that the value of their input is not properly recognized.

A number of methods can be used for guideline development. The two most common methods, which should be combined, are the evidence-based method and the expert consensus method. In the evidence-based method, formal criteria are developed for acceptable types of studies. Generally, acceptable studies are randomized controlled trials and prospective cohort studies. Case-control studies are marginally acceptable, but case reports are not (see section on level of evidence for CPGs).

In the consensus panel method, a group of practitioners and other experts evaluate existing evidence or reach a consensus on best methods and pathways. There are formal techniques to manage consensus development, including nominal group voting, forced ranking, and Delphi methods. Variations center on whether evidence analysis is used as a first step in the process, how the panel members are selected, and what rules are followed for recommendations and consensus. The composition of the consensus panel clearly affects the viewpoint and the outcome of the guideline-development process.<sup>6</sup>

Individual authors can also develop guidelines, however this method is not supported by the literature for use in CPG development. One-author guidelines are very susceptible to bias due to the author's viewpoint, affiliation, and criteria on evidence. These are usually referred to as *narrative reviews*, which most practitioners are familiar with. They are written by a single topic expert based on his or her understanding of the literature. The process cannot be replicated and does not permit the reader to check the assumptions of the author. This is in contrast to a *systematic review*, which has already been discussed as a mandatory element for valid CPG development.

The literature review pointed out the importance of ensuring that CPGs that are "systematically developed". One becomes overwhelmed by the seemingly endless number of organizations outlining methodologies of how they develop their CPGs, and how they ensure that they are "systematically developed". Upon a thorough review, the methodology by 4 organizations producing CPGs have been singled out as the most relevant for consideration in the current chiropractic CPG development process.

#### Scottish Intercollegiate Guidelines Network

The Scottish Intercollegiate Guidelines Network (SIGN) was formed in 1993. Their objective is to improve the quality of health care for patients in Scotland by reducing variation in practice and outcome, through the development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence.

The membership of SIGN includes all the medical specialties, nursing, pharmacy, dentistry, professions allied to medicine, patients, health service managers, social services, and researchers. The work of SIGN is supported by an Executive based at the Royal College of Physicians of Edinburgh. The SIGN guideline development programme is funded by the Clinical Resource & Audit Group of the Scottish Executive Health Department.

SIGN guidelines are developed by multidisciplinary working groups with representation from across Scotland. The guideline development groups are selected in consultation with the member organisations of SIGN. Each guideline is based on a systematic review and critical appraisal of the current scientific literature. This means that the evidence base for the guideline is identified, selected, and evaluated according to a defined methodology. In this way, potential sources of bias in the guideline are minimized and the likely validity of the recommendations is maximized.

The guideline recommendations are graded according to the strength of the supporting evidence. This provides groups of practitioners working in the NHS in Scotland with information to help select and prioritize recommendations for local implementation, depending on local needs, priorities, and resources.

SIGN guidelines are developed using an explicit methodology based on three key principles:

- Development is carried out by multidisciplinary, nationally representative groups.
- A systematic review is conducted to identify and critically appraise the evidence.
- Recommendations are explicitly linked to the supporting evidence.

#### Cancer Care Ontario Practice Guideline Initiative

The Cancer Care Ontario (CCO) Practice Guidelines Initiative (PGI) coordinates the development of evidence based CPGs for specific cancer conditions related to interventions that include treatment, screening, diagnosis, and follow-up. The CPGs are produced by provincial teams, known as Disease Site Groups (DSGs), each composed of health professionals, community representatives and researchers who work collaboratively to produce CPGs for a particular cancer disease site (e.g. lung cancer, breast cancer).

Their process of CPG development involves the following steps:

- 1 A clinical problem is identified and defined.
- 2 High quality research studies are selected, reviewed and their results are integrated.
- **3** A systematic review of the study results leads to the formulation of a draft practice guideline, known as an evidence-based (EBR) recommendation report.
- **4** The EBR is distributed to the practising community for feedback.
- **5** The feedback is integrated into the report.
- **6** A final CPG is approved by the Practice Guidelines Coordinating Committee and is disseminated to relevant targets.

Therefore this method combines an evidence-based approach using systematic review with a consensus model approach. The evidence-based approach ensures the best available evidence is used to make recommendations. There are also 2 consensus approaches incorporated into the development of the CPGs. In one approach, as members of the DSGs evaluate the evidence, they must work together to reconcile differences in the interpretation of the evidence.

There is also a second consensus approach used, the Practitioner Feedback stage of the development cycle, which involves obtaining and incorporating the opinions of the clinical community in Ontario in a systematic fashion. A questionnaire of the EBR is sent out to a sample of the clinical community for whom the recommendations are considered to be relevant. The questionnaire assesses several dimensions, including the clarity of the rationale, usefulness of the guideline, clarity and completeness of the literature search on which the guidelines are based, agreement with the evidence, agreement that the document should be approved as a CPG, and intentions to use the guideline in one's own practice. The questionnaire responses are analysed and incorporated into the final approved guideline.<sup>15</sup>

Since the definition of CPGs explicitly acknowledge the role of the patient perspective, patient views should be part of any formal CPG development process, and most definitely at the stage of CPG approval.

#### Canadian Dental Association (CDA) Guidelines

"The development of CPGs in dentistry is in its infancy. Although a number of organizations have produced parameters of care and expert-derived or consensus-based guidelines and standards of care, there are very few published, peer-reviewed, evidence-based CPGs validated by practising dentists."<sup>16</sup>

Although the dentistry model is in its infancy, a review of other professions in Canada has demonstrated that they have not even reached that stage yet. Optometry, psychology, nursing, physiotherapy and most likely all other allied health professions have not yet developed a national process to systematically develop CPGs. Provincial medical associations and specialty groups do develop guidelines, however they are done to varying levels of quality, with little standardization across the board. In this aspect, the chiropractic profession in Canada has been a pioneer in the effort to develop CPGs, however it has still not established an elaborate system for development. For this reason, and because of the similarity in coverage and nonmedical interventions used by the chiropractic and dental professions, it is assumed that the guideline development model of the Canadian dental profession<sup>17</sup> outlined below is applicable to the chiropractic profession.

The Canadian Collaboration on Clinical Practice Guidelines in Dentistry (CCCD) is the national, autonomous body responsible for the creation of evidence-based guidelines for dentistry in Canada. The CCCD is a selfdirecting organization whose mandate is to involve practising dentists in the entire process of creating guidelines for Canadian dentists. The CCCD had its conceptual beginnings in 1997, when an ad hoc committee of the CDA obtained a mandate from the CDA board of governors to develop a national strategy for CPG development and implementation in dentistry. The CCCD has developed guiding principles for the development of CPGs (Table 2).

The *CCCD Council* is made up of representatives from the national dental associations (2), provincial dental associations (4), the dental specialty organizations (2), the

Principle	Explanation
Inclusive	CPGs will be developed by dental practitioners and supported by a methodology resource group and administrative staff
Evidence-based	Rigorous scientific methods will be used to assemble, organize and synthesize the best available evidence
Transparent	All processes will be open, transparent and thoroughly documented
Valid	To ensure that CPGs are useful in clinical situations, feedback will be sought from relevant stakeholders, including practitioners and supporting organizations, at defined points throughout the development cycle
Accessible	CPGs will be widely disseminated so that they are available to practitioners, patients and the public
Current	CPGs will be updated on a regular, scheduled basis to incorporate new evidence

Table 2Guiding principles for the development of dental CPGs

dental regulatory authorities (4), and faculties of dentistry (2). The council is responsible for formulating policy with respect to guideline process, for selecting and prioritizing topic areas in consultation with the profession, and for overseeing the development and dissemination of guidelines.

The *Clinical Advisory Group* is a multidisciplinary team of volunteer dentists who have a particular interest or expertise in the content area of a guideline topic under development. This group is chaired by rotating chairpersons who have knowledge about the methods in guideline development. This group does not require having expertise in the methodology of systematic reviews. The responsibility of each group is to coordinate the development of an individual guideline that it has been tasked with.

The *Methodology Resource Group* consists of individuals with expertise and methodological skills in the retrieval and evaluation of scientific evidence. This group includes one or more salaried research assistants, who assist with the systematic reviews and formatting and editing of the CPGs. A person knowledgeable about the methodology of systematic reviews chairs the group. This group has 3 functions: 1) provide the methodological support needed by the Clinical Advisory Group; 2) Oversee and advise the research technicians who carry out the technical systematic review and 3) provide educational opportunities in methodology for interested participating practitioners.

The *CPG Coordinator* is a paid administrator who assumes a wide variety of administrative functions and reports to the CCCD Council. Once the process of CPG development is underway, it is anticipated that up to a dozen CPGs will be at some stage of development at any given time. The responsibility of the Coordinator is to liaise with the chairpersons of the committees, assist the chairpersons with budgets and timelines, schedule and organize meetings of the various groups, and prepare the final versions of the CPGs.

#### Canadian Medical Association Infobase

The CMA, which houses the largest and most reputable guideline clearinghouse in Canada, has developed principles intended to be used in the development of clinical practice guidelines. It is these guiding principles that the CMA database administrators follow in determining whether or not a CPG meets the criteria for inclusion. The 14 principles for the guideline development process are<sup>18</sup>:

- **1** The goal of clinical practice guidelines should be to improve quality of health care.
- 2 Clinical practice guidelines should be sufficiently

flexible to allow patients and physicians to exercise judgement when choosing available options.

- **3** Clinical practice guidelines should enable informed decision making by patients and physicians by enhancing professional learning, patient education and patient-physician communication.
- 4 Clinical practice guidelines should recognize that the physician's primary responsibility is to his or her own patient, although it may have to be balanced against the needs of other people and society in general.
- **5** Ethical issues should be considered in all phases of the clinical practical guideline process.
- **6** Organizations with clinical practice guideline programs should articulate clear goals and use and explicitly document processes for setting priorities and assigning resources to the development, implementation, evaluation and revision of guidelines.
- **7** Clinical practice guidelines should be developed by physicians in collaboration with representatives of those who will be affected by the specific interventions in question.
- 8 Developers of clinical practice guidelines should state the objectives and methods and identify the intended users before the guideline is developed.
- **9** Clinical practice guidelines should a) cite specific evidence bearing upon the conclusion; b) indicate the strength of the evidence and c) specify the date of the most recent evidence considered.
- **10** Before implementation, clinical practice guidelines should be reviewed by expert and user groups and, if possible, tested through such mechanisms as field trials.
- 11 When appropriate, the developers of a clinical practice guideline should use a standardized summary to report the development process and key considerations.
- 12 The clinical practice guideline process should include specifically tailored, effective and coordinated strategies for voluntary implementation that emphasize patient, physician and other health provider involvement.
- **13** The effectiveness of the clinical practice guideline process should be assessed with a well-designed evaluation that incorporates user feedback.
- 14 Clinical practice guidelines should be reviewed and revised as advances in medical knowledge occur.

In summary, there are 5 distinct steps in the development of any CPG, which incorporate all of the information relayed above.

- 1 Identifying and refining the subject area.
- **2** Convening and running guideline development groups.
- **3** On the basis of systematic reviews, group assessment of evidence about the clinical question or condition.
- **4** Evidence translated into a recommendation within a clinical practice guideline.
- **5** External review of the guideline.

#### C. Level of evidence required in a clinical practice guideline

"If the purpose of guidelines is truly to synthesize knowledge and improve patient care, then there is little excuse for not conducting broad systematic literature searches or critically appraising the available evidence using accepted methodology. Above all, guidelines must give precedence to scientific evidence over opinions. Chiropractors have made major contributions to the development of rigorous clinical practice guidelines and these models must be used to update our current documents."<sup>19</sup>

The level of evidence required for research to be required of guideline quality is a very controversial issue. There is always tension, even in the most medically based guidelines, between the desire to use solid research evidence versus the need to rely on the consensus of expert opinion in many crucial areas where the research evidence is uncertain, incomplete, or absent. Exclusive reliance on clinical trial evidence may lead to guidelines that are too limited in areas in which recommendations can be made or that cannot be generalized. Defining consensus too simplistically or casually may lead to arbitrary bias.<sup>20</sup>

Various guideline organizations have developed grading systems for evidence. All of them categorize the evidence in different class levels, and within each class, can usually subdivide the evidence levels. One of the more influential organizations, the Agency for Healthcare Research and Quality (AHRQ), has developed a 4-tier grading system for evidence. They are classified according to the following levels, from highest to lowest<sup>21</sup>:

- 1 Meta-analysis of randomized clinical trials (RCTs), or at least one RCT.
- 2 At least one well-designed controlled study without

randomization, or at least one other quasi-experimental study.

- 3 Well-designed non-experimental descriptive studies.
- 4 Expert committee reports, opinions, or clinical experiences of respected authorities.

There have been rules of evidence that have been established to grade evidence according to its strength. The general hierarchy of medical research, otherwise known as an evidence ladder, is as follows:<sup>22</sup>

- 1 High-quality systematic reviews.
- 2 Large randomized trials with clear-cut results.
- **3** Small randomized trials with uncertain results (i.e. positive trends without statistical significance).
- 4 Nonrandomized trials with contemporary controls.
- **5** Nonrandomized trials with historical controls.
- 6 Cohort studies.
- 7 Case-control studies.
- 8 Dramatic results from uncontrolled studies.
- 9 Case series and other descriptive studies.
- **10** Reports of expert committees and opinions of respected authorities, based on clinical experience.

There is *no clear* indication in the literature as to what level of evidence is required for research to be considered a guideline. In fact, the type and level of evidence used by medical and other organizations in developing their guidelines, is very inconsistent. Even more apparent in reviewing the literature is that CPG developers, mostly medical organizations, do not often explicitly state the classification of evidence used to develop the guidelines. Most studies found that the level or description of evidence used by medical organizations in developing guidelines is inadequate. For example, in one study analyzing 95 published guidelines in cardiology, the authors found that only 13% of the guidelines graded the evidence using defined scales and that few documented a reproducible search strategy, essential for qualifying the evidence.<sup>1</sup>

The literature is replete with explanations as to why applying scientific evidence to CPGs is often complicated by mismatches between evidence and usual practice circumstances. The reasons of why conventional scientific evidence may not be the best or most complete method to form the evidence base for CPGs are that:<sup>20</sup> 1) It is impossible to design a study that captures every permutation of the ways in which diseases present; 2) patients

included in RCTs may be unrepresentative of general clinical populations, which may be characterized by treatment resistance, comorbidity, nonadherence; 3) most RCTs are designed to show that a particular intervention is superior to placebo or at most one other treatment, rather than to answer the broader question about the best way to treat a disorder by choosing from a wide variety of choices. An article in a Canadian medical journal stated that RCTs with quantitative outcome assessment may fail to capture what is important about the success or failure of guidelines to improve health care. "It is possible that qualitative research methods, with careful attention to the changing experience of clinicians and patients, may yield more immediately useful insights. If so, levels of evidence based on a hierarchy of study designs, as is now popular, may not be an appropriate metric in trials of CPGs."<sup>23</sup> It is clear that CPG developers need to fill the resulting gaps with the opinions of expert groups and consensus methods.

This highlights the fact that although most medical literature, academicians and researchers demand that high level, quality, clinical trials form the underpinning of CPGs, in reality this is not the practice. Consensus as evidence is used by even the most specialized of medical groups, for example the American Society of Anesthesiologists (ASA), in their CPG development process.<sup>9</sup> According to the ASA, published studies alone may not provide necessary or complete information regarding relevant details of clinical practice. Accordingly, additional sources of information and evidence are actively and deliberately sought. Practitioner opinion is obtained through several mechanisms, ranging from the simple recording of consensus within a designated task force to large-scale surveys and feedback from presentations or open forums at national conventions. Consensus data is obtained from multiple sources, including surveys of expert consultants and of the broader population of practitioners, open forum presentations and Internet commentary.<sup>41</sup>

The problem with using expert opinion as evidence is that it is more vulnerable to bias and potential conflicts of interest. This perspective typically defines expertise by one's content knowledge, rather then by one's skill in research methodology and critical appraisal. These factors lead to biased sampling methods, implicit consideration of the data, and unscientific procedures for the application of evidence.<sup>15</sup> In order for consensus and expert opinion methods to be reliable and valid, they must include consideration of the scientific evidence, incorporate the views of various stakeholder groups, and employ methods to diffuse and control problematic intragroup interactions that influence recommendations.<sup>15</sup>

Although there are an estimated 250,000 published randomized controlled trials (RCTs),<sup>15</sup> complementary and alternative medicine (CAM), including chiropractic, cannot claim this body of evidence available to conventional medicine. CAM health practices (such as chiropractic) face a unique challenge due to the lack of such studies. The nature of supporting scientific evidence for CAM is an obstacle in the development of CPGs that strictly follow the medical hierarchy of evidence. These CPGs link recommendations to the strength of the science base, according to the traditional hierarchy of evidence from RCTs downwards.

One train of thought is that a prudent approach to practice guidelines in CAM, and chiropractic, is to postpone them until a larger body of high-quality scientific evidence becomes available.<sup>3</sup> This is not a universally accepted belief however. Some would argue that the need for CAM to collect evidence in a format acceptable to Western medicine is itself a false premise. Reliance on empirical data from controlled experiments to infer effectiveness is a reductionist epistemology that is not shared by CAM practices.<sup>24</sup> Outcome measures for judging effectiveness in allopathic medicine, which emphasize organ specific end points, differ from the holistic measures used in CAM, which emphasize overall well-being, the patient's personal experience, and dynamic relational issues.<sup>25</sup> Because of these issues, the notion that chiropractic practice guidelines must be "evidence based" according to the Western medicine hierarchy of medicine can be disputed, and the development of recommendations based on expert opinion and consensus development should also be advocated. In fact, as already demonstrated, even in conventional medicine the development of recommendations by consensus opinion is an accepted option until meaningful clinical trial evidence becomes available.<sup>25</sup> For those proponents who believe that chiropractic should only be evidence-based, it can be disputed that this is not in the patient's best interests to withhold CPGs in chiropractic until high level evidence becomes available, something which can take 10 or 20 years to develop. Until that time, chiropractic patients deserve to have less rigorous CPGs for conditions they frequently present with even though there is a dearth of high quality clinical trial evidence supporting them.

#### D. Structure/format of clinical practice guidelines

The structure and format of CPGs vary drastically across all organizations producing them. Some are very shortperhaps a page or two long- others, like the AHCPR Clinical Practice Guideline on low back pain<sup>26</sup> are novels with very detailed sections.

The inconsistency in CPG formats has prompted many researchers to evaluate the components that are found in guidelines that are considered good quality, and to evaluate hundreds of guidelines and grade them compared to a format that should be followed in an optimal guideline. Leading CPG organizations, such as the Agency for Healthcare Research and Quality and the Institute of Medicine do have sections on their websites that outline format and components of a good CPGs. Most of the guidelines are based on detailed formats based on the allopathic model of disease. For this reason, it would not be useful to review these formats in detail for the purpose of structuring chiropractic guidelines.

A study published in the Journal of the American Medical Association provides an excellent literature synthesis of the formats of CPGs in the peer-reviewed medical literature.<sup>4</sup> Using the principles formulated by major medical organizations (including the CMA, AMA and IOM) involved in guideline development, a group of experts in this study identified key elements for the development and format of CPGs. The elements were formulated by this group through a careful series of review and pilot testing by guideline developers, evaluators, implementers, and groups of practising clinicians. Reviewers included consultants at the National Library of Medicine, the IOM, American College of Physicians, and the AHCPR. These are the components this group decided should be incorporated in the CPG structure:<sup>4</sup>

- **1** Purpose of the guideline is specified.
- **2** Rationale and importance of the guideline are explained.
- **3** The participants in the CPG process and their areas of expertise are specified.
- **4** Targeted health problem or technology is clearly defined.

- **5** Targeted patient population is specified.
- 6 The intended audience or users of the CPG are specified.
- 7 The principle preventive, diagnostic, and therapeutic options available to clinicians and patients are specified.
- 8 The health outcomes are specified.
- **9** The method by which the guideline underwent external review is specified.
- **10** An expiration date or date of scheduled review is specified.
- 11 The method of identifying scientific evidence is specified.
- **12** The time period from which evidence is reviewed is specified.
- **13** The evidence used is identified by citation and referenced.
- 14 The method of data extraction is specified.
- **15** The method for grading and classifying the scientific evidence is specified.
- **16** Formal methods of combining evidence or expert opinion are used and described.
- **17** Benefits and harms of specific health practices are specified.
- 18 Benefits and harms are quantified.
- **19** The effect of health care costs from specific practices is specified.
- 20 Costs are quantified.
- 21 The role of value judgements used by guideline developers in making recommendations is discussed.
- 22 The role of patient preferences is discussed.
- **23** Recommendations are specific and apply to the stated goals of the guideline.
- **24** Recommendations are graded according to the strength of the evidence.
- **25** Flexibility in the recommendations is specified.

How and whether all these criteria are packaged into the structure of a CPG is highly variable. In fact, it was found that most published CPGs are falling considerably short of these standards.

One extreme option is to structure the CPG with each of the above elements as chapters. That would be a cumbersome task, and in fact would make the guideline very complicated and difficult to follow. There is certainly no one correct "format" for guidelines, however most guidelines are broken down into not more then 10 headings, and subheadings which incorporate as many of the above elements as possible.

The American Psychiatric Association produces CPGs with the following standard sections<sup>27</sup>:

Preface

Statement of Intent

Reference Coding System

Literature Review Process

- I Executive Summary
- II Disease Definition, Epidemiology, Natural History
- **III** Treatment Principles and Alternatives
- IV Formulation and Implementation of a Treatment Plan
- V Clinical Features Influencing Treatment
- VI Research Directions
- VII Individuals and Organizations that Submitted Comments
- VIII References

Most other medical organizations follow variations of the above format. The Canadian Dental Association has proposed that their CPGs will abide by the following structure:<sup>17</sup> 1) structured abstract; 2) statement of the question and the rationale for the choice of topic; 3) comprehensive methodology section; 4) results of the literature search and of relevant outcomes; 4) interpretive summary; 5) description of the consensus process; 6) draft recommendations; 7) methods, results and modifications generated by the practitioner feedback survey and external reviews.

For the chiropractic profession, the challenge in putting together a format and structure for CPGs again boils down whether or not the profession is willing to adhere to the medical paradigm of disease entity. This would entail focusing a guideline on a specific health problem, and on an intervention for managing the problem. This is the only format that will be acceptable for inclusion in the medically operated guideline network in North America. This is a core underlying philosophical decision that needs to be made by all CAM disciplines, and particularly chiropractic, which finds itself in the crossroads between the allopathic and alternative models of health delivery.

This obstacle – the difference in terminology and underlying philosophy of disease – poses a significant challenge in developing the format and subject areas for chiropractic CPGs. Practice guidelines in conventional medicine, for example, have little ambiguity about the definition of the medical condition or interventions under consideration. The identity of a target condition may be less clear in CAM (chiropractic), because of different philosophies about the causes of disease and thus different systems of diagnosis.<sup>3</sup> "The individualization of treatment that characterizes CAM is antithetical to the goals of practice guidelines, which tend to seek reductions in practice variation. This tension between individualization and uniformity represents another obstacle to practice guideline development, especially in light of the varied practice patterns of CAM."<sup>3</sup>

For these reasons stated above, deciding on a guideline format goes hand and glove with deciding the parameters of the guidelines. In fact, the format of the CPGs, subject areas to be covered and the parameters of CPGs are intrinsically linked. And all are dependent on the underlying model of health care – whether its basis is the conventional allopathic model or a more holistic approach which cannot reduce the guidelines to very specific disease processes, managed by very targeted, specific interventions.

Once a final clinical practice guideline incorporating the above components has been developed, consideration can be given to condensing the information into more user-friendly formats. The best example of this is the series of guidelines developed in the 1990's by the AHCPR.

The CPG on Acute Low Back Problems in Adults is a 160-page document that contains a complete methodology and analysis<sup>26</sup>. It presents recommendations for health care providers with brief supporting information, tables and figures, and pertinent references. *The Quick Reference Guide for Clinicians* is a distilled version, with summary points for ready reference on a day-to-day basis. The consumer version, otherwise known as the *Patient Guide*, is an information booklet for use by the general public to increase patient knowledge and involvement in health care decision-making.

Although breaking down the CPGs into more userfriendly formats is a useful exercise, it is only done by the few government-sponsored agencies that have the funds and resources, and accountability to the general public to do so.

#### E. Determining parameters and selecting subject areas to be covered in clinical practice guidelines

"Good guidelines start with a specific clinical question, articulate relevant issues, seek and synthesize sound evidence, assign values to outcomes, generate recommendations and try to influence what clinicians do."<sup>23</sup>

The parameters (e.g. condition based, treatment based) to be covered by a CPG is the core issue in guideline development, and is developed concurrently with the subject area of the guideline. These two issues are intertwined and cannot be addressed separately.

A thorough review of the literature, both online and through Medline searches, clearly indicated that there are no fixed parameters that guidelines follow. In fact, guidelines are developed based on conditions, presenting complaints, diagnostic procedures, therapeutic and preventive interventions, management of common conditions, and so forth. There is no "right" parameter for guidelines- the only consistent finding is that whatever the parameter is, it is usually specific and targeted, and broad parameter scopes are rare.

"Guidelines can be developed for a wide range of subjects. Clinical areas can be concerned with conditions (abnormal uterine bleeding, coronary artery disease) or procedures (hysterectomy, coronary artery bypass surgery). Given the large number of potential areas, some priority setting is needed to select an area for guideline development. Potential areas can emerge from an assessment of the major causes of morbidity and mortality for a given population, uncertainty about the appropriateness of healthcare processes or evidence that they are effective in improving patient outcomes, or the need to conserve resources in providing care.

The topic for guideline development will usually need to be refined before the evidence can be assessed in order to answer exact questions. The usual way of refining the topic is by a dialogue among clinicians, patients, and the potential users or evaluators of the guideline. Discussions about the scope of the guideline will also take place within the guideline development panel.

If the topic is not refined, the clinical condition or question may be too broad in scope. For example, a guideline on the management of diabetes could cover primary, secondary, and tertiary care elements of management and also multiple aspects of management, such as screening, diagnosis, dietary management, drug therapy, risk factor management, or indications for referral to a consultant. Though all of these could legitimately be dealt with in a guideline, the task of developing such a guideline would be considerable; therefore a group needs to be clear which areas are and are not within the scope of their activities. It is possible to develop guidelines that are both broad in scope and evidence based, but to do so usually requires considerable time and money, both of which are frequently underestimated by inexperienced developers of evidence based clinical practice guidelines.<sup>28</sup>

Developing guidelines on "chiropractic practice" is an incredibly broad topic that breaks all the rules of identifying subject areas. It is likely the reason that the CCA Clinical Practice Guidelines have not been accepted in the CMA Infobase, or have not been accepted in the medical community. Although the CCA guidelines are broken down into more detailed subjects inside the document, the literature clearly indicates that this format is unacceptable to be valid in mainstream health care practice. This is the single greatest flaw that must be addressed in future CPGs in order to become more congruent with the mainstream literature and acceptable in the health care community.

The literature supports the notion that this can be rectified by developing unique issue-specific clinical practice guidelines on separate topics, as is done by all other guideline developers. For each topic selected, a whole set of different individuals with expertise in that specific topic work on a CPG, independently from other guidelines. The end result is many different chiropractic clinical practice guidelines, independently created, and having no relation to each other. This would in effect mean there would be many different concurrent CPGs being developed, each taking up a lot of resources and funds. The issue of importance then becomes setting priorities for selecting CPG topics, since both funds and resources are limited.

There is ample literature that assesses priority setting for CPG topic selection. A Canadian study proposed the following framework for priority setting by Canadian groups developing clinical practice guidelines<sup>29</sup>:

**1** Before selecting topics for guidelines, developers should consider consulting with members of their respective organizations, potential users and other stakeholders; meaningful patient and community involvement should be carefully considered.

- 2 During these consultations thought should be given to what sort of topic is feasible given the resources of the developers, the conditions of practice into which the guidelines will be introduced and the likelihood that the guidelines will improve the health of the population and limit costs to the health care system; when available, quantitative data should be incorporated.
- **3** Documentation of the process leading to a particular guideline topic should be maintained, made available to members and other stakeholders and forms the basis for evaluating the guideline development process.

The Hamilton Region Cancer Center uses the following criteria for prioritizing and selecting topics for clinical practice guideline development:

- **1** Prevalence of condition.
- 2 Burden of illness.
- **3** Potential for significant health benefits (or risk).
- **4** Relevance to local practice patterns.
- 5 Degree of variation in health care practice patterns.
- 6 Likelihood to influence change in clinical practice.
- 7 Costs of health practices.
- 8 Availability of high-quality evidence to support practice.

In a Canadian study<sup>30</sup> guideline developers in Canada ranked the criteria that should be used to decide topic areas for CPGs. There was considerable agreement on the criteria that should be used to set priorities for CPG activities: the burden of disease on population health, the state of scientific knowledge, the cost of treatment and the economic burden of disease on society were seen as important factors, whereas the costs of guidelines development and practitioner interest in guidelines development were seen as less important. Organizations were unable to give much information on how they set priorities.

In another Canadian article on this topic<sup>31</sup>, it was found that an Ontario Medical Association (OMA) committee producing a list of priority topics took the following factors into account: feedback from OMA sections indicating that there was considerable confusion for practitioners over conflicting advice for appropriate practice; utilization data from the ministry demonstrating that the use of numerous procedures had increased rapidly over previous years; and feedback from practising physicians identifying areas in which it was felt there was a need for guidelines to aid practice. In describing the CDA's approach to developing CPGs, the author states<sup>16</sup> that for a guideline to be useful, it should address a common clinical topic about which there is uncertainty. Resources should not be used to develop guidelines for obscure questions for which there already exists well-known answers or reasonably consistent practice patterns. He also believes that guidance for clinicians is most needed in areas where the evidence is weak and conflicting, and that choosing guideline topics based on the availability of "good evidence" should be avoided.

The literature has demonstrated that choosing the parameters and topics of CPGs is a methodologically demanding exercise in itself, and must be done systematically in order to achieve desired benefits from CPGs. It is an arduous process that can take months to carry out, and requires planning and organization. This first step needs to be done with as much stakeholder involvement as possible, in order to ensure compliance and implementation of the CPGs down the road.

#### F. Utilization of clinical practice guidelines

The implementation and utilization of CPGs is a complex and challenging issue. Most of the literature on CPGs deals with implementation strategies after guidelines are completed. This is a critical process because the utilization of CPGs is a great challenge. The investments made available for guideline development have not been matched by investments for implementation. As difficult as the development process is, getting people to use clinical practice guidelines is even more challenging.<sup>8</sup>

A common theme in the literature review is that even with the development of thousands of CPGs over the last several years, their implementation and utilization by clinicians is disappointingly low. It might be assumed that providing the best evidence would be enough to influence physician behavior; unfortunately the literature clearly demonstrates that this is not the case. Physicians, and other health providers, have varying degrees of readiness to accept new information. Some embrace new evidence immediately (innovators), while others wait years until their peers start accepting new evidence The laggards remain traditional to their traditional views and practices and will not change no matter what.<sup>10</sup>

Another study found that the presentation of practice guidelines to a group of physicians without first working with the early adopters and the early majority is much more likely to fail. This is true even if the guideline's recommendations are evidence based. "Some of the early majority and most of the late majority will not dispute the validity of the evidence, but will believe that the recommendations do not directly apply to their patients or will not work effectively in their setting. These concerns travel quickly through an organization and can potentially poison the well for future change. Successful guideline implementation is best accomplished by first identifying and working with the early adopters to pilot the changes and using the preliminary data to modify and refine the intervention. The second step is to insure these changes are implemented in a manner that is very visible to the rest of the organization. This allows the early majority to evaluate the impact of the changes and incorporate them into their practice. This can be facilitated by having key physicians in the early majority act as observers for the pilot physicians. Once the changes have begun in the early majority, the dissemination process is usually self-sustaining at this point."<sup>32</sup>

A study reviewing the barriers to utilization of guidelines found that the main barriers included lack of awareness and familiarity, lack of agreement, lack of selfefficacy and confidence, lack of outcome expectancy and inertia of previous practice.<sup>33</sup> Physicians may also perceive that the evidence presented in the guidelines does not address their particular patient's problems, in which case they fall back on their own experience and judgement. Another barrier is the lack of time in a physician's schedule to review the CPGs.<sup>10</sup>

Due to the poor adoption and utilization of guidelines, CPGs have not fulfilled the benefits that have been anticipated by their development. The implementation and utilization of CPGs is an active process; the passive publication of recommendations is insufficient to have an impact on the practising clinician. Influencing clinical behavior change is a hot topic of study, and must be carefully examined if CPGs are to have any chance of being utilized. The literature review indicated some methods to increase utilization of guidelines, which include:<sup>34,35</sup>

- Understanding physician motivation.
- CPGs introduced through interactive continuing medical education events.
- Incorporation of proper incentives.

- Authoritative endorsements.
- Leading community clinicians endorsing CPGs.
- Respected peers presenting guidelines at local society meetings.
- Brief, readily accessible summaries of guidelines.
- Electronic, user-friendly publication on a Web Site.

It is intuitive that chiropractors exhibit the same clinical behavior tendencies as do physicians. Changing their practice styles is a challenging process, probably even more so than physicians who tend to follow more structured clinical protocols to begin with. For this reason, it should be expected that getting chiropractors to modify their clinical behavior through the use of voluntary CPGs would pose a great challenge. Unfortunately, the process of developing CPGs is draining and exhausting for all concerned, therefore considering the implementation challenges at the same time will stall all progress.<sup>36</sup> While the literature indicates that the two processes, development and implementation of CPGs are intrinsically linked; the low probability of utilization should not preclude the development of CPGs to begin with.

# 5. Recommendations for the development of chiropractice clinical practice guidelines

- A. Purpose of chiropractic clinical practice guidelines
- 1 The primary purpose of CPGs is to assist chiropractors and their patients in arriving at decisions on appropriate chiropractic care for specific clinical circumstances. The CPG must be developed for the purpose of improving and optimizing patient care. If this is not the underlying purpose, a CPG should not be developed.
- **2** The CPG is *not* a practice standard. Standards are defined by a governing body and detail the absolute limits on acceptable clinical practice. CPGs on the other hand, should be used on a voluntary basis by the chiropractor to assist him/her in making more informed decisions.
- **3** In Canada, CPGs should not be used to restrict healthcare choices nor to decrease costs of care; they should not be considered a legal standard of care by courts.

- B. Development of chiropractic clinical practice guidelines
- 1 Developing a quality CPG is a labor and resource intensive exercise that should be expected to take from one to two years to complete. It is imperative that the appropriate resources are made available and the proper protocol is followed so that the final product is considered valid in the research and health practice community.
- **2** The CPG must be developed by a multidisciplinary, nationally representative group. The use of single authors should be avoided.
- **3** A systematic review of the literature must be conducted to identify and critically appraise the evidence. This process must be clearly explained and described in the guideline document, and carried out only by persons with skills and experience in systematic reviews.
- **4** The recommendations in the CPG must be explicitly linked to the supporting evidence.
- **5** A variation on the model of CPG development adopted by the Canadian Dental Association should be adopted by the Canadian Chiropractic Association and the Canadian Federation of Chiropractic Regulatory Boards in developing national CPGs.
- **6** There should be a central body that has overall responsibility in CPG development, selecting CPG topic areas and overseeing the dissemination of guidelines. This group should contain representatives from the licensing bodies, provincial associations, academic centers and national association. It should be its own entity.
- 7 There should be separate and distinct advisory groups that are formed for every specific CPG, composed of experts in the topic chosen, and each chaired by a unique chairperson.
- 8 There should be a methodology group, which performs the systematic literature reviews for all of the CPGs, which is composed of individuals with skills in research methodology and literature review. These individuals should be paid for their work and act as the resource group to all the advisory groups.
- **9** The process should be managed by paid administrator(s) /coordinator(s) assuming all the administrative functions for all the groups and for the overall production of guidelines.

- **10** The 14 guiding principles of the Canadian Medical Association CPG Database should be incorporated into the process as much as possible. In fact, dialogue and liaison with the CMA should be initiated to ensure that any CCA guidelines developed would get widespread acceptance in the medical community.
- 11 The body steering the development of CPGs for the chiropractic profession in Canada should develop its own guiding principles, incorporating as much of the mentioned principles as possible. There will also be guiding principles that are unique to chiropractic and these all together should guide the process and be made official.
- 12 Consideration should be given to maintaining a database of guidelines, like the CMA, for chiropracticrelated guidelines. Other practices, such as acupuncture and other adjunctive therapies and health practices chiropractors employ, should be able to be maintained in the chiropractic database. Such a database would position the chiropractic profession well with both mainstream and evidence-backed complementary health care guidelines.
- *C. Level of evidence in chiropractic clinical practice guidelines*
- 1 Due to the paucity of randomized trials and scientific research in the profession, chiropractic CPGs should be based both on scientific evidence and consensus methodology. The literature accepts both as evidence for CPGs, however the methodology used to determine evidence should be well founded and explicitly stated in the CPG.
- **2** Since the chiropractic paradigm is not completely congruent with the conventional scientific hierarchy, a different hierarchical system for chiropractic research should be established. For each topical CPG developed, 3 sources of evidence should be considered: conventional scientific hierarchy, chiropractic scientific hierarchy, and consensus methodology.
- **3** Consensus methodology is a key evidence source to be used in chiropractic CPGs. It is important to examine the consensus models and develop reliable and valid models with experts in the field. Consensus should include input from practitioners, patients, and other health practitioners.
- 4 The rating of evidence for each CPG must be done by

more than one individual, and should clearly follow a process that is reproducible. The same evidence grading structures should be used for all chiropractic CPGs developed.

- D. Structure/Format of clinical practice guidelines
- 1 The chiropractic CPGs need to be structured around one health condition and/or intervention. The current format of the CCA guidelines is a guideline on an entire profession, which is not supported by the literature review. This is likely the main reason the CCA CPGs are not accepted in the conventional guideline community, and this must be rectified to ensure greater acceptance.
- 2 The CPG format needs to be developed by key chiropractic stakeholders. At the very least, it should include the following components: abstract, statement of the topic, rationale for choosing and description of the topic, comprehensive methods section, results of the literature search, interpretive summary with classification of evidence, description of the consensus process, interpretation of the consensus process with classification of evidence, recommendations.
- **3** Once comprehensive CPGs have been developed, more concise summary formats should be made available for clinicians and patients.
- E. Parameters and subject areas in chiropractic clinical practice guidelines
- 1 Chiropractic CPG topics should be specific and focused on a health condition or intervention, as is done by other guideline developers.
- **2** More than one CPG topic should be worked on a time, by different groups led by different chairpersons.
- **3** Priorities for guideline topics should be set by the chiropractic stakeholders; in fact this should be the first and most important task of the group.
- **4** Some of the criteria that should be considered in developing topics are the prevalence of a condition, burden of illness, potential for significant health benefits or risks, relevance to chiropractic practice patterns, degree of variation in chiropractic practice patterns, likelihood to influence change in clinical practice.
- 5 Choosing the parameters and topics of CPGs should be done in a methodologically sound way, ensuring the

input of all chiropractic stakeholders and practitioner representatives in the CPG process. For maximal buyin to the guidelines, priority-setting meetings should be organized to rank the topics of greatest importance to the profession, and such topics should not be chosen arbitrarily by a few individuals.

#### F. Utilization of clinical practice guidelines

- 1 The bottom line is that even when done well, CPGs are not utilized by clinicians. Reasons why chiropractors have not used the current CCA CPGs and their motivation for behavioral change need to be examined. A mechanism must be set in place to address these issues, so that future guidelines will be utilized to a greater extent.
- **2** The greatest single procedural enhancement to encourage the utilization of CPGs is to include sample groups of chiropractors and patients in the development of guidelines, starting from subject selection prioritization exercises to the reviewing of draft CPGs for feedback. Excluding the average practitioner and patient in the process is a barrier to utilization.

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#### APPENDIX A

<i>Recommended websites with content on clinical practice guidelines</i>	http://www.sign.ac.uk/guidelines/fulltext/50/section5.html
	http://www.cda-adc.ca/jcda/vol-67/issue-7/379.html
http://sogc.medical.org/SOGCnet/sogc_docs/common/guide/ library_e.shtml	http://www.cma.ca/cma/common/start.do?lang=2
http://www.ccopebc.ca/guidelines/hem/cpg6_6f.html	http://www.ccachiro.org/client/cca/JCCA.nsf/Articles/ EAF80E057986920A85256AE100577C35?OpenDocument
http://www.psychiatry.ox.ac.uk/cebmh/guidelines/index.html	http://ahsn.lhsc.on.ca/guide/definitions.htm
http://medicine.ucsf.edu/resources/guidelines/	http://www.fhs.mcmaster.ca/fammed/guidelin.htm
http://www.cche.net/usersguides/guideline.asp	http://medicine.ucsf.edu/resources/guidelines/
http://www.hlth.gov.bc.ca/msp/protoguides/	http://www.ahcpr.gov/clinic/uspstfix.htm
http://gacguidelines.ca/	http://www.uwo.ca/fammed/clfm/guidelin.html
http://www.cche.net/usersguides/main.asp	http://www.ahcpr.gov/clinic/index.html
http://www.albertadoctors.org/resources/guideline.html	

#### **APPENDIX B**

Recommended readings and resource material for clinical practice guideline developers

Highly recommended - not in references

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