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Canadian Dermatology Association Clinical Practice Guidelines

Neil H. Shear[1], Kirk Barber[2], Jerry Tan[3], and Pat Rich

The benefits of timely, high-quality, and evidence-based clinical practice guidelines (CPGs) that translate the best evidence into best practice in dermatology include

- improving patient care provided by members of the Canadian Dermatology Association by focusing on quality and evidence,
- enhancing the professional development of members,
- enhancing the clinical care provided to patients with dermatologic conditions by nondermatologists,
- reducing variations in practice and discouraging ineffective or potentially harmful interventions, and
- identifying areas in which further information or research is required to improve clinical care.

Although CPGs are acknowledged to play an increasingly important role in improving the quality of care, a recent analysis of almost 300 CPGs showed that published guidelines are falling "considerably short" of the standards set for their development "and that much more attention is needed by those involved in both guideline creation and in guideline review and publication."[1]

This document is intended to provide the framework to ensure that the Canadian Dermatology Association (CDA) produces guidelines that are relevant, credible, and applicable. The process outlined draws heavily from the *Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence in Action*, published in January 2013 by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF).[2] The CDA also acknowledges work done by the Canadian Association of Gastroenterologists, the Canadian Cardiovascular Society, and the Society of Obstetricians and Gynaecologists of Canada, which all have well-established frameworks for developing CPGs and on whose work we have drawn to produce this document.[3-5]

CPGs are not intended to take the place of professional judgment or to support "cookbook" medicine. Neither are they intended to support cost-control or rationing measures. CDA members should always consider individual patients and act in their best interests in partnership with them. CPGs are intended to provide a source of guidance for clinicians based on the best scientific evidence on a particular topic.

This document is intended to guide any and all CPGs developed by the CDA. The CDA will not endorse guidelines developed by other organizations or individuals that do not follow the process outlined below.

The Process of CPG Development

CPGs can be defined as systematically developed recommendations accompanied by a systematically derived background summary of the quality of evidence and the potential benefits and harms to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.[3] As defined by the US Institute of Medicine, guidelines are "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."[6]

Some of the most useful CPGs deal with clinically important topics for which there is sufficient evidence but published findings are in conflict, for which evidence is changing rapidly, or for which practice patterns are contentious or vary widely.[5]

Certain key principles underpin the CDA's guideline development process:

- Standardization: All guidelines will be developed using the same process and principles.
- Quality of evidence: All recommendations will be based on the highest standards of available evidence.
- Transparency: The process and evidence used to develop the guideline will be clearly stated and accessible. Conflict-of-interest (COI) statements for guideline developers will be publicly accessible, and the process for resolving potential conflicts must be published. Recommendations contained in the guidelines will be actionable and clear to follow.
- Timeliness: Guidelines will be reviewed and updated as necessary on a regular basis.

[1]Sunnybrook Dermatology, Toronto, ON, Canada
[2]Calgary Dermatology, Calgary, AB, Canada
[3]Windsor Clinical Research, Windsor, ON, Canada

Corresponding Author:
Neil H. Shear, Sunnybrook Dermatology, 2075 Bayview Avenue, M1-700, Toronto, ON M4N 3M5, Canada.
Email: neil.shear@sunnybrook.ca

- Patient centred: The guideline development process must involve patients, and recommendations should focus on quality-based care that will improve patient outcomes.

The Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument is intended to assess guidelines after completion and defines quality guidelines as having the following attributes:

1. Explicit scope and purpose: Specific descriptions are given of the overall guideline objectives, the health questions covered, and the population (patients, the public, etc) to which the guideline is meant to apply.
2. Stakeholder involvement: The development group should include representation from relevant professional groups, patients and/or their advocates, and users of the CPG.
3. Rigour of development: Systematic methods are used to search for evidence; methods for formulating recommendations are clearly described; strengths and limitations of the body of evidence are clearly described; methods for formulating recommendations are clearly described; recommendations take into account health benefits, side effects, and risks; recommendations are linked explicitly to supporting evidence; the guideline is externally reviewed by experts prior to publication; and a procedure for updating the guideline is provided.
4. Clarity of presentation: Recommendations are specific and unambiguous, different options for management of the condition or health issue are clearly presented, and key recommendations are easily identifiable.
5. Applicability: The guideline provides advice and/or tools on how the recommendations can be put into practice, and the guideline describes facilitators and barriers to its application, potential resource implications, and key monitoring and/or auditing criteria.
6. Editorial independence: The views of the funding body must not have influenced content; competing interests of guideline development group members have been recorded and potential COIs addressed.[7]

As outlined by the Institute of Medicine and the Guidelines International Network, guidelines should deal with the following issues[6,8]:

- method and scope,
- COI,
- guideline development group composition,
- decision-making process,
- evidence reviews,
- recommendation wording,
- recommendation strength,
- external review,
- updating, and
- financial support.

As outlined by the AAO-HNSF, the following steps should be taken in guideline development[2]:

1. defining a topic,
2. convening a process and structure for guideline development,
3. identifying and assessing evidence from a systematic review,
4. translating evidence into recommendations,
5. conducting an external review of the guideline, and
6. disseminating and implementing the guideline.

1. Defining a Topic

The need for a particular CPG will be determined by one or more of the following criteria:

1. needs assessments of the membership,
2. proposals brought forward by one or more active CDA members, and
3. topics identified as priorities by the CDA Board of Directors.

Any proposal for a guideline should address the following[9]:

- the clinical problems and outcomes to be addressed;
- the groups, institutions, or individuals supporting the proposal;
- background to the clinical topic;
- evidence of variation in practice in the management of the condition;
- benefits likely to arise from the development and successful implementation of the proposed guideline;
- key areas of concern for patients, carers, and/or the organisations that represent them;
- the patient group to which the guideline will apply;
- aspects of management of the clinical condition that the proposed guideline will address and clinical setting;
- the size and strength of the evidence base that is available to support recommendations on effective practice, citing key supporting studies; and
- any existing guidelines or systematic reviews in the field.

High-priority topics will have the potential for evidence-based practice to improve health outcomes, minimize undesirable variations in care, and reduce the burden of disease and health disparities.[2]

Potential topics will be reviewed by the CDA Board of Directors, with selection based on an assessment of need; whether the topics are appropriate for the CDA to address as

an authoritative source; whether the topics will provide information, or organization thereof, of value to members; and the availability of funding for the particular topics.

Final approval of a CPG proposal will be made by the CDA Board of Directors.

All aspects of a CDA-approved CPG initiative must be administered by the CDA office, including funding. If the CPG is being developed in partnership with another organization, clarity in accountability and financial oversight must be provided with the proposal.

2. Convening a Process and Structure for Guideline Development

Upon Board of Directors approval of a CPG, one or two CDA members will be selected by the board to serve as chair or co-chairs of a CPG development group.

The CPG development group chair or co-chairs will be responsible for the selection of members of the guideline development group who have clinical interest and/or content expertise in the topic. Consideration for selection should also include geographic representation, subspecialty representation, professional writing ability, experience in guideline development methodology, and the ability to attend meetings and meet assignment deadlines. The group should consist of

1. chair or co-chairs;
2. staff lead;
3. content experts, including those with expertise in guideline methodology; and
4. stakeholders from relevant disciplines including patients and/or patient advocates, primary care, and allied disciplines, including nursing.

All members of the guideline development group will serve on a volunteer basis.

The involvement of patients is important to ensure that the guideline addresses issues that matter to them and that their perspectives are reflected in the guideline. Patients can identify issues that may be overlooked by health professionals, can highlight areas in which the patient perspective differs from the views of health professionals, and can ensure that the guideline addresses key issues of concern to patients.[9]

Patients and/or patient advocate members of the group have the responsibility of ensuring that patient views and experiences inform the group's work. This includes the following[9]:

- ensuring that key questions are informed by issues that matter to patients,
- identifying outcome measures they think are important for each key question,
- considering the extent to which the evidence presented by group members has measured and taken into account these outcome measures,
- identifying areas in which patients' preferences and choices may need to be acknowledged in the guideline,
- making sure that the degree to which the evidence addresses patients' concerns is reflected in the guideline, and
- helping ensure that the guideline is sensitively worded (eg, treating patients as people, not as objects of tests or treatments).

Prior to consideration of appointment, each individual must complete a COI declaration statement. The chair or co-chairs should be completely free of any COIs with respect to the subject of the CPG. Their COI statements will be reviewed by the Board of Directors. Other COI declarations will be reviewed by the chair or co-chairs to assess whether any conflicts require partial or total removal of the individual from the guideline development process. Existence of a COI will not necessarily preclude a member from serving on the guideline development group. External funders will not be part of the guideline development group or process.

A defined process will be developed by the CDA for convening and managing meetings of the guideline development group. This process will include at least one in-person meeting of all group members. The AAO-HNSF manual provides a useful step-by-step overview of the process of guideline development.[2]

The guideline development process will take a maximum of 18 months from selection of the CPG topic to publication.

Joint CPGs with other specialty societies may be developed, both nationally and internationally. The CDA will work in partnership with other organizations to appoint members to a CPG development group when collaboration with these organizations to develop joint recommendations is deemed beneficial. For each collaborative guideline panel, the CDA will develop an agreement with partner organizations on how key guideline elements (such as COIs and disagreement on final recommendations) will be handled in the event of disagreement between the organizations.

3. Identifying and Assessing Evidence From a Systematic Review

The validity of an evidence-based guideline depends, in large part, on an unbiased and systematic review. The goal is to locate the best evidence from all relevant sources, producing a comprehensive body of evidence that will allow clinical questions to be answered and highlight gaps in the evidence base where formal consensus methods are needed.[2]

The AAO-HNSF advocates using evidence in a supporting role in guideline development. In such a model, the literature search is one of several approaches used to help translate evidence into action, and the ratio of benefit to harm and cost is considered equal to or greater than the level of evidence in formulating recommendations.

Some topics may lack supporting published evidence but still benefit users because of conflicting options on most appropriate practice. Use of expert opinion or consensus is appropriate, provided this is made explicit and transparent in the guideline. However, such opinion- or consensus-based guidance should not dominate.

The purpose of the systematic review of the literature is to determine whether

1. CPGs on a particular topic already exist and
2. medical evidence exists that will influence the formulation of the CPG.

The Canadian Association of Gastroenterology notes that it may be preferable to adapt an existing CPG on a particular topic rather than to develop one de novo. For adaptation, interventions and medications available in Canada that may not be addressed in CPGs from other jurisdictions should be addressed. Retrieved guidelines should be assessed for their quality using a recognized guideline appraisal system, such as the AGREE II instrument. Guidelines of sufficient quality can then be assessed for their acceptability and applicability to the topic. Some, or all, of the specific recommendations in a particular guideline may be adapted by the guideline development group.

If a decision is made to proceed with a systematic review, it is recommended that the systematic review be carried out with the aid of a medical information specialist. Past reviews, meta-analyses, and previous guidelines may be considered to summarize historical data.

Literature searches should cover at least 10 years, and those addressing economics and/or quality of care should also be included when available. In the absence systematic reviews, the search for supporting evidence should itself be systematic, with any statements adjusted to account for level of confidence.[2]

In general, medical evidence should be restricted to peer-reviewed sources. Data presented in abstract form only should, as a rule, not be considered. However, pivotal studies in abstract form could be included provided that the source is designated as non-peer-reviewed and deemed critical for an adequate appraisal of the topic. Unpublished data cannot be used in the guideline development process.

Guidelines, like primary studies, may be retrieved using systematic search techniques, but because some (eg, National Institute for Health and Care Excellence guidelines) are published only by organizations and not in journals, other search strategies may be required. The National Guideline Clearinghouse (http://www.guidelines.gov) in the United States is considered the most comprehensive Web site on which to find guidelines on a given topic.

An attempt should be made during the literature search to identify both qualitative and quantitative studies that reflect patients' experiences and preferences in relation to the clinical topic. The types of studies identified generally include patients' views on[9]

- positive and negative experiences of the condition, including diagnosis, medications and other treatments, follow-up care, and quality of life;
- unfulfilled needs;
- information needs and preferences;
- participation in decision making about treatment; and
- overall satisfaction with care received.

A copy of the MEDLINE version of the patient search strategy is available on the Web site of the Scottish Intercollegiate Guidelines Network (http://www.sign.ac.uk).

The Grading of Recommendations Assessment, Development and Evaluation methodology should be used to rate the quality of the evidence and the strength of the recommendations.[10]

4. Translating Evidence Into Recommendations

The process of translating the accumulated evidence into recommendations involves developing key action statements that reflect issues judged most important by the guideline development group. The AAO-HNSF guidelines recommend the development of 10 to 18 of these statements depending on the scope of the guideline.[2]

The PICO format should be used for developing answerable clinical questions. This approach is based on 4 components: population, intervention, comparator, and outcome. This can be extended to the PICOTS format, which adds the dimensions of time frame and setting. In some instances, the SPICE format may more intuitive for questions generated from clinical practice and might be simpler to apply. SPICE is based on 5 components: setting, population, intervention, comparator, and evaluation.

Recommendations should be worded to provide clear and unambiguous guidance to practitioners. This can be done by specifying the patients to whom the recommendation applies, the intervention, and the outcome expected to change. Active verbs such as *do*, *offer*, *give*, and *counsel* provide clearer guidance than passive constructions such as "should be considered."[3]

All recommendations will begin with "We recommend" (when the strength and quality of evidence are strong) or "We suggest" (when the strength and quality are not strong).

Each individual recommendation will be accompanied by a grading matrix, which will include

1. grading of the quality of medical evidence and
2. grading of the strength of the recommendations.

It is advisable that a formal consensus process (such as a modified Delphi technique) be adopted by the CPG development group. All members of the group must agree on the definition of consensus prior to initiation of the guideline development process, with a two-thirds majority being the minimum for consensus.

When consensus has been obtained, those members rejecting the statement or accepting with major reservations should be allowed to voice their dissenting positions and have them recorded in the meeting minutes for insertion in the final report.

As stated in AGREE II, an assessment of a guideline should encompass all the following areas[7]:

- Domain 1: Scope and Purpose
- Domain 2: Stakeholder Involvement
- Domain 3: Rigour of Development
- Domain 4: Clarity of Presentation
- Domain 5: Applicability
- Domain 6: Editorial Independence

As suggested in the AAO-HNSF manual, the final CPG document should contain the following components[2]:

- abstract,
- introduction,
- guideline purpose,
- health care burden,
- methods,
- guideline key action statements,
- implementation considerations,
- research needs,
- disclaimer,
- acknowledgments,
- author information, and
- financial disclosure.

A guideline must be a maximum of 10,000 words in length, not including supplemental tables and appendices.

5. Conducting an External Review

After completion of the CPG, the document will be circulated for external review.

External reviewers should constitute a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (eg, health care, specialty societies), agencies (eg, federal government), patients, and representatives of the public.[2]

The document will also be posted on the members-only section of the CDA Web site for review by members for a 2-week period. Only feedback that identifies errors or is factual and supported by published evidence will be considered by the guideline development group. In certain circumstances, the draft guideline may be posted for public review.

6. Disseminating and Implementing the Guideline

When finalized, the CPG will be submitted for publication in the CDA's official journal (the *Journal of Cutaneous Medicine and Surgery*) and will be the intellectual property of the CDA.

In generating the CPG report, the developers should consider developing tools that will enhance the use of the report (eg, decision aids, algorithms, photographs, patient and physician educational material, practice tools).

It is suggested that the report writers adhere to the checklist developed by the Conference on Guideline Standardization (http://gem.med.yale.edu/cogs/) or incorporated into AGREE II. The purpose of this statement is to define a standard for guideline reporting that will promote guideline quality and facilitate implementation.

Potential tools for dissemination include the following:

1. posting on the CDA Web site;
2. making the CPG available to the National Guideline Clearinghouse;
3. presentation at the CDA annual meeting; and
4. other initiatives, such as collaboration with other specialty societies, presentations at national and international meetings, and research trials.

The process used by the Canadian Diabetes Association to disseminate diabetes guidelines provides a good example of the comprehensive nature of a well-constructed process to ensure maximum dissemination and uptake of CPGs.[11]

Framework for the Management of COIs

Relationships between individual physicians and industry may create COIs, potentially resulting in undue influence on professional judgment, particularly in the CPG development process.

Because CPGs are intended to guide current standards of care, potential COIs must be addressed in a consistent fashion. The purpose of this framework is to outline steps required to identify and manage potential COIs.

To minimize the risk for COI, bias, or undue influence, funding for any CDA-sponsored CPG will adhere to the following principles:

1. there can be no direct industry funding of participants;
2. the CPG should be underwritten through unrestricted, pooled industry funds from multiple sponsors when possible;
3. financial transparency is required; and
4. CPG panelists and authors should be unaware of the identity of industry funders, and vice versa, until the final draft for submission.

COI Management Process

A. Identification of COI

1. Each proposed member of the CPG panel must provide full disclosure of all potential sources of COIs by completing and submitting declarations of COIs for the 24-month period prior to the start date of the consensus process. Disclosures will pertain to proposed members, their spouses, and close family members.
2. Potential competing interests will include both financial and nonfinancial interests. Financial interests with industry could include:

- declared research funding or support,
- stock (investments),
- honoraria,
- consultant,
- speakers bureau,
- employment, and
- corporate board positions.
- Nonfinancial interests could include
- intellectual property (patents, copyrights);
- prior provision of public positions, statements, or expert testimony; and
- employee and contractor relationships with government agencies, health ministries, cancer boards, third-party drug benefit plans, government lobbying groups, public advocacy agencies, and foundations.

B. Assessment of Disclosures

All CPG participants disclose their potential COIs in writing, and these disclosures are reviewed by the CPG development group chair or co-chairs. COI statements prepared by the group chair or co-chairs will be assessed by a designated CDA board member. Disclosures will be classified as minimal, moderate, or significant as follows:

1. Minimal COI: advisory board participation, speaking honoraria, member of public advocacy group or foundation, research funding for clinical trial.
2. Moderate COI: consultant, speakers' bureau.
3. Significant COI: research funding for individual protocol, stockholder, employee of pharmaceutical firm, holder of intellectual property, government or governmental agency employee or contractor.

C. Framework for Managing Declared COIs

Management of declared COIs must balance the need for unbiased opinion and discussion with the potential loss of valuable or critical information through the exclusion of content experts who have disclosed actual or potential COIs.

The chair or co-chairs of the CPG development group may consider excluding any member who is felt to have a COI that may seriously affect the actual or perceived integrity and validity of the consensus process. This will be assessed on a case-by-case basis.

Declaration of Conflicting Interests

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References

1. Shaneyfelt TM, Mayo-Smith MF, Rothwangl J. Are guidelines following guidelines? The methodological quality of clinical practice guidelines in the peer-reviewed medical literature. *JAMA*. 1999;281(20):1900-1905.
2. Rosenfeld RM, Shiffman RN, Robertson P. Clinical practice guideline development manual, third edition: a quality-driven approach for translating evidence into action. *Otolaryngol Head Neck Surg*. 2013;148(1 Suppl):S1-S55.
3. Singh H, Leontiadis GI, Hookey L, et al. Canadian Association of Gastroenterology policy on the application for, and implementation of, clinical practice guidelines. *Can J Gastroenterol Hepatol*. 2014;28(9):473-480.
4. Society of Obstetricians and Gynaecologists of Canada. SOGC guideline development manual. Available at: http://comingsoon.jogc.com/pb/assets/raw/Health%20Advance/journals/jogc/SOGC-Guideline-Development-Manual.pdf. Accessed October 16, 2016.
5. Canadian Cardiovascular Society. CCS guidelines and position statements: development procedures and policies. Available at: http://www.ccs.ca/images/Guidelines/Dev_proces/Gui-PS-development-Proc_policies.pdf. Accessed October 16, 2016.
6. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, eds. Clinical practice guidelines we can trust. Washington, DC: National Academies Press; 2011.
7. Brouwers M, Kho ME, Browman GP, et al, for the AGREE Next Steps Consortium. AGREE II: advancing guideline development, reporting and evaluation in health care. *Can Med Assoc J*. 2010;182(18):E839-E842.
8. Qaseem A, Forland F, Macbeth F, et al. Guidelines International Network: toward international standards for clinical practice guidelines. *Ann Intern Med*. 2012;156(7):525-531.
9. Scottish Intercollegiate Guidelines Network. SIGN 50: a guideline developer's handbook. Available at: http://www.sign.ac.uk. Accessed October 16, 2016.
10. Grading of Recommendations Assessment, Development and Evaluation Working Group 2007 (modified by the EBM Guidelines Editorial Team). Available at: https://www.essentialevidenceplus.com/product/ebm_loe.cfm?show=grade. Accessed January 9, 2017.
11. Canadian Diabetes Association. Clinical practice guidelines. Available at: http://guidelines.diabetes.ca/?_ga=1.34234273.1215266739.1476631559. Accessed October 16, 2016.